



Esthetic Outcomes in Relation to Implant-Abutment Interface Design Following a Standardized Treatment Protocol in a Multicenter Randomized Controlled Trial—A Cohort of 12 Cases at 1-Year Follow-up



Michael K. McGuire, DDS¹/E. Todd Scheyer, DDS, MS¹
 Daniel K. Ho, DMD, DMSc, MSc²/Clark M. Stanford, DDS, PhD³
 Jocelyne S. Feine, DDS, MS, HDR⁴/Lyndon F. Cooper, DDS, PhD⁵

The design of an implant-abutment interface may have an impact on the peri-implant soft tissue esthetics. In an ongoing randomized controlled trial (RCT) with 141 participants, the authors evaluated the peri-implant tissue responses around three different implant-abutment interface designs used to replace single teeth in the esthetic zone. The aim of this report is to describe the treatment protocol utilized in this ongoing RCT by (1) demonstrating in detail a clinical case treated under this protocol and (2) reporting peri-implant soft tissue responses in a cohort of 12 representative cases from the RCT at 1-year follow-up. Male and female adults requiring single implants in the anterior maxilla were enrolled in the RCT according to the study protocol. Five months following any required extraction and/or socket bone grafting/ridge augmentation, one of the following three implant-abutment interfaces was placed and immediately provisionalized: (1) conical interface (CI; OsseoSpeed, Dentsply Implants), n = 4; (2) flat-to-flat interface (FI; NobelSpeedy Replace, Nobel Biocare), n = 4; or (3) platform-switch interface (PS; NanoTite Certain Prevail, Biomet 3i), n = 4. Twelve weeks later, definitive crowns were delivered. Throughout the treatment, peri-implant buccal gingival zenith height and mesial/distal papilla height were measured on stereotactic device photographs, and pink esthetic scores (PES) were determined. The demographics of the participants in each of the three implant-abutment interface groups were very similar. All 12 study sites had ideal ridge form with a minimum width of 5.5 mm following implant site development performed according to the described treatment protocol. Using this treatment protocol for single-tooth replacement in the anterior maxilla, the clinicians were able to obtain esthetic peri-implant soft tissue outcomes with all three types of implant-abutment interface designs at 1-year follow-up as shown by the Canfield data and PES. The proposed treatment protocol for single-tooth replacement in the esthetic zone provides a reliable method to obtain and assess the esthetic outcome as a function of implant-abutment interface design and is now in its fifth year of follow-up. (Int J Periodontics Restorative Dent 2015;35:149–159. doi: 10.11607/prd.2341)

¹Private Practice, Houston, Texas, USA.

²Assistant Professor, Department of Periodontics, School of Dentistry, University of Texas Health Science Center at Houston, Houston, Texas, USA.

³Centennial Fund Professor, Department of Prosthodontics, College of Dentistry, University of Iowa, Iowa City, Iowa, USA.

⁴Professor, Oral Health and Society Research Unit, Faculty of Dentistry, McGill University, Montreal, Quebec, Canada.

⁵Stallings Distinguished Professor, Department of Prosthodontics, School of Dentistry, University of North Carolina, Chapel Hill, North Carolina, USA.

Correspondence to: Dr Michael K. McGuire, PerioHealth Professionals,
 3400 South Gessner Road, Suite 102, Houston, TX 77063, USA;
 fax: (713) 952-0614; email: mkmperio@swbell.net.

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The focus of dental implant research in recent decades has shifted from achieving functional osseointegration to maximizing implant esthetic outcomes. From a systematic review, den Hartog et al concluded that implants used to replace a single tooth in the esthetic zone following immediate, early, or conventional approaches all resulted in comparable success with respect to survival, marginal peri-implant

bone levels, and incidence of biologic and technical complications at 1 year.¹ Nevertheless, esthetic outcome variables such as peri-implant soft tissue architecture and patient satisfaction could not be assessed due to a scarcity of well-controlled clinical trials utilizing such outcome variables.

In an attempt to objectively evaluate clinical parameters associated with implant esthetics, investigators have proposed different indices or score systems to measure esthetic outcomes. Meijer et al proposed the Implant Crown Esthetic Index, which includes nine variables associated with anatomical form, color, and surface characteristics of implant crown and peri-implant soft tissues to assess esthetics of implant-supported single crowns.² Fürhauser et al introduced the pink esthetic score (PES), which evaluates the esthetics of peri-implant labial soft tissues by using a simple scoring system of 0, 1, and 2 to evaluate seven parameters.³ A limitation of this system is the reference base and the lack of positive/negative direction in the comparison. For example, if the reference tooth was worse than the experimental site, the evaluator would be forced to mark it down in the PES index because the experimental site would not be the same as (in fact, it would be better than) the reference tooth. To further analyze implant esthetics objectively, Belser et al modified the PES and developed the white esthetic score (WES) to examine the form, volume, hue/value, texture, and translucency of implant restorations.⁴

Clearly, an essential factor in implant esthetic success is the soft tissue architecture that enhances the implant restoration. Factors influencing the esthetic outcome of dental implant therapy have been the subject of many studies. Evidence indicates that a thin gingival biotype, a thin or damaged buccal bone, and buccal malposition of the implant are all risk factors for buccal gingival recession around implants, especially in immediate implant placement.⁵ Cosyn et al also reported an increased risk of advanced midbuccal recession (> 10%) associated with immediate implant placement; however, the risk of gingival recession may be reduced in patients with an intact buccal bone wall and a thick tissue biotype or when immediate implant insertion is performed in a flapless approach with immediate provisionalization.⁶ By analyzing implant esthetics with the PES and the WES, Raes et al showed that flapless implant surgery resulted in less midbuccal gingival recession than flap surgery when performed by experienced clinicians.⁷ Nevertheless, studies examining various surgical and restorative procedures in optimizing peri-implant soft tissue esthetics showed conflicting results, and more well-conducted clinical trials are required to investigate this topic of interest and establish and validate measures to record patient-related outcomes.⁸

The design of abutments and the implant-abutment interface also exert a biologic impact on peri-implant hard/soft tissues, thereby affecting the esthetic outcome. Weinländer et al reported that im-

plant prostheses restored with convex abutments had significantly higher PES scores than those with concave abutments.⁹ Stress patterns in the marginal bone also have been shown to depend on the design of the implant-abutment interface, with a conical interface withstanding a larger axial load than a flat-top interface.¹⁰ However, most studies investigating the influence of the implant-abutment interface on peri-implant tissues relied on laboratory and computer models, which provided limited insight into clinical situations. Furthermore, the data from currently available clinical studies examining the impact of implant-abutment interface design on the peri-implant soft tissue response are scarce and inconclusive.¹¹ The aim of this report is to describe the treatment protocol used in a large randomized clinical trial that primarily examined the soft tissue responses around implants with different implant-abutment interface designs. The implant therapy treatment protocol used in this study for single-tooth replacement in the esthetic zone is discussed in detail, and case data on the esthetic outcome of a cohort of 12 representative cases at 1-year follow-up are reported.

Method and materials

Study design and treatment protocol

This study evaluated three representative cases from four study centers to illustrate the treatment protocol carried out in an ongoing, prospective,

Table 1 Study inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Provision of informed consent	1. Insufficient interocclusal distance for implant placement and restoration at study site
2. Age \geq 18 y	2. Tooth adjacent (mesially and/or distally) is ankylosed
3. Requiring 1 or more single implants replacing missing or nonrestorable teeth in maxilla from first right premolar to first left premolar	3. More than 2 mm of vertical bone loss as measured from the midbuccal crest of bone on the adjacent teeth
<i>The following should be considered at inclusion but cannot be fulfilled until visit 2:</i>	
4. Edentulous for at least 5 months at study site	4. Site development (bone tissue) performed at less than 5 months before visit 2
5. Buccopalatal bone width of at least 5.5 mm at study site	5. Untreated rampant caries and/or uncontrolled periodontal disease
6. Mesiodistal bone level distance between adjacent teeth of at least 5.5 mm at study site	6. Angle Class II division 2 malocclusion
7. Keratinized midbuccal mucosal height of at least 2 mm at study site	7. Use of tobacco within last 6 months
8. Teeth adjacent (mesial and distal) to study site must consist of two stable teeth on natural roots without signs of periodontal bone loss ($>$ 1 mm)	8. Uncontrolled diabetes
9. Teeth adjacent (mesial and distal) to study site must demonstrate a stable occlusal guidance that will allow for nonfunctional disocclusion in all eccentric positions	9. Current alcohol or drug abuse
10. Opposing dentition with teeth, implants, or prostheses	10. Systemic or local disease or condition that compromises postoperative healing and/or osseointegration
	11. Use of any substance that will influence bone metabolism
	12. Need for systemic corticosteroids or any other medication that would influence postoperative healing and/or osseointegration
	13. History of radiation in the head and neck region
	14. Known pregnancy; pregnancy tests will be performed as per local requirements
	15. Unable or unwilling to return for follow-up visits for a period of 5 years
	16. Unlikely to be able to comply with study procedures according to investigators' judgment
	17. Involvement in the planning and conduct of the study (applies to both sponsor or staff at the study center)
	18. Previous enrollment or randomization of treatment in the present study

rhBMP-2 = recombinant human bone morphogenetic protein 2.

comparative clinical evaluation of single-tooth replacements using different implant-abutment interfaces in 141 subjects.¹² The 12 study participants reported in this article were recruited under protocols approved

by the institutional review board (IRB) at each institution or a private IRB. They required single-tooth replacements in the maxillary anterior region, including first premolar sites. Participants were enrolled according

to the inclusion and exclusion criteria outlined in Table 1. The study's outline is summarized in Fig 1. Figure 2 depicts a representative case from the day of implant site preparation to 1-year follow-up.

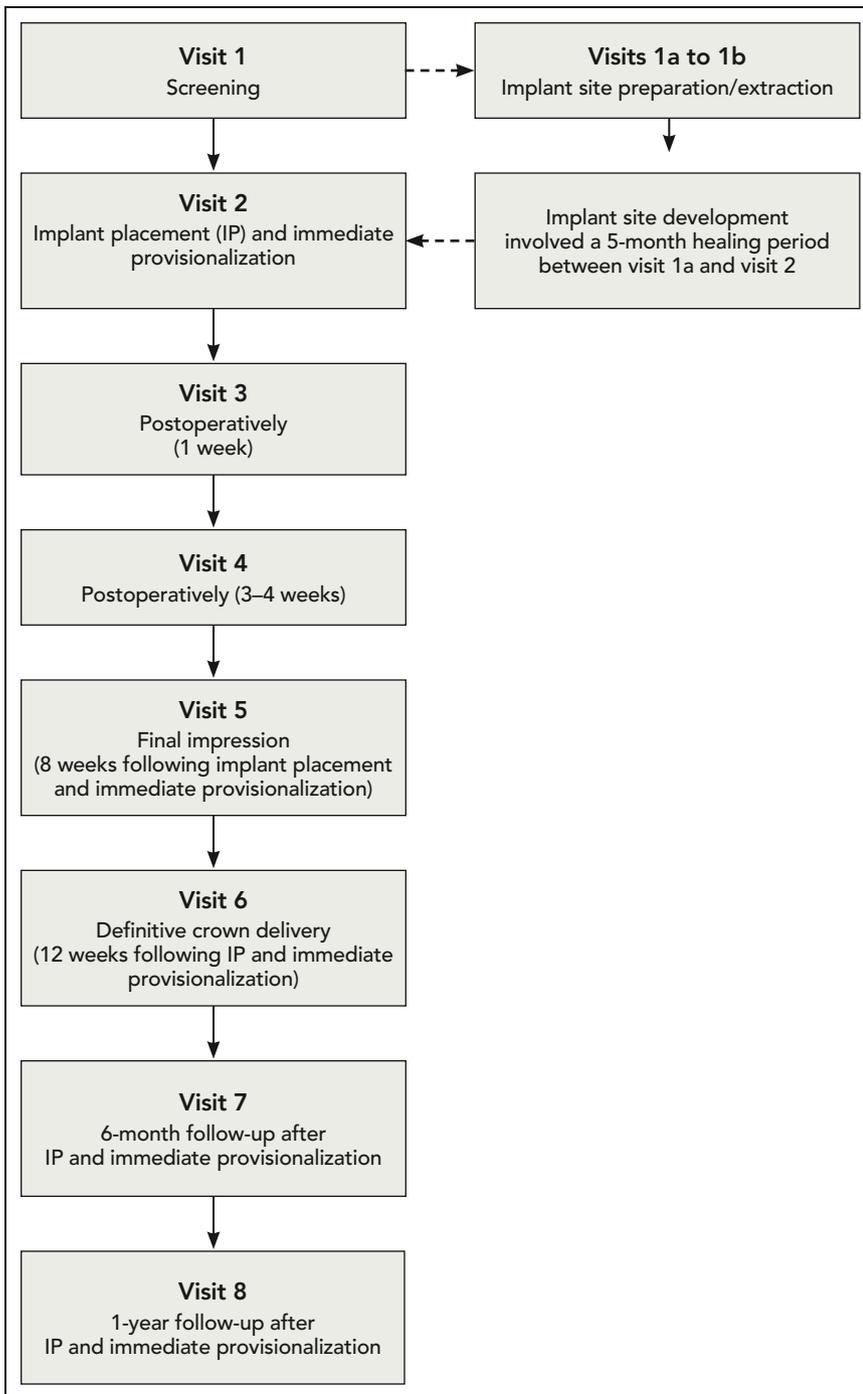


Fig 1 Study flowchart.

Implant site development was performed on deficient healed alveolar ridges and extraction sites by grafting with mainly recombinant

human bone morphogenetic proteins-2 (rhBMP-2, Infuse, Medtronic) with or without mineralized bone allograft as indicated by the clinical

situation (Figs 2a to 2d). These ridge-augmentation procedures were done to create a fairly ideal ridge form for implant placement with a minimum width of 5.5 mm to eliminate the bony ridge variable from the esthetic outcome and permit evaluation of all three implant-abutment interfaces at a similar starting point. After 5 months, at the time of implant placement, one of three implants was randomized to each patient. The three types of implant-abutment interfaces utilized were (1) conical interface (CI; OsseoSpeed, Dentsply Implants); (2) flat-to-flat interface (FI; Nobel-Speedy Replace, Nobel Biocare); (3) platform-switch interface (PS; NanoTite Certain Prevail, Biomet 3i), as shown in Fig 3. Implants were planned to be inserted using a flapless/tissue-punch approach (Figs 2e to 2i). The implant-abutment interface was intended to be positioned 3 mm apical to the planned gingival zenith. Implant primary stability was determined by the lack of axial and lateral implant movement when torqued at the manufacturers' suggested values.

Titanium abutments (CI = Direct Abutment, Dentsply Implants; FI = Snappy Abutment, Nobel Biocare; PS = GingiHue Abutment, Biomet 3i) were utilized for the intended immediate provisionalization. Provisional crowns were made of bis-acryl composite resin using putty matrices with relining to fit the prefabricated abutment margins, retained with temporary cement or screws and relieved from occlusal contacts in centric and eccentric positions (Figs 2j to 2o).

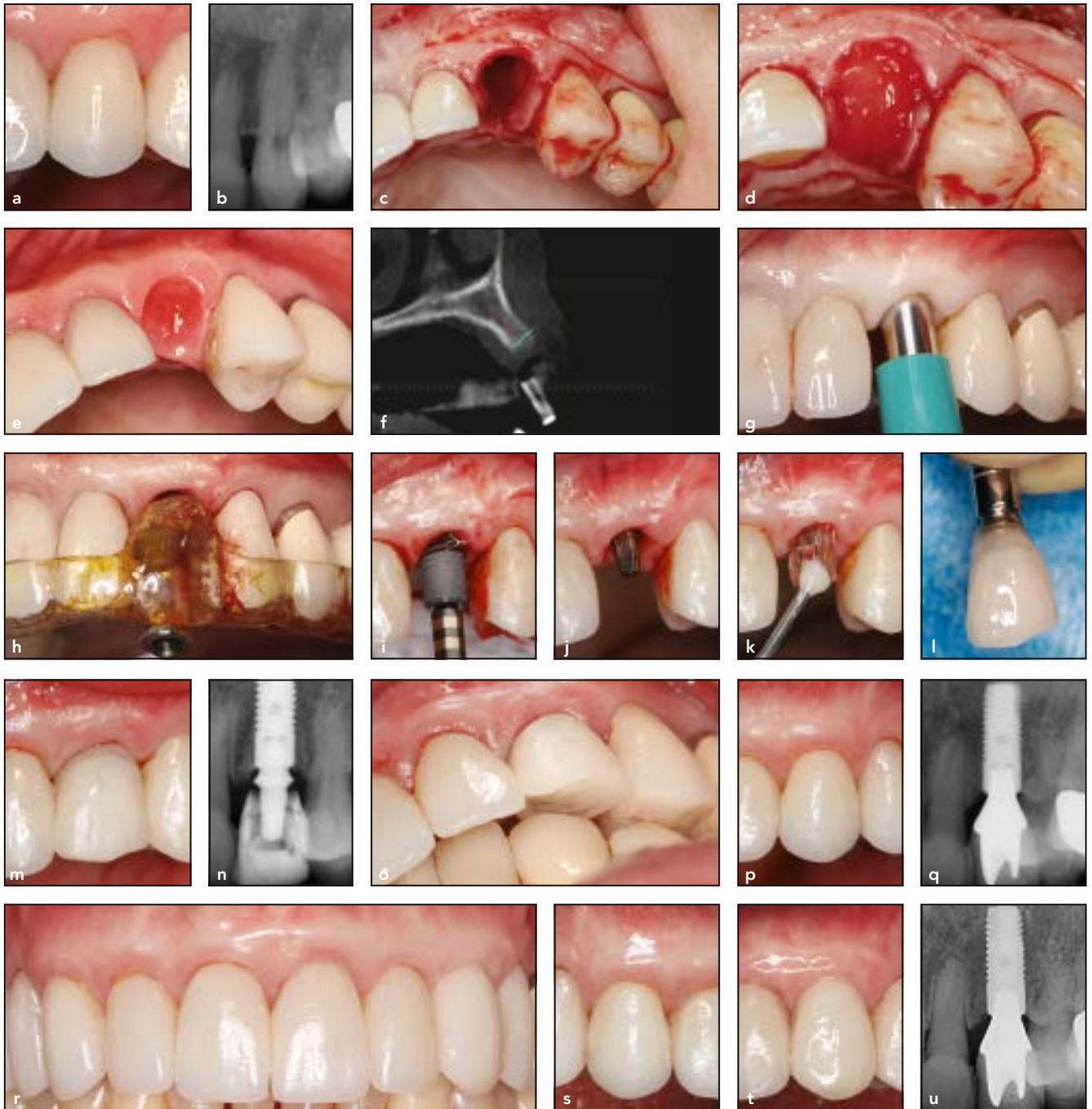


Fig 2 Case example—visit 1 to visit 8. (a) Preoperative clinical photograph of maxillary left canine (FDI no. 23). (b) Preoperative radiograph of no. 23 requiring extraction due to internal resorption. (c) No. 23 postextraction. (d) Socket grafted with recombinant human bone morphogenetic protein-2 and a resorbable collagen membrane. (e) Five months after socket bone grafting. (f) Computed tomography scan taken with surgical guide. (g) Flapless implant surgical approach. (h) Surgical guide in place during implant surgery. (i) Placement of implant (OsseoSpeed) with the implant-abutment interface positioned 3 mm apical to the planned gingival zenith according to study protocol. (j) Placement of temporary abutment (Direct Abutment). (k) Fabrication of provisional restoration at the time of implant placement. (l) Fabricated provisional restoration. (m) Cementation of provisional restoration. (n) Radiograph showing provisional restoration. (o) Provisional restoration relieved from occlusion. (p) Definitive restoration 6 months after implant placement using customized computer-aided design/computer-assisted manufacture zirconia abutments (Atlantis, Dentsply) and lithium disilicate crowns (IPS E-max, Ivoclar). (q) Radiograph of definitive restoration 6 months after implant placement. (r) Maxillary anterior teeth at 1-year follow-up. (s) Natural maxillary right canine. (t) Restored no. 23. (u) Radiograph of implant at 1-year follow-up.

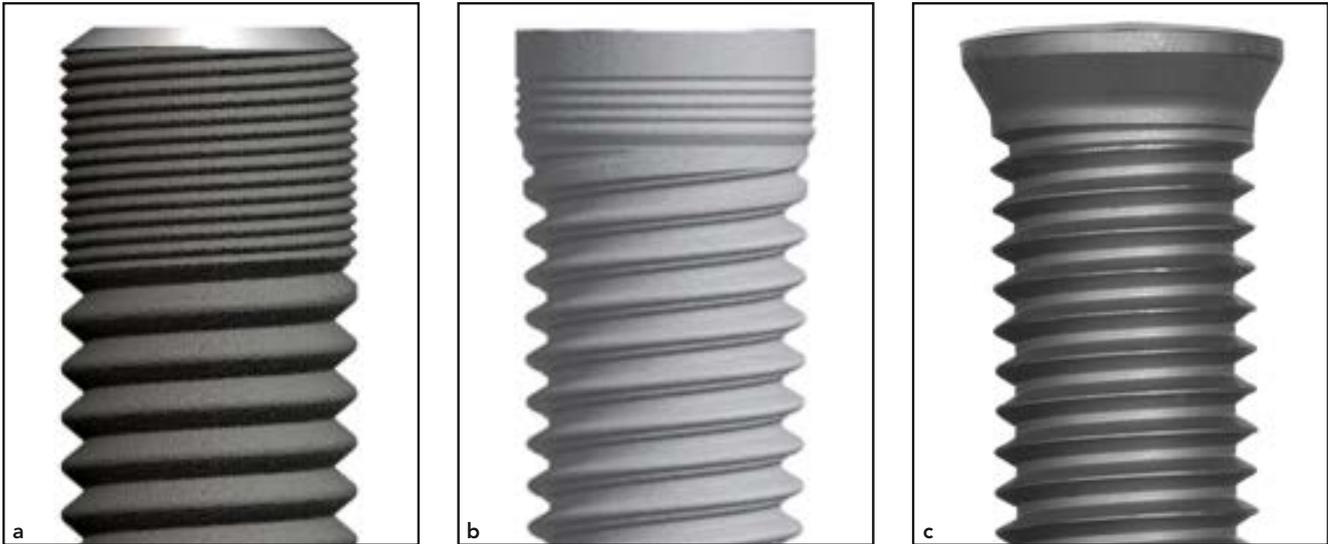


Fig 3 Three types of implant-abutment interfaces. (a) Conical: OsseoSpeed; (b) flat-to-flat: NobelSpeedy Replace; and (c) platform-switch: NanoTite Certain Prevail.

Eight weeks following implant insertion, implant stability was confirmed by the absence of pain and mobility when implant-level impression copings were connected to the implants. Tooth shade selection and elastomeric final impressions were made. Four weeks later, computer-aided design/computer-assisted manufacture (CAD/CAM) zirconia abutments (Atlantis, Dentsply Implants) were placed and lithium disilicate crowns (IPS E-max, Ivoclar) (crowns were made in one laboratory, Studio 32) cemented using RelyX Unicem (3M ESPE). Clinical, radiographic, and photographic evaluations were performed at the time of definitive restoration delivery, at 6 months,

and 1 year following implant placement (Figs 2p to 2u). All procedures in this study were performed according to the ethical standards of the IRB and the latest updates of the Helsinki Declaration.

Peri-implant soft tissue assessment

The peri-implant buccal gingival zenith height and papilla height were measured in two ways: using (1) UNC 15 probes (Hu-Friedy) and (2) a stereotactic photographic dental device (Canfield Scientific). Only method 2 will be presented here. Gingival zenith height was the distance from the most apical

aspect of the peri-implant gingival margin to the incisal edge. Papilla heights (mesial and distal) were the distance from the tip of the papilla to a horizontal line drawn tangent to the most apical aspect of the gingival margin of adjacent teeth. The stereotactic device used in this study involved a positioning device and a digital camera that allowed for measurements to be taken on standardized intraoral photographs. Images were unaltered and imported as JPEG files, and images containing periodontal probes with millimeter marking were calibrated by measuring the number of pixels between the probe's millimeter marking. Gingival zenith height and mesial/distal papilla heights were

Table 2 Case series demographics and implant site development characteristics

Variable	Conical interface (OsseoSpeed)	Flat-to-flat interface (NobelSpeedy Replace)	Platform-switch interface (NanoTite Certain Prevail)	Total
Number of subjects	4	4	4	12
Age (y): mean \pm SD (range)	40 \pm 12 (25–53)	44 \pm 21 (20–67)	50 \pm 13 (35–62)	45 \pm 15 (20–67)
BMI: mean \pm SD (range)	27 \pm 12 (19–46)	25 \pm 4 (18–28)	30 \pm 4 (27–35)	27 \pm 7 (18–46)
Sex: male/female	2/2	2/2	2/2	6/6
Implant sites*	11, 21, 23, 24	11, 22, 22, 24	11, 12, 12, 24	–
Site history: extraction/ healed ridge	2/2	3/1	2/2	7/5
Bone graft: Y/N	3/1	4/0	4/0	11/1
rhBMP-2 only	2	2	0	4
rhBMP-2 + allograft	1	1	4	6
Allograft only	0	1	0	1
Membrane	2	2	0	4

rhBMP-2 = recombinant human bone morphogenetic protein 2.
*FDI tooth-numbering system.

measured for each implant crown in pixels by two observers using the ImageJ program.

Peri-implant soft tissue also was assessed using PES, with which seven variables were measured: mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiency, soft tissue color, and texture.³ PES was assessed by bilateral digital images produced from a handheld digital camera system and a digital image scoring format. Each PES variable was given a score ranging from 0 to 2, with 0 being the poorest and 2 being the best score. Each clinical photograph was scored by five clinicians. Total mean PES calculations were made to compare gingival esthetic differences.

Results

Patient demographics and implant site development

There were six men and six women in this cohort, with a mean age of 45 years and mean BMI of 27 (Table 2). Participants in each of the three groups receiving different implants with different implant-abutment interfaces (CI, FI, and PS) all had comparative mean age and BMI (Table 2). Of the 12 implant sites, 7 sites were extraction sockets and 5 sites were healed ridges (Table 2). All sockets had ridge preservation and 4 of 5 the healed ridges. Ten sites had rhBMP-2 as part of the bone augmentation procedures (Table 2).

Five months after augmentation, all 12 sites were judged to have ideal ridge form with a minimum width of 5.5 mm.

Canfield data and pink esthetic scores of peri-implant soft tissues

Changes in the dimension of buccal gingival zeniths and mesial/distal papillae around implant restorations were evaluated at visits 6, 7, and 8 using the Canfield stereotactic device. Examples of Canfield measurements at visits 6 and 8 are shown in Fig 4. Outcomes were reported as mean changes at visit 7 (6-month follow-up) and visit 8 (1-year follow-up) with respect to

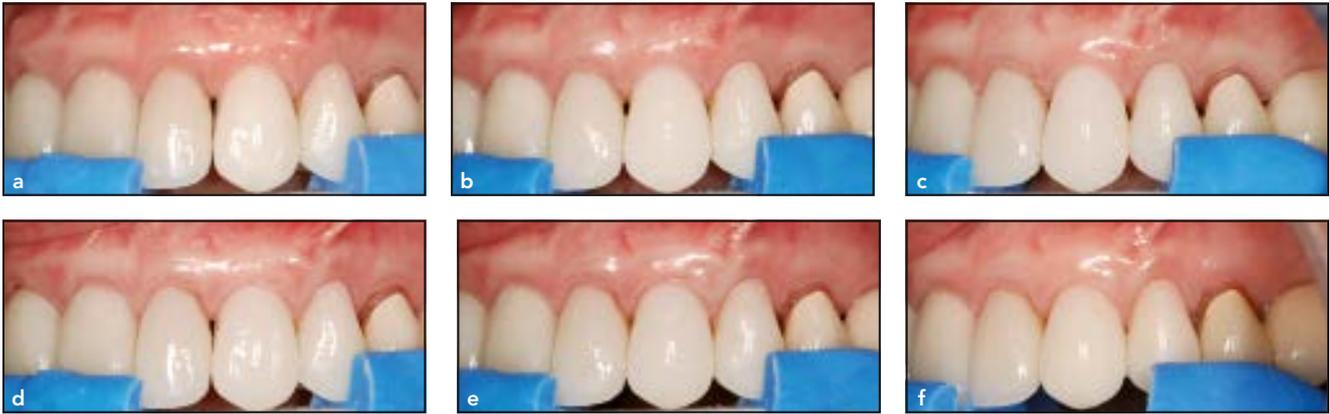


Fig 4 Case example—Canfield measurement at visit 6 and visit 8. Visit 6: Canfield measurements for (a) mesial papilla (2.9 mm), (b) buccal gingival zenith (10.9 mm), and (c) distal papilla (3.7 mm). Visit 8: Canfield measurements for (d) mesial papilla (3.1 mm), (e) buccal gingival zenith (10.4 mm), and (f) distal papilla (3.8 mm).

visit 6 (permanent restoration delivery). Figure 5 shows clinical photographs, Canfield measurement photographs, radiographs, and total mean PES at 1-year follow-up of all 12 implant restorations and peri-implant soft tissues. It was not the intent of this report to perform statistical analyses of the Canfield and PES data due to the small sample size ($n = 12$).

Discussion

This report described a treatment protocol used in a large randomized controlled trial (RCT) for single-tooth replacement in the esthetic zone. This article also reported peri-implant soft tissue responses from the three types of implant-abutment interfaces, namely CI (OsseoSpeed), FI (NobelSpeedy Replace), and PS (NanoTite Certain Prevail) in a cohort of 12 representative cases shown in Fig 5. At the 1-year follow-up, the evaluation of

soft tissue esthetics by the Canfield stereotactic device and the PES revealed comparable outcomes from all three implant-abutment interface designs (see Fig 5). There were minimal changes in gingival zenith and papilla heights from the time of definitive crown delivery to the 1-year follow-up, suggesting that the treatment protocol used in this study for implant site preparation, implant placement, and immediate provisionalization was predictable in achieving esthetic outcomes. Fürhauser et al evaluated 30 single-tooth implants using PES and reported mean scores ranging from 2.3 to 13.8.³ In this report, all single-tooth implants placed under the proposed protocol resulted in a very high PES (> 10) with respect to that reported by Fürhauser et al.³ Because the intent of this article was to report but not to compare the peri-implant soft tissue responses among three types of implant-abutment interfaces in a cohort of 12 representative cases

from the authors' ongoing RCT, no statistical analyses were performed on the clinical parameters measured.

A standardized method was used to evaluate soft tissue changes around implants.¹³ By capturing clinical photographs using a digital camera connected to a stereotactic device and subsequently measuring the number of pixels between the probe's millimeter markings, the investigators were able to minimize the bias that can arise when measurements are only done clinically by eye using periodontal probes. Standardized photography and computer software allowed for high accuracy in measurements, thereby reducing errors due to variability among clinicians and the four centers involved in this study.¹⁴ Moreover, clinicians were blinded when assessing the Canfield and PES photographs. Clearly, this methodology facilitated objective evaluations of gingival esthetics around implants.

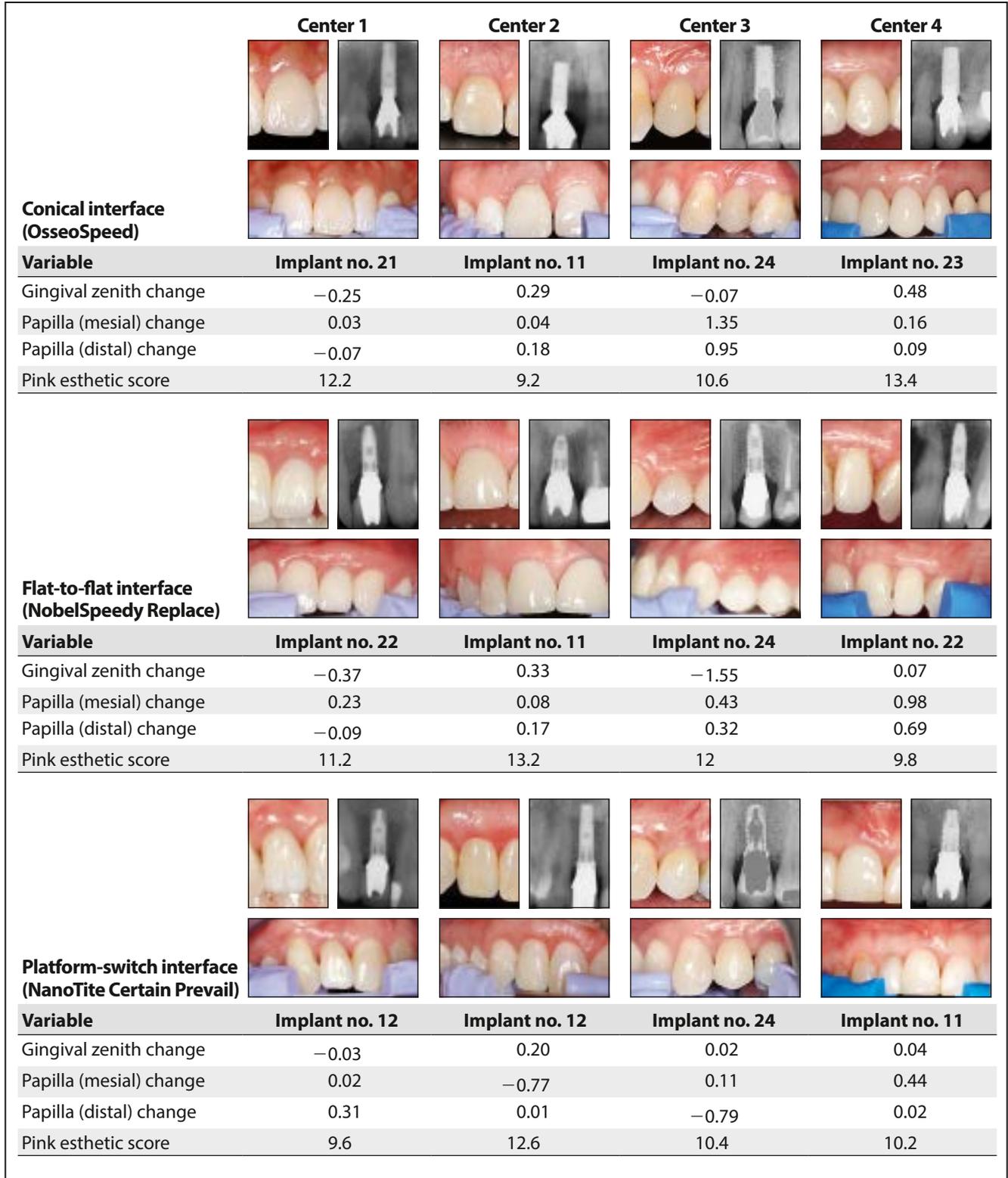


Fig 5 Canfield measurements, pink esthetic scores (PES), and radiographs of implant study sites. Canfield data on gingival zenith and mesial/distal papilla heights represent mean change in millimeters between visits 6 and 8 (measurements obtained by two clinicians). Positive number is gain, negative number is loss. PES data represent the total mean PES at visit 8 (scores were given by five clinicians). FDI tooth-numbering system used for implants.

The rationale of the proposed treatment protocol was to standardize as much as possible the variables at implant study sites so that the only variable affecting the esthetic outcome would be the type of implant-abutment interface design. For example, prerequisite bone-grafting procedures, including ridge preservation and ridge augmentation, were performed to obtain at least 5.5 mm of buccopalatal ridge width at study sites. Clinicians were allowed to utilize a combination of rhBMP-2 (Infuse), bone allograft, and/or barrier membrane based on their clinical judgment. The augmented ridges that did not meet the required minimum width of 5.5 mm 5 months postgrafting were excluded from the study. In addition, the selected implant diameters were standardized based on study site anatomy—sites with < 6 mm ridge width and mesiodistal distance received implants with body diameters of 3.25 to approximately 3.5 mm, and sites with \geq 6 mm ridge width and mesiodistal distance received implants with body diameters of either 3.25 to approximately 3.5 mm or 4.0 mm. Moreover, the vertical implant positioning was guided by the protocol so that the outermost aspect of the implant-abutment connection was 3 mm apical from the planned gingival zenith. Furthermore, a flapless approach was intended to be utilized for implant placement to reduce variability in soft tissue healing, in addition to possibly minimizing the

risk for midbuccal recession.⁶ Immediate provisionalization was carried out with titanium abutments as dictated by the protocol, and Atlantis abutments were used for all implants. The definitive crowns were manufactured by one central lab to reduce differences that could affect measured outcomes. In summary, the treatment protocol was designed to ensure equivalence in factors defining the baseline conditions for implant placement and restoration so that peri-implant soft tissue responses would primarily be the result of implant-abutment interface design.

Even though the four study centers were actively involved in the development of this treatment protocol to ensure standardization and understanding, the protocol still encountered practical challenges. For example, bone profiling was sometimes necessary so implant platforms could be placed 3 mm apical to the planned gingival zenith. In addition, the quality of the bony ridge at study sites could vary between pristine sites versus rhBMP-2/allograft-augmented sites; however, the implants placed in this cohort of study all exhibited good primary stability that allowed for immediate provisionalization. Although clinicians strived to place implants with platforms about 2 mm palatal to the most buccal aspect of the buccal bony plate,¹⁵ it was not possible to measure this distance because of the flapless implant placement approach. Still, the fabrication of provisional crowns

with optimal emergence profiles critical for soft tissue esthetics around definitive implant restoration¹⁶ was left to the discretion of the clinicians. These challenges could potentially affect the esthetic outcome of peri-implant tissues. Nevertheless, the proposed treatment protocol for single-tooth replacement in the esthetic zone had prepared the study sites to be as similar as possible so all three types of implant-abutment interface design could potentially achieve esthetic outcomes. The study is also following other variables that could influence esthetic outcomes, such as inflammatory markers, and is employing three-dimensional ridge analysis and sophisticated patient-reported outcomes to further understand the outcome achieved.

Conclusions

The proposed treatment protocol for single-tooth replacement in the esthetic zone provides a reliable method to obtain and assess the esthetic outcome as a function of implant-abutment interface design. All three types of implant-abutment interfaces—CI, FI, and PS—have the potential to offer predictable and esthetic outcomes for single-unit implant therapy at the 1-year follow-up. However, any differences in the esthetic outcomes between the three types of implant-abutment interface designs may not become apparent until years later.

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