A Randomized Controlled Trial Evaluating Grafting the Facial Gap at Immediately Placed Implants

Bryan P. Jacobs, DMD, MS1
Homayoun H. Zadeh, DDS, PhD2
Ingeborg De Kok, DDS, MS3
Lyndon Cooper, DDS, PhD4

Immediate implant placement in extraction sockets requires management of postextraction alveolar resorption. This randomized controlled trial evaluated the facial alveolar bone dimension 10 months following immediate implant placement with or without the addition of anorganic xenograft at the time of flapless, one-stage placement of a sloped-platform implant. The primary outcome of facial crestal alveolar bone thickness revealed no difference in the mean dimension (no graft: 1.47 ± 0.85 mm; graft: 1.63 ± 0.71 mm; P = .950). Secondary outcomes, including pink esthetic score, were not different between the two groups. This study suggests that bone formation does occur along the facial surface of implants placed into extraction sockets. Int J Periodontics Restorative Dent 2019 (10 pages). doi: 10.11607/prd.3774

Treatment of tooth loss in the esthetic zone is a relatively frequent situation encountered by dental clinicians. Timely replacement of an extracted tooth is a primary concern of patients—for both functional and esthetic purposes. Accepted treatment sequences range from separate extraction, grafting, and implant surgeries to extraction through loading in the same visit. Within each of these potential timelines, wide varieties of techniques and protocols have been put forth. Immediate implant placement (type I) is a common treatment approach for tooth replacement. Survival and success are comparable to placement into healed ridges. The 2-year (98%) and 5-year (95%) survival rates have been consistently high. However, unpredictable bone and soft tissue outcomes in the esthetic zone following immediate placement are prominent concerns.

The well-documented postextraction changes to alveolar bone architecture underscore this challenge. Following extraction, the residual alveolus will undergo both quantitative and qualitative changes that are more pronounced on the buccal surface. At 6 months, hard tissue loss was found to average 3.8 mm in the horizontal dimension and 1.2 mm vertically. Socket walls will be reduced both in height and...
width, with approximately 50% of the buccolingual dimension lost during the first year postextraction.\textsuperscript{6,9,10} The disproportionate loss of facial bone is related to the relatively thin dimension of the facial tooth socket wall, its relative exposure to surgical trauma, and the loss of bundle bone upon extraction.\textsuperscript{9,11}

Deproteinized bovine bone (DBB) grafting may limit the volumetric changes of the facial alveolus following extraction and implant placement.\textsuperscript{12,13} In an attempt to have greater and more predictable tissue preservation following implant placement in extraction sockets, grafting of the facial extraction gap with DBB resulted in (1) modified healing, (2) greater hard tissue volume, and (3) an improved level of marginal bone-to-implant contact.\textsuperscript{14}

A recent randomized clinical trial examined grafting the horizontal gap with DBB, plus 10% collagen, following immediate implant placement.\textsuperscript{15} Less dimensional change was seen in the grafted group vs the control. Notably, the protocol included mucogingival flap reflection at the time of surgery—it is unknown whether this finding would apply when using a flapless approach. Managing the resorption of the buccal plate following extraction and implant placement is addressed by many different clinical protocols. Other factors previously considered to influence alveolar ridge resorption following extraction include the possible influence of implant placement and uses of submerged healing, elevated mucoperiosteal flaps, and membranes.\textsuperscript{9}

It has been suggested that resorption can be reduced if the surgical and restorative procedures are all performed without flap elevation.\textsuperscript{16} Among these factors, the grafting of the gap between the residual buccal plate and the implant wall is integral to many of these.

Grafting of the gap between the implant and socket buccal bone wall may impact this process. This study, a randomized, controlled trial in humans, aimed to examine the dimension of bone formed on the facial aspect of implants placed into extraction sockets following the placement of xenograft in the facial extraction gap vs the same treatment without grafting. It was hypothesized that, with a flapless surgical protocol, there would be no radiographic differences in the dimension of bone formed on the facial surface of the implant or any clinical differences in soft tissue and esthetic outcomes.

### Clinical Protocol

Following consent, participants had preoperative records made at their first appointment. Included were mounted maxillary and mandibular casts, standardized digital photographs, and a small-volume cone beam computed tomography (CBCT) scan (160-micron slice thickness; Orthophos XG 3D, Dentsply Sirona). Implant surgeries were planned for placement of 4.5-mm–diameter sloped implants (OsseoSpeed TX Profile, Dentsply Sirona) in sockets of teeth to be extracted using planning software (Simplant Pro, Dentsply Sirona). Planning involved orientation of the implant’s long axis to pass through the incisal edge of the planned crown and the facial aspect of the implant-abutment interface to be aligned with the first premolar to first premolar with no adjacent edentulous spaces, be at least 18 years of age, and consent to the trial. Participants were excluded if they met any of the following criteria: untreated caries or periodontal disease, smoked tobacco within the past 12 months, American Society of Anesthesiologists Class 3 or higher and/or immune-compromised, pregnant or planned to be pregnant within the study period, history of bruxism, and/or a history of bisphosphonate use. Participants were discontinued if, following extraction, the surgical site was found to be nonideal, defined as any dehiscence, fenestration, or facial crestal bone level greater than 4 mm from the soft tissue margin.

### Materials and Methods

#### Patient Selection

This prospective trial was conducted under internal review board (IRB) approval by the University of North Carolina at Chapel Hill (UNC-CH) Office of Human Research (#11-1057) as well as the Western IRB (protocol D-2011-019). Thirty-three consecutive patients were recruited from the patient pool at the UNC-CH School of Dentistry (n = 22) and the University of Southern California School of Dentistry (n = 11).

The inclusion criteria included that participants require extraction of a single tooth from the anterior maxilla (first premolar to first premolar with no adjacent edentulous spaces), be at least 18 years of age, and consent to the trial. Participants were excluded if they met any of the following criteria: untreated caries or periodontal disease, smoked tobacco within the past 12 months, American Society of Anesthesiologists Class 3 or higher and/or immune-compromised, pregnant or planned to be pregnant within the study period, history of bruxism, and/or a history of bisphosphonate use. Participants were discontinued if, following extraction, the surgical site was found to be nonideal, defined as any dehiscence, fenestration, or facial crestal bone level greater than 4 mm from the soft tissue margin.
horizontally with the facial osseous crest (Fig 1). Implants were placed with the implant-abutment interface approximately 2 mm palatal from the mucosal zenith. Pre-extraction facial bone measurements were also made from CBCT images.

The second appointment included extraction, implant placement, and provisionalization (Fig 2). Preoperative antibiotics (2 g amoxicillin or 600 mg clindamycin) and analgesics (800 mg ibuprofen) were given 60 minutes before surgery. Patients rinsed for 90 seconds with an antimicrobial rinse (chlorhexidine gluconate 0.12%). Articaine with epinephrine (Septocaine, Septodont) infiltration was used to achieve anesthesia. Teeth were extracted using periotomes and root-tip forceps to avoid facial bone fracture (Fig 3). Implant placement was carried out in a flapless manner, per the manufacturer’s recommendations. All implants were 4.5-mm-diameter sloped-platform implants of 11, 13, or 15 mm in length (Table 1).

Table 1 Number of Implants by Length (mm)

<table>
<thead>
<tr>
<th>Length (mm)</th>
<th>11</th>
<th>13</th>
<th>15</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No graft</td>
<td>1</td>
<td>10</td>
<td>3</td>
<td>14</td>
</tr>
<tr>
<td>Graft</td>
<td>6</td>
<td>9</td>
<td>4</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>19</td>
<td>7</td>
<td>33</td>
</tr>
</tbody>
</table>
Following implant placement, randomization with allocation to the grafting or no grafting group was revealed. For patients assigned to receive a graft, large-particle DBB (Bio-Oss, Geistlich Pharma) was placed in the gap facial to the implant to the level of the implant platform followed by an absorbable collagen dressing (Collagen Plug, Zimmer Dental). A figure-of-eight suture (4-0 chromic gut; Ethicon, Johnson & Johnson) was used to secure the dressing and graft about the abutment. Both groups were treated with a single-stage approach. Regarding provisionalization, bonded pontics were designed and milled from resin nanoceramic material (Lava Ultimate Restorative, 3M ESPE). Alternatively, the participant’s natural crown or an interim acrylic single-tooth removable partial denture was fabricated (Fig 4).

Immediately postoperatively, a periapical radiograph was exposed. A 1-week postoperative course of antibiotics was prescribed, as well as a 2-week prescription of twice daily chlorhexidine gluconate 0.12% rinses. Acetaminophen/hydrocodone or ibuprofen was prescribed for analgesia and at-home oral care instructions were given. A postsurgical follow-up visit was conducted at 1 week to ensure compliance with care instructions and to observe soft tissue healing. Additional visits were scheduled as necessary to adjust or rebond interim restorations.

Twelve weeks after implant placement, healing abutments were removed. Screw-retained provisionalization was carried out using abutment-level temporary cylinders. No flaps were raised.

Final impressions were made 6 weeks after provisionalization. Full-arch impressions were taken with polyvinyl siloxane (PVS) material using a closed-tray technique, without customization or modification of the impression transfer. Opposing arch impressions and interocclusal records in maximum intercuspation were made with PVS material as well. Intraoral photographs were taken with shade tabs to help guide the laboratory in the fabrication of the definitive restoration.

Definitive restorations were delivered approximately 7 months postoperatively. The temporary restoration was removed, and a gold-shaded titanium custom CAD/CAM abutment (gold-hue Atlantis Abutment, Dentsply Sirona) was placed and torqued to 25 Ncm (Fig 5). Lithium disilicate crowns (IPS e.max, Ivoclar Vivadent) were then placed, adjusted as necessary, and, following the participant’s esthetic approval, cemented with resin-modified glass-ionomer cement (GC FujiCEM Automix, GC America).

Postoperative Records and Measurements

Final follow-up for the investigation took place an average of 9.7 months after implant placement. The following records were made/taken: PVS impression of the maxillary anterior sextant, standardized digital photographs, and a small-volume CBCT scan.

Pre-extraction and follow-up CBCT radiographs were managed in parallel. A representative two-dimensional slice (perpendicular to the panoramic curve and bisecting the mesiodistal dimension of the tooth or implant) was selected. For the pre-extraction images, measurements were made from the facial cementoenamel junction (CEJ) to the most coronal point of the facial

---

**Fig 4** Patient’s extracted right central incisor modified to be used as a bonded pontic provisional restoration (a), and later as a screw-retained provisional restoration (b).
bone crest. Bone thickness facial to the tooth was measured along a line perpendicular to the long axis of the root at the following points: 1 mm subcrestal, at midroot, and 1 mm from the apex of the tooth. For the posttreatment images, bone thickness facial to the implant was measured along a line perpendicular to the long axis of the implant at the following points: 1 mm subcrestal, mid-implant, and 1 mm from the apical end of the implant (Fig 6).17

Quantitative photographic analysis using the standardized digital photographs was carried out using ImageJ (National Institutes of Health). Preoperative and follow-up 1:2 aspect ratio photos, taken perpendicularly to the facial aspect of the tooth, were processed simultaneously. Images were each calibrated (to assign a pixels-to-mm ratio) to a periodontal probe positioned vertically against an adjacent tooth surface. A common reference line was defined, oriented to fixed points on adjacent teeth. Vertical measurements were made from the reference line to the mesial papilla, the distal papilla, and the most apical point along the facial gingiva/mucosa (Fig 7). Differences between the preoperative and follow-up images were then calculated.18

Pink Esthetic Scores (PES) were assigned by a group of seven calibrated individuals (one prosthodontist, six prosthodontic residents). Cases were presented by digital projection in a random order, using retracted frontal photos of the maxillary anterior teeth.19 Additionally—for lateral incisor, canine, and premolar sites—a photo perpendicular to the facial aspect of the crown in question was presented as well, so as to better visualize papilla. Each evaluator
independently scored every case in a manner blinded to each patient’s assignment. Scores were compiled, the high and low scores dropped from each case, and PES assigned as the mean of the five intermediate scores.

Statistical Analyses

Preoperative descriptive statistics were compared between groups. Chi-square test was applied to look at the association between group and sex. Wilcoxon rank sum test was used to examine age differences between the two groups. Linear mixed models (LMMs) were used to detect differences in baseline CBCT values based on group assignment or age. Spearman correlation analysis was applied to the preoperative CBCT values and age as well. Follow-up data were evaluated in a number of ways. LMMs were used to examine differences in follow-up CBCT measurements, based on group and age. Soft tissue outcomes were examined in the 22-person UNC-CH subset. LMMs were also used to compare soft tissue changes based on group, age, and position along the tooth (mesial papilla, midfacial, distal papilla). PES was compared using Wilcoxon rank sum test. Spearman correlation analysis was applied to the follow-up soft tissue measurements and age, and separately to the follow-up CBCT measurements and age. For all tests, the level of significance was set at $\alpha = .05$.

Results

A total of 33 patients (14 men and 19 women) with a mean age of 58 years were enrolled (Table 2). Nineteen patients (mean age: 53 years; range: 23 to 86) were assigned to the graft group. Fourteen patients (mean age: 65 years; range: 38 to 91) were assigned to the no-graft group. There was no association between group and sex ($P = .966$). There was no statistically significant difference in mean age between groups ($P = .058$).

Implants were placed in 15 central incisor sites, 9 lateral incisor sites, 6 canine sites, and 3 premolar sites. One patient had implant mobility noted at the provisionalization stage. The implant was removed, the defect curetted, and a new implant placed at the same visit. This second implant subsequently healed uneventfully and was included in the study. Implant survival was thus 32/33 (97%).

Preoperative CBCT measurements of the facial plate showed a mean distance of 3.17 mm from the CEJ to the alveolar crest. Mean values for facial bone thickness were all less than 1 mm (range: 0.90 to 0.99 mm). There was no statistically significant difference in the preoperative facial plate measurements based on either group assignment or age. There was a significant correlation between facial bone thickness measured 1 mm subcrestally and bone thickness both midroot ($P < .001$) and 1 mm from the apex ($P = .007$).

Twenty-eight of the 33 participants had posttreatment CBCT scans ($n = 28$ for follow-up CBCT). There were no differences in the posttreatment facial bone dimensions in CBCT measurements of the two study groups ($P = .950$) or based on age ($P = .396$) (Table 3). Facial bone thickness measured 1 mm subcrestally was significantly correlated with the thickness measured at the mid-implant level ($P < .001$).

<table>
<thead>
<tr>
<th>Table 2 Description of Study Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Subjects, n</td>
</tr>
<tr>
<td>Mean age ± SD (y)</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>No. of surgeries by site</td>
</tr>
<tr>
<td>Central incisor</td>
</tr>
<tr>
<td>Lateral incisor</td>
</tr>
<tr>
<td>Canine</td>
</tr>
<tr>
<td>First premolar</td>
</tr>
<tr>
<td>Mean preoperative buccal plate (mm)</td>
</tr>
<tr>
<td>CEJ to crest</td>
</tr>
<tr>
<td>1 mm subcrestal</td>
</tr>
<tr>
<td>Midroot</td>
</tr>
<tr>
<td>1 mm from apex</td>
</tr>
</tbody>
</table>

SD = standard deviation; CEJ = cementoenamel junction.
No statistically significant differences in soft tissue changes were detected between groups \( (P = .846) \) or between positions along the tooth (mesial papilla vs midfacial vs distal papilla; \( P = .089 \)). Mean changes in peri-implant soft tissue levels at the midfacial aspect were \( 0.92 \pm 0.67 \text{ mm (no graft)} \) and \( 0.94 \pm 1.13 \text{ mm (graft)} \), at the mesial papilla were \( 0.57 \pm 0.59 \text{ mm (no graft)} \) and \( 0.33 \pm 0.46 \text{ mm (graft)} \), and at the distal papilla were \( 0.79 \pm 0.75 \text{ mm (no graft)} \) and \( 0.49 \pm 0.62 \text{ mm (graft)} \), with positive values indicating apical movement. Older patients experienced greater soft tissue change, regardless of the grafting group \( (P = .038) \). Specifically, age was correlated with midfacial change \( (P = .040) \) and distal papilla change \( (P = .034) \). The mean PES for each group was 8.2, with a range of 4.4 to 13.4 (Table 4). There was no difference in PES between the groups \( (P = .794) \).

### Discussion

This study demonstrates that mucosal and hard tissue alterations following flapless, immediate placement of sloped-platform implants were not significantly different with or without the addition of xenograft in the facial extraction gap. The mean midfacial tissue loss of approximately 0.9 mm and mean papilla loss of 0.3 to 0.8 mm are consistent with previously published findings. These results differ from other immediate placement and loading studies conducted using this implant system in its non-sloped format: In a comparison of implant placement and loading in healed ridges and extraction sockets without grafting, no midfacial tissue loss was recorded at 1 to 5 years. De Rouck et al reported that mean tissue loss 1 year following similar grafting and implant placement, but with provisionalization, was 0.41 mm (mesial papilla), 0.31 mm (distal papilla), and 0.53 mm (midfacial). At 3 years, substantial improvement was noted with significant tissue rebound noted at both papilla: 0.05 mm (mesial papilla), 0.08 mm (distal papilla), and 0.34 mm (midfacial). Only patients with thick biotype and intact facial plate were included in these studies. Several possible factors may contribute to the different midfacial data reported here. One possibility is the positive impact of immediate provisionalization that was not performed in the present study. A series of studies by Chu et al and Saito et al demonstrated that both grafting the gap with xenograft and immediate provisionalization positively impacted the location and dimension of the midfacial mucosa. A second possibility is that De Rouck et al included only thick biotypes, while this study involved all biotypes. The impact of biotype on the midfacial tissue position after implant surgery remains incompletely defined. Third, it is possible that the sloped implant design places the implant/abutment interface in a more apical position when the implant is oriented to enable cement-retained restorations. Apical positioning of an implant is a known factor affecting greater midfacial tissue recession at implants.

Other studies have demonstrated that positive PES scores are achieved following immediate placement of implants accompanied by grafting. Although it is not possible to directly compare the mean PES scores between different studies, Cosyn et al reported a mean PES of 10.48 ± 2.47 compared to the current study’s PES scores (8.2 ± 2.1). Both scores meet an acknowledged threshold for esthetic success, suggesting general similarity between these studies.
The initial facial alveolar wall prior to extraction was < 1 mm, and the dimension of bone formed at the facial aspect of implants placed into sockets with and without grafting of the gap was greater than 1 mm. This is a key observation; maintaining at least 1 mm of bone facial to implants is important for tissue stability and long-term implant success. These results are similar to a 2-year clinical trial subgroup of 20 patients treated with 37 immediate implants in the anterior maxilla with a flapless approach and autogenous bone grafting of the gap, where CBCT measurements demonstrated that preoperative facial plate measurements at three locations were all less than 1 mm. Postoperative measurements were all greater 1 mm at both time points.27

The results of the present study differ from those reported by Sanz et al.15 In the latter study, the investigators observed significantly less alveolar bone atrophy in cases with thin (< 1 mm) facial bone, where the xenograft was placed in the horizontal gap, compared to nongrafted sites. Several methodologic differences may account for differences in the outcomes of the two studies, including (1) flapless extraction and implant placement in this study, (2) placement of sloped platform implants in the present study, and (3) quantification of bone dimensional changes using CBCT compared to direct measurements by Sanz et al.15 The present study’s extraction sockets could not be stratified into thin vs thick alveolar bone, since very few sites had thick phenotype to result in a meaningful comparison.

Patient age, which was not one of the principle variables at the outset, was found to be an important factor. While a patient’s group assignment did not significantly affect their soft tissue outcomes, the outcomes were significantly correlated with age. This is interesting, as young patients are often considered the highest-risk esthetic patients due to greater gingival display.28

Sloped implants have been indicated for use in healed ridges, where the facial and lingual bone have differential heights, and the goal is to preserve as much bone as possible.29 The justification for their use in anterior immediate sites stems from the fact that facial bone resorption outpaces that of the palatal bone and thus they may better fit the anatomy of the future healed site. When placed perpendicular to the occlusal plane, the 4.5-mm-diameter Profile implant platform exhibits a difference of 1.5 mm from the facial to palatal platform. With increasing angulation to accommodate the anatomy of the anterior maxilla tooth socket, the depth of the facial implant/abutment interface increases (Fig 8). In this study, positioning was on a case-by-case basis, but often the facial platform of the implant was placed several millimeters apical to the intended facial restorative margin, so as to place the palatal aspect of the implant below the palatal osseous crest. Further investigation is warranted, as less facial soft tissue resorption was noted by Noelken et al in a similar investigation.29

Another factor to be considered in the clinical scenario examined here is abutment design. For the present trial, custom CAD/CAM-designed gold-shaded titanium abutments with concave submucosal emergence profiles were used. The gold shading was selected to both help combat mucosal graying as well as give a natural appearance underneath the definitive ceramic crown. The concave nature of the abutment may permit greater thickness of mucosa to form on the facial surface at this critical region of the implant-abutment interface.

There are at least two limitations inherent to the current study design. It was decided to use cover screws for grafted patients and healing abutments for nongrafted patients. This was done to minimize implant mobility, especially in the cases of grafted patients. Further, the use of cover screws has been shown to reduce the risk of bacterial ingress and infection. The results of this study suggest that sloped platform implants may be a viable option in anterior immediate sites, provided that proper attention is paid to the positioning of the implant and the use of appropriate abutments.
patients. Issues around the dimensions of the facial extraction gap also must be considered. All patients were assigned to a group, regardless of gap size. While not objectively measured, it was noted that it was difficult to find space to place graft particles in five of the graft patients. Choosing to include patients with small gap sizes may have diluted any potential differences between the two study groups. In addition, unlike many other immediate placement studies involving grafting of the gap that involve immediate provisionalization, this study used a staged approach commonly involving a bonded pontic provisionalization strategy.

Conclusions

The present results concerning the immediate placement of sloped implants into anterior maxillary extraction sockets for single-tooth replacement confirm high implant survival reported by others. After 10 months, CBCT scans demonstrated that facial bone > 1 mm thick could be maintained facial to implants placed with or without grafting of the gap. Clinical measurements of facial and interproximal tissues that reveal minor tissue changes in this time period were associated with reported esthetic success, defined by PES evaluation. When a protocol utilizing specific implant placement parameters, defined provisionalization procedures, and CAD/CAM abutments is consistently applied, biologic and clinical outcomes that support esthetics can be realized.

Acknowledgments

This project was partially supported through a research grant from Dentsply Sirona Implants. The expert statistical assistance of Dr. Ceibh Phillips is acknowledged. Drs. Zadeh and Cooper have received honoraria from Dentsply Sirona. Drs. Jacobs and De Kok declare no conflicts of interest.

References


doi: 10.11607/prd.3774


