Immediate dental implant placement in the aesthetic zone
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Immediate single-tooth implant placement in bony defects in the aesthetic zone:

a 1-year randomized controlled trial.

This chapter is an edited version of the manuscript:
Slagter KW, Meijer HJ, Bakker NA, Vissink A, Raghoebear GM.
Abstract

Aim:

To assess whether outcome of immediate implant placement in the aesthetic zone in bony defects was non-inferior to delayed implant placement after one year regarding marginal bone level (MBL).

Materials and Methods:

Forty patients with a failing tooth in the aesthetic zone and a labial bony defect of ≥5 mm after removal of a tooth were randomly assigned for immediate (n=20) or delayed (n=20) implant placement. Second stage surgery and provisionalization occurred after three months healing. Follow-up was at 1 month and 1 year after definitive crown placement. The study was powered to detect a difference in MBL of >0.9 mm. Buccal bone thickness, soft tissue peri-implant parameters, aesthetic indexes and patients' satisfaction were also assessed.

Results:

One year after definitive crown placement, MBL level loss was 0.49±0.46 mm mesially and 0.49±0.46 mm distally for the immediate group and 0.45±0.41 mm and 0.68±0.64 mm for the delayed group, respectively. Regarding differences in means, non-inferiority was observed after 1 year (mesially: immediate vs. delayed: difference in mean 0.04 mm (95%CI -0.22 to 0.30 mm, p=0.40), distally: immediate vs. delayed: difference in mean 0.21 mm (95%CI -0.10 to 0.51 mm, p=0.58). No significant differences in the outcome variables were observed.

Conclusion:

Immediate implant placement with delayed provisionalization was non-inferior to delayed implant placement with delayed provisionalization in labial bony defects of ≥5 mm regarding change in MBL. Although not powered for other outcome variables, no clinically relevant differences were observed in these variables.
Introduction

The survival of immediately placed and provisionalized implants in the aesthetic zone is very high.\textsuperscript{1,2,3} However, it is not just implant survival that determines the success of an implant treatment as implant treatment in the aesthetic zone is also in need of a favourable hard and soft peri-implant tissue outcome.\textsuperscript{4,5} A recent randomized clinical trial\textsuperscript{6} verified this for marginal bone level (MBL) in extraction sockets with no bony defects and showed that indeed the MBL outcome is favourable too. Although unknown to what extent the peri-implant soft tissues react on missing support of hard peri-implant tissues, it has been hypothesized that the risk on developing facial gingival recession is low when the bone labially from the implants has no dehiscences and a sufficient thickness at implant placement.\textsuperscript{7} In this respect, it was reported that large U- and UU-shaped defects are accompanied by more gingival recession 1-year after immediate tooth replacement, reason why Kan et al\textsuperscript{8} recommended a delayed approach, viz. to combine implant placement with hard and/or soft tissue grafting when a labial bone defect is present at implant placement. Recently, however, it was reported that newer techniques allow for a favorable treatment outcome of implants placed in fresh extractions sockets with labial plate dehiscences.\textsuperscript{9-11} Thus, an intact labial plate is presumably not essential to allow for immediate implant placement with a favorable outcome. No studies yet assessed the treatment outcome of implants placed in fresh extraction sockets with labial plate dehiscences in the aesthetic zone in a prospective, randomized clinical trial design. Therefore, the aim of this randomized controlled trial was to assess whether the 1 year treatment outcome of immediate implant placement and delayed provisionalization is non-inferior regarding change in marginal bone level (MBL) to delayed implant placement and delayed provisionalization in case of implant placement in fresh extraction sockets with labial bony defects of ≥5 mm in the aesthetic zone.

Materials and methods

Study design

Between January 2010 and January 2012 all eligible consecutive patients >18 years with a failing tooth in the maxillary aesthetic zone (incisor, canine or first premolar) referred for single tooth implant treatment were asked to join this randomized clinical trial. Pre-operative, a cone beam computed tomography (CBCT)-scan was made to assess whether there was sufficient bone on the palatal side to place an implant as for primary stability of the implant sufficient palatinal bone is necessary in case of labial dehiscence. Patients were excluded from participation in this study when they met one or more of the following criteria: inadequate oral hygiene, insufficient mesio-distal width for implant placement, periodontal disease, smoking, ASA (American Society of Anesthesiologists) score ≥II\textsuperscript{12}, and a bony defect of ≤5 mm in vertical direction of the labial socket wall after removal of the tooth. The size of the bony defect was determined after extraction of the failing tooth. The shape of the osseous defect was assessed by a bone sounding technique with a periodontal probe at the buccal, the mesial, and distal aspect of the failing tooth, and the mesial and distal aspect of the immediately adjacent teeth.
For allocation to either group a computerized random number generator was used. A research-nurse not involved in the study blindly allocated the patients to (Figure 1 and 2):

- An immediate group: immediate placed implant (NobelActive, Nobel Biocare AB, Goteborg, Sweden) and delayed provisionalization;
- A delayed group: delayed placed implant (NobelActive, Nobel Biocare AB, Goteborg, Sweden) and delayed provisionalization.

Informed consent was obtained from all patients. The study was approved by the local medical ethical committee (NL32240.042.10) and registered in a trial register (ISRCTN57251089).

**Surgical protocol**
Preoperatively, patients started prophylactic antibiotic therapy (amoxicillin 500mg t.i.d. for 7 days or clindamycin 300mg q.i.d. in case of amoxicillin allergy). Oral disinfection consisted of a 0.2% chlorhexidine mouthwash, twice daily for 7 days. All surgeries were performed under local anesthesia and performed by the same experienced oral and maxillofacial surgeon (GR). In all cases, the failing teeth were removed with a sulcular incision, careful detachment of the periodontal ligament and use of periotomes. After removal of the tooth, the alveolus was meticulously cleansed and any alveolar debridement was removed with a sterile gauze. If the sterile gauze was still contaminated, more cleaning took place. Before implant placement, bone grafts were harvested from the maxillary tuberosity with the use of chisels. The wound of the bone graft in the tuberosity region was closed with Vicryl 4-0 (Ethicon, Johnson&Johnson, Amersfoort, The Netherlands).

**Immediate** placement group:

The implant site was prepared on the palatal side of the alveolus following the protocol of the manufacturer using a surgical template based on the ideal position of the prospective implant crown. The last used burr, depending on the diameter of the implant, was placed in the prepared alveolus. Next, the tuberosity bone graft was shaped with the use of a forceps to match the labial bony defect. The bone graft was placed in the extraction socket, with the cortical side facing the periosteum, under the periosteum covering the labial plate defect. A mixture of autologous bone and Bio-Oss® (Geistlich, Wolhusen, Switzerland) spongiosa granules (0.25-1.0 mm) was tightly packed into the remaining space between the burr and the bone graft. Regarding the corono-apical position of the implants (NobelActive, Nobel Biocare AB, Goteborg, Sweden) the shoulder of the implant was placed at a depth of 3 mm apical to the most apical aspect of the prospective clinical crown, with help of the surgical template. Immediately after implant placement a corresponding cover screw was placed. To achieve an optimal aesthetic outcome, next a soft tissue graft, harvested from tuberosity region where the bone graft was taken from, was placed on top of the bone graft and implant according to the method described in detail by Raghoebar et al.13 The wound was closed with Ethilon 5-0 (Ethicon, Johnson&Johnson, Amersfoort, The Netherlands).

During the three months osseointegration phase, patients were allowed to wear a removable partial denture not interfering with the wound. After three months, the implant was uncovered by a small incision at the site of the cover screw, followed by an implant-level impression according to the procedure described in the prosthetic protocol section.
Figure 1. Cohort flow diagram.

- **Enrollment**
  - Assessed for eligibility (n=40)
    - Excluded (n=0)
      - Not meeting inclusion criteria (n=0)
      - Declined to participate (n=0)
      - Other reasons (n=0)
    - Randomized (n=40)
      - Allocated to intervention (n=20)
        - Received allocated intervention (n=20)
        - Did not receive allocated intervention (give reasons) (n=0)
      - Lost to follow-up (give reasons) (n=0)
      - Discontinued intervention (give reasons) (n=0)
      - Analysed (n=20)
        - Excluded form analysis (give reasons) (n=0)

- **Allocation**
  - Allocated to intervention (n=20)
    - Received allocated intervention (n=20)
    - Did not receive allocated intervention (give reasons) (n=0)

- **Follow-Up**
  - Lost to follow-up (give reasons) (n=0)
  - Discontinued intervention (give reasons) (n=0)

- **Analysis**
  - Analysed (n=20)
    - Excluded form analysis (give reasons) (n=0)
**Figure 2A. Schedule of visits and procedures study group immediate placement and delayed provisionalization.**
Figure 2b. Schedule of visits and procedures study group delayed placement and delayed provisionalization.
Delayed placement group:
The alveolus was locally augmented with the same procedure as described for the immediate group, with exception of placement of an implant. After 3 months a pedicled mucoperiosteal flap was raised to expose the maxilla, after which the NobelActive implant was placed according to the requirements of the manufacture using a surgical template. The implants were placed, comparable to the implants placed in the immediate placement group, 3 mm below the cervical junction of the adjacent teeth. The wound was primary closed with Ethilon 5-0 (Ethicon, Johnson&Johnson, Amersfoort, The Netherlands). After three months the implant was uncovered following the same procedure as described for the immediate group, again followed by an implant-level impression. Patients were allowed to wear a removable partial denture until the provisionalization took place.

Prosthetic protocol
An implant-level impression was made immediately after uncovering the implant. After the impression was taken, a corresponding healing abutment was placed. A screw-retained provisional crown composed of an engaging temporary abutment and composite was then fabricated in the dental laboratory. This same day, the provisional crown was fastened directly onto the implant with 20 Ncm by a manual torque wrench. A final open tray impression using polyether impression material (Impregum Penta, 3M ESPE, Seefeld, Germany) was taken at implant level after a provisional phase of 3 months in both groups. In the dental laboratory, one lab technician made the digital design of the definitive crown to the desired form of the abutment. This digital design was used to retrieve individualized zirconia abutments (NobelProcera, Nobel Biocare AB, Goteborg, Sweden). Depending on the location of the screw access hole, the final crown was either cement-retained or screw-retained. Abutment screws were torqued with 32 Ncm. Cement-retained crowns were cemented with glass ionomer cement (Fuji Plus, GC Europe, Leuven, Belgium). All prosthetic procedures were performed by a single experienced prosthodontist (HM).

Outcome measures
Primary outcome measure of this study was the change in marginal peri-implant bone level (MBL) proximal to the implant, from placement of the implant to one month (T1) after connecting the definitive crown and from placement of the implant to one year (T12) after connecting the definitive crown. Secondary outcome measures included buccal bone thickness (BBT), implant survival, change in interproximal peri-implant mucosa (IML) and midfacial peri-implant mucosal level (MML) as compared with the gingival level of the pre-operative failing tooth. Furthermore, papilla volume, health of keratinized gingiva, amount of plaque, amount of bleeding and pocket probing depth were assessed. Aesthetic outcome was assessed by means of objective indices (Implant Crown Aesthetic Index (ICAI)\(^4\), the pink esthetic score (PES)\(^5\) and the white esthetic score (WES)\(^6,7\). Patients' satisfaction was assessed using the Oral Health Impact Profile (OHIP) index\(^8\) and the Visual Analogue Scale (VAS)\(^9\) on a 0-10 scale.

Radiographic assessments
To calculate changes in MBL, one month (T1) and one year (T12) after placement of the definitive crown, a standardized digital peri-apical radiograph was taken with an individualized aiming device\(^10\), pre-
operatively (Tpre), immediately following implant placement (baseline T0), one month (T1), and twelve
months (T12) after definitive crown placement. The vertical distance from the shoulder of the implant to the
first-bone-to-implant contact was measured at the distal and mesial site of the implant. The radiographs of
T1 and T12 were analyzed using the manufacturer-provided implant diameter as a reference. Measurements
were performed independently by two examiners (KS and Harry Slagter), after which the average of both
measurements was used.

To calculate buccal bone thickness (BBT) labial of the implant, one month (T1) and one year (T12) after
placement of the definitive crown a CBCT scan was made. The scanner (iCAT 3D exam scanner,KaVo Dental
GmbH, Biberach, Germany) was validated for measuring bone thickness by Fourie et al.21 To allow for
reproducible measurements, a CBCT imaging and software protocol was developed and validated.22 Area
of interest was the distance from the central axis of the implant to the outer contour of the buccal bone
at the neck of the implant. Buccal bone thickness measurements (in mm) were performed calculating the
distance to the buccal bone outline minus the radius of the interior contour of the implant (as provided by
the implant company). Measurements were performed independently by two examiners (KS and HM), after
which the average of both measurements was used.

**Survival rate**

Survival rate was defined as the percentage of functional implants one year after definitive crown
placement. The criteria for successful osseointegration according to Smith & Zarb (1989) were adapted.

**Photographic assessments**

Before implant placement (Tpre) at T1 and at T12, standardized digital photographs (Nikon D300s, Nikon
Corporation, Yurakucho, Tokyo, Japan) were taken using a technique as described earlier.17 A manual
periodontal probe (Williams Color-Coded probe; Hu-Friedy, Chicago, IL, USA) with known dimensions was
held in close proximity and parallel to the long axis of the adjacent tooth to calibrate the photographs. Full
screen analysis of the photographs was performed using a digital picture editing program (Keynote, Apple
Inc, Cupertino, CA, USA). The changes in IML and in MML were compared with the original gingival level
of the failing tooth. These measurements were independently performed by two examiners (KS and Harry
Slagter) after which the average of both measurements was used.

**Clinical assessments**

The following clinical variables were assessed at T1 and T12 at the implant and adjacent teeth before
implant placement (Tpre):
- Papilla volume: assessing the mesial and distal papilla adjacent to the implant using the papilla
  index23;
- Amount of plaque: assessed at four sites per implant/adjacent tooth (mesial, buccal, distal and
  palatal) using the modified plaque index24;
- Amount of bleeding: using the modified sulcus bleeding index24;
- Gingiva: using the gingival Index25;
- Probing pocket depth: assessed at four sites per implant/adjacent tooth (mesial, buccal, distal and palatinal) using a manual periodontal probe (Williams Color-Coded probe; Hu-Friedy, Chicago, IL, USA) measuring to the nearest 1 mm. All data were recorded by a single one blinded examiner (KS).

Aesthetic assessments
The aesthetic outcome was assessed on standardized digital photographs (Nikon D300s, Nikon Corporation, Yurakucho, Tokyo, Japan taken at Tpre and T1, and T12 in both groups. An additional photograph was taken of implant crowns replacing the lateral of canine capturing the contra lateral tooth. Peri-implant mucosa and implant crown aesthetic outcomes were determined using ICAI\textsuperscript{14} and PES-WES.\textsuperscript{16,17} Measurements were performed independently by two examiners (KS and Diederik Hentenaar).

Patients’ satisfaction
Patients’ satisfaction was surveyed at T1 and T12 using the validated OHIP-14 questionnaire. Overall satisfaction was assessed using a 100-mm visual analogue scale (VAS).

Statistical analysis
For determination of the sample size, G*power version 3.1 was used.\textsuperscript{26} A radiographic change in MBL of \(>0.9\) mm (SD 1 mm) after 12 months of definitive crown placement was regarded as a relevant difference between study groups.\textsuperscript{1} With an expected effect-size of 0.9 mm, an alpha of 0.05 and a power of 0.80, 38 patients were required, 19 in each group. 40 patients were included to account for anticipated drop-out rate. Shapiro-Wilk test, together with normality plots were used to assess normal distribution of the continuous variables. Differences between groups were evaluated by one-way analyses of variance (ANOVA) for continuous data and by Fisher’s exact test or chi-Square test for categorical data. Regarding MBL, T-tests for equality of means with associated confidence intervals (CI) were calculated. If the difference of 0.9 did not pass the 95\% CI borders, non-inferiority was considered established. In case of uncertainty of the significance because of the relatively small number of patients analysed and the large number of outcomes, Bonferroni correction was considered in case of a p-value 0.01<0.05. A p-value of 0.05 was considered to indicate statistical significance. All analyses were performed using SPSS (PASW Statistics 20.0, SPSS Inc.; IBM Corporation, Chicago, IL, USA).

Results

Inter-and intra-observer correlation
The inter- and intra-observer correlations for both the radiographic and photographic measurements were very high. For details see Slagter et al.\textsuperscript{4}

Patients
Baseline characteristics and treatment specifications of the immediate group (n=20) and delayed group (n=20) are shown in Table 1 and Figure 3 and 4. All patients received their assigned treatment (Figure 1). No extensive bleedings at the donor and receptor site were observed.
Table 1. Baseline characteristics and treatment specifications per study group.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Immediate group (n=20)</th>
<th>Delayed group (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean±SD</td>
<td>Range</td>
</tr>
<tr>
<td>Age</td>
<td>43.7 ±13.9</td>
<td>18-63</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Cause of tooth loss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fracture (crown or root)</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Agenesis</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Caries</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Endodontic failure</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Periodontal failure</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Root resorption</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Bone defect</td>
<td>Mean±SD (mm)</td>
<td>8.35 ±2.18</td>
</tr>
<tr>
<td>Implant location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Incisor 1</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Incisor 2</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Canine</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Implant length</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 mm</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>15 mm</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>18 mm</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Implant diameter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.5 mm</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>4.3 mm</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Type of final restoration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screw-retained</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Cement-retained</td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>
Three patients (immediate: group 1; delayed: group 2) had an antral perforation due to harvesting the tuberosity bone. The wound overlying the antral perforation was primary closed and healing was uneventful. Wound healing at the grafting/implantation site was undisturbed with the exception of one patient (group 2) in whom a small bone sequester had to be removed. After removal of the bone sequester, wound healing was uneventful and the remaining bone was sufficient for implant placement. No complications were observed during the follow up.

**Marginal bone level**

MBL loss at the mesial and distal site after 1 month and 12 months after placement of the definitive crown was comparable for both treatment approaches (Table 2). Non-inferiority for the change in MBL between the groups was observed, both for the 1 month (mesially: immediate group vs. delayed group: difference in mean 0.04 mm (95%CI -0.24 to 0.23 mm, p=0.83, distally: 0.23 mm (95%CI -0.84 to 0.54 mm, p=0.70) and 1 year (mesially: 0.04 mm (95%CI -0.22 to 0.30, p=0.40, distally: 0.21 mm (95%CI -0.10 to 0.51 mm, p=0.58) time point.

**Buccal bone level**

Mean buccal bone thickness at the neck of the implant 1 month and 12 months after placement of the definitive crown is shown in Table 2. Buccal bone thickness did not change between between T1 and T12.

**Survival rate**

One year implant survival rate was 100% in both groups.

**Interproximal and midfacial peri-implant mucosal level**

IML and MML, did not change significantly between with time in both groups (Table 2).

**Clinical outcome**

Plaque, bleeding and gingival indexes as well as the pocket probing depth were low and remained low throughout the study period (Table 3).

**Aesthetic assessments**

At the 1-year evaluation, no significant differences in ICAI as well as PES/WES were seen between the groups (Table 2). The aesthetic outcome was mainly dependent on the appearance of the implant crown and less by the aspect of the peri-implant mucosa, and did not differ between the groups.

**Patients' satisfaction**

OHIP-14 scores did not differ between the groups (Table 4; p>0.05). Overall satisfaction scores one year after placement of the crown were 8.4±1.4 and 8.1±1.3 for the immediate and delayed group, respectively.
Table 2. Changes regarding marginal bone level, marginal soft tissue level and aesthetic evaluation from pre-operative (Tpre), one month (T1) to 12 months (T12) after definitive crown placement.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A</th>
<th>Group B</th>
<th>P-value</th>
<th>Group A</th>
<th>Group B</th>
<th>P-value</th>
<th>Group A</th>
<th>Group B</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tpre</strong> <strong>Mean (sd)</strong></td>
<td>Tpre</td>
<td>T1</td>
<td></td>
<td>T12</td>
<td></td>
<td>T12</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Marginal bone level in mm (±sd)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Mesial of implant</td>
<td>0.49 (±0.46)</td>
<td>0.45 (±0.41)</td>
<td>0.79</td>
<td>0.56 (±0.39)</td>
<td>0.51 (±0.43)</td>
<td>0.74</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal of implant</td>
<td>0.71 (±0.51)</td>
<td>0.48 (±0.47)</td>
<td>0.15</td>
<td>0.74 (±0.51)</td>
<td>0.54 (±0.45)</td>
<td>0.18</td>
<td></td>
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<tr>
<td>BBT changes in mm</td>
<td></td>
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<td></td>
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<tr>
<td>Buccal of implant (mean ±sd)</td>
<td>1.01 (±0.55)</td>
<td>0.79 (±0.46)</td>
<td>0.19</td>
<td>1.00 (±0.47)</td>
<td>0.71 (±0.28)</td>
<td>0.07</td>
<td></td>
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<tr>
<td><strong>Marginal soft tissue level changes in mm (±sd)</strong></td>
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<tr>
<td>Mesial of implant</td>
<td>0.15 (±0.18)</td>
<td>0.18 (±0.16)</td>
<td>0.73</td>
<td>0.15 (±0.16)</td>
<td>0.15 (±0.16)</td>
<td>0.99</td>
<td></td>
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<tr>
<td>Distal of implant</td>
<td>0.17 (±0.16)</td>
<td>0.23 (±0.17)</td>
<td>0.32</td>
<td>0.18 (±0.18)</td>
<td>0.21 (±0.17)</td>
<td>0.53</td>
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<tr>
<td>Mid-facial of implant</td>
<td>0.13 (±0.28)</td>
<td>0.30 (±0.49)</td>
<td>0.20</td>
<td>0.15 (±0.28)</td>
<td>0.34 (±0.55)</td>
<td>0.17</td>
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<tr>
<td><strong>PES</strong></td>
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<tr>
<td></td>
<td>7.00 (2.10)</td>
<td>6.90 (1.30)</td>
<td>0.63</td>
<td>7.80 (1.66)</td>
<td>7.40 (1.59)</td>
<td>0.71</td>
<td></td>
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<tr>
<td><strong>WES</strong></td>
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<td></td>
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<tr>
<td></td>
<td>5.00 (2.33)</td>
<td>5.40 (1.65)</td>
<td>0.70</td>
<td>7.99 (1.73)</td>
<td>7.60 (1.09)</td>
<td>0.68</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PES/WES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>10.68 (3.40)</td>
<td>11.10 (3.46)</td>
<td>0.43</td>
<td>16.20 (2.20)</td>
<td>15.10 (1.71)</td>
<td>0.38</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ICAI</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>9.60 (6.54)</td>
<td>14.10 (8.57)</td>
<td>0.23</td>
<td>3.80 (2.18)</td>
<td>6.20 (3.94)</td>
<td>0.35</td>
<td>4.20 (2.38)</td>
<td>5.2 (4.10)</td>
<td>0.37</td>
</tr>
</tbody>
</table>
Figure 3. Immediate implant treatment with delayed provisionalization.

a. Clinical situation pre-operative.
b. Pre-operative radiograph.
c. Clinical situation post-operative.
d. Post-operative radiograph.
Figure 4. Delayed implant treatment with delayed provisionalization.

a. Clinical situation pre-operative.
b. Pre-operative radiograph.
c. Clinical situation post-operative.
d. Post-operative radiograph.
Table 3. Clinical outcome measures pre-operative (Tpre), and one month (T1) and 12 months (T12) after definitive crown placement.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Tpre group</th>
<th>Tpre group</th>
<th>P-value</th>
<th>T1 group</th>
<th>T1 group</th>
<th>P-value</th>
<th>T12 group</th>
<th>T12 group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Papilla index: 0/1/2/3/4</td>
<td>Immediate</td>
<td>Delayed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mesial (#patient)</td>
<td>0/7/2/11/0</td>
<td>2/6/6/6/0</td>
<td>0.17</td>
<td>1/5/3/11/0</td>
<td>2/8/4/6/0</td>
<td>0.45</td>
<td>0/3/8/9/0</td>
<td>0/6/5/9/0</td>
<td>0.43</td>
</tr>
<tr>
<td>Distal (#patient)</td>
<td>0/7/5/8/0</td>
<td>2/6/6/6/0</td>
<td>0.53</td>
<td></td>
<td></td>
<td>0.28</td>
<td>0/3/8/9/0</td>
<td>0/7/7/6/0</td>
<td>0.32</td>
</tr>
<tr>
<td>Gingival index: 0/1/2/3 (#patient)</td>
<td>19/1/0/1</td>
<td>17/1/1/1</td>
<td>0.55</td>
<td>18/2/0/0</td>
<td>20/0/0/0</td>
<td>0.35</td>
<td>18/2/0/0</td>
<td>20/0/0/0</td>
<td>0.24</td>
</tr>
<tr>
<td>Plaque index: 0/1/2/3 (#patient)</td>
<td>18/2/0/0</td>
<td>20/0/0/0</td>
<td>0.47</td>
<td>20/0/0/0</td>
<td>20/0/0/0</td>
<td>NA</td>
<td>18/1/1/0</td>
<td>20/0/0/0</td>
<td>0.35</td>
</tr>
<tr>
<td>Bleeding index: 0/1/2/3 (#patient)</td>
<td>9/9/2/0</td>
<td>9/6/3/2</td>
<td>0.39</td>
<td>11/7/1/0</td>
<td>12/8/0/0</td>
<td>0.59</td>
<td>11/9/0/0</td>
<td>15/5/0/0</td>
<td>0.16</td>
</tr>
<tr>
<td>Pocket depth in mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mesial (mean ±sd)</td>
<td>3.0±1.7</td>
<td>3.3±1.7</td>
<td>0.51</td>
<td>3.1±0.6</td>
<td>3.2±0.7</td>
<td>0.80</td>
<td>3.3±0.7</td>
<td>3.6±0.8</td>
<td>0.27</td>
</tr>
<tr>
<td>Distal (mean ±sd)</td>
<td>3.3±1.1</td>
<td>3.6±1.6</td>
<td>0.43</td>
<td>3.6±0.7</td>
<td>3.3±0.7</td>
<td>0.25</td>
<td>3.5±0.8</td>
<td>3.8±0.8</td>
<td>0.33</td>
</tr>
<tr>
<td>Buccal (mean ±sd)</td>
<td>1.6±0.8</td>
<td>2.3±1.2</td>
<td>0.10</td>
<td>2.8±0.8</td>
<td>3.3±0.9</td>
<td>0.17</td>
<td>3.2±0.8</td>
<td>3.3±0.7</td>
<td>0.53</td>
</tr>
<tr>
<td>Palatal (mean ±sd)</td>
<td>2.2±0.9</td>
<td>2.9±1.9</td>
<td>0.12</td>
<td>2.8±0.4</td>
<td>2.9±0.6</td>
<td>0.76</td>
<td>2.7±0.6</td>
<td>3.1±0.5</td>
<td>0.09</td>
</tr>
</tbody>
</table>
### Table 4. Oral Health Impact Profile (OHIP) scores at baseline (T1) and one year (T12) of functioning.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Immediate group</th>
<th>P-value</th>
<th>Delayed group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question 1</strong>&lt;br&gt;Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?</td>
<td>0/17/3/0/0&lt;br&gt;0/14/5/1/0</td>
<td>0.41</td>
<td>0/19/1/0/0&lt;br&gt;0/16/3/1/0</td>
<td>0.32</td>
</tr>
<tr>
<td><strong>Question 2</strong>&lt;br&gt;Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?</td>
<td>0/18/2/0/0&lt;br&gt;0/16/2/2/0</td>
<td>0.35</td>
<td>0/19/1/0/0&lt;br&gt;0/18/1/1/0</td>
<td>0.60</td>
</tr>
<tr>
<td><strong>Question 3</strong>&lt;br&gt;Have you had a painful aching in your mouth?</td>
<td>0/11/7/2/0&lt;br&gt;0/9/10/1/0</td>
<td>0.59</td>
<td>0/9/9/2/0&lt;br&gt;0/10/8/2/0</td>
<td>0.95</td>
</tr>
<tr>
<td><strong>Question 4</strong>&lt;br&gt;Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?</td>
<td>0/12/7/1/0&lt;br&gt;0/11/5/4/0</td>
<td>0.34</td>
<td>0/16/3/1/0&lt;br&gt;0/16/2/2/0</td>
<td>0.77</td>
</tr>
<tr>
<td><strong>Question 5</strong>&lt;br&gt;Have you been self-conscious of your teeth, mouth or dentures?</td>
<td>0/10/4/4/2&lt;br&gt;0/11/4/5/0</td>
<td>0.54</td>
<td>0/13/4/3/0&lt;br&gt;0/15/3/1/0</td>
<td>0.53</td>
</tr>
<tr>
<td><strong>Question 6</strong>&lt;br&gt;Have you felt tense because of problems with your teeth, mouth or dentures?</td>
<td>0/12/5/3/0&lt;br&gt;0/14/3/3/0</td>
<td>0.72</td>
<td>0/11/5/4/0&lt;br&gt;0/16/1/3/0</td>
<td>0.15</td>
</tr>
<tr>
<td><strong>Question 7</strong>&lt;br&gt;Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?</td>
<td>0/17/3/0/0&lt;br&gt;0/16/4/0/0</td>
<td>0.68</td>
<td>0/19/1/0/0&lt;br&gt;0/16/4/0/0</td>
<td>0.17</td>
</tr>
<tr>
<td><strong>Question 8</strong>&lt;br&gt;Have you had to interrupt meals because of problems with your teeth, mouth or dentures?</td>
<td>0/18/2/0/0&lt;br&gt;0/18/2/0/0</td>
<td>1.00</td>
<td>0/18/2/0/0&lt;br&gt;0/20/0/0/0</td>
<td>0.24</td>
</tr>
<tr>
<td>Question</td>
<td>Description</td>
<td>Score 1</td>
<td>Score 2</td>
<td>Score 3</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>---------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td><strong>Question 9</strong></td>
<td>Have you found it difficult to relax because of problems with your teeth, mouth or dentures?</td>
<td>0.38</td>
<td>0.14</td>
<td>0.14</td>
</tr>
<tr>
<td><strong>Question 10</strong></td>
<td>Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?</td>
<td>0.54</td>
<td>0.54</td>
<td>0.54</td>
</tr>
<tr>
<td><strong>Question 11</strong></td>
<td>Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?</td>
<td>0.37</td>
<td>0.37</td>
<td>0.37</td>
</tr>
<tr>
<td><strong>Question 12</strong></td>
<td>Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?</td>
<td>0.79</td>
<td>0.79</td>
<td>0.79</td>
</tr>
<tr>
<td><strong>Question 13</strong></td>
<td>Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?</td>
<td>0.68</td>
<td>0.68</td>
<td>0.68</td>
</tr>
<tr>
<td><strong>Question 14</strong></td>
<td>Have you been totally unable to function because of problems with your teeth, mouth or dentures?</td>
<td>0.31</td>
<td>0.31</td>
<td>0.31</td>
</tr>
</tbody>
</table>
Discussion

The present study showed that immediate placement with delayed provisionalization was not inferior to delayed placement with delayed provisionalization at a level of >0.9 mm MBL. Although not a priori powered to compare the other outcome variables, no clinically relevant differences were observed regarding clinical, esthetic and patient-reported outcomes too. Immediate placement offers a shorter treatment time due to the lower number of surgical procedures by combining extraction, implant placement, and bone grafting in one operative procedure.27-29

Clinical outcomes
Change in MBL in this study is considerably less than the generally accepted magnitude of up to 1 mm for the first year after implant placement described in the systematic review of Lang et al.1 and the 0.81±0.48 mm according to the systematic review of Slagter et al.1 concerning immediate implant placement. It has to be mentioned that MBL loss usually predominantly occurs during the first year after immediate implant placement and hardly progresses thereafter.1 Thus, the 1-year results are considered to reflect the level of MBL related to a specific treatment in healthy subjects, a result that supports the immediate implant placement approach.

A successful aesthetic outcome is presumably dependent on establishment of an optimal three-dimensional implant position within the available bone dimensions as well as the maintenance of adequate buccal bone over the buccal implant surface.30,31 In the present study, the buccal bone thickness appeared at least to be stable up to 1 year after implant placement and provisionalization in both patient groups and was thus considered to be independent of timing of implant insertion. Literature regarding BBT is scarce. Comparison with other studies, although measured in a different study design, learned that in the present study BBT after 1 year for immediate placed implants was more than the value of 0.16 mm thickness reported in the immediate implant group of Raes et al.32 but less than the 2.12 mm BBT reported by Degidi et al.33 For the delayed placed implants, BBT in the present study was more than the 0.20 mm reported by Raes et al.32

Regarding the peri-implant soft tissues, the phenomenon biotype has been reported to affect the aesthetic result.34 Possibly the thickness of the mucosa can positively influence the stability of the peri-implant soft tissues. In future studies, the effect of biotype on treatment outcome should be an integral part of the treatment design.

Aesthetic assessments

Although not upfront powered, the PES/WES and ICAI scores were comparable for the studied approaches and were comparable to results published in the literature regarding immediately and delayed placed single tooth implants placed in the aesthetic zone.16,95-96 The scores of the pink component of PES/WES and ICAI were favorable and comparable for the immediate and delayed approaches, again supporting immediate placement of implants in larger bony defects when primary stability of the implant can be achieved.
Patients’ satisfaction
In the field of implant dentistry there is an increasing focus on patient-reported outcome measures.37 Immediate placement with immediate provisionalization is associated with high satisfaction rates.38 This is in line with the satisfaction perceived by patients with immediate implant placement in this study. Regarding the OHIP-14, no differences were observed between both groups during the entire follow-up, again in line with other studies regarding immediate implant placement.39,40 The two protocols, while yielding comparable results in terms of clinical outcomes and patient satisfaction, differed considerably in time to teeth and the number of scheduled visits (Figure 2), with the immediate implant placement reducing both the time and visit number to final restoration.

Limitation
The procedure to replace a failing tooth in the aesthetic zone with a bony defect with an immediate implant is a complex procedure. Raghoebar et al13 showed that gingival mid-labial aesthetics most benefitted from a full thickness palatal graft compared to a connective tissue graft or closing with a membrane. Due to the complexity of this procedure, to achieve an optimal result it was recommended that the surgery should be done by experienced surgeons.13 Therefore, in the current study all surgeries were performed by one single experienced surgeon. The latter approach compromises the applicability of the reported approach for general applications.

Conclusion
Immediate placement with delayed provisionalization is non-inferior regarding a change in MBL of >0.9 mm to delayed placement with delayed provisionalization in labial bony defects of ≥5 mm in the aesthetic zone after a 1-year follow-up. In addition, although not powered for these outcome variables, no clinically relevant differences in other outcomes were observed.
References


