Feasibility of immediate placement of single-tooth implants in the aesthetic zone: a 1-year randomized controlled trial.

This chapter is an edited version of the manuscript:
Abstract

Aim:

to assess whether outcome of immediate implant placement and immediate provisionalization after one year was non-inferior to immediate implant placement and delayed provisionalization regarding Marginal Bone Level (MBL).

Materials and Methods:

Forty patients with a failing tooth in the aesthetic zone were randomly assigned for immediate implant placement with immediate (n=20) or delayed (n=20) provisionalization. Follow-up was at 1 month and after one year. The study was powered to detect a difference in MBL of <0.9 mm. Apart from MBL, soft tissue peri-implant parameters, aesthetic indexes and patient satisfaction were assessed. (www.isrctn.com: ISRCTN57251089)

Results:

After one year, MBL changes were 0.75±0.69 mm mesially and 0.68±0.65 mm distally for the immediate group and 0.70±0.64 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 0.08 mm (95%CI -0.38 to 0.53, p=0.71), distally: Immediate vs. Delayed: difference in mean 0.09 mm (95%CI-0.37 to 0.56 mm, p=0.66)). No significant differences in the other outcome variables were observed.

Conclusion:

This study showed that immediate placement and immediate provisionalization was non-inferior to immediate placement with delayed provisionalization. In addition, although not powered for these outcome variables, no clinically relevant differences in other outcomes were observed.
Introduction

Traditionally, placement and restoration of dental implants is a process involving a long period\(^1\), therefore the quest for a shorter treatment period is imminent. Currently, there is a growing tendency to place single tooth implants in the aesthetic zone immediately after extraction of a failing tooth, preferably combined with immediate provisionalization.\(^2,3\) This tendency is probably related to evolving society factors, with more demanding patients and a wish for direct treatment. Innovations in implant surfaces and designs have facilitated the possibilities for such an approach.\(^4\) In view of these developments, immediate placement and provisionalization of implants is nowadays presumed to be a reliable treatment option for single tooth implants in the aesthetic zone.\(^5,6\)

In line with this presumption, in a systematic review and pooled analysis\(^7\), it was demonstrated that immediate placement with immediate provisionalization of dental implants in the aesthetic zone resulted in an excellent short-term treatment outcome in terms of implant survival. Besides implant survival, establishment and maintenance of healthy hard and soft peri-implant tissues are crucial too, particularly in the aesthetic zone.\(^8,9\) Therefore, the interest in hard and soft tissue dynamics related to immediate single tooth implant placement in the aesthetic zone increased.\(^10,11\)

To objectively rate implant-based aesthetics, a number of aesthetic indexes has been developed including the Implant Crown Aesthetic Index (ICAI)\(^12\); the pink aesthetic score (PES)\(^13\), and the white aesthetic score (WES)\(^14,15\). To rate the opinion of the patients themselves patient-centered outcomes as the Visual Analogue Scale (VAS)\(^16\) and Oral Health Impact Profile (OHIP)\(^17\) have been developed.

Inherent to the shift in interest to patient-centered outcomes, few studies have yet been conducted in which outcome measures are systematically assessed.\(^18,19\) Currently, to the best of our knowledge, no randomized clinical trials assessing the full panel of outcome measures, including changes in the hard and soft tissue dimensions, implant survival, aesthetic evaluation and patient-centered outcome in the aesthetic zone, have been published. Therefore, the aim of this randomized controlled trial was to assess whether outcome of immediate implant placement and immediate provisionalization after one year was non-inferior to immediate implant placement and delayed provisionalization regarding MBL. Our null hypothesis stated that the difference in means of MBL between the two treatment groups would be greater or equal to 0.9 mm. Soft peri-implant tissues, aesthetics and patient-centered outcomes in the aesthetic zone were also assessed.

Materials and methods

Study design

All consecutive patients (age ≥ 18 year) with a failing tooth in the maxillary aesthetic zone (incisor, canine or first premolar) referred to the department of Oral and Maxillofacial Surgery between January 2010 and January 2012 for single tooth implant treatment, were considered if adequate oral hygiene and sufficient space were present and when eligible asked to participate in this randomized clinical trial (Figure 1 and 2). The size of the bone defect was assessed after extraction of the failing tooth. The shape of the osseous defect was checked by a bone sounding technique with a periodontal probe at the midfacial, the mesial,
and distal aspect of the failing tooth, and the mesial and distal aspect of the immediately adjacent teeth. The patient was only included in the present study if the buccal socket wall had a bony defect of ≤5 mm in a vertical direction. For allocation to a group determined by the bony defect, a computerized random number generator was used. A research-nurse not involved in the study blindly allocated the patients to:

- **Group A**: *immediate* placed implant (NobelActive, Nobel Biocare AB, Goteborg, Sweden) and *immediate* provisionalization;
- **Group B**: *immediate* 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 (www.isrctn.com: 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 composed of a 0.2% chlorhexidine mouthwash, twice daily for 7 days.

All surgeries were performed under local anesthesia. First, the attached periodontal ligament from the failing tooth was carefully detached by an incision in the sulcus. Periotomes were used to extract the failing tooth atraumatically. No mucoperiosteal flap was raised. 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. The remaining space between the burr and the peri-implant bone was locally augmented. As grafting material, autogenous bone from the retromolar–ramus area was gathered using a bonescraper (Bonescraper, Biomet 3i, Warsaw, Indiana, USA) 1:1 mixed with anorganic bone (Geistlich Bio-Oss, Geistlich Pharma AG, Wolhusen, Switzerland). Regarding the corono-apical position of the implants, 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 a surgical template.

**Group A**: *immediate* placed implant and *immediate* provisionalization

An implant-level impression was made immediately after implant placement. After the impression, a corresponding healing abutment was placed. In the dental laboratory, a screw-retained provisional crown was fabricated by means of an engaging temporary abutment and composite. The provisional restoration was free from centric and eccentric contacts with the antagonist teeth. Approximately 6 hours following implant placement, the healing abutment was removed, and the provisional crown was screwed directly onto the implant with 20 Ncm by a manual torque wrench (Manual Torque Wrench Prosthetic; Nobel Biocare AB).

**Group B**: *immediate* placed implant and *delayed* provisionalization.

immediately after implant placement a corresponding cover screw was placed. Following a standard protocol for an optimal aesthetic outcome, a free oval full thickness soft-tissue graft was punched and harvested from the palatal mucosa. The diameter of the punch was 2 mm larger than the socket access.
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=19)
- Excluded from 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=1, patient did not show up at appointments)
Discontinued intervention (give reasons) (n=0)

Analysis

Analysed (n=20)
- Excluded from analysis (give reasons) (n=0)
That 2 mm of epithelium was removed from soft tissue graft. The 2 mm zone of the soft tissue graft denuded from epithelium was located beneath the mucosa at the recipient site. This was done to facilitate closure and healing of the grafted area. The graft was sutured with Ethilon 5-0 (Johnson & Johnson, Amersfoort, The Netherlands) on top of the reconstructed socket. 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 group A. All surgical procedures were performed by one experienced oral and maxillofacial surgeon (GR).

Prosthetic protocol
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, a digital design of the definitive crown was made to the desired form of the abutment. The digital design was used to retrieve individualized zirconia abutments (NobelProcera, Nobel Biocare AB). Depending on the location of the screw access hole, the final crown was either a cemented-retained or screw-retained zirconia crown (Procera, NobelBiocare AB). 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 one 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, 12 months after placement of the definitive crown on the mesial and the distal site. Secondary outcome measures included implant survival, change in interproximal peri-implant mucosa (IML) and change in midfacial peri-implant mucosal level (MML) as compared with the gingival level of the pre-operative failing tooth. Furthermore, papilla volume, biotype prior to removal of the tooth, health of keratinized gingiva, amount of plaque, amount of bleeding and pocket probing depth were assessed. Aesthetic outcome was assessed by means of objective indexes (ICAI, PES/WES). Patients’ satisfaction was assessed using the Oral Health Impact Profile (OHIP) index and the Visual Analogue Scale (VAS) on a 0-10 scale.

Radiographic assessments
To calculate changes in MBL, a standardized digital peri-apical radiograph was taken with an individualized aiming device21, pre-operatively (Tpre), immediately following implant placement (baseline, To), 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 known implant diameter as a reference. The manufacturer provided the exact dimension of the implants used. Measurements were independently performed by two examiners (KS and Harry Slagter), after which the average of both measurements was used.
Survival rate
Survival rate was defined as the percentage functional implants one year after definitive crown placement in both groups. The criteria for successful osseointegration according to Smith & Zarb (1989) were adapted.

Photographic assessments
Before implant placement (Tpre) and after placement of the definitive crown standardized digital photographs (Nikon D300s, Nikon Corporation, Yurakucho, Tokyo, Japan) were taken at T1 and T12 using a technique as described earlier. A manual periodontal probe (Williams Color-Coded probe; Hu-Friedy, Chicago, IL, USA) was held in close proximity and parallel to the long axis of the adjacent tooth. The known dimensions of the periodontal probe allowed for calibration of 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 both at the implant and adjacent teeth before implant placement (Tpre) and after finalization of the definitive crown:

- Papilla volume: assessing the mesial and distal papilla adjacent to the implant using the papilla index;
- Amount of plaque: assessed at four sites per implant/adjacent tooth (mesial, buccal, distal and palatal) using the modified plaque index;
- Amount of bleeding: using the modified sulcus bleeding index;
- Gingiva: using the gingival Index;
- Probing pocket depth: assessed at four sites per implant/adjacent tooth (mesial, buccal, distal and palatal) using a manual periodontal probe (Williams Color-Coded probe; Hu-Friedy, Chicago, IL, USA) measuring to the nearest 1 mm.

All data were retrieved by one blinded examiner (KS).

Aesthetic assessments
The aesthetic outcome was assessed on standardized digital photographs (Nikon D300s, Nikon Corporation) taken at Tpre and T1, and T12 in both groups. An additional photograph was taken of implant crowns replacing the lateral or canine capturing the contra lateral tooth. Peri-implant mucosa and implant crown aesthetic outcomes were determined using ICAI12 and PES-WES14. Measurements were independently performed by two examiners (KS and Diederik Hentenaar).

Patients' satisfaction
Patients’ satisfaction was assessed at T1 and T12 using the validated OHIP-14 questionnaire. Overall satisfaction compared to Tpre was questioned using a 100-mm VAS scale.
Figure 2A. Schedule of visits and procedures study group A: immediate placement and immediate provisionalization.
Figure 2B. Schedule of visits and procedures study group A: immediate placement and delayed provisionalization.
Statistical analysis
For determination of the sample size, G*power version 3.1 was used.\textsuperscript{25} A radiographic 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{5}. 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 deal with possible redrawing. 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. Inter- and intra-examiner measurements were repeated twice by two independent observers in a random order. 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
Measurements were repeated twice by two independent observers in a random order. For the radiographic assessment, the interobserver intraclass correlation coefficient was 0.88 (95CI 0.83-0.92). The intraobserver intraclass correlation coefficient was 0.89 (95CI 0.83- 0.97) for observer one and 0.83 (95CI 0.80-0.95) for observer two. For the photographic assessment, the interobserver intraclass correlation coefficient was 0.93 (95CI 0.88-0.98). The intraobserver intraclass correlation coefficient was 0.93 (95CI 0.87-0.96) for observer one and 0.90 (95CI 0.88-0.96) for observer two. For ICAI and PES-WES, the interobserver intraclass correlation coefficient were 0.88 (95CI 0.77-0.94) and 0.87 (95CI 0.75-0.94), respectively. The reliability from all different assessments proved to be acceptable.

Patients
Baseline and clinical characteristics of groups A (n=20) and B (n=20) as well as details on surgical and prosthetic procedures are depicted in Table 1 and Figures 3 and 4. One patient in group B was lost to follow up immediately after definitive crown placement. All patients received their assigned treatment.

Change in marginal bone level
Table 2 shows the mean MBL changes at the mesial and distal site after twelve months in relation to the time point of connecting the definitive crown. Regarding differences in means, non inferiority was observed (at a level of 0.9 mm), both after 3 months (mesially: Group A vs. B: difference in mean 0.02 mm (95%CI -0.42 to 0.46 mm, p=0.64, distally: Group A vs. B: difference in mean 0.06 mm (95%CI -0.40 to 0.52 mm, p=0.66) as well as after 1 year (mesially: Group A vs. B: difference in mean 0.08 mm (95%CI -0.38 to 0.53 mm, p=0.71, distally: Group A vs. B: difference in mean 0.09 mm (95%CI -0.37 to 0.56 mm, p=0.66). To analyze the uneven
Table 1. Baseline characteristics and treatment specifications per study group.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A (n=20)</th>
<th>Group B (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age ±sd (range)</td>
<td>39.4±16.9 (19-70)</td>
<td>42.3±14.2 (23-66)</td>
</tr>
<tr>
<td>Male/female</td>
<td>5/15</td>
<td>8/12</td>
</tr>
<tr>
<td>Implant site location I1/I2/C</td>
<td>7/8/5</td>
<td>13/6/1</td>
</tr>
<tr>
<td>Cause of tooth loss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Fracture (crown or root)</td>
<td>7/10</td>
<td></td>
</tr>
<tr>
<td>• Agenesis</td>
<td>6/0</td>
<td></td>
</tr>
<tr>
<td>• Caries</td>
<td>0/1</td>
<td></td>
</tr>
<tr>
<td>• Endodontic failure</td>
<td>2/6</td>
<td></td>
</tr>
<tr>
<td>• Periodontal failure</td>
<td>0/0</td>
<td></td>
</tr>
<tr>
<td>• Root resorption</td>
<td>5/3</td>
<td></td>
</tr>
<tr>
<td>Bone defect mean±sd (mm)</td>
<td>3.4±1.19</td>
<td>4.2±1.08</td>
</tr>
<tr>
<td>Length implant (mm) 13/15/18</td>
<td>2/16/2</td>
<td>2/9/9</td>
</tr>
<tr>
<td>Diameter (mm) 4.3/ 3.5</td>
<td>12/8</td>
<td>15/5</td>
</tr>
<tr>
<td>Type of final restoration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Screw-retained</td>
<td>14/12</td>
<td></td>
</tr>
<tr>
<td>• Cement-retained</td>
<td>6/8</td>
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</tbody>
</table>
distribution of the agenesis patients (6 vs. 0, see Table 1) additional analyses were performed, comparing both groups with the agenesis patients excluded, as well as an analysis in group A comparing the differences between the agenesis patients and other patients, showing no significant differences between both groups (data not shown).

Survival rate
No implants were lost during the study resulting in an implant survival rate of 100% at one year after placement of the definitive crown for both groups.

Change in interproximal and midfacial peri-implant mucosal level
Table 2 shows the soft tissue level changes from the pre-operative situation up to 12 months after placement of the definitive crown at the mesial, distal and mid-facial site. Again, the largest IML change was observed early after placement of the definitive crown, with an observed statistical significant, persisting difference with regard to the mesial papilla in both groups (0.89±0.46 mm (immediate) and 0.32±0.43 mm (delayed), p<0.001). Between the 1 and 12 months evaluation, only minor, non-significant changes were observed with regard to IML and MML.

Clinical outcome
The health of the keratinized gingiva remained stable, and the plaque and bleeding indexes remained low throughout the study period (Table 3). Even at one year of follow-up no plaque was seen in both groups. Pocket probing depth remained stable for both groups on all four measured sites: mesial, distal, buccal and palatal.

Aesthetic assessments
The ICAI and PES/WES scores are shown in Table 2. After one year, an acceptable clinical ICAI and PES/WES outcome was seen in 94% patients of both groups A and B. The total aesthetic outcome was mainly influenced by the appearance of the implant crown (WES) and to a lesser extent by the peri-implant mucosa (PES). A positively significant difference in aesthetic outcome was measured over time within each group. No significant difference was measured between both groups.

Patients’ satisfaction
At the first follow-up visit after definitive crown placement, no significant differences between both groups were observed. After one year, however, VAS scores were 8.2±0.9 and 9.1±0.8 for groups A and B, respectively (p<0.002). Regarding the OHIP-14 (Table 4), no statistical significances were observed between both groups one year after definitive crown placement.
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 Tpre Mean (sd)</th>
<th>Group A T1 Mean (sd)</th>
<th>P-value</th>
<th>Group B Tpre Mean (sd)</th>
<th>Group B T1 Mean (sd)</th>
<th>P-value</th>
<th>Group A T12 Mean (sd)</th>
<th>Group B T12 Mean (sd)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marginal bone level in mm(±sd)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mesial of implant</td>
<td>0.70 (±0.67)</td>
<td>0.68 (±0.64)</td>
<td>0.92</td>
<td>0.75 (±0.69)</td>
<td>0.68 (±0.65)</td>
<td>0.73</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal of implant</td>
<td>0.69 (±0.71)</td>
<td>0.64 (±0.63)</td>
<td>0.80</td>
<td>0.70 (±0.64)</td>
<td>0.68 (±0.64)</td>
<td>0.68</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Marginal soft tissue level changes in mm (±sd)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Mesial of implant</td>
<td>0.90 (±0.45)</td>
<td>0.44 (±0.45)</td>
<td>0.003</td>
<td>0.89 (±0.46)</td>
<td>0.32 (±0.43)</td>
<td>0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal of implant</td>
<td>0.44 (±0.45)</td>
<td>0.78 (±0.67)</td>
<td>0.54</td>
<td>1.00 (±0.58)</td>
<td>0.79 (±0.66)</td>
<td>0.33</td>
<td></td>
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</tr>
<tr>
<td>Mid-facial of implant</td>
<td>1.15 (±0.81)</td>
<td>0.78 (±0.86)</td>
<td>0.18</td>
<td>0.95 (±0.62)</td>
<td>0.85 (±0.86)</td>
<td>0.71</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>PES</td>
<td>7.00 (2.05)</td>
<td>6.90 (1.32)</td>
<td>0.63</td>
<td>7.80 (1.66)</td>
<td>7.40 (1.59)</td>
<td>0.71</td>
<td>7.50 (1.59)</td>
<td>7.40 (1.46)</td>
<td>0.79</td>
</tr>
<tr>
<td>WES</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>8.10 (0.90)</td>
<td>7.90 (1.08)</td>
<td>0.79</td>
</tr>
<tr>
<td>PES/WES</td>
<td>11.60 (3.33)</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>15.80 (2.05)</td>
<td>15.30 (2.11)</td>
<td>0.50</td>
</tr>
<tr>
<td>ICAI</td>
<td>9.6 (0.54)</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 immediate provisionalization.
   a. Clinical situation pre-operative.
   b. Pre-operative radiograph.
   c. Clinical situation post-operative after one year.
   d. Post-operative radiograph after one year.
Figure 4. Immediate implant treatment with delayed provisionalization.

a. Clinical situation pre-operative.

b. Pre-operative radiograph.

c. Clinical situation post-operative after one year.

d. Post-operative radiograph after one year.
Table 3. Clinical outcome measures from pre-operative to 12 months after definitive crown placement.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Tpre Mean (sd)</th>
<th>Tpre Mean (sd)</th>
<th>P-value</th>
<th>T1 Mean (sd)</th>
<th>T1 Mean (sd)</th>
<th>P-value</th>
<th>T12 Mean (sd)</th>
<th>T12 Mean (sd)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Papilla volume (papilla index 0/1/2/3/4)</td>
<td>1.95 (1.10)</td>
<td>1.95 (0.85)</td>
<td>0.99</td>
<td>2.16 (0.83)</td>
<td>2.37 (0.60)</td>
<td>0.38</td>
<td>2.35 (0.81)</td>
<td>2.67 (0.77)</td>
<td>0.23</td>
</tr>
<tr>
<td>Mesial</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Distal</td>
<td>2.05 (0.99)</td>
<td>1.68 (0.67)</td>
<td>0.19</td>
<td>2.37 (0.76)</td>
<td>2.00 (0.67)</td>
<td>0.12</td>
<td>2.45 (0.76)</td>
<td>2.28 (0.75)</td>
<td>0.49</td>
</tr>
<tr>
<td>Health of gingiva (gingival index 0/1/2/3)</td>
<td>0.00 (0.00)</td>
<td>0.00 (0.00)</td>
<td>NA</td>
<td>0.90 (0.31)</td>
<td>0.79 (0.42)</td>
<td>0.35</td>
<td>0.80 (0.70)</td>
<td>0.94 (0.24)</td>
<td>0.41</td>
</tr>
<tr>
<td>Amount of plaque (plaque index)</td>
<td>0.10 (0.31)</td>
<td>0.05 (0.23)</td>
<td>0.59</td>
<td>0.00 (0.00)</td>
<td>0.05 (0.23)</td>
<td>0.31</td>
<td>0.00 (0.00)</td>
<td>0.00 (0.00)</td>
<td>NA</td>
</tr>
<tr>
<td>Bleeding after probing (bleeding index)</td>
<td>0.75 (0.55)</td>
<td>0.68 (0.58)</td>
<td>0.71</td>
<td>0.60 (0.60)</td>
<td>0.47 (0.61)</td>
<td>0.52</td>
<td>0.25 (0.44)</td>
<td>0.22 (0.43)</td>
<td>0.85</td>
</tr>
<tr>
<td>Pocket probing depth (mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mesial</td>
<td>2.70 (0.80)</td>
<td>2.44 (0.71)</td>
<td>0.31</td>
<td>3.50 (0.83)</td>
<td>3.21 (0.71)</td>
<td>0.25</td>
<td>2.95 (0.76)</td>
<td>3.11 (0.32)</td>
<td>0.41</td>
</tr>
<tr>
<td>Distal</td>
<td>2.85 (1.09)</td>
<td>2.61 (0.70)</td>
<td>0.43</td>
<td>3.15 (0.49)</td>
<td>3.21 (0.92)</td>
<td>0.80</td>
<td>3.05 (0.61)</td>
<td>3.50 (0.71)</td>
<td>0.41</td>
</tr>
<tr>
<td>Buccal</td>
<td>1.60 (0.75)</td>
<td>1.89 (0.96)</td>
<td>0.31</td>
<td>2.65 (1.42)</td>
<td>2.79 (0.86)</td>
<td>0.72</td>
<td>3.05 (0.83)</td>
<td>3.00 (0.59)</td>
<td>0.83</td>
</tr>
<tr>
<td>Palatal</td>
<td>1.65 (0.81)</td>
<td>2.06 (0.80)</td>
<td>0.13</td>
<td>2.30 (0.66)</td>
<td>2.79 (0.42)</td>
<td>0.18</td>
<td>2.90 (0.55)</td>
<td>2.89 (0.32)</td>
<td>0.94</td>
</tr>
</tbody>
</table>

NA = not applicable
Table 4. OHIP scores from one month to one year of functioning.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A T0-T1 P-value</th>
<th>Group B T0-T1 P-value</th>
<th>Group A T1-T12 P-value</th>
<th>Group B T1-T12 P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question 1</strong> Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?</td>
<td>0/18/0/2/0 0/17/0/2/0</td>
<td>0.96</td>
<td>0/20/0/0/0 0/17/2/0/0</td>
<td>0.20</td>
</tr>
<tr>
<td><strong>Question 2</strong> Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?</td>
<td>0/20/0/0/0 0/16/3/0/0</td>
<td>0.06</td>
<td>0/16/1/3/0 0/16/2/0/0</td>
<td>0.29</td>
</tr>
<tr>
<td><strong>Question 3</strong> Have you had a painful aching in your mouth?</td>
<td>0/15/2/3/0 0/14/2/3/0</td>
<td>0.90</td>
<td>0/20/0/0/0 0/17/2/0/0</td>
<td>0.60</td>
</tr>
<tr>
<td><strong>Question 4</strong> Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?</td>
<td>0/14/2/4/0 0/11/6/2/0</td>
<td>0.99</td>
<td>0/15/4/1/1 0/15/3/1/1</td>
<td>0.43</td>
</tr>
<tr>
<td><strong>Question 5</strong> Have you been self-conscious of your teeth, mouth or dentures?</td>
<td>0/14/3/2/1 0/15/2/2/0</td>
<td>0.22</td>
<td>0/13/4/3/0 0/16/2/1/0</td>
<td>0.65</td>
</tr>
<tr>
<td><strong>Question 6</strong> Have you felt tense because of problems with your teeth, mouth or dentures?</td>
<td>0/18/2/0/0 0/15/2/2/0</td>
<td>0.75</td>
<td>0/17/2/1/0 0/14/3/1/1</td>
<td>0.45</td>
</tr>
<tr>
<td><strong>Question 7</strong> Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?</td>
<td>0/19/1/0/0 0/18/0/1/0</td>
<td>0.33</td>
<td>0/14/4/1/0 0/15/4/0/0</td>
<td>0.29</td>
</tr>
<tr>
<td><strong>Question 8</strong> Have you had to interrupt meals because of problems with your teeth, mouth or dentures?</td>
<td>0/14/4/1/1 0/17/1/1/0</td>
<td>0.37</td>
<td>0/15/4/1/0 0/16/3/0/0</td>
<td>0.94</td>
</tr>
<tr>
<td><strong>Question 9</strong> Have you found it difficult to relax because of problems with your teeth, mouth or dentures?</td>
<td>0/14/1/5/0 0/17/1/1/0</td>
<td>0.38</td>
<td>0/13/4/3/0 0/15/2/2/0</td>
<td>0.54</td>
</tr>
<tr>
<td>Question 10</td>
<td>Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?</td>
<td>0/14/1/5/0 0/13/3/3/0</td>
<td>0.47</td>
<td>0/17/2/1/0 0/13/3/1/1</td>
</tr>
<tr>
<td>Question 11</td>
<td>Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?</td>
<td>0/16/2/2/0 0/17/2/0/0</td>
<td>0.37</td>
<td>0/14/4/1/0 0/15/2/2/0</td>
</tr>
<tr>
<td>Question 12</td>
<td>Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?</td>
<td>0/18/2/0/0 0/17/2/0/0</td>
<td>0.23</td>
<td>0/15/4/1/0 0/15/3/1/0</td>
</tr>
<tr>
<td>Question 13</td>
<td>Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?</td>
<td>0/18/2/0/0 0/17/2/0/0</td>
<td>0.21</td>
<td>0/13/4/3/0 0/15/3/1/0</td>
</tr>
<tr>
<td>Question 14</td>
<td>Have you been totally unable to function because of problems with your teeth, mouth or dentures?</td>
<td>0/19/0/1/0 0/17/2/0/0</td>
<td>0.21</td>
<td>0/18/2/0/0 0/17/2/0/0</td>
</tr>
</tbody>
</table>
Discussion

The present study showed that immediate placement and immediate provisionalization was not inferior to immediate placement with delayed provisionalization with the difference in means of MBL between the two treatment groups being smaller <0.90 mm, thereby rejecting the null-hypothesis. Only some statistically significant differences were observed in VAS-score and mesial IML after one year. These differences were not regarded clinically relevant.

Peri-implant hard and soft tissue dimensions

The results of the present study are in line with other clinical studies on immediate placement in the aesthetic zone with regard to change in MBL. In a recent systematic review, a mean MBL change of 0.81±0.48 mm was reported. These results were based on 43 studies reporting on immediate placement of single tooth implants in the aesthetic zone. This study is in line with these findings with a reported MBL change after one year of 0.75±0.69 mm mesially and 0.68±0.65 mm distally for the immediate group and 0.70±0.64 mm and 0.68±0.64 mm for the delayed group). In this systematic review, a change of IML of 0.38±0.23 mm and a mean change of MML of 0.54±0.39 mm was reported, the mean change of IML and MML reported in this study was within this range.

It has been described that immediate implant placement is associated with an increased risk for recession of the peri-implant tissues. In this study, in our opinion, recession of peri-implant tissues was still clinically acceptable after one year (IML of 1.00±0.58 mm and MML 0.95±0.62 mm). The observed significant difference between groups A and B with regard to the mesial IML, probably can be explained by the absence of immediate support by a provisional crown in group B as well as the use of a removable denture. Theoretically, after placement of a provisional crown, peri-implant tissues have the possibility to gain height due to support of the provisional crown.

Clinical outcome

We reported a 100% survival rate of immediately placed implants in the aesthetic zone, comparable with known numbers. With regard to the papilla volume, we showed that papilla volume gained after one year. This phenomenon has also been demonstrated in studies involving conventional and immediate implant placement. In this study, pocket probing depths and the health of the keratinized gingiva remained stable throughout the study period, while the plaque and bleeding indexes remained low in both groups.

Aesthetic assessments

PES/WES scores did not differ statistically between both groups and were comparable to the aesthetic results published in the literature regarding single tooth implants in the aesthetic zone. This is an important observation, as the present study specifically assessed differences in the aesthetic zone. Obviously further improvement of the aesthetic results is always desirable.
Patients’ satisfaction
Over the last years, there is an increasing focus on patient-reported outcome measures within the field of implant dentistry. Immediate placement and provisionalization are known to be associated with high subjective satisfaction rates. This is in line with the patients’ satisfaction perceived by the patients in this study. Regarding the OHIP-14, no significant differences were observed between these groups during the entire follow-up, again in line with other studies. The significant difference after one year in the VAS score, though, is not considered to be a clinically relevant difference as more than a 13 point difference on the 100-point VAS is needed to obtain a clinically relevant difference. In addition, the observed difference might be explained by the fact that patients in group A were satisfied immediately, as provisionalization was performed the same day, while the other patients had to deal with a removable denture for three months making them even more satisfied with the final results as they had experienced the misery of wearing a removable denture for three months.

Limitations of the study
Some limitations have to be addressed. First, and most important, regarding the non-inferiority design we have to admit that the chosen maximal difference in means of <0.9 mm is debatable. In retrospect, a (much) smaller difference in means would have been better to prove non-inferiority. For now, we can only conclude that immediate provisionalization is not inferior to delayed provisionalization when considering a margin <0.9 mm as equal. However, because the data shows that the difference in MBL between both groups in fact is much smaller, it is reasonable to assume that with a smaller difference in means (and thus a larger sample size), immediate provisionalization would also be non-inferior to delayed provisionalization. On basis of these results (comparable results for both treatment designs), it also can be presumed that any difference observed between both treatments when increasing the sample size will be clinically rather irrelevant. Regarding the other outcome parameters we can only conclude that it seems that there is not a large difference between both groups. However, as this study was not powered do detect relevant differences for these outcome measures, no firm conclusions can be drawn from these observations. The second limitation is directly linked to the imbalance between both groups after randomization. All agenesis patients (n=6) were allocated to group A after randomization. Taking a closer look at these patients, no significant differences were present between agenesis patients and patients with a failing tooth for other reasons allocated to group A. It is therefore unlikely that this imbalance between both groups influenced our results.

In this study a maximum bony defect of 5 mm was used. However, it is difficult to measure the bony defect when the tooth is still in situ. The reasons of tooth loss can be very diverse, so randomization took only place on the bony defect. Given the seemingly favourable outcomes of immediate placement in this study, immediate placement in a larger bony defect should certainly be considered in future studies.

Conclusion
The present study showed that immediate placement and immediate provisionalization was non-inferior compared with immediate placement with delayed provisionalization regarding MBL at a level <0.9 mm. The outcome is hampered by the large margin for differences in means taken for non-inferiority. In this respect, further research in larger groups of patients is warranted to monitor the outcome measures, also on the long-term.
References


