Wide diameter immediate post-extractive implants vs delayed placement of normal-diameter implants in preserved sockets in the molar region: 1-year post-loading outcome of a randomised controlled trial

Key words  delayed implantation, immediate post-extractive implants, single implants, socket preservation, wide diameter implants

Purpose: To compare the effectiveness of 6.0 to 8.0 mm-wide diameter implants, placed immediately after tooth extraction, with conventional 4.0 or 5.0 mm diameter implants placed in a preserved socket after a 4-month period of healing in the molar region.

Materials and Methods: Just after extraction of one or two molar teeth, and with no vertical loss of the buccal bone in relation to the palatal wall, 100 patients requiring immediate post-extractive implants were randomly allocated to immediate placement of one or two 6.0 to 8.0 mm-wide diameter implants (immediate group; 50 patients) or for socket preservation using a porcine bone substitute covered by a resorbable collagen barrier (delayed group; 50 patients), according to a parallel group design in one centre. Bone-to-implant gaps were filled with autogenous bone retrieved with a trephine drill used to prepare the implant sites for the immediate wide diameter post-extractive implants. Four months after socket preservation, one to two 4.0 or 5.0 mm-wide delayed implants were placed. Implants were loaded 4 months after placement with fixed provisional restorations in acrylic, and replaced after 4 months by fixed, definitive, metal-ceramic restorations. Patients were followed to 1 year after loading. Outcome measures were: implant failures, complications, aesthetics assessed using the pink esthetic score (PES), peri-implant marginal bone level changes, patient satisfaction, number of appointments and surgical interventions recorded, when possible, by blinded assessors.

Results: Three patients dropped out 1 year after loading from the immediate group vs six from the delayed group. Five implants out of 47 failed in the immediate group (10.6%) vs two out 44 (4.6%) in the delayed group, the difference being not statistically significant (difference in proportion = 6.0%, 95% CI: -8.8% to 20.8%, P = 0.436). In the immediate group 10 patients were affected by 10 complications, while in the delayed group four patients were affected by four complications. The difference was not statistically significant (difference in proportion = 12%, 95% CI: -2% to 26%, P = 0.084). At delivery of the definitive prostheses, 4 months after loading, the mean total PES score was 9.65 ± 1.62 and 10.44 ± 1.47 in the immediate and delayed groups, respectively. At 1 year after loading, the mean total PES score was 9.71 ± 2.71 and 10.86 ± 1.37 in the immediate and delayed groups, respectively. The Total PES score was statistically significantly better at delayed implants both at 4 months (mean difference = 0.79; 95% CI: 0.05 to 1.53; P = 0.03) and at 1 year (mean difference = 1.15; 95% CI: 0.13 to 2.17; P = 0.02). Marginal bone levels at implant insertion (after bone grafting) were 0.04 mm for immediate and 0.11 mm for delayed implants, which was statistically significantly different (mean difference = 0.07; 95% CI: 0.02 to 0.12; P < 0.0001).
One year after loading, patients in the immediate group lost on average 1.06 mm and those from the delayed group 0.63 mm, the difference being statistically significant (mean difference = 0.43 mm; 95% CI: 0.15 to 0.61; $P < 0.0001$). All patients were fully or partially satisfied both for function and aesthetics, and would undergo the same procedure again both at 4 months and 1 year after loading. Patients from the immediate group required on average 7.48 ± 1.45 visits to the clinician and 2.14 ± 0.49 surgical interventions and to have their definitive prostheses delivered vs 10.30 ± 0.99 visits and 3.08 ± 0.40 surgical interventions for the delayed group, the difference being statistically significant ($P < 0.001$ for visits, and $P < 0.001$ for surgical interventions).

**Conclusions:** Preliminary 1 year follow-up data suggest that immediate placement of 6.0 to 8.0 mm wide diameter implants in molar extraction sockets yielded inferior aesthetic outcomes than ridge preservation and delayed placement of conventional 4.0 to 5.0 mm diameter implants.

**Conflict of interest statement:** This trial was partially funded by the manufacturer of the implants evaluated in this investigation (MegaGen Implant Co, Gyeongbuk, South Korea). However, data belonged to the authors and in no way did the manufacturer interfere with the conduct of the trial or the publication of its results.

### Introduction

Osseointegrated dental implants were traditionally placed in healed ridges after teeth were extracted. With this approach, sockets are left to heal for 3 to 6 months after extractions, before dental implants are placed. Long treatment periods and a second surgical intervention are required for implants to be placed. In addition, removable prostheses are often used during the implant healing period, but many patients find these uncomfortable. It would therefore be beneficial if the post-extractive healing period could be shortened without jeopardising implant success. Immediate post-extractive implants are those implants placed immediately in a fresh socket after extraction. The main advantage to placing implants immediately after extraction is to shorten the treatment period, however, they might be at higher risk of complication and failure.

Another potential advantage of immediate post-extractive implants is they could decrease the naturally occurring bone resorption after tooth extraction, which may improve the final aesthetic outcome. However, the clinical relevance of this occurrence needs to be critically evaluated. Another strategy to further minimise bone loss at post-extractive implants could be to use wider diameter implants. Large implants could be more easily stabilised in wide sockets and less bone grafting might be required. No randomised controlled trial (RCT) has compared wide diameter with conventional diameter implants. However, there is a small RCT comparing 7.0 mm-wide post-extractive implants with 7.0 mm-wide delayed implants placed in preserved sockets healed for 4 months, that showed minor statistically significant differences (about 1.3 mm more horizontal bone resorption at crestal level for immediate implants), which may not have a major clinical impact, since no differences could be observed from the aesthetic evaluation.

Delayed implant placement after complete socket healing is often preferred in an attempt to minimise the risk of implant failures and complications. This is usually associated with ridge preservation procedures to counteract the naturally occurring contraction of the alveolar ridges after extractions. Various ridge preservation techniques are currently used, ranging from soft tissue grafts to autogenous or bone substitutes grafts.

It would be useful to know if it is possible to have similar or even better clinical outcomes by placing immediately wide diameter implants in post-extractive sites, or rather it is better to have a more...
careful and traditional approach, by augmenting the extraction sites and placing conventional diameter implants after complete bone healing.

The aim of this RCT was to compare the effectiveness of 6.0 to 8.0 mm-wide diameter implants, placed immediately after tooth extraction, with conventional diameter implants placed in preserved sockets after a 4-month period of healing in the molar region. At protocol stage it was planned to follow the patients up to 3 years after loading. The present article is reported according to the CONSORT statement to improve the quality of reports of parallel-group randomised trials (http://www.consort-statement.org/).

Materials and methods

Trial design

This was a single-centre randomised controlled trial (RCT) of parallel group design, with balanced randomisation and blind assessment. The two groups were: immediate post-extractive 6.0 to 8.0 mm-wide diameter implants (test group; Figs 1a to j) vs delayed placement of 4.0 or 5.0 mm-wide diameter implants in preserved molar sites, 4 months after extraction (control group; Figs 2a to h).
Eligibility criteria for participants

Any patient requiring at least one immediate post-extractive implant in the first and/or second molar sites, who was at least 18 years old and able to sign an informed consent form, was eligible. There also had to be sufficient bone to allow the placement of immediate implants of at least 5.0 mm long with a diameter of at least 6.0 mm. For patients with multiple molar areas to be restored, the operator was free to select the implant sites to be included in the trial at the screening visit. Only one prosthesis per patient was included. Exclusion criteria were:

- General contraindications to implant surgery;
- Immunosuppressed or immunocompromised;
- Irradiation in the head or neck area;
- Uncontrolled diabetes;
- Pregnancy or lactation;
- Untreated periodontitis;
- Poor oral hygiene and motivation;
- Addiction to alcohol or drugs;
- Psychiatric disorders;
- Unrealistic expectations;
- Acute infection (abscess) in the site intended for implant placement;
- Necessity to lift the maxillary sinus epithelium;
- Unable to commit to 3-year follow-up post-loading;
- Under treatment or had previous treatment with intravenous amino-bisphosphonates;
- Lack of bony wall completely surrounding the implant;
- Participation in other studies that interfered with present protocol.

Patients were categorised into three groups based on the number of cigarettes they declared to smoke per day – as non-smokers, moderate smokers (up to 10 cigarettes per day) or heavy smokers (more than 10 cigarettes per day).
Setting and locations

Patients were recruited and treated by one single operator (Dr Felice) at eight private practices and two university clinics (Bologna and Chieti) following identical and standardised procedures. All patients received thorough explanations and signed a written informed consent form prior to being enrolled. After molar extractions, patients were randomised according to a parallel group design to receive one immediate 6 to 8 mm-wide post-extractive implant (Figs 1a to j), or a ridge preservation procedure followed by delayed placement of 4.0 or 5.0 mm diameter implants (Figs 2a to h).

Interventions

Patients received a single dose of prophylactic antibiotic 1 h prior to the intervention: 2 g of amoxicillin or 600 mg of clindamycin, if allergic to penicillin. Patients rinsed with 0.2% chlorhexidine mouthwash for 1 min prior to the intervention and were treated under local anaesthetic using articaine with adrenaline 1:100.000. No intravenous sedation was used. Teeth were extracted asatraumatically as possible in an attempt to preserve the buccal alveolar bone and the interdental septa, without flap elevation when possible. Teeth were decoronated and, when needed, roots were separated and individually extracted. Sockets were carefully cleaned of any granulation tissue remains. In the presence of sufficient buccal bone (assessed using the highest peak of the palatal wall as a reference point; if the assessment was difficult small 3.0 to 4.0 mm long flaps were elevated) to completely surround the implant, patients were finally included in the study and randomised to an intervention group by opening a corresponding sealed envelope. The wider diameter of the socket was measured with a periodontal probe. Sites allocated to immediate implant placement were prepared using a 5.0 mm diameter trephine drill, as suggested by the implant manufacturer. Different types of anatomical conditions could be present (Figs 3a to g). When needed, sites were enlarged with wide diameter conventional twist drills. All implant sites were underprepared by at least one twist drill size, depending on bone quality, to ensure adequate implant primary stability with a drilling speed of 1500 rpm. No crestal twist drills were used. One or two 6.0 to 8.0 mm diameter RESCUE implants (MegaGen Implant, Gyeongbuk, South Korea) 5.0, 6.0, 7.0, 8.5, 10.0 and 11.5 mm long, and with external connection, were placed with the motor set at an insertion torque of 20 Ncm. Implants were placed about 1.0 to 2.0 mm subcrestally below the most apical bone peak. The largest residual gap between the bony walls and the implant was measured with a periodontal probe in millimetres and any residual gaps between implants and the socket walls were filled with the granular autogenous bone previously retrieved with the trephine drill. Cover screws were placed and clinical pictures of the vestibular and occlusal aspects of the implants in place were taken. A surgical haemostatic collagen dressing of equine origin (Gingistat, Acteon Inc, Mount Laurel, NJ, USA) was placed over the implants and under the flaps and was stabilised by a cross suture. Wounds over the submerged implants were left partially open and the implants were left to heal unloaded for 4 months. Baseline periapical radiographs of the study implants were taken with the paralleling technique. If peri-implant marginal bone levels were difficult to see, a second periapical radiograph was taken.

Patients randomised to the delayed group had flaps elevated without incisions for 3.0 to 4.0 mm and had their sockets loosely packed with a mixture of cancellous and cortical porcine-derived bone granules with a granulometry of 250 to 1000 micron (Gen-Os, OsteoBiol, Tecnoss, Giaveno, Italy). A resorbable collagen membrane derived from equine pericardium (Evolution, OsteoBiol) was trimmed and adapted to cover the entire socket and at least 2.0 mm of the surrounding crestal bone. It was fixed with tags (Frios Membrane Tacks; Dentsply Sirona Implants, Mannheim, Germany) and partially covered by the mobilised soft tissues sutured with a cross suture. In this way barriers were left partially exposed since complete soft tissue coverage was not achieved.

A 400 mg dose of ibuprofen was prescribed two to four times a day during meals, for as long as was required. Those allergic to non-steroidal anti-inflammatory drugs or patients with stomach problems were prescribed 1 g paracetamol tablets. Patients
were instructed to use a 0.2% chlorhexidine mouthwash for 1 min twice a day for 2 weeks, and to avoid brushing and possible trauma on the surgical sites. Postoperative antibiotics were prescribed amoxicillin 1 g three times a day for six days. Those allergic to penicillin were prescribed 300 mg of clindamycin three times a day for six days. After 1 week patients were checked and sutures were removed.

Four months after extraction, patients from the immediate group had their implants assessed for stability, impressions were taken at implant level, using copy transfer and individualised trays, and provisional acrylic restorations were delivered.

Patients in the delayed group had implants placed 4 months after the socket preservation procedure. After local anaesthesia flaps were elevated, implant sites were prepared without cleaning the preserved socket and 4.0 or 5.0 mm diameter MegaGen ExFeel implants with external connection were placed. The operator used the following implant lengths: 7.0, 8.5, 10.0 and 11.5 mm. If there was not enough bone around the implant to ensure good aesthetic because coronal threads were exposed, the operator could augment the sites with the Gen-Os bone substitute and Evolution resorbable barriers. Baseline periapical radiographs were taken. The previously described postoperative instructions were given, the only difference being that if no augmentation procedures were performed, post-operative antibiotics were not given. Implants were left to heal submerged for an additional 4 months before provisional restorations, as for the immediate post-extractive group.

The provisional restorations were replaced by definitive metal-ceramic prostheses 4 months after loading. Implant stability was assessed by tightening the abutment screws with a force of 20 Ncm. Occlusal and vestibular pictures of the study implants were taken with 1:4 magnification, including the two adjacent teeth, and an independent masked assessor recorded patient satisfaction. Patients received further oral hygiene instructions and were recalled for maintenance every 6 months. At the 1-year post-loading follow-up, implant stability was assessed by removing the prostheses and delivering a reverse torque of 20 Ncm on the implants or by attempting to rock single crowns, which were not removed, with the handles of two dental instruments. Periapical radiographs were obtained, occlusal and vestibular pictures of the study implants taken and the independent masked assessor recorded patient satisfaction.
Outcome measures

This study tested the null hypothesis that there were no differences in clinical outcome between the two procedures against the alternative hypothesis of a difference. Outcome measures were:

- Implant failures defined as implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection, and any mechanical complications rendering the implant not usable (e.g. implant fracture). Stability of individual implants was measured at the delivery of provisional crowns, 4 months after implant placement and 4 months after delivery of the definitive crowns by applying a torque of 20 Ncm with a dedicated wrench. Implant stability was reassessed 1 year after loading using the metal handles of two instruments for single crowns, or after having removed the prostheses on two implants.

- Prosthesis failure was defined as a restoration that could not be placed because of implant failure and replacement of the definitive prosthesis for any reasons.

- Any biological or biomechanical complications. Examples of biological complications are fistula and peri-implantitis. Examples of biomechanical complications are loosening or fracture of the abutment screws.

- Peri-implant marginal bone level changes evaluated on periapical radiographs taken with the paralleling technique at implant placement, initial loading and 1 year after loading. In case of an unreadable radiograph, a second was obtained. Radiographs were scanned into TIFF format with a 600 dpi resolution, and stored on a personal computer. Peri-implant marginal bone levels were measured using OsiriX (Pixmeo Sarl, Bernex, Switzerland) software. If the entire implant was represented on the periapical radiograph the software was calibrated for each image using the implant length, otherwise the known distance of the two more coronal consecutive threads was used. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.01 mm. Reference points for the linear measurements were the coronal margin of the implant collar and the most coronal point of visible bone-to-implant contact. The measurements at the mesial and distal sides of each implant were averaged at implant level, patient level and finally at group level.

- Aesthetic evaluation of the vestibular and occlusal clinical pictures, taken with a magnification of 1:4 and including the two adjacent teeth at delivery of the definitive crowns and 1 year after loading, and performed on a computer screen by an independent blinded clinician (Dr Barausse). The aesthetic evaluation was carried out using the pink esthetic score (PES)25. In brief, seven variables were evaluated: mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiencies, soft tissue colour and texture. A 0–1–2 scoring system was used, with 0 being the lowest and 2 being the highest value, with a maximum achievable score of 14 per implant.

- Patient satisfaction. At delivery of definitive prostheses (4 months after initial loading) and 1 year after loading, the blinded outcome assessor provided patients with a mirror to see the implant-supported crown and they were asked to express their opinions. Specifically, the patients were asked: “Are you satisfied with the function of your implant-supported tooth?” Possible answers were: “Yes, absolutely”, “Yes, partly”, “Not sure”, “Not really” or “Absolutely not”. They were then asked: “Are you satisfied with the aesthetic outcome of the gums surrounding this implant?”. Possible answers were: “Yes, absolutely”, “Yes, partly”, “Not sure”, “Not really” or “Absolutely not”. Finally, patients were asked whether they would undergo the same procedure again and could answer either “Yes” or “No”. The questions were always posed with exactly the same wording.

- The number of surgical interventions and patients’ appointment with the practitioner were recorded from tooth extraction up to initial loading (delivery of the provisional prostheses) by study group.

Sample size, random sequence, allocation concealment and blinding

The sample size was estimated for the primary outcome measure of this study to compare 1% of failures at delayed implants with 5% at immediate implants.
A two-group continuity corrected chi-square test with a 0.050 two-sided significance level will have 80% power to detect the difference between a proportion of 0.050 and a proportion of 0.010 (odds ratio of 0.192) when the sample size in each group is 333. The maximum number that could be enrolled over more than a 3-year recruitment period was 100. One computer generated restricted randomisation list was created. Only one investigator (Dr Esposito), who was not involved in the selection and treatment of the patients, knew the random sequence and had access to the random list stored on a password-protected portable computer. The randomised codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. After extraction and quantification of the amount of buccal bone loss, the patient was finally entered into the study and the envelopes were sequentially opened. Therefore, treatment allocations were concealed to the investigators in charge of enrolling and treating the patients.

A blinded outcome assessor (Dr Elisa Soardi, who was replaced at the end of the follow-up by Dr Barausse), not involved in the treatment of the patients, evaluated implant stability and recorded patient satisfaction. The same blinded practitioner (Dr Barausse) measured aesthetic and marginal bone levels, without knowing group allocation, therefore the outcome assessors were blind, however complications were registered and treated by the surgeon in a non-blinded mode.

## Results

A total of 109 patients were screened and 100 patients were consecutively enrolled on the trial. Nine patients were not included because they did not have 5.0 mm of bone height (six patients and four of them required a sinus lift procedure), or because they did not have a sufficiently preserved vestibular bone wall (three patients). All were treated according to the allocated interventions. Three patients dropped out from the immediate group vs six patients from the delayed group, all having a single crown. Reasons for dropping out were:

### Immediate group
- Not reachable after definitive crown delivery.
- Not willing to come since too busy after definitive crown delivery.
- Moved away after definitive crown delivery; replied by phone to the satisfaction questionnaire.

### Delayed group
- Not reachable after provisional crown deliveries (three patients).
- Moved away after definitive crown delivery; replied by phone to the satisfaction questionnaire.
- Too busy after delivery of definitive crown, then not reachable.
- Nobody able to take him to the practice after definitive crown delivery; replied by phone to the satisfaction questionnaire.

The following radiographs and clinical pictures were missing:

### Immediate group
- Periapical radiograph at placement: three patients;
- Periapical radiograph at loading: seven patients;
- Periapical radiograph at 1 year: five patients;
- Clinical pictures at 4 months post-loading: nine patients;
- Clinical pictures at 1 year post-loading: two patients.
Delayed group

- Periapical radiograph at placement: five patients;
- Periapical radiograph at loading: eight patients;
- Periapical radiograph at 1 year: six patients;
- Clinical pictures at 4 months post-loading: 10 patients;
- Clinical pictures at 1-year post-loading: five patients.

Data of all remaining patients were evaluated in the statistical analyses. The main deviation from the protocol were:

Immediate group

- One patient did not want to have the definitive crown for financial reasons and is still wearing his provisional crown.
- In two patients the trephine drill could not be used since the septa was missing and there was too little bone available in the maxillary sinus. The implants were anchored on the palatal wall and Gen-Os was used instead of autogenous bone collected with the trephine to fill the vestibular bone to implant gap.
- For financial reasons three patients directly received the definitive crowns, without having the provisional crowns.
- One patient received the definitive crown, without having the provisional for financial reasons, with a 2-month delay, since she was missing appointments.
- In one patient the bone to implant gap at implant placement was filled with Gen-Os instead of autogenous bone because the bone-crashing device was not available.

Delayed group

- Three patients had their provisional crowns delivered with 2, 3 and 5 months delay as they did not attend their appointments.
- One patient showed up one month late for the abutment connection procedure.

Patients were recruited and had their teeth extracted between May 2010 and October 2013. The follow-up for all remaining patients was up to 1 year after implant loading. Patient demographics are presented in Table 1. A total of 54 implants were placed in the immediate group and 53 in the delayed group and there were no apparent significant baseline imbalances between the groups, with the exception that immediate post-extractive implants were much shorter than delayed implants.

- Seven implants failed: five out of 47 from the immediate group (10.6%) and two out of 44 from the delayed group (4.6%). The differences in the proportion of implant failures between groups were not statistically significant (difference in proportion = 6.0%, 95% CI: -8.8% to 20.8%, \( P = 0.436 \)).

Immediate group

One non-smoking female presented with the coronal portion of the buccal threads exposed at her implant in tooth position 46, 3 months after placement. The patient had pain and the implant was mobile and was removed. The patient refused to have the failed implant replaced.

One male smoker complained about discomfort at his implant in tooth position 16, 3 months after placement. The implant was mobile and was removed and was successfully replaced after 4 months.

One female smoker had her implant in tooth position 26 mobile at abutment connection. This was successfully replaced after 4 months.

One male heavy smoker had his implant in tooth position 47 mobile at abutment connection. This was successfully replaced after 4 months.

One female heavy smoker presented with her implant in tooth position 17 mobile and causing discomfort 9 months after loading. It was successfully replaced after 4 months.
Delayed group

One female heavy smoker had her implant in tooth position 17 mobile at abutment connection. This was successfully replaced after 4 months.

One female non-smoker had her implant in tooth position 46 mobile at abutment connection. This was successfully replaced after 4 months.

Table 1  Patient and intervention characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Immediate [n = 50] (%)</th>
<th>Delayed [n = 50] (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females</td>
<td>26 (52%)</td>
<td>23 (46%)</td>
</tr>
<tr>
<td>Males</td>
<td>24 (48%)</td>
<td>27 (54%)</td>
</tr>
<tr>
<td>Mean age at implant insertion (range)</td>
<td>52.9</td>
<td>54.4</td>
</tr>
<tr>
<td>Non-smokers</td>
<td>37 (74%)</td>
<td>39 (78%)</td>
</tr>
<tr>
<td>Smoking up to 10 cigarettes/day</td>
<td>10 (20%)</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>Smoking more than 10 cigarettes/day</td>
<td>3 (6%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Mean wider diameter of the sockets in mm</td>
<td>9.6</td>
<td>10.4</td>
</tr>
<tr>
<td>Number of implants placed</td>
<td>54</td>
<td>53</td>
</tr>
<tr>
<td>Buccal bone-implant gap in mm</td>
<td>0.60±1.05</td>
<td>0</td>
</tr>
<tr>
<td>Additional augmentation at placement of delayed implants only</td>
<td>–</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Sites augmented with autogenous bone at implant placement</td>
<td>14 (28%)</td>
<td>0</td>
</tr>
<tr>
<td>Implants in first upper molar position</td>
<td>21 (38.9%)</td>
<td>15 (28.3%)</td>
</tr>
<tr>
<td>Implants in second upper molar position</td>
<td>12 (22.2%)</td>
<td>10 (18.9%)</td>
</tr>
<tr>
<td>Implants in first lower molar position</td>
<td>9 (16.7%)</td>
<td>16 (30.2%)</td>
</tr>
<tr>
<td>Implants in second lower molar position</td>
<td>12 (22.2%)</td>
<td>12 (22.6%)</td>
</tr>
<tr>
<td>Implants inserted with a torque inferior to 20 Ncm</td>
<td>18 (33.3%)</td>
<td>25 (47.2%)</td>
</tr>
<tr>
<td>Partial fixed prostheses in upper jaws</td>
<td>3 (6%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Single crowns in upper jaws</td>
<td>27 (54%)</td>
<td>23 (46%)</td>
</tr>
<tr>
<td>Partial fixed prostheses in lower jaws</td>
<td>1 (2%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Single crowns in lower jaws</td>
<td>19 (28%)</td>
<td>24 (48%)</td>
</tr>
<tr>
<td>Implants with 4.0 mm diameter</td>
<td>0</td>
<td>20 (37.7%)</td>
</tr>
<tr>
<td>Implants with 5.0 mm diameter</td>
<td>0</td>
<td>33 (62.3%)</td>
</tr>
<tr>
<td>Implants with 6.0 mm diameter</td>
<td>9 (16.7%)</td>
<td>0</td>
</tr>
<tr>
<td>Implants with 6.5 mm diameter</td>
<td>6 (11.1%)</td>
<td>0</td>
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<tr>
<td>Implants with 7.0 mm diameter</td>
<td>22 (40.7%)</td>
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</tr>
<tr>
<td>Implants with 7.5 mm diameter</td>
<td>2 (3.7%)</td>
<td>0</td>
</tr>
<tr>
<td>Implants with 8.0 mm diameter</td>
<td>15 (27.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Implants 5.0 mm long</td>
<td>17 (31.5%)</td>
<td>0</td>
</tr>
<tr>
<td>Implants 6.0 mm long</td>
<td>18 (33.3%)</td>
<td>0</td>
</tr>
<tr>
<td>Implants 7.0 mm long</td>
<td>9 (16.7%)</td>
<td>14 (26.4%)</td>
</tr>
<tr>
<td>Implants 8.5 mm long</td>
<td>1 (1.9%)</td>
<td>19 (35.9%)</td>
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<tr>
<td>Implants 10.0 mm long</td>
<td>8 (14.8%)</td>
<td>19 (35.9%)</td>
</tr>
<tr>
<td>Implants 11.5 mm long</td>
<td>1 (1.9%)</td>
<td>1 (1.9%)</td>
</tr>
</tbody>
</table>

• Prosthesis failures closely reflected implant failures. Only single crowns could not be placed or were lost because of implant failures and all but one patient was successfully rehabilitated. One patient from the immediate group did not want to replace her mandibular implant, which failed one month before abutment connection.

• Ten complications occurred in 10 patients out of 47 from the immediate group (21.3%) vs four complications in four patients out of 44 in the delayed group (9.1%); the difference not being statistically significant (difference in proportion = 12.2%, 95% CI: -2.1% to 25.5%, P = 0.084). Complications were:

Immediate group

One male non-smoker complained of pain 1 week after extraction. There was no exudate, but soft tissues were inflamed with abundant food residues at tooth site 16. Rinsing of the site with 0.2% chlorhexidine which was prescribed three times a day for 21 days with 600 mg ibuprofen three times a day for 4 days. Antibiotic therapy (1 g amoxicillin and clavulanic acid twice a day for 6 days) was prolonged for another week. The issue was resolved in 10 days.

One female non-smoker complained of pain 3 months after implant placement in tooth site 46. The buccal threads were exposed and the implant was mobile. It was removed, but the patient refused to have it replaced.

One male smoker complained about discomfort of the implant in tooth position 16, 3 months after placement. The implant was mobile and was successfully replaced.

In one female smoker a vestibular bone dehiscence was observed at the implant in tooth position 46 during the abutment connection procedure. The area was treated with a bone substitute (Gen-Os) and a resorbable collagen barrier (Evolution) and was left to heal for 6 months before loading the implant. There were no further problems.

One female non-smoker complained about pain relating to the implant in tooth position 37, 3 months after placement. A vestibular recession with pockets and peri-implant mucositis was present. Soft tissues were in direct contact apically with the implant threads. Chlorhexidine 0.2% rinsing was prescribed.
three times a day for 21 days. Her symptoms improved, but the patient was not willing to undergo further treatment.

One male smoker complained about discomfort of the implant in tooth position 16, 6 months after loading. A vestibular recession with bone loss and peri-implant mucositis was present (Fig 4). Chlorhexidine 0.2% rinsing was prescribed three times a day for 21 days. His symptoms improved, but the patient was not willing to undergo further treatment.

One male non-smoker presented with a vestibular recession at the implant in tooth position 37, 7 months after loading. He did not complain, apart from noting slight discomfort at the level of the peri-implant mucosa. Chlorhexidine 0.2% rinsing was prescribed three times a day for 21 days. The patient refused further treatment.

One male non-smoker complained about pain at his implant in position 36, 7 months after loading. A vestibular pocket was present corresponding to bone loss, and the buccal implant threads were in direct contact with the inflamed mucosa. Chlorhexidine 0.2% rinsing was prescribed three times a day for 21 days. Symptoms improved and the patient was not keen to have additional treatment.

One male smoker complained about discomfort at his implant in position 16, 9 months after loading. The coronal third of the implant was exposed in the mesio-vestibular location, but the implant was stable (Figs 5a and b). Chlorhexidine 0.2% rinsing was prescribed three times a day for 21 days. The symptoms regressed and the patient did not want any further treatment. Up to 1 year after loading the situation was stable and asymptomatic.

One female heavy smoker presented with her implant in tooth position 17 mobile and causing discomfort 9 months after loading. It was successfully replaced after 4 months.

### Delayed group

One male smoker complained of pain 1 week after extraction. There was no exudate, but the soft tissues were inflamed with abundant food residuals at tooth site 47. Rinsing of the site with chlorhexidine 0.2% was prescribed three times a day for 21 days, together with 600 mg of ibuprofen three times a day for 4 days. Antibiotic therapy (1 g amoxicillin + clavulanic acid twice a day for 6 days) was prolonged for another week. The symptoms were resolved in 10 days.

One male non-smoker complained of discomfort 1 week after extraction. There was no exudate, but soft tissues were inflamed with abundant food residuals at tooth site 37. Rinsing of the site with chlorhexidine 0.2% was prescribed three times a day for 21 days, together with 600 mg of ibuprofen three times a day for 4 days. Symptoms cleared in 10 days.

One patient complained about mobility at the implant in position 36, 8 months post-loading. The screw had loosened and was retightened at 30 Ncm. A screw at the implant in position 17 was noticed to have loosened at the 1 year post-loading control and was retightened at 30 Ncm.

- **Aesthetic evaluation**: Four months after loading, after delivery of the definitive prostheses, the average total PES score, assessed by a blind assessor, was $9.65 \pm 1.62$ and $10.44 \pm 1.47$ in the immediate and delayed groups, respectively, the difference being statistically significant in favour of delayed implants (mean difference $= 0.79$; 95% CI: 0.05 to 1.53; $P = 0.03$, ...)
Table 2 PES scores at delivery of definitive prosthesis (4 months after loading) by groups and by different aesthetic domains; standard deviation is in parenthesis.

<table>
<thead>
<tr>
<th>Mesial papilla</th>
<th>Distal papilla</th>
<th>Soft tissue level</th>
<th>Soft tissue contour</th>
<th>Alveolar process deficiencies</th>
<th>Soft tissue colour</th>
<th>Soft tissue texture</th>
<th>Total PES score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate = 37</td>
<td>1.62 ± 0.48</td>
<td>1.27 ± 0.42</td>
<td>1.20 ± 0.74</td>
<td>1.43 ± 0.50</td>
<td>1.31 ± 0.61</td>
<td>1.72 ± 0.45</td>
<td>1.10 ± 0.37</td>
</tr>
<tr>
<td>Delayed = 35</td>
<td>1.71 ± 0.44</td>
<td>1.30 ± 0.52</td>
<td>1.54 ± 0.66</td>
<td>1.37 ± 0.49</td>
<td>1.63 ± 0.55</td>
<td>1.77 ± 0.43</td>
<td>1.11 ± 0.32</td>
</tr>
<tr>
<td>Difference</td>
<td>0.09</td>
<td>0.03</td>
<td>0.34</td>
<td>-0.06</td>
<td>0.28</td>
<td>0.05</td>
<td>0.01</td>
</tr>
<tr>
<td>P-value</td>
<td>0.396</td>
<td>0.788</td>
<td>0.04*</td>
<td>0.60</td>
<td>0.02*</td>
<td>0.59</td>
<td>0.81</td>
</tr>
</tbody>
</table>

*Statistically significant difference.

Table 3 PES scores at 1 year after loading by groups and by different aesthetic domains; standard deviation is in parenthesis.

<table>
<thead>
<tr>
<th>Mesial papilla</th>
<th>Distal papilla</th>
<th>Soft tissue level</th>
<th>Soft tissue contour</th>
<th>Alveolar process deficiencies</th>
<th>Soft tissue colour</th>
<th>Soft tissue texture</th>
<th>Total PES score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate = 37</td>
<td>1.56 ± 0.62</td>
<td>1.29 ± 0.52</td>
<td>1.12 ± 0.75</td>
<td>1.49 ± 0.59</td>
<td>1.23 ± 0.65</td>
<td>1.73 ± 0.51</td>
<td>1.30 ± 0.61</td>
</tr>
<tr>
<td>Delayed = 37</td>
<td>1.70 ± 0.45</td>
<td>1.38 ± 0.48</td>
<td>1.49 ± 0.65</td>
<td>1.62 ± 0.48</td>
<td>1.54 ± 0.61</td>
<td>1.84 ± 0.37</td>
<td>1.30 ± 0.46</td>
</tr>
<tr>
<td>Difference</td>
<td>0.14</td>
<td>0.08</td>
<td>0.27</td>
<td>0.13</td>
<td>0.31</td>
<td>0.11</td>
<td>0.00</td>
</tr>
<tr>
<td>P-value</td>
<td>0.26</td>
<td>0.43</td>
<td>0.03*</td>
<td>0.28</td>
<td>0.03*</td>
<td>0.27</td>
<td>0.99</td>
</tr>
</tbody>
</table>

*Statistically significant difference.

Table 2). At 1 year after loading, the mean total PES score was 9.71 and 10.86 in the immediate and delayed groups, respectively, the difference being still statistically significant in favour of delayed implants (mean difference = 1.15; 95% CI: 0.13 to 2.17; P = 0.02, see Table 3). At both time intervals the differences were only observed at the “soft tissue level” and “alveolar process deficiencies” domains (Tables 2 and 3).

- Marginal bone levels were evaluated by a blinded outcome assessor on periapical radiographs taken at implant placement after bone grafting (when performed), at initial loading at 1 year after loading (Table 4). At baseline, the average bone levels around immediate implants were 0.04 mm versus 0.1 mm at delayed implants, the difference being statistically different (difference = 0.07 mm; 95% CI: 0.02 to 0.12; P < 0.0001). At initial loading, the average bone levels around immediate implants were 0.43 mm vs 0.36 mm at delayed implants, the difference being statistically different (difference = -0.07 mm; 95% CI: -0.01 to -0.13; P = 0.03). At 1 year, the average bone levels around immediate implants were 1.11 mm vs 0.74 mm at delayed implants, the difference being statistically different (difference = -0.37 mm; 95% CI: -0.07 to -0.67; P < 0.0001). Bone level changes at 1 year were 1.06 mm at immediate implants and 0.63 mm at delayed implants. Significantly more bone loss occurred at immediate implants (mean difference = -0.43 mm; 95% CI: -0.15 to -0.61; P < 0.0001; see Table 5).

- Patient satisfaction was assessed at 4 months and at 1 year after loading only for those patients who did not experience an implant failure. At 1 year, one out of three patients in the immediate group, and two out of six patients who did not attend the control visit (drop-out), expressed their satisfaction score by telephone. At 4 months post-loading, after delivery of the definitive prostheses, none of the 46 patients from the immediate group and three patients out of 45 from the delayed group declared they were partially satisfied by the function of their prostheses. All the remaining patients expressed total satisfaction (P = 0.07). Two patients from 46 in the immediate group and one patient out of 45 from the delayed group declared they...
were partially satisfied about the aesthetics of their prostheses, with all the remaining patients expressing total satisfaction ($P = 0.57$). One year post-loading, three patients out of 43 from the immediate group and three patients out of 44 from the delayed group declared they were partially satisfied with the function of their prostheses, while all the remaining patients expressing total satisfaction ($P = 0.952$). Three patients out of 43 from the immediate group and none of the 44 from the delayed group declared they were partially satisfied with the aesthetics of their prostheses, with all remaining patients expressing total satisfaction ($P = 0.85$). All patients said they would undergo the same procedure again, both at 4 months and 1 year after loading.

• Number of surgeries and visits to the practitioners: Patients from the immediate group required on average $7.48 \pm 1.45$ visits and $2.14 \pm 0.49$ surgical interventions to the dentist to have the definitive prostheses delivered vs $10.30 \pm 0.99$ visits and $3.08 \pm 0.40$ surgical interventions for the delayed group, the difference being statistically significant in favour of the immediate group (mean difference = 2.82; 95% CI: 1.60 to 4.02; $P < 0.001$ for visits, and mean difference = 0.94; 95% CI: 0.53 to 1.35; $P < 0.001$ for surgical interventions).

### Discussion

This trial was designed to assess whether it could be advantageous to place 6.0 to 8.0 mm wide implants immediately after molar extraction or if it would be preferable to preserve the socket and wait for bone healing before placing implants with a conventional 4.0 or 5.0 mm diameter. Five implants (10%) failed in the immediate post-extractive group vs two implants (4%) in the delayed group. This is within the expected range. Therefore, the present study supports the notion that post-extractive immediately loaded implants could be at a higher risk of failure than delayed implants, which is in agreement with other RCTs\(^3,8,26-28\), comparing immediate vs delayed implant placement. Also, complications were more common in the immediate group (10 vs 4), which is again in agreement with previous RCTs\(^3,8,26-28\). However we encountered a specific complication not reported in previous studies...

### Table 4

Peri-implant marginal bone levels up to 1 year after loading, by study group.

<table>
<thead>
<tr>
<th>Implant placement</th>
<th>Initial loading</th>
<th>1-year after loading</th>
<th>$P$-value intragroup</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Mean (95% CI)</td>
<td>N</td>
</tr>
<tr>
<td>Immediate</td>
<td>47</td>
<td>0.04 (-0.01; 0.09)</td>
<td>39</td>
</tr>
<tr>
<td>Delayed</td>
<td>45</td>
<td>0.11 (0.02; 0.20)</td>
<td>40</td>
</tr>
<tr>
<td>Difference</td>
<td>45</td>
<td>0.07 (0.02; 0.12)</td>
<td>39</td>
</tr>
<tr>
<td>$P$-value intergroup</td>
<td></td>
<td>0.03*</td>
<td></td>
</tr>
</tbody>
</table>

*Statistically significant difference.

### Table 5

Peri-implant marginal bone level changes up to 1 year after loading, by study group.

<table>
<thead>
<tr>
<th>Difference placement – initial loading</th>
<th>Difference placement – 1 year</th>
<th>$P$-value intragroup</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>Mean (95% CI)</td>
<td>N</td>
</tr>
<tr>
<td>Immediate</td>
<td>39</td>
<td>0.40 (0.26; 0.54)</td>
</tr>
<tr>
<td>Delayed</td>
<td>40</td>
<td>0.26 (0.12; 0.40)</td>
</tr>
<tr>
<td>Difference</td>
<td>39</td>
<td>-0.14 (-0.06; -0.22)</td>
</tr>
<tr>
<td>$P$-value intergroup</td>
<td></td>
<td>&lt; 0.0001*</td>
</tr>
</tbody>
</table>

*Statistically significant difference
RCTs, even in those previously conducted by our group. In fact, seven patients (14%) in the immediate 6 to 8 mm wide-diameter post-extractive group developed vestibular bone dehiscence from 3 months after implant placement to 9 months post-loading. This unpleasant early permanent complication, which did not jeopardise implant success rates, was definitively not in favour of the use of post-extractive wide diameter implants. It is interesting to observe that in another RCT, where 12 patients were rehabilitated with immediate 7 mm-wide post-extractive implants were compared with 12 patients rehabilitated with 7 mm-wide diameter delayed implants, no complications were reported. On the other hand, that study reported a statistically significant mean bone horizontal resorption of 1.3 mm at crestal level for immediate implants, which could be considered at least in line with the data of the present study. One can only speculate upon the reasons for these differences, however the sample size of the present trial was more than four times bigger than the other trial and the post-loading follow-up the double of the time. In view of the unknown consequences of this vestibular implant dehiscence of wide diameter implants on the long-term clinical outcome, longer follow-ups are mandatory.

Despite more failures and complications occurring with immediate post-extractive implants, the difference with delayed implants was not statistically different, possibly because of the reduced sample size. At 1 year after loading, immediate implants lost 0.43 mm more bone than delayed implants. The difference was statistically significant, and also the aesthetic outcome was better in delayed implants of conventional diameter, especially with regard to soft tissue levels and alveolar process deficiencies. Apparently, this difference tended to increase over time. The most likely reason was the buccal dehiscence observed in seven patients was treated with immediate wide diameter implants. On the other hand, significantly fewer dental appointments and surgeries were needed when placing immediate implants.

At baseline, the two groups were comparable, with the exception of implant length. In fact, immediate implants were on average much shorter than delayed implants. However, in view of the positive published results of short implants, it is unlikely that this difference could have strongly influenced the short-term results of the present trial.

On the other hand, immediate post-extractive implants offered one major advantage: patients from the immediate group were rehabilitated 4 months before those allocated to delayed implant placement, with fewer surgical interventions and visits up until delivery of the definitive prostheses. However, this temporal and financial advantage may not be enough to endorse using wide-diameter post-extractive implants in relation to a higher risk of failure and complication rates.

The main limitation of the present trial was insufficient sample size. In fact, the authors were only able to recruit 100 patients instead of the 700 suggested by the sample size calculation. In addition, many clinical pictures and radiographs were unfortunately lost. However, this is currently among the three published RCTs with the larger sample size. Another limitation could be that immediate wide diameter implants were compared with delayed conventional diameter implants, meaning that the role of the implant diameter could be “confused” by the different timing of placement. While this is true, and other RCTs could test the relevance of the implant diameter for post-extractive implants only, the present results are not in favour of the use of immediate post-extractive wide diameter implants. We decided to use the control procedure considered to be the gold standard, less risky and more likely to be used in clinical practice.

Since in the present investigation both procedures were tested in real clinical conditions, and patient inclusion criteria were broad, results can be generalised with confidence to a wider population with similar characteristics.

**Conclusions**

Preliminary 1-year follow-up data suggest that immediate placement of 6.0 to 8.0 mm-wide diameter implants in molar extraction sockets yielded inferior aesthetic outcomes to ridge preservation and delayed placement of conventional 4.0 to 5.0 mm diameter implants.
References


