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# Immediate non-occlusal loading of immediate post-extractive versus delayed placement of single implants in preserved sockets of the anterior maxilla: 4-month post-loading results from a pragmatic multicentre randomised controlled trial



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**Purpose:** To compare the effectiveness of immediate post-extractive single implants with delayed implants placed in preserved sockets after 4 months of healing. Implants that achieved an insertion torque of at least 35 Ncm were immediately non-occlusally loaded.

**Materials and methods:** Just after tooth extraction and in the presence of a loss of the buccal plate bone less than 4 mm, compared to the palatal wall, 106 patients requiring a single immediate post-extractive implant in the maxilla from second premolar to second premolar were randomly allocated to immediate implant placement (immediate group; 54 patients) or to socket preservation using anorganic bovine bone covered by a resorbable collagen barrier (delayed group; 52 patients) according to a parallel group design at three different centres. Bone-to-implant gaps were to be filled with anorganic bovine bone, however this was not done in 17 patients (corresponding to 40% of those who should have been grafted). Four months after socket preservation, delayed implants were placed. Implants placed with an insertion torque >35 Ncm were immediately loaded with non-occluding provisional single crowns, replaced, after 4 months, by definitive crowns. Outcome measures were implant failures, complications, aesthetics assessed using the pink esthetic score (PES), and patient satisfaction, recorded by blinded assessors. All patients were followed up to 4 months after loading.

**Results:** Nineteen (35%) implants were not immediately loaded in the immediate group versus 39 (75%) implants in the delayed placement group because an insertion torque >35 Ncm could not be obtained. No patient dropped out. Two implants failed in the immediate group (4%) versus none in the delayed group. More minor complications occurred in the immediate group (8) than in the delayed group (1) and this was statistically significant ( $P = 0.032$ ). At delivery of definitive crowns, 4 months after loading, aesthetics were scored as 12.8 and 12.6 in the immediate and delayed groups, respectively. There was no statistically significant difference ( $P = 0.5$ ). Patients of both groups were equally satisfied.

**Conclusions:** There were more complications at immediate post-extractive implants when compared to delayed implants. The aesthetic outcome appears to be similar for both groups and it seems more difficult to obtain a high insertion torque in sockets preserved with anorganic bovine bone.

**Conflict-of-interest statement:** *MegaGen Italia, the distributor of the implants used in this investigation, partially supported this trial and donated the implants used in this trial, however the research data belonged to the authors and by no means did MegaGen Italia interfere with the conduct of the trial or the publication of the results.*

## ■ Introduction

An immediate post-extractive implant is a dental implant placed immediately after tooth extraction in a fresh socket. While this procedure definitely shortens the duration of the treatment since one does not have to wait for soft tissue healing (2–6 weeks) or for bone healing (4–6 months), it might be at higher risk of complications/failures<sup>1</sup>.

After tooth extraction, the alveolar bone remodels and resorbs<sup>2–5</sup>. Two-thirds of this reduction occurs within the first 3 months and within 1 year the clinical width of the alveolar ridge is reduced by approximately 50%<sup>2–5</sup>. The mean vertical loss of tissues at single extracted sites ranges between 1 and 4 mm<sup>2–5</sup> depending on site location. This physiologic phenomenon occurs at different rates and degrees among various individuals and in some cases it can be very pronounced<sup>2–5</sup>. This localised alveolar bone resorption may affect the possibility of placing dental implants and their aesthetic outcome, particularly in aesthetic areas and in those patients exposing visible portions of gums when speaking and smiling. In fact, the resorbed alveolar crest could be a cause of social discomfort and embarrassment.

Another possible advantage of post-extractive implants is that they could decrease the naturally occurring bone resorption after tooth extraction which may improve the final aesthetic outcome, however this has never been proven<sup>1</sup>. There are only two randomised controlled trials (RCTs)<sup>6,7</sup> comparing immediate post-extractive implants with delayed implant placement. No statistically significant differences were observed, but it is possible that clinically significant differences were hidden by the small number of patients included in both trials (126 patients in total).

Delayed implant placement after healing of the socket is used to minimise the risk of implant failures/complications. Just after extractions, sockets can be subjected to a ridge preservation procedure to decrease the naturally occurring bone resorption. Various ridge preservation techniques are currently used ranging from soft tissue grafts to autogenous or bone-substitute grafts<sup>2,4,5,8–19</sup>. The number of reliable RCTs is limited<sup>2,5,16</sup>, however they have shown that various ridge preservation procedures are effective in decreasing the physiologic bone resorption<sup>2,4,5,12</sup>,

even though some preservation techniques were associated with a substantial number failures and complications<sup>4,20,21</sup> or appear to be ineffective<sup>10</sup>.

It would be useful to know whether a better clinical outcome could be obtained by preserving the extraction sites to place delayed implants after bone healing, or whether similar results can be obtained by placing the implants immediately after tooth extraction, shortening the procedure by several months.

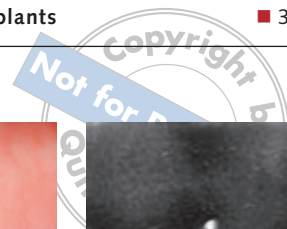
The aim of this pragmatic multicentre RCT was to compare the effectiveness of single implants placed immediately after tooth extraction in fresh extraction sockets with implants placed in a preserved socket after 4 months of healing. Implants that achieved an insertion torque of at least 35 Ncm were immediately non-occlusally loaded. At protocol stage, it was planned to follow the patients up to 5 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

### ■ Patient selection

Any patient requiring at least one single immediate post-extractive implant in the maxilla from second premolar to second premolar, between two natural teeth (or crowned teeth), being at least 18 years old and able to sign an informed consent form was eligible for inclusion (Figs 1a–1c, 2a and 2b). There also must be sufficient bone to allow the placement of a single implant at least 7 mm long with a 4 mm diameter. Exclusion criteria were:

- general contraindications to implant surgery
- immunosuppressed or immunocompromised
- irradiation in the head or neck area
- uncontrolled diabetes
- pregnant or lactating
- untreated periodontitis
- poor oral hygiene and motivation
- substance abuse
- psychiatric disorders or unrealistic expectations
- acute infection (abscess) in the site intended for implant placement



- necessity to lift the maxillary sinus epithelium
- unable to commit to a 5-year follow-up post-loading
- under treatment or had previous treatment with intravenous amino-bisphosphonates
- participation in other clinical trials interfering with present protocol
- a site (just after tooth extraction prior to implant placement) in which more than 4 mm in height of the buccal wall was missing after tooth extraction (assessed using the highest peak of palatal wall as reference point).



**Fig 1a** Preoperative view of tooth 11 affected by a vertical root fracture.



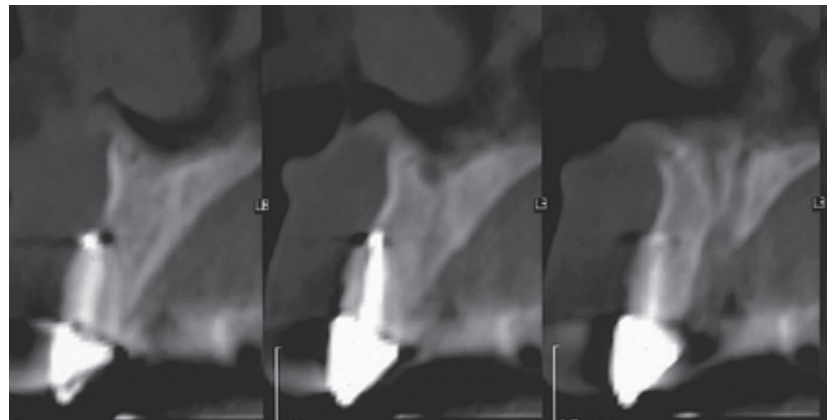
**Fig 1b** Preoperative radiograph showing tooth 11 before extraction.

Patients were divided into three groups based on the number of cigarettes they declared to consume per day: non-smokers, moderate smokers ( $\leq 10$  cigarettes per day) and heavy smokers ( $> 10$  cigarettes per day).

Patients were recruited and treated by three different clinicians: Felice, Jacotti and Pistilli, using similar and standardised procedures in private practices. Each clinician/centre was supposed to treat 30 patients (15 in each group). The principles outlined in the Declaration of Helsinki on clinical research involving human subjects were followed. All patients received thorough explanations and signed a written informed consent form prior to being enrolled in the trial. After tooth extraction, patients were randomised to receive an immediate post-extractive implant (Figs 1a–1v) or a ridge preservation procedure followed by a delayed implant (Figs 2a–2v).

### ■ Clinical procedures

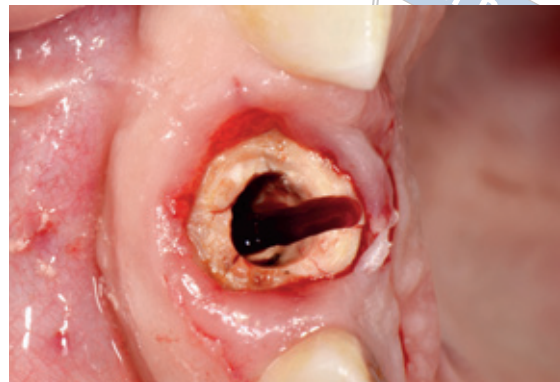
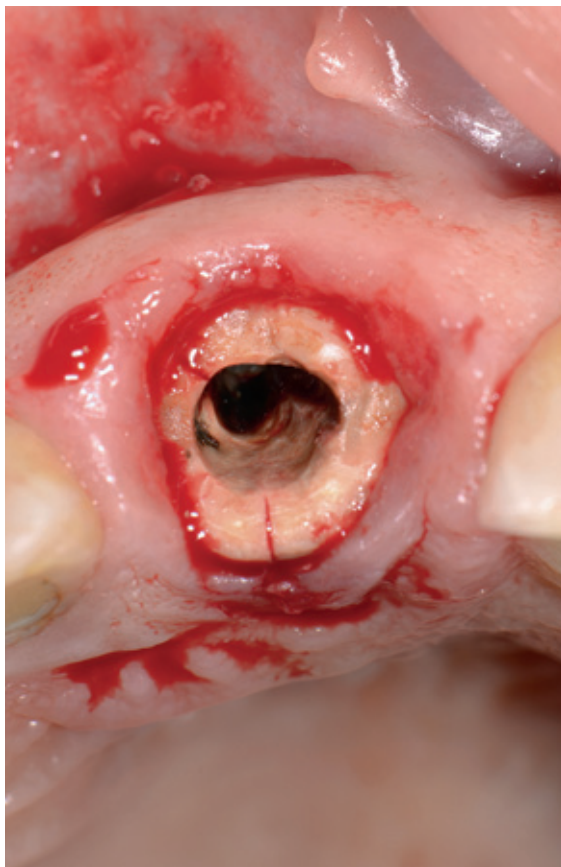
Patients received a single dose of prophylactic antibiotic 1 hour prior to the intervention: 2 g of amoxicillin or 600 mg of clindamycin, if allergic to penicillin. Patients rinsed with chlorhexidine mouthwash 0.2% for 1 minute prior to the intervention. Patients were treated under local anaesthesia using articaine with adrenaline 1:100,000. No intravenous sedation was used. After crestal incision and flap elevation, teeth were extracted as atraumatically as possible while attempting to preserve the buccal alveolar bone (Figs 1d–1h). Sockets were carefully cleaned from any remains of granulation tissue. In the presence of less than 4 mm in height of missing buccal wall (assessed using the highest



**Fig 1c** Preoperative computerised tomography scans showing the vertical fracture at tooth 11.

peak of palatal wall as reference point) the patient was finally included in the study and randomised to one of the intervention groups by opening the corresponding sealed envelope. Sites allocated to immediate implant placement were prepared using drills with increasing diameters as suggested by the implant manufacturer (Fig 1j). Tapered titanium EZ Plus™ dental implants (MegaGen, Gyeongbuk, South Korea) with internal connection, and RBM (resorbable blast media) treated surfaces, already provided with their definitive straight abutments, were used (Figs 1k–1o, 2p and 2q). Operators were free to choose implant lengths (7, 8.5, 10, 11.5, 13 and 15 mm), diameters (4 and 5 mm) and whether to place the implants directly with their abutments or not (Figs 1k and 2p) according to clinical indications and their preferences.

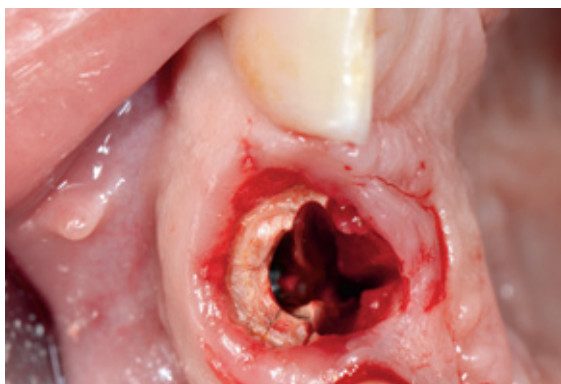
**Fig 1d** After crown removal, the fracture lines at the palatal and at the bucco-distal aspects of the root are visible.



**Fig 1e** The root is carefully sectioned with a high speed bur first palatally to minimise the risk of buccal plate fracture.



**Fig 1f** The root is also sectioned mesially and distally.



**Fig 1g** The palatal section of the root was removed first.

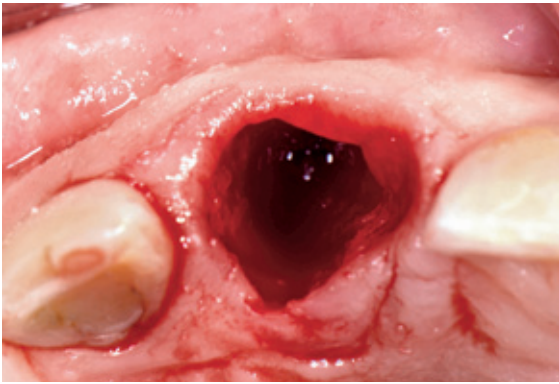


**Fig 1h** Once the palatal portion of the root was removed, it was easier to luxate the remaining vestibular tooth portion, minimising the damage of the buccal plate.

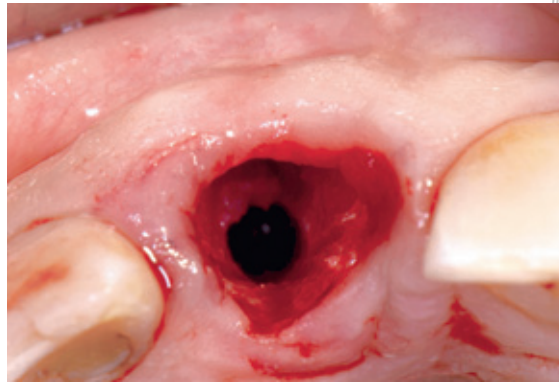
The head of the implants was placed about 1 to 2 mm below the most coronal bone peak (Fig 1o), and slightly palatally. The motors were set with an insertion torque of 35 Ncm. Implants placed with an insertion torque >35 Ncm were immediately loaded with a non-occluding acrylic provisional crown, otherwise abutments were removed and implants

were submerged and left to heal for 4 months. The wound over submerged implants could have been left partially open if complete soft tissue coverage was difficult to obtain.

The horizontal gap between the buccal bone and the implant was measured and spaces were to be loosely packed with granules of anorganic bovine



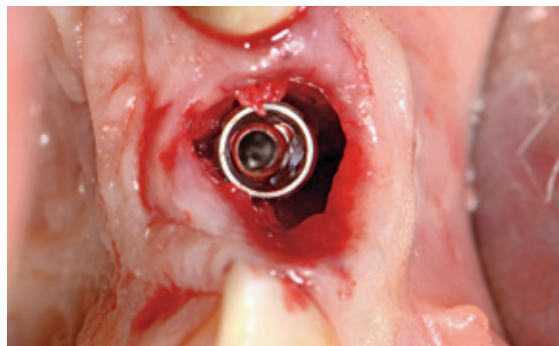
**Fig 1i** Occlusal view of the extraction socket.



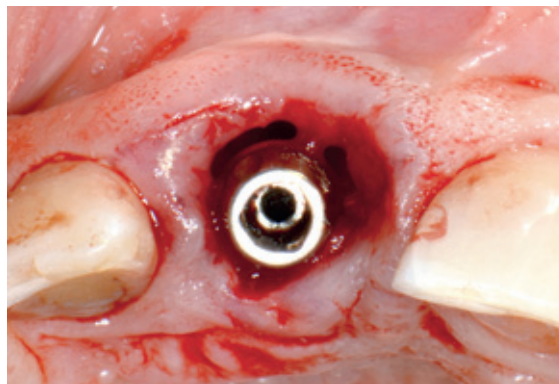
**Fig 1j** The implant recipient site is prepared a bit more palatally than the original root position.



**Fig 1k** The implant is placed.



**Fig 1l** According to the protocol, the gap between the implant and the bone should have been filled with the bone substitute but this is one of the protocol deviations where this was not done.



**Fig 1m** A temporary abutment is placed.

bone (Bio-Oss®, Geistlich Pharma, Wolhusen, Switzerland). Decisions whether or not to use resorbable barriers were left to the clinicians. Periapical radiographs and clinical pictures of the vestibular and occlusal aspects (Figs 1m–1o) were taken, and flaps were sutured around the abutments. Impressions were taken at abutment level and provisional

crowns were fabricated and provisionally cemented the same day (Figs 1p and 1q). All provisional crowns were not in contact with the opposite dentition both in static or dynamic occlusion.

Patients randomised to the delayed group had their sockets loosely packed with Bio-Oss granules (Fig 2d), and then a resorbable barrier (Bio-Gide®;



**Fig 1n** Vestibular view with the temporary abutment in place.



**Fig 1o** Baseline post-implantation periapical radiograph.



**Fig 1p** Immediate provisional acrylic screw-retained crown (out of occlusion) in place.



**Fig 1q** View of the patient showing the provisional crown.



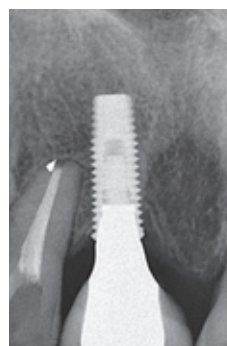
**Fig 1r** The peri-implant soft tissues are healthy at removal of the provisional crown 4 months after implant placement.



**Fig 1s** Vestibular view showing the healthy peri-implant tissues surrounding the removed provisional crown.



**Fig 1t** Definitive crown in position.



**Fig 1u** Periapical radiograph at definitive crown delivery.



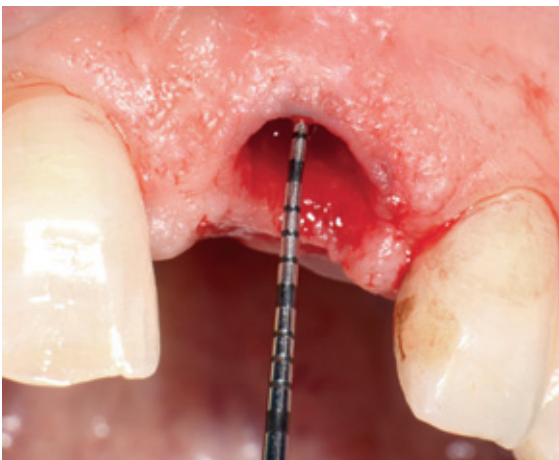
**Fig 1v** View of the patient showing the definitive crown.



**Fig 2a** Clinical view of a central incisor (21) to be extracted.



**Fig 2b** Periapical radiograph of the central incisor (21) to be extracted. The tooth was resorbed and a peri-apical infection is present.



**Fig 2c** After tooth extraction, the integrity of the buccal wall is measured with a periodontal probe to evaluate whether the patient is eligible for the trial.



**Fig 2d** The patient was randomised to have the socket preserved with anorganic bovine bone.

Geistlich Pharma) was trimmed and adapted to cover the entire socket and at least 2 mm of the surrounding crestal bone (Figs 2e and 2f). The soft tissues were sutured with a cross suture without mobilising the flaps, and consequently barriers were left partially exposed since complete soft tissue coverage was not achieved (Fig 2g). Occlusal clinical pictures of the extraction site after flap suturing were obtained.

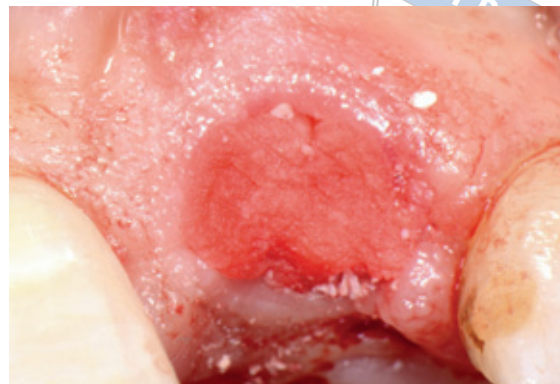
Ibuprofen 400 mg was prescribed to be taken 2 to 4 times a day during meals, as long as required. Patients were instructed to use 0.2% chlorhexidine mouthwash for 1 minute twice a day for 2 weeks, and to avoid brushing and possible trauma on the surgical sites. Postoperative antibiotics were prescribed: amoxicillin 1 g twice a day for 6 days. Patients allergic to penicillin were prescribed clindamycin 300 mg twice a day for 6 days. Patients of the immediate group were also instructed to avoid chewing on the

provisional crowns for about 1 month. After 1 week, patients were checked. Sutures were removed and occlusal clinical pictures of the implant sites were obtained. After 1 month, patients were checked again and occlusal clinical pictures of the implant sites were obtained.

Approximately 3.5 months after tooth extraction, patients of the immediate group had the implants assessed for stability, impressions were taken at implant level using copy transfer and individualised trays, and metal-ceramic crowns were fabricated and provisionally cemented on customised abutments within 2 weeks after the impressions (Figs 1t–1v). Patients of the delayed group had implants placed 4 months after extraction following the same procedures previously described for the immediate group. After local anaesthesia, flaps were elevated, implant sites were prepared without cleaning the preserved socket, and implants were placed and immediately



**Fig 2e** A resorbable barrier was trimmed in order to completely cover the bone substitute.



**Fig 2f** The resorbable barrier was adapted below the soft tissues.



**Fig 2g** The membrane was stabilised below the soft tissues with sutures.



**Fig 2h** Periapical radiograph after the socket preservation procedure: the anorganic bovine bone filling the entire socket is clearly visible.



**Fig 2i** One week after the socket preservation procedure, a small portion of the membrane was still exposed.



**Fig 2j** One month after the socket preservation procedure the wound is completely closed, though the barrier beneath is still visible.

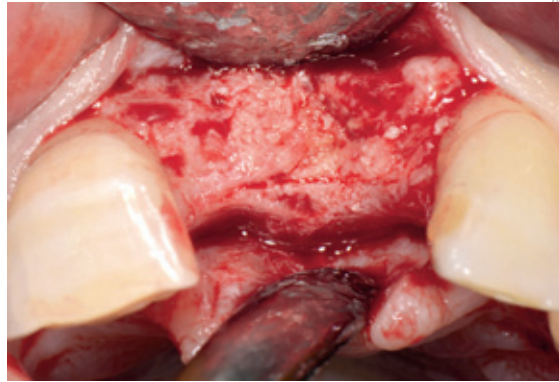
loaded as previously described (Figs 2k–2q). If after implant placement surgeons felt that the site would benefit, for aesthetic reasons, from a local bone augmentation procedure (i.e. exposed implant threads), the surgeon could augment the site using Bio-Oss

granules and Bio-Gide resorbable barriers. After suturing, provisional non-occluding acrylic crowns were cemented the same day of implant placement (Fig 2s) and baseline periapical radiographs were taken (Fig 2t). The same postoperative instruc-





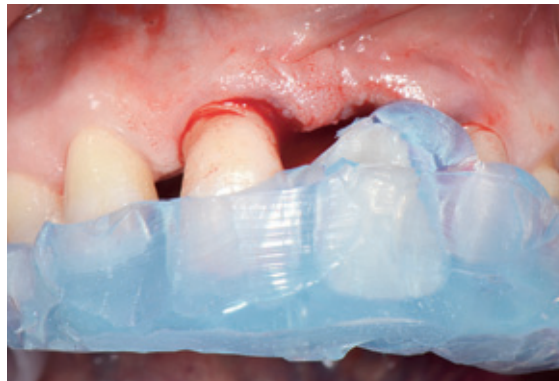
**Fig 2k** Post-extractive site after 4 months of healing.



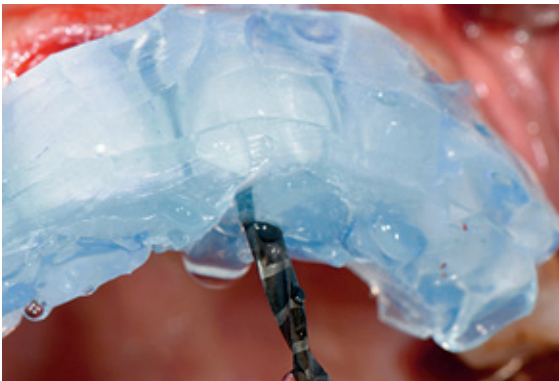
**Fig 2l** After flap elevation, a ridge of sufficient thickness was observed.



**Fig 2m** A provisional acrylic crown was placed in a surgical stent.



**Fig 2n** Stent and provisional crown in position prior to implant placement.



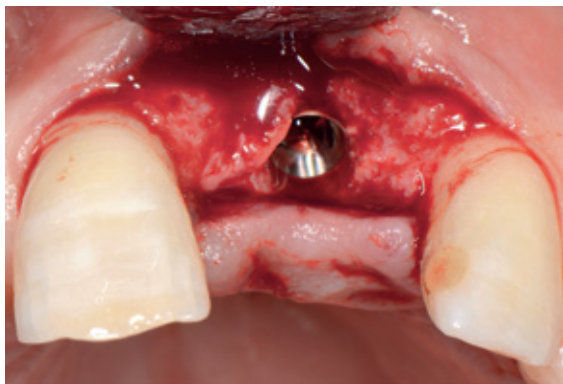
**Fig 2o** The stent guided the surgeon when placing the implant.



**Fig 2p** After implant preparation the implant is inserted in the underprepared osteotomy site to achieve, ideally, an insertion torque >35 Ncm.

tions as previously described were given, with the only difference being that if no augmentation procedures were performed, postoperative antibiotics were not given. The same prosthetic procedures were followed and 4 months after implant place-

ment, patients received the definitive metal-ceramic crowns that were provisionally cemented (Figs 2u and 2v). At delivery of definitive crowns, implant stability was assessed applying a reverse torque of 20 Ncm with the dedicated wrench, occlusal and



**Fig 2q** The implant was successfully inserted with the required torque and the provisional abutment was removed.



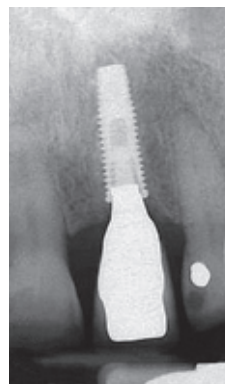
**Fig 2r** The flap was sutured and a implant-level impression was taken.

**Fig 2s** A non-occluding screw-retained provisional acrylic crown was delivered.



**Fig 2t** Periapical radiograph showing the implant with its screw-retained provisional crown just after implant placement.

**Fig 2u** Four months after initial loading, a metal-ceramic definitive crown is delivered.



**Fig 2v** Periapical radiograph just after delivery of the definitive crown.

vestibular pictures of the study implants were taken including the two adjacent teeth (with a 1:4 magnification), and the local independent blinded assessors recorded patient satisfaction.

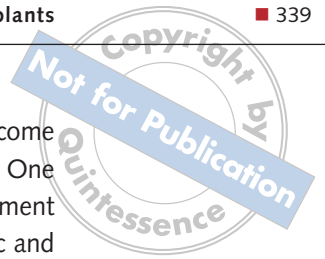
### ■ Outcome measures

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: implant mobility or removal of stable implants dictated by progressive marginal bone loss or infection. The stability of individual implants was measured at delivery of definitive crowns (4 months after implant placement) by applying a reverse torque of 20 Ncm with



a dedicated wrench. Implant stability was re-assessed 4 months after loading using the metal handles of two instruments.

- 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 and fracture of the provisional crown.
- Peri-implant marginal bone level changes evaluated on intraoral radiographs taken with the paralleling technique at implant placement and 1 and 5 years after loading (this outcome will be reported when the 1-year data after loading is available).
- Aesthetic evaluation of the vestibular and occlusal clinical pictures, taken with a 1:4 magnification and including the two adjacent teeth at delivery of the definitive crowns, 1 and 5 years after loading, and performed on a computer screen by an independent blinded dentist (ES). The aesthetic evaluation was conducted using the pink esthetic score (PES)<sup>22</sup>. In brief, seven variables were evaluated: mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiencies and soft tissue colour and texture. A 0-1-2 scoring system was used, 0 being the lowest and 2 being the highest value, with a maximum achievable score of 14.
- Patient satisfaction. At delivery of definitive crowns, and 1 and 5 years after loading (to be assessed/reported at the appropriate time), the local blinded outcome assessors provided a mirror to the patients showing the implant-supported crown after which patients 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' and 'absolutely not'. Then they were 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' and 'absolutely not'. Finally, patients were asked whether they would undergo the same therapy again. Possible answers were 'yes' or 'no'. The questions were always posed with exactly the same wording.

At each centre there was a local blinded outcome assessor who recorded all outcome measures. One blinded dentist (ES), not involved in the treatment of the patients, scored and evaluated aesthetic and marginal bone levels without knowing group allocation, therefore the outcome assessor was blind. In order to evaluate the reproducibility of the assessor, all PES measurements were calculated twice, with at least a 2-month interval between the two series of evaluations. The intraclass correlation between the two assessments was 0.875.

### ■ Statistical analysis

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. Initially, seven centres agreed to participate in this trial. Each centre had to recruit 30 patients to be equally allocated to both interventions, therefore 210 patients were to be included. Seven computer-generated restricted randomisation lists were created. Only one investigator (ME), who was not involved in the selection and treatment of the patients, knew the random sequence and had access to the random list stored in a password protected portable computer. The randomised codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. After tooth extraction and quantification of the amount of buccal bone loss (<4 mm), the patient was finally entered in the study and the envelopes were sequentially opened. Therefore, treatment allocations were concealed to the investigators in charge of enrolling and treating the patients.

All data analysis was performed according to a pre-established analysis plan by a biostatistician with expertise in dentistry analysing the data without knowledge of the group codes. The patient was the statistical unit of the analyses. An intention-to-treat (ITT) analysis was used. Differences in the proportion of patients with implant failures and complications (dichotomous outcomes) were compared between

**Table 1** Patient and intervention characteristics.

	Immediate (%) [n = 54]	Delayed (%) [n = 52]
Females	32 (59)	28 (54)
Males	22 (41)	24 (46)
Mean age at implant insertion (range)	48 (28–70)	50 (30–72)
Non-smokers	43 (80)	41 (79)
Smoking up to 10 cigarettes/day	8 (15)	7 (14)
Smoking more than 10 cigarettes/day	3 (6)	4 (8)
Mean bone loss at buccal sites {SD}	1.69 {0.80}	1.46 {0.92}
Implants in central incisor position	8 (15)	7 (14)
Implants in lateral incisor position	13 (24)	6 (12)
Implants in canine position	2 (4)	5 (10)
Implants in first premolar position	11 (20)	12 (23)
Implants in second premolar position	20 (37)	22 (42)
Implants with 4 mm diameter	51 (94)	52 (100)
Implants with 5 mm diameter	3 (6)	0 (0)
Implants 7 mm long	0	0
Implants 8.5 mm long	1 (2)	2 (3)
Implants 10 mm long	19 (35)	14 (27)
Implants 11.5 mm long	15 (28)	9 (17)
Implants 13 mm long	19 (35)	27 (52)
Implants 15 mm long	0 (0)	0 (0)
Mean implant length	11.5 mm	11.8 mm
Implants not loaded immediately (insertion torque <35 Ncm)	19 (35)	39 (75)
Mean horizontal gap implant-buccal bone in mm {SD}	1.9 {1.1}	0
Sites augmented with Bio-Oss at implant placement	25 (46)	0 (0)
Post-extractive sites which should have been grafted but were not	17 (40)	0 (0)
Post-extractive sites where grafting was not needed	12 (22)	0 (0)
Sites with complete flap closure after tooth extraction	25 (46)	0 (0)

the groups using the Fisher exact probability test. Differences of means at patient level for continuous outcomes (PES) between groups were compared by *t* tests. The Mann–Whitney U test was used to compare the medians of the two groups for patient satisfaction. Differences in the proportion of patients with implant failures and complications (dichotomous outcomes) and of PES (continuous outcome) were compared among the three centres using the chi-square test and one-way analysis of variance F ratio test, respectively. A post-hoc subgroup analysis

(ANOVA test) was conducted to evaluate whether the lack of grafting (protocol deviation) in 17 patients who had a bone-to-implant gap and should have been grafted at placement of immediate implants could have affected the aesthetic outcome. All statistical comparisons were conducted at the 0.05 level of significance.

## ■ Results

During initial monitoring it was noticed that most of the centres were not recruiting, and soon after four centres withdrew without having treated a single case. One centre (Dr Felice) took over the patient quota of one of the centres that withdrew, and therefore treated 60 patients instead of the 30 patients as initially agreed. Another centre (Dr Jacotti) did not manage to meet the agreed recruiting quota and managed to recruit and treat 16 out of 30 patients.

One-hundred-twenty-nine patients were screened at the three centres and 106 patients were consecutively enrolled in the trial. Twenty-three patients were not included for the following reasons: 10 patients had more than 4 mm of buccal bone loss after extraction, 6 patients did not want to participate in the study, 3 patients were treated with intravenous amino-bisphosphonates, and 2 patients were unable to attend all of the requested follow-up appointments. All patients were treated according to the allocated interventions. No patient dropped out and data of all patients were evaluated in the statistical analyses. The main deviations from the protocol were: 17 patients (40%; 9 treated by Dr Jacotti, 6 by Dr Felice and 2 by Dr Pistilli) out of 42 who should have had the implant-to-bone gap filled with the bone substitute did not have the sites grafted. One centre (Dr Jacotti) used another resorbable membrane (CopiOs, pericardium membrane, Zimmer Dental, Carlsbad, CA, USA) rather than the one agreed at protocol stage, and 2 patients had one implant adjacent to the study implants instead of both natural teeth. All data of patients affected by protocol deviations are presented in this report according to an intention-to-treat analysis.

Patients were recruited and received the post-extractive implants from September 2009 to December 2010. The follow-up of all patients was up to 4

months after implant loading. Patient demographics are presented in Table 1. Fifty-four implants were placed in the immediate group and 52 in the delayed group and there were no apparent significant baseline imbalances between the two groups. At implant placement, 25 (46%) implants of the immediate group versus no implant of the delayed group were augmented with Bio-Oss (only in one case was a barrier used). For 29 implants of the immediate group and all implants of the delayed group a complete flap closure after tooth extraction was not achieved. Nineteen (35%) implants of the immediate group and 39 (75%) implants of the delayed group did not reach an insertion torque of at least 35 Ncm and therefore were conventionally loaded after 4 months of unloaded healing. No augmentation procedure was implemented at placement of any of the delayed implants.

Two implants failed, both from the immediate group, which means that 4% of the immediate post-extractive implants failed (Table 2). The differences in proportions of implant failures was not statistically significant (Fisher's exact test  $P = 0.50$ ; proportion difference = 0.04; 95% CI -0.02 to 0.10). One implant was painful at the 1-week control and then also at the 1-month control; when tested for stability the implant was mobile and was removed. The other implant was found to be mobile at the time of final impression (4 months after initial placement/loading) when screwing the copy transfer. The provisional crown became loose about 20 days earlier, but the patient did not inform the treating dentist since he already had a scheduled appointment. One failed implant was successfully replaced. The second patient postponed the placement of a replacement implant due to lack of time. The data of the replaced implants were not recorded since they were outside the scope of the present study.

Eight minor complications occurred in 8 patients of the immediate group (15%) versus 1 complication in the delayed group (2%) (Table 3). Significantly more complications occurred in the immediate group (Fisher's exact test  $P = 0.032$ ; difference in proportions = 0.13; 95% CI 0.03 to 0.23). Seven complications were successfully treated or resolved spontaneously, the remaining 2 complications were associated with implant failure. The complications in the immediate group were partial fracture of the provisional crown

**Table 2** Summary of implants placed/implant failures up to 4 months after loading by study centre.

	Felice	Jacotti	Pistilli	Total
Immediate	30/2	9/0	15/0	54/2
Delayed	30/0	7/0	15/0	52/0
Total	60/2	16/0	3%	106/2

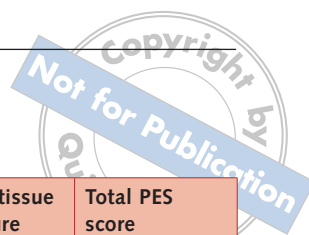
**Table 3** Summary of patients experiencing complications up to 4 months after loading by study centre.

	Felice	Jacotti	Pistilli	Total
Immediate	30/6	9/0	15/2	54/8
Delayed	30/1	7/0	15/0	52/1
Total	60/7	16/0	30/2	106/9

(4 patients), loosening of the provisional crown (2 patients), prolonged postoperative discomfort during chewing that lasted 4 months (1 patient) and prolonged postoperative pain resulting in implant mobility at 1 month after loading (1 patient). The only complication that occurred in the delayed group was a loosening of a provisional crown.

Four months after loading, the average PES score, assessed by a blinded assessor, was 12.8 for the immediate group and 12.6 for the delayed group (Table 4), the difference being not statistically significant ( $P = 0.55$ ). The subgroup analysis evaluating whether the PES scores of the 17 patients of the immediate group who should have been grafted and were not (protocol deviation) showed no statistically significant differences in PES scores among the three compared subgroups ( $P = 0.2594$ ; Table 5).

Patient satisfaction was assessed at 4 months after loading only for those patients who did not experience an implant failure. Regarding function of the prosthesis, 50 patients of the immediate group declared to be absolutely satisfied versus 51 patients of the delayed group. One patient from each group declared to be partially satisfied and 1 patient from the immediate group declared to be uncertain about the function of his crown. Regarding aesthetics, all patients declared to be completely satisfied. Both groups of patients were equally satisfied by the function and aesthetics of their implant-supported crowns. All patients declared that they would undergo the same procedure again.

**Table 4** PES scores (SD) at 4 months after loading by groups and by different aesthetic domains.

	Mesial papilla	Distal papilla	Soft tissue level	Soft tissue contour	Alveolar process deficiencies	Soft tissue colour	Soft tissue texture	Total PES score
Immediate [n = 52]	1.85 (0.36)	1.75 (0.44)	2.00 (0.0)	1.75 (0.44)	1.94 (0.24)	1.75 (0.44)	1.71 (0.46)	12.75 (1.25)
Delayed [n = 52]	1.75 (0.44)	1.73 (0.45)	2.00 (0.0)	1.81 (0.40)	1.96 (0.19)	1.69 (0.47)	1.67 (0.47)	12.62 (1.05)
Difference	0.10	0.02	0.0	0.06	0.02	0.06	0.04	0.14
<i>P</i> value								0.55

The comparison between the three centres is presented in Tables 2 and 3. There were no statistically significant differences for implant failures ( $P = 0.46$ ), complications ( $P = 0.30$ ) and PES scores ( $P = 0.07$ ) among centres.

## ■ Discussion

This trial was designed to assess whether it could be advantageous to place implants immediately after tooth extraction or if it would be preferable to preserve the socket, wait for bone healing and then place the implants. In addition, implants inserted with a torque of at least 35 Ncm were immediately loaded with provisional non-occluding resin crowns. In the immediate group, the patient could essentially enter with a tooth to be extracted and leave the same day with an aesthetically acceptable implant-supported crown. Two implants (4%) failed in the immediate group and this is within the range of what was expected. This failure rate for single implants is within the range if not lower than the failure rate for immediately loaded single implants reported in other studies<sup>23-31</sup>. The present study supports the notion that post-extractive immediately loaded implants could be at a higher risk of failure and complications than delayed implants. However, there was also one major advantage: most of the patients in the immediate group (65%) could be rehabilitated the same day of tooth extraction, thereby reducing operative times and costs.

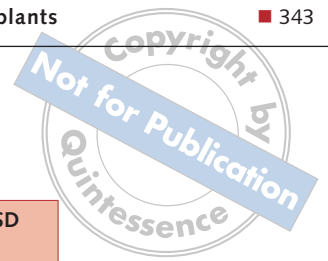
The present findings are in agreement with other RCTs<sup>6,7</sup> testing the same hypothesis. While there are some obvious differences among the present trial and those mentioned above (i.e. the majority of implants in the present study were immediately non-occlusally loaded, which also increases the risk

of implant failure), the results of all these studies are in substantial agreement, suggesting that immediate post-extractive implants are at a higher risk for failures/complications. In particular, there were significantly more complications when implants were immediately placed in post-extractive sockets.

It was not always possible to achieve an insertion torque of at least 35 Ncm at implant placement. More precisely, 19 (35%) implants of the immediately loaded group and 39 (75%) implants of the delayed group had to be left unloaded for 4 months to minimise the risk of their failures. This data suggests that after 4 months of healing, the consistency of the alveoli filled with Bio-Oss is still rather soft. The practical implication is that it is easier to achieve higher insertion torques at immediate post-extractive sites than at augmented sites healed for 4 months.

Regarding the aesthetic outcome, no statistically significant differences or trends were observed 4 months after loading between groups for PES scores. This could be interpreted as both procedures achieving the same aesthetic outcome, however in the immediate group substantial deviations from the research protocol occurred: 40% of the sites that should have been grafted with the bone substitute at implant placement because a buccal bone-to-implant gap was present (Figs 1l–1o) were actually not grafted. It is unclear why surgeons decided not to graft in those occasions; possibly they treated the cases as they were used to. However, this deviation does not seem to have influenced the 4-month PES score of the post-extractive group to a significant degree (Table 5).

The other main limitation of the present trial is the insufficient sample size. In fact, the present authors were only able to recruit half of the patients that were planned mainly because four centres that



**Table 5** Post-hoc subgroup analysis evaluating the influence of grafting or not at immediate post-extractive implants (54 patients).

Group	N	%	Implant failures	Mean PES	SD
Buccal gap grafted with Bio-Oss according to protocol	25	46	0	13.0	1.1
Buccal gap present but not grafted (protocol deviation)	17	31	2	12.4	1.6
No buccal graft present	12	22	0	12.6	1.1

ANOVA test showed not statistically significant difference ( $P = 0.2594$ ) of PES scores between the three groups.

accepted to participate in the protocol did not treat any patients. On the other hand, this trial recruited almost double the number of patients in other similar trials<sup>6,7</sup>, making this study the largest published trial so far.

While comparing the clinical outcome among different centres there were no statistically significant differences for implant failures, complications and PES scores, though the sample was too small to detect possible differences between operators. A sample size of around 350/400 subjects per group would probably be needed to be able to answer this question. 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

There are more complications with immediate post-extractive implants compared to delayed implants. The aesthetic outcome appears to be similar for both groups and it seems more difficult to obtain a high insertion torque in sockets preserved with anorganic bovine bone.

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