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Single post-extractive ultra-wide 7 mm-diameter implants versus implants placed in molar healed sites after socket preservation for molar replacement: 6-month post-loading results from a randomised controlled trial

Key words *delayed implants, dental implants, post-extractive implants, socket preservation wide-diameter implants*

Purpose: To test the hypothesis that there is no difference in clinical, radiographic and aesthetic outcomes positioning single post-extractive ultra-wide 7 mm-diameter implants or waiting 4 months to place implant, after molar extraction and the socket preservation procedure.

Material and methods: Patients requiring one implant-supported single restoration to replace a failed tooth in the molar region of both maxilla and mandible were selected. Patients were randomised according to a parallel group design into two arms: implant installation in fresh extraction sockets augmented with corticocancellous heterologous bone and porcine derma (group A) or delayed implant installation 4 months after tooth extraction and socket preservation using the same materials (group B). Ultra-wide 7 mm-diameter implants were submerged for 4 months. Outcome measures were implant success and survival; complications; horizontal dimensional changes measured on cone beam computed tomography (CBCT) scans at three levels, localised 1, 2 and 3 mm below the most coronal aspect of the bone crest (level A, B and C); peri-implant marginal bone level changes; implant stability quotient (ISQ); and pink esthetic score (PES).

Results: Twelve patients were randomised to group A and 12 to group B. No patients dropped out. No implant failed or complications occurred up to 6-months post-loading. Six months after loading there was more horizontal alveolar bone reduction at immediate post-extractive implants, which was statistically significant. At level A was 1.78 mm ± 1.30 in group A, 0.45 mm ± 0.42 in group B, (difference 1.33 mm ± 1.39; 95% CI: 0.38 to 1.95; $P = 0.003$); at level B was 0.98 mm ± 1.13 in group A, 0.14 mm ± 0.22 in group B, (difference 0.84 mm ± 1.16; 95% CI: 0.24 to 1.07; $P = 0.019$); at level C was 0.55 mm ± 0.74 in group A, 0.03 mm ± 0.24 in group B, (difference 0.51 mm ± 0.76, 95% CI: 0.01 to 0.87; $P = 0.032$). One year after implant placement, mean peri-implant marginal bone loss was 0.43 mm ± 0.37 for group A and 0.10 mm ± 0.10 for group B, showing a statistically significant difference between groups (difference 0.33 mm ± 0.30; 95% CI: 18 to 0.52; $P = 0.010$). Mean ISQ value was 78.8 ± 2.8 for group A and 79.9 ± 3.6 for group B, showing no statistically significant differences between groups (difference 1.1 ± 2.6; 95% CI: 0.04 to 2.96; $P = 0.422$). Mean PES was similar in both groups (10.7 ± 1.5 [range: 8 to 13] in group A and 11.7 ± 1.2 [range: 10 to 13] in group B; difference 1.0 ± 2.2; 95% CI: -0.23 to 2.23; $P = 0.081$).

Conclusions: Single post-extractive ultra-wide 7 mm-diameter implants, in combination with socket preservation, might be a possible strategy in the replacement of hopeless molars in both jaws, with high implant and prosthetic survival and success rates, and good aesthetic outcomes. Longer follow-ups are needed to properly evaluate this therapeutic option.

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Introduction

Following tooth extraction, residual alveolar ridge resorbs[1]. The amount of horizontal bone loss is generally the greatest and occurs more frequently on the buccal side[1]. A recent systematic review evaluating the dimensional changes of the alveolar process concluded that after 6 months of healing, the vertical resorption of the alveolar bone was 11% to 22%, whereas the horizontal resorption of the alveolar bone was 29% to 63%[2]. Previous tooth condition as well as damage of the bone tissue during tooth removal may also result in additional bone loss[3]. To prevent this clinical situation, different socket preservation techniques have been proposed[4-6]. Most of these techniques were based on careful tooth extraction, filling of the alveolar socket with different grafting materials and seal procedures, and undisturbed healing.

Immediate placement of dental implants into fresh extraction sockets of single-rooted teeth is an accepted procedure[7-10]. Immediate placement of dental implants into mandibular molar sockets has also been presented as a successful alternative to the delayed protocol, with cumulative survival rates similar to those for implants placed into healed molar extraction sites[9-10]. The main advantages of this procedure are fewer surgical interventions and shorter implant treatment times. In addition, it has been hypothesised that immediate implant placement in fresh extraction sockets may limit the extent of bone remodelling, avoiding the need for further bone augmentation procedures as horizontal peri-implant defects less than 2 mm are usually spontaneously filled during bone healing[11]. An essential factor for successful immediate implant placement is initial stabilisation of the implant with the apical and/or lateral bone[12]. Nevertheless, in molar extraction sockets, achieving initial implant stability may be challenging as a result of the width of the alveolar socket, poor bone quality and anatomical limitations beyond the apices of molar roots, such as the inferior alveolar nerve, as well as the maxillary sinus.

Wide-diameter implants of different lengths were introduced to overcome the limitations of reduced bone height, and to enhance the bone-to-implant contact (BIC) area, increasing the surface area for osseointegration[13]. A wide-diameter implant has been defined as an implant with a diameter larger than 4.5 mm[14]. The wide-diameter implants should also have the advantage of reaching primary stability by anchoring on the socket walls, and reducing the gap between the post-extractive socket and the implant itself. After osseointegration, the wide-diameter implants may have a significant advantage when used in the molar regions, as they allow for more favourable distribution of occlusal forces, and minimise the stresses around the crestal bone[15].

The aim of the present study was to test the hypothesis that there is no difference in clinical, radiographic and aesthetic outcomes positioning single post-extractive ultra-wide 7 mm-diameter implants (Fig 1) or waiting 4 months to place the same diameter implant, after molar extraction and socket preservation procedure. The null hypothesis was that there is no difference between groups. This null hypothesis was tested against the alternative hypothesis of differences between them. This trial has been reported in accordance with the guidelines provided by the CONSORT (Consolidated Standards of Reporting Trials) statement for the evaluation of randomised controlled trials (http://www.consort-statement.org)[16].

Materials and methods

This study was designed as a randomised controlled trial of parallel group design, aimed to evaluate patients with mandibular and maxillary hopeless molars, requiring an implant-supported single crown restoration. Private patients were selected and consecutively treated in a private centre in Rome, Italy, between June 2014 and December 2014. The same clinician (MT) performed both surgical and prosthetic procedures. This study was con-

ducted in accordance with the principles outlined in the Helsinki Declaration of 1964 for biomedical research involving human subjects, as amended in 2008. Patients were duly informed about the nature of the study. A written informed consent form for surgical and prosthetic procedures, as well as for the use of the clinical and radiological data, was obtained for each patient.

Any subject requiring one implant-supported single restoration to replace a failed tooth in the molar region of both jaws, with less than 5 mm between the root apex and the inferior alveolar nerve or maxillary sinus, measured on the CBCT scan, being at least 18 years old, and able to sign an informed consent form was considered eligible for this study and consecutively enrolled. Each patient received only one implant. The selected site had to have adjacent teeth/implants. Final patient inclusion was made after atraumatic tooth extraction: fresh extraction sockets had to have intact buccal walls[17]. Exclusion criteria were:

- General contraindications to oral surgery (such as stroke, recent cardiac infarction, severe bleeding disorder, uncontrolled diabetes or cancer);
- Heavy smokers (≥ 11 cigarettes/day);
- Addiction to alcohol or drugs;
- Acute and chronic infections in the site intended for implant placement;
- Poor oral hygiene (full mouth bleeding and full mouth plaque index higher than 25%)
- Pregnancy or nursing;
- Psychiatric therapy;
- Patients treated or under treatment with intravenous aminobisphosphonates;
- Previous radiotherapy of the oral and maxillofacial region within the last 5 years;
- Absence of teeth in the opposing jaw;
- Severe clenching or bruxism;
- Patients unable to commit to the scheduled follow-up.

Clinical procedures

Potentially eligible patients were evaluated clinically and their medical histories were recorded. A preoperative periapical radiograph, a CBCT (cone beam computed tomography) scan and pictures were obtained for each included patient. Bone volumes were analysed using CBCT scan (CRANEX 3D; Soredex, Tuusula, Finland).

Fig 1 Osstem TSIII Ultra-Wide 7 mm-diameter implant.

Patients underwent professional oral hygiene prior to the surgery and received prophylactic antiseptic (0.2% chlorhexidine mouthwash 1 min prior to the surgery) and antibiotic therapy (2 g of amoxicillin and clavulanic acid or clindamycin 600 mg if allergic to penicillin 1 h prior to surgery). All patients were treated under local anaesthesia using articaine hydrochloride with adrenaline 1:100000 (Orabloc, Pierrel, Milan, Italy). Teeth extractions were performed flapless, as atraumatically as possible, with the aid of a periotome and atraumatic elevators (PT1 and EPTSMS, Hu-Friedy Italy, Milan, Italy) to reduce trauma on the bony walls. Multiple-rooted teeth were sectioned at the furcation, and the roots were individually extracted. Afterwards, the residual extraction socket was washed with physiological solution and it was debrided thoroughly from granulation tissue and residual periodontal ligament fibres with a curette (CL866, Hu-Friedy). Finally, bony wall continuity was evaluated with the aid of a periodontal probe (PCPUNC156, Hu-Friedy). Afterwards, the sequentially numbered sealed envelope corresponding to the patient recruitment number was opened by a blinded independent assistant to know whether to place the implant (group A) or to preserve the socket (group B).

In group A (Figs 2a to 2f), the initial osteotomy was made into the interradicular bone using the 2 mm sidecut pilot drill (Osstem, Seoul, Korea). In case of thin interradicular septa, a high speed round diamond bur was used under copious irrigation with sterile saline to mark the central part of the interradicular bone. The preparation of the osteotomy continued with the use of the tapered implant drills

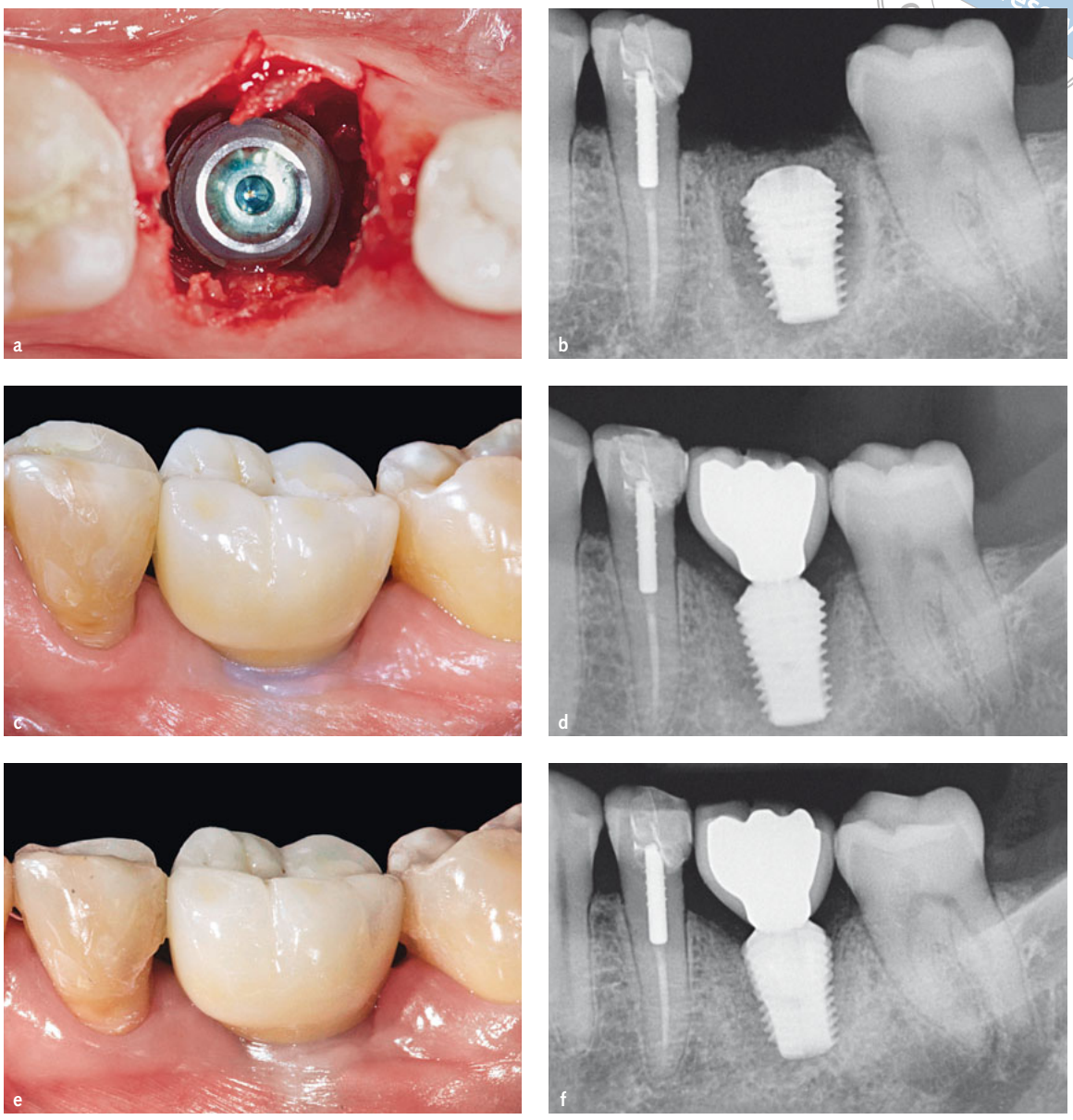

Fig 2a–f Group A: implant inserted in fresh extraction socket (a); periapical radiograph after implant installation (b); final crown delivered (c) and periapical radiograph (d); one-year follow-up clinical (e) and radiographic (f) examination.

(Tapered and Ultra-Kit, Osstem) in the centre of the socket and in relation to the desired axis of the planned rehabilitation. Afterwards a 7-mm diameter implant (Ultra-Wide, Osstem) was immediately introduced into the prepared sites at a speed of 25 rpm with the motor set at 45 Ncm torque. Due to anatomical limitations beyond the apices of molar roots (inferior alveolar nerve or maxillary sinus), implant stability was reached, engaging both the prepared interradicular bone and the socket walls. The implant platform was positioned at the alveolar crest level or slightly below. Then, the primary stability was evaluated using the Osstell Mentor device (Osstell, Göteborg, Sweden). Thereafter, residual alveolar socket around the implant was grafted with cortico-cancellous heterologous bone, with a graft particle size between 250 and 1000 µm (OsteoBiol Gen-Os; Tecnoss srl, Giaveno, Italy). Finally, the bone graft was covered with a porcine derma (Derma, OsteoBiol) that was shaped according to the shape and dimension of the alveolar socket and was stabilised with a 4-0 Polyglactin 910 suture (Vicryl V271, Ethicon, New Jersey, USA), without attempting full coverage of the wound.

In group B (Figs 3a to 3 h), socket preservation and seal closure procedures were performed with the same procedure described for group A but the ultra-wide 7 mm-diameter implant was placed 4 months

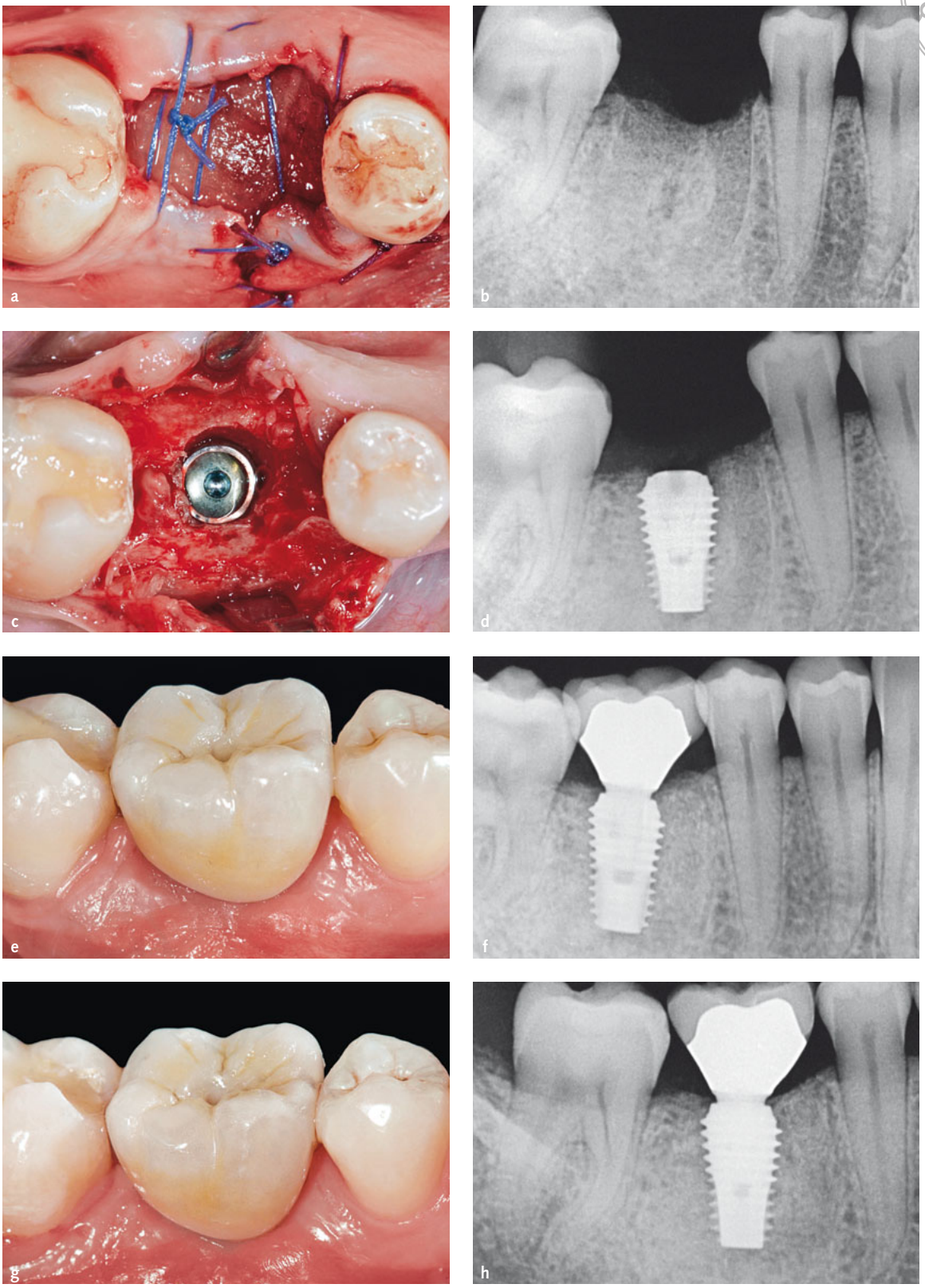

Fig 3a–h Group B: occlusal view of socket preservation (a); periapical radiograph after socket preservation (b); implant inserted in healed socket (c); periapical radiograph after implant installation (d); final crown delivered (e) and periapical radiograph (f); 1-year follow-up clinical (g) and radiographic (h) view.

after tooth extraction, according to the clinical guideline suggested by the manufacturer.

In both groups, 1 g of amoxicillin (or 300 mg of clindamycin) was administered every 12 h for 5 days after tooth extraction; while, in group B, 2 g of amoxicillin (or 300 mg of clindamycin) was also administered 1 h before delayed implant placement. Paracetamol 500 mg plus codeine 30 mg was

prescribed as needed. Patients were instructed not to take them in the absence of pain. Chlorhexidine mouthwash 0.2% for 1 min twice a day for 2 weeks was prescribed. A soft diet was recommended for 2 weeks after surgical procedures. One week and 1 month after tooth extraction/implant placement, all patients was recalled and checked.

In both groups, 4 months after implant placement, a second-stage surgery using a 'H' incision was performed making the incision slightly palatal and lingual, in order to have more keratinised tissues on the buccal side. A healing abutment was placed and no provisional was delivered. The implant was manually tested for stability, tightening the abutment with a 20 Ncm torque by the blind assessor. A preliminary impression with a pick-up impression coping was taken using a polyether material. Two months after second-stage surgery, a screw-retained lithium disilicate single crown, bonded chairside on a CAD/CAM (computer-aided design and computer-aided manufacturing) zirconia abutment, was delivered. The occlusion was adjusted to avoid any premature contacts. Periapical radiographs and clinical pictures were taken. Follow-up visits were scheduled every 3 months up to 1 year after implant placement.

Outcome measures

- Implant failure was defined as implant mobility and/or any infection dictating implant removal or implant fracture or any other mechanical complication rendering the implant useless. The stability of each individual implant was measured manually by tightening the abutment screw at delivery of definitive crowns or by assessing the stability of the implant- supported crown using the handle of two metallic instruments at 6-months follow-up in function.
- A prosthesis was considered a failure if it needed to be replaced by a new prosthesis.
- Any biological (pain, swelling, mobility and suppuration) and/or technical complications (abutment and/or veneering material fracture, screw loosening and/or fracture) was recorded during follow-up by the operator (MT), who performed all the surgical and prosthetic procedures.
- Mesial and distal bone level changes were measured as the distance from the mesial and distal margin of the implant neck (inserted slightly below the buccal bone level) to the most coronal point where the bone appeared to be in contact with the implant. For each implant, mean values of mesial and distal measurements were averaged. It was evaluated on periapical digital radiographs taken with the paralleling technique using a film-holder (Rinn XCP, Dentsply, Illinois, USA), at implant placement (baseline), at initial loading (definitive prosthesis delivery) and 6 months later. All readable radiographs were displayed in an image analysis program (DFW2.8 for windows, Soredex,), calibrated for every single image, using the known distance of two consecutive implant threads. In the case of a unreadable radiograph, the radiograph was made again. All the radiographic measurements were assessed by a blinded clinician not previously involved in the study (EX).
- Horizontal dimensional changes. In both groups, CBCT scans were performed before tooth extraction after socket preservation procedures and 1 year after tooth extraction. Although three scans were performed in 1 year, CBCT setting parameters were set as low as reasonably achievable (Table 1), making the level of radiation dose derived from the second and third scans lower than the first. The data were exported as Digital Imaging and Communication in Medicine (DICOM) and opened using OnDemand3D software version 1.0.9.3223 (Cybermed, California, USA) to perform all measurements. A superimposition of the preoperative and postoperative DICOM data was performed based on unchanged anatomical areas (e.g. the cranial base) and manually checked for a complete match by using the Fusion adjunctive module (Cybermed) (Fig 4). The horizontal ridge width were measured at three levels localised 1, 2 and 3 mm below the most coronal aspect of the bone crest (Fig 5), and named levels A, B and C, respectively. Bone loss was calculated for each value, as a linear difference between pre- and post-treatment measurements. Measurements with respect to these reference points and lines were performed in the centre of the alveolar socket. All the radiographic measurements were assessed by a blinded clinician (EX).

Table 1 Radiation dose of the CBCT scans.

	FOV (mm)	Voxel size (µm)	Time (s)	kV	mA	DAP (mGycm²)
Before extraction	80 x 150	0.3	4.5	90	6.3-10.0	579.7 - 920.2
Immediately post	60 x 80	0.3	2.3	90	5.0-8.0	192.4 - 307.8
1 year later	60 x 80	0.3	2.3	90	4.0-5.0	192.4 - 307.8

FOV: Field of View; DAP: Dose-area Product.

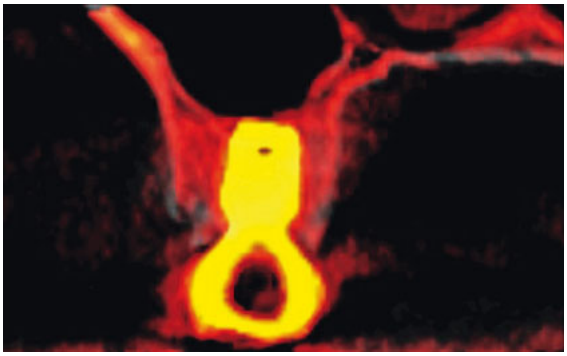

Fig 4 Superimposition of the preoperative (grey) and post-operative (red) CBCT scans.

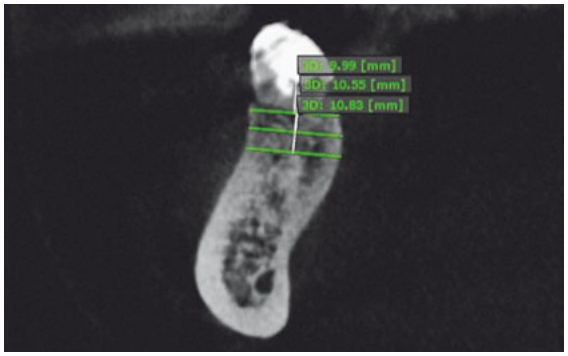

Fig 5 Horizontal ridge measures at three levels localised 1, 2 and 3 mm below the most coronal aspect of the bone crest.

- Implant stability quotient (ISQ) was recorded by means of resonance frequency analysis by the same clinician that performed all the surgical and prosthetic procedures. The values were assessed at implant placement (baseline) and at the second-stage surgery by using the Osstell Mentor device (Osstell). Two measurements were taken for each implant: one buccopalatal from the buccal side and one mesiodistal from the mesial side and both measurements were averaged with the result being displayed by the device in ISQ units, ranging from 1 to 100.
- A blinded clinician (EX) analysed the clinical pictures, taken 1 year after tooth extraction, on a computer screen. The pictures of the vestibular and occlusal aspects had to include one adjacent tooth per side. The aesthetic evaluation was performed according to the pink esthetic score (PES)[18]. Seven variables (mesial papilla, distal papilla, soft tissue level, soft tissue contour, alveolar process deficiency, soft tissue colour and texture) were assessed with a 2-1-0 score, with 2 being the best and 0 being the poorest score.

Statistical analysis

A priori sample size was calculated for the radiographic peri-implant marginal bone level by means of G*Power 3.1.7 software for Mac OS X (version 10.9.2; University of Düsseldorf, Düsseldorf, Germany), given effect size d = 0.7143, error probability $\alpha = 0.05$ and power = 0.70 (1-β error probability), resulting in a sample size of 26 patients for each group. Effect size was expressed as Cohen's d and it was determined using previously reported data on similar topics published by Atieh et al[4] that show a higher bone gain of 0.41 ± 0.57 mm for the immediately placed implants, compared with 0.04 ± 0.46 mm for the delayed placed implants ($P = 0.14$). A pre-generated random list, consisting of a randomised sequence of consecutive numbers matching the two different procedures within group A or group B, was created using Random number generator pro 1.91 for Windows (Segobit Software; www.segobit.com). Opaque envelopes containing the randomisation codes were sequentially numbered and sealed. According to a pre-generated list, an independent consultant, not previously involved in the trial, prepared all the envelopes. Data were collected in spreadsheets (Excel software, Microsoft Corporation, Washington, USA). All data analysis was carried out according to a pre-established analysis plan by a biostatistician with expertise in dentistry without knowing group allocation. The patient was the statistical unit of the analyses. A comparison of the baseline characteristics between groups

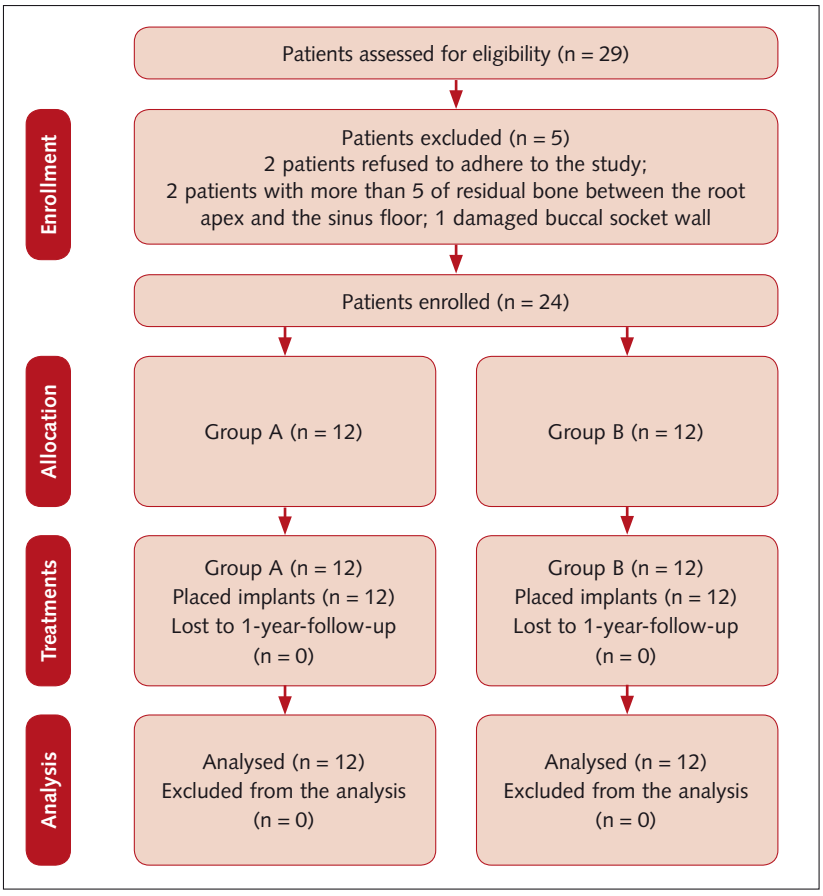

Fig 6 CONSORT flow diagram.

were presented. Differences in the proportion for dichotomous outcomes (crown/implant failures and complications) were compared between the groups using the Fisher's exact probability test. Differences between the groups for continuous outcomes (mean marginal bone level changes, ISQ and PES scores) were compared using analysis of variance (ANOVA). Comparisons between the various follow-up endpoints and the baseline measurements were made by a paired Student t-test, to detect any changes in marginal bone loss for each group. All statistical comparisons were conducted at the 0.05 level of significance.

■ Results

A flow diagram of activities through the phases of the trial is shown in Figure 6. In total, 29 patients were screened between June 2014 and December 2014, but five were not enrolled for the following reasons: two patients refused to participate in the study; two maxillary patients presented more than 5 mm of residual bone between the root apex and the sinus floor; one patient presented a damaged buccal socket wall greater than 2 mm, without loss of soft tissue, after tooth extraction. Thus, 24 patients (8 males and 16 females), with a mean age of 53.9 years (range: 37 to 67) were considered eligible for the study and consecutively treated (12 patients in group A and 12 patients in group B). A total of 24 procedures were performed and 24 implants (four 8.5-mm long, 18 10 mm-long and two 11.5 mm-long) placed. All patients were followed for at least 6 months after loading. No patient dropped out of the study within 1 year after implant insertion and no deviation from the protocol occurred. All the data collected were included in the statistical analysis. There were no apparent baseline imbalances between the two groups apart from the presence of longer implants in group B. The main patient and implant characteristics between groups are reported in Table 2.

At the 1-year follow-up examination, no implants failed and no biological or mechanical complications occurred during the entire follow-up.

All the implants in both groups were placed at the alveolar crest level or slightly below, hence, the mean bone levels at baseline were 0 in both groups. At definitive prosthesis delivery, marginal bone loss was 0.41 mm ± 0.38 mm in group A and 0.11 mm ± 0.09 mm in group B. The difference was statistically significant (0.30 mm ± 0.42; 95% CI: 0.00 to 0.40; $P = 0.02$). One year after implant placement, marginal bone loss was 0.43 mm ± 0.37 mm in group A and 0.1 mm ± 0.1 in group B. The difference was statistically significant (0.33 mm ± 0.42; 95% CI: 0.18 to 0.52; $P = 0.01$; Table 5). Nevertheless, in five patients of group B (41.7%) and only one of group A (8.3%), the marginal bone levels remain stable during follow-up, with no bone loss below the implant platform.

Horizontal bone width changes between groups, measured at each level between tooth extraction and at the 1-year follow-up, showed a statistically significant difference with a lower value in the group (group B). At level A it was 1.78 mm ± 1.30 in group A, 0.45 mm ± 0.42 in group B, (difference: 1.33 mm ±1.39; 95% CI: 0.38 to 1.95; $P = 0.003$); at level B it was 0.98 mm ± 1.13 in

Table 2 Main patient and implant characteristics.

	Group A (n=12)	Group B (n=12)
Number of female patients (n = 16)	7 (43.7%)	9 (57.3%)
Age at insertion (range)	51.6 (37–67)	56.2 (42–67)
Total number of smokers (< 10 cigarettes per day)	0 (0%)	0 (0%)
Total number of mandibular implants (total = 12)	6 (50%)	6 (50%)
8.5 mm-long implants (n = 4)	3 (75%)	1 (25%)
10.0 mm-long implants (n = 18)	9 (50%)	9 (50%)
11.5 mm-long implants (n = 2)	0 (0%)	2 (100%)
Implants in first molar position (n = 21)	10 (47.6%)	11 (52.4%)
Implants in second molar position (n = 3)	2 (66.6%)	1 (33.3%)

Table 3 Horizontal bone levels within groups reported in mm ± SD (95% CI).

Immediate implant placement (group A)			
	Baseline (tooth extraction)	**1-year after tooth extraction**	***P* value**
Level A	11.73 ± 1.50 (10.75–12.44)	9.95 ± 0.63 (9.41–10.11)	0.001
Level B	11.88 ± 1.32 (11.09–12.59)	10.90 ± 1.12 (9.86–11.12)	0.062
Level C	11.78 ± 1.44 (10.87–12.50)	11.23 ± 1.13 (10.01–11.29)	0.313
Socket preservation and delayed implant placement (group B)			
	Baseline (tooth extraction)	**1-year after tooth extraction**	
Level A	12.02 ± 1.67 (11.47–13.36)	11.58 ± 1.63 (10.48–12.32)	0.513
Level B	12.20 ± 1.35 (11.77–13.31)	12.06 ± 1.33 (11.33–12.84)	0.796
Level C	12.13 ± 1.39 (11.79–13.36)	12.10 ± 1.33 (11.59–13.09)	0.953

Table 4a Overall (maxilla and mandible) horizontal bone loss between groups reported in mm ± SD (95% CI).

	Group A	Group B	Difference	*P* value
Level A	1.78 ± 1.30 (0.75–2.23)	0.45 ± 0.42 (0.17–0.65)	1.33 ± 1.39 (0.38–1.95)	0.003
Level B	0.98 ± 1.13 (-0.04–1.24)	0.14 ± 0.22 (-0.02–0.22)	0.84 ± 1.16 (-0.24–1.07)	0.019
Level C	0.55 ± 0.74 (-0.16–0.68)	0.03 ± 0.24 (-0.05–0.21)	0.51 ± 0.76 (0.01–0.87)	0.032

Table 4b Horizontal bone loss between groups: comparison of jaws reported in mm ± SD (95% CI).

	Group A	Group B	*P* value
Mandible (n = 12)			
Level A	0.66 ± 0.36 (0.44–1.02)	0.49 ± 0.60 (-0.21–0.76)	0.565
Level B	0.36 ± 0.19 (0.13–0.43)	0.17 ± 0.32 (-0.22–0.29)	0.240
Level C	0.07 ± 0.07 (0.00–0.12)	0.02 ± 0.34 (-0.18–0.37)	0.732
Maxilla (n = 12)			
Level A	2.91 ± 0.74 (2.48–3.66)	0.41 ± 0.16 (0.35–0.60)	0.000
Level B	1.61 ± 1.36 (-0.12–2.07)	0.12 ± 0.04 (0.08–0.14)	0.023
Level C	1.03 ± 0.80 (0.02–1.31)	0.05 ± 0.05 (0.00–0.08)	0.013

Table 5 Outcomes comparison between groups taken 1 year after implant placement (6 months after loading).

	Group A (n = 12)	Group B (n = 12)	Difference	*P* value
Peri-implant marginal bone loss, mm ± SD (95% CI)	0.43 ± 0.37 (0.19–0.61)	0.10 ± 0.10 (0.04–0.16)	0.33 ± 0.30 (0.18–0.52)	0.010
Implant stability quotient	78.80 ± 2.80 (76.92–80.08)	79.90 ± 3.60 (78.95–83.05)	1.10 ± 2.60 (0.04–2.96)	0.422
Pink esthetic score	10.7±1.5 (10.15–11.85)	11.7±1.2 (10.85–12.15)	1.0 ± 2.2 (-0.23–2.23)	0.081

group A, 0.14 mm ± 0.22 in group B, (difference: 0.84 mm ± 1.16; 95% CI: 0.24 to 1.07; $P = 0.019$); at level C it was 0.55 mm ± 0.74 in group A, 0.03 mm ± 0.24 in group B, (difference: 0.51 mm ± 0.76, 95% CI: 0.01 to 0.87; $P = 0.032$) (Tables 3 and 4a). However, sub-group analyses showed a statistically significant difference in the maxilla but not in the mandible (Table 4b).

ISQ mean values at baseline (implant placement) were 65.5 ± 7.6 for group A and 70.2 ± 4.2 for group B. No statistically significant difference was found between groups (difference: 4.7 ± 10.6; 95% CI: -2.01 to 10.01; $P = 0.080$). One year after implant placement, the ISQ mean value was 78.8 ± 2.8 for group A and 79.9 ± 3.6 for group B. No statistically significant difference was found between groups (difference: 1.1 ± 2.6; 95% CI: 0.04 to 2.96; $P = 0.422$, Table 5).

PES was similar in both groups (10.7 ± 1.5 [range: 8 to 13] in group A and 11.7 ± 1.2 [range: 10 to 13] in group B) with no significant difference between groups, 1 year after implant placement (6 months after loading) (difference: 1.0 ± 2.2; 95% CI: -0.23 to 2.23; $P = 0.081$, Table 5).

■ Discussion

The present randomised controlled trial (RCT) was conducted with the aim of understanding which procedure would be preferable after having extracted a hopeless molar in both jaws, between immediate post-extractive ultra-wide 7 mm-diameter implants in combination with socket preservation procedures, and socket preservation procedures alone, with delayed implant placement.

This RCT revealed statistically significant differences both in MBL and horizontal marginal bone level changes between the two investigated approaches, with lower values for socket preservation procedure alone, with delayed implant placement (group B). Therefore, the null hypothesis of the present study was rejected in favour of the alternative hypothesis of a difference.

The main limitations of this study are the limited power of the analysis due to a limited number of participants, and the short follow-up period. Originally the study was designed as a multicenter study. Then, only one centre started the study. Unfortunately, the authors were unable to comply with the original planned sample size. Nevertheless, the authors intended to evaluate the initial bone remodelling that occurs in the healing period. Hence, a 6-month post-loading follow-up period may be effective to fulfil the aim of the present study. However, due to the short follow-up period and the small number of participants, the present study has reduced the power to detect small differences. Hence, the results of the present study may be used to calculate an adequate sample size for a future RCT, in order to be able to refute the null hypothesis.

High survival rate and no complications were reported in the present study. These results are in accordance with other previously published studies on wide-diameter implants, which achieved high success rates under both conventional and immediate conditions[19-24]. Overall, the success rate of wide-diameter implants ranged from 76% to 100%, with a follow-up of between 9 months and 5 years[9]. Gomez-Roman and coworkers reported a 99.4% success rate for 164 implants placed in native bone, versus 97.1% for 86 immediate implants, placed in both jaws[20]. The Kaplan-Maier survival curve revealed no statistically significant differences between groups. Furthermore, of the 22 immediate implants placed in the molar and premolar regions, all were in function[20]. Penarrocha-Diago and coworkers, in a retrospective case series study, showed that the success rate for implants placed in healed bone was 96.9%, while the success rate for implants

placed in post-extraction sites was 100%[23]. On the contrary, some retrospective studies showed a higher failure rate for the conventionally placed and loaded 5.00 mm-wide diameter implants compared with the standard (3.75 and 4.00 mm) size implants[25,26]. Implant failure was mainly associated with the operators' learning curves, poor bone density, implant design and site preparation[27]. Atieh and co-workers, in a controlled clinical trial on 24 implants placed in either a fresh molar extraction socket or a healed site, reported a relatively high failure rate after 1 year of function[4]. Success rates were 83.3% and 66.7% for the delayed and immediate placement groups respectively, with no significant difference between the two groups. However, in most of these studies, machined rather than roughened implant surfaces were used.

Inconsistent with the success rate, the horizontal bone loss, measured 1 year after implant placement at three levels localised 1, 2 and 3 mm below the most coronal aspect of the bone crest, were significantly higher when implants were immediately placed rather than in implants placed in healed sites. These results do not agree with the results experienced in a retrospective study published by Peñarrocha-Diago et al[22]. The authors reported that an overall mean implant bone loss was 0.83 mm in the case of the immediate implants, versus 0.85 mm for those positioned in healed bone with no statistically significant differences. Possible explanations were that different socket preservation procedures, as well as, different implant systems, placed at different heights, were used. In the present study, all sites were grafted with heterologous bone, while Peñarrocha-Diago et al used autologous bone obtained during drilling if the bone-implant gap was more than 2 mm[23]. On the contrary, with a bone-to-implant gap of 2 mm or less, and in case of the delayed implant protocol, no graft material was used. Conversely, the overall marginal bone loss experienced in the present study was similar or better than other studies on wide-diameter implants[23,28]. In most of these studies, the baseline for radiographic data collection was set after initial bone remodelling, while, in the present trial, the baseline was taken at implant insertion. The favourable bone remodelling experienced in the present trial could be attributed to the use of platform-switched abutments[29], the reduction in the gap between the wide-diameter implant surface and the bony socket walls[12], and the positive effect of the socket preservation technique[6,30].

The major clinical conclusion of this RCT was that single post-extractive ultra-wide 7 mm-diameter implants may be considered an effective and reliable treatment option in the short-term to rehabilitate a hopeless molar in both jaws when patients need to shorten the overall treatment time and to reduce the number of surgical procedures. Furthermore, the sub-group analyses also demonstrated that this reduction was more evident in the maxilla rather than in the mandible. Moreover, CBCT scan analysis showed that buccal bone loss was the greatest and occurs more frequently on the first millimeter below the bone crest. A possible explanation of this result is that the wide implant may reduce the quantity of vital bone that forms in the healing extraction socket. To overcome this possible drawback, implants should be positioned 1.5 to 2.0 mm below the buccal bone level. Due to the anatomical limitations, at least 5 mm between the root apex and the inferior alveolar nerve or maxillary sinus is needed.

In the present study, high implant stability was recorded in both groups without statistically significant differences. These results are in accordance with other similar studies[28]. A high primary implant stability is positively associated with successful immediately loaded implant integration and long-term clinical outcomes[30-37]. This may suggest that the implant design may play an important role in determining implant survival in the posterior jaws[4,31,38]. Three to five millimetres of native bone beyond the end of the socket are needed to engage the implants in the mandible and maxilla, respectively. Moreover, at least two millimetres from the alveolar nerve are suggested to perform a safe procedure, so that at least 5 mm of residual bone are needed in both jaws. The difficulty in achieving primary implant stability in fresh molar extraction sockets, even with a tapered implant design, may jeopardise the overall implant success. In the present study, although no immediate loading protocol was planned, ultra-wide 7 mm-diameter implants achieved high ISQ values for both post-extractive and healed sites, with no statistically significant differences between them. Although the results obtained suggest that crestal bone loss during the first year of follow-up is more apparent in

the immediate post-extractive implants, there was no statistically significant difference in the aesthetic outcome. The soft tissue aesthetics were rated with a mean PES of 11.7 ± 1.2 and 10.7 ± 1.5 for the single post-extractive ultra-wide 7 mm-diameter implants and implants placed in healed sites, respectively. However, the absence of the difference could be hidden by either an insufficient sample size or a short follow-up period.

Immediate placement of implants into fresh extraction sockets is an option for replacing missing teeth. It reduces the number of surgical interventions required for treatment and the time interval between dental extraction and the placement of implant-supported prostheses. However, this technique involves numerous challenges related to site-specific anatomic, occlusal and biomechanical factors. In order to overcome the drawback of this approach, careful CBCT scan evaluation, proper site preparation and positioning implants 1 to 2 mm below the bone crest are fundamental prerequisites for implant success. However, operators' learning curves, poor bone density, implant design and site preparation may make such procedures complicated. Furthermore, there is a wide variability in the anatomy of maxillary molars, which makes the interradicular bone anatomy different in each case.

■ Conclusions

These preliminary results at 6 months after loading showed that single post-extractive ultra-wide 7 mm-diameter implants might be a possible strategy in the replacement of hopeless molars in both jaws, with high implant and prosthetic survival and success rates, and good aesthetic outcomes. Longer follow-ups and a higher number of participants are needed to properly evaluate these therapeutic options.

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