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Natural or palatal positioning of immediate post-extractive implants in the aesthetic zone? 1-year results of a multicentre randomised controlled trial

Key words *delayed, immediate, post-extractive implants*

Purpose: To evaluate whether there is a difference in aesthetic outcomes positioning immediate post-extractive implants in the natural position (where the tooth should have been in relation to adjacent teeth/implants) or about 3 mm more palatally.

Materials and methods: Just after tooth extraction, 30 patients requiring one single immediate maxillary post-extractive implant, from second to second premolar, were randomly allocated to receive either an implant positioned in the natural "central" position where the tooth should have been (central group; 15 patients) or about 3 mm more palatally (palatal group; 15 patients) according to a parallel group design at three different centres. When needed, sites were reconstructed and bone-to-implant gaps were filled with granules of anorganic bovine bone, covered by resorbable collagen barriers. Implants were left submerged for 4 months and rehabilitated with provisional crowns, replaced after 4 months by metal-ceramic definitive crowns. Patients were followed to 1 year after loading. Outcome measures were: crown and implant failures, complications, aesthetics assessed using the pink esthetic score (PES), peri-implant marginal bone level changes and patient satisfaction, recorded by blinded assessors.

Results: Two patients from the palatal group dropped-out up to 1 year after loading. One implant failed in each group (6.7%), the difference being not statistically significant (difference in proportion = -0.01; 95% CI -0.20 to 0.18; *P* (Fisher's exact test) = 1.000). One patient from the central group was affected by one complication, vs two palatal group patients (two complications); the difference being not statistically significant (difference in proportion = -0.09; 95% CI -0.32 to 0.15; P (Fisher's exact test) = 0.583). One year after loading, the mean PES was 9.93 ± 2.67 for the central and 8.75 ± 4.37 for the palatal group; the difference being not statistically significant (mean difference = 1.18; 95% CI: -1.87 to 4.23; *P* (*t* test) = 0.427). One year after loading, patients in the central group lost on average 0.23 ± 0.17 mm of peri-implant marginal bone and those of the palatal group 0.24 ± 0.25 mm, the difference being not statistically significant (mean difference = -0.01; 95% CI: -0.23 to 0.21; *P* (*t* test) = 0.926). Patients in both groups were equally satisfied at 1 year after loading for both function and aesthetics (*P* (Mann-Whitney U test) = 0.494 and *P* (Mann-Whitney U test) = 0.076, respectively).

Conclusions: These preliminary results suggest that positioning of immediate post-extractive implants 3 mm more palatally is not improving aesthetics, however, the sample size of the present study was limited, thus larger trials are needed to confirm of reject the present findings.

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Introduction

Immediate post-extractive implants are placed immediately after teeth extractions in fresh sockets. Immediate post-extractive implants have gained popularity over the years because they shorten treatment duration since we do not have to wait for soft tissue healing (2 to 6 weeks) or bone healing (4 to 6 months), though they might be at higher risk of complications and failures[1].

Of particular interest for both clinicians and patients is the aesthetic aspect. Despite several randomised controlled trials (RCTs) evaluating aesthetics at post-extractive implants compared with delayed implant placement[2-11], the matter of which procedure might be preferable is still unresolved, since contradictory findings were presented by different groups. However, some evidence exists suggesting that grafting at immediate post-extractive sites can improve the aesthetic outcome[12,13], whereas the use of large diameter implants at immediate post-extractive sites is to be avoided because of the poorer aesthetic outcome[14,15]. Another aspect often presented in courses and conferences over the past decade is the idea that in order to obtain an improved aesthetic outcome at immediate post-extractive sites, implants should be placed in a slightly more palatal position than the ideal centre of the socket. This suggestion, based on clinical observations and experience, has become a rule, even though nobody really attempted to evaluate whether this procedure actually brings the hoped-for aesthetic improvements.

It would be useful to know whether placing immediate post-extractive implants in a slightly palatal position in aesthetic areas could have a better aesthetic outcome than placing implants in the natural "central" position where the tooth would have been.

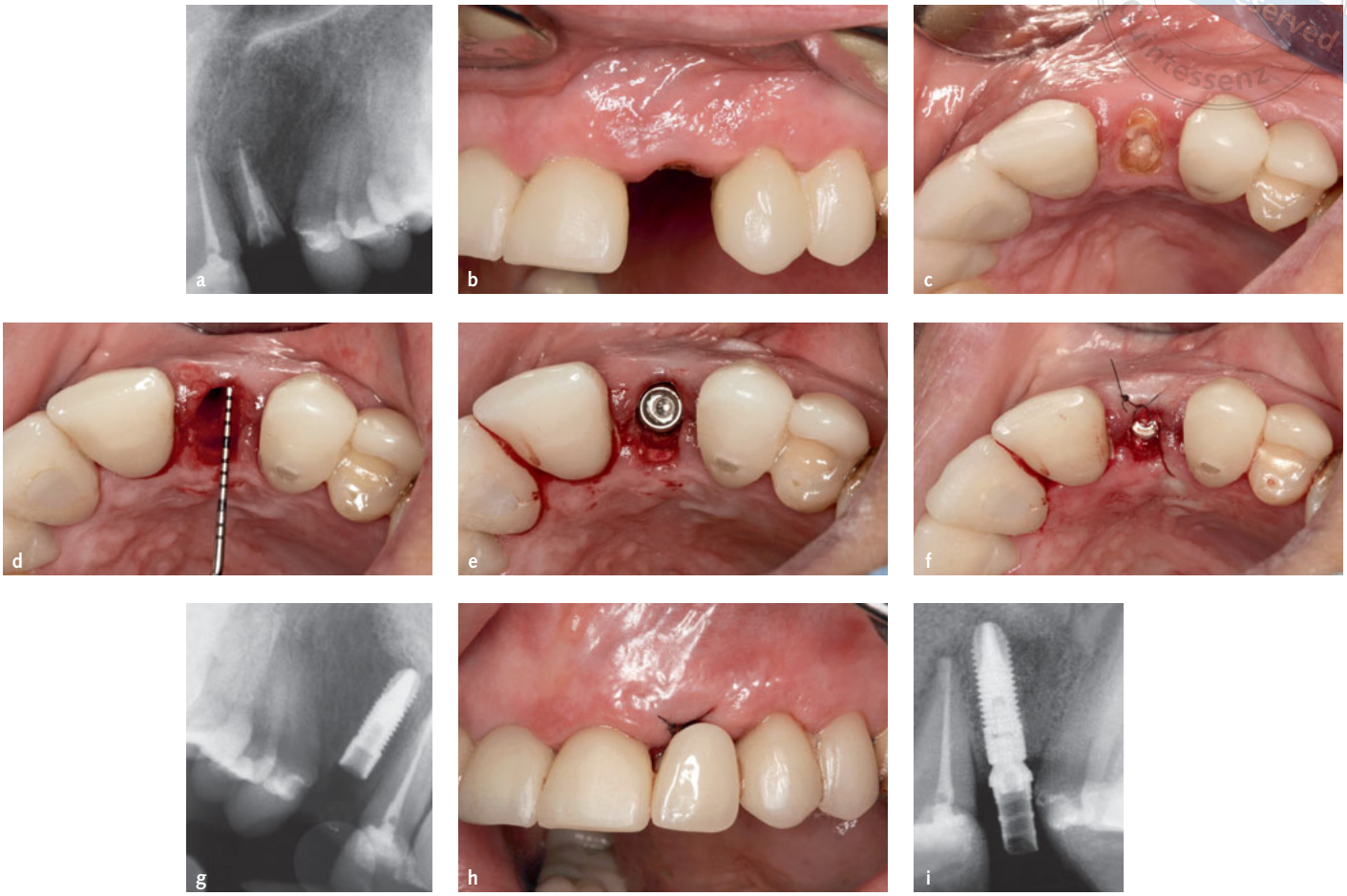
The aim of this multicentre RCT was to compare the aesthetics of immediate post-extractive single maxillary implants placed in a slightly palatal position, vs implants placed in the natural "central" position where the tooth would have been. At protocol stage, it was planned to follow the patients up 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 to second premolar, between two natural or crowned teeth or implants, being at least 18 years old and able to sign an informed consent form was eligible for inclusion. There also must be sufficient bone to allow the placement of a single implant at least 10 mm long with a 3.3 mm diameter. 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;
- Substance abuse;
- Psychiatric disorders or unrealistic expectations;
- Acute infection (abscess) or suppuration in the site intended for implant placement;
- Under treatment or had previous treatment with intravenous amino-bisphosphonates;
- Unable to commit to a 5-year follow-up post-loading;
- Referred only for implant placement if the follow-ups cannot be done at the treatment centre;
- Participation in other clinical trials that interfered with current protocol.



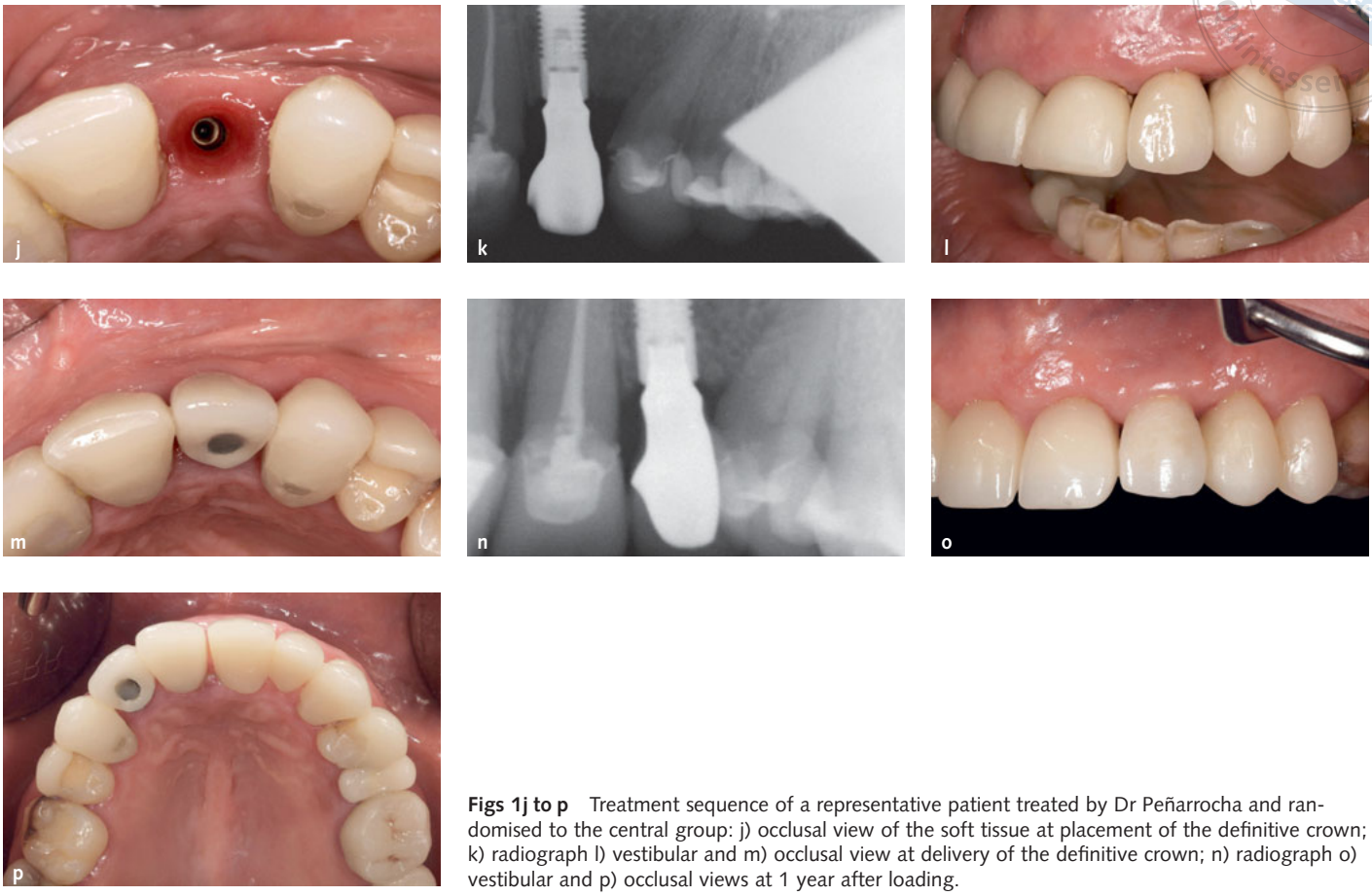
Figs 1a to i Treatment sequence of a representative patient treated by Dr Peñarrocha and randomised to the central group: a) preoperative periapical radiograph showing the root 22 to be extracted; b) vestibular and c) occlusal views; d) after tooth extraction, the wider diameter of the site was measured with a periodontal probe and e) the site was randomly allocated to receive one immediate post-extractive implant placed in the natural position (where the tooth should have been in relation to adjacent teeth/implants) and grafted after implant placement; f) sutures in place; g) baseline post-implantation radiograph; h) positioning of a provisional adhesive prosthesis; i) radiograph at initial loading with a provisional crown.

Future implant sites were categorised into two groups according to the treating clinicians: i) having a thick biotype, or ii) thin biotype. Patients were divided into three groups based on the number of cigarettes they declared to consume per day: i) non-smokers, ii) moderate smokers (up to 10 cigarettes per day) and iii) heavy smokers (more than 10 cigarettes per day).

Patients were recruited and treated by three different doctors: González, Fernández and Peñarrocha, using similar and standardised procedures in private practices. Each clinician/centre was supposed to treat 10 patients (five in each group). All patients received thorough explanations, were invited to ask any related questions, and signed a written informed consent form prior to be enrolled in the trial to show that they had understood and agreed to the clinical procedures. After tooth extraction, patients were randomised according to a parallel group design to receive one post-extractive implant placed in the natural "central" position where the tooth should have been (Figs 1a to p) or about 3 mm more palatally (Figs 2a to q).

Clinical procedures

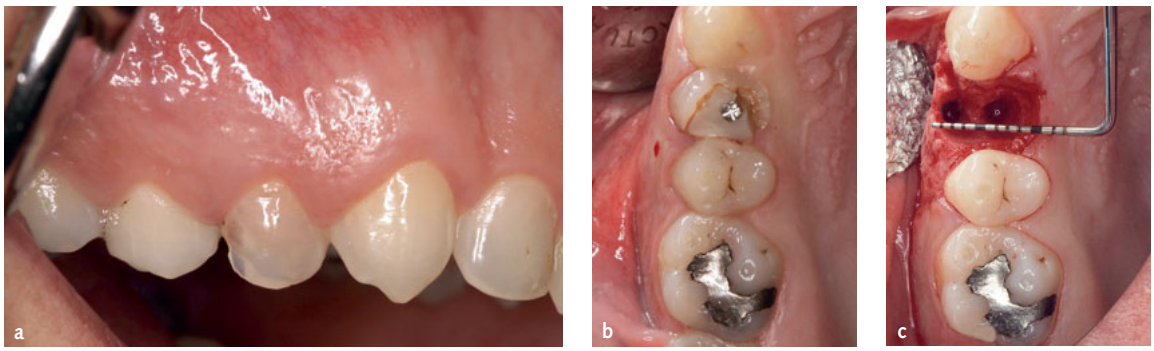
Patients received a single dose of prophylactic antibiotic 1 h prior to the intervention: 2 g of amoxicillin or 600 mg of clindamycin, if allergic to penicillin. Patients then rinsed with chlorhexidine mouthwash 0.2% for 1 min prior to the intervention. Patients were treated under local anaesthesia using articaine with adrenaline 1:100.000. After crestal incision and flap elevation, teeth were extracted as atraumatically



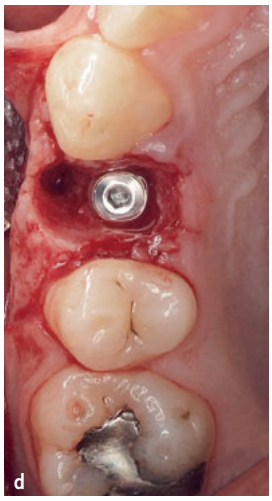
Figs 1j to p Treatment sequence of a representative patient treated by Dr Peñarrocha and randomised to the central group: j) occlusal view of the soft tissue at placement of the definitive crown; k) radiograph l) vestibular and m) occlusal view at delivery of the definitive crown; n) radiograph o) vestibular and p) occlusal views at 1 year after loading.

as possible attempting to preserve the buccal alveolar bone. Sockets were carefully cleaned of any remains of granulation tissue. The wider diameter of the extraction socket was measured using a graduated periodontal probe in mm, rounded to half a mm. Sockets were divided into:

1. "Nicely preserved", when the buccal plate was intact;
2. "Partially preserved", when up to 4 mm of buccal bone was missing;
3. "Poorly preserved", when more than 4 mm of buccal bone was missing.



Figs 2a to q Treatment sequence of a representative patient treated by Dr Peñarrocha and randomised to the palatal group: a) vestibular and b) occlusal view of fractured teeth 14 to be extracted; c) after tooth extraction, the wider diameter of the site was measured with a periodontal probe and d) the site was randomised to the palatal group (about 3 mm more palatally than the natural tooth position, e) the bone-to-implant gaps were filled with anorganic bovine bone, f) covered with a resorbable barrier and left to heal for 4 months; g) sutured; h) periapical radiograph after implant placement; i) occlusal postoperative view a 1 week j) and 1 month; k) periapical radiograph, l) vestibular and m) occlusal views at delivery of the provisional crown; n) periapical radiograph at delivery of the definitive crown; o) radiograph, p) vestibular and q) occlusal views at 1 year after loading.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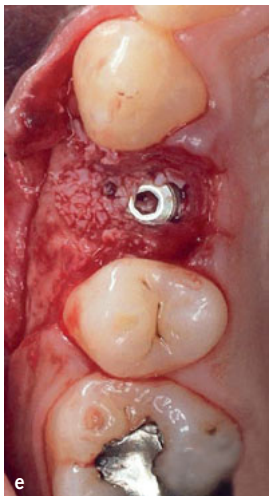
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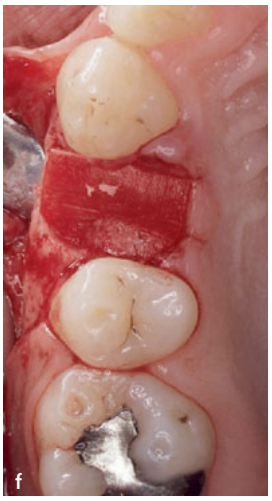
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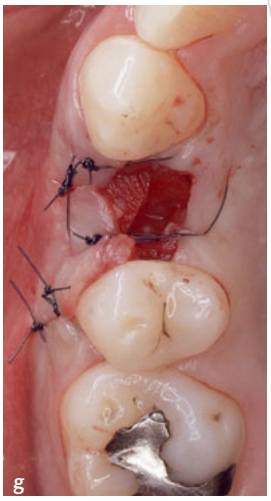
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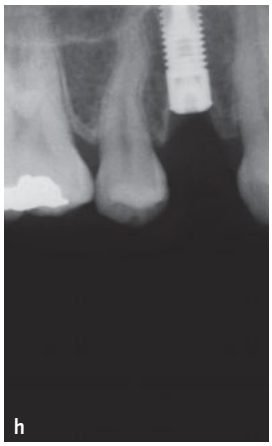
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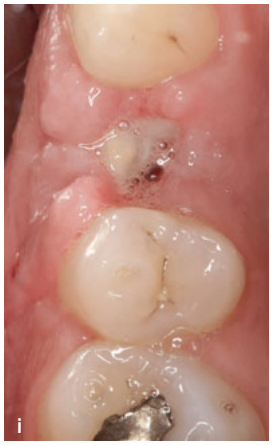
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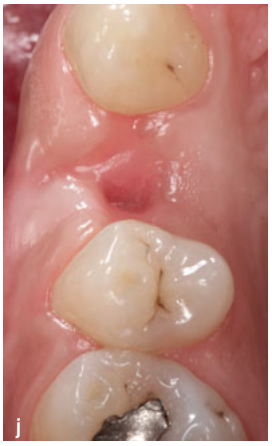
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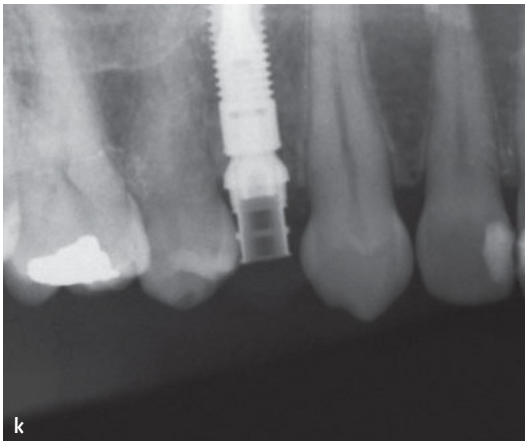
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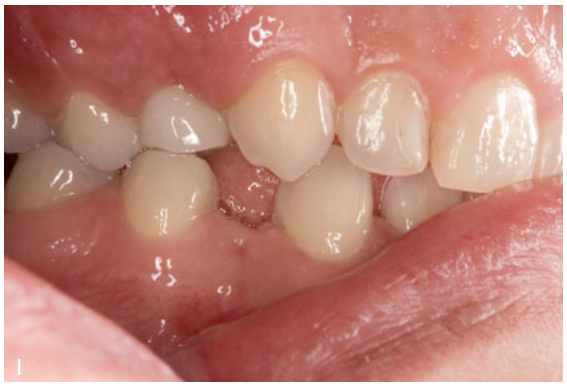
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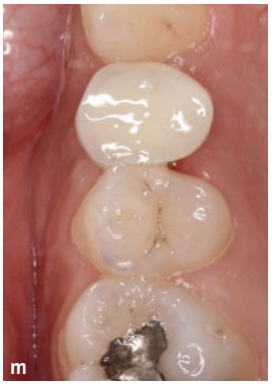
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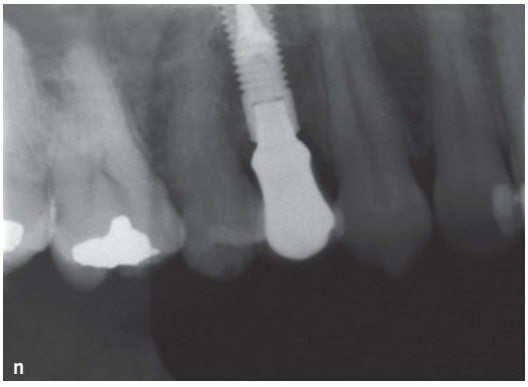
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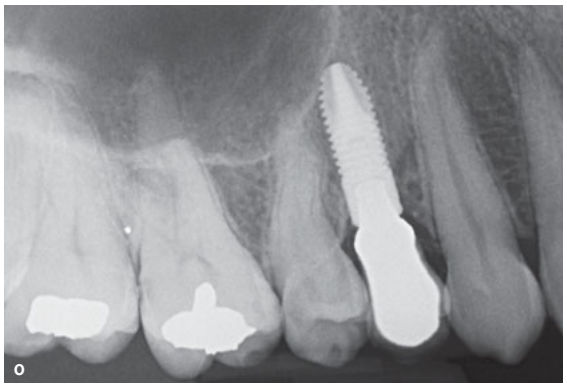
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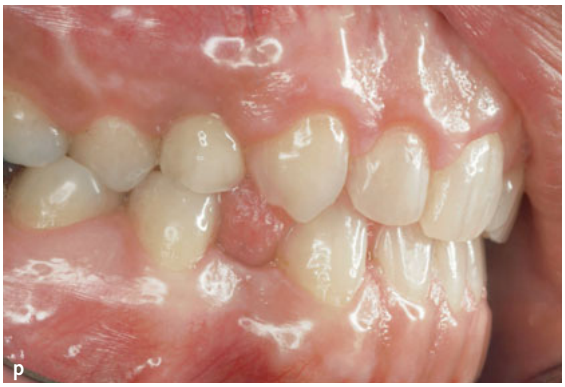
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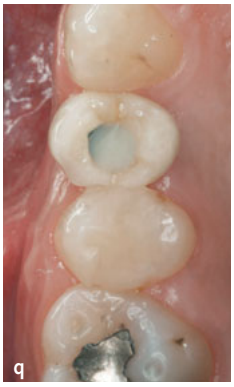
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The height of the buccal bone was assessed using the highest pick of the palatal wall as a reference point. If the investigator judged that no implant could be placed, the patient was excluded from the study and no envelope containing the random code was opened. The thickness of the buccal wall was measured in the middle portion of the crest with a calliper 1 mm below the crest, rounded to half a millimetre. At this point the patient was finally included in the study, the sequentially numbered sealed envelope corresponding to the patient recruitment number was opened to know whether to place the implant in a natural "central" position, where the tooth should have been, or about 3 mm more palatally. Drills with increasing diameters (2 mm, 3 mm, and when needed, 3.3 mm, 3.8 mm and 4.3 mm) were used to prepare the implant site as suggested by the manufacturer. Ticare Inhex cylindrical implants (Mozo-Grau Ticare, Valladolid, Spain) with internal connection and RBM (Resorbable Blast Media) titanium surface were placed subcrestally, about 1 mm to 2 mm below the most apical bone peak.

Operators were free to choose implant lengths (10 mm, 11.5 mm. 13 mm or 15 mm) and diameters (3.3 mm, 3.75 mm, 4.25 mm or 5 mm) according to clinical indications and their preferences. The implant insertion torque was measured with the motor set at 25 Ncm and reported as superior to 25 Ncm, or up to 25 Ncm. Once the implant had been placed, periapical radiographs and clinical pictures were taken, the larger distance (gap) between the bony wall and the neck of the implant was measured, and rounded to half a millimetre with a periodontal probe as well as the largest defect location (buccal, palatal mesial, distal). Operators reconstructed with granules of anorganic bovine bone (Bio-Oss, Geistlich Pharma AG, Wolhusen, Switzerland) all poorly preserved sockets and partially preserved sockets and filled the gaps of nicely preserved sockets. In the presence of deficient buccal bone to obtain an ideal aesthetics, the area was also buccally augmented with the same bone substitute. The grafted areas were then covered with a resorbable collagen membrane derived from bovine tendon fibres (MG-Reguarde; Mozo-Grau Ticare), which was trimmed and adapted to cover the entire socket and at least 2 mm of the surrounding crestal bone. Flaps were sutured, but the wounds could be left partially open when a complete soft tissue coverage was hard to achieve. A baseline periapical radiograph was taken. If the peri-implant marginal bone could not be evaluated, a second radiograph was to be taken. Implants were left to heal submerged for 4 months.

Ibuprofen (400 mg) was prescribed two to four times a day during meals, for as long as required. Patients were instructed to use 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: in the form of 1 g amoxicillin three times a day for 7 days. Patients allergic to penicillin were prescribed 300 mg clindamycin three times a day for 7 days. After 1 week, patients were checked and sutures were removed. After 1 month, patients were rechecked. After 4 months of submerged healing, implants were exposed using an "H" incision, making the incision slightly palatal to have more keratinised tissues on the buccal side. Implants were manually tested for stability; temporary abutments were placed and provisional acrylic resin crowns were cemented the same day.

Periapical radiographs of the study implants were taken. If the marginal bone levels were not readable, the radiograph was retaken. Oral hygiene instructions were delivered. Three months after initial loading, implants were manually tested for stability by the blinded assessors, who tightened the abutments with a 20 Ncm torque using a dynamometrical manual wrench able to deliver a variable tightening torque from 10 to 35 Ncm. Definitive impression with pick-up impression copings were made using a polyether material. During the following month, the stability of the implants was tested again. Definitive metal-ceramic crowns were provisionally cemented on Titanium Hex or angled preparable abutments Ticare Inhex (Mozo-Grau) and the occlusion was checked. Periapical radiographs of the study implants were taken. Patient satisfaction was then evaluated and oral hygiene instructions were reinforced.

Patients were entered into a maintenance programme, with recalls at least every 6 months for the entire duration of the study. At the 1-year after initial follow-up, if the vestibular profile was judged to be deficient, a connective tissue graft was to be harvested from the palate and placed in a pouch, made with a horizontal incision 2 mm to 3 mm from the implant sulcus without releasing incisions, to make the tissues thicker.

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/crown failures: 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) were considered implant failures. If a definitive crown had to be replaced for any reason, it accounted as a crown failure. Stability of individual implants was measured at initial loading and delivery of definitive crowns, applying a torque of 20 Ncm with a dedicated wrench. Implant stability was re-assessed 1 year after loading using the metal handles of two instruments.
- Any biological or biomechanical complications. Examples of biological complications were fistula and peri-implantitis. Examples of biomechanical complications were 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, delivery of definitive crowns and 1 year after loading. In case of an unreadable radiograph, a second radiograph 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 the DFW2.8 software for Windows (Soredex, Tuusula, Finland). The software was calibrated for every single image using the known implant length or diameter. 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 and then at group level.
- Aesthetic evaluation of the vestibular and occlusal clinical pictures was taken with a 1:4 magnification and including the two adjacent teeth 1 year after loading, and was performed on a computer screen. The aesthetic evaluation was done using the pink esthetic score (PES)[16]. 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 to 1–2 scoring system was used, 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 crowns and 1 year after loading the local blinded outcome assessors provided a mirror to the patients showing the implant-supported crown, and 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", "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", "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 the same wording.

At each centre there was a local blind outcome assessor who recorded all outcome measures. One blinded dentist (Dr Xhanari), who was not involved in the treatment of the patients, evaluated aesthetics and marginal bone levels without knowing group allocation. Therefore the outcome assessor was blind.

Statistical analysis

No sample size calculation was performed. Initially, 13 centres agreed to participate in the trial. Each centre had to recruit 10 patients to be equally allocated to both interventions; therefore 130 patients were to be included. Thirteen computer-generated restricted randomisation lists were 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 tooth extraction and quantification of the amount of buccal bone loss, the patient was finally entered in the study and the corresponding envelope was sequentially opened. Therefore, treatment allocation was concealed from the investigators in charge of enrolling and treating the patients.

All data analysis was performed according to a pre-established analysis plan by a clinician with expertise in statistics (Dr Trullenque-Eriksson) analysing the data without knowledge of the group codes. The patient was the statistical unit of the analyses. Differences in the proportion of patients with implant failures and complications (dichotomous outcomes) were compared between the groups using Fisher's exact probability test. Differences of means at patient level for continuous outcomes (PES and bone levels) between groups were compared by *t* tests. 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 and bone levels (continuous outcome) were compared between the three centres using the Fisher's exact test and ANOVA test, followed by Tukey's HSD *post hoc* test to detect differences between groups, respectively. All statistical comparisons were conducted at the 0.05 level of significance.

■ Results

During initial monitoring, it was noted that most of the centres were not recruiting, and nine centres withdrew without having treated a single case. Another centre did not manage to fulfil the agreed quota of patients and apparently managed to recruit and treat seven out of 10 patients. However, data, radiographs and clinical pictures were grossly incomplete, and were therefore not considered of any use for the study.

Thirty patients were screened at the three centres and all were consecutively enrolled on the trial. All patients were treated according to the allocated interventions. Two patients, both belonging to the palatal group, dropped out from Dr Peñarrocha's centre after delivery of the definitive crowns. One patient moved to northern Spain and was not willing to come back for the follow-up evaluations, and the other patient became unreachable. The following radiographs and pictures from Dr Encinas were missing or unreadable:

- Nine baseline periapical radiographs at implant placement;
- Nine baseline periapical radiographs at implant loading;
- Seven periapical radiographs at delivery of definitive crowns;
- Four periapical radiographs at 1 year after loading.

The main deviations from the protocol were: None of the centres showed correspondence between the random codes originally received and the actual randomisation procedure implemented. The centres replied that they all respected the random allocation, but not the association between patient recruitment number and the number on the envelopes.

Dr Peñarrocha delivered one definitive crown, without a provisional, in the patient of the palatal group who experienced one post-operative complication, since the patient became tired of attending the practice and the aesthetic demands were not very high.

Patients were recruited and received the post-extractive implants between January 2012 and October 2014. The follow-up of all patients was to 1 year after implant loading. Patient demographics are presented in Table 1. There were no apparent significant baseline imbalances between the two groups.

One implant failed in each group. The differences in the proportion of implant failures between groups were not statistically significant (difference in proportion = -0.01; 95% CI -0.20 to 0.18; *P* (Fisher's exact test) = 1.000). Twelve days after placement of an implant in position 15, the patient, a moderate smoker, reported pain at the implant apex, which was diagnosed as a periapical infection. A full-thickness flap was raised and the lesion was debrided. Ten days later the patient presented with fistula and the implant was mobile and was removed. When the initial radiograph was studied more carefully, a not-correctly-performed endodontic treatment of the neighbouring molar with a small apical radiolucency was observed. The molar was endodontically retreated and the failed implant was successfully replaced with a new implant 4 months later. The

Table 1 Patient and intervention characteristics.

	Central [n =15] (%)	Palatal [n = 15] (%)
Females	7 (46.7%)	12 (80%)
Males	8 (53.3%)	3 (20%)
Mean age at implant insertion (range)	47.5 (23-70)	47 (20-65)
Thin biotype	8 (53.3%)	7 (46.7%)
Thick biotype	7(46.7%)	8 (53.3%)
Non-smokers	11 (73.3%)	8 (53.3%)
Smoking up to 10 cigarettes/day	3 (20 %)	1 (6.7%)
Smoking more than 10 cigarettes/day	1 (6.7%)	6 (40 %)
Socket diameter in mm [SD]	7.20 [1.32]	6.27 [1.82]
Buccal bone thickness in mm [SD]	1.70 [1.13]	1.53 [1.26]
Nicely preserved sites	11 (73.3%)	6 (40%)
Partially preserved sites (less than 4 mm buccal bone height loss)	2 (13.3%)	6 (40%)
Poorly preserved sites (more than 4 mm buccal bone height loss)	2 (13.3%)	3 (20%)
Implants in central incisor position	5 (33.3%)	3 (20%)
Implants in lateral incisor position	2 (13.3%)	4 (26.7%)
Implants in canine position	0	0
Implants in first premolar position	6 (40 %)	5 (33.3%)
Implants in second premolar position	2 (13.3%)	3 (20%)
Implants with 3.75 mm diameter	8 (53.3%)	8 (53.3%)
Implants with 4.25 mm diameter	7 (46.7%)	7 (46.7%)
Implants 11.5 mm long	4 (26.7%)	3 (20%)
Implants 13 mm long	9 (60 %)	8 (53.3%)
Implants 15 mm long	2 (13.3%)	4 (26.7%)
Mean implant length in mm	12.87	13.23
Insertion torque up to 25 Ncm	7 (46.7)	5 (33.3%)
Mean horizontal widest implant to bone gap in mm [SD]	2.53 [1.13]	3.50 [1.39]
Buccal location of the widest implant to bone gap	11 (73.3%)	12 (80 %)
Mesial location of the widest implant to bone gap	1 (6.7%)	1 (6.7%)
Distal location of the widest implant to bone gap	0	0
Palatal location of the widest implant to bone gap	3 (20 %)	2 (13.3%)
Sites not augmented at implant placement	7 (46.7%)	8 (53.3%)
Sites augmented at implant placement only in the gap	6 (40 %)	5 (33.3%)
Sites augmented at implant placement only buccally	1 (6.7%)	0
Sites augmented at implant placement both in the gap and buccally	1 (6.7%)	2 (13.3%)
Obtained full flap closure above the implant	6 (40 %)	6 (40%)
Sites grafted with autogenous soft tissue 1 year after loading	0	0

other implant failure occurred in a heavy smoker; her palatal implant in position 22 was painful and was removed 4 months after placement. It was replaced with another implant that was never loaded since she received a fixed metal-ceramic prosthesis, having as the central and the canine as the abutment teeth.

Two complications occurred in two patients from the palatal group, vs one complication in the central group. The differences in proportions of complications between groups were not statistically significant (difference in proportion = -0.09; 95% CI -0.32 to 0.15; *P* (Fisher's exact test) = 0.583). The complications in the palatal group were: pain at the implant apex observed 3 weeks after placement. No periapical radiolucency could be seen. An infection was suspected, so the implant was surgically treated.

Table 2 PES scores at 1-year after loading by groups and by different aesthetic domains; SD in parenthesis.

	Mesial papilla	Distal papilla	Soft tissue level	Soft tissue contour	Alveolar process deficiencies	Soft tissue colour	Soft tissue texture	Total PES score
Central = 14	1.50 (0.52)	1.64 (0.50)	1.64 (0.75)	1.36 (0.50)	1.36 (0.75)	1.14 (0.77)	1.29 (0.91)	9.93 (2.67)
Palatal = 12	1.67 (0.65)	1.67 (0.78)	1.42 (0.79)	0.92 (0.90)	0.83 (0.58)	1.17 (0.94)	1.08 (0.90)	8.75 (4.37)
Mean difference	-0.17	-0.02	0.23	0.44	0.52	-0.02	0.20	1.18
P value	0.475	0.926	0.461	0.150	0.060	0.944	0.576	0.427

Table 3 Peri-implant marginal bone levels at 1 year after loading by study group.

	Central implants N mean (SD)	Palatal implants N mean (SD)	Mean difference	95% CI of the difference	*P* value from unpaired sample *t* test
Implant placement	10 0.32 (0.31)	11 0.60 (0.47)	-0.28	-0.65; 0.09	0.129
Initial loading	9 0.49 (0.30)	10 0.53 (0.25)	-0.04	-0.30; 0.23	0.783
4 months after loading	9 0.68 (0.32)	12 0.63 (0.29)	0.04	-0.24; 0.32	0.743
1 year post-loading	10 0.81 (0.43)	12 1.02 (0.57)	-0.21	-0.66; 0.25	0.358
Mean changes from loading to 1 year	9 0.23 (0.17)	8 0.24 (0.25)	-0.01	-0.23; 0.21	0.926
95% CI of the difference (loading to 1 year)	0.10; 0.36	0.03; 0.45			
P value from paired *t* test from loading to 1 year	0.004*	0.031*			

*Statistically significant difference

A full-thickness flap was raised, the apex was debrided with a curette, rinsed with physiologic solution and sutured. The implant was closely monitored over 6 months and the complication completely resolved. The other implant become painful after its placement and was removed 4 months later. The only complication that occurred in the central group was one partial fracture of the provisional crown, and this was immediately repaired with composite.

One year after loading, the average PES score, assessed by a blind assessor, was 9.93 ± 2.67 for the central group and 8.75 ± 4.37 for the palatal group, the difference being not statistically significantly different (mean difference = 1.18; 95% CI: -1.87 to 4.23; *P* (*t*-test) = 0.427; Table 2).

Marginal bone levels were evaluated by a blinded outcome assessor on periapical radiographs taken at implant placement before bone grafting (when performed), at initial loading, at 4 months after loading (delivery of definitive crowns), and 1 year after initial loading (Table 3). At baseline, the average bone levels around central implants were 0.32 ± 0.31 mm vs 0.60 ± 0.47 mm at palatal implants, the difference not being statistically different (mean difference = -0.28; 95% CI: -0.65 to 0.09; *P* (*t*-test) = 0.129). At 1 year, the average bone levels around central implants were 0.8 ± 0.43 mm vs 1.02 ± 0.57 mm at palatal implants, the difference not being statistically different (mean difference = -0.21; 95% CI: -0.66 to 0.25; *P* (*t*-test) = 0.358). Bone level changes at 1 year were 0.23 ± 0.17 mm at central implants and 0.24 ± 0.25 mm at palatal implants, the difference not being statistically significant (mean difference = -0.01; 95% CI: -0.23 to 0.21; *P* (*t*-test) = 0.926).

Patient satisfaction was assessed at 1 year after loading only for those patients who did not experience an implant failure. Regarding function, the 14 central group patients declared they were "absolutely satisfied", vs 10 "absolutely satisfied" and two "partially satisfied" patients in the palatal group. Regarding aesthetics, the 14 patients from the central group said they were "absolutely satisfied", vs seven "absolutely satisfied" and five "partially satisfied" in the palatal group. There were not statistically significant differences between the groups for satisfaction with function and aesthetics of their implant supported crowns (function *P* (Mann-Whitney U test) = 0.494, aesthetics *P* (Mann-Whitney U test) = 0.076). All patients said they would undergo the same procedure again.

Comparisons between the three centres are presented in Table 5. One year after loading, there

Table 4 Peri-implant marginal bone level changes at 1 year after loading by study group.

	Placement to loading N mean (SD)	Placement to 4-month N mean (SD)	Placement to 1 year N mean (SD)	*P*-value from paired *t*-test from placement to 1 year
Central implants	9 0.14 (0.16)	9 0.32 (0.24)	9 0.37 (0.24)	0.002*
Palatal implants	10 -0.12 (0.41)	11 -0.02 (0.43)	9 0.20 (0.42)	0.189
Mean difference	0.26	0.34	0.17	
95% CI of the difference	-0.05; 0.57	0.005; 0.66	-0.17; 0.51	
P-value from unpaired sample *t*-test	0.096	0.047*	0.315	

*Statistically significant difference

Table 5 Comparison of clinical outcomes between different centres at 1 year.

	Gonzales	Encinas	Peñarrocha	*P* value
Drop-out	0/10	0/10	2/10	0.310
Implant failures	0/10	1/10	1/8	0.735
Complications	1/10	1/10	1/8	1.000
PES score	N = 10 11.20 ±1.93[a]	N = 9 5.67 ± 3.12[a,b]	N = 7 11.57 ± 1.27[b]	< 0.001*
Peri-implant bone loss (mm)	N=10 0.24 ± 0.24	–	N=7 0.23 ± 0.15	0.951
Fully satisfied with function	10/10	7/9	7/7	0.175
Fully satisfied with aesthetics	8/10	6/9	7/7	0.313
Would redo the intervention	10/10	9/9	7/7	-

*Statistically significant difference; [a,b] subsets that differ significantly from each other.

were no statistically significant differences between the centres for number of drop-outs (*P* (Fisher's exact test) = 0.310), implant failures (*P* (Fisher's exact test) = 0.735), complications (*P* (Fisher's exact test) = 1.000), peri-implant bone level changes (P (*t* test) = 0.951), and the number of patients fully satisfied with function (P (Fisher's exact test) = 0.175) and aesthetics (P (Fisher's exact test) = 0.313); all patients would redo the treatment. There was a statistically significant difference between centres in terms of PES scores, with one centre having significantly lower scores than the other two (5.67 ± 3.12 vs 11.20 ± 1.93 and 11.57 ± 1.27; $P < 0.001$; Table 5).

■ Discussion

This trial was designed to assess whether it could be advantageous, from an aesthetic point of view, to position immediate post-extractive implants about 3 mm more palatally or to place them in the natural position where the tooth should have been in relation to adjacent teeth/implants. Only one implant failed in each group, one complication occurred in the central group and two complications in the palatal group, and this was within the expected range.

Regarding aesthetic outcome, no statistically significant differences were observed for PES scores 1 year after loading between groups. This could be interpreted as both procedures achieving the same aesthetic outcome. However, these results should be interpreted critically in view of the insufficient sample size, since a tendency favouring implants positioned centrally could be observed. This observation is totally against the current way of thinking, since almost universally clinicians recommend placing implants slightly more palatally to achieve a better aesthetic outcome. However, the ability to achieve the best aesthetics most likely mainly depends on the manual skills and experience of the individual operators, as suggested by comparing the aesthetics data of the three centres. If fact, there was a statistical and clinically significant difference in PES scores at one year post-loading between centres, with one centre having substantially lower scores then the other two (5.67 vs 11.20 and 11.57; – see Table 5).

Regarding peri-implant marginal bone levels, no differences or trends could be seen between the two procedures. No comparisons with the outcome of other studies can be made, since no other studies were published at the time of writing this manuscript on this topic.

The main limitations of the present trial were the insufficient sample size and the lack of some of the patient radiographs and clinical pictures, as this further reduced the sample size. Unfortunately, out of the 13 centres that originally agreed to participate in the trial, only three actually delivered the agreed information. To avoid the common problem of studies being mutilated by non-compliant clinicians, a more careful and strict selection of centres should be operated to invite only those clinicians who are highly motivated and able to conduct clinical research to participate in clinical trials.

Acknowledging all its limitations, the results of the present study do not support the common notion that in order to achieve better aesthetics implants should be placed in a slightly more palatal position. 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

These preliminary results suggest that the positioning of immediate post-extractive implants about 3 mm more palatally does not improve aesthetics. However, the sample size of the present study was limited, thus larger trials are needed to confirm of reject the present findings.

■ References

1. Esposito M, Grusovin MG, Polyzos IP, Felice P, Worthington HV. Interventions for replacing missing teeth: dental implants in fresh extraction sockets (immediate, immediate-delayed and delayed implants). Cochrane Database of Systematic Reviews 2010: Chichester, UK: John Wiley & Sons, Ltd.
2. Lindeboom JA, Tjiook Y, Kroon FH. Immediate placement of implants in periapical infected sites: a prospective randomized study in 50 patients. Oral Surg, Oral Med, Oral Pathol, Oral Radiol Endod 2006;101:705–710.
3. Palattella P, Torsello F, Cordaro L. Two-year prospective clinical comparison of immediate replacement vs. immediate restoration of single tooth in the esthetic zone. Clin Oral Implants Res 2008;19:1148–1153.
4. Block MS, Mercante DE, Lirette D, Mohamed W, Ryser M, Castellon P. Prospective evaluation of immediate and delayed provisional single tooth restorations. J Oral Maxillofac Surg 2009;67:89–107.
5. Schropp L, Isidor F. Papilla dimension and soft tissue level after early vs. delayed placement of single-tooth implants: 10-year results from a randomized controlled clinical trial. Clin Oral Implants Res 2015;26:278–286.
6. Esposito M, Barausse C, Pistilli R, Jacotti M, Grandi G, Tuco L, Felice P. Immediate loading of post-extractive versus delayed placed single implants in the anterior maxilla: outcome of a pragmatic multicenter randomised controlled trial 1-year after loading. Eur J Oral Implantol 2015;8:347–358.
7. Felice P, Pistilli R, Barausse C, Trullenque-Eriksson A, Esposito M. Immediate non-occlusal loading of immediate post-extractive versus delayed placement of single implants in preserved sockets of the anterior maxilla: 1-year post-loading outcome of a randomised controlled trial. Eur J Oral Implantol 2015;8:361–372.
8. Esposito M, Zuchelli G, Cannizzaro G, Checchi L, Barausse C, Trullenque-Eriksson A, Felice P. Immediate, immediate-delayed (6 weeks) and delayed (4 months) post-extractive single implants: 1-year post-loading data from a randomised controlled trial. Eur J Oral Implantol y 2017;10:11–26.
9. Rieder D, Eggert J, Krafft T, Weber HP, Wichmann MG, Heckmann SM. Impact of placement and restoration timing on single-implant esthetic outcome - a randomized clinical trial. Clin Oral Implants Res 2014.
10. Huynh-Ba G, Meister DJ, Hoders AB, Mealey BL, Mills MP, Oates TW, Cochran DL, Prihoda TJ, McMAhan CA. Esthetic, clinical and patient-centered outcomes of immediately placed implants (Type 1) and early placed implants (Type 2): preliminary 3-month results of an ongoing randomized controlled clinical trial. Clin Oral Implants Res 2016;27:241–252.
11. Tonetti MS, Cortellini P, Graziani F, Cairo F, Lang NP, Abundo R, Conforti GP, Marquardt S, Rasperini G, Silvestri M Wallkamm B, Wetzel A. Immediate versus delayed implant placement after anterior single tooth extraction: the timing randomized controlled clinical trial. J Clin Periodontol 2017;44:215–224.
12. De Angelis N, Felice P, Pellegrino G, Camurati A, Gambino P, Esposito M. Guided bone regeneration with and without a bone substitute at single post-extractive implants: 1-year post-loading results from a pragmatic multicentre randomised controlled trial. Eur J Oral Implantol 2011;4:313–325.
13. Cardaropoli D, Gaveglio L, Gherlone E, Cardaropoli G. Soft tissue contour changes at immediate implants: a randomized controlled clinical study. Int J Periodontics Restorative Dent 2014;34:631–637.
14. Tallarico M, Xhanari E, Pisano M, Gatti F, Meloni SM. Molar replacement with 7 mm-wide diameter implants: to place the implant immediately or to wait 4 months after socket preservation? One year after loading results from a randomised controlled trial. Eur J Oral Implantol 2017;10: in press.
15. Checchi V, Felice P, Zucchelli G, Barausse C, Piattelli M, Pistilli R, Grandi G, Esposito M. Wide diameter immediate post-extractive implants versus delayed placement of normal-diameter implants in preserved sockets in the molar region: 1-year post-loading outcome of a randomised controlled trial. Eur J Oral Implantol 2017;10: in press.
16. Fürhauser R, Florescu D, Benesch T, Haas R, Mailath G, Watzek G. Evaluation of soft tissue around single-tooth implant crowns: the pink esthetic score. Clin Oral Implants Res 2005;16:639–644.