

Silvio Mario Meloni, Marco Tallarico, Francesco Maria Lolli, Alessandro Deledda, Milena Pisano, Sascha A. Jovanovic

Postextraction socket preservation using epithelial connective tissue graft vs porcine collagen matrix. 1-year results of a randomised controlled trial



Silvio Mario Meloni, DDS, PhD, MS
Assistant Professor,
Dentistry Unit, University
Hospital of Sassari, Italy

Key words bone volume, porcine collagen matrix, socket preservation, soft tissue graft

Purpose: To compare epithelial connective tissue graft vs porcine collagen matrix for sealing postextraction sockets grafted with deproteinised bovine bone.

Materials and methods: A total of 30 patients, who needed a maxillary tooth to be extracted between their premolars and required a delayed, fixed, single implant-supported restoration, had their teeth atraumatically extracted and their sockets grafted with deproteinised bovine bone. Patients were randomised according to a parallel group design into two arms: socket sealing with epithelial connective tissue graft (group A) vs porcine collagen matrix (group B). Outcome measures were: implant success and survival rate, complications, horizontal and vertical alveolar bone dimensional changes measured on Cone Beam computed tomography (CBCT) scans at three levels localised 1, 3, and 5 mm below the most coronal aspect of the bone crest (levels A, B, and C); and between the palatal and buccal wall peaks (level D); and peri-implant marginal bone level changes measured on periapical radiographs.

Results: 15 patients were randomised to group A and 15 to group B. No patients dropped out. No failed implants or complications were reported 1 year after implant placement. Five months after tooth extraction there were no statistically significant differences between the 2 groups for both horizontal and vertical alveolar bone dimensional changes. At level A the difference was 0.13 ± 0.18 ; 95% CI 0.04 to 0.26 mm ($P = 0.34$), at level B it was 0.08 ± 0.23 ; 95% CI -0.14 to 0.14 ($P = 0.61$), at level C it was 0.05 ± 0.25 ; 95% CI -0.01 to 0.31 mm ($P = 0.55$) and at level D it was 0.13 ± 0.27 ; 95% CI -0.02 to 0.32 mm ($P = 0.67$). One year after implant placement there were no statistically significant differences between the 2 groups for peri-implant marginal bone level changes (difference: 0.07 ± 0.11 mm; 95% CI -0.02 to 0.16; $P = 0.41$).

Conclusions: When teeth extractions were performed atraumatically and sockets were filled with deproteinised bovine bone, sealing the socket with a porcine collagen matrix or a epithelial connective tissue graft showed similar outcomes. The use of porcine collagen matrix allowed simplification of treatment because no palatal donor site was involved.

Conflict of interest statement: *This study was not supported by any company and there are no conflicts of interest.*

Marco Tallarico, DDS, MS
Private Practice, Rome, Italy

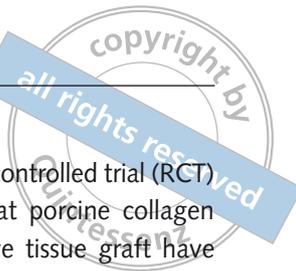
Francesco Maria Lolli, DDS
Dentistry Unit, University
Hospital of Sassari, Italy

Alessandro Deledda, DDS
Private Practice, Arzachena,
Italy

Milena Pisano, DDS
Private Practice, Arzachena,
Italy

Sascha A. Jovanovic, DDS, MS
Private Practice,
Los Angeles, USA

Correspondence to:
Silvio Mario Meloni
Dipartimento Scienze
Chirurgiche Microchirurgiche e Mediche
Università degli Studi di
Sassari
Viale S. Pietro 43/b,
07100 Sassari, Italy
Tel: 0039079228216
Fax: 0039079229002
Email: melonisilviomario@
yahoo.it or smeloni@uniss.it



■ Introduction

The success of osseointegrated dental implants depends on whether there is a sufficient volume of healthy bone at the recipient site at the time of implant placement^{1,2}. The alveolar ridge is a portion of the jaw that develops in conjunction with teeth eruption. The volume and the shape of the alveolar ridge is determined by the shape of the teeth and their axis of eruption. Following tooth extraction, the alveolar ridge undergoes a remodelling process that may result in a dimensional alteration that may compromise the functional and aesthetic outcomes of implant therapy, and which occasionally leads to the need of further hard and/or soft tissue augmentation. Alveolar ridge resorption has been widely described in the literature as mainly occurring during the first 3 months after tooth extraction³ and particularly involving the buccal bone wall of the socket^{4,5}, resulting in the loss of as much as 50% of the buccal wall⁶⁻⁸. Furthermore, after the extraction of a failing tooth, the remaining soft and hard tissues are mostly deficient as a result of previous trauma, or periodontal or endodontic infections. Thus, it seems prudent to try to prevent alveolar ridge resorption in order to preserve the alveolar ridge at tooth extraction. Preservation of postextraction sockets seems to be effective in reducing ridge resorption after tooth extraction⁹⁻¹¹. Nevertheless, no recommendations for a specific technique or material can be made yet, as a consequence, further studies are needed to clarify these issues. Socket preservation is a procedure in which a graft material (for example autogenous bone, allograft bone, xenograft materials) and alloplastic materials are placed in the socket of an extracted tooth at the time of extraction. It can then be sealed with a membrane (resorbable or not) or with epithelial connective tissue graft harvested from the hard palate¹². However, there is controversy about the need to use epithelial connective tissue graft instead of collagen membranes and the efficacy of socket preservation with covering graft material, due to the higher morbidity, given that the soft tissue graft has to be harvested from a donor site of the patient. Nevertheless, there is also generally a lack of clinical evidence about the best extraction socket sealing procedure in the literature^{13,14}.

The aim of this randomised controlled trial (RCT) was to test the hypothesis that porcine collagen matrix and epithelial connective tissue graft have similar outcomes when sealing postextraction sockets with deproteinised bovine bone. The null hypothesis was that there would be no difference between these interventions. This trial is reported in accordance with the CONSORT (Consolidated Standards of Reporting Trials) statement (<http://www.consort-statement.org>) for improving the quality of reporting of parallel-group randomised trials.

■ Materials and methods

Any patient needing a single tooth extraction between maxillary premolars, aged 18 years or over, able to sign an informed consent form; and requiring replacement with a fixed single implant-supported prosthesis, was eligible for this trial. Cone Beam computed tomography (CBCT) scans were used for initial screening. Patients were not admitted to the study if any of the following exclusion criteria was present: general contraindications to implant surgery; pregnant or nursing; untreated periodontitis; severe bruxism or clenching; immunosuppression; previous history of irradiation of the head and neck area; uncontrolled diabetes; heavy smoker (> 10 cigarettes/day); poor oral hygiene and motivation; current or past treatment with bisphosphonates; substance abuse (alcohol, drugs); psychiatric disorders; fenestration or dehiscence ≥ 3 mm on the CBCT scan; coronal diameter of the post-extractive socket < 8 mm; and inability to complete the follow-up.

This study was designed as a RCT and conducted at two private centres, one in Sardinia and one in Rome, between October 2012 and February 2013. Surgical and prosthetic procedures were performed by two clinicians (SMM and MT) with extensive experience in implant placement and socket preservation procedures. Fifteen patients were to be recruited at each centre.

The investigation was conducted according to the principles embodied in the Helsinki Declaration of 1975 for biomedical research involving human subjects, as revised in 2000. All patients were informed about the nature of the study and gave their written consent.



Fig 1 a) Occlusal view of postextraction socket sealed with epithelial connective tissue graft. b) Epithelial connective tissue graft after harvesting from the palate.

■ Clinical procedures

All patients were evaluated clinically and their medical histories were recorded. Bone volumes were analysed using CBCT scan (CRANEX 3D; Soredex, Tuusula, Finland). Patients received oral hygiene instructions and debridement, after which they rinsed with 0.2% chlorhexidine mouthwash for 1 min prior to the intervention (Curasept, Curaden Healthcare, Saronno, Italy). A prophylactic antibiotic therapy was prescribed (2 g of amoxicillin or 600 mg clindamycin if allergic to penicillin) for each patient 1 h before the intervention. All patients were treated under local anaesthesia using articaine hydrochloride with epinephrine 1:100000 (Orabloc, PierreL, Milan, Italy).

All extractions were performed flapless, as atraumatically as possible, with the aid of a periosteal elevator. Afterwards, the socket was washed with physiological solution and curetted. After a superficial de-epithelisation using rotating burs (8400S, Intensive, Montagnola, Switzerland), the postextraction socket was carefully curetted with alveolar curettes in order to contain any bleeding and the socket was grafted with deproteinised bovine bone (Bio-Oss, Geistlich Pharma AG, Wolhusen, Switzerland). Once the extraction socket was grafted, the envelope containing a randomisation code to assign the epithelial connective tissue graft sealing (group A) or the porcine collagen matrix (Mucograft, Geistlich Pharma AG) sealing (group B) was opened by a blinded independent physician.

In group A the bone graft was covered with an epithelial connective tissue graft (Fig 1a and 1b). The tissue graft was harvested from the hard palate gingiva. An epithelial connective tissue graft of 2 mm thickness was harvested with a surgical blade (Swann-Morton, Sheffield, England). After haemo-

stasis, the donor site was filled with collagen (Condress, Abiogen Pharma, Milan, Italy) and sutured with a 5-0 suture (Vicryl, Ethicon J and J International, Sint-Stevens-Woluwe, Belgium). Finally, the grafted postextraction socket was sealed with a 5-0 suture (Vicryl, Ethicon J and J International). In group B, the bone graft was covered with a porcine collagen matrix that was shaped according to the shape and dimension of the alveolar socket and was sutured with a 5-0 suture (Vicryl, Ethicon J and J International; Fig 2a and 2b).

Temporary, resin-bonded, cast metal framework prostheses, such as Maryland bridges, were used in the anterior region. The retention of these frameworks was achieved by chemically bonding both the conditioned tooth surface and the sandblasted metal alloy.

Five months after socket preservation, the bone volumes were analysed using the same CBCT scan machine used at baseline (CRANEX 3D; Soredex). Afterwards, implants were placed using a conventional approach consisting of an intrasulcular and crestal incision, which was performed to elevate a mucoperiosteal flap. A drill sequence was used to prepare the recipient site according to the manufacturers' instruction. All the implants were installed with an insertion torque ranging between 35 and 45 Ncm, as measured using a manual torque wrench by the surgical operator. Both groups received the same tapered implants (Nobel Replace, Nobel Biocare, Göteborg, Sweden), with narrow (NP) or regular platform (RP) and lengths of 10 to 13 mm. Then, flaps were sutured with a 4-0 sutures (Vicryl, Ethicon J and J International). All the implants were placed according to a single-stage protocol. The same Maryland bridge was adjusted chairside in order to fit passively over the healing abutment,

Fig 2 a) Occlusal View of Postextraction socket sealed with collagen matrix. b) Porcine collagen matrix.



and was used temporarily. Eight to twelve weeks after implant placement, open tray impressions were taken using a polyether material (Impregum, 3M ESPE, Seefeld, Germany) with a custom open tray (Diatray Top, Dental Kontor, Stockelsdorf, Germany) and a fixed, screw-retained, acrylic temporary restoration was used to replace the Maryland bridge. Titanium- or zirconia-ceramic restorations were fabricated by computer-aided design (CAD)/computer-aided manufacturing (CAM) technology. At the time of prosthesis delivery, occlusion was adjusted and the crowns were either screwed or cemented using eugenol-free zinc oxide cement (Temp Bond NE, Kerr Corporation, California, USA) 3 to 4 months after implant placement. Patients were recalled every 3 months for maintenance.

■ Outcome measures

The primary outcome measures were:

Implant success and survival rates

A 'successful implant' is when the following criteria are fulfilled completely:

1. Does not cause allergic, toxic, or gross infectious reactions either locally or systematically.
2. Offers anchorage to a functional prosthesis.
3. Does not show any signs of fracture or bending.
4. Does not show any mobility, when individually tested by tapping or rocking with a hand instrument.
5. Does not show any signs of radiolucency on an intraoral radiograph using a paralleling technique strictly perpendicular to the implant-bone interface.

Implant failure was defined as an implant which had to be removed at implant insertion due to lack of stability, implant mobility, removal of stable implants dictated by progressive marginal bone loss or infection; and any mechanical complications (e.g. implant fracture) rendering the implant unusable. The stability of individual implants was assessed during the delivery of definitive crowns by tightening the abutment screw with a torque of 20 Ncm, and then 1 year after implant placement by the percussion test¹⁵.

Complications

Any biological (pain, swelling, suppuration, etc) and/or mechanical complication (fracture of the framework and/or the veneering material, screw loosening etc) was considered.

The secondary outcome measures were:

Horizontal and vertical volumetric/dimensional changes

In both groups, CBCT scans were performed before teeth extraction and 5 months after socket preservation procedures (Figs 3a, 3b, 4a and 4b). The following parameters were used: field of view (FOV) of 60 x 80 mm; voxel size of 0.2 mm; focal spot of 0.5 mm; up to 20 s, 90 kV and 12 mA according to patient size. Four measures were recorded for all preserved sites, before and after treatment. The horizontal ridge width was measured at three levels localised 1, 3, and 5 mm below the most coronal aspect of the bone crest; and named levels A, B, and C, respectively (Fig 5). The vertical dimension between the palatal and buccal wall peaks was measured, and named

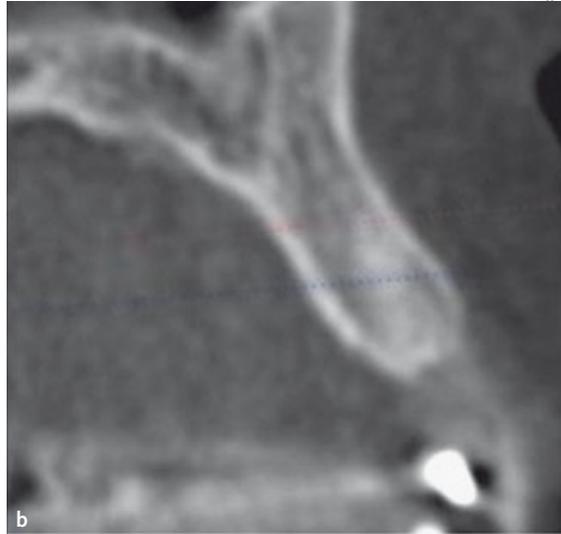
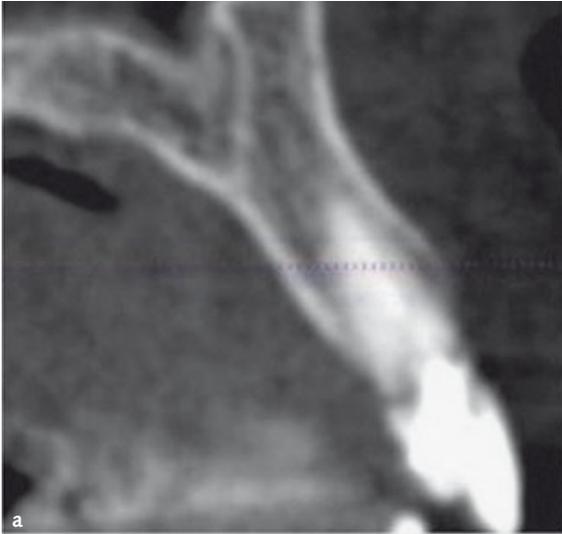
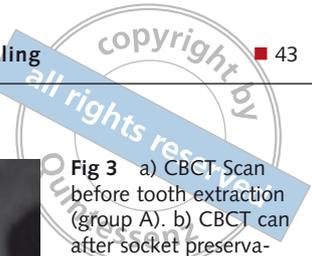


Fig 3 a) CBCT Scan before tooth extraction (group A). b) CBCT scan after socket preservation with epithelial connective tissue graft (group A).

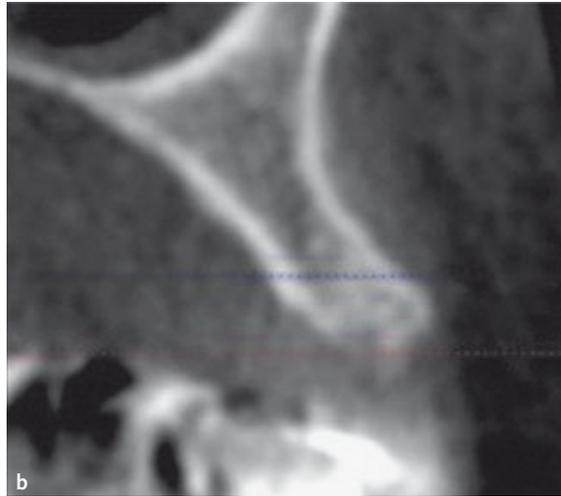
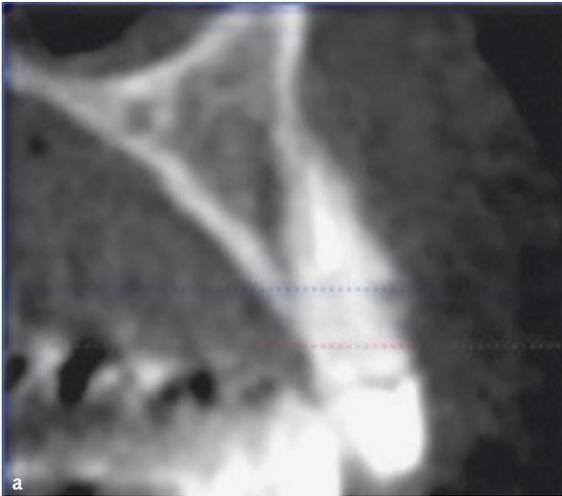


Fig 4 a) CBCT scan before tooth extraction (group B). b) CBCT scan after socket preservation with porcine collagen matrix (group B).

level D. Bone loss was calculated for each value, expressed as a linear difference, corresponding to the difference between pre- and post-regeneration measurements. The data were exported as Digital Imaging and Communication in Medicine (DICOM) and opened using OnDemand3D software version 1.0.9.3223 (Cybermed, Irvine, California, USA) in order to perform all measurements. A superimposition of the pre- and post-operative DICOM data was performed on unchanged anatomical areas (e.g. the cranial base) and manually checked for a complete match by using the Fusion adjunctive module (Cybermed). The most apical point of the pre-extraction socket (the most apical point of the root apex), was defined in the baseline image and two reference lines were drawn subsequently. A vertical reference line was drawn in the centre of the

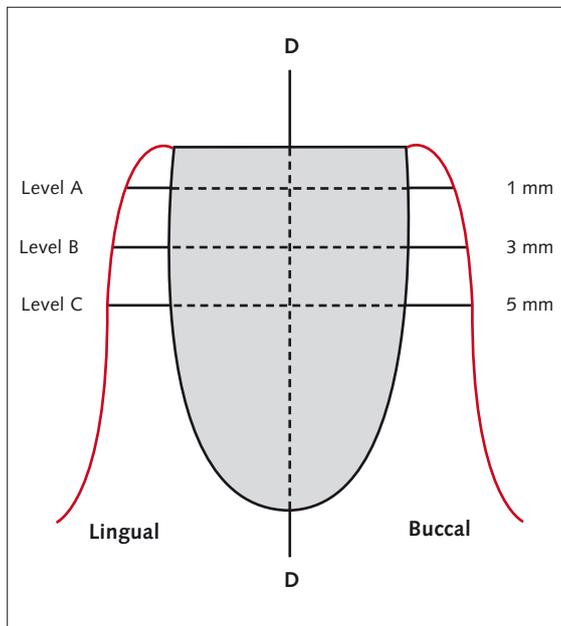


Fig 5 Volumetric changes. Vertical and horizontal measurements.

tooth socket, crossing the apical reference point. A horizontal reference line was drawn perpendicular to the vertical line, crossing the apical reference point. Measurements with respect to these reference points and lines were then performed in the centre of the alveolar socket.

Peri-implant marginal bone level changes

The distance from the most coronal margin of the implant collar and the most coronal point of bone-to-implant contact, evaluated on intraoral digital radiographs taken with the paralleling technique using a film-holder (Rinn XCP, Dentsply, Illinois, USA) at implant placement (baseline) and after 1 year of use, was taken as the peri-implant marginal bone level. The radiographs were accepted or rejected for evaluation based on the clarity of the implant threads. All readable radiographs were displayed in an image analysis program (DFW2.8 for windows, Soredex) on a 24-inch LCD screen (iMac, Apple, California, USA) and evaluated under standardised conditions (SO 12646:2004). The software was calibrated for every single image using the known distance of the implant diameter or length. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.01 mm and averaged at patient level.

One blind assessor, not involved in the treatment of the patients, made all clinical assessments without knowing the group allocation. Horizontal and vertical volumetric/dimensional changes, as well as the peri-implant marginal bone level changes were evaluated by the same blinded calibrated radiologist not previously involved in the study.

Sample size and randomisation

The sample size was calculated by considering a difference in the horizontal bone change of 1.54 mm between groups, according to Vasilic et al¹⁶, and by assuming less vertical resorption of the alveolar bony ridge as previously described¹⁷. Based on these values, it was determined that 15 subjects per group would be enough to provide at least 80% power with an α error probability of 0.05.

For randomisation of the sites to be assigned to groups a pre-generated random sequence was

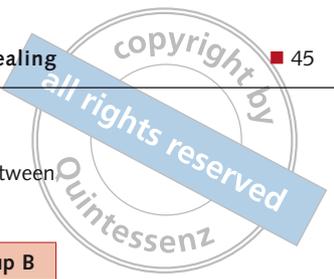
created using the Excel software (Microsoft Corporation, Washington, USA), which consisted of a randomised sequence of non-consecutive numbers matching the two different procedures within group A or group B. Opaque envelopes were sealed according to the pre-generated list. An independent consultant (RP) not previously involved in the trial prepared all the envelopes. Data were collected in spreadsheets (Excel) by a physician at the Dentistry Unit, University of Sassari, Italy.

Statistical analysis

All data analysis was carried out according to a pre-established analysis plan. A bio-statistician with expertise in dentistry analysed the data using QI Macros SPC software (version 2010; KnowWare International, Colorado, USA) for Microsoft Office Excel (Microsoft Corporation, Washington, USA). The differences of means at patient level for continuous outcomes (horizontal and vertical volumetric/dimensional changes and peri-implant marginal bone level changes) between groups were compared by independent sample t-tests. The differences in the proportion of patients with implant failures and complications (dichotomous outcomes) were compared between the groups using the Fisher's exact probability test. Marginal bone remodelling were also compared between the two centres using the one-way analysis of variance. All statistical comparisons were conducted at the 0.05 level of significance.

Results

In total, 35 patients were screened between May and September 2012, but 5 patients (2 at Dr Silvio Mario Meloni's centre and 3 at Dr Marco Tallarico's centre) refused to adhere to the strict clinical and radiological follow-up and were not enrolled. A total of 30 patients (12 males, 18 females), with a mean age of 48 years (range 26 to 72) were considered eligible and allocated to the study groups of this trial. Fifteen patients were randomised to group A and 15 patients to group B. Each centre treated the same number of 15 patients according to the allocated interventions. A total of 30 procedures were



performed. Each patient received one implant scoring out of a total of 30 implants (10 narrow platform and 20 regular platform). There were no apparent baseline imbalances between the 2 groups apart from the presence of more canines in group A. No patient dropped out of the study within 1 year after implant placement and no deviation from the protocol occurred. All data collected was included in the statistical analysis.

One year after implant placement no implants failed and no biological or mechanical complications occurred during the entire follow-up.

At level A, bone loss was 0.54 ± 0.25 mm (95% CI 0.39 to 0.69 mm) in group A and 0.67 ± 0.31 mm (95% CI 0.48 to 0.86 mm) in group B (difference: 0.13 ± 0.18 ; 95% CI 0.04 to 0.26 mm). No statistically significant difference was observed between the groups ($P = 0.34$). At level B, bone loss was 0.83 ± 0.26 mm (95% CI 0.67 to 0.99 mm) in group A and 0.91 ± 0.38 mm (95% CI 0.67 to 1.15 mm) in group B (difference: 0.08 ± 0.23 ; 95% CI -0.14 to 0.14 mm). No statistically significant difference was observed between the groups ($P = 0.61$). At level C, bone loss was 0.26 ± 0.17 mm (95% CI 0.15 to 0.37 mm) in group A and 0.31 ± 0.18 mm (95% CI 0.20 to 0.42 mm) in group B (difference: 0.05 ± 0.25 ; 95% CI -0.01 to 0.31 mm). No statistically significant difference was observed between

Table 1 Patients' and interventions' characteristics between groups.

	Group A	Group B
Males	5	7
Females	10	8
Mean age at implant insertion	49.7	46.8
Smokers (< 10 cigarettes/day)	1	1
Narrow implant diameter	4	6
Regular implant diameter	11	9
Implants in incisor position	2	3
Implants in canine position	5	2
Implants in premolar position	8	10

the groups ($P = 0.55$). At level D, bone loss was 1.60 ± 0.69 mm (95% CI 1.17 to 2.03 mm) in group A and 1.47 ± 0.58 mm (95% CI 1.11 to 1.83 mm) in group B (difference: 0.13 ± 0.27 ; 95% CI -0.02 to 0.32 mm). No statistically significant difference was observed between the groups ($P = 0.67$). The main results are summarised in Table 2 and Table 3.

Both groups lost peri-implant marginal bone at 1 year after implant placement. Patients treated with epithelial connective tissue graft (group A) lost an average of 0.90 ± 0.18 mm (95% CI 0.81 to 0.99 mm) of peri-implant marginal bone vs 0.84 ± 0.21 mm (95% CI 0.81 to 0.99 mm) for patients treated with porcine collagen matrix (group B). The main results

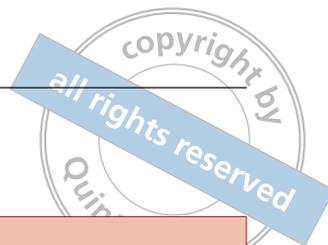
Table 2 Horizontal and vertical volumetric/dimensional measurements (mean \pm standard deviation; 95% CI, reported in millimetres) taken immediately after tooth extraction (T_0) and 5 months later (T_1).

Group A (N =15)	Level A	Level B	Level C	Level D
T_0	8.24 ± 0.67 ; 7.82 to 8.66	8.18 ± 0.32 ; 7.98 to 8.38	8.21 ± 0.52 ; 7.89 to 8.53	17.28 ± 1.20 ; 16.54 to 18.02
T_1	7.70 ± 0.52 ; 7.38 to 8.02	7.35 ± 0.43 ; 7.08 to 7.62	7.99 ± 0.46 ; 7.70 to 8.28	15.68 ± 1.13 ; 14.98 to 16.38
Group B (N=15)	Level A	Level B	Level C	Level D
T_0	8.39 ± 0.66 ; 7.98 to 8.80	8.53 ± 0.41 ; 8.28 to 8.78	8.27 ± 0.58 ; 7.91 to 8.63	16.91 ± 1.34 ; 16.08 to 17.74
T_1	7.72 ± 0.46 ; 7.44 to 8.00	15.44 ± 1.33 ; 14.61 to 16.27	7.96 ± 0.56 ; 7.61 to 8.31	7.62 ± 0.43 ; 7.35 to 7.89

Table 3 Horizontal and vertical volumetric/dimensional changes (mean \pm standard deviation; 95% CI) between groups. Data were reported in millimetres (mm).

	Level A	Level B	Level C	Level D
Group A (N=15)	0.54 ± 0.25 ; 0.39 to 0.69	0.83 ± 0.26 ; 0.67 to 0.99	0.26 ± 0.17 ; 0.15 to 0.37	1.60 ± 0.69 ; 1.17 to 2.03
Group B (N=15)	0.67 ± 0.31 ; 0.48 to 0.86	0.91 ± 0.38 ; 0.67 to 1.15	0.31 ± 0.18 ; 0.20 to 0.42	1.47 ± 0.58 ; 1.11 to 1.83
Difference	0.13 ± 0.18 ; 0.04 to 0.26	0.08 ± 0.23 ; -0.14 to 0.14	0.05 ± 0.25 ; -0.01 to 0.31	0.13 ± 0.27 ; -0.02 to 0.32
P Values	0.34*	0.61*	0.55*	0.67*

*No significant differences between groups ($P > 0.05$).

**Table 4** Peri-implant marginal bone levels changes (mean \pm standard deviation; 95% CI) between groups.

Group A (N = 15)	Group B (N = 15)	Difference
0.90 \pm 0.18 mm (0.81 to 0.99 mm)	0.84 \pm 0.21 mm (0.72 to 0.96 mm)	0.07 \pm 0.11 (-0.02 to 0.16)*

*Not statistically significant ($P = 0.41$).

Table 5 Horizontal and vertical volumetric/dimensional changes (Levels A-D), and peri-implant marginal bone levels (MBL) changes between groups and centres. Data were reported (mm) as mean \pm standard deviation; 95% CI.

	Level A	Level B	Level C	Level D	MBL
Epithelial connective tissue graft					
Dr Meloni	0.60 \pm 0.22; 0.30 to 0.70	0.78 \pm 0.28; 0.56 to 1.04	0.24 \pm 0.15; 0.07 to 0.33	1.64 \pm 0.74; 0.95 to 2.25	0.89 \pm 0.16; 0.82 to 0.98
Dr Tallarico	0.48 \pm 0.30; 0.03 to 0.57	0.88 \pm 0.30; 0.43 to 0.97	0.28 \pm 0.23; 0.00 to 0.40	1.56 \pm 0.81; 1.09 to 2.51	0.91 \pm 0.20; 0.79 to 0.88
<i>P</i> Values	0.50*	0.60*	0.75*	0.87*	0.84*
Porcine collagen matrix					
Dr Meloni	0.72 \pm 0.36; 0.29 to 0.91	0.94 \pm 0.48; 0.38 to 1.22	0.36 \pm 0.17; 0.25 to 0.55	1.44 \pm 0.59; 0.99 to 2.01	0.84 \pm 0.19; 0.71 to 0.89
Dr Tallarico	0.62 \pm 0.33; 0.21 to 0.79	0.88 \pm 0.36; 0.79 to 1.41	0.26 \pm 0.21; 0.02 to 0.38	1.50 \pm 0.70; 1.19 to 2.41	0.84 \pm 0.24; 0.64 to 0.85
<i>P</i> Values	0.66*	0.83*	0.43*	0.89*	0.99*

*No significant differences among centres ($P > 0.05$).

are summarised in Table 4. No statistically significant difference was observed between the groups (difference: 0.07 \pm 0.11 mm; 95% CI -0.02 to 0.16; $P = 0.41$).

The comparison of horizontal and vertical volumetric/dimensional changes, and peri-implant marginal bone level changes between the two centres is presented in Table 5. No differences were observed between the centres.

■ Discussion

The present RCT was conducted with the aim of understanding which procedure would be preferable for sealing a post-extractive socket grafted with deproteinised bovine bone, between epithelial connective tissue graft harvested from the palate and porcine collagen matrix. To the best of our knowledge, at the time of writing this article, there were no other published RCTs comparing the use of deproteinised bovine bone in association with an epithelial connective tissue graft or with a porcine collagen matrix to seal post-extractive sockets. This makes it difficult to evaluate how the present results fit with other comparable studies.

The results of the present study are in accordance with another RCT on 20 patients that compared the

porcine collagen matrix with an epithelial connective tissue graft to increase the keratinised gingiva/mucosa. This study concluded that porcine collagen matrix was as effective and predictable as the connective tissue graft for attaining a band of keratinised tissue. Nevertheless, its use was associated with a significantly lower patient morbidity, avoiding graft donor site involvement and soft tissue recessions¹⁷.

The main limitation of the present investigation was the recruitment of maxillary patients. Thus, the results may be generalised only to the maxilla between premolars. Another limitation is the small sample size that may have hidden some differences. Nevertheless, based on a post-hoc power analysis, a larger sample is required to confirm these results. The post-hoc power calculation revealed that 522 patients (261 in each group) would be needed to reach a 80% statistical power with a confidence interval of 95%. Additional multicentre RCTs are needed to confirm whether or not these preliminary results are sufficient and to evaluate the possible advantages of using porcine collagen matrix for the treatment of postextraction sockets in the the post-operative patient's perceptions of pain and discomfort. Other studies could be designed to compare soft tissue grafts to conventional resorbable membranes and to investigate other sealing procedures such as collagen sponge.



Many researchers have demonstrated the effects of extraction on alveolar tissues over the years. They have shown that, as a consequence of tooth loss, the volume of tissues in the edentulous ridge decreases, especially on the buccal side, resulting in a palatal and lingual shift of the residual crest¹⁸⁻²⁰. This process seems to be important as it may compromise future implant placement or conventional prosthetic restorations²¹. Socket preservation may aid in reducing the bone dimensional changes following tooth extraction. However, they do not prevent bone resorption⁸. Although different techniques have been proposed for maintaining original alveolar ridge dimensions, complete preservation has not been achieved yet. Regardless of the reasons for socket preservation, there seems to be a consensus that sufficient alveolar bone volume and favourable architecture of the alveolar ridge are essential to achieve ideal function and aesthetics in implant dentistry. Preserving or reconstructing the extraction socket of a failed tooth according to the principles of guided bone regeneration increases the possibilities of providing aesthetically pleasing restorations to our patients. Much evidence exists on dimensional changes in the alveolar ridge following tooth extraction. A recent systematic review consisting of 20 studies demonstrated a horizontal dimensional reduction (3.79 ± 0.23 mm) greater than the vertical reduction (1.24 ± 0.11 mm on buccal, 0.84 ± 0.62 mm on mesial and 0.80 ± 0.71 mm on distal sites) at 6 months⁸. Lekovic et al²², in a split-mouth study found less bone resorption in sockets sealed with collagen membrane compared to sockets healed without any membrane. Isaella et al²³, in a RCT reported that ridge preservation using a freeze-dried bone allograft and collagen membrane, improved ridge height and width dimensions when compared to extraction alone. In a RCT, Barone et al²⁴ concluded that the ridge-preservation approach using porcine bone in combination with collagen membrane significantly reduced the resorption of hard tissue ridge after tooth extraction, compared to extraction alone.

Data comparing socket seal surgery in humans are limited and a few studies have investigated how the sealing procedures of fresh extraction alveolar sockets can prevent alveolar resorption. Brkovic et al conducted a RCT to evaluate the efficacy of an

adjunctive resorbable dense collagen membrane to bone substitutes. Twenty patients were randomly allocated into two groups. After tooth extraction, each socket was filled with a cone consisting of β -tricalcium phosphate (β -TCP) and type I collagen. The sockets in the test group were covered with dense collagen membranes, whereas the sockets in the control group were not. Primary closure was achieved in both groups with mucoperiosteal flaps. Clinical assessments were performed at baseline and at re-entry surgery after 9 months of healing. No statistically significant differences were found between the test and control groups on horizontal ridge resorption (0.86 vs 1.29 mm, respectively) or on vertical dimensional changes (0.12 vs 0.5 mm, respectively)²⁵.

The choice between epithelial connective tissue graft vs porcine collagen matrix may depend on several variables, such as tissue biotype, size of the defect, the experience of the clinician, and the patient's preference. The use of porcine collagen matrix as an adjunct to the bone preservation of the post-extractive sockets grafted with deproteinised bovine bone may represent an alternative to the epithelial connective tissue graft by reducing surgical time and patient morbidity²⁶. Porcine collagen matrix has demonstrated very good results in the treatment of localised gingival recessions, both in terms of root coverage as well as in aesthetic outcomes^{26,27}. However, these results should be interpreted with care and data should be investigated further in controlled clinical trials. The clinicians involved in this study were highly experienced in the management of post-extractive implant sites. This factor may limit the extrapolation of the present results; however, all of the procedures were tested in real clinical conditions and they can be generalised with confidence to a wider population with similar characteristics.

■ Conclusions

When tooth extraction is performed atraumatically and the sockets are filled with deproteinised bovine bone, sealing the socket with porcine collagen matrix or epithelial connective tissue graft provides similar outcomes. The use of porcine collagen matrix

allowed simplification of the treatment, thus it is suitable in sealing postextraction sockets grafted with deproteinised bovine bone. These findings suggest that this approach effectively reduces the need for harvesting from the palate-epithelial connective tissue graft. Furthermore RCTs with larger sample sizes and longer follow-ups are needed to confirm our findings.

■ References

- Clementini M, Morlupi A, Canullo L, Agrestini C, Barlatani A. Success rate of dental implants inserted in horizontal and vertical guided bone regenerated areas: a systematic review. *Int J Oral Maxillofac Surg* 2012;41:847–852.
- Papaspyridakos P, Chen CJ, Singh M, Weber HP, Galucci GO. Success criteria in implant dentistry: a systematic review. *J Dent Res* 2012;91:242–248.
- Schropp L, Wenzel A, Kostopoulos L, Karring T. Bone healing and soft tissue contour changes following single-tooth extraction: a clinical and radiographic 12-month prospective study. *Int J Periodontics Restorative Dent* 2003;23:313–323.
- Lekovic V, Kenney EB, Weinlaender M, Han T, Klokkevold P, Nedic M, Orsini M. A bone regenerative approach to alveolar ridge maintenance following tooth extraction. Report of 10 cases. *J Periodontol* 1997;68:563–570.
- Botticelli D, Berglundh T, Lindhe J. Hard-tissue alterations following immediate implant placement in extraction sites. *J Clin Periodontol* 2004;31:820–828.
- Schropp L, Kostopoulos L, Wenzel A. Bone healing following immediate versus delayed placement of titanium implants into extraction sockets: a prospective clinical study. *Int J Oral Maxillofac Implants* 2003;18:189–199.
- Van der Weijden F, Dell'Acqua F, Slot DE. Alveolar bone dimensional changes of post-extraction sockets in humans: a systematic review. *J Clin Periodontol* 2009;36:1048–1058.
- Tan WL, Wong TL, Wong MC, Lang NP. A systematic review of post-extraction alveolar hard and soft tissue dimensional changes in humans. *Clin Oral Implants Res* 2012;23(suppl 5):1–21.
- Atieh MA, Alsabeeha NHM, Payne AGT, Duncan W, Esposito M. Interventions for replacing missing teeth: alveolar ridge preservation techniques for oral implant site development. *Cochrane Database Syst Rev* 2012;(11):CD010176.
- Vittorini Orgeas G, Clementini M, De Risi V, de Sanctis M. Surgical techniques for alveolar socket preservation: a systematic review. *Int J Oral Maxillofac Implants* 2013;28:1049–1061.
- Weng D, Stock V, Schliephake H. Are socket and ridge preservation techniques at the day of tooth extraction efficient in maintaining the tissues of the alveolar ridge? *Eur J Oral Implantol* 2011;4(Suppl): 59–66.
- Landsberg CJ. Socket seal surgery combined with immediate implant placement: a novel approach for single-tooth replacement. *Int J Periodontics Restorative Dent* 1997;17:140–149.
- Fickl S, Zuhr O, Wachtel H, Stappert CF, Stein JM, Hürzeler MB. Dimensional changes of the alveolar ridge contour after different socket preservation techniques. *J Clin Periodontol* 2008;35:906–913.
- Ten Heggeler JM, Slot DE, Van der Weijden GA. Effect of socket preservation therapies following tooth extraction in non-molar regions in humans: a systematic review. *Clin Oral Implants Res* 2011;22:779–788.
- Atsumi M, Park SH, Wang HL. Methods used to assess implant stability: current status. *Int J Oral Maxillofac Implants* 2007;22:743–754.
- Vasilic N, Henderson R, Jorgenson T, Sutherland E, Carson R. The use of bovine porous bone mineral in combination with collagen membrane or autologous fibrinogen/fibronectin system for ridge preservation following tooth extraction. *J Okla Dent Assoc* 2003;93:33–38.
- Sanz M, Lorenzo R, Aranda JJ, Martin C, Orsini M. Clinical evaluation of a new collagen matrix (Mucograft prototype) to enhance the width of keratinized tissue in patients with fixed prosthetic restorations: a randomized prospective clinical trial. *J Clin Periodontol* 2009;36:868–876.
- Petrokovski J, Massler M. Alveolar ridge resorption following tooth extraction. *J Prosthet Dent* 1967;17:21–27.
- Younis L, Taher A, Abu-Hassan MI, Tin O. Evaluation of bone healing following immediate and delayed dental implant placement. *J Contemp Dent Pract* 2009;10:35–42.
- Barone A, Ricci M, Calvo-Guirado JL, Covani U. Bone remodelling after regenerative procedures around implants placed in fresh extraction sockets: an experimental study in Beagle dogs. *Clin Oral Implants Res* 2011;22:1131–1137.
- Abrams L. Augmentation of the deformed residual edentulous ridge for fixed prosthesis. *Compend Contin Educ Gen Dent* 1980;1:205–213.
- Lekovic V, Camargo PM, Klokkevold PR, Weinlaender M, Kenney EB, Dimitrijevic B, Nedic M. Preservation of alveolar bone in extraction sockets using bioabsorbable membranes. *J Periodontol* 1998;69:1044–1049.
- Isabella JM, Greenwell H, Miller RL, Hill M, Drisko C, Bohra AA, Scheetz JP. Ridge preservation with freeze-dried bone allograft and a collagen membrane compared to extraction alone for implant site development: a clinical and histologic study in humans. *J Periodontol* 2003;74:990–999.
- Barone A, Aldini NN, Fini M, Giardino R, Guirado JL, Covani U. Xenograft versus extraction alone for ridge preservation after tooth removal: a clinical and histomorphometric study. *J Periodontol* 2008;79:1370–1377.
- Brkovic BM, Prasad HS, Rohrer MD, Konandreas G, Agrogiannis G, Antunovic D, Sándor GK. Beta-tricalcium phosphate/type I collagen cones with or without a barrier membrane in human extraction socket healing: clinical, histologic, histomorphometric, and immunohistochemical evaluation. *Clin Oral Investig* 2012;16:581–590.
- Thoma DS, Sancho-Puchades M, Ettl DA, Hämmerle CH, Jung RE. Impact of a collagen matrix on early healing, aesthetics and patient morbidity in oral mucosal wounds – a randomized study in humans. *J Clin Periodontol*. 2012;39:157–165.
- Cardaropoli D, Tamagnone L, Roffredo A, Gaveglio L. Treatment of gingival recession defects using coronally advanced flap with a porcine collagen matrix compared to coronally advanced flap with connective tissue graft: a randomized controlled clinical trial. *J Periodontol* 2012;83:321–328.