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Clinical outcomes of implants placed in ridge-preserved versus nonpreserved sites: A 4-year randomized clinical trial

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Abstract

Background: Consistent bone changes occur after tooth removal, often compromising the success of implants placed within the socket left to natural healing The long-term effect of ridge preservation on implant outcomes is still unclear.

Purpose: The aim of the study was to assess success and survival rates of implants placed in extraction sockets, with spontaneous healing, or grafted with cortical porcine bone, or collagenated corticocancellous porcine bone.

Materials and methods: Ninety patients in need for a single premolar/molar tooth extraction and an implant treatment were selected for the present study. Patients were randomly distributed among 3 groups: sites that healed naturally (*ctrl*), or sites that received ridge preservation with either cortical (*cort*) or collagenated corticocancellous porcine bone (*coll*). Three months after, all the experimental sites were reentered to insert implants. Marginal bone levels were recorded; soft tissues were analyzed and summarized with the Pink Esthetic Score (PES). Forty-two patients out of 90 (initial cohort study) completed the entire follow-up of 4 years.

Results: Cumulative survival and success rates for all implants were 100% at a 4-year evaluation. Mean marginal bone loss (MBL) was 1.14 $\pm$ 0.23 mm in the *cort* group, 1.13 $\pm$ 0.29 mm in the *coll* group, and 1.92 $\pm$ 0.07 mm in the *ctrl* group. There were no significant differences between the 2 grafting materials but MBL was significantly greater in the nongrafted sites (P value < .001). The PES resulted significantly better (9.42 $\pm$ 0.75) for the *cort* group than for the *coll* group (8.53 $\pm$ 1.18) and *ctrl* group (6.07 $\pm$ 1.89) at 4-year evaluation.

Conclusions: Ridge preservation was more effective than natural healing in preserving marginal bone and in achieving better esthetic outcomes around implants 4 years after placement. The cortical porcine bone showed better clinical outcomes than collagenated corticocancellous porcine bone.

KEYWORDS

dental implants, ridge preservation, tooth extraction

1 | INTRODUCTION

The healing process of tooth extraction sockets has been profusely studied in several experimental conditions.[1–4] It has been demonstrated that a consistent bone dimensional change takes place both in height and in width after tooth removal, and that the major reduction occurs during the first 3 to 6 months.[5] Alveolar ridge preservation (ARP) has been introduced in order to counteract dimensional changes and to facilitate the future prosthetically driven implant placement and rehabilitation.[6] Different grafting materials are available on the market but none of them is reported to prevaricate the others in terms of the percentage of newly formed bone.[7] Grafting materials have been classified according to their origin (autologous, allografts, xenografts, and alloplastic grafts), but, recently, the increased knowledge of the biology underlying the healing process of biomaterials has allowed clustering of the grafts according to their substitution rate:

low or fast reabsorption potential.[8,9] Among xenografts, cortical demineralized biomaterials are the most used and they are associated to a lower resorption rate of the graft.[10] On the contrary, collagenated grafts showed clear signs of faster reabsorption in different histological studies.[11–14]

There is controversy in literature about the relative burden of ridge preservation procedure in the long-term prognosis of dental implants. A recent systematic review suggested that the amount of bone loss around dental implants was the same between preserved and nonpreserved sites.[15] However, there is a lack of long-term clinical studies on the topic.

Handling of soft tissues around dental implants represents a great concern among clinicians because of growing demands for optimal esthetic outcomes. According to Buser and colleagues, the reduction of the gingival recession depends on some main factors like implant position and facial bone wall thickness and height.[16] In addition, the surgeon expertise might influence the overall esthetic outcome of implant therapy, especially in case of immediate implant placement.[17] It is well established that the peri-implant soft tissues contour follows the underlying osseous crest. Therefore, the preventive use of ARP techniques after tooth-extraction could promote the quality of soft tissues contour for future implant placement.

The aim of the present randomized clinical study was to evaluate the survival, success, and esthetic outcome of implants placed in extraction sockets, which had spontaneous healing (*ctrl*), or grafted with either cortical porcine bone (*cort*), or collagenated corticocancellous porcine bone (*coll*).

2 | MATERIALS AND METHODS

2.1 | Study group

The present randomized study was approved by the Versilia Hospital research Ethical Committee (ethical approval form 214/2012; ClinicalTrials.gov Identifier: NCT02644070). Patients recruiting and treatment were conducted in 2 different clinical centers from December 2011 to December 2013: Universities of Pisa and Ancona. The protocol was carried on according to the principles outlined in the Declaration of Helsinki as revised in 2000; this paper is reported according to the CONSORT statement for randomized clinical trials.[18]

2.2 | Inclusion criteria

Patients were recruited according the following criteria: (1) patients able to sign an informed consent form; (2) patients aged ≥18 years; and (3) patients who required single-tooth extraction and an implant-supported restoration.

2.3 | Exclusion criteria

The exclusion criteria included: (1) history of systemic conditions contraindicating oral surgery; (2) long-term nonsteroidal anti-inflammatory therapy; (3) oral bisphosphonate therapy; (4) pregnancy or lactation; (5) unwillingness to return for the follow-up visits; (6) cigarette consumption >10 per day; and (7) sites with an acute infection/inflammation.

FIGURE 1 Atraumatic tooth extraction. Tooth extraction was performed without raising a full thickness flap, and, if necessary, the tooth was sectioned to make the extraction the least traumatic possible

The randomization sequence was generated with a software and it was secured in password-protected computers, and finally enclosed in numbered, opaque, and sealed envelopes. The envelopes were opened numerically after tooth extraction. Data were collected by a third operator, who was not involved in enrollment or treatment of the patients.

2.4 | Surgical procedure

All clinicians had previously received calibration for the accuracy of measurements during a 1-week training session (April 2011). Patients were prescribed with prophylactic antibiotic therapy (2 g of amoxicillin or clindamycin 600 mg if allergy to penicillin was present) 1 hour before tooth extraction and continued the antibiotic therapy after the intervention (1 g of amoxicillin or 300 mg clindamycin) twice a day for 5 days. All patients rinsed their mouth for 1 minute with ozonized water (Aquolab EB2C Srl), for decontamination purposes, prior to the surgery (and twice a day for the following 3 weeks). Local anesthesia was obtained using lidocaine with adrenaline 1:50 000. Tooth extraction was performed without raising a full thickness flap, and, if necessary, the tooth was sectioned to make the extraction the least traumatic possible (Figure 1). The surgeon followed the indication to treat the extraction socket according to the instruction contained in the random envelope: (1) extraction sockets with spontaneous healing––*ctrl*; (2) extraction sockets grafted with collagenated cortico-cancellous porcine bone, with a particle size between 600 and 1000 lm (MP3, OsteoBiol_; Tecnoss, Coazze, Turin, Italy)––*coll*; and (3) extraction sockets grafted with cortical porcine bone, with a particle size between 600 and 1000 lm (Apatos, OsteoBiol_; Tecnoss)––*cort*. In the test groups, the sockets were grafted reaching the buccal and palatal alveolar bone walls and a collagen membrane (Evolution,

FIGURE 2 Clinical view of a test extraction socket that was grafted up to the buccal and palatal alveolar bone walls

OsteoBiol_; Tecnoss) was pushed under the interdental papillae with the aid of surgical periotomes (PT1,3,4,5; Hu-Friedy Mfg B.V., Rotterdam, the Netherlands) without covering the bone walls (Figure 2). Soft tissues at the level of interdental papillae were prepared with a pouch procedure. The membrane was stabilized with stitches in order to prevent graft particles leakage (Figure 3); therefore, the collagen membrane remained exposed to the oral cavity. In the control group, the sutures were used to stabilize the blood clot. No releasing incisions or muco-periosteal flaps were performed in any of the groups. Patients were prescribed also with naproxen sodium 550 mg tablets as an anti-inflammatory to be taken twice a day. Three months after healing, all the experimental sites were reentered (Figures 4 and 5) to insert dental implants (BT Evo; Biotec, Vicenza, Italy) with the aid of a tailored surgical stent, which was used for all measurements thereafter. After

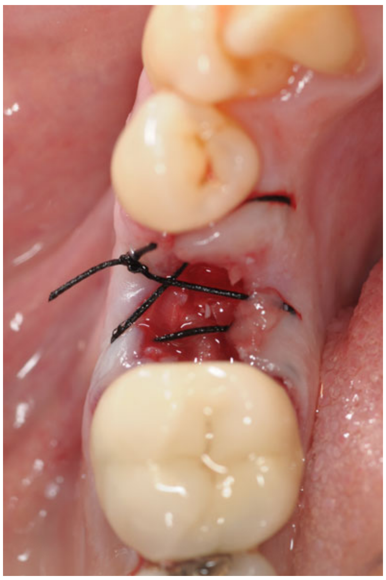

FIGURE 3 A collage membrane was stabilized with stitches in order to prevent graft leakage

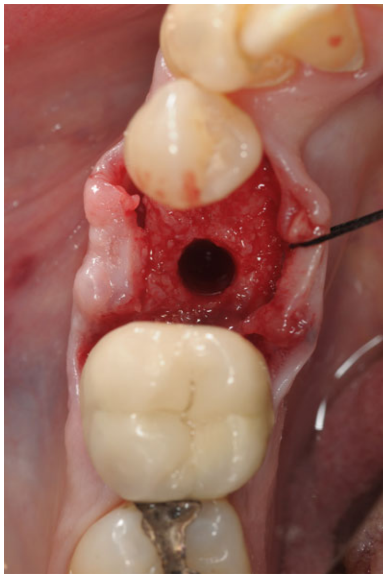

FIGURE 4 Three months after healing, all the experimental sites were reentered to perform implant insertion. Clinical view of the implant bed

a 4-month period of undisturbed healing, a transfer was screwed to the implant in order to register an impression with a customized tray. A customized final abutment was prepared and connected to the implant, and the definitive metal-ceramic restoration was cemented. All patients were enrolled in a personal periodontal health maintenance program, which included hygiene instructions and recall visits.

2.5 | Radiologic examination

Peri-implant marginal bone levels were evaluated on intraoral radiographs, at the mesial and distal sites (mMBL*x* and dMBL*x*, with *x* referring to the time-point of the follow-up). The marginal bone level (MBL) is the distance of the implant shoulder to the first bone-to-implant contact. Mesial and distal values were pooled prior to statistical analyses. The reference point was the fixture-abutment interface. Digital intraoral periapical radiographs were taken (70 kVp, 7 mA, Schick Technologies, Long Island City, New York). A paralleling device

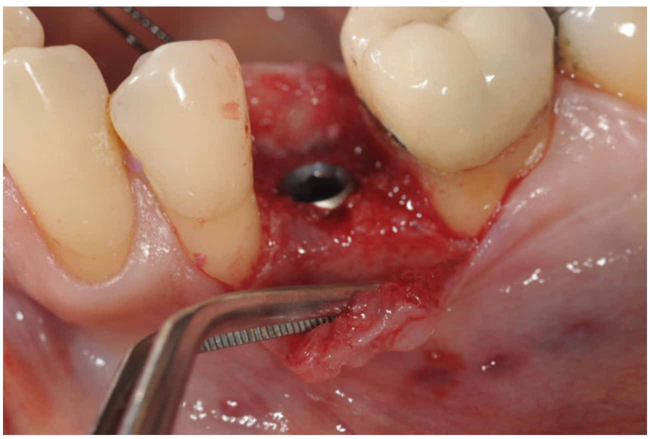

FIGURE 5 Three months after healing, all the experimental sites were reentered to perform implant insertion. Clinical view of the positioned implant

TABLE 1 Table of distribution and relative frequencies of demographic data and surgical features, *n* (%)

	cort (*n* = 14)	*coll* (*n* = 15)	*ctrl* (*n* = 13)	Pearson's chi-squared
Age (yy)	55.0 ± 15.4	53.8 ± 10.6	49.6 ± 12.07	
Sex				
Male	6 (14.29)	6 (14.29)	5 (11.90)	0.0563
Female	8 (19.05)	9 (21.43)	8 (19.05)	
Tooth				
Premolars	8 (19.05)	10 (23.81)	7 (16.67)	0.5245
Molars	6 (14.29)	5 (11.90)	6 (14.29)	
Arch				
Upper jaw	10 (21.43)	9 (21.43)	6 (14.29)	0.9827
Lower jaw	9 (11.90)	6 (14.29)	7 (16.67)	
Reasons for extraction				
Decay	2 (4.76)	8 (19.05)	6 (14.29)	5.480
Endo-fail	4 (9.52)	2 (4.73)	3 (7.14)	
Fracture	8 (19.05)	5 (11.90)	4 (9.52)	
Need for further augmentation	0	0	6 (46.15)	
Failures	0	0	0	
Cumulative survival rate	100%	100%	100%	
Cumulative success rate	100%	100%	100%	

Abbreviations: *coll*, collagenated corticocancellous porcine bone; *cort*, cortical porcine bone; *ctrl*, control; PP, per protocol analysis.

and individualized bite blocks, made of polyvinylsiloxane impression material, were used for the standardization of the x-ray orientation (Flexitime, Heraeus/Kulzer, Hanu, Germany). Radiological calibration was performed using the known thread-pitch distance of the implants (pitch = 1.0 mm). Previous known values, such as fixture diameter and length, were used for calibration when the threads were not clearly visible on the radiographs. Measurements were taken to the nearest millimeter, using a computer software (UTHSCSA Image Tool, Version 3.00, University of Texas Health Science, San Antonio, Texas).

2.6 | Soft tissues analysis

Intraoral photographs were taken at baseline and follow-up visits to evaluate soft tissues. A digital camera (Canon 1300D, Canon Inc, Tokyo, Japan) was used, at a fixed angle and magnification setting. A periodontal probe was used to perform direct measurements on the peri-implant mucosa. The assessment of the Pink Esthetic Score (PES) was performed on digital photographs, which were analyzed by 2 examiners: mesial papilla, distal papilla, soft tissue level, curvature of facial mucosa, root convexity/soft-tissue color, and texture.[19] Each parameter is assessed with a 0-1-2 score with 2 being the best and 0 being the worst score. The score for each parameter is added to get the PES for each implant (maximum possible score being 10).

2.7 | Implant success and survival rates

Patients were clinically evaluated every 6 months after loading and any complication was recorded. Implant failure was defined by the presence of implant mobility or by the presence of persistent or chronic infection. The stability of each implant was evaluated at each moment of the follow-up with 2 metallic handles of dental instruments. Survival and success rates and their respective cumulative values (SRs and CSRs) were calculated according to the criteria suggested by Albrektsson and colleagues in 1986.[22] Successful implants were those within a cut-off of registered mean radiological peri-implant bone resorption, not greater than 1.5 mm during the first year of loading and 0.2 mm the years after.

2.8 | Statistical analysis

All data were described with mean and standard deviation. Statistical significance for the clinical and radiographic data over time was assessed with the global nonparametric Brunner-Langer model for longitudinal data in factorial experiments. A *P* value <.05 was used as cut-off for significance. Post hoc analyses were performed with Wilcoxon signed rank tests for the paired cases and Mann-Whitney-Wilcoxon tests for the nonpaired cases. The Holm-Bonferroni method was used for the adjustment of multiple comparisons. A robust analysis of variance and a Spearman's correlation coefficient were performed. All analyses were calculated with a free statistical software (R 3.3.3; R Development Core Team, http://www.r-project.org).

3 | RESULTS

3.1 | Patients

One hundred patients were screened for the present study; 5 patients were excluded because they refused to be included in a randomized controlled trial, 3 patients were excluded because, during tooth extraction, a muco-periosteal flap had been raised, and 2 patients were excluded at tooth extraction because they were affected by an acute infection involving soft tissues. A total of 90 patients were allocated to the study groups of the trial. Of the original cohort,

TABLE 2 Absolute values for peri-implant crestal bone loss (distal and mesial, and the mean with SD), and alterations compared with baseline (restoration) as on the radiographs (mm)

Variable	Group	Baseline	1-year	2-years	4-years
mMBL	*cort*	0.35 ± 0.49	0.57 ± 0.51	1.00 ± 0.00	1.21 ± 0.42
dMBL		0.42 ± 0.51	0.78 ± 0.42	1.00 ± 0.00	1.07 ± 0.26
MeanMBL		0.39 ± 0.48	0.67 ± 0.42	1.00 ± 0.00	1.14 ± 0.06
ΔMBL_{0-x}			−0.28 ± 0.37	−0.60 ± 0.48	−0.75 ± 0.37
mMBL	*coll*	0.20 ± 0.41	0.66 ± 0.48	0.93 ± 0.25	1.20 ± 0.41
dMBL		0.13 ± 0.35	0.73 ± 0.45	1.00 ± 0.00	1.06 ± 0.25
MeanMBL		0.16 ± 0.36	0.70 ± 0.36	0.96 ± 0.12	1.13 ± 0.07
ΔMBL_{0-x}			−0.53 ± 0.54	−0.80 ± 0.36	−0.96 ± 0.51
mMBL	*ctrl*	0.15 ± 0.37	0.92 ± 0.27	1.46 ± 0.51	1.92 ± 0.27
dMBL		0.30 ± 0.48	0.92 ± 0.27	1.61 ± 0.50	1.92 ± 0.27
MeanMBL		0.23 ± 0.38	0.92 ± 0.27	1.53 ± 0.37	1.92 ± 0.27
ΔMBL_{0-x}			−0.69 ± 0.43	−1.30 ± 0.59	−1.69 ± 0.43
	Statistic	Degrees of freedom		*P* value	
Graft	18.855997	1.941649		3.03e−08	
Time	146.885241	2.846653		5.20e−90	
Graft/time	9.057483	5.103366		2.78e−08	

ANOVA-type statistic (ATS) of factorial model shows that the grafting procedure (*cort*, *coll*, and *ctrl*) and time not only give a significant effect on marginal bone loss, but also have interaction with each other.
Scientific notation for *P* values of the inferential analysis are reported at the bottom of the table. Overall, significant peri-implant bone loss was observed in the global test. In the paired post hoc tests, the greatest loss was observed in the control group. Abbreviations: dMBL, distal marginal bone level; mMBL, mesial marginal bone level; MeanMBL, mean marginal bone level; ΔMBL_{0-x}, change in marginal bone level.

42 patients completed the 4-year follow-up analysis. The high drop-out rate recorded was related to some centers who failed to send the information needed to complete the follow-up. The sample included 17 men (40.47%) and 25 women (59.52%) with a mean age of 52.8 ± 2.31 years. The homogeneity of study groups was checked in relation to sex (P = .05; Table 1).

Sixteen teeth were extracted because of severe decay, 16 because of root fracture, and 9 because they appeared compromised secondary to endodontic failure. Seventeen were first molars, 15 were second premolars, 9 were first premolars, and 1 was a canine.

Fifteen sites were grafted with collagenated corticocancellous bone (*coll*; Figure 6), 14 sites with cortical porcine bone (*cort*; Figure 7), and 13 sites were left to heal natural spontaneously healing (*ctrl*; Figure 8). No implants were lost during the entire follow-up resulting in an implant survival rate of 100% at $T_{4\text{-year}}$.

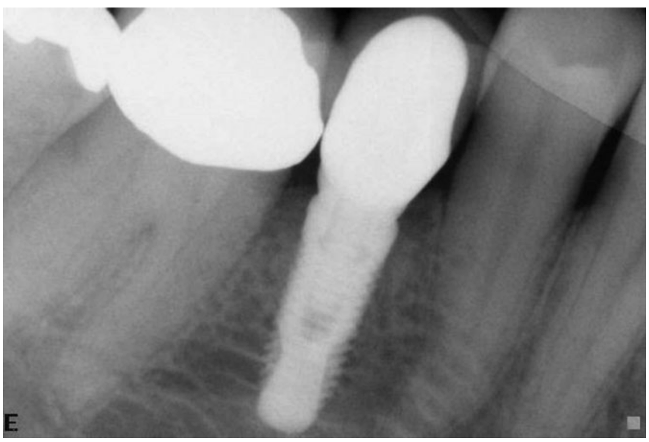

FIGURE 6 Radiographic appearance of an implant in the *coll* group (preserved with collagenated corticocancellous bone) at a 4-year evaluation

3.2 | Hard tissue measurements

Absolute values for marginal bone levels (|MBL|) at different time-point and related changes over time (ΔMBL) are presented in Table 2. During the 4-year period, significant peri-implant bone-level changes were observed in the global analysis ($P \leq .001$). In the paired analysis, the mean marginal bone change at 3 and 4 years was significantly greater than that at 1 and 2 years. The total amount of marginal bone loss from T_0 to $T_{4\text{-year}}$ was 1.14 ± 0.23 mm in the *cort* group (95% confidence interval [CI]: 1.00-1.27), 1.13 ± 0.29 mm in the *coll* group (95% CI: 0.96-1.29) and 1.92 ± 0.07 mm in the *ctrl* group (95% CI:

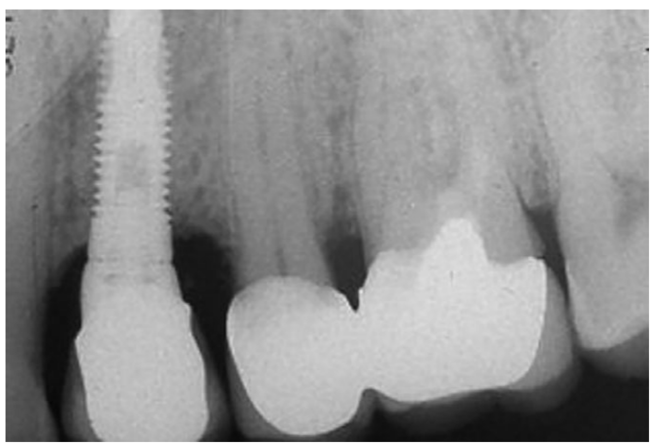

FIGURE 7 Radiographic appearance of an implant in the *cort* group (preserved with cortical porcine bone) at a 4-year evaluation

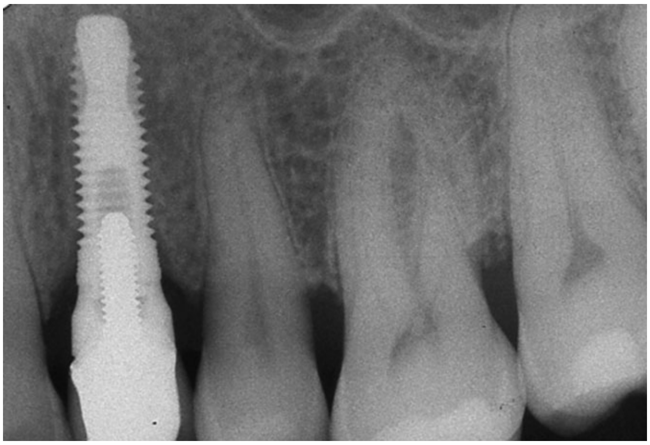

FIGURE 8 Radiographic appearance of an implant in the *ctrl* group (natural healing) at a 4-year evaluation

1.75-2.09). The Brunner-Langer model demonstrated that changes in MBL were significantly dependent on time ($P \leq .001$). Furthermore, the grafting procedure ($P \leq .001$) and the interaction of time and grafting procedure ($P \leq .001$) had an influence on bone resorption. The plot of the relative effect of time and grafting procedure on marginal bone level is pictured in Figure 9. The main bone remodeling occurred in the control group (*ctrl*) when compared to grafted sites with the post hoc analysis for nonpaired cases. Furthermore, additional augmentation procedure (simultaneously with implant insertion) was required for 13.7% of the implants placed in grafted sites versus 41.6% of the implants placed in nongrafted sites.

3.3 | Soft tissue measurements

Table 3 reports the esthetic outcome of the peri-implant mucosa quantified with the modified PES. The overall Brunner-Longer model showed that the *cort* group had a significant (P values <.05) higher PES score (9.42 ± 0.75) than both *coll* and *ctrl* group (8.53 ± 1.18 and 6.07 ± 1.89, respectively for the *coll*- and *ctrl*-group) at a 4-year

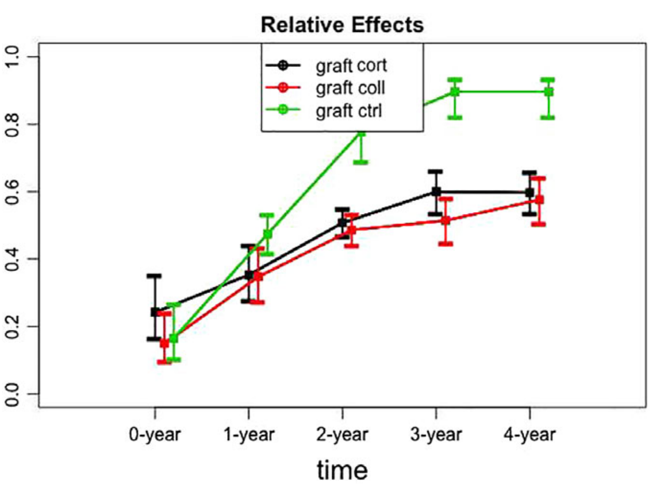

FIGURE 9 Plot of the mean absolute marginal bone level (MBL) at each moment of the follow-up for the *cort* group, *coll* group, and *ctrl* group

evaluation (Figure 10). Unbundling the overall score into its 5 pure addends, the parameter that pushed higher the mean PES for the *cort* group was the root convexity/soft tissue color and texture item. The overall PES did not significantly change between the third and fourth year after restoration. Therefore, 3 years after treatment, the esthetic outcome was stable for the entire cohort (Figure 11). Furthermore, the width of keratinized gingiva (WKG) was significantly influenced by the grafting procedure 4 years after restoration as demonstrated with the Brunner-Langer model (P value < .001): mean WKG was 3.21 ± 0.57 for *cort* group, 3.20 ± 0.67 for *coll* group, and 2.46 ± 0.77 mm for the *ctrl* group.

3.4 | Survival and success rate

The survival rate was 100% for each group 4 years after loading. Regarding success rates, no implants incurred radiographic bone loss greater than 1.5 mm neither during the first year of function nor in the following follow-ups. Thus, the success rate at a 4-year evaluation was 100%.

4 | DISCUSSION

The aim of the present randomized clinical trial was to assess the 4-year clinical and radiological outcome of implants placed in sockets preserved with different grafting materials or healed naturally. The implant survival rate of this study was 100% at a 4-year evaluation. Similar rates have been seen in other studies investigating the ARP procedure.[20,21] Implants showed neither signs nor symptoms of peri-implant disease, and neither surgical nor prosthetic complications; moreover, the success rate was 100% according to Albrektsson criteria. Apostolopoulos and Darby recently reported the results of a retrospective evaluation of success and survival rates of dental implants places after RP with a mean follow-up of 36.5 months: there was a 100% survival rate for implants placed in grafted as well as in naturally healed sockets; on the other hand, the implant success rate was 51% in grafted sites and 58% for nongrafted implant sites.[23] It must be remarked that the authors used different success criteria as defined by Karoussis and colleagues in 2004.[24] That might account for the lower success rate reported by the authors when compared with that of the present study.

Present results showed that peri-implant marginal bone loss was significantly greater in nongrafted sites than in grafted sites at the 4-year evaluation. There were no differences regarding marginal bone change between the collagenated corticocancellous and the cortical porcine bone groups. Both grafts seemed to preserve the peri-implant marginal bone better than the natural healing. This result was in line with previous studies presenting similar experimental design. Walker and colleagues in 2016 compared changes in alveolar ridge dimensions at molar sites following tooth extraction with or without ridge preservation.[25] They found that loss of ridge height was significantly less in the group of preserved alveolar ridges. However, none of the grafts in this study could entirely preserve the pristine ridge contour of the postextractive socket.

A recent meta-analysis synthesized the available information from randomized controlled trials on different grafting materials used in the ridge preservation technique.[26] The results of a Bayesian Network

TABLE 3 Means and medians for each item of the modified PES and the total score at each moment of the follow-up for the 3 groups

Variable	Group	Baseline	1-year	2-years	3-years	4-years
Mesial papilla	*cort*	0.35 ± 0.49	1.42 ± 0.51	1.64 ± 0.49	1.71 ± 0.46	1.71 ± 0.46
		0 **0** 1	1 **1** 2	1 **2** 2	1 **2** 2	1 **2** 2
Distal papilla		0.42 ± 0.51	1.57 ± 0.64	1.71 ± 0.46	1.85 ± 0.36	1.85 ± 0.36
		0 **0** 1	0 **1** 2	1 **2** 2	1 **2** 2	1 **2** 2
Level of soft-tissue margin		1.07 ± 0.61	1.92 ± 0.26	2 ± 0	2 ± 0	2 ± 0
		0 **1** 2	1 **2** 2	2 **2** 2	2 **2** 2	2 **2** 2
Curvature of facial mucosa		0.64 ± 0.63	1.85 ± 0.36	2 ± 0	2 ± 0	2 ± 0
		0 **1** 2	1 **2** 2	2 **2** 2	2 **2** 2	2 **2** 2
Root convexity/soft-tissue color and texture		1.50 ± 0.51	1.85 ± 0.36	1.85 ± 0.36	1.85 ± 0.36	1.85 ± 0.36
		1 **1.5** 2	1 **2** 2	1 **2** 2	1 **2** 2	1 **2** 2
Σ PES score		4 ± 1.56	8.64 ± 1.59	9.21 ± 0.97	9.42 ± 0.75	9.42 ± 0.75
		2 **4** 6	5 **9** 10	7 **9.5** 10	8 **9** 10	8 **9** 10
Mesial papilla	*coll*	0.13 ± 0.35	1.06 ± 0.59	1.66 ± 0.48	1.66 ± 0.48	1.73 ± 0.45
		0 **0** 1	0 **1** 2	1 **2** 2	1 **2** 2	1 **2** 2
Distal papilla		0.13 ± 0.35	1.06 ± 0.70	1.46 ± 0.51	1.66 ± 0.48	1.66 ± 0.48
		0 **0** 1	0 **1** 2	1 **1** 2	1 **2** 2	1 **2** 2
Level of soft-tissue margin		0.93 ± 0.59	1.53 ± 0.51	1.60 ± 0.50	1.80 ± 0.41	1.80 ± 0.41
		0 **1** 2	1 **2** 2	1 **2** 2	1 **2** 2	1 **2** 2
Curvature of facial mucosa		0.66 ± 0.48	1.46 ± 0.51	1.80 ± 0.41	1.86 ± 0.35	1.86 ± 0.35
		0 **1** 1	0 **1** 2	1 **2** 2	1 **2** 2	1 **2** 2
Root convexity/soft-tissue color and texture		1.20 ± 0.41	1.40 ± 0.50	1.46 ± 0.51	1.46 ± 0.51	1.46 ± 0.51
		0 **1** 2	1 **1** 2	1 **1** 2	1 **1** 2	1 **1** 2
Σ PES score		3.06 ± 1.38	6.53 ± 2.13	8.00 ± 1.51	8.46 ± 1.40	8.53 ± 1.18
		1 **3** 6	3 **7** 10	6 **9** 10	7 **9** 10	7 **9** 10
Mesial papilla	*ctrl*	0	1.00 ± 0.40	1.07 ± 0.27	1.07 ± 0.27	1.23 ± 0.43
		0 **0** 0	0 **1** 2	1 **1** 2	1 **1** 2	1 **1** 2
Distal papilla		0	0.84 ± 0.55	1.07 ± 0.49	1.15 ± 0.37	1.30 ± 0.48
		0 **0** 0	0 **1** 2	0 **1** 2	1 **1** 2	1 **1** 2
Level of soft-tissue margin		0.53 ± 0.51	1.15 ± 0.37	1.07 ± 0.49	1.38 ± 0.50	1.38 ± 0.50
		0 **1** 1	1 **1** 2	0 **1** 2	1 **1** 2	1 **1** 2
Curvature of facial mucosa		0.53 ± 0.51	1.23 ± 0.43	1.23 ± 0.43	1.30 ± 0.48	1.30 ± 0.48
		0 **1** 1	1 **1** 2	1 **1** 2	1 **1** 2	1 **1** 2
Root convexity/soft-tissue color and texture		0.69 ± 0.75	0.76 ± 0.72	0.84 ± 0.68	0.84 ± 0.68	0.84 ± 0.68
		0 **1** 2	0 **1** 2	0 **1** 2	0 **1** 2	0 **1** 2
Σ PES score		1.76 ± 1.36	5.00 ± 2.08	5.30 ± 2.01	5.76 ± 1.78	6.07 ± 1.89
		0 **1** 4	2 **5** 10	3 **5** 10	4 **5** 10	4 **5** 10

ATS of factorial model shows that the grafting procedure (*cort*, *coll*, and *ctrl*) and time not only give a significant effect on PES, but also have interaction with each other.

	Degrees of freedom	*P* value	Statistic
Graft	19.910932	1.84	2.343929e–08
Time	182.434367	2.10	2.444623e–83
Graft/time	5.924672	3.78	0.0003947775

The bold is here used for the median since it is an index (PES). The bold is not used for significance values.
Scientific notation for *P* values of the inferential analysis are reported atthe bottom of the table. Overall, significant increase in the PES was observed in the global test. in the paired post hoc tests, the values for the *cort* group were higher than both the *ctrl* and the *coll* group at a 4-year evaluation.

meta-analysis performed by Iocca and colleagues showed that socket grafting is more favorable compared to naturally healed sockets. However, the authors emphasized the fact that an important issue was still unanswered––whether RP should be considered clinically significant in the long-term outcome of dental implants.

Mardas and colleagues, in 2010, concluded that survival and success rates, and marginal bone changes of implants placed in the preserved ridges were comparable to that of implants placed in untreated sockets.[27] However, the meta-analysis investigated only outcomes of trials having a follow-up equal or shorter than 12 months. Furthermore, implants placed in nongrafted sites often required a secondary bone augmentation procedure at the time of implant placement. In the present study, 46% of implants placed within nongrafted sockets needed additional bone augmentation, on

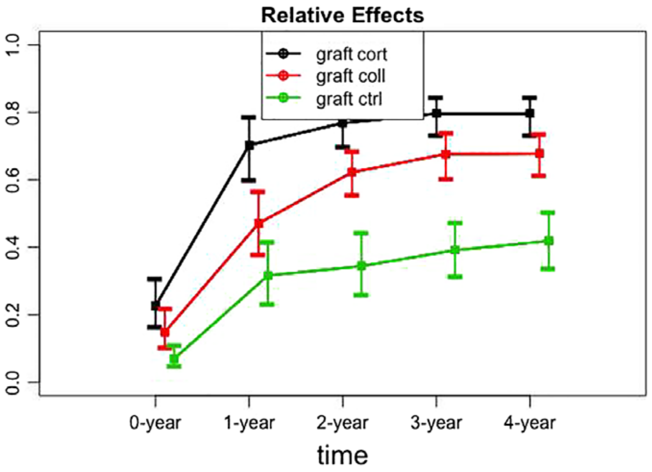

FIGURE 10 Plot of the mean PES at each moment of the follow-up for the *cort* group, *coll* group, and *ctrl* group

the contrary, none of the implants placed in the test groups reported the need for further augmentation at the moment of implant placement.

Ridge preservation is particularly valuable in order to achieve enhanced restorative and esthetic outcomes. In fact, the maintenance of the ridge contour often facilitates the following therapies limiting the risk of esthetic complications. This prospective study had a follow-up period of 4 years and it is, to the best of authors' knowledge, one of the few studies reporting peri-implant soft tissues results over a longer period. The implants within the *cort* group achieved the best PES at a 4-year evaluation. The mean score for this group was significantly higher than both the *coll* and the *ctrl* group, regardless of implant position (molar/premolar). Root convexity was the item that influenced the overall PES the most; it could be speculated that the cortical porcine bone, showing a lower resorption rate over a given amount of time, contributed to a more pronounced vestibular bulge in correspondence of the missing root. Chen and colleagues suggested that bone fillers with a low substitution rate could reduce the amount of postsurgical oro-facial bone resorption and soft tissues recession.[28]

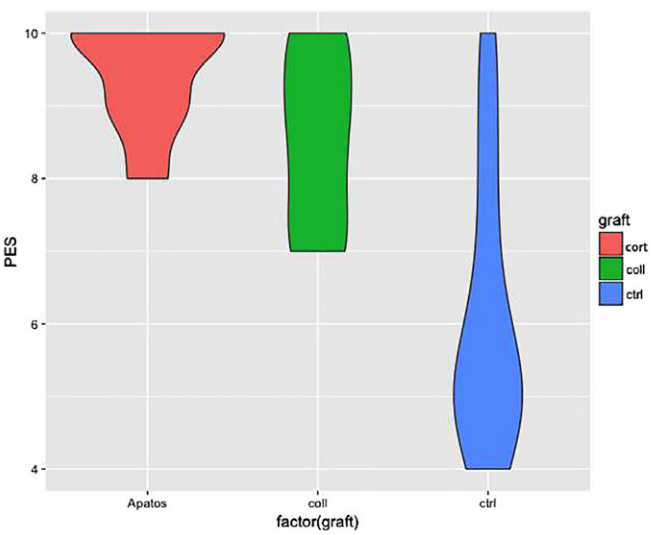

FIGURE 11 Violin plot with mean values and Kernel density distribution of the modified PES for the 3 groups at the 4-year evaluation

Increasing importance has been gained by esthetic parameters in the assessment of implant success. Most of the studies reporting esthetic outcomes in preserved sites were performed in the anterior area, therefore, it is difficult to relate the results of the present study to those of the previous literature. Cosyn and colleagues (2015) reported a mean PES of 11.4 at 12 months in the anterior area treated with ridge preservation and contour augmentation.[29] This value was higher than that reached by the *cort* group in the present study (9.42), but some relevant considerations must be highlighted. The follow-up period of the present study was 4 years that is much longer compared that of the 12-month study by Cosyn, therefore several changes may occur in this time laps (modifications in the adjacent teeth, peri-implant mucosa alterations, patients' discontinuity in following hygiene instructions). Furthermore, the authors of the above-mentioned study performed a connective tissue graft to improve the esthetic outcome whether in the present study none of the sites was treated with additional soft tissues augmentation. Cosyn used the original PES by Furhauser which ranges from 0 to 14 whether in this study the authors used the modified PES by Belser which ranges from 0 to 10.[30] One more thing, Cosyn and colleagues included only patients with thick gingival biotype and without bone defects. Therefore, a cautious interpretation of those data must be done.

Findings from the present study should be interpreted with due caution because there is lack in literature of similar long-term studies on implant outcomes in preserved sites. Furthermore, the significant loss because of patients' follow-up accounted for an important limitation of the present study.

5 | CONCLUSIONS

The 4-year evaluation suggested that the ridge preservation led to better implant clinical outcomes independently from the type of grafting materials. The cortical-porcine bone showed better esthetic results probably because of its property of holding soft tissues for a longer period. Even if results from the present study regarded posterior areas they gave hint of the importance of ridge preservation in order to obtain a favorable alveolar ridge architecture.

CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest with the contents of this article.

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