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Split bone block technique: 4-month results of a randomised clinical trial comparing clinical and radiographic outcomes between autogenous and xenogeneic cortical plates

KEY WORDS

autogenous bone, bone regeneration, randomised clinical trial, xenogeneic bone

ABSTRACT

Purpose: To evaluate short-term clinical and radiographic outcomes of bone regeneration procedures using thin cortical porcine xenogeneic bone plates in combination with autogenous bone chips compared with thin autogenous cortical plates and autogenous bone chips.

Materials and methods: A total of 19 patients (12 women and 7 men, mean age 58.24 ± 3.09 years) were randomly allocated to two different groups regarding surgical procedure: autogenous cortical plates (ACP group) and xenogeneic cortical plates (XCP group). Preoperative CBCT scans were performed for each patient. Surgical time and postoperative pain were recorded, as well as tissue healing and graft resorption after 4 months, then another surgical procedure was performed to place dental implants. Data were analysed using an analysis of covariance.

Results: Twenty-one surgical procedures were performed on 19 patients (10 from the XCP group and 9 from the ACP group). The operative time was significantly lower in the XCP group (25.45 ± 3.88 minutes) than in the ACP group (44.10 ± 3.60 minutes). The XCP group also showed less pain, but not significantly less, than the ACP group. The graft resorption rate in the ACP and XCP groups was 2.03 ± 1.58% and 3.49 ± 2.38% respectively, showing no statistically significant difference.

Conclusions: Despite the limited sample size and non-uniform distribution between the maxilla and mandible as surgical sites, the results suggest that XCP and ACP grafts are similar in terms of bone volume gain and graft resorption rate, with no significant differences in wound healing or complication rate. Nevertheless, the XCP group recorded lower pain levels and required significantly less operative time compared to the ACP group.

Conflict-of-interest statement: *The authors declare there are no conflicts of interest related to this study.*

Introduction

Implant therapy is currently one of the most common and predictable treatments in daily clinical practice for partially or fully edentulous patients, achieving high long-term survival rates[1,2]. An adequate quality and quantity of bone can be considered prerequisites for successful dental implant treatment[3,4]. However, severe bone resorption often precludes the ideal placement of dental implants[5-9]; thus, different procedures such as maxillary sinus elevation, inferior alveolar nerve

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lateralisation and bone augmentation techniques have been proposed to solve this problem, including onlay grafts and guided bone regeneration (GBR), and are widely used for alveolar ridge augmentation prior or simultaneous to implant placement[10]. The main disadvantages of these techniques include their high complication rate and cost, patient discomfort and the fact that they seem to be highly technique-sensitive; as such, their application to a wide community of operators and different clinical settings remains unclear[11].

Recently, a new approach has been described for the treatment of 3D combined bone defects[12]. The aim of this technique is to create a space using autogenous cortical plates (ACPs), which are filled out with particulate autogenous bone to achieve sufficient bone volume augmentation for ideal implant placement. This technique has shown successful results[12,13].

Studies examining this technique harvested a bone block measuring approximately 3 mm wide from the mandibular ramus using a microsaw[12,13]. This block was then divided into two thin cortical plates to make the framework to be filled with autogenous bone chips; this is called the split bone block (SBB) technique[12,13]. This part of surgery, besides being a highly sensitive technique, is extremely time-consuming. Although autogenous bone is considered the gold standard for GBR because of its biological characteristics[14], it would be interesting to look for an alternative to ACP harvesting that exhibits comparable biological behaviour. Such an alternative would make this technique easier, more secure and more profitable for professionals, and less painful for patients.

Xenogeneic biomaterials have been proven to have osteoconductive properties and to be safe in terms of compatibility and foreign body reaction[10]. They also exhibit some advantages in comparison to autogenous bone, such as lower morbidity and unlimited availability. The most widely used type of xenogeneic bone in oral surgery is deproteinised cancellous bovine bone matrix (DBBM) due to its human-like porous structure[15,16]. Alternatives include porcine-derived grafts that have recently been developed and present a crystalline structure very similar to human bone tissues and a higher calcium–phosphate ratio and stiffness than bovine xenogeneic bone[17]. Porcine-derived grafts have shown good bone regeneration properties when used as particulate granules[18]; however, their use as cortical plates to provide a frame for 3D bone regeneration procedures has not yet been described.

The aim of this study was to evaluate the outcome of 3D bone regeneration procedures using thin porcine xenogeneic cortical plates (XCPs) in combination with autogenous bone chips compared with thin ACPs and autogenous bone chips.

Materials and methods

Study design

This clinical study was designed as a randomised clinical trial. Before the study began, the protocol was reviewed and approved by the Ethics Committee at the Hospital Clínico San Carlos, Madrid, Spain (19/551-RP), and the study was conducted in accordance with the principles outlined in the Declaration of Helsinki on clinical studies involving humans. The protocol was also registered in the US National Institutes of Health Clinical Trials Registry (identifier: NCT04205591). The study followed the guidelines for reporting established by the Consolidated Standards of Reporting Trials (CONSORT) checklist (http://www.consort-statement.org/).

Patients

Patients were enrolled in the study if they had insufficient bone height (≤ 6 mm), width (≤ 3 mm) or both in the maxilla or mandible. Smokers (> 10 cigarettes per day) and patients with severe systemic disease (class III or IV according to the American Society of Anaesthesiology [ASA] classification) were excluded. Informed written consent was obtained from all patients after the objectives and protocol of the study and the possible side effects had been explained.

During the study period (from May 2013 to September 2019), 189 patients attended the dental office requesting implant treatment. Among these patients, 19 met the inclusion criteria and

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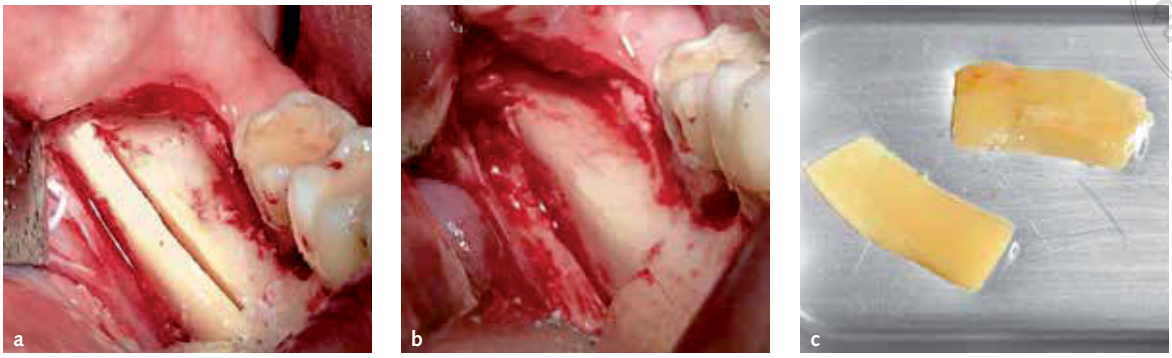
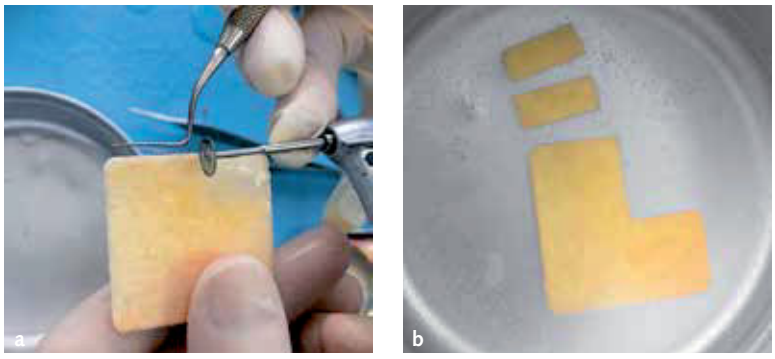


Figs 1a-c **(a)** Bone harvesting osteotomies at the external oblique line. **(b)** Graft obtaining area after autogenous bone block extraction. **(c)** 1.5-mm thick cortical plates resulting from splitting of the autogenous bone block.



Figs 2a-b **(a)** Division of porcine XCP. **(b)** Resulting 1.5-mm thickness laminae.

were recruited for the trial. The study group comprised 12 women and 7 men aged between 23 and 73 years. There was heterogeneity in the systemic diseases present in some of the selected patients, such as diabetes, heart failure and osteoporosis; however, none of these conditions are known to jeopardise implant success[19].

Randomisation

Bone augmentation procedures using ACPs or XCPs were conducted, both using autogenous bone chips to fill the resulting gap. Participants were randomly allocated to either the ACP or XCP group by a blinded assistant. Random allocation was performed using random numbers generated using QuickCalcs software (GraphPad Software, La Jolla, CA, USA). Blocked randomisation was performed to maintain equal group sizes. Allocation concealment was assured by a study monitor who was not involved in the clinical aspects of the trial. Treatment allocation was done using sealed opaque envelopes that were opened before starting the surgery. As a result, nine patients were randomly assigned to the ACP group and nine to the XCP group, two of whom (one from each group) underwent two surgical procedures. All surgical procedures were performed by the same oral surgeon (JT) with extensive experience in performing regenerative techniques on dental implants.

Obtaining and adapting grafts

To obtain ACP, an approximately 3-mm thick bone block was harvested from the external oblique line of the mandible using a Piezosurgery device (Mectron, Carasco, Italy). Inserts OT7 and OT6 were used for cutting parallel to the handpiece and OP1 for a 90-degree angled cutting motion, cooled with sterile physiological solution. The block was split using a microsaw (Frios MicroSaw, Dentsply Sirona, Charlotte, NC, USA) following the SBB technique to obtain two ACPs with a thickness of around 1.5 mm (Fig 1).

Xenogeneic graft consists of a thin porcine cortical plate (OsteoBiol Lamina, Tecnoss, Giaveno, Italy). The microsaw used to split the cortical bone lamina was the same as that used in the autogenous bone block splitting procedure (Fig 2).

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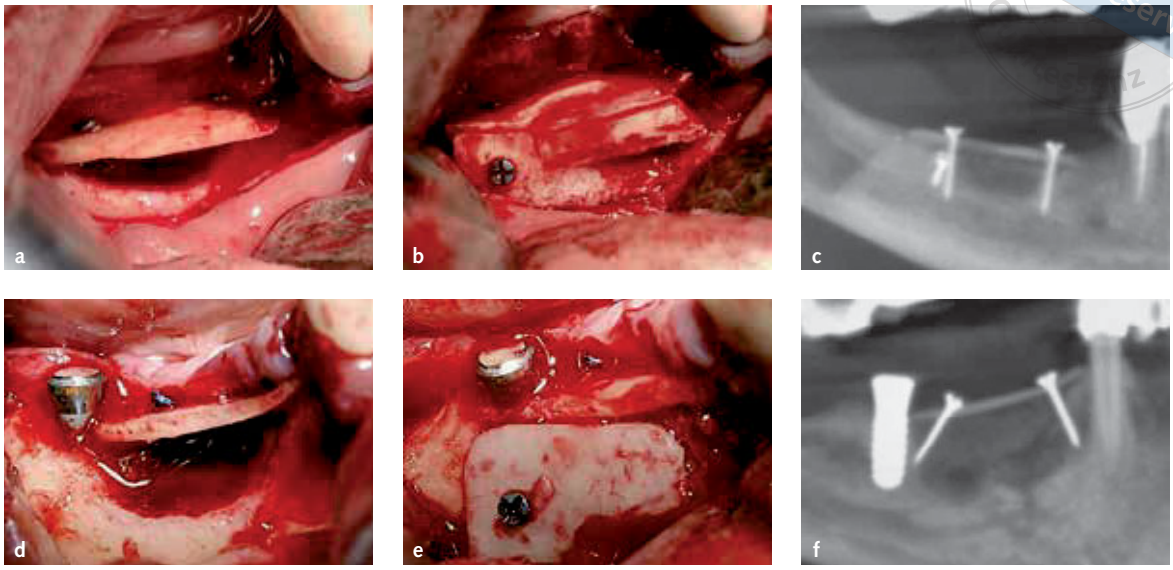

Figs 3a-f Bone frameworks created using **(a-c)** ACPs and **(d-f)** porcine XCPs and their radiographic aspect immediately after surgery.

In both groups, autogenous bone chips, which filled the framework created, were harvested from the external oblique line of the mandible using a bone scraper (Curved Safescraper Twist, Meta, Reggio Emilia, Italy).

Surgical procedure

All patients were clinically assessed and a preoperative CBCT scan was taken with a 9000 3D unit (120 kVp, 20.27 mAs, 14.7 s, field of view 8 cm × 8 cm) (KODAK Dental Systems, Carestream Health, Rochester, NY, USA) to evaluate the bone defect morphology, calculate the amount of graft needed and plan the surgical procedure. All procedures were performed under local anaesthesia with 4% articaine and 1:100,000 adrenaline (Ultracain D-S Forte, Sanofi-Aventis, Paris, France).

Cortical plate harvesting procedure

In the ACP group, a horizontal crestal incision was designed and a full-thickness flap was raised to correctly access and visualise the hard tissue. The autogenous bone block was then harvested from the mandibular ramus, along the external oblique line, using a Piezosurgery to perform the osteotomy. Three osteotomies were carried out based on bone block size: two vertical osteotomies (mesial and distal) and one horizontal osteotomy that connected the two vertical osteotomies by their most apical side. A thin chisel was used to connect the osteotomies and continue the extraction of the bone block. The bone block was then split into two plates that were approximately 1.5 mm thick to form the graft framework. The donor site was closed using 5/0 non-resorbable sutures (Supramid, Serag-Wiessner, Naila, Germany).

In the XCP group, the only procedure performed was the splitting of the porcine bone lamina following the same guidelines as in the ACP group.

3D bone reconstruction procedure

In both groups, a bone scraper was used to obtain autogenous bone chips from the external oblique line and the plates were smoothed to remove any sharp edges that could later jeopardise soft tissue healing. The two plates were fixed to the buccal and lingual/palatal side of the bone defect using osteosynthesis screws (AO/ASIF 4.0 self-drilling screws, Synthes, Umkirch, Germany) (1.2 mm diameter, 10 mm length), creating a gap that was filled with the bone chips harvested previously (Fig 3).

Finally, the flaps were repositioned to cover the bone grafts completely, with periosteal releasing

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incisions made to allow tension-free closure of the flaps with 4/0 nylon sutures (Serag-Wiessner).

After surgery, patients received 4 mg dexamethasone by intramuscular injection. Postoperative antibiotic therapy (1 g amoxicillin every 8 hours for the following 7 days) was prescribed to all patients, and postoperative instructions included a liquid/soft diet for 2 weeks and 0.12% chlorhexidine mouthrinse until suture removal, which took place 12 to 14 days after surgery. During the postoperative period, patients were not allowed to wear prostheses for a minimum of 8 weeks. After 4 months, patients underwent another clinical and radiographic examination with CBCT, then further surgery was performed to remove the fixation screws and place dental implants.

Outcome variables

Operative time

In the ACP group, operative time was measured from the moment immediately after exposure of the bone defect until the final wound closure, including the harvesting of the bone block and filling chips, the cortical plate splitting procedure, its fixation to the buccal and lingual/palatal side of the bone defect using osteosynthesis screws and the filling of the framework with the bone chips harvested previously. In the same way, in the XCP group the time was measured from the exposure of the bone defect until the bone framework was completely filled and the wound was sealed, including the harvesting of bone chips from the external oblique line.

Postoperative pain

Pain was classified into three categories based on total analgesic drug consumption (1 g paracetamol, maximum three tablets per day) after surgical treatment: severe pain, when the patient took more than eight painkillers; moderate pain, when the patient took four to eight painkillers; or mild pain, when the patient needed fewer than four painkillers.

Tissue healing

To evaluate soft tissue healing, photographic records were taken of each patient 7 days, 15 days, 21 days, 1 month, 2 months and 3 months after surgery. Two trained observers (IFT and JT), both dentists with expertise in oral surgery, scored the photographs independently according to the healing index proposed by Landry et al[20]. The Cohen Kappa index was applied to assess the agreement between the two observers, achieving 94% intra-examiner reproducibility.

Radiographic analysis

Preoperative and postoperative CBCT scans were taken of all patients using a 9000 3D unit. All scans were exported in Digital Imaging and Communications in Medicine (DICOM) format and saved in files coded for the image acquisition protocol. DICOM images were assessed using DICOM viewer software (OsiriX version 8.0.1, Pixmeo, Geneva, Switzerland).

Bone augmentation of the surgical sites was measured on immediate postoperative parasagittal CBCT scans using OsiriX. The analysis was carried out using the closed polygon tool within a region of interest (ROI) containing the entire trabecular bone area of the alveolar ridge.

Postoperative CBCT scans were taken 4 months after surgery. The final area of regenerated bone was measured using the closed polygon tool, outlining the remaining area of regenerated bone in the bone framework.

All measurements were performed in a random order by two trained observers (IFT and JT), dentists with expertise in oral radiology. Intra-observer reliability was assessed between measurements performed 2 weeks apart to eliminate memory bias, and three measurements were taken from each site and averaged. Intra- and inter-observer agreement were assessed using the intraclass correlation coefficient (ICC) for continuous variables (0.91, $P < 0.001$ and 0.85, $P = 0.001$, respectively).

After implant placement, periapical control radiographs were taken to assess peri-implant bone resorption (Fig 4).

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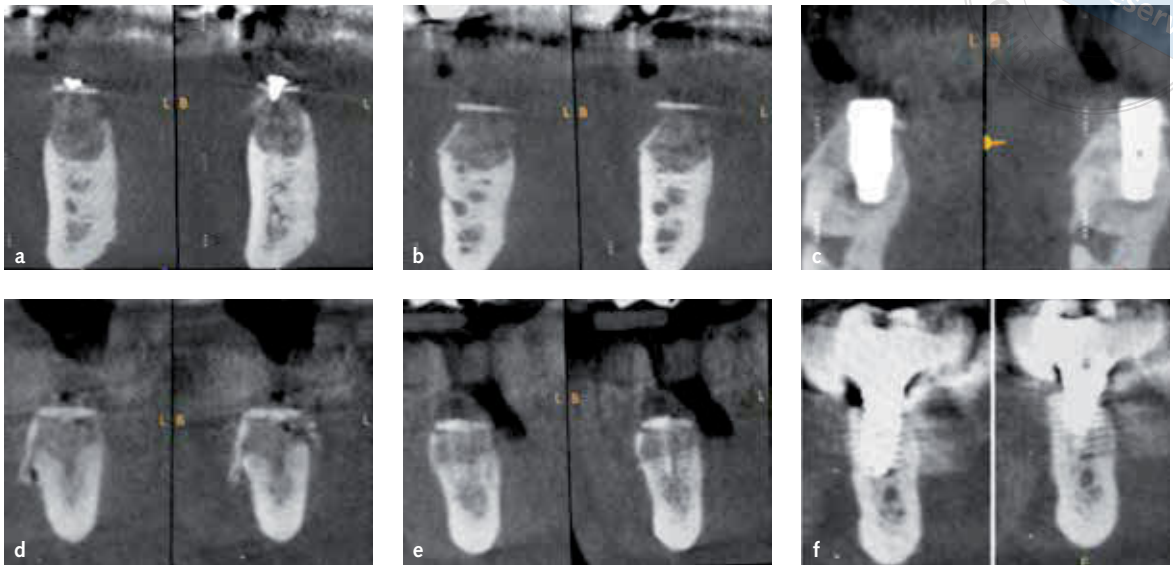

Figs 4a-f Bone volume variations over time: XCP regeneration **(a)** immediately after surgery, **(b)** after 4 months healing and **(c)** at implant placement, and ACP regeneration **(d)** immediately after surgery, **(e)** after 4 months healing and **(f)** at implant placement.

Implant outcomes

Implant survival was assessed based on radiographic marginal bone loss (MBL), probing pocket depth (PPD) and the presence of bleeding on probing (BoP) measured at baseline and after 1, 2, 3 and 4 years. MBL was measured by taking intraoral periapical radiographs using a parallel technique (VistaScan, Dürr, Bietigheim-Bissingen, Germany) and using image analysis software (CS 3D Imaging Software, Carestream Dental, Atlanta, GA, USA). Implant connections were used as the reference point for measuring MBL, which was assessed as the distance from the bone level existing at the mesial and distal implant surfaces to the aforementioned reference point. Image magnification was determined and calibrated using the known distance between the first four implant threads. PPD and BoP were measured in six different sites for each implant.

Statistical analysis

The sample size calculation was based on the primary outcome parameter, resorption, and performed using the data of a previous pilot study conducted in the Faculty of Odontology at Complutense University of Madrid, (identifier 19/551-R_P), considering a type I error rate of 5% and a type II error rate of 20%. Four patients were included in the pilot study, the mean resorption rate of the two ACP groups and two XCP groups was 2.58 ± 1.96 and 5.24 ± 2.09, respectively, and the common standard deviation (SD) was 2.03, to obtain 80% power to detect a statistically significant difference ($\alpha = 0.05$). This estimation resulted in a total of eight patients per group, but this was increased to nine to prevent attrition bias due to potential patient withdrawals.

Normality and homogeneity of variances were assessed using a Shapiro-Wilk and Levene test, respectively. All variables were analysed using an analysis of covariance (ANCOVA) in order to evaluate the independent effect of each variable (age, sex, smoking, operative time, postoperative pain, healing time and graft type) on the main variable (bone resorption). Additionally, a chi-square and Student *t* test were used to independently evaluate the influence of graft type on postoperative pain and operative time, respectively. Implant outcomes were analysed using a repeated measures analysis of variance (ANOVA), comparing MBL in both groups at baseline and 1, 2, 3 and 4 years after prothesis delivery. All statistical tests were performed at a significance level of 5%,

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Table 1 Characteristics of the study sample

Group									
XCP (n = 11)					ACP (n = 10)				
Patient	Sex (M/F)	Age (y)	Smoking (Y/N)	Area (Mx/Mb)	Patient	Sex (M/F)	Age (y)	Smoking (Y/N)	Area (Mx/Mb)
1	M	66	N	Mb	1	F	61	N	Mb
2*	F	49	N	Mb	2	M	73	N	Mb
3	F	37	N	Mb	3	M	68	Y	Mx
4	M	70	Y	Mb	4*	F	72	N	Mb
5	F	55	Y	Mb	5	F	49	N	Mx
6	F	55	N	Mb	6	F	23	N	Mx
7	M	57	N	Mx	7	M	58	N	Mx
8	F	64	Y	Mx	8	F	72	N	Mx
9	F	79	N	Mx	9	M	36	N	Mx
10	F	58	N	Mb					
Total	3/7	59.0 ± 11.6	3/7	3/7	Total	4/5	56.8 ± 17.7	1/8	6/3

Mb, mandible; Mx, maxilla.
*Patients who received two different surgical procedures.

Table 2 Main outcomes

Outcome	ACP	XCP	*P* value
Operative time (minutes)	44.10 ± 3.60	25.45 ± 3.88	< 0.01
Postoperative pain (%)	Mild: 30	Mild: 63.6	> 0.05
	Moderate: 70	Moderate: 36.4	
	Severe: 0	Severe: 0	
Dehiscence	1	2	> 0.05
Bone resorption (%)	2.03 ± 1.58	3.49 ± 2.38	> 0.05

using SPSS software (version 22.0, IBM, Armonk, NY, USA).

Results

During the study period, 189 patients were evaluated, 19 (12 women and 7 men) of whom met the inclusion criteria and were recruited for this randomised controlled clinical trial. A total of 21 SBB procedures were performed: 10 in the ACP group and 11 in the XCP group. The mean age of the patients was 58.24 ± 3.09 years (range 51.79 to 64.69 years). Only four patients (one in the ACP group and three in the XCP group) were smokers, and only three (one in the ACP group and two in the XCP group) took any form of drugs, none of which were known to jeopardise implant success. Nine surgical procedures were performed in the maxilla (six in the ACP group and three in the XCP group) and 12 in the mandible (four in the ACP group and eight in the XCP group), with the latter being the area most frequently operated on, specifically the fourth quadrant. The characteristics of the study sample are detailed in Table 1.

Operative time

The mean operative time was 34.33 ± 2.23 minutes (range 29.68 to 38.99 minutes). It was significantly greater in the ACP group than in the XCP group (44.10 ± 3.60 minutes vs. 25.45 ± 3.88 minutes; $P < 0.01$) (Table 2).

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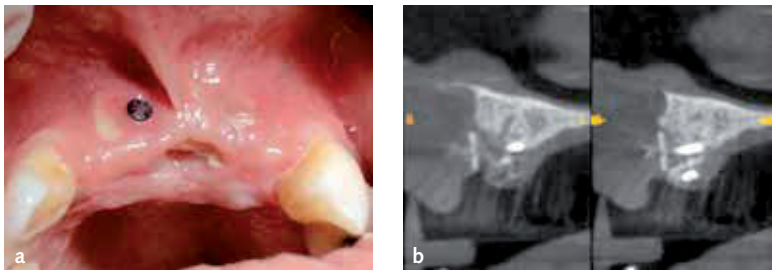

Figs 5a-b Tissue dehiscence and graft exposure causing regeneration failure.

Postoperative pain

Ten surgical procedures were rated as mildly painful and 11 as moderately painful. No patients classified the surgery as severely painful. In the ACP group, 70% of patients had moderate pain while only 36.4% in the XCP group experienced the same, although this difference was not statistically significant ($P > 0.05$) (Table 2).

Tissue healing

Healing was uneventful in 16 patients; however, during the 4-month period following bone graft placement, three patients presented partial graft exposure in one site (15%): one graft in one patient in the ACP group and two grafts in two different patients in the XCP group. The mean healing period was 5.19 ± 0.49 months (range 4 to 14 months, confidence interval 4.18–6.20). There were no statistically significant differences between the groups in terms of graft exposure or healing period.

After 4 months, another surgical procedure was performed, to remove the fixation screws and place dental implants. At this stage, the clinical observation revealed that 18 grafts were correctly incorporated (nine in the ACP group and nine in the XCP group), since they were fixed to the recipient site and kept immobile, and sufficient new bone formation for implant placement was achieved. In cases with tissue dehiscence and graft exposure, bone augmentation was not achieved (Fig 5). No dropouts were registered during the observation period.

Radiographic outcomes

The preoperative and postoperative CBCT scans were analysed using OsiriX. In the ACP group, the mean bone volume measured on the preoperative CBCT scan was 50.00 ± 19.65 mm³ and after 4 months, the mean resorption was 2.03 ± 1.58%. On the other hand, the XCP group recorded a mean bone volume of 46.72 ± 15.40 mm³ on the postoperative CBCT scan, showing mean resorption of 3.49 ± 2.38% after the healing period. The difference between bone resorption in both groups was not statistically significant.

The cases in which graft exposure occurred (one in the ACP group and two in the XCP group) were excluded from the radiographic analysis, resulting in nine cases per group, because soft tissue dehiscence can compromise graft incorporation and revascularisation (Fig 5).

Implant outcomes

A total of 36 implants were placed, 19 in the ACP group and 17 in the XCP group. No adverse events related to implant surgery were recorded. After a follow-up period of 4 years, no implant failure was observed, resulting in a 100% survival rate.

Regarding PPD in the ACP group, the measurements were 2.89 ± 0.81 mm at baseline; 3.41 ± 0.85 mm at 1 year, computed from 19 implants; 3.90 ± 1.12 mm at 2 years from 17 implants; 4.28 ± 1.15 mm at 3 years from 13 implants; and 4.40 ± 1.23 mm at 4 years from nine implants. The XCP group reported 3.38 ± 0.72 mm at baseline; 3.92 ± 0.93 mm at 1 year from 17 implants; 4.22 ± 1.25 mm at 2 years from 15 implants; 4.40 ± 1.37 mm at 3 years from nine implants; and 4.57 ± 1.58 mm at 4 years from five implants.

The ACP group recorded mean MBL of 0.64 ± 0.31 mm, 0.80 ± 0.26 mm, 0.96 ± 0.22 mm and 1.11 ± 0.18 mm at 1, 2, 3 and 4 years, respectively,

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whereas the XCP group recorded mean MBL of 0.50 ± 0.28 mm, 0.61 ± 0.29 mm, 0.69 ± 0.38 mm and 0.82 ± 0.10 mm at 1, 2, 3 and 4 years, respectively (Fig 6). No statistically significant differences were observed between the groups ($P > 0.05$).

For BoP, in the ACP group none was noticed at baseline, then one implant presented BoP at 1 year (5%), three at 2 years (16%), two at 3 years (15%) and two at 4 years (22%), whereas in the XCP group one implant presented BoP at baseline (6%), three at 1 year (18%), two at 2 years (13%), two at 3 years (22%) and one at 4 years (20%).

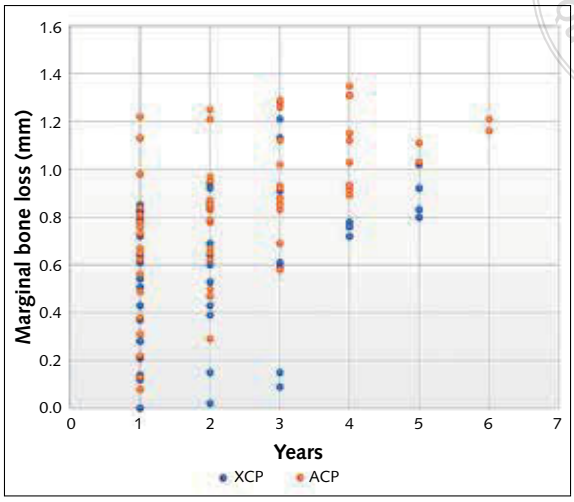

Fig 6 Scatter plot of MBL in both groups.

Discussion

No statistical differences were observed between performing surgery with ACPs or porcine XCPs in terms of resorption, although operative time tended to be shorter and postoperative pain tended to be less severe in the XCP group. The aim of this study was to assess the clinical outcomes of a novel surgical GBR procedure in atrophic edentulous maxillary and mandibular regions using porcine cortical plates to form a framework to be filled with particulate autogenous bone. The main objective was to compare this new approach with the gold standard technique first proposed by Khoury and Hanser[12], which offers a biocompatible and mechanically stable concept for space maintenance and blood clot protection.

The use of autogenous bone is the gold standard for GBR due to its osteogenic, osteoinductive and osteoconductive capacities, along with the impossibility of producing an immune reaction. A large variety of intra- and extraoral donor sites have been described, but intraoral sites offer more advantages, such as easy surgical access and minimal postoperative morbidity[21,22]. However, the main disadvantage of autogenous intraoral grafts, and specifically those taken from the mandibular ramus, is the limited availability of bone due to its reduced thickness and the possibility of inferior alveolar nerve injury. A study performed by Kane et al[23] showed a mean distance between buccal cortical bone and the inferior alveolar nerve of 4.7 mm. Yu and Wong[24] recorded a mean distance of 7.2 mm at the second molar, considering cuts less than 5 mm deep as safe. These data must be interpreted cautiously, considering centrifugal and vertical resorption suffered by the mandible due to tooth loss[25].

The use of xenogeneic grafts provides an unlimited bone quantity and avoids the surgical complications associated with the SBB technique. Several xenogeneic grafts of different origins have been developed over the past decades, with bovine xenogeneic bone being the first applied to human patients and the most frequently studied[22]. Recently, porcine bone grafts have been developed that display similar characteristics to human bone and present a relatively lower risk of zoonosis than bovine xenogeneic bone[22]. Moreover, studies have demonstrated that bovine and porcine xenogeneic bone are similar in their cell response and bone regeneration properties[17,26]. However, the few available studies about porcine xenogeneic bone refer to its use as a particulate biomaterial, the present randomised clinical trial being the first to study the behaviour of porcine XCPs following the SBB technique.

The ACP group recorded greater horizontal bone augmentation, whereas the XCP group achieved greater vertical bone augmentation. When comparing the ACP data from different studies to those in the present study, some variations can be highlighted, since authors like Khoury and Hanser[13] and Yu and Wong[24] obtained higher

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values but others like Merli et al[27] recorded values lower than or similar to those in the present study. The present authors found no significant differences between groups in terms of bone resorption. It was difficult to compare the present results to those from previous studies, as there are no human clinical trials comparing porcine XCPs and ACPs with this technique. Taking other techniques into consideration, the present data are in agreement with Thoma et al[28] who reported no significant differences when comparing the resorption of xenogeneic and autogenous bone blocks after 4 months.

Although other authors have described similar postoperative discomfort when comparing harvesting bone blocks and bone chips for the external oblique line[29], the present results indicate that harvesting both blocks and chips leads to higher postoperative discomfort compared to bone chips alone; this may be a result of the longer operative time.

One of the most significant advantages of using non-autogenous bone grafts is the remarkable reduction in surgical time. A study by the developers of the original technique recorded time values ranging from 4.5 to 15 minutes depending on the degree of corticalisation of mandibular bone, from the beginning of the osteotomy to the total luxation of mandibular bone block, omitting the time required for bone splitting[12]. In the present study, the total surgical time required to make the framework in each group was recorded, with a mean time of 44.10 ± 3.60 minutes in the ACP group and 25.45 ± 3.88 minutes in the XCP group. The time required for the surgical procedure performed using porcine XCPs was considerably shorter as it was only necessary to trim the plate, saving approximately 20 minutes. Another variable to consider is the specific instrumentation necessary to remove the block, such as Piezosurgery[30] or microsaws[12]; such instruments are not required for this technique, which also leads to lower cost.

The 'Khoury technique' has a low complication rate, with minor nerve injury and moderate pain being the most frequent complications[12]. Severe graft resorption and graft lost due to postoperative graft site infection or donor site infection are also early complications that must be considered with this technique[31]. In the present study, painkiller intake after surgery was evaluated to estimate the pain level. The outcomes for the ACP group were in line with those for the original technique, but in the XCP group most of the surgical procedures (70%) were classified as mildly painful by the patients, probably due to the fact that bone block extraction was not required; this is in accordance with data obtained by Thoma et al[28] who performed a study using xenogeneic bone blocks and autogenous bone blocks for lateral ridge augmentation in the mandible. In addition, no statistically significant correlations could be established between pain and operative time, most likely due to the small sample size. Previous studies considered operative time as a risk factor for postoperative complications following oral surgery[32,33], but the present study did not yield significant results in this respect.

In the present study, four of the 21 surgical procedures performed led to complications: three complications were dehiscences (one in the ACP group and two in the XCP group) and one was nerve injury with paraesthesia (ACP group) (Table 2). With the exception of nerve damage, these complications could probably have been avoided with better soft tissue handling and use of muscular dissection and/or perioplasty to reduce flap tension[27]. Dehiscence was found to be a major complication that resulted in a significant loss of bone graft, even though the exposure rate seems to be similar to other bone augmentation techniques, such as those obtained by titanium mesh[34].

Regarding implant outcomes, a 100.0% survival rate was achieved in both groups after a follow-up period of 2 to 4 years. These data are in accordance with those obtained by Khoury and Hanser[13], who reported an implant survival rate of 100.0% after 3 years and 98.7% after 10 years. De Stavola and Tunkel[35] and Cordaro et al[36] reported survival rates of 100.0% for implant treatments after similar graft surgeries at 1 year and 32 to 48 months, respectively.

Limitations and future directions

This study had a relatively short and heterogeneous follow-up period because the follow-up interval

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was from 2 to 4 years. The small sample size and imbalances in the surgical site distribution were the main limitations that prevented predicable conclusions from being obtained. Further studies with a larger sample size and examining the same surgical sites are required to assess the present results.

Conclusions

Despite the limitations of this study, the results indicated that both ACP and XCP obtained similar outcomes in terms of bone volume gain and graft resorption after 4 months. XCP was not found to display any benefits compared to ACP apart from reduced operative time; however, further studies should be conducted to address the possible advantages of XCP.

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