A new technique of alveolar bone augmentation: "Pack into Bone". A retrospective case-series study

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Abstract: Purpose: To provide an overview of an innovative surgical approach to guided bone regeneration, the Pack Into Bone (PIB) technique. **Methods:** Twenty subjects, eight men and 12 women, aged 34 to 68 (mean 51.5) were selected. They were treated with the PiB technique, and upon re-entry surgery, performed 8 months postoperatively, implants were placed, and bone samples were collected by using trephine burs for histological and histomorphometric analysis purposes. **Results:** Mean ridge width varied between 4.71 (W0) mm and 7.37 mm (W1), measured 8 months postoperatively, with a mean W augmentation of 2.69 mm ± 0.19. Mean height ranged between 8.0 mm (H0) and 11.15 mm (H1), measured 8 months after surgery with a mean augmentation of 3.53 mm ± 0.14 ($P < 0.05$). (*Am J Dent* 2024;37:41A-44A).

Clinical significance: Stability and versatility are the pillars of the PIB technique compared to common GBRs. The PIB technique is effective and reduces the difficulty in stabilizing the graft, is more feasible for operators, and decreases morbidity for the subjects.

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Introduction

There are several ridge augmentation techniques employed as effective solutions to regenerate bone for dental implant purposes.[1] Some of the methods are autogenous bone block grafts, alveolar ridge split expansion, alveolar distraction, osteogenesis and guided bone regeneration (GBR).[2,3] Bone grafting can be autologous, homologous or heterologous (porcine or equine), with varying success rates, averaging 95%.[1]

Some techniques using autologous bone can be invasive and require intraoral harvesting from the ascending mandibular ramus[4] or symphysis or maxillary tuberosity. Over time, it has been shown that surgeons can achieve equal or better results without autogenous grafts.[3]

Hämmerle et al[5] reported no statistically significant differences in implant longevity between native and regenerated bone.

Recently, slowly resorbable porcine heterologous cortical bone lamina have been introduced and some authors have used them to regenerate bone defects to increase the bone volume needed for implantation.[6,7]

Porcine membranes and bone grafts are compatible with human tissue and reduce the likelihood of graft infection, compared to non-resorbable membranes and titanium mesh, which have been shown to have a high rate of complications (e.g., membrane exposure, infection, and more invasive reinterventions).

This study evaluated the efficacy in treating horizontal and vertical crestal defects of a technique, namely the "Pack into Bone Technique" (PIB), in which the particle graft is wrapped in a collagen membrane and then placed into the area bound by the porcine cortical lamina. The results were analyzed 8 months after the procedure by histological, histomorphometric and radiographic analysis of the bone ridge.

Materials and Methods

The study is a retrospective case series, and 20 patients were treated between September 2021 and October 2023. All subjects were informed of the procedures they would undergo and provided full informed consent. The Declaration of Helsinki guidelines, as revised in 2013, were followed in the present investigation (Protocol number 4729)..

Inclusion/exclusion criteria - Inclusion criteria were as follows: (1) At least 18 years of age; (2) Proper oral hygiene; (3) Bone augmentation procedure is required to achieve the correct horizontal and/or vertical dimension of the edentulous ridge for placement of one or more implants in a prosthetically guided position; (4) Willingness to undergo follow-up examinations.

Exclusion criteria – (1) General contraindication to surgical intervention; (2) Patient undergoing bisphosphonate therapy; (3) Radiotherapy history of head and neck in the past 5 years; (4) Uncontrolled systemic diseases, hindering the standard healing process (i.e., diabetes); (5) Occurrence of acute infection sites that could not be resolved at extraction; (6) Untreated periodontal diseases; (7) Smoking habits (> 10 cigarettes/day).

All 20 clinical cases met the above inclusion/exclusion criteria.

Pre-treatment - Before surgery, all subjects underwent a preparation phase which included mechanical debridement (with ultrasonic and manual instruments, if necessary) to achieve a Full Mouth Bleeding Score (FMBS) and Full Mouth Plaque Score (FMPS) ≤ 15. The subjects' age, sex, and dental status were recorded, and their dental history was updated immediately before surgery.

Surgical procedure - All subjects underwent antibiotic prophylaxis 1 hour before surgery with 2 g amoxicillin + clavulanic acid in tablets (amoxicillin 875 mg + clavulanic acid

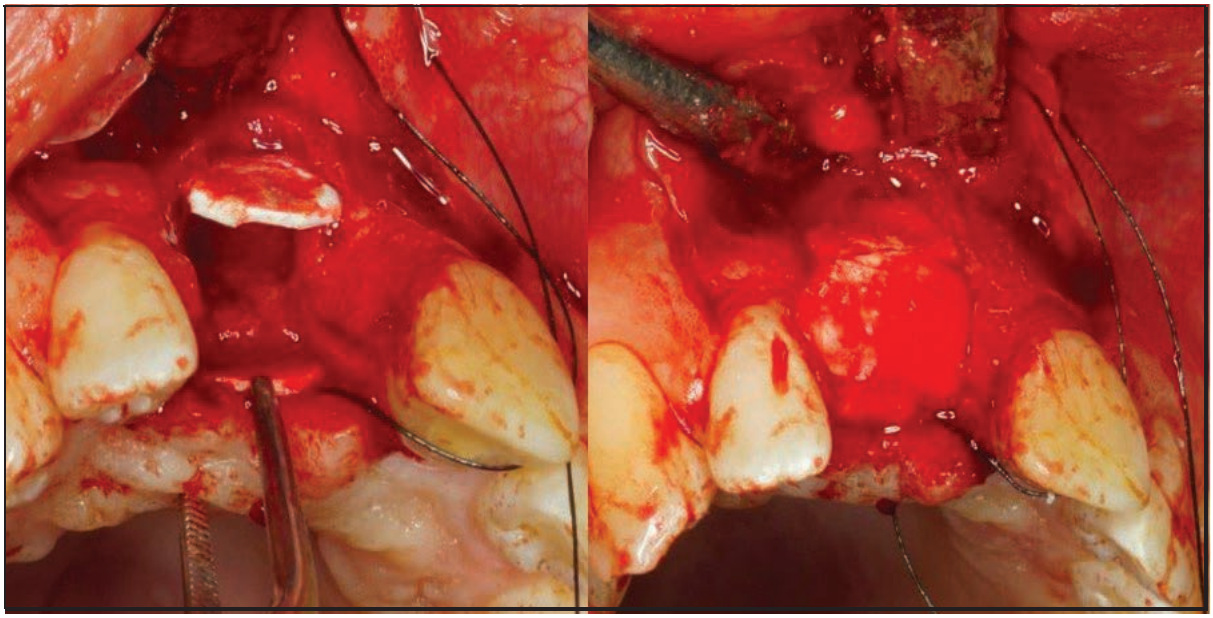

Fig. 1. Bone augmentation with "Pack-into-Bone" technique in zone 1.1. **A.** insertion of the OsteoBiol Lamina 0.5 mm into the slot. **B.** insertion of the "pack" into the created space.

125 mg × 2 tablets) and a 1-minute mouthrinse with 0.20% chlorhexidine digluconate (Curasept ADS[a]), immediately before the procedure. After administration of local anesthesia (4% articaine,1:100,000 with adrenaline[b]), a crestal incision was performed in the edentulous area, continuing with an intrasulcular incision in the closest adjacent teeth on both sides of the defect, and a vestibular full-thickness flap and a lingual full-thickness flap were raised. Dedicated piezoelectric osteotomy tips (OT7-OT1[c]) were used to create a 2 mm slot on the wall of the bone defect area to insert and stabilize a heterologous cortical lamina (OsteoBiol Lamina,[d] thickness 0.4-0.6 mm), and, to foster blood clot formation, some perforations were made on the cortical bone of the edentulous area with small round piezoelectric tip (OT-13[c]). The lamina, which had a semi-rigid consistency and did not need to be hydrated before application, was then shaped with sterile scissors and inserted into the surgically prepared slot, creating a space into which the osteoconductive bone material could be placed (Fig. 1A). The space between the lamina and the crestal wall of the defect was filled with the "pack": a 1:1 mixture of dual-phase heterologous bone (OsteoBiol GTO[d]) and autologous bone chips retrieved with a scraper from the apical surgical area of the bone defect, wrapped in the micro-rough side of the collagen membrane (OsteoBiol Evolution[d]) (the other side is smooth) (Fig. 1B). The "pack" filling the empty area is compacted and self-stabilizes due to the binding properties of the membrane and collagen gel (OsteoBiol TSV[d] Gel), contained in the OsteoBiol GTO.

In cases where the bone ridge allowed, implants were inserted after the slot was created and before the graft material was placed, using the implant to anchor and suture the “pack”.

The flap was then closed with a single line of interrupted sutures, which were removed 14 days after surgery.

Subjects were prescribed post-operative antibiotics for 6 days (amoxicillin 875 mg + clavulanic acid 125 mg 2/day) and anti-inflammatory therapy (ibuprofen 400 mg 3/day, days 1-2; 400 mg 2/day, days 3-4).

After completion of the PIB procedure, graft healing was monitored at 1, 2 and 4 weeks. In cases where only ridge augmentation was performed, implants were placed after 8 months. After a full-thickness flap was lifted and graft stability was established, implants were placed using a submerged healing protocol (Helix GM[e]).

Before implant site preparation, biopsies of the augmented bone hard tissue were taken with a 3 mm diameter trephine bur when allowed by the planned implant size. Each biopsy specimen was assigned a unique identification number.

After 3 months of healing, implants were uncovered, and healing abutments were collocated for prosthetic rehabilitation, while 8 months were instead necessary for cases of simultaneous implantation and regeneration.

Histological and histomorphometric analyses - Cored bone tissue was fixed in 10% phosphate-buffered formalin and subsequently decalcified in a hydrochloric acid/formic acid solution (4/5%). After decalcification, cored tissue was dehydrated in a series of alcohol baths and then embedded in paraffin. Histological sections (5 μm-thick) were then prepared and stained with hematoxylin/eosin. The slides were digitally scanned at various magnification levels. Histomorphometric analyses were performed using the ImageJ[f] software to evaluate the presence and features of the new bone tissue, of the spare grafted material, and the integration of the grafted material with the surrounding tissues. On each slide, the percentage of bone, not resorbed biomaterial, and soft tissue (either bone marrow or unmineralized connective tissue) were measured.

Radiographic analysis - A post-op CT scan was done 8 months following the regenerative surgery and before the second procedure; sagittal cuts of the pre-operative and post-operative CT scan were superimposed, using the adjacent teeth as reference. On the preoperative scan (T0), presurgical crestal width (W0) and presurgical crestal height (H0) linear measurements were made near the implant insertion site. Without altering the palatal and apical reference points, the

postsurgical (T1) crestal width (W1) and postsurgical crestal height (H1) were measured linearly on the postoperative scan. Horizontal bone gain (WG) and (HG) vertical bone gain was then measured as the difference between W1 and W0, and H1 and H0. When more than one implant was planned, only the largest horizontal and vertical bone gain was sampled for the analyses. All linear measurements were taken with coDiagnostiX[g] software, rounded to the nearest 0.1 mm. Both pre-op and post-op CT scan were done with the CBCT Newtom 5G XL[h]

Statistical analysis - Continuous variables were reported as mean ± standard deviation (standard error for differences). Variables were compared between baseline and after 8 months. Because of the non-normal distribution (Shapiro-Wilk test) and reduced sample size, Wilcoxon's paired-sample signed ranks test was employed for within-group comparison; the significance level was set at $P< 0.05$. Statistical analysis was conducted with R statistical software.[i]

Results

The results of this study showed that the PIB approach was effective in treating 20 subjects. Eight men and 12 women, aged 34 to 68 years (mean 51.5), were treated. All cases healed adequately with no complications that compromised graft integration.

In six of these cases, implants were placed at the same time as crestal regeneration, while 10 biopsy samples were taken at the regeneration-only sites.

Mean ridge width varied between 4.71 (W0) mm and 7.37 mm (W1), measured 8 months postoperatively, with a mean WG of 2.69 mm ± 0.19. At the same time, the mean height ranged between 8.0 mm (H0) and 11.15 mm (H1), measured 8 months after surgery with a mean HG of 3.53 mm ± 0.14. These differences were considered statistically significant ($P< 0.05$). The increments obtained allowed adequate bone support for the implants.

Histological samples had a composition of 44.1% ± 23.9 of vital bone and 9.74% ± 8.09 of unresorbed residual biomaterial. Soft tissues, which included nonmineralized connective tissue and bone marrow, constituted 24.1% ± 23.6 of the total tissue in the remaining samples.

Discussion

In this retrospective evaluation study, the PIB technique proved to be effective for both ridge width and height augmentation (Fig. 2) to provide adequate and satisfactory tissue restoration from an esthetic and functional standpoint.[2,8]

In this study, resorbable laminae were used to delimit the defect area which was filled with the "pack" consisting of autologous and heterologous particulate grafts wrapped in a collagen membrane. The laminae were introduced as a resorbable cortical barrier, and they were shown to be effective for vertical and horizontal regeneration within the bone defect, as well as alveolar preservation and sinus floor lift.[9-13] Specifically, the lamina, collocated into the vestibular slot provided the necessary stability to the graft, allowing for the regeneration of the defect. The lamina has been shown to reduce hard tissue resorption[12] further limiting infection and minimizing surgical treatment time.[14]

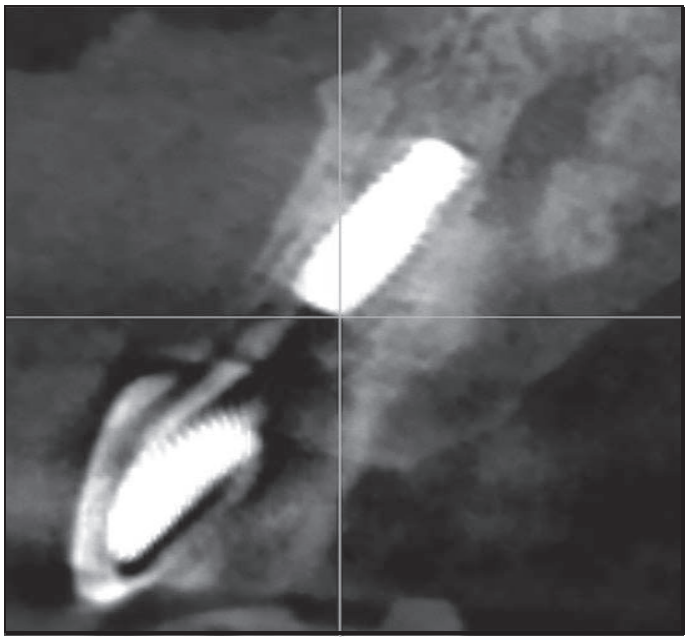

Fig. 2. Two-year follow-up CT scan of the crestal bone augmentation procedure with implant-prosthetic rehabilitation. The complete osseointegration of the implant into the regenerated bone can be observed.

For porcine bone particulate, OsteoBiol GTO is preloaded in a syringe and pre-hydrated (no preparatory hydration step with saline or blood), reducing handling time and potential cross-contamination.[15] In addition, GTO consists of 20% TSV gel, a mixture of porcine collagen types I and III with polyunsaturated fatty acids and a biocompatible synthetic copolymer in an aqueous solution. The gel component makes it manageable at low temperatures (< 8°), while at body temperature it increases viscosity to stabilize the graft, which becomes sticky.

Romasco et al[15] demonstrated the efficacy, safety and biomodulation of innovative porcine dual-phase bone grafts, engineered to emulate autologous bone, in many bone regeneration procedures over 20 years of research. The properties of these biomaterials help to provide the three-dimensional stability necessary for the formation of new bone tissue in severe atrophies.[16] Bleeding slots and micro-perforations in the defective bone promote blood supply to the lamina and particulate, thereby increasing graft vascularization and blood clot formation.[17]

The technique described in this study included the second implant surgical steps after 8 months, at which time it was found that the lamina was resorbed and not clinically distinguishable, like what was shown in a previous study.[18] However, some studies show the possibility of re-entry after 6 months with the use of OsteoBiol Evolution membrane.[19]

In six cases, implants were placed at the same time as crestal regeneration, which was appropriate and effective, in line with studies that have demonstrated the effectiveness of regeneration procedures at the time of implant placement, using OsteoBiol Evolution membrane and particle graft, reducing the number of procedures required.[20]

Graft efficacy is influenced by the connection between host tissue and bone surrogates, as such a link has been observed during numerous histological studies on biopsies.[21] The histomorphometric results are similar to those of a study

by Pagliani et al[10] in which the total sample area averaged 70.0± 14.9% mineralized tissue for the lateral bone augmentation procedures, with an average of 24.8± 13.9% PB particles in all samples of the different types of procedures.

Among the advantages of this technique, we can report that the use of heterologous lamina (OsteoBiol Lamina), compared to regenerative techniques using autologous graft, allows for the possibility of not harvesting a bone block from a donor site, making this procedure less invasive for the patient and less complex for the clinician, and therefore reproducible by more professionals. Furthermore, due to its simplicity of execution and the self-stabilizing nature of the graft material, it allows for the avoidance of fixation pins as described in other techniques involving the use of laminae.[6,17] In addition, the use of the membrane wrapped around the particulate not only limits its resorption but also reduces the risk of its dispersion.

Moreover, this method is less risky and invasive for the operator and the patient than the use of non-resorbable membranes, which can become exposed, infected, and cause dehiscence, requiring a second, more invasive surgery to remove the non-resorbable membrane.[22]

Notwithstanding the above findings, this article has limitations: considering the small size of our sample, the lack of a control group, and the short follow-up, the real capabilities of this technique may be different from what was experimented. Another limitation of our 2D volumetric measurement method is that changes in width and height were probed with linear values, which could also be assessed volumetrically.

Further studies, with a randomized design and, as a control group, other techniques with proven efficacy and supported by several studies, should be conducted.

a. Curasept S.p.A., Saronno, Italy.
b. Pierrel S.p.A., Capua, Italy.
c. Mectron, Carasco, Genova, Italy.
d. Tecnoss, Giaveno, Italy.
e. Neodent Straumann, Basel, Switzerland.
f. National Institutes of Health, Bethesda, MD, USA.
g. Dental Wings, Chemnitz, Germany.
h. Cefla s.c., Verona, Italy.
i. Foundation for Statistical Computing, Vienna, Austria.

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