



Ridge Augmentation Using Customized Allogenic Bone Blocks: Proof of Concept and Histological Findings

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Loss of alveolar bone volume, both horizontally and vertically, is an inevitable outcome after tooth extraction.¹ Resorption occurs primarily on the buccal aspect and increases over time.² If an appropriate 3D positioning of implants cannot be achieved in the residual bone, ridge augmentation should be performed. Besides an increase in bone volume, the rehabilitation of the contour of the alveolar process also plays an important role, especially in the aesthetic zone.

Different techniques have been developed to allow for reconstruction of the deficient ridge. The use of particulate bone grafting material allows easy contouring but requires a membrane to stabilize the graft and to avoid the ingrowth of undesired soft tissue cells.³ Titanium meshes, titanium reinforced ePTFE membranes, and membranes made of ePTFE, titanium, collagen, or polylactide alone have been introduced. The use of particulate grafting material together with nonresorbable membranes is technically demanding, and stability as a prerequisite for rapid incorporation is difficult to achieve.^{4,5} Furthermore,

Aim: To evaluate handling and healing patterns of customized allogenic bone blocks for vertical and horizontal alveolar defect augmentation.

Materials and Methods: In 2 patients, 3 combined horizontal and vertical post-foraminal mandibular defects were grafted using computer-aided design (CAD) trimmed individual block grafts, 3D-designed on preoperative computed tomography scans. After a healing period of 6 months, graft resorption was measured and bone trephines were taken in progress of implant bed preparation. Four months later, implants were restored with single crowns. Moreover, clinical and radiological implant parameters were assessed 6 and 12 months after restorative rehabilitation.

Results: Uneventful healing was observed in 2 of the 3 cases. A partial exposure of 1 block after 8 weeks could be successfully treated by block reduction and application of a soft tissue graft. Histological evaluation revealed predictable bone formation within all augmented areas, and both patient satisfaction and long-term stability parameters were considered excellent.

Conclusions: It was concluded that the application of individual CAD allografts supports bone formation at deficient sites with reduced patient morbidity, decreased surgery time, and high patient acceptance. (*Implant Dent* 2013;0:1–7)

Key Words: alloblock, customized graft, augmentation, bone substitute, CAD

nonresorbable membranes have to be removed before implant placement. On the other hand, resorbable materials are lacking of adequate stability, particularly for vertical augmentations.⁶

In contrast to particulated materials, block grafts have the advantage of easy and stable fixation using osteosynthesis screws.⁷ Using a lag screw technique, they might also provide a press-fit immobilization. In combination with autogenous bone blocks, the use of an additional barrier membrane is discussed controversially in literature. Some authors concluded that a membrane is not necessary and may even delay block incorporation.^{8,9}

Others found comparable bone volume after application of membranes.¹⁰ Nevertheless, if particulated material is used to fill voids between block and recipient site, application of membranes helps to keep the granules in place.¹¹ Moreover, after covering the site with collagen membranes, the collagen matrix supports secondary soft tissue closure in case of dehiscence and exposure of the graft to the oral environment.⁵ Particularly for vertical alveolar onlay grafting, dehiscences were found to occur in up to 50% of the cases.¹²

Block grafts have gained popularity in recent years. For large augmentation

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ISSN 1056-6163/13/00000-001
Implant Dentistry
Volume 0 • Number 0
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DOI: 10.1097/ID.0b013e3182885fa1

volumes, the patient's ilium is the predominating donor site.¹³⁻¹⁵ For smaller augmentation volumes, intraoral autogenous block grafts offer the advantages of reduced operating time, reduced morbidity, avoidance of hospitalization, and unsightly scars.^{16,17} From the 2 most commonly used sites, the symphysis offers easier access than the ramus and higher volume but is associated with a higher complication rate.¹⁸ A recent prospective study analyzing the morbidity of chin grafts found much higher rates of complications than previously reported.¹⁹ The authors therefore strongly recommend not using chin grafts as donor site of first choice.¹⁹

As an alternative to autografts, different allograft materials have been developed. They have shown predictable results in different grafting indications in general medicine and dentistry.²⁰⁻²⁴ The preparation process of the different manufacturers are considered valid with regards to the inactivation of viruses, bacteria, and their sterilization.²⁵⁻²⁸ In contrast to demineralized freeze-dried bone allografts and deproteinized xenogenous bone blocks, partly deproteinized bone allografts show better graft stability and can be easily fixed using osteosynthesis screws.⁷

In a small case series of 5 alveolar defects in 3 patients, a freeze-dried allogenic cancellous onlay block has been used with satisfactory results.²⁹ Recently, a larger case series of 82 blocks in 73 patients using cortico-cancellous, solvent-dehydrated allogenic bone blocks showed predictable bone regeneration at alveolar defect sites.⁷ However, blocks that had not been perfectly adapted to the contour of the defect showed some resorption at the interface between the block and recipient site. Despite the avoidance of donor site complications of autogenous block harvesting, the necessity of meticulous shaping of the block did not contribute to a significant reduction of the overall surgical time.

To reduce the surgical time and stress for the patient, it was proposed to preshape allogenic bone blocks before surgery using a stereolithographic model of the patient's jaw.³⁰ This technique reduces the surgical time but not the working time for the surgeon.

Moreover, stereolithographic models are considered to be aseptic but not sterile, and the storage of the pre-designed blocks until surgery is not clarified. At last, because these blocks come with a width of maximum 1.5 cm, several alloblocks are needed for larger augmentation areas what hampers the preparation further.³⁰ In the age of 3D implantology, computerized planning and computer-aided design (CAD) processing might be useful tools to both perfect the graft adaption to the recipient site and decrease the overall surgeon's and/or operation time.

In the present proof of concept study, a new allograft augmentation technique will be introduced, using customized allogenic bone blocks (CABB) individually shaped for the recipient site using a preoperative dental computed tomography (CT) and a CAD-CAM technique. Particularly for extended onlay graft procedures, it might be a useful tool to avoid the donor site morbidity of autografts and decrease the time of surgery and patients' treatment discomfort.

MATERIALS AND METHODS

The study was performed after the STROBE Statement (Strengthening the Reporting of Observational studies in Epidemiology; www.strobe-statement.org), based on specific checklists for enforcement of cohort, case-control, and cross-sectional observational studies. To maintain a high quality of the present case report, study design, data acquisition, interpretation, and manuscript preparation was performed following the checklist for cohort studies.

Patient Selection

Each subject enrolled to this proof of concept study had at least 1 horizontal and vertical bone defect of the mandible in a size that required multiple intraoral donor sites or extraoral bone harvesting. Because the patients rejected this kind of surgery, the implantation of an individually pre-shaped human bone block allograft was offered.

Two systemic healthy female patients (case 1: 55 years, case 2: 45 years), nonsmokers for at least 6 months and not pregnant, were enrolled in the study.

After initial examination, the patients were instructed in oral hygiene and a professional tooth cleaning was performed. Plaque and bleeding scores had to be $\leq 15\%$ before any surgery was done.

Allogenic Bone Graft Material

Human cancellous bone derived from the head of the tibia was used as block material. It was processed following the Tutoplast-protocol (Tutogen Medical GmbH, Neunkirchen am Brandt, Germany). This proprietary process uses several physicochemical steps to remove cells and antigenicity, inactivate all kinds of pathogens that may be still present besides careful donor selection and testing. Furthermore, it dehydrates the bone for convenient storage at room temperature and uses final low-dose gamma irradiation for sterilization.³¹

Planning and Manufacturing of the Blocks

CT scans were performed of both patients wearing a waxed-up radiopaque scan prosthesis to evaluate the ideal position of the implants. Data was transferred to a 3D planning software (SimPlant; Materialise Dental NV, Leuven, Belgium). Taking into account clinical and aesthetic considerations, ideal implant positions and respective defect morphology were defined (Fig. 1). Using a special software tool, the missing bone area could then be drawn directly on the 3D surface of the deficient ridge. These data, providing a 3D information about the morphology of the bone graft, were converted in a *.stl file and sent to the company (Materialize, Leuven, Belgium). There, CNC programming was done and the graft was milled out of a single block of bone allograft (Fig. 2). After cleaning, packaging, and sterilization, the individual bone block was sent back to the surgeon.

Surgical Technique

Bone blocks were retained sterile from the double blister package and rehydrated with sterile 0.9% saline solution. To maintain complete rehydration even in the center of the blocks, the rehydration was performed in a sterile syringe, retracting the plunger every

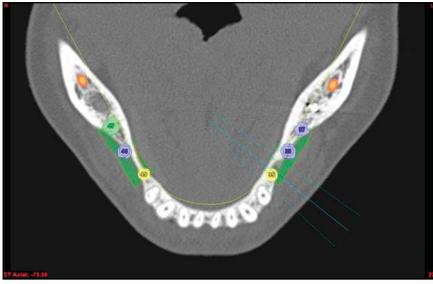


Fig. 1. Three-dimensional evaluation of the bone defect and CAD graft shaping.

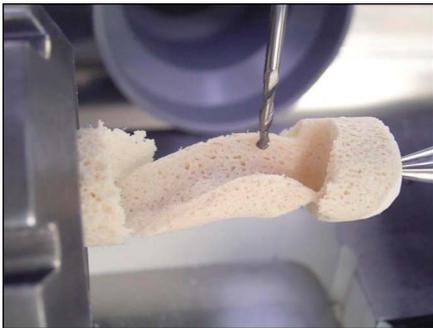


Fig. 2. Milling process of the customized autogenous bone block (CABB).



Fig. 3. Block configuration after rehydration in sterile saline solution.

few minutes for at least 30 minutes until no more air bubbles came out of the block graft (Fig. 3).

Surgeries were done under infiltration with local anesthesia (Ultracain-DS forte; Aventis Pharma, Frankfurt,

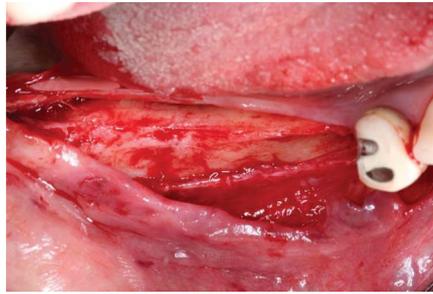


Fig. 4. Horizontal and vertical defect after mucoperiosteal flap elevation.

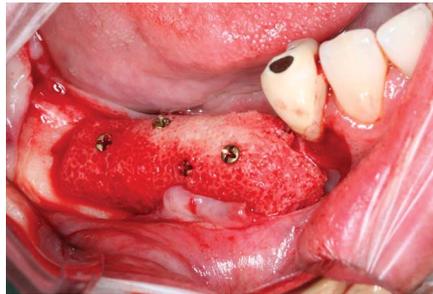


Fig. 5. Application of CABB and fixing with microscrews.



Fig. 6. Conventional x-ray after surgery.

Germany). A midcrestal incision was made at the recipient site and extended intrasulcularly to the neighboring teeth. Releasing incisions were performed interdentially (Fig. 4). On the buccal side, a full-thickness flap was raised

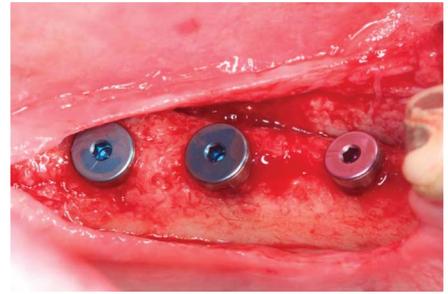


Fig. 7. Complete osseous organization of the graft after 6 months allows for implant installation.

to the mucogingival junction. After separating the periosteum, the preparation of the flap was continued with a split thickness technique. Lingually, a full-thickness flap was prepared and the periosteum was separated at the base, allowing for mobilization of the flaps and tense-free soft tissue closure over the graft. Residual soft tissue was removed to get access to the bone. The cortical bone at the recipient site was perforated with a fissure bur to support blood vessel outgrowth. The pre-shaped and rehydrated bone block was applied and fixed using 4 osteosynthesis screws (Mondeal; PSM Medical Solutions, Tuttlingen, Germany).

The heads of the screws were countersunk even to the block surface as reference point for resorption measurement (Fig. 5). To get a smoother transition of the round edges of the blocks maintaining a minimal thickness of the material, particulated allograft material (Navigraft; Tutogen) was applied in the peripheral areas. Grafted areas were covered with a collagen membrane (Bio-Gide; Geistlich, Wohlhusen, Switzerland). The flaps were repositioned and sutured passively with a combination of mattress and running polypropylene 6-0 sutures (Premilene; Braun Melsungen, Melsungen, Germany).

Table 1. Soft Tissue Thickness, Surgery Time, Screw Number, Postoperative Pain and Presence of Wound Healing Complications at CABB-Grafted Sites

	Area	Soft Tissue Thickness, mm	Surgery Time, min	No. of Screws	Pain 1 d postoperative (VAS)	Wound-Healing Complications
P1 right mandible	45, 46, 47	0.5	46	4	4	Dehiscence
P1 left mandible	35, 36, 37	0.6	35	4	3	No
P2 right mandible	45, 46, 47	0.8	42	4	4	No

VAS indicates visual analog scale.

Table 2. Radiological Bone Resorption at Implants and Clinical Parameters 6 and 12 months After Prosthetic Restoration

Patient and Area	Implant Position	6 mo					12 mo				
		RD	RM	SUP	PI	GI	RD	RM	SUP	PI	GI
P1 right mandible	45	0	0	No	0	0	0	0	No	0	0
	46	1	1.5	No	0	0	1	1.5	No	0	0
	47	0.5	1.5	No	0	0	0.5	1.5	No	0	0
P1 left mandible	35	1.5	0.0	No	0	0	1.5	0.0	No	0	0
	36	1.5	1.5	No	0	0	1.5	1.5	No	0	0
	37	0	1.5	No	0	0	0	1.5	No	0	0
P2 right mandible	45	3	3.0	No	0	0	3	3.0	No	0	0
	46	3.5	3.5	No	1	1	4	4.0	No	1	1
	47	3	3.0	No	0	0	3	3.0	No	0	0

RD indicates distal resorption, RM, mesial resorption.

Postsurgical Protocol

A conventional x-ray was performed after the surgery (Fig. 6). Patients were instructed to avoid any mechanical trauma of the wound. Mechanical alteration and tooth brushing in the treated area was not allowed for 4 weeks. Plaque control was achieved by mouth rinsing with chlorhexidine solution (0.12% Butler Paroex; Sunstar, Chicago, IL) twice a day for 1 minute. Ibuprofen (Ibuprofen; Merck AG, Darmstadt, Germany)

as a nonsteroid and anti-inflammatory analgesic was prescribed. Augmentin tablets 875/125 mg (GlaxoSmithKline, Brentford, Middlesex, GB) was prescribed for 7 days. Sutures were removed 2 weeks after surgery. Wounds were controlled every 4 weeks.

Implant Insertion and Reevaluation

After 6 months, sites were reopened and block resorption was assessed by measuring the distance of the head of the osteosynthesis screw to the

surface of the regenerated bone using a periodontal probe. A biopsy was taken in progress of implant bed preparation at 6 implant sites by replacing the first implant bur with a trephine (inner diameter: 2 mm; Stoma, Tuttlingen, Germany).

Six Camlog and 3 Astra implants were installed according to the manufacturer's protocols. Hereby, platform of Camlog implants were positioned 2



Fig. 8. Trephine harvested in progress of implant bed preparation.

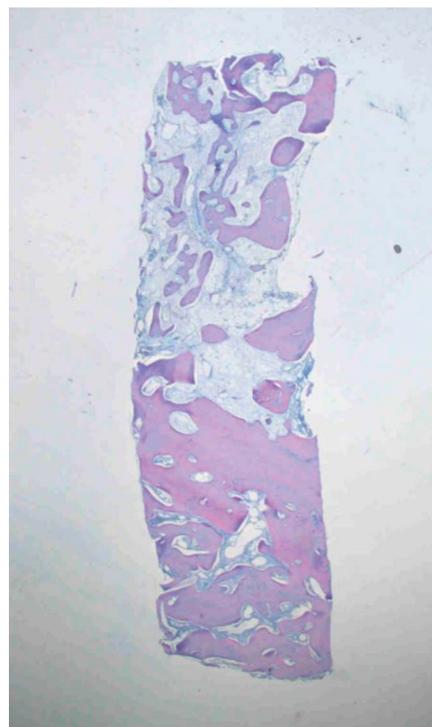


Fig. 9. Histological overview of the trephine showing recipient bed on bottom and graft area on top (magnification, $\times 12.5$, hematoxylin and eosin).

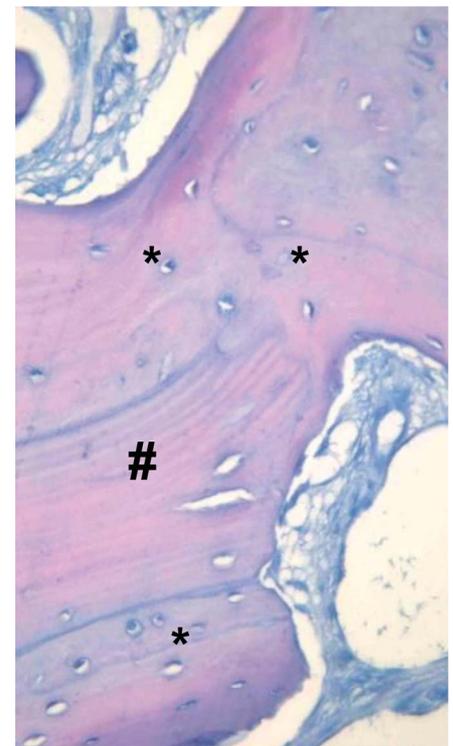


Fig. 10. In higher magnification, remnants of the allogeneous bone block (#empty lacunae) are surrounded by newly formed bone matrix (*osteocytes in lacunae) (magnification, $\times 400$, hematoxylin and eosin).

mm supracrestally and Astra implants even. At implant uncovering 4 months later, a free gingival graft was positioned on the buccal side of the healing abutments to thicken the soft tissue and improve keratinized gingiva around the implants. Restorative procedures started after soft tissue maturation. At 6 and 12 months after restorative rehabilitation with single crowns, the radiological position of interproximal bone level as the distance between platform and crestal bone, plaque index (PI), gingival index (GI), and suppuration (SUP) were assessed.

Histological Processing and Evaluation

The trephines were fixed in 4% neutral buffered formalin solution for at least 3 days. Samples were decalcified using EDTA and embedded in paraffin. Serial sections of 7- μ m thickness were stained with hematoxylin/eosin. For image acquisition, a digital camera (Nikon D100; Nikon GmbH, Duesseldorf, Germany) was mounted on a binocular light microscope (Olympus BX50; Olympus, Hamburg, Germany).

RESULTS

During the grafting procedure, individual bone blocks fitted exactly to the recipient sites. No further grinding or adapting was necessary (Fig. 5). Total surgery time was assessed 41 \pm 4.5 minutes on average. Soft tissue thickness was measured between 5 and 8 mm (Table 1).

Initial wound healing was uneventful in all cases. Postoperatively, no infection or clinical signs of inflammation could be observed. However, 2 months after surgery, a partial exposure of 6 \times 10 mm of 1 bone block was observed. In this case, a full-thickness flap was raised and the superficial 1 mm of the exposed bone was removed using a round diamond bur until it started to bleed out of the bone matrix. A connective tissue graft from the palate (10 \times 20 mm) was placed on top of the bone graft, and the flap was closed over the site. Antibiotics and analgesics as aforementioned were

prescribed again, and sutures were removed after 2 weeks.

After 6 months healing time, all augmented sites revealed inflammation-free soft tissue conditions. Grafted areas showed revitalization and slight bleeding out of the bone matrix after mucoperiosteal flap elevation. In line with the other sites, the formerly exposed area was without any sign of inflammation at the time of implant placement. All planned implants could be installed (Fig. 7).

Graft Resorption and Clinical Measurements

Volume loss of the grafts evaluated at the osteosynthesis screws in progress of implant installation showed an average height loss of 2 mm in the case that showed the wound-healing complication, whereas the other 2 grafted areas revealed no resorption. Crestal bone loss at implants 6 and 12 months after prosthetic rehabilitation are shown in Table 2. An average bone loss of 1.69 \pm 3.31 mm (1.64 + 1.22 mm) was observed 6 (12) months after installation of the implants (Table 2). Clinical parameters GI, PI, and SUP showed stable conditions after 6 and 12 months (Table 2).

Histological Evaluation

The histology of all 6 trephines showed complete bony regeneration of the augmentation material (Figs. 8 and 9). In some areas, the bone substitute matrix could still be distinguished in some areas due to their slightly different staining behavior and empty osteocytes lacunae. The majority of the individual bone substitute remnants were surrounded by the newly formed bone (Fig. 10). Normal bone marrow was visible between the bone trabeculae. Absorption of the material was observed regularly, directly connected with new bone apposition.

DISCUSSION

In the present case report, augmentation of 3 extended alveolar defects using customized allogeneous bone blocks (CABB) was evaluated. It was found that due to their good adaptation to the recipient site, blocks were fast

and easy to apply, reducing the surgery time and patients' discomfort. Despite a delayed partial exposure of one block with subsequent loss of the superficial part, osseous organization of the grafts occurred in all cases.

Extensive augmentations of the severely compromised alveolar process require high surgical skills and experience and are very often treated with autogenous blocks from intraoral or extraoral donor sites.³² The use of allogeneous bone blocks may avoid donor site morbidity, reducing the risk of complications and perioperative discomfort for the patient. In some cases, even general anesthesia and extraoral bone harvesting may not be required anymore because alloblocks are not limited in availability.

The allograft material used for the production of CABB is well established for many years for dental and orthopedic applications. Particles of this material have been shown to be nearly completely absorbed and replaced by new vital bone in the maxillary sinus within 8 to 10 months.^{33,34} The newly formed bone has the same quality and density as the patient's residual bone.³⁵ It was successfully used in periodontal defects³⁶ and furcation defects.³⁷ Implants placed in extraction sockets 4 to 7 months after grafting with this material had a 3-year survival rate of 97.6%.³⁸ Even huge defects after tumor resection exceeding 100 cm³ could be successfully reconstructed with this material.³⁹ In a prospective randomized trial investigating healing outcome of grafted radius fractures, it was found that this material offers the same results as autogenous bone.⁴⁰

If a material is not used in granule form but in block shape, the stabilization and intimate contact of the block surface to the recipient bed has been considered crucial for a successful outcome.⁴¹ However, trimming and adaptation of a standard alloblock requires additional surgery time. The blocks have to be placed several times on the defect for checking the fit and have to be removed again to be trimmed. This process induces a high risk for contamination in the mouth by saliva or extraorally by the surgeon.³⁰ Moreover, particularly in nonexperienced hands,

the preparation of a blood-loaded block might be accompanied by an infection risk for the surgeon or a total loss of the graft caused by inadequate use of the preparation burs and falling down in a nonsterile area.

Because individually preformed blocks do not need to be trimmed chair-side, they fit perfectly without the necessity of any chair-side adaptation. Surgical time and thus surgical costs are reduced drastically. In contrast to blocks adapted during previous surgery by the surgeon on a stereolithographic model, industrially produced CABBs do not require the surgeon's practical experience and time before performing the actual surgery. Moreover, from the hygienic point of view, CABBs remain absolutely sterile until the actual surgical procedure.

In terms of treatment costs, both stereolithographic models and CAD individualization are extending the expenses, which can be compensated by reduced surgery time. However, a part of that compensation will be consumed by increased material costs. Compared with autogenous bone blocks, especially harvested from extraoral donor sites, the overall costs of the treatment might be considered much lower. Furthermore, the surgical procedure of application of CABB might be easier to perform than trimming and adaptation of autogenous bone blocks.

Although the graft fixation seems to be facilitated using CABB, the soft tissue management still stays crucial. A tensionless flap design is still mandatory to keep the flap closed during healing time.¹¹ In one of the cases, a late exposition of the block occurred. As expected, early vascularization seems to be a similar risk for both CABB and conventional techniques.

Graft resorption during the initial healing period may be the result of the initial remodeling of the graft. In contrast to xenogenous bone grafts such as BioOss, remodeling of collagen-rich allogeneous bone is considered fast, which might be accompanied with superficial volume loss.⁴² However, complete deproteinization as applied in xenogenous materials leads to fragile block properties. This impedes the ability of screw fixation and decreases the speed of

osseous remodeling.⁴³ In the present study, only in 1 site an advanced resorption of the block grafts was observed, as a result of a late dehiscence and necessity of block graft reduction.

Crestal bone resorption after implant installation is owed to the remodeling around the implant or further remodeling of CABB. It was shown that also implants placed in preexisting bone show crestal bone loss. Several theories have been stated about this phenomenon, starting from microleakage at the implant-abutment connection to inflammatory effects based on sealing material to inadequate loading.⁴⁴ In this context, it has to be pointed out that although a crestal bone loss occurred, no implant was lost during the initial observing period. One implant showed higher clinical parameters. However, a relation to the CABB grafting is doubtful due to the health of the neighboring implants. Clinically controlled studies with larger patient numbers will be necessary to specifically assess the differences between CABB, conventional allogeneous bone block augmentation, and autogenous block grafts.

CONCLUSIONS AND CLINICAL RELEVANCE

Use of customized allogeneous bone blocks supports bone formation and reduces surgery time, the risk of contamination of the graft, and the patient morbidity. Although soft tissue management still remains crucial, it might be a useful tool for easy and patient-friendly treatment of extended alveolar bone defects.

DISCLOSURE

Dr Schlee states that he has "financial interest in 3D-Blocks provided by Botiss Biomaterials, Berlin, Germany". Dr Rothamel claims to be a consultant for, and receives payments for lectures, from Botiss Biomaterials, Berlin, Germany. The other authors do not have any financial interests in any of the products mentioned in this article.

ACKNOWLEDGMENTS

The authors wish to thank Tatjana Huck (dental hygienist) for having

acted as blinded outcome assessor and recording patient's satisfaction and VAS. The material was given free of charge to the patients by Tutogen Medical. Histological evaluation of the trephines was paid by Tutogen medical.

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