maxgraft[®] cortico

SHELL TECHNIQUE WITH ALLOGENIC CORTICAL STRUTS

Surgical guide

innovative

efficient

atraumatic

ard tissue

Content maxgraft[®] cortico Surgical guide

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1. Introduction

maxgraft[®] cortico is a prefabricated cortical bone plate from post-mortem human donor bone, that can be used for the shell technique. The concept of the shell technique is the preparation of a biological container, which creates the necessary space for the full incorporation of particulated bone graft material to rebuild new bone for dental implant placement, also published as cortical lamina technique¹ or framework technique².

maxgraft[®] cortico was developed to avoid donor-site morbidity and to prevent the time-consuming harvesting and splitting of autogenous intraoral bone blocks. It functions as non-native, avital cortical plate that is firmly integrated for optimal stabilization of the particulated augmentation material.

 Deepika-Penmetsa, S., Thomas, R., Baron, T., Shah, R., & Mehta, D. (2016). Cortical lamina technique: A therapeutic approach for lateral ridge augmentation using guided bone regeneration. Journal of Clinical and Experimental Dentistry, 9(1), 0–0.
 Wallowy, P., & Dorow, A. (2012). Lateral Augmentation of the Maxilla and Mandible Using Framework Technique With Allogeneic Bone Grafts. The Journal of Oral Implantology, 38(6), 661–667.

2. Indications and general information

2.1 Indications for maxgraft[®] cortico

Implantology – Oral Surgery – CMF Surgery

- Vertical augmentation
- Horizontal augmentation
- Complex three-dimensional augmentations
- Single tooth gaps
- Fenestration defects

Highest success rates can be achieved for defects with a maximum size of 6 mm horizontally or vertically. maxgraft® cortico can be used for both upper and lower jaw. Application in the posterior mandible is facilitated due to the possibility of an additional lingual flap mobilization.

2.2 Product properties

- Acellular cortical bone from the femur diaphysis (multi-organ-donors, post-mortem)
- Osteoconductive properties supporting natural and controlled tissue remodeling
- Fully mineralized for natural stability, no flexibility
- Reliable thickness of approx. 1 mm
- Standardized size 25 x10 mm
- 5 years shelf life at room temperature
- Safe and sterile

2.3 Use of maxgraft[®] cortico in conjunction with other biomaterials

maxgraft® cortico is intended to be used in conjunction with additional biomaterials. A variety of different bone grafting materials are available. Allogenic material (maxgraft® granules) with its preserved human collagen provides excellent osteoconductive properties and enables complete remodeling and thus is the recommended choice. Mixing with autogenous chips and Emdogain® can support a faster ossification. Also other mixtures of different materials (e.g. bovine or synthetic biomaterials) can be used to fill the containment. Generally we recommend to use a mixture of allogenic and autogenous bone. The final decision depends on the defect morphology and preferences of the patient and surgeon.

3. Surgical procedure

Preoperative assessment 3.1 and treatment planning

Careful patient selection is critical for the outcome of the surgical procedure and the long-term success of the treatment. Proper case selection requires thorough review of the patient's medical and dental history, the anatomy and the residual bone height as well as bone quality by clinical and radiographic examination. Special attention should be paid to patient-related factors that may affect bone healing. General contraindications are considered to be the same as for GBR, such as but not limited to an acute inflammation and poor oral hygiene. A preoperative antibiotic treatment may be considered. Further site-specific assessment should include treatment planning for the ideal implant type, diameter, length, number and position. These parameters help to determine the appropriate volume of new bone that has to be created.

3.2 Shell technique with maxgraft[®] cortico

Basic information/requirements 3.2.1

Depending on the scope of the procedure and patient profile the shell technique is performed under local or general anesthesia. For a successful procedure, please comply with the following recommendations:

- During treatment planning, carefully assess the soft tissue situation.
- A passive and careful flap preparation and tension-free wound closure is critical for the success of the shell technique.
- The temporary restoration following augmentation must not exert any mechanical pressure on the graft.

3.2.2 Step-by-step procedure

Step 1 — Flap Preparation

A flap large enough to allow full access to the entire defect should be raised. Also an adequate revascularization of the particulated bone grafting material is crucial and needs to be ensured. The required size and position of the bone plate can be determined either during digital planning of the operation or in situ following flap elevation.

Step 2 — Trimming

By using the botiss cortico trimmer and a rotating diamond disc, maxgraft® cortico is cut to the appropriate size extraorally. The botiss cortico trimmer also facilitates the preparation of the pilot holes for the later fixation of cortico to the local bone. By predrilling the fixation holes the risk of fracturing maxgraft[®] cortico can be reduced.

Note: Hydration of the bone plate is not needed. During the surgery, maxgraft[®] cortico can be placed into saline or antibiotic solution. It is pivotal to drill threaded holes into the cortical plates, which prevent the plates from gliding on screw threads. Therefore, a drilling head with 0.2 mm smaller diameter than that of the applied screws is recommeded for drilling (e.g. use a 1 mm drilling head for 1.2 mm screws).



Note: For best success rates it is recommended to limit the augmentation to 6 mm horizontally or vertically.



Step 3 — Placement and fixation

To create a fixed compartment maxgraft® cortico must be positioned in adequate distance to the local bone. Based on the ideal implant position, the plate should be positioned with at least 1 mm distance to the implant surface when placed laterally. Tension free fixation without bending of the plate is highly important.



Note - screws: Usually 2 screws are sufficient to fixate cortico to the patients' bone. It is crucial that the fixation of maxgraft[®] cortico ensures complete immobility of the bone plate. Screws consisting of surgical steel with a diameter of 1.0 mm, or titanium with 1.2 - 1.4 mm and a length of 8 -11 mm are appropriate for most defects. Use of flat-headed osteosynthesis screws and a predrilling of fixation holes is strongly recommended.



- Self-tapping screws should be avoided as they may result in fracture of the plate due to the aggressive thread design

- Sinking the screw head into the bone plate should be avoided, as this might result in a loss of stability. Note - lateral distance: The maximum lateral distance is limited by sufficient stabilization of the plate and adequate soft tissue coverage of the augmentation site.

Optional - groove technique



Advanced surgeons may use the groove technique for improved primary stability of the plate. An approximately 1 mm wide and straight groove, in which maxgraft® cortico can be positioned before fixation, is cut in the local bone using piezoelectric or rotating instruments.

Step 4 — Adaptation of the edges

To prevent perforations of the soft tissue, sharp edges need to be removed explicitly, e.g. by using a diamond ball mill.



Step 5 — Filling of the defect

The space between local bone and cortical plate is filled with particulated bone grafting materials. The use of autogenous and allogenic materials is recommended.

Note: The excellent osteoconductive properties of allogenic granules

(maxgraft® granules) enables a fast regeneration of vital bone and a com-

plete remodeling. Thus they are the primary recommended particles.

Mixing with autogenous bone chips can support and speed up the initial

ossification. The use of Emdogain® may support wound healing.





The augmentation area needs to be covered with a long lasting barrier membrane (e.g. Jason® membrane).



Note: Membrane coverage of the augmented site is mandatory. The barrier membrane prevents the ingrowth of soft tissue into the particulate material.

Step 7 — Wound closure

The suture has to be absolutely tension-free and saliva-proof.

Note: Proper soft tissue management is crucial for the surgical success. A tension-free wound closure and a sufficient quality of the soft tissue significantly reduces the risk of complications such as dehiscences.

Tenting technique

Especially for vertical defects maxgraft[®] cortico can be placed horizontally to tent off the soft tissue. By adapting the width of the plate, the crestal dimensions can be adjusted to fit the desired type of implant. By using rotating instruments or piezoelectric devices, the contact points of the plate to the local bone can be flatened for optimal immobilization. A safety distance of approximately 1 mm to the neighboring teeth should be maintained. After fixation of the plate, the particles can be placed from the buccal aspect and the whole area can be covered with a barrier membrane to immobilize the particles. An additional lateral application of additional plates is not necessary.

3.2.3 Suturing technique

Single button or continuous (interlocking) sutures should be used for primary closure. Deep apical sutures with elastic Gore-Tex® threads can be used for immobilization of the flaps, eliminating any tension on wound edges, which may lead to dehiscence.

4. Post-operative care

- 1. The patient should be instructed not to mechanically irritate the surgical site, e.g. by tooth brushing or chewing hard food and to report any suspicious events such as soft tissue perforations and wound dehiscence immediately. A post-operative CBCT or X-ray should be considered.
- 2. Remove sutures about ten days after surgery.
- 3. Arrange further review visits to monitor early wound healing.

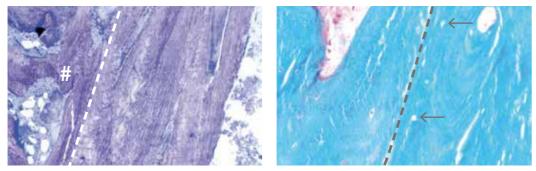




5. Healing

Remodeling and new bone formation 5.1

Postoperatively, maxgraft® cortico usually gets primarily integrated within 6 months. Since the bone plate consists of cortical bone it is not resorbed quickly, but will be secondarily remodeled. Resorption mainly takes place in areas that are located outside the contour. New vital bone is formed directly adjacent to the allogenic plate at the side facing the local bone. When compared to autogenous grafts cortico shows an enduring stability



Depicted is a work-up of a biopsy specimen of an integrated cortico plate (right site of the dashed line and stabilizing allogenic particles (#) after five months of healing. maxgraft® cortico is characterized by empty osteocyte lacunae (arrows), whereas the newly generated bone shows a large number of vital osteocytes. Biopsy provided by Jan Kielhorn (Öhringen, Germany) processed by Prof. Smeets (UKE Hamburg, Germany)

Re-entry 5.2

Depending on the location, type and extent of the defect, the entire healing time is four to six months when using allogenic and/or autogenous bone particles. However, the right time for the re-entry needs to be assessed individually by the surgeon.



Implant placement 5.3

The implant has to be anchored securely in the cancellous bone and should not have any contact with the plate. A minimum of 1 mm cancellous bone surrounding the implant is recommended in order to ensure a sufficient long-term function in vital bone tissue.



6. Further information

Advantages of maxgraft[®] cortico 6.1

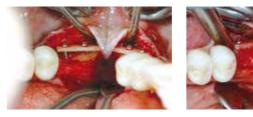
- Natural and fully biocompatible barrier
- Volume stable due to full mineralization
- Universal application, whenever a bony wall is missing
- Standardized size of 25 x 10 mm
- Reliable thickness of approx. 1 mm
- Less invasive than autogenous techniques
- Unlimited availability compared to autogenous bone grafts

6.2 maxgraft[®] cortico vs. autogenous bone

Compared to autogenous bone harvested from the iliac crest or intraoral sites, maxgraft® cortico provides a prolonged barrier.

6.3 Stability vs. vitality

The volume stability is provided by maxgraft® cortico, the particulated grafting material ensures rapid formation of new vital bone

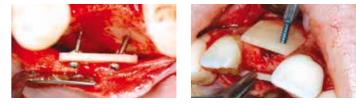


Learning curve of the surgical procedure 6.4

Like other surgical procedures, performing the shell technique with maxgraft® cortico requires a learning curve. Prior to initial use, courses or hands-on workshops should be attended. Preferably the surgeon has experience in harvesting autogenous bone grafts. Furthermore, a supervision by an experienced surgeon can be recommended to check the indication of the specific case. Advanced surgeons can apply the groove technique for placing the bone plate in the lateral lower or upper jaw.

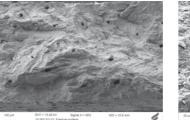
The easiest indication is a lateral augmentation with contact of the plate to the local bone. The difficulty is increased when the contact to the local bone is diminished or when a second plate is fixed on the opposite site of the ridge

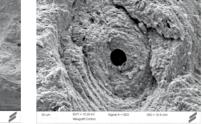




6.5 Safety

maxgraft[®] cortico is acellular and resistant to bacterial degradation even when exposed.





Dense cortical bone structure of maxgraft® cortico (Institute Straumann AG, Basel, Switzerland)



Pictures kindly provided by Dr. Christoph Keller, Stuttgart, Germany

Post-operative treatment

The general principles of implant insertion always have to be respected. If the initially desired height of the bone cannot be achieved by the augmentation there is the risk of placing the implant "too deep". In this case re-augmentation with granules is highly recommended.

Fracture of the plate

maxgraft[®] cortico is a highly stable bone plate. It has to be fixated free of any movement without excessive pressure or tension. In the unlikely event of a fracture it must be fixated with an additional screw or replaced by a new bone plate. The use of the cortico trimmer (Cat.No. 34000) reduces the risk of fracture during cutting and extraoral drilling and is ideal for precise adaptation. (Animation available)

Wound dehiscence

In absence of any kind of signs of infections rinsing with Rivanol/H2O2 once a week for

Smoothing sharp edges or reducing free standing parts of plate below tissue level if possible. Filling the dehiscence gap with Socketol or, if too shallow, with Solcoceryl may be beneficial. Continue treatment until secondary wound closure is complete or if healthy tissue conditions are achieved.

Soft tissue perforations

Late soft tissue perforations after normal wound healing:

In absence of any signs of infection reduce sharp edges or remove free standing parts of the plate. maxgraft[®] cortico does not have to be removed completely. Free parts of the plate may be covered using Solcoceryl.

In case of irritations of surrounding soft tissue, use rinsing protocol as described above. Soft tissue management may be performed earliest after six weeks if necessary.

Loosening of the plate at the time of re-entry

If the plate should not be connected to the bony site in rare cases, it should be removed. The augmentation site is usually fully regenerated.

8. Cases

SINGLE TOOTH RESTAURATION WITH MAXGRAFT® CORTICO

CLINICAL CASE BY

Dr. Krzystof Chmielewski, Gdansk, Poland





Single tooth defect with severely resorbed vestibular wall

Fixation of maxgraft[®] cortico using an osteosynthesis screw





Covering with a PRF matrix for improved soft tissue healing

Tension-free wound closure

CLINICAL CASE BY

Dr. Christoph Keller, Stuttgart, Germany





Narrow ridge in the molar region

Large buccal bone deficit



Solid bone formation



Augmentation with maxgraft® granules mixed with particulated PRF matrizes and fixation of a second maxgraft[®] cortico

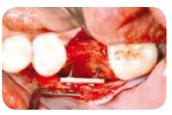


Situation after a healing period Stable implantation of four and a half months



Covering of the augmentation area with Jason® membrane





Stable fixation of cortico, note the non-parallel angulation of the screws for improved immobilization



Situation after four months of healing. The defect was previously filled with spongious allograft particles and covered with a collagen membrane

COMBINED DEFECT PALATALLY AND FACIALLY

CLINICAL CASE BY

Dr. Kai Höckl, Freiburg, Germany

Clinical situation post-operative Healing after ten days





facially and palatally



Fixation of maxgraft[®] cortico



Removal of sharp edges



Filling of the defect with autogenous chips and covering with Jason[®] membrane





CLINICAL CASE BY

Jan Kielhorn, Öhringen, Germany





Fixation of maxgraft[®] cortico, taking into account the bone level of the next tooth and

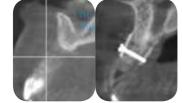


thorough removal of sharp edges

Contouring with particles also outside of maxgraft® cortico to prevent perforations



Wound closure





Re-entry after five months



Solid integration of cortico and implant placement

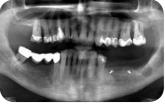


Filling of the defect

Covering with PRF matrix

Soft tissue improvement with mucoderm[®] crestally and laterally





Provisional restauration in place OPG post-augmentation

CBCT pre- and post-op

CLINICAL APPLICATION OF MAXGRAFT® CORTICO



Adequate distance to the local bone, angulated positioning of the screws and application of the groove technique



Uneventful soft tissue healing



Mix of allograft and autogenous chips



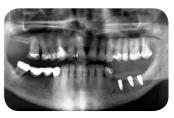
Implant insertion eight months after augmentation



Tension-free wound closure



Emergence profile prior to installation of provisionals



OPG post-implantation

9. Important guidelines / FAQ

Q: In which situation should the plate be removed?

A: Only if the plate is mobile.

Q: What is the recommended time until implant placement?

A: This depends on the chosen grafting material and the defect size. Usually four to six months produce sufficient new bone for dental implant placement.

Q: Can maxgraft[®] cortico be bend to follow the ridge contour?

A: No, maxgraft[®] cortico is fully mineralized and not flexible at all. For the incisor region, the plate can be cut in the middle and fixed as two parts.

Q: Can remaining fragments be resterilized?

A: Each plate must be used for a single patient only to guarantee sterility. Sterilization will destroy the structure, rendering the fragment ineffective.

Q: Is it mandatory to use a collagen membrane, as there are no membranes used with the autogenous shell technique?

A: In terms of guided bone regeneration a membrane is mandatory.

10. Specifications





ArtNo.				
31251	maxgraft®	cortico,	25 x	1
31253	maxgraft®	cortico,	25 x	1

34000 cortico trimmer



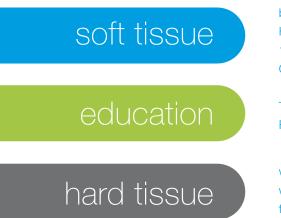
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Content 1 piece

3 pieces

1 x

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