maxgraft®
maxgraft® bonering
maxgraft® bonebuilder
Processed Human Allograft

Dr. B. Giesenhagen & Dr. M. Schlee et al.
Processed Human Allograft

Introduction

Various bone graft materials are available to replace and regenerate bone matrix lost by tooth extraction, cystectomy or bone atrophy following loss of teeth or inflammatory processes. Of all grafting options autologous bone is considered the „gold standard“, because of its biological activity due to vital cells and growth factors.

Yet, the autologous bone from intra-oral donor sites is of restricted quantities and availability, and the bone tissue obtained from the iliac crest is described to be subject to fast resorption. Moreover, the harvesting of autologous bone requires a second surgical site associated with an additional bone defect and potential donor site morbidity. Thus, application of processed allogenic bone tissue appears a sufficient alternative.

New bone formation after grafting with allogenic bone tissue begins with an acute inflammatory response, within which granulation tissue gradually accumulates, and by activation of osteoclasts. The incorporation process begins with the vascularization of the allograft. By activation of osteoclasts the immune system facilitates the remodelling of the graft. These large cells completely degrade medullary bone, thereby allowing its substitution by osteoblasts.

The immunological compatibility of processed allogenic bone is not different from autologous tissue. In patients who had allograft surgery no circulating antibodies could be detected in blood samples. Moreover, several histological studies have well documented that there was no difference in the final stage of incorporation between allograft and autologous graft.

Classification

Autologous:
- patient’s own bone, mostly harvested intra-orally or from the iliac crest
- intrinsic biological activity

Allogenic:
- bone from human donors (cadaver bone or femoral heads of living donors)
- natural bone composition and structure

Xenogenic:
- from other organisms, mainly bovine origin
- Long-term volume stability

Alloplastic:
- synthetically produced, preferably calcium phosphate ceramics
- no risk of disease transmission

C+TBA is a non-profit organization aiming to maintain continuous medical supply of allografts under pharmaceutical conditions. Serving as a platform for the definition of safety standards and assurance of compliance with defined product qualities, C+TBA focuses on the specifications of human bone tissue as required in a large number of diseases that are associated with the loss of bone tissue.

C+TBA is certified and audited by the Austrian Ministry of Health in accordance with the European Directives and regulated by the Austrian Tissue Safety Act (GSG 2009).

In Directive 2004/23/EC of March 31st 2004, the European Parliament and the Council of the European Union defined the future general conditions and quality standards for the handling of tissue of human origin, which were further specified in Directives 2006/17/EC and 2006/86/EC. Detailed regulation of the removal, quality control, processing, stockpiling, storage, and distribution of human tissue and cells, provisions have been obligatory for all member states since April 2006. The individual measures are to be undertaken at pharmaceutical level within the framework of a GMP-compliant quality management system.
maxgraft® is exclusively produced from bone tissue donated in German, Swiss and Austrian hospitals. All products originate either from living donors by explantation of femoral heads during hip replacement surgery or from multi-organ donors.

The procurement, standardized by a predefined protocol, is carried out by certified procurement centers. All donations are based on the written consent from the patient and on highly selective exclusion criteria with regard to the patient’s state of health. For all multi-organ donors the highest ethical and safety-related requirements are met. Donor tissue is only approved for processing after having passed a thorough inspection including a strict serological screening protocol.

Family members of the deceased are obligated to answer a questionnaire to ensure compliance with the stated exclusion criteria.

After donor acceptance a series of serological testing is performed. In addition to antibody screening (Ab), nucleic acid tests (NAT) are executed to span the diagnostic gap.

Blood samples are taken simultaneously to tissue explantation during total hip replacement surgery or within 24h post mortem in case of multi-organ donation.

Serological testing

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The C+TBA Cleaning Process

After shaping and crude cleaning, the donor tissue undergoes ultrasonication to remove blood, cells and tissue components, but mainly to promote the removal of fat from the cancellous structure of the bone, improving the penetration of subsequent substances.

During a chemical treatment non-collagenic proteins are denatured, potential viruses are inactivated and bacteria are destroyed. In the subsequent oxidative treatment, persisting soluble proteins are denatured and potential antigenicity is eliminated.

Finally, the tissue undergoes lyophilization, a dehydration technique which facilitates the sublimation of frozen tissue water from solid phase to gas phase, thereby preserving the structural integrity of the material.

The tissue can be reconstituted rapidly due to microscopic pores within the material, which were created by the sublimating ice crystals. It has been well established that the lyophilization process preserves structural properties that improve graft incorporation.

The final sterilization by gamma irradiation guarantees a sterility assurance level (SAL) of $10^{-6}$ while ensuring structural and functional integrity of the product and its packaging.

Step 1: After crude removal of surrounding soft tissue, fat and cartilage, the donor tissue is brought into its final shape.

Step 2: The defatting of the donor tissue allows moderate penetration of solvents during subsequent processing.

Step 3: A treatment with alternating durations of diethyl ether and ethanol leaches out cellular components and denatures non-collagenic proteins, thereby inactivating potential viruses.

Step 4: An oxidative treatment further denatures persisting soluble proteins, thereby eliminating potential antigenicity.

Step 5: Freeze-drying by lyophilization preserves the natural structure of the tissue and maintains a residual moisture of < 5%, allowing quick rehydration and easy handling.

Step 6: Double packing and final sterilization by gamma-irradiation guarantees a 5-year shelf-life at room temperature.

Safety and Quality

Test samples are taken from every donor tissue to perform a LAL-test (Limulus Amebocyte Lysate) for bacterial endotoxin. Reference samples are filed for a minimum of 15 years.

Limulus Amebocyte Lysate test:

Endotoxin activates a serine protease catalytic coagulation cascade in the Limulus’ hemolymph. The first component of the cascade, Factor C (FC), is activated by endotoxin binding. After downstream activation of clotting enzyme, application of a chromogenic substrate results in color change.

Virus inactivation

The critical viral inactivation steps of the process – dynamic immersion in ethanol, hydrogen peroxide and gamma irradiation – have been validated for reliability and reproducibility by an independent test facility. Suspensions of model viruses for non-enveloped and enveloped DNA viruses (HBV), and non-enveloped (HAV) and enveloped RNA viruses (HIV, HCV, HTLV) have been applied. The process shows an overall efficacy in inactivating all test viruses globally > 6 logs (reference value for efficient viral inactivation > 4 logs) and therefore can be considered effective in removing potential viral contaminants.

Biomechanical properties have recently been analyzed by the Institute of Material Science of the Technical University of Vienna, Austria. After the determination of E-modulus and pressure resistance no significant alterations were detected in irradiated products (post rad.) compared to non-irradiated ones (post proc.).

C’TBA’s allograft products provide a stable scaffold for revascularization and osteoblast migration. Simultaneously, due to the preserved collagen content, the graft presents high flexibility supporting physiological bone formation and remodeling.

In an extensive experimental setting virus inactivating capacity of the process was validated and considered effective.
maxgraft® is a sterile, high-safety allograft product, derived from human donor bone, processed by the Cells + Tissue Bank Austria.

For experienced oral and maxillofacial surgeons, allograft bone blocks for block augmentation are the only real alternative to harvesting patients’ autologous bone, preventing well known risks such as donor-site morbidity, infection, postoperative pain and loss of bone stability. The excellent biological regeneration capability of maxgraft® results in a predictable clinical outcome.

Properties
- Preserved biomechanical properties
- Sterile without antigenic effects
- Storable at room temperature for 5 years
- Osteoconductive properties supporting natural and controlled tissue remodelling

The macroscopic structure of maxgraft® cancellous granules affirms the physiological constitution of the graft.

Indications:
Implantology, Periodontology, Oral Surgery & CMF

Granules
- Localized augmentation of the ridge for future implant placement
- Reconstruction of the ridge for prosthetic therapy
- Filling of osseous defects, such as extraction sockets
- Elevation of maxillary sinus floor
- Repair of intrabony periodontal defects

Blocks
- A predictable and highly effective alternative to traditional block grafting
- Ridge augmentation

Biopsy of processed maxgraft® bone 5 months after implantation. The allogenic particle (P) can be recognized by the empty cavities of the osteocytes and is strewn with circular resorption lacunae. The particle is embedded into newly formed bone matrix (B).

The trabecular structure of cancellous bone allows optimal graft revascularization, rapid formation of new bone tissue and complete bone remodelling.
mineralized collagen

The thermogravimetric analysis shows the mass reduction following heating and helps to determine the content of water and organic components like collagen. Heating from room temperature up to 1000°C resulted in a staged mass reduction. The first reduction of 34.64% can be attributed to the vaporization of water and the combustion of collagen, the second (3.88%) to the vaporization of carbon dioxide.

Surface

SEM pictures of maxgraft® illustrate the structure of the processed bone. Processing does not affect structural features and with its interconnecting macroporosity, maxgraft® is natural human bone matrix. Because of the special production process without sintering, maxgraft® retains its collagen matrix. At a higher magnification the structure of the mineralized collagen fibers can be recognized.
maxgraft® bonering
Allogenic Bone Ring

The maxgraft® bonering technique

maxgraft® bonering is a pre-fabricated ring of processed allogenic donor bone, which is placed press-fit into a trephine drill-prepared ring bed. At the same time an implant is inserted into the ring. The bony integration of both maxgraft® bonering, and the implant, occurs via the surrounding vital bone.

Preparation of ring bed

After determination of the position of the implant by the pilot drill, the ring bed is prepared with the trephine. Subsequently, the planator allows an even paving of the local bone for optimal contact with maxgraft® bonering and in addition, removes the cortical layer for improved graft revascularization. For starters it can be of advantage to begin with the planator. Thereby, the position of the implant can be manually adjusted before its final position is assigned by the pilot drill.

The maxgraft® bonering technique allows bone augmentation and implantation in a one-stage procedure. The technique is applicable for almost all indications, including sinus lift with limited maxillary bone height.

Indications:

- Implantology
  - Vertical augmentation (in combination with horizontal augmentation)
  - Single tooth gap
  - Edentulous space

Advantages

- simultaneous implant placement and bone augmentation
- no second surgical procedure
- significant reduction of treatment time

Immediate implant insertion through maxgraft® bonering ensures primary stability of implant and graft.

The height of maxgraft® bonering is adjustable to the defect.

The maxgraft® bonering technique enables vertical bone augmentation and direct implant insertion.

www.botiss-bonering.com
One-stage bone augmentation and implant placement

Soft tissue management

maxgraft® bonering surgical kit

With this surgical kit, botiss provides all necessary instruments to apply the maxgraft® bonering technique. The kit includes two convenient sizes of trephines, which precisely fit together with the two maxgraft® bonering diameters. The planator allows paving of the local bone to create a congruent and fresh contact surface of the implant area. Trephines and planator are perfectly adjusted to the pilot drill. The diamond disc and the diamond ball mill serve to manipulate the maxgraft® bonering for excellent adjustment to the local bone and for improved soft tissue healing. Altogether, these instruments allow optimal preconditions for the bony ingrowth of maxgraft® bonering.

All instruments are made of high quality surgical steel.

Product Specifications

maxgraft® bonering

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<tr>
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11
maxgraft® bonebuilder provides an allogenic bone implant, which is individually adjusted to the patient’s bone defect. With maxgraft® bonebuilder, harvesting of autologous bone and manual adjustment of the obtained transplant is no longer required. Donor site morbidity, operation time and costs can be significantly reduced.

The maxgraft® bonebuilder technology

In-house planning

botiss virtually designs the patient matched allogenic bone implant based on the CT/DVT-scan of the bone defect. The design of the bone implant undergoes a final inspection by the clinical user and is, by individual order, released for production. The botiss partner Cells + Tissuebank Austria receives a *.stl milling file and the patient matched allogenic bone implant is produced under cleanroom conditions. The resulting allogenic bone implant is ready for insertion into the defect with only minor adjustments.

Indications

- Extensive bone defects
- Atrophic maxilla/mandibula
- Horizontal/vertical augmentation

Advantages

- Individualized allogenic bone implant
- Significantly reduced operation time
- Improved wound healing

After placement, the maxgraft® bonebuilder block is fixed with osteosynthesis screws. Residual defect volume should be filled with bone regeneration material and the augmentation site should be covered with a collagen membrane.

The strong capillary action of the 3-dimensional, porous trabecular bone network enables fast and efficient penetration of fluids, nutrients and blood, resulting in excellent handling, reliability and predictability in the daily clinical use.

Based on this model botiss designs a virtual block, which matches the surface structure of the defect and allows stable implant insertion after augmentation.

The CT/DVT-data of the bone defect is transferred into a 3D model.

The patient matched maxgraft® bonebuilder block allows optimal horizontal and vertical reconstruction of the atrophic ridge.
1. Upload of CT/DVT-data on www.botiss-bonebuilder.com

After registration, CT/DVT-data of the patient’s defect can be uploaded on the botiss server. All radiological data have to be single sliced, unlinked images (single-frame data images). The only data type suitable for 3D planning is DICOM (*.dcm). Please find further information on the correct data format on our website.

2. Design of the customized allogenic bone block

botiss creates a 3-dimensional model of the radiological images and designs a virtual patient matched bone implant in consultation with the clinical user. Alternatively, the clinical user can design the bone block by himself and upload the final *.stl file of the designed implant on www.botiss-bonebuilder.com.

3. Design quality check

The clinical user receives a 3D PDF file containing the virtually constructed maxgraft® bonebuilder block and has to confirm its design. Alternatively, the virtual bone block can be adjusted according to specific requirements.

4. Individual order

The production of the block starts after the clinical user fills in the patient based order form for the bone block to the attention of C+TBA, the responsible tissue bank.

5. Production of the individual bone block

At C+TBA the *.stl data of the design is imported into a milling machine and a block of maximally 23x13x13mm is produced.

The maxgraft® bonebuilder technology allows complex reconstruction in cases of extensive jaw atrophy.

Each block is designed individually according to the patient’s defect and the desired dimension of the augmentation.

Product Specifications

maxgraft® bonebuilder
Art.-No.  Content

PMi Individual planning and production of a bone transplant
max. dimensions 23x13x13mm
Clinical Application

Clinical Case by
Dr. Fernando Rojas-Vizcaya,
Castellón, Spain

Socket preservation with maxgraft® granules

Clinical situation in the maxilla before extraction
Situation after tooth extraction and mobilization of mucosal flap
Augmentation of the maxillary ridge and filing of extraction sockets with maxgraft® granules. Placement of mucoderm® to improve soft tissue situation and Jason® membrane to cover surgical site
Mobilization and pre-fixation of the surrounding soft tissue

Tension-free wound closure
4 months post OP: Bone is at the level of the planned crowns
Clinical situation 4 months post-OP
Maxillary ridge in situ after preparation of mucosal flap

Insertion of four implants
Placement of abutments
Positioning of prosthesis
Closure of mucosal flap

After immediate loading protocol: Prosthesis will guide soft tissue during healing process

Antibiotics
When performing hard tissue augmentation, the patient should be treated with a sufficient dose of antibiotics to minimize the risk of infection and related possible graft loss. A potential treatment plan could include starting the antibiosis one day prior or at least one hour before surgery by ingestion of a full daily dose. In case of extensive jaw reconstruction a bacteriological screening (saliva sample) should be considered.
Clinical Application

Clinical Case by
Dr. Damir Jelušić, Opatija, Croatia

Ridge augmentation with maxgraft® cancellous block

X-ray and CAD/CAM-based 3D image of maxillary ridge before surgery

Manual adjustment of maxgraft® blocks on a CAD/CAM-based model

Clinical situation

Atrophic maxillary ridge after preparation of mucosal flap

Fixation of the prepared maxgraft® blocks

Filling of residual gaps with cerabone® and covering with Jason® membrane

Tension-free closure of mucosal flap

CAD/CAM-based 3D image 3 days post-OP

Clinical situation 5 months post-OP

X-ray 5 months post-OP

Insertion of 3 implants and gingiva formers

GBR/GTR
Resorbable collagen membranes act as a temporary barrier against ingrowth of fast proliferating fibroblasts and epithelium into the defect, and maintain the space for controlled regeneration of bone. The Jason® membrane is a pericardium membrane providing a long-lasting barrier function for ~3-6 months. mucoderm®, a 3-dimensional stable matrix, supports revascularization and fast soft tissue integration and thus, is a valid alternative to patients’ own connective tissue. When applying mucoderm® simultaneously with a bone graft material please assure adequate mobilization of the surrounding soft tissue.
Clinical Application

Clinical Case by
Dres. Bernhard Giesenhagen and
Orcan Yüksel, Frankfurt, Germany

Part I: Vertical augmentation with maxgraft® bonering

Vertical augmentation with maxgraft® bonering

For the reconstruction in an atrophied jaw a vertical augmentation of up to 3mm above local bone level can easily be achieved. If more vertical height is desired, enhancing additives such as bone morphogenic proteins (BMP) or growth factors are in discussion to be beneficial. For vertical and horizontal augmentation of a severely atrophied mandible, the width of the ridge (in case of parallel-walled ridge) has to be at least 4mm for successful application of maxgraft® bonering.

The maxgraft® bonering allows for direct implant insertion during sinus lift by providing the necessary primary stability. The sinus cavity should be filled with an additional grafting material (e.g. cerabone®, maxresorb® or maxresorb® inject).
Clinical Application

Part II: Sinus lift with maxgraft® bonering

Preparation of a lateral window for sinus floor elevation in the first quadrant

Mobilization of the Schneiderian membrane

Insertion of the first implant and placement of cerabone®

Placement of maxgraft® bonering

Implant insertion passing through maxgraft® bonering from the crestal side

Filling of the residual sinus cavity with cerabone®

Placement of Jason® membrane

Clinical situation in the second quadrant: Vertical and horizontal defect in the maxillary ridge; sinus cavity is filled with cerabone®

Preparation of the defect with a trephine

Press-fit placement of maxgraft® bonering into the defect

Direct implantation passing through the cancellous ring

Tension-free suturing after placement of Jason® membrane

X-ray 9 months post-OP: Full integration of maxgraft® bonering and implants and proceeding remodelling of the grafts

Rehydration
The processing of maxgraft® products preserves the natural collagen content of the bone tissue and a residual moisture of ~5%. Thus, the products don’t have to be re-hydrated but are ready for instant use. Be aware that hyper-hydration can result in the loss of structural integrity!
Clinical Application

Clinical Case by
Dr. Darius Pocebutas, Kaunas, Lithuania

Horizontal augmentation in a single tooth gap with maxgraft® bonering

- Clinical situation pre-OP
- Pilot drill in the recipient site
- Preparation of the ring bed with the trephine
- Paving of the local bone using the planator from maxgraft® bonering surgical kit

- Measurement of the defect
- Adjustment of maxgraft® bonering to desired height
- Placement of the ring into the ring bed
- Due to its structure the ring is instantly soaked with blood

- Implant insertion passing through maxgraft® bonering; the shape of the ring mimics the anatomic structure of the ridge
- Gaps are filled with cerabone® and the augmentation site is covered with a Jason® membrane
- Tension-free wound closure

Graft exposure

Wound dehiscence and graft exposure can be common complications of block augmentation. After removal of necrotic soft tissue and infected hard tissue (use rotating instruments if necessary) the augmented area should be rinsed with chlorhexidine. Subsequently, the graft has to be covered again, if necessary, by harvesting a palatal soft tissue transplant.
Clinical Application

Clinical Case by
Dr. Markus Schlee, Forchheim, Germany

Ridge augmentation with maxgraft® bonebuilder

3D design of maxgraft® bonebuilder
Patient matched maxgraft® bonebuilder block
Clinical situation in situ

Fixation of maxgraft® bonebuilder with screws for osteosynthesis
Covering of the block with Jason® membrane
Tension-free suturing of the wound

Re-entry 5 months post-OP; Full ingrowth of the block
Implant insertion
Wound closure around gingiva formers

Design quality check
The design of maxgraft® bonebuilder has to be checked very carefully before it is released for production. Only the surgeon himself can assess the patients’ soft tissue situation and therefore, the required dimensions of the block. The botiss construction team will adjust the design of the block until it perfectly meets the expectations of the clinician.
Clinical Case by Dr. Michele Jacotti, Brescia, Italy

Ridge augmentation with maxgraft® bonebuilder

Virtual planning of the block
Patient matched maxgraft® bonebuilder
Situation after mucosal flap preparation and perforation of the cortical layer
Exact positioning of the maxgraft® bonebuilder block

Fixation of the block with screws for osteosynthesis
Careful wound closure
Clinical situation at re-entry 5 months post-OP
Full bony ingrowth of the block

3D implant positioning
Stable implant insertion
Abutment placement after ingrowth of the implants
Final prosthesis

3D construction
The surgeon is free to design his own maxgraft® bonebuilder block by using a suitable software package. The output format of the design file has to be *.stl for import into the C+TBA milling machine.
Clinical Application

Clinical Case by
Dr. Viktor Kalenchuk, Chernivtsi, Ukraine

Ridge augmentation with maxgraft® bonebuilder

Clinical situation before augmentation

CT scan of region 36, 37 before surgery

Situation after tooth extraction and mobilization of mucosal flap

maxgraft® bonebuilder

Immediate implant insertion in regio 34, 35; positioning and fixation of maxgraft® bonebuilder

Filling of residual volume with cerabone®

Covering of the augmentation site with collprotect® membrane

Wound closure and suturing

CT scan of region 36, 37 after surgery

Fixation
maxgraft® blocks are fixed with screws for osteosynthesis, preferably with flat-headed screws to avoid perforation of the surrounding soft tissue.
## Product Specifications

### maxgraft® cancellous granules

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### maxgraft® cortico-cancellous granules

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### maxgraft® blocks

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### maxgraft® bonebuilder

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<td>Individual planning and production of a bone transplant max. dimensions 23x13x13mm</td>
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The maxgraft® bonering surgical kit is delivered in an autoclavable instrument rack.
Innovation.
Regeneration.
Aesthetics.

Distributed by:

Straumann AB
Krokslätts Fabriker 45
431 37 Mölndal
Tel: +46 31 708 75 00
Fax: +46 31 708 75 19
www.straumann.se

Straumann B.V.
Einsteinweg 15
Postbus 338
3400 AH IJsselstein
Tel: +31 30 604 66 11
Fax: +31 30 604 67 28
www.straumann.nl

Straumann s.r.o.
Na Žertvách 2196
180 00 Prague 8
Czech Republic
Tel.: +420 284 094 650
Fax: +420 284 094 659
www.straumann.cz

Straumann A/S
Post boks 1751, Vika
0122 Oslo
Tel: +47 23 35 44 88
Fax: +47 23 35 44 80
www.straumann.no

Straumann SA/NV
Belgicastraat 3 Box 3
1930 Zaventem
Tel: +32 2 790 10 00
Fax: +32 2 790 10 20
www.straumann.be

Straumann UK
3 Pegasus Place
Gatwick Road
West Sussex
Crawley RH10 9AY
Tel: +44 1293 65 12 30
Fax: +44 1293 65 12 39
www.straumann.co.uk

botiss
dental GmbH
Uhlandstraße 20-25
10623 Berlin / Germany
Fon: +49 30 20 60 73 98 30
Fax: +49 30 20 60 73 98 20

 Straumann AB
Krokslätts Fabriker 45
431 37 Mölndal

 Straumann A/S
Post boks 1751, Vika
0122 Oslo

 Straumann SA/NV
Belgicastraat 3 Box 3
1930 Zaventem

 Straumann s.r.o.
Na Žertvách 2196
180 00 Prague 8
Czech Republic

 Straumann UK
3 Pegasus Place
Gatwick Road
West Sussex
Crawley RH10 9AY

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