Rapid-Prototype Titanium Bone Forms for Vertical Alveolar Augmentation Using Bone Morphogenetic Protein-2: Design and Treatment Planning Objectives

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Reconstruction of complex maxillofacial defects where the use of bone morphogenetic protein-2 composite grafts may be preferred can be done using perforated titanium shells or forms that confine the graft material and simultaneously establish the desired shape of the augmentation without resorting to autogenous block bone grafting. Reported here is a method for creation of rapid-prototype titanium bone forms, which was developed from a software program, to reproduce bone morphology precisely. The technique and treatment planning objectives are elucidated, especially with regard to complex vertical augmentations. ORAL CRANIOFAC TISSUE ENG 2012;2:321–326. doi: 10.11607/octe.0033

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Alveolar vertical bone reconstruction is one of the more difficult problems to manage in maxillofacial surgery, as it confronts the issue of expanding jawbone structure under conditions of an often-limited periosteal/skeletal envelope. In 2003 Van Steenberghe et al1 were the first to demonstrate, with both animal and clinical data, that subperiosteally placed titanium barriers could facilitate vertical bone augmentation that remained stable, even after implant placement. The barrier was prepared in wax from a stereolithographic model and then fabricated in titanium. During surgery, prior to the placement of the barrier, multiple trephinations of the basal bone were performed to allow for formation of a blood clot.2,3 Wounds were closed primarily over the barrier, which was filled with blood only. Others have used hand-shaped titanium mesh with various grafting materials placed underneath the mesh4,5 to enhance bone growth, including autogenous bone and demineralized allograft or xenograft,6–15 sometimes in combination with bone morphogenetic proteins (BMPs).16,17

The BMPs are a group of osteoinductive, sequentially arranged amino acids and polypeptides that are capable of stimulating adult mesenchymal stem cells to become osteoblasts. BMP was conceptually described by Urist18 and Urist et al,19 who showed that ectopic bone had formed in rabbits and rats from extracted heterogeneous bone transplants. Subsequently, BMP was characterized and cloned, providing a tool to more fully study the role of cytokines in bone repair. DNA cloning20 made possible the availability of various recombinant BMPs for definitive use in animal models and in maxillofacial bone defects, including mandibular continuity defects,21 maxillary clefts,22 the pneumatized maxillary sinus,23 traumatic defects, and preprosthetic alveolar ablations.24

Computer simulation and stereomodeling technology have allowed surgeons to perform surgery based on accurate reconstructions, helping to minimize operating time. Advance planning may enhance the quality of the surgical reconstruction,25,26 which is being studied at present in animal models as well as clinically.27–29

To further elucidate this process from a clinical standpoint, the authors present here the design, planning, and use of perforated bone forms made of titanium in a rapid-prototyping process for BMP-2 composite grafting.
MATERIALS AND METHODS

The use of rigid bone forms, also termed titanium shells, is intended for BMP-2 jawbone reconstruction, especially for vertical alveolar augmentation. Indications include:

1. Alveolar vertical defects of 5 mm or more
2. Mandibular and maxillary complex defects
3. Mandibular segmental defects

The method for using a titanium shell consists of several phases: design, titanium printing, presurgical, surgical, postoperative, and hardware removal.

Design Phase

**Step 1: Imaging.** All patients must undergo three-dimensional (3D) computed tomographic (CT) scanning. The thickness of each cut should be 1 mm. Data obtained from each set of exposures are then reconstructed into 2D and 3D CT images while all artifacts are erased. The final goal of this step is to create a 3D CT with minimum artifact from conventional CT digital files (Figs 1 and 2).

**Step 2: Computer-Aided Design.** The 3D CT is then converted into a 3D computer-aided design (CAD) program format.

**Step 3: Initial Draft.** After a readable file has been obtained, an initial draft of the 3D CAD file is created, including design of the anatomical morphology of the reconstructed bone. This prescription is then used to model a bone form, which overlays the prescribed augmentation and rests on preexisting bone.

The initial draft should adhere to the following guidelines (Figs 3 and 4):

- The bone form should be designed to fit the natural continuity of the existing ridge and simulate the preexisting ridge. The design draft may take into consideration possible bone graft resorption.
- The internal buccolingual width of the bone form at the alveolar crest should be at least 6 mm—that is, adequate for standard dental implant placement.
- The height of the shell should not exceed the height of the adjacent cementoenamel junction.
- The thickness of the titanium wall is designed to be 0.8 mm. The distance from the adjacent teeth should leave a gap of 1.5 mm from the cervix of the teeth.
- The titanium shell is perforated with multiple holes 0.3 to 1 mm apart. The diameters of the holes vary but are typically 1 to 3 mm. Depending on the size and shape of the shell, separate holes, 1.1 mm in diameter, are planned for use in securing the bone form with 1-mm titanium screws at the buccal aspect (Fig 4). Generally, there is no need for additional screw fixation lingually to complicate the surgical procedure.
- Most shells are intended to be one-piece shells, but where there would be severe undercuts—for example, in a bone form for creating a new maxilla (Fig 5)—a one-piece shell will not allow for a path of insertion. Therefore, a two-piece shell should be designed, with the segments connected using interlocking.

**Step 4: Subtraction.** The existing bone is then subtracted from the model to allow printing of the bone form (Fig 6).

**Step 5: Review.** A review of the initial file is done using three file formats: a CAD program (enabling the objects to be rotated in real time), isometric views (top, bottom, etc), and sectional views of critical areas to ensure accurate coverage and shape. In some cases, a plaster cast or a stereolithographic 3D print of the CT scan can be made to aid in the design and review process.

**Step 6: Conversion into the Correct File Format.** After assessment of the initial file, all of the marks are gathered and the final file is created and converted into an STL file. The STL file is then sent for 3D sinter printing in titanium.

Titanium Printing Phase

The printing method uses Arcam electron beam melting (EBM) technology (Arcam EBM). EBM offers a...
direct CAD-to-metal process, allowing production of patient-specific custom-made bone forms using data derived from CT. These titanium shells are built layer by layer from metal powder and melted by an electron laser beam. Each layer is melted to the exact geometry defined by the 3D CAD model. The titanium pieces are built in a vacuum at elevated temperatures, resulting in stress-free shells.

The EBM production platforms are capable of delivering beam power of up to 3,500 W while maintaining a scan speed that allows for melting at several points simultaneously. The vacuum system is designed to maintain a controlled vacuum level of $1 \times 10^{-4}$ or better throughout the build cycle.

The titanium used for bone form fabrication is titanium-aluminum-vanadium alloy (Ti-6Al-4V) (with an oxygen level of 0.13%). The resultant bone form is finished manually at the end of the process to smooth any rough surfaces.

**Presurgical Phase**

Whenever dental extractions are needed in the area to be reconstructed, these are performed atraumatically to avoid disturbing the fit of the bone form. When numerous extractions are required, consideration should be given to performing extractions prior to bone form placement surgery to reduce the risk of infection, improve soft tissue closure, and reduce the potential for resorption of the basal bone.

**Surgical Phase**

Under intravenous sedation or general anesthesia, the patient should be prepared and draped in a sterile fashion. A mucoperiosteal flap is elevated using either a crestal or sulcular incision. The flap is developed such that watertight closure can be obtained without wound tension.

During this time, INFUSE Bone Graft (Medtronic) is prepared by reconstituting lyophilized recombinant human BMP-2 with sterile water to a concentration of 1.5 mg/mL and then applying this to an absorbable collagen sponge (ACS).

At this point, the fit of the shell to the bone is checked, and the best path of insertion under the flap is established. The cortical bone can be perforated if desired using a round bur. After the shell has been inserted, a 50/50 mixture of BMP-2/ACS and allograft, xenograft, or autograft is placed using a 2.5-mL "top free" syringe. The authors’ preference is to mix BMP-2/ACS with locally harvested autogenous bone.
and expand this with demineralized freeze-dried bone allograft to achieve the desired composite mixture. The shell is then fixed into place, pressure is applied to confine the graft, and fastening screws are placed at the periphery of the bone form. Closure of the wound is obtained without tension using resorbable sutures. A layer of free fat obtained from the buccal fat pad can be applied over the shell to aid in closure. Collagen tape can also be used just below the wound margin, but not covering the entire shell, as an aid to soft tissue wound healing (not to serve as a barrier membrane). If wound closure cannot be accomplished, an imperforate bone form is prepared in advance and the shell is left uncovered during the healing period (Fig 7).

**Postoperative Phase**

Postoperatively, patients receive antibiotic coverage (amoxicillin 1.5 g/day) for 7 days. The wound is examined every week for 4 weeks. Patients should not wear dentures at the site for at least 6 weeks and preferably for the entire healing period. The patient is instructed to adhere to a soft diet.

Bone formation under the titanium bone form can be observed radiographically by 4 months. The bone form is usually removed 4 to 6 months after placement. For large vertical augmentations, the newly formed bone may not yet be firm by 6 months.

If premature exposure occurs and the titanium shell is exposed, it should be removed as soon as possible. By 8 weeks postsurgery, there is usually enough structural integrity of the graft, except in the areas of direct exposure, so that the shells can be removed by this point. Shells should not be kept in place too long after exposure—perhaps no longer than 3 to 4 weeks, especially if infection develops.

**Hardware Removal**

Five months is considered the optimal healing time for removal of most bone forms. For removal, a shell is separated over the crest using a drill or disk, and then the buccal screws are removed. The surgeon must take care to avoid damaging the still-developing bone. In some cases, a predesigned “breaking line” is made to ease removal (Fig 8). Complex anatomical structures such as nerves can be avoided by use of an easily retrievable design (Fig 9). A design that also performs the role of fixation, such as for continuity defects, may not need to be completely removed, such as the two-piece design shown in Fig 10, in which the lingual border portion is intended to be left in place permanently.
SUMMARY

A rapid-prototype titanium bone form can be used for vertical alveolar augmentation. This allows for a nearly perfect fit to existing bone morphology and therefore is a significant advantage over titanium mesh. The bone form simplifies the treatment of very complex defects. Overall, the technique results in the formation of new bone for dental implant placement with decreased patient morbidity, including less operative time, compared to conventional reconstructive methods.29

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REFERENCES


