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ORIGINAL ARTICLE

Maxillary sinus augmentation using computer-aided design/computer-aided manufacturing (CAD/CAM) technology

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Abstract

Background Maxillary sinus augmentation is a common method for increasing bone height for insertion of dental implants. In most cases, the graft is manually cut into a roughly appropriate shape by visual estimation during the operation; accordingly, the shape of the graft depends considerably on the experience of the surgeon. We have developed a computer-aided design/computer-aided manufacturing (CAD/CAM) technique to generate custom-made block grafts for sinus augmentation, and a customized cutting guide to precisely position the lateral wall and facilitate membrane elevation, using cone-beam computed tomography (CBCT).

Methods Custom-made blocks of hydroxyapatite (HA) were preoperatively cut to the required shape, based on a three-dimensional (3D) simulation, using CAD/CAM technology. The custom-made HA blocks were used for sinus augmentation.

Results Five patients underwent bilateral sinus elevation with custom-made HA blocks. Six months later, implants were placed. Two years after placement, all implants were in function. No clinical or prosthetic complications were encountered.

Conclusions We present a CAD/CAM technique for the fabrication of custom-made block grafts for sinus augmentation.

Keywords sinus augmentation; bone grafts; computer-aided design/computer-aided manufacturing (CAD/CAM); custom-made

Introduction

The posterior maxilla represents a challenge for dental implant procedures when the available bone is reduced because of alveolar ridge resorption and/or hyperpneumatization of maxillary sinus (1). Consequently, bone grafting within the maxillary sinus is often required for the placement of implants in this area (1).

The classical sinus augmentation procedure, as invented by Tatum (2) but first described by Boyne and James 1980 (3), consists of the creation of a window in the lateral maxillary sinus wall. This window is luxated inward and upward together with the Schneiderian membrane to a horizontal position forming the new sinus floor; the space between the old and new floors is filled with graft material.

Autogenous bone has long been considered the gold standard as a graft material because of its osteoinductive and osteoconductive properties (4,5). However, limitations of autogenous bone grafting include the requirement for additional surgery for harvesting, the availability of grafts of sufficient size and shape and the risk of donor site morbidity, which may include pain, bleeding or infection (4–11). In addition, some research articles state that autogenous bone resorbs at an above-average rate, which can lead to posterior pneumatization of the sinus and/or implant failure (4,6–11).

The limitations of autogenous grafts can be overcome by using bone substitutes, including allografts (6,7), xenografts (7–9) and synthetic bone grafts (10). When performing sinus augmentation, bone substitute materials can be as effective as autogenous bone, as demonstrated in several studies (4,6–12).

Maxillary sinus augmentation via a lateral window approach is a safe and successfull procedure to gain bone height for implant placement in an atrophic posterior maxilla (13,14). The survival rate for implants placed in these grafted sinuses has been reported by Wallace and Froum (13) and Del Fabbro and Testori (14) to average 91.8% and 91.5%, respectively. However, despite the high success rate, complications can occur, such as perforation of the Schneiderian membrane (15–18), bleeding (17), implant displacement into the sinus and infection (15–18).

Since the variety of anatomical modalities in the shape of the inner aspect of the maxillary sinus defines the surgical approach, accurate preoperative identification of these structures is important (19,20). The most reliable method in terms of being preoperatively informed about the size and shape of the maxillary sinus is a cone-beam computed tomography (CBCT) scan (19,20). The resulting images provide clinicians and patients with an intuitive visualization of the sinus anatomy, including the position of septa and endosseous arterial branch (21).

Despite these diagnostic advances, current sinus augmentation procedures still require bone substitutes blocks to be manually cut, shaped and formed at the time of implantation, resulting in an expensive and time-consuming process. Moreover, positioning the lateral wall during lateral sinus augmentation has remained an intuitive process, whereby the surgeon relies on mental navigation to achieve proper identification (22). In the case of the sinus augmentation procedure, however, inaccurate osteotomy cuts to define the lateral window can potentiate sinus membrane perforation, particularly when the membrane is thin and the anatomical environment is challenging (22).

Computer-aided design/computer-aided manufacturing (CAD/CAM) technologies have recently opened new frontiers in biomedical applications (23). In the present study, we introduce a CAD/CAM technique for the fabrication of anatomically-shaped, custom-made porous hydroxyapatite (HA) scaffolds, which can be predictably used for maxillary sinus augmentation; in addition, we develop a CAD/CAM cutting guide to precisely position the lateral wall and facilitate Schneiderian membrane elevation.

Materials and methods

Patient selection

Between January 2008 and January 2010, all patients referred to the Dental Clinic, University of Varese, for treatment with oral implants, presenting with bilateral edentulism of the posterior maxilla, were taken into consideration for inclusion in this study. Inclusion criteria were crestal bone height of 2–5 mm between the sinus floor and the alveolar ridge. Exclusion criteria consisted of poor oral hygiene, active periodontal infections, sinus pathology, uncontrolled diabetes, bruxism and smoking habit. All patients were selected after careful evaluation of their medical histories and dental examinations, including panoramic radiographs and CBCT scans. The mucosa thickness and pathology, bone height and thickness, sinus structure and major blood vessels were assessed. The study protocol was explained to each subject and signed informed consent was obtained. The study was performed according to the principles outlined in the World's Medical Association's Declaration of Helsinki on experimentation involving human subjects, as revised in 2008, and it was approved by the Local Ethics Comittee for Human Studies at the University of Varese, Italy.

CAD/CAM procedures

CAD/CAM procedures involved three steps: the virtual planning and design of the custom-made scaffold and the customized cutting guide (Figure 1a, b); the manufacture of the scaffold and the guide (Figure 2a); and the sinus augmentation procedure (Figure 2b–f).

Virtual planning of the custom-made scaffold and the cutting guide

CBCT datasets of the posterior edentulous maxilla were acquired and subsequently loaded in the digital imaging and communications in medicine (DICOM) format into a specific 3D reconstruction software (Mimics^{R}, Materialise, Leuven, Belgium). The hard tissue threshold was selected so that only bone was reconstructed from the slices. With this software, it was possible to perform an accurate 3D reconstruction of the maxilla and the sinus; after this, an anatomically-shaped, custom-made scaffold for maxillary sinus augmentation was drawn. The 3D geometries of the maxilla and the scaffold were then saved as stereolithographic (STL) files. Subsequently, these files were transferred to a 3D CAD program (Rhinoceros^{R}, Robert McNeel & Associates, Seattle, WA, USA). This software was used to presurgically outline the ideal lateral boundaries of the maxillary sinus for bone grafting surgery. The maxillary sinus was outlined in 3D, and the software was used to trace the desired lateral window and osteotomy cuts in 3D. The cutting paths were verified in all planes of space to ensure that the planned osteotomy cuts would maximize the operator's ability to begin Schneiderian membrane reflection, thus obtaining

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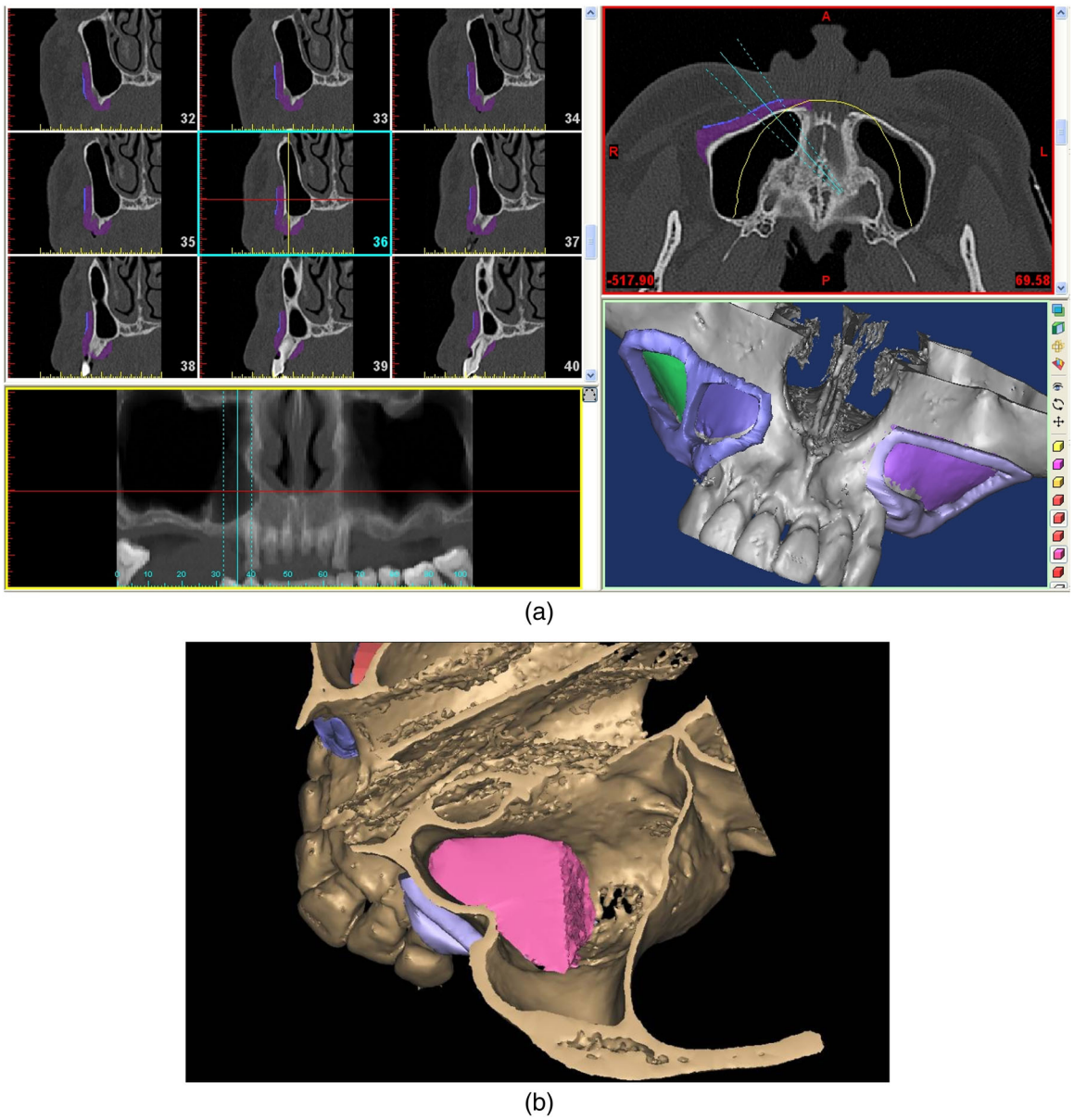


Figure 1. Three-dimensional (3D) reconstruction of the maxilla before bilateral sinus augmentation: (a) computer-aided-design (CAD) project with the cutting guides, virtual osteotomies and anatomically-shaped, custom-made blocks has been performed; (b) another view of the anatomically-shaped, custom-made blocks

the ideal customized cutting guide. This cutting guide was designed such that it would exactly fit onto the bone surface and would have a slit conforming to the simulated osteotomy plane. The 3D geometry of the cutting guide was then saved as a separate STL file.

Manufacture of the custom-made scaffold and the cutting guide

The 3D geometry of the anatomically-shaped, custom-made scaffold was imported into a proprietary CAM software, used to generate a set of tool-paths for fabrication on a proprietary computer-numerical-control (CNC) milling machine. A coral-derived HA (Biocoral^{R}, Leader-Novaxa, Milan, Italy) block was then placed in the CNC milling machine and milled into the exact shape of the 3D project. In this way, an anatomically-shaped, custom-made HA scaffold was manufactured. The cutting accuracy of the machine was within 25 μm. The original size of the HA block was $15 \times 15 \times 30$ mm. Finally, the same CAD/CAM procedure was used to fabricate the surgical polytetrafluoroethylene (PTFE) device, composed of a customized cutting guide, based on preoperative simulations. The HA cut block and the PTFE cutting guide were sterilized before surgery.

Sinus augmentation procedure

The surgical procedure was carried out according to Tatum (2). Local anaesthesia was obtained by infiltrating 4% articaine containing 1:100.000 adrenaline (Ubistesin^{R}, 3 M Espe, St. Paul, MN, USA). After a horizontal crestal incision and two vertical incisions in the buccal mucosa, a mucoperiosteal flap was raised to expose the lateral wall of the maxillary sinus. The CAD/CAM bone-supported

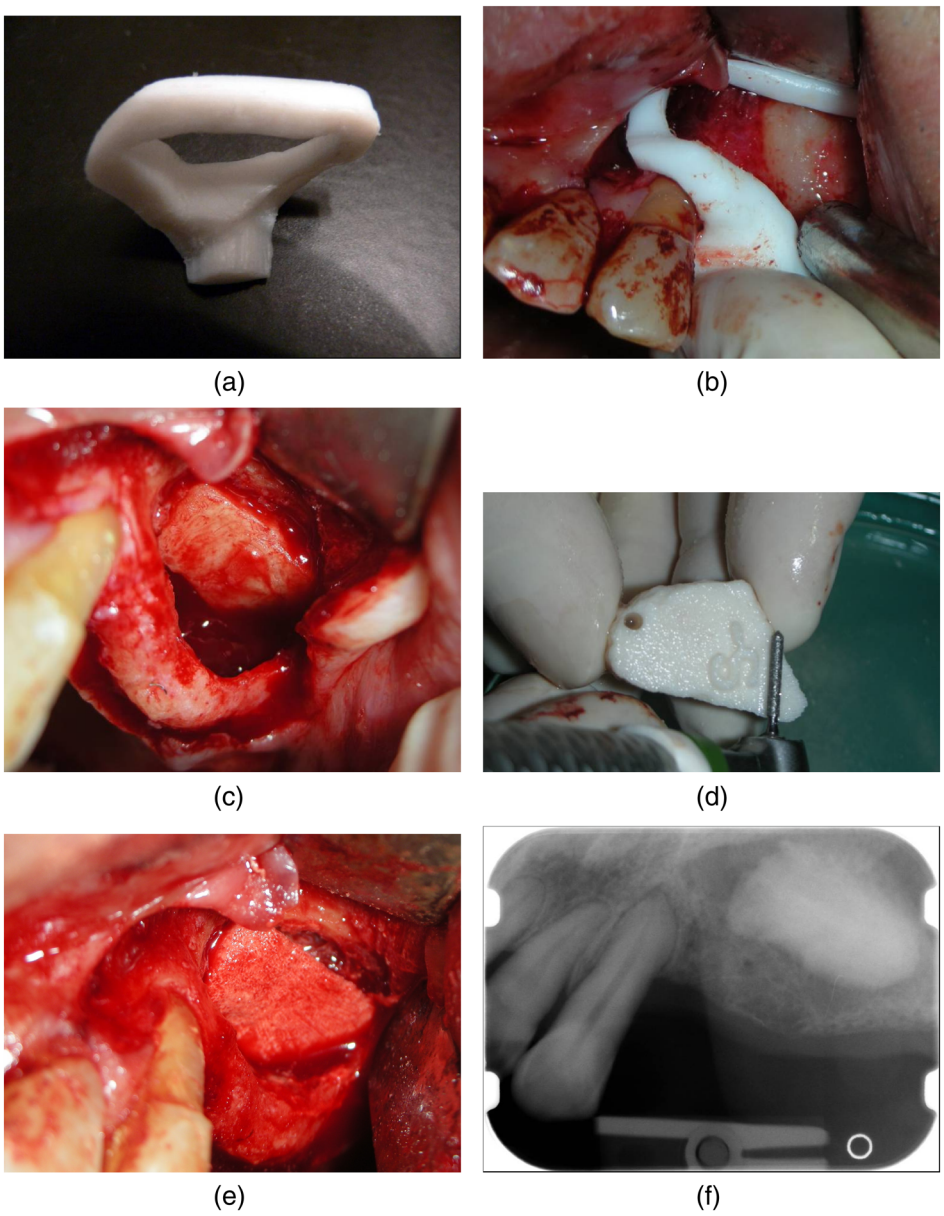


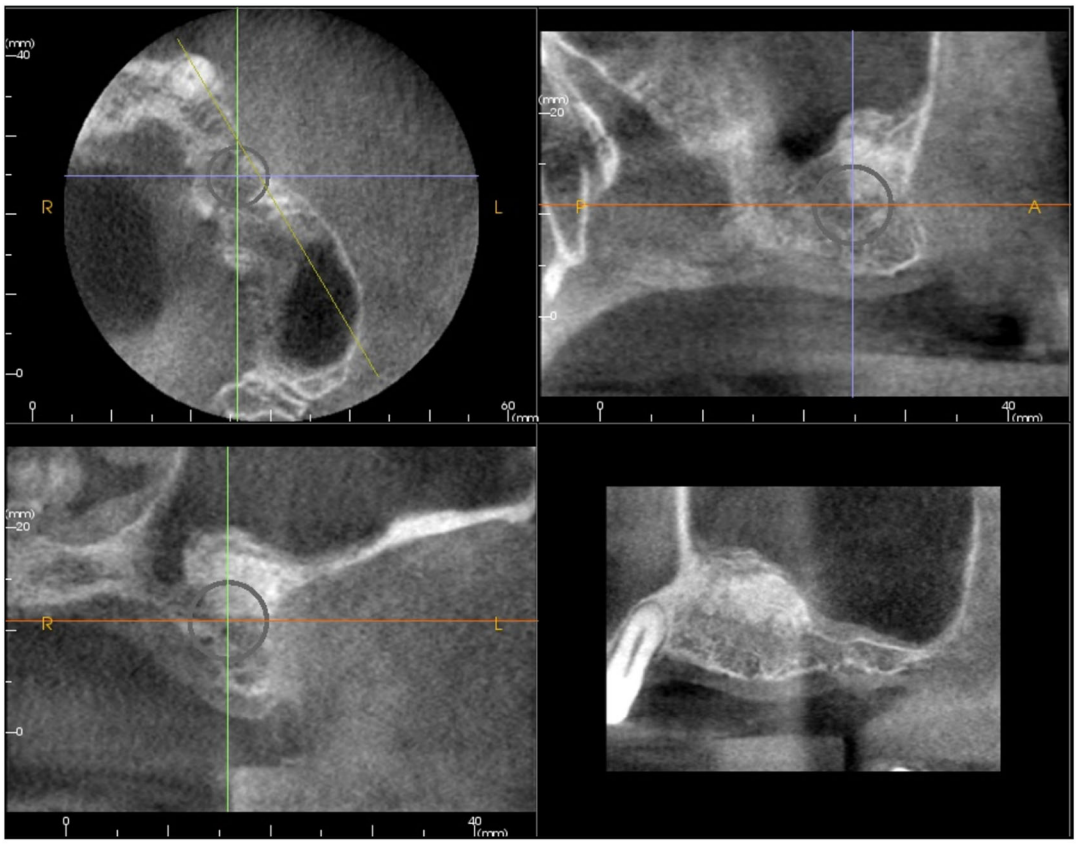
Figure 2. Surgical procedure: (a) PTFE customized cutting guide post manufacture, prior to insertion; (b) the PTFE customized cutting guide is fitted to the underlying bone, verified for stability and then used to outline the planned configuration of the lateral wall; (c) the bony window fragment is moved mesially, the sinus membrane is reflected and separated from the bony surface of the sinus floor with an elevator, and the space created; (d) the anatomically-shaped, custom made HA block is removed from its support and ready for use; (e) the custom-made HA block is inserted into the sinus. The block fits securely to the residual bone, immediately filling the whole empty space; (f) periapical radiograph taken immediately after maxillary sinus elevation, showing the HA block that completely fills the defect

cutting guides were adapted to the underlying bone and verified for stability. The guides fitted exactly onto the bone surface, had a slit conforming to the simulated osteotomy plane and were then used to outline the planned configuration of the lateral wall. A bone window was approximately outlined with piezosurgery inserts under constant irrigation. Care was taken not to penetrate the Schneiderian membrane. The CAD/CAM cutting guides remained on the bone surface during outlining of the lateral window. After cutting the bone, the guide was disengaged. The bony window fragment was moved mesially, the sinus membrane was reflected and separated from the bony surface of the sinus floor with an elevator and the space created. Finally, the anatomically-shaped custom-made HA block was inserted into the sinus. The block fitted securely to the residual bone, immediately filling the whole empty space. No membrane was used. Complete wound closure was performed with interrupted, non-resorbable sutures (Supramid^{R}, Novaxa, Milan, Italy). All patients received oral antibiotics, 2 g/day for 6 days (Augmentin^{R}, GlaxoSmithKline Beecham, Brentford, UK). Postoperative pain was controlled by administering 100 mg nimesulide (Aulin^{R}, Roche Pharmaceutical, Basel, Switzerland) every 12 h for 2 days, and detailed instructions about oral hygiene were given, with mouth-rinses with 0.12% chlorhexidine (Chlorexidine^{R}, OralB, Boston, MA, USA) administered for

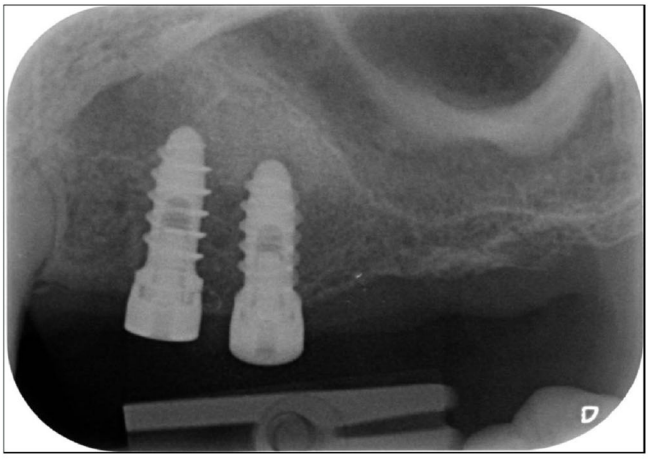
7 days. Suture removal was performed at 8–10 days. The grafted sinuses were allowed to heal for 6 months before implant placement.

Implant placement and prosthetic procedures

Six months after maxillary sinus elevation, the CBCT control of the grafted area confirmed that an adequate bone volume was present, so that selective laser sintering implants (TixOs^{R}, Leader-Novaxa, Milan, Italy) were placed (Figure 3a, b). A two-stage technique was used to place the implants (24). The implants were left submerged for a period of 3–4 months. Then, second-stage surgery was conducted to gain access to the underlying implants and healing abutments were placed. A mesio-distal crestal incision, limited to the implant site, was placed and the ridge mucosa was elevated to uncover the implant, followed by the replacement of the cover screw with a healing abutment. The mucosal flap was adjusted to the healing abutment and then sutured in position. The abutments were placed 2 weeks after the second surgery, so that acrylic interim restorations could be provided, cemented



(a)



(b)

Figure 3. Six months after sinus augmentation: (a) radiographic CBCT analysis confirms a post-grafting opacity of the maxillary sinus floor, and no clinical signs of sinus pathology are observed; (b) implants are placed

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with temporary cement (Temp-Bond^{R}, Kerr, Orange, CA, USA). Provisional restorations were used to monitor implant stability under a progressive load and to obtain good soft tissue healing around the implant before fabrication of the definitive restorations. The placement of the definitive prosthetic restorations was performed on an individual basis, after soft tissue maturation, at least 3 months after implant placement. All definitive restorations were ceramo-metallic, cemented with temporary cement (Temp-Bond^{R}). These restorations were carefully evaluated for proper occlusion, and protrusion and laterotrusion were assessed on the articulator and intraorally (24). Patients were enrolled in an annual recall programme.

Clinical and radiographic evaluation

At each annual follow-up recall, clinical, radiographic and prosthetic parameters were assessed. The two following clinical parameters were investigated for each implant: presence/absence of pain, suppuration or exudation; and presence/absence of implant mobility, tested manually using the handles of two dental mirrors. Standardized intraoral periapical radiographs were taken, before and after implant placement and at each recall evaluation, using an alignment system with a rigid film-object X-ray source coupled to a beam-aiming device to achieve reproducible exposure geometry. Customized positioners, made of polyvinyl siloxane, combined with an alignment system with a rigid film-object X-ray source coupled to a beam-aiming device, were used for precise repositioning and stabilization of the radiographic template. The radiographs were taken to evaluate the presence/absence of continuous peri-implant radiolucencies. Finally, prosthesis function was tested. Static and dynamic occlusion was evaluated, using standard occluding papers. Careful attention was dedicated to the analysis of any potential prosthetic complications. The evaluation of implant survival and implant success was performed according to well-established clinical and radiographic parameters (25). Implants were divided into two categories: survived and failed implants. A survived implant was classified as such when it was still functional at the end of the study. To achieve implant success, the following clinical and radiographic success criteria had to be fulfilled: absence of pain on function; absence of suppuration or exudation; absence of clinically detectable implant mobility; absence of continuous peri-implant radiolucency; and absence of prosthetic complications (25).

Results

A total of five patients (three males, two females, aged 45–57 years) were selected for this study. Ten maxillary sinus augmentations were performed. During maxillary sinus augmentation, the customized PTFE cutting guide allowed the surgeon to precisely transfer the virtual planned osteotomy into the surgical environment. In fact, the cutting guide fitted extremely well in the anatomical environment and accurately identified the boundaries that were presurgically planned. The clinically-sized, anatomically-shaped custom-made HA blocks fitted securely into the sinus. No surgical complications occurred. Immediately after surgery, the post-operative intraoral periapical radiographs showed that the HA blocks exactly filled the defects. Six months after surgery, radiographic CBCT analysis confirmed a post-grafting opacity of the maxillary sinus floor in all patients. No clinical signs of sinus pathology were observed, and no patients showed any sign of maxillary sinusitis. A total of 19 implants were placed. At the end of the study, after 2 years of functional loading, all implants were in function, and no clinical or prosthetic complications had occurred. The radiographic evaluation revealed a low tendency to marginal bone resorption and a good stability of peri-implant bone tissue.

Discussion

Modern CBCT scans have been used with increased frequency as a diagnostic tool in oral and maxillofacial surgery. This modality is advantageous based on cost-effectiveness, shorter radiography time, higher resolution, excellent spatial resolution and lower radiation exposure compared to conventional computed tomography (CT) (19–21). Nowadays, intimate knowledge of the anatomy and information provided by CBCT scans can help to prevent surgical complications during sinus floor elevation procedures, such as membrane perforation or intraoperatory bleeding, which can complicate treatment (19–21,26); moreover, such information may enable us to fabricate custom-made scaffolds for maxillary sinus augmentation using CAD/CAM technology (22,23).

To date, surgeons have estimated the size and shape of a bone graft through preoperative planning, using radiographs, and deciding the final shape and manually cutting a bone graft into shape during the operation. With this approach, however, the accuracy of the shape of the resulting bone graft depends heavily upon each surgeon's level of skill, as it can be difficult to shape the graft into an appropriate configuration (23). Moreover, the amount of graft material required may vary considerably according to the level of the door axis in respect to the sinus floor; the sinus size shows a great variety between different persons and even between different sides in the same patient.

Owing to recent improvements in CAD technology, combined with advanced 3D cutting machinery, it is now possible to cut a block of bone substitute into the most appropriate shape, that has been preoperatively calculated using 3D simulation (23).

In the present study we developed a CAD/CAM technique that calculates the size and shape of a bone graft and cuts a HA block into the desired shape. A block of porous HA, which has excellent osteoconductivity and mechanical properties suitable for machine-cutting, was preoperatively cut into a highly accurate 3D shape, based on the preoperative

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simulation using CAD/CAM technologies. In addition, a customized CAD/CAM osteotomy template was designed and manufactured before surgery, based on preoperative simulations, and used during the operation. Five patients were treated with a bilateral sinus floor elevation technique according to Tatum (2), i.e. an osteotomy of the lateral wall of the maxillary sinus. The guide was securely fitted onto the bone surface, and an osteotomy was performed through the slit. The bone window was outlined and the bony window fragment was moved mesially, the sinus membrane was reflected and separated from the bony surface of the sinus floor with an elevator and the space created; then, the anatomically-shaped custom-made HA block was inserted into the sinus. The block fitted securely to the residual bone, immediately filling the empty space. A postoperative radiograph showed that the HA block exactly filled the sinus defect. Six months after maxillary sinus elevation, implants were placed. Two years after implant placement, all implants were in function with no evidence for clinical or prosthetic complications.

Attempts to calculate a 3D shape of the bone defects using CT data, construct its stereolithography model and manually shape an autogenous bone graft have been reported recently (27). A previous case report documented the use of CT scan to generate a computer-guided osteotomy template to precisely locate the margins of the lateral window in the maxillary sinus augmentation, that would allow the pre-fabrication of a customized cutting guide (22).

In modern implant dentistry, priority should be given to those interventions that look simpler, are less invasive, involve less risk of complications and reach their goal within the shortest time frame (28). To the best of our knowledge, however, this is the first clinical trial to use CBCT scan and CAD/CAM technology to generate anatomically-shaped, customized block grafts for maxillary sinus augmentation. The main advantages of this tecnique are reduced intervention time, with precise adaptation of the scaffold, reduced risk of complications and improved intervention quality. This protocol has a limit. In fact, the dimensions of the custom-made block are, at least in part, related to the dimensions of the outlined lateral bony window. For this reason, it can be difficult to completely fill the space between the old and the new floor with the CAD/CAM block alone, and there is a potential risk of small defects in graft placement, anteriorly/posteriorly to the CAD/CAM block. This limitation, however, could be easily overcome by using particulate grafts in association with the custom-made, CAD/CAM block. In fact, a small amount of particulate may be used to fill the small gaps between the custom-made, CAD/CAM block and the residual bone crest. In this context, the CAD/CAM block graft would fill the largest area of the sinus, providing structural rigidity and supporting the Schneiderian membrane, while particulate grafts may offer the benefits of filling the small gaps adjacent to the custom-made scaffold. In several clinical studies, in fact, bone grafts in either block or particulate form have been used in sinus augmentation, with considerable success (4–12,29).

The use of CAD/CAM technology can lead to a more objective approach of producing bone grafts, which does not rely on the individual skills of the surgeon. This technique needs to be applied in a larger cohort of patients to verify the results; however, computer-controlled fabrication via CAD/CAM technology may hold the key for a solution in automating scaffold production that can cater for variations in the shapes and requirements of different tissues and also size variations between different individuals (30). In the near future, the availability of custom-made scaffolds engineered from the patient's own stem cells could revolutionize the way we currently treat bone defects in implant dentistry.

Disclosure

The authors declare that they have no financial relationship with any commercial firm that may pose a conflict of interest for this study. No grants, equipment, or other sources of support were provided.

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