CLINICAL REPORT

Individually Prefabricated Prosthesis for Maxilla Reconstruction

Sekou Singare, PhD,[1,4] Yaxiong Liu, PhD,[2] Dichen Li, PhD,[2] Bingheng Lu, PhD,[2] Jue Wang, PhD,[1] & Sanhu He[3]

[1] Key Laboratory of Biomedical Information Engineering of the Ministry of Education, and Institute of Biomedical Engineering, Xi'an Jiaotong University, Xi'an, China
[2] State Key Lab for Manufacturing Systems Engineering, Xi'an Jiaotong University, Xi'an, China
[3] Department of Maxillofacial Surgery, School of Stomatology, Xi'an Jiaotong University, Xi'an, China
[4] Department of Mechatronic Engineering, Dongguan University of Technology, Guangdong, China

Keywords
Individual template; designed prosthesis; computer-aided reconstruction; rapid prototyping; rapid tooling.

Correspondence
Sekou Singare, The Key Laboratory of Biomedical Information Engineering of Ministry of Education and Institute of Biomedical Engineering, Xi'an Jiaotong University, Xi'an, 710049, China. E-mail: sekou2d@yahoo.com, sekousingare@hotmail.com

Accepted 18 September 2006

doi: 10.1111/j.1532-849X.2007.00266.x

Abstract

The reconstruction of maxillofacial bone defects by the intraoperative modeling of implants may reduce the predictability of the esthetic result, leading to more invasive surgery and increased surgical time. To improve the maxillofacial surgery outcome, modern manufacturing methods such as rapid prototyping (RP) technology and methods based on reverse engineering (RE) and medical imaging data are applicable to the manufacture of custom-made maxillary prostheses. After acquisition of data, an individual computer-based 3D model of the bony defect is generated. These data are transferred into RE software to create the prosthesis using a computer-aided design (CAD) model, which is directed into the RP machine for the production of the physical model. The precise fit of the prosthesis is evaluated using the prosthesis and skull models. The prosthesis is then directly used in investment casting such as "Quick Cast" pattern to produce the titanium model. In the clinical reports presented here, reconstructions of two patients with large maxillary bone defects were performed using this new method. The custom prostheses perfectly fit the defects during the operations, and surgery time was reduced. These cases show that the prefabrication of a prosthesis using modern manufacturing technology is an effective method for maxillofacial defect reconstruction.

Conventionally, reconstructions of maxillary defects have been achieved with autografts[1–3] or prosthetic maxillary obturators.[4] Bone grafts have become the common method used in maxillofacial surgery; however, use of a bone graft increases length of surgery, blood loss, and donor site morbidity, and risks failure of the graft due to bone resorption.[5] A prosthetic maxillary obturator is an alternative for maxillary defect reconstruction. Although acceptable results can eventually be achieved in many cases, patients may become dissatisfied, because the removable prosthesis lacks sufficient retentiveness for adequate speech, swallowing, and acceptable esthetic appearance. Poor retention because of denture bulkiness and poor residual dentition can result in leakage and oronasal regurgitation. Patients must maintain adequate hygiene at the surgical site and around the prosthesis.[2] Due to these limitations, a bridging titanium implant can be used as an alternative for functional maxillary reconstruction. Reconstruction of the defect by means of bridging titanium implants avoids the need for bone grafting and the problems associated with resorption of grafted bone, and requires only a minor surgical procedure for implant insertion.

Conventional CT and MRI scans are standardized and are important diagnostic tools for assessing the extent of tumor resection.[6,7] The reconstructed 3D data from the CT can be transferred in the operating room to accurately determine the resection margins of the tumor, simplifying the surgical procedure;[8] however, tumor resection or defect reconstruction based on 3D imaging modalities presents difficulties in defining the resection plane with sufficient accuracy. On the other hand, stereolithographic models are more concrete, allowing the surgeon to actually simulate the surgical procedure or even to generate patient-specific templates that can be used in the surgery.

In the field of maxillofacial surgery, implants are often manufactured on life-size stereolithographic models.[9] Because of the manual sculpting necessary for anatomically-shaped implant geometry, this technique does not allow an accurate geometrical modeling approach as does computer-aided design (CAD)-based implant modeling. As the result of the development of modern design and manufacturing technology, a customized medical implant and surgical resection template that matches skeletal anatomy can now be accurately designed

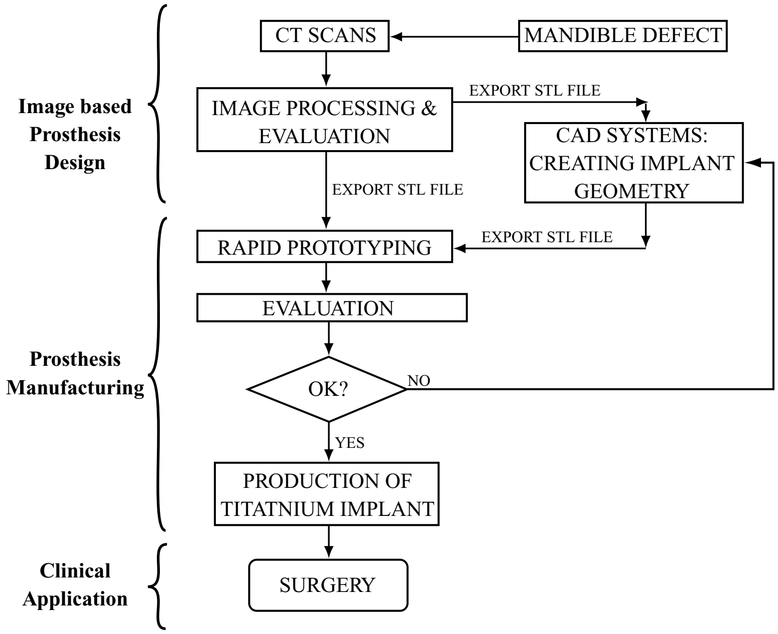

Figure 1 Computer-aided geometric modeling for the production of custom implants.

using a CAD technique.[10-12] The physical model of the individual implant, template, or skull replica can be produced through rapid prototyping (RP), rapid tooling (RT), and computer aided manufacturing/computer numerical control (CAM/CNC) processes.[13-24] The RP model facilitates surgical simulation and planning.[9,25-28]

This report describes a new method of constructing a prefabricated implant based on modern CAD and RP techniques. The method provides a long-term, stable, precisely-fitting replacement prosthesis for large maxillary bone defects. The CAD model prosthesis is designed using reverse engineering (RE) software and is directly fabricated using a stereolithography machine. This direct fabrication avoids the necessity for indirect manual modeling on full-size models. Two patients have received maxillary reconstruction with this type of implant with satisfactory results.

The proposed approach as shown in Figure 1 includes an image-based prosthesis design process, manufacture, and clinical application.

Image-based prosthesis design

The skull of the patient is scanned using CT, and the 2D image slices from the CT scans are imported into commercial Materialise Interactive Medical Image Control System (MIMICS) software (Materialise NV, Leuven, Belgium). The CT data are then segmented to generate a 3D volumetric image of the patient's skull anatomy. Once the 3D volumetric has been generated, contours are calculated and exported as follows:

1. As Initial Graphics Exchange Specification (IGES) format, which is directly imported into Geomagics Studio 6.0 (Raindrop Geomagic, Inc., Research Triangle Park, NC) as a point cloud for implant CAD design.
2. As binary data such as standard tessellation language (stereolithography)(STL) format, which is directly imported into stereolithography for the production of a life-size skull model.

After 3D reconstruction in MIMICS, the next step is to reconstruct the CAD model of the implant from the point cloud. The imported point cloud first must be processed in RE software (Geomagic Studio 6, Raindrop Geomagic, Inc.) to reduce the file size. The points are then denoised and wrapped as polygonal surfaces. Certain defects, such as holes in the surface, must be removed to obtain close manifolds (Figs 2A and 3A).

Prosthesis geometry modeling before tumor resection

The prosthesis for repairing the maxilla can actually be designed before resection of the tumor. First, the approximate area occupied by the tumor is identified on the initial CT diagnostic images. Using the information acquired from imaging diagnostics, the location of the exact tumor borders are identified, traced (Fig 2B), and cut out to isolate the tumor image. The cut out tumor image serves as the design template for the tumor resection. The prosthesis geometrical design includes: the segment to be resected, the margin from the border of the segment to be resected, and microplates for fixation (Fig 2C). Three individual microplates with bone-adherent surfaces for fixation are constructed to blend well with the outer contours of the segment to be resected to allow prosthesis fixation; these bone adherent surfaces are derived directly from the data of the maxilla contour, and the resection border planes are used for the margins of the prosthesis body. The nonuniform rational B-spline (NURBS) surfaces are then fitted into these geometrical contours to generate the individual prosthesis CAD model and tumor resection template. Basically, the resection template

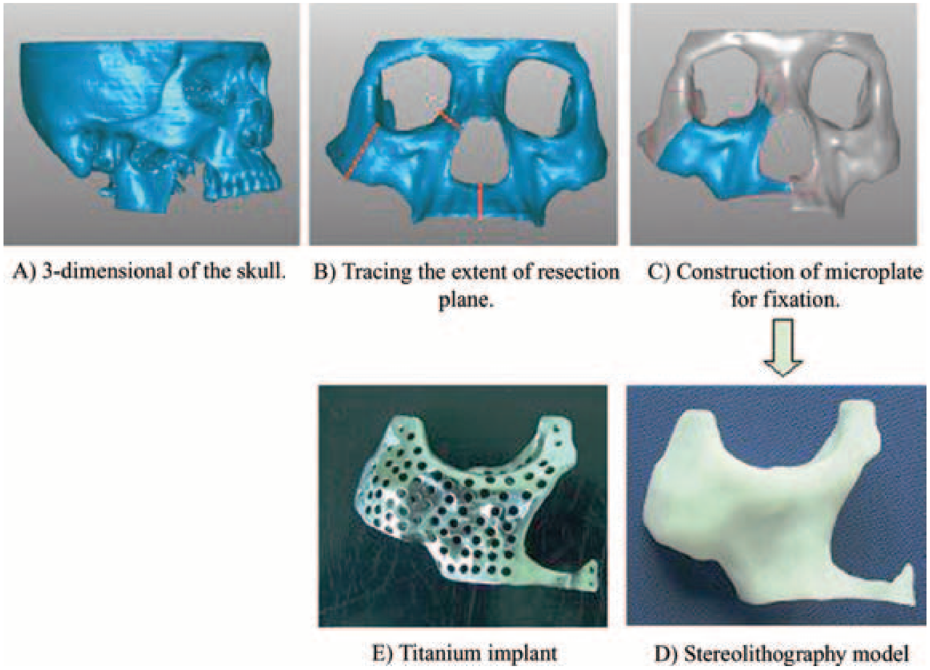

Figure 2 CAD implant construction before tumor resection.

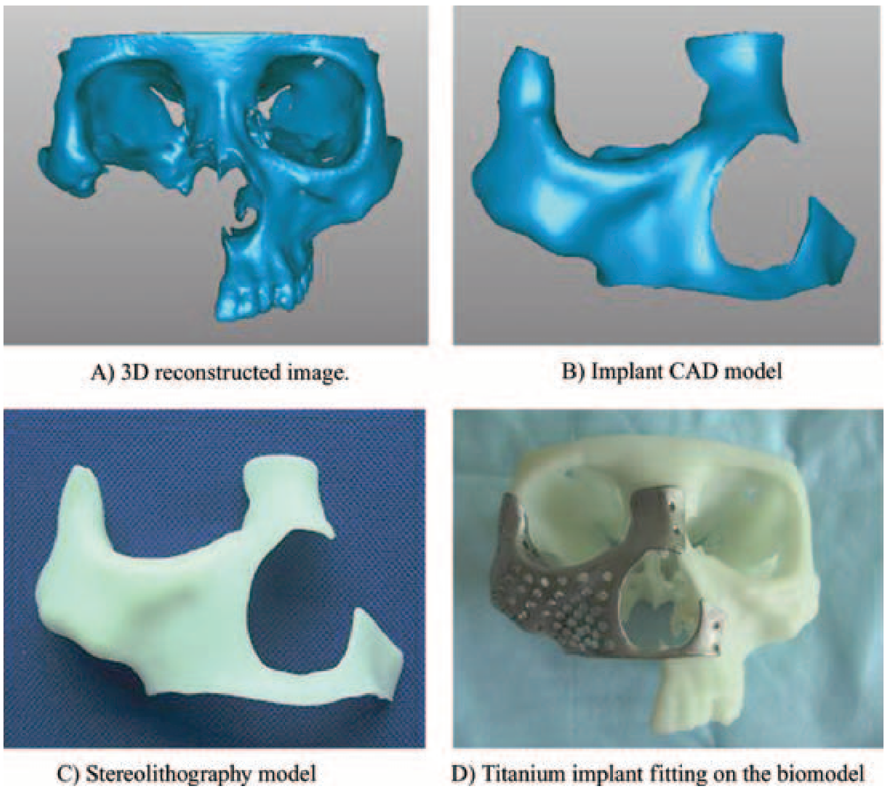

Figure 3 CAD implant construction after tumor resection.

geometry can be used as a surgical aid for tumor resection, with the prosthesis used to bridge the maxillary defect after tumor removal.

Prosthesis geometrical modeling after tumor resection

For a unilateral bone defect, such as the one shown in Figure 3A, the missing tissue is reconstructed by using mirror imaging techniques. First, the mirror plane is created (reference system), and the nondefect side (healthy maxilla) is mirrored to the defect side. The overall implant shape is obtained by applying a Boolean subtraction of the damaged portion of the maxilla with the skull. Individual microplates for fixation are derived directly from the maxilla contour data, and the prosthesis margins are derived from the border of the defect. Next, NURBS patches are used to fit across these geometrical contours to generate the prosthesis CAD surface model, and the surface is thickened to generate the solid model (Fig 3B).

Manufacturing

The CAD data for the prosthesis with corresponding resection templates are translated into an STL file format and imported into the RP machine to fabricate the physical object (Figs 2D and 3C). During surgery, the individual SLA template will be placed in its predefined position, and the optimal position of the resection plane can be found easily. Alternatively, the SLA model prosthesis can be fitted on the skull biomodel to evaluate symmetry, accuracy of surface fitting, etc. In addition, the surgery can be simulated on the biomodel (Fig 3D).

Finally, the stereolithography apparatus (SLA) prosthesis pattern is directly used in investment casting such as Quick-Cast for production of the titanium prosthesis (Figs 2E and 3D). Holes are inserted in the implant body after completion of the CAD/CAM process for better soft-tissue integration.

Clinical application

Case 1

As shown in Figure 4B, a 64-year-old patient, who had been diagnosed with gingival carcinoma of the right upper jaw, underwent maxillary reconstruction. Using the information acquired from imaging diagnostics, a resection template was CAD/CAM fabricated with the titanium implant to provide one-step reconstruction. During surgery, the tumor was exposed, and the resection template was fitted to the surface of the affected bone in order to mark the resection margin. Then the segment of the affected bone inside the marked area was resected based on the contour of the individual resection template SLA model to ensure adequate tumor clearance. The upper jaw was then immediately reconstructed with the custom-made titanium prosthesis as shown in Figure 4A. In this case, the information acquired from 3D-CT reconstructed data have contributed to

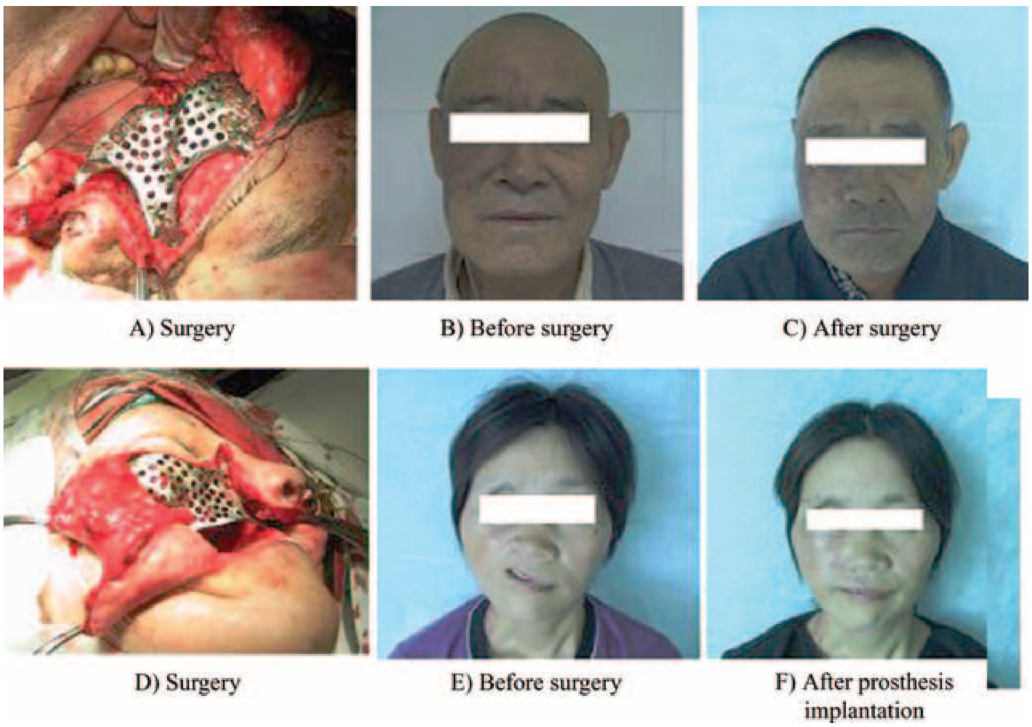

Figure 4 Maxilla reconstruction.

the assessment of tumor extension, as well as its location in the patient's anatomy, and also were helpful in the determination of adequate limits of tumor resection. As a result, resection and reconstruction were thus highly precise, safe, and fast. There were no difficulties during reconstruction, because the individual titanium implant is prefabricated with a geometry fitting to that of the template. As a consequence, the implant closes the bone defect perfectly and so the contour is reconstructed precisely. No complications or tumor recurrences were seen in a 1-year follow-up period, and the patient was satisfied with the result.

Case 2

As shown in Figure 4E, a 34-year-old female patient presented at the hospital reporting pain in her right upper teeth for the past 2 months and nasal blood secretions for the past 20 days. Clinical examination revealed swelling of her right maxilla sinus with middling density and uneven quality, extending into the middle nasal meatus. The inner wall of the maxillary sinus had broken into the nasal septum. Adenocarcinoma of the maxilla was diagnosed.

The patient underwent maxillary bone resection for the first surgery; her wound healed well with no recurrence of the tumor, but with 1/3 facial deformation and severe diplopia. She returned to the hospital for deformation correction and repair. The customized titanium maxillary prosthesis was fabricated as shown in Figure 3 and implanted successfully at the correct position during surgery (Fig 4D).

Clinical outcome

Three-dimensional CT images and stereolithographically-produced models were helpful for the determination of the extent of the necessary resection area and defect reconstruction.

The customized prefabricated prostheses fit the maxillary defects well in both patients, and no adjustments were needed during the surgery. As a result, briefer surgical time was required. Rigid fixation of both implants was achieved using screws. The reconstructed maxillary contour and facial symmetry were judged to be good in both patients, as shown in Figures 4C and 4F. (Post-surgical swelling is obvious in Fig 4C, but this swelling was eventually relieved.) Complications were not observed during the follow-up period.

Discussion

The maxillary skeleton serves as the functional and esthetic keystones of the midface. Defects in the palatomaxillary complex can lead to devastating functional and cosmetic consequences.[29] Multiple reconstructive techniques, such as autologous tissue transfers and alloplastic materials, have been available for many years, but reconstruction of extensive defects with autologous bone is limited by the amount of available donor bone, difficulty with 3D contouring, and poor tissue tolerance and acceptance.[30] The use of alloplastic materials, such as reconstruction plates, has several risks, including plate exposure, plate and screw fracture, screw loosening, infection, and limited esthetic and functional restoration.[31] On the other hand, some studies have recommended a bridging plate for advanced oral cancer with a poor prognosis or poor performance status rather than vascularized free bone.[32,33]

Until now most implants have been manually shaped intraoperatively on the surgical site. Intraoperative adaptation of the implant is a difficult task, however, due to lack of visualization of the facial anatomy, with the result that an undesirable shape can be obtained when use of complex 3D contouring is required.[28] Furthermore, intraoperative modeling is time-consuming and reduces accuracy, often leading to more invasive surgery, and impairing esthetic results. The use of a CAD/CAM system is an adequate method for the design and manufacture of very complex 3D prosthesis shapes that are difficult, if not impossible, to create with conventional techniques. Intraoperative adaptation can be avoided when using prefabricated individual titanium implants. On the other hand, the use of CAD-based prosthesis modeling can avoid indirect manual fabrication on a life-size stereolithography model, which always increases cost, decreases precision, and does not use the advantages of geometric design in CAD/CAM.[18]

As the majority of tumor-related maxilla deformities are unilateral, CAD using RP technologies is an effective technique for generating a precise prosthesis shape for reestablishing maxilla symmetry and an individual template for tumor resection. Compared with intraoperative navigation systems for tumor resection, the use of an individual resection template eliminates the need for complex equipment and time-consuming work under radiographic control or registration procedures in the operating room.[34]

Creating the 3D model of bone structures extracted from CT image data allows not only for prosthesis design, but also provides very good visualization of the defect for preoperative surgical evaluation and planning. The preoperative preparation, symmetry, and precise fit implant evaluation can be performed much more easily on the physical model generated by RP. As a consequence, the operating time is reduced, and potential intraoperative errors can be modified preoperatively and thus avoided during the actual surgery.

The cases presented demonstrate the efficacy and accuracy of using combined technologies of 3D-CT data and a stereolithography-produced model for tumor resection guidance and defect reconstruction. One drawback of this approach is that it depends on preoperative CT imaging and, therefore exposes the patient to high radiation exposure. On the other hand, the solid modeling of implant and surgical template in a CAD system is time-consuming, which makes it unsuitable for emergency cases.

We can conclude that CT imaging, RP, and computer modeling have improved the surgical planning and the manufacture of customized implants and have also achieved efficient immediate reconstruction. In such clinical cases, a computer-generated model allows the fabrication of a custom prosthesis that very accurately represents the anatomic defect. The use of these techniques leads to reduced operating time, fewer surgical errors, more precise fit, and high stability after screw fixation. Other advantages include simplification of the surgical procedure; the method also permits testing implant fit before the actual surgery, and determination of accurate positioning of the implant. As result, the actual surgery consists only of defining the defect and placement and fixation of the implant.

Acknowledgments

The authors express their deepest gratitude and thanks to the National Natural Science Foundation of China (No. 50235020, No. 50575170) and DongGuan Research Development Special Foundation (No. 2006D015) for their assistance with the rapid prototyping activities presented in this paper.

References

1. Ostric SA, Martin WJ, Stock C, et al: The model graft: reconstruction of the maxilla using a fibular bone graft template. J Craniofac Surg 2006;17:145-147
2. Peng X, Mao C, Yu GY, et al: Maxillary reconstruction with the free fibula flap. Plast Reconstr Surg 2005;115: 1562-1569
3. Pryor SG, Moore EJ, Kasperbauer JL: Orbital exenteration reconstruction with rectus abdominis microvascular free flap. Laryngoscope 2005;115:1912-1916
4. Uckan S, Oguz Y, Uyar Y, et al: Reconstruction of a total maxillectomy defect with a zygomatic implant-retained obturator. J Craniofac Surg 2005;16:485-489
5. Okura M, Isomura ET, Iida S, et al: Long-term outcome and factors influencing bridging plates for mandibular reconstruction. Oral Oncol 2005;41:791-798
6. Gagliardi G, Bayar S, Smith R, et al: Preoperative staging of rectal cancer using magnetic resonance imaging with external phase-arrayed coils. Arch Surg 2002;137:447-451
7. Kahler DM, Zura RD, Mallik K: Computer guided placement of iliosacral screws compared to standard fluoroscopic technique. 5th Symposium on CAOS Computer Assisted Orthopaedic Surgery. 2002, Davos, Switzerland
8. Bettega G, Dessenne V, Cinquin P, et al: Computer assisted mandibular condyle positioning in orthognatic surgery. J Oral Maxillofac Surg 1996;54:553-558
9. Bill JS, Reuther JF, Dittmann W, et al: Stereolithography in oral and maxillofacial operation planning. Int J Oral Maxillofac Surg 1995;24:98-103
10. Dean D, Min KJ, Bond A: Computer aided design of large-format prefabricated cranial plates. J Craniofac Surg 2003;14:819-832
11. Singare S, Dichen L, Bingheng L, et al: Design and fabrication of custom mandible titanium tray based on rapid prototyping. Med Eng Phys 2004;26:671-676
12. Singare S, Dichen L, Bingheng L, et al: Customized design and manufacturing of chin implant based on rapid prototyping. Rapid Prototyping J 2005;11:113-118
13. Barker TM, Earwaker WJ, Frost N, et al: Integration of 3-D medical imaging and rapid prototyping to create stereolithographic models. Aust Phys Eng Sci Med 1993;16: 79-85
14. Bouyssie JF, Bouyssie S, Sharrock P, et al: Stereolithographic models derived from x-ray computed tomography. Reproduction accuracy. Surg Radiol Anat 1997;19:193-199
15. D'Urso PS, Barker TM, Earwaker WJ, et al: Stereolithographic biomodelling in cranio-maxillofacial surgery: a prospective trial. J Craniomaxillofac Surg 1999;27:30-37
16. Ellis DS, Toth BA, Stewart WB: Three dimensional imaging and computer-designed prostheses in the evaluation and management of orbitocranial deformities. Adv Ophthalmic Plast Reconstr Surg 1992;9:261-272
17. Eufinger H, Wehmoller M, Machtens E, et al: Reconstruction of craniofacial bone defects with individual alloplastic implants based on CAD/CAM-manipulated CT-data. J Craniomaxillofac Surg 1995;23:175-181
18. Eufinger H, Wehmöller M: Individual prefabricated titanium implants in reconstructive craniofacial surgery: Clinical and technical aspects of the first 22 cases. Plast Reconstr Surg 1998;102:300-308
19. Goh JC, Ho NC, Bose K: Principles and applications of computer-aided design and computer-aided manufacturing (CAD/CAM) technology in orthopaedics. Ann Acad Med Singapore 1990;19:706-713
20. Heissler E, Fischer FS, Bolouri S, et al: Custom-made cast titanium implants produced with CAD/CAM for the reconstruction of cranium defects. Int J Oral Maxillofac Surg 1998;27:334-338
21. Hieu LC, Bohez E, Vander Sloten J, et al: Design for medical rapid prototyping of cranioplasty implants. Rapid Prototyping J 2003;9:175-186
22. Warnke PH, Springer IN, Wiltfang J, et al: Growth and transplantation of a custom vascularised bone graft in a man. Lancet 2004;364:766-770
23. Winder J, Cooke RS, Gray J, et al: Medical rapid prototyping and 3D CT in the manufacture of custom made cranial titanium plates. J Med Eng Technol 1999;23:26-28
24. Winder J, Bibb R: Medical rapid prototyping technologies: state of the art and current limitations for application in oral and maxillofacial surgery. J Oral Maxillofac Surg 2005;63:1006-1015
25. Abe M, Tabuchi K, Goto M, et al: Model-based surgical planning and simulation of cranial base surgery. Neurol Med Chir (Tokyo) 1998;38:746-751
26. Anderl H, Zur Nedden D, Muhlbauer W, et al: CT-guided stereolithography as a new tool in craniofacial surgery. Br J Plast Surg 1994;47:60-64
27. Sailer HF, Haers PE, Zollikofer CP, et al: The value of stereolithographic models for preoperative diagnosis of craniofacial deformities and planning of surgical corrections. Int J Oral Maxillofac Surg 1998;27:327-333
28. Muller A, Krishnan KG, Uhl E, et al: The application of rapid prototyping techniques in cranial reconstruction and preoperative planning in neurosurgery. J Craniofac Surg 2003;14:899-914
29. Genden EM, Wallace D, Buchbinder D, et al: Iliac crest internal oblique osteomusculocutaneous free flap reconstruction of the postablative palatomaxillary defect. Arch Otolaryngol Head Neck Surg 2001;127:854-861
30. Blake GB, MacFarlane MR, Hinton JW: Titanium in reconstructive surgery of the skull and face. Br J Plast Surg 1990;43:528-535
31. Doty JM, Pienkowski D, Goltz M, et al: Biomechanical evaluation of fixation techniques for bridging segmental mandibular defects. Arch Otolaryngol Head Neck Surg 2004;130:1388-1392
32. Head C, Alam D, Sercarz JA, et al: Microvascular flap reconstruction of the mandible: a comparison of bone grafts and bridging plates for restoration of mandibular continuity. Otolaryngol Head Neck Surg 2003;129:48-54
33. Poli T, Ferrari S, Bianchi B, et al: Primary oromandibular reconstruction using free flaps and thorp plates in cancer patients: a 5-year experience. Head Neck 2003;25:15-23
34. Birnbaum K, Schkommodau E, Decker N, et al: Computer-assisted orthopedic surgery with individual templates and comparison to conventional operation method. Spine 2001;26:365-370