Computer-Aided Design and Manufacturing for Digital Orthopedics

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1 Introduction

Over the past decades, the surgical guides or templates as the high-precision technologic tools have been applied for various surgeries such as the oral implantology, oncology, nasal prosthesis implant placement, cervical or lumbar pedicle screw placement, total hip arthroplasty (THA), treatment of sacroiliac joint fracture, total knee arthroplasty (TKA), etc. The surgical template is a guide aiming at directing the drilling, osteotomy, or tumor resection, providing an accurate placement of the implant or prosthesis, etc. Therefore, with the use of it, the preoperative planning can be transferred to the actual surgical site, and the precision and safety and reliability of the surgery can be improved. The general workflow of the template design and manufacturing (shown in Fig. 5.1) is described as follows: on the basis of the original medical image data (computed tomography (CT), cone beam computed tomography (CBCT), magnetic resonance imaging (MRI), etc.), image processing (including segmentation and registration) is conducted through the preoperative planning software. Then, modeling of the critical anatomical structures is realized for 3D visualization. Based on the series of 2D images (coronal, sagittal, and axial) and the 3D-reconstructed models, preoperative planning is performed, including 2D/3D geometrical measurements, the optimization design of the position and orientation of surgical trajectory, the simulation of implant placement, etc. According to the result of preoperative planning, the surgical template can be designed using key technologies of reverse engineering, point cloud, and surface reconstruction. Then, it can be fabricated through numerical control machining, additive manufacturing (3D printing) technologies, etc., and the clinical application can be finally conducted.

Compared with the surgical navigation system, the advantages of surgical template applications are convenience and ease of use. Furthermore, the surgical procedures can be optimized and executed in a shorter time, with less time spent in the operating room, thus enabling significant cost savings to hospitals and fewer risks to the patient.

The early production of the surgical template is mainly dependent on manual design and fabricating methods, which are not standardized and efficient. Pesun et al. described a technique fabricating a guide with gutta-percha to be used for oral implant placement. Then, with the development of computer technologies, the computer-aided design (CAD) and the computer-aided manufacturing (CAM) have been widely used for producing the customized surgical guides in the field of digital orthopedics. Furthermore, the rapid prototyping (RP) or 3D printing has now become the mainstream fabricating method over the past years due to the great enhancement of production efficiency and accuracy. For example, Zhang et al. designed a patient-specific drill template through the CAD software (Imageware, Siemens PLM Software, Germany) and produced using the stereolithography rapid prototyping technique for total hip arthroplasty. The key technologies involved in this method are image processing, preoperative planning, template design, and fabrication, which are discussed as follows.

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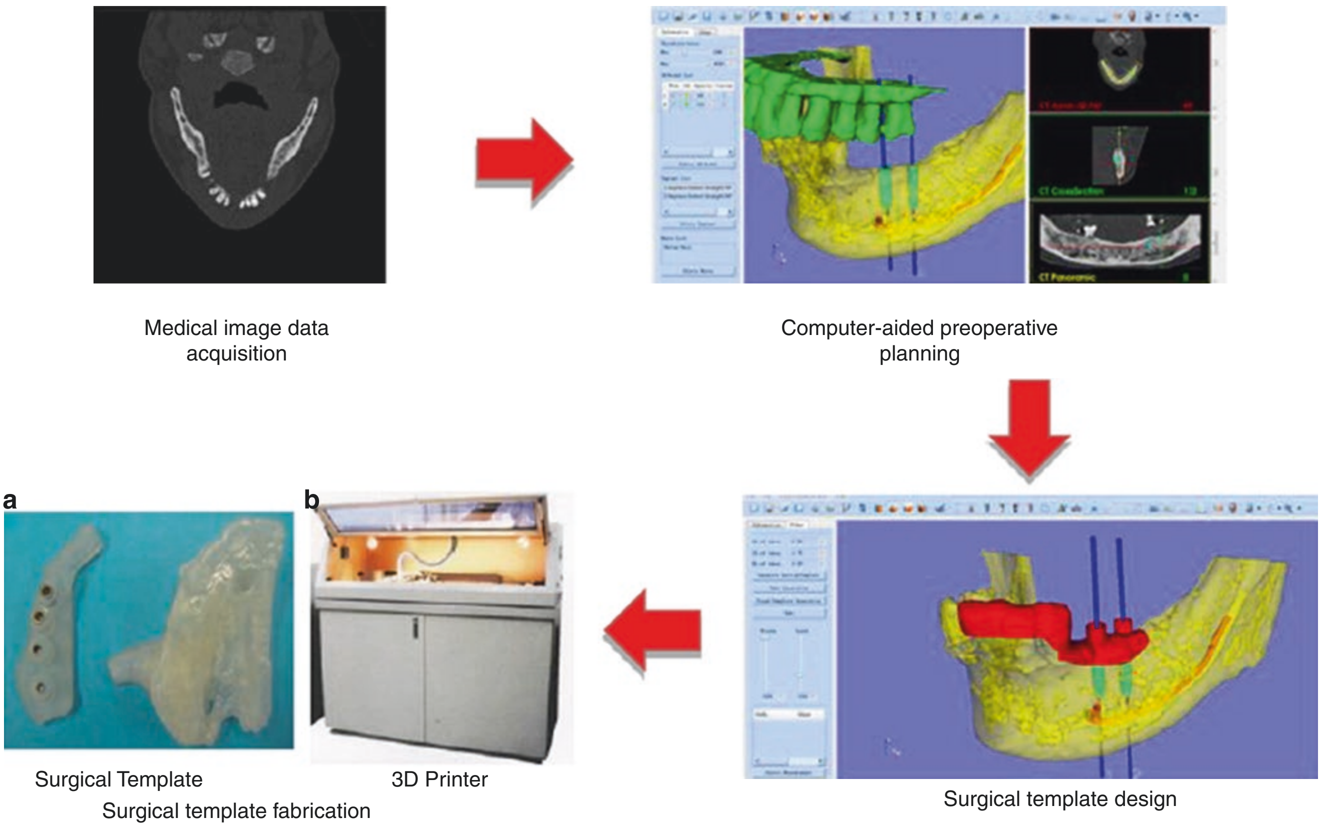

Fig. 5.1 The general workflow of the template design and manufacturing

2 Image Processing

Medical image processing is the core and prerequisite of the preoperative planning. With the aid of image processing, the important information such as focus, hard and soft tissues, blood vessels, and nerves can be extracted for the clinical diagnosis and treatment.

2.1 Image Segmentation

Image segmentation is the key procedure of image processing, and its main purpose is to divide the image into different regions with special signification and make the results approximate to the anatomical structures.

Manual segmentation of medical images (CT, MR, PET, etc.) is time-consuming and can hardly deal with some complex situations when the difference in features between the targets and the surrounding tissues cannot be identified. Nowadays, researchers are focusing on the development of automatic image segmentation algorithm. Although some novel algorithm have been proposed, a related limitation is that the accuracy of the segmented result for some cases may not be sufficient to meet the clinical requirements. For example, some tumors are detected as structures within or on the edge of the liver, and can be missed if some slices at the top or at the bottom of the liver are not segmented. So far, the major segmentation algorithms include region growing method, watershed algorithm, the deformable biomechanical model method, level set method, Markov random fields algorithm, Voronoi-diagram algorithm, fuzzy connectedness algorithm, etc. In addition, there are some methods based on special theories, for example, the artificial neural network algorithm, the methods based on wavelet transform, statistics, fractal theory, mathematical morphology, etc.

2.2 Image Registration

Medical images acquired from different sensors can provide more complete information to gain more complex and detailed scene representation for the treatment verification. For example, MRI records the anatomical body structures, and ultrasound or CT monitors functional and metabolic body activities. Therefore, multimodality image registration is a crucial procedure in all image analysis tasks which is the process of bringing two or more images into spatial alignment.

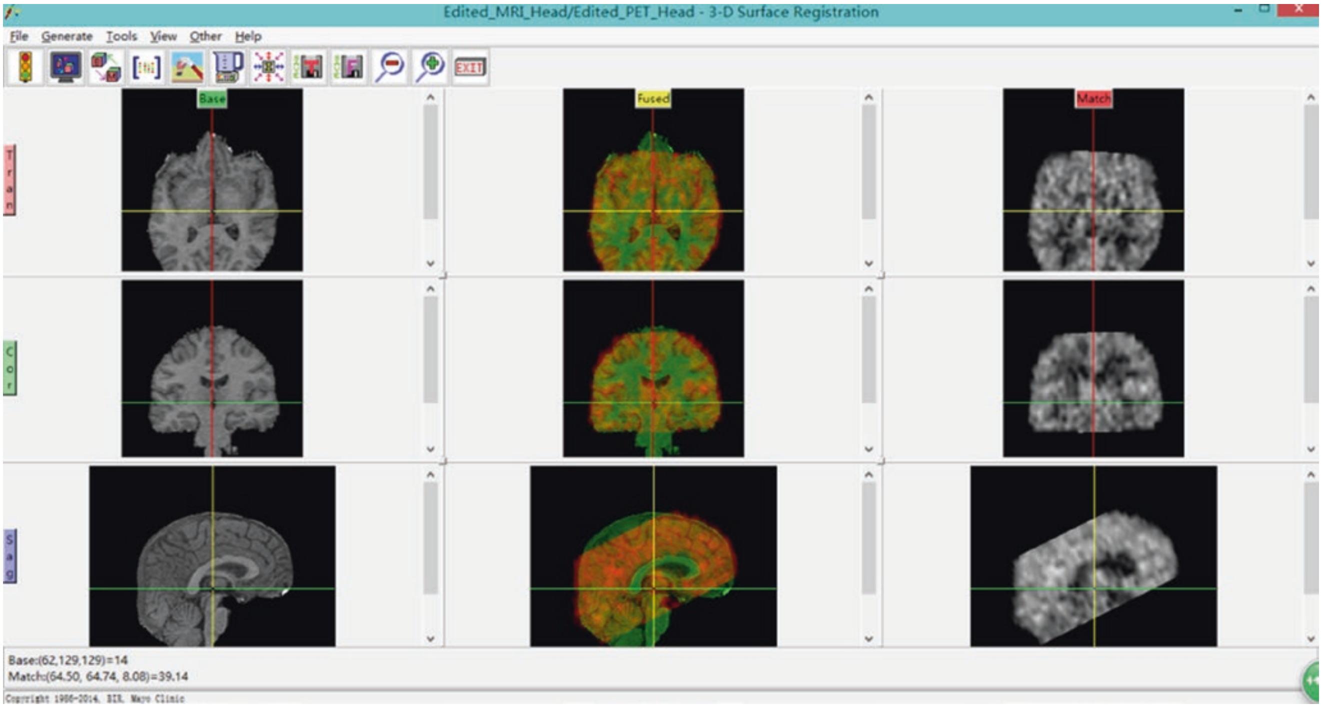

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Fig. 5.2 3D surface registration between MRI head and PET head performed through the software of Analyze

Currently, the major registration methods are divided into two categories: the feature-based algorithms (e.g., iterative closest point) and intensity-based algorithms (e.g., maximization of mutual information). Nowadays, more advanced methods are presented for image registration, for example, iterative principal axes method, maximum likelihood approach, fast Fourier transform-based method, local frequency representations algorithm, etc. In addition, some softwares have been developed for image registration using various approaches based on the abovementioned methods. For example, the functions of 2D registration, 2D nonrigid registration, 3D surface registration, and 3D voxel registration are provided in the software of Analyze (Fig. 5.2 shows the result of 3D surface registration between MRI head and PET head).

However, the semiautomatic approach, still a great challenge since registration of images with complex nonlinear and local distortions, multimodal registration, and registration of N-D image (where $N > 2$), belongs to the most difficult tasks in this field.

Because of the deformations caused by the movements of the soft tissue or surgical manipulations, the current approach, the so-called rigid registration, is not accurate. Recently, numerous nonrigid, patient-specific, and fully automatic registration algorithms have been proposed for real-time enhancement of intraoperative images and “prediction” of the amount of deformations. For example, Rivaz et al. presented an algorithm for nonrigid registration of ultrasound images that modeled the deformation with free-form cubic B-splines.

2.3 Three-Dimensional Visualization

The purpose of visualization is to provide a 3D (and even 4D) image so that the surgeon no longer needs to refer to 2D images from multiple modalities (radiograph or CT/MRI image). Today, the 3D reconstruction algorithm can be categorized into two classifications: surface rendering and volume rendering.

Surface rendering is the method of extracting surfaces from the structures in the images and displaying groups of polygonal surfaces, and the surface is basically constructed through the cuberille method, marching cube method, or dividing cube method. The marching cube method is the most widely used one, for example, Fig. 5.3 shows a 3D surface mesh pelvis model reconstructed through the vector-based surface rendering command in 3D-DOCTOR.

Volume rendering is the technology of computing rays through the volumes to produce a projection image. Since it does not suffer from data misclassification as part of the segmentation stage and all the original data in the rendered image can be retained, volume rendering is generally considered to be the most appropriate volume visualization technique (Fig. 5.4 shows the volume rendering in Mimics). The methods of volume rendering have been developed such as ray-casting algorithm, splatting algorithm, or shear-warp algorithm.

However, even though computers are continually getting faster, the presented volume visualization algorithms still remain as challenges to improve the rendering speed of large

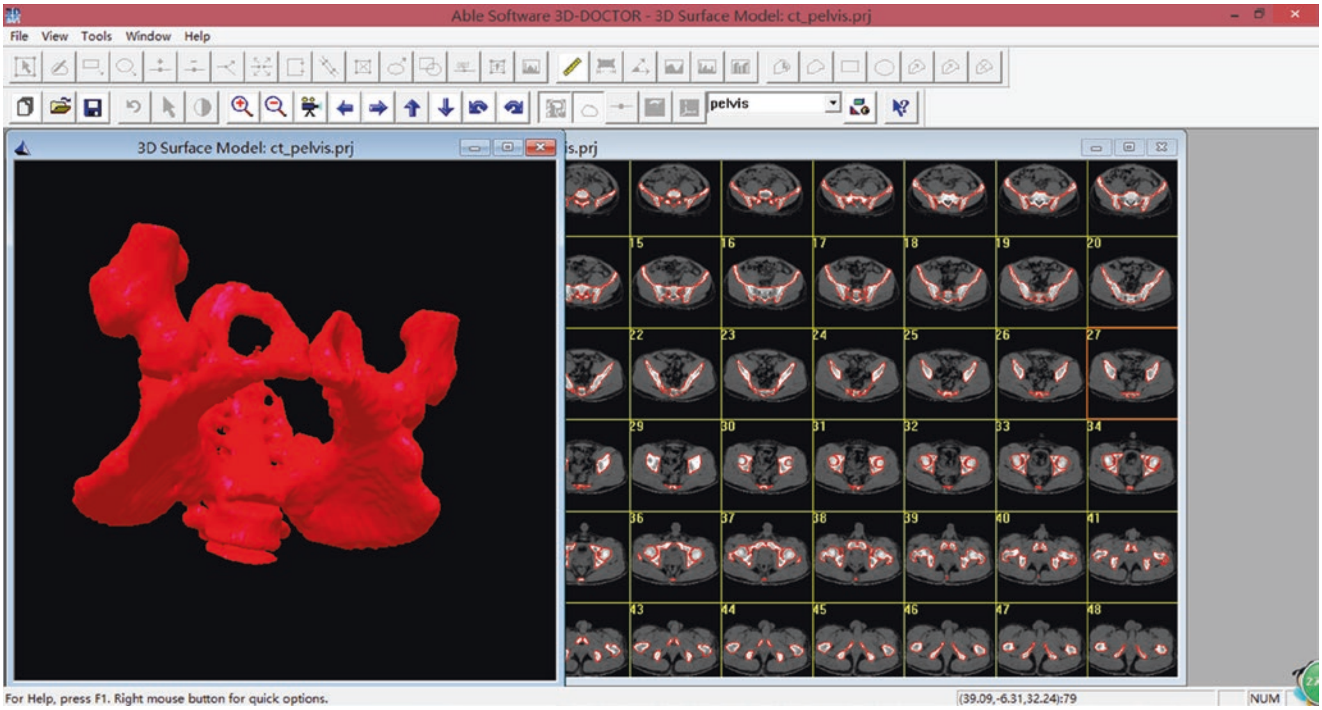


Fig. 5.3 The surface rendering of pelvis processed through the software of 3D-DOCTOR

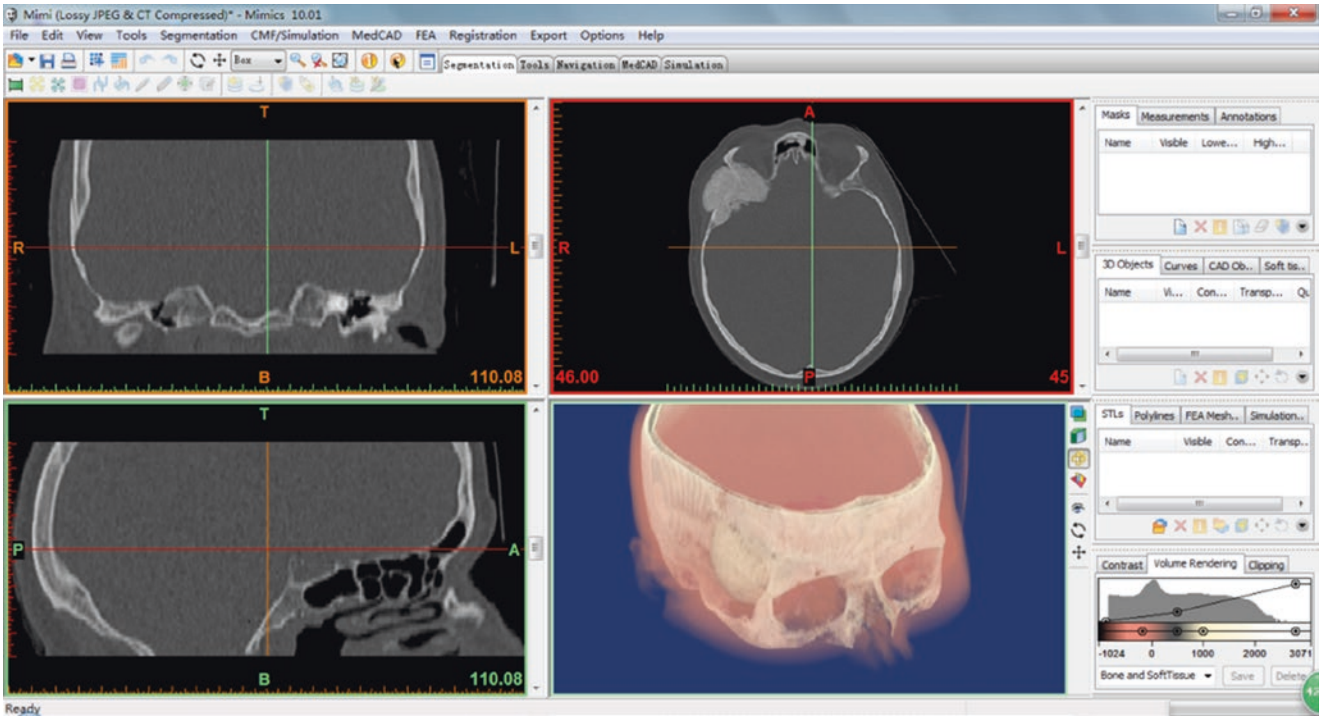


Fig. 5.4 The volume rendering method in the software of Mimics

datasets and the quality of their reconstructed images. Since the graphics processing unit (GPU) can deliver giant computational raw power compared to the central processing unit (CPU) on a per-dollar basis, the GPU-based volume rendering systems have been developed to produce clearer images and effectively convey visual information over the recent years. For example, Pelt et al. proposed an interactive GPU-based illustrative volume rendering framework to achieve real-time interaction and prompt parametrization of the illustrative styles. Schlegel et al. presented a novel approach in direct volume rendering based on GPU ray-casting for obtaining fast, plausible volume illumination and shading effects. Nelson et al. described a new GPU-based volume rendering method using the properties of spectral/hp finite element fields with the goal of producing accurate and interactive images. Liu et al. (2013) presented a novel approach for GPU-based high-quality volume rendering of large out-of-core volume data.

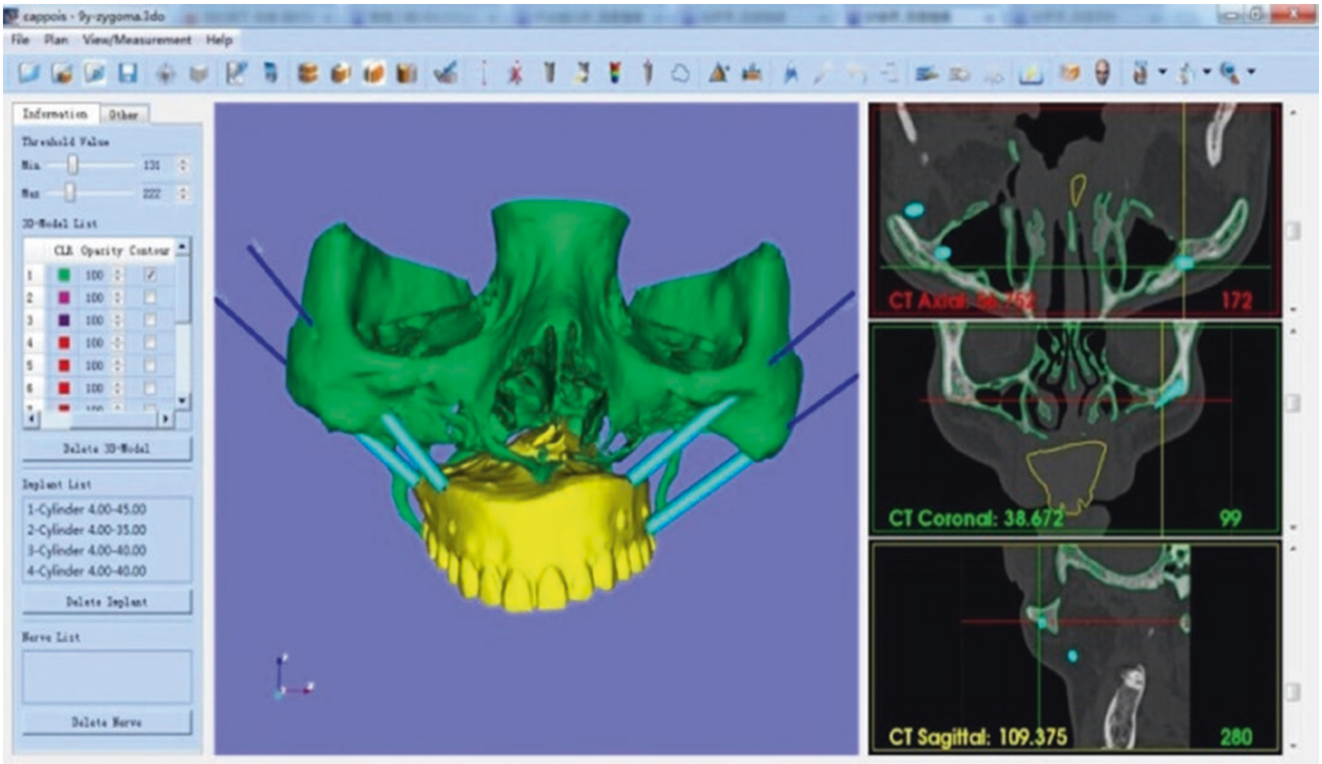
3 Preoperative Planning

The computer-aided preoperative planning has been a hot topic and the basis for the following template design and manufacturing. It is regarded to be the process of using computer technologies to design, simulate, and optimize the surgical scheme (3D geometrical measurement, virtual surgical trajectory of tumor resection, simulation of implant or prosthesis placement, etc.) according to both 2D and 3D data. Nowadays, some commercial computer-aided preoperative planning softwares have been developed and widely used, for example, Analyze, 3D-DOCTOR, Mimics, etc. In addition, there are also some open-source softwares such as CamiTK, 3D Slicer, GIMIAS, etc.

In the following, the details of self-developed software called Computer-Assisted Preoperative Planning for Oral Implant Surgery (CAPPOIS) are described. It is divided into five following modules:

1. The module for image importing and 3D reconstruction: Original CT image data in DICOM (Digital Imaging and Communications in Medicine) file format can be imported. The image grayscale and contrast can be adjusted; the bone can be segmented from its neighboring areas including soft tissue, water, adipose, etc.; and then a 3D cranio-maxillofacial model can be reconstructed and rendered.
2. The module for multi-planar reconstruction: A panoramic curve following the curvature of the jaw bone on one of the imported axial CT image slices can be drawn manually, and then on the basis of this panoramic curve, the series of panoramic images and cross-sectional images can be reconstructed. With respect to a plan of the mandible type, several points of inferior alveolar nerves can be labeled according to the series of panoramic images, and then these nerves can be reconstructed and highlighted in the 3D view.
3. The module for basic operations in 2D/3D views: Translation, rotation, and zooming in and out of the 2D/3D views can be done interactively. 3D cranio-maxillofacial models can be rendered and the transparency of the models can be adjusted. In addition, geometrical measurement can also be realized in the 2D/3D views, e.g., after selecting the required anatomical landmarks on the cranio-maxillofacial model, the distance between any two points and the angle among any three points can be calculated.
4. The module for implant design and adjustment: A certain type of virtual implants can be selected from an implant system library, including Branemark, ITI, FRIALIT, AVANA, Replace, CAMLOG, etc., and placed into the ideal areas in a 2D/3D view. The position and orientation of the implant can be adjusted by taking into account prosthetic requirements and available local bone. If the information of an implant is changed on a 2D/3D view, its information in all the other views will be updated simultaneously. Distance between an implant and alveolar nerves can be calculated, and collision detection among implants and bone density analysis around an implant can be done as well. In addition, relevant abutments and dentures can be designed.
5. The module for graphical user interfaces (GUI): Export/import, redo/undo, storage, retrieval, and deletion of the preoperative planning data can be realized. The preoperative planning information can be saved and exported in a special file format, so that it can be used in the subsequent software for the design of surgical templates.

After comprehensively analyzing the abovementioned functions, we designed the architecture of the software. The key technology of the software involved some algorithms in the field of medical image processing and computer graphics. The major algorithms included DICOM file parsing, image segmentation and 3D visualization, spline curve generation, multi-planar reconstruction, spatial search and 3D distance computing, cutting, volume measurement, etc. For each algorithm, we developed a set of dynamic-link libraries (DLL) using Microsoft Visual C++, as well as the Visualization Toolkit (VTK, an open-source, freely available software system for 3D computer graphics, image processing, visualization etc., http://www.vtk.org/) and Insight Toolkit (ITK, an open-source software toolkit for



1-Cylinder 4.00-45.00
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Fig. 5.5 The user interface of a self-developed preoperative planning software of CAPPOIS

performing registration and segmentation, http://www.itk.org/) via object-oriented programming methodology; therefore, a three-layer modular software model was developed. This basis can be extended by virtually any new approach or algorithm, which then becomes seamlessly integrated into the method set of the preoperative planning software framework. The aim is to provide well-defined levels of abstraction (the hiding of implementation details) from the individual components, so that new technology can be incorporated into the system without a complete software rewrite. We choose Qt (a free, open-source, and cross-platform application development framework widely used for the development of GUI programs, http://qt.nokia.com/products) for its powerful cross-platform support features. The main interface of the software is shown in Fig. 5.5.

The user interface and functions of CAPPOIS parallels Simplant (Materialise, Belgium), which is already commercially available; however, since the visualization and image processing algorithms involved in our software are developed by using VTK and ITK, a plug-in evolutive software architecture is established, allowing for expandability, accessibility, and maintainability in our system. In addition, aiming to make the software simply accessible and fulfill the research requirements in academia, our future work is to make CAPPOIS a free, open-source, and cross-platform (Windows, Linux, and Mac OS X operating systems) software for preoperative planning in oral implantology.

4 Computer-Aided Design for Surgical Templates

On the basis of the preoperative planning result, the patient-specific template can be designed for improving the surgical accuracy and reliability. Currently, the major template designing approaches can be divided into two groups: (1) utilization of commercial softwares and (2) comprehensive applications of traditional CAD softwares.

4.1 Utilization of Commercial Softwares

Some commercial preoperative planning systems have been available for the design of surgical guides, including two approaches: (1) The software suppliers provide the service of designing a customized template according to the preoperative planning results such as NobelGuide® (Nobel Biocare, Kloten, Switzerland), SurgiGuide® (Materialise Dental, Leuven, Belgium), etc. (2) Some softwares also supply the specific modules of template design for local design such as 3Shape Dental System® (3Shape A/S, Copenhagen, Denmark), coDiagnostiX™ (IVS Solutions AG, Chemnitz, Germany), Signature® Personalized Patient Care (SPPC) (Biomet Inc., Warsaw, IN), etc.

For example, Vasak et al. performed the preoperative planning through NobelGuide®, and the result was then sent to a certified manufacturing facility (Nobel Biocare) for template design and fabrication. Since the designing process is often completed in the companies without the surgeon's participation, the final product may deviate from the expected object, and it is hard to correct or optimize. Particularly for larger surgical guides, this technology is associated with high cost and production time. Boonen et al. designed a drilling and cutting template through Signature® Personalized Patient Care for total knee arthroplasty (TKA). Kuhl et al. utilized the coDiagnostiX™ to design a surgical template for guided implant surgery.

In addition, some research groups also developed their own template designing software and presented in the literature. For example, Yang et al. developed a semiautomatic computer-aided software which enables surgeons to design and optimize the template individually for various surgeries, including oral implantology, cervical pedicle screw insertion, iliosacral screw insertion, and osteotomy.

Since most commercial softwares provide the solutions of template design for specified kinds of surgery (oral implantology and orthopedics), as for other surgeries such as nasal prosthesis implantation, cervical or lumbar pedicle screw placement, treatment of sacroiliac joint fracture, etc., the template design mainly depends on traditional CAD software.

4.2 Comprehensive Applications of Traditional CAD Softwares

Some CAD softwares and third-party 3D modeling software such as UG Imageware, Rhino 3.0 (Robert McNeel & Associates, Seattle, USA), and Magics RP (Materialise, Leuven, Belgium) are now utilized to design the template. Among them, UG Imageware is most widely used for total hip arthroplasty, iliosacral screw insertions, and C2 translaminar screw insertion. And, Ciocca et al. designed a template through Rhino 3.0 to guide the insertion of craniofacial implants for nasal prosthesis retention. Hirao et al. utilized Magics RP to design a custom-made drilling guide for malunited pronation deformity after first metatarsophalangeal (MTP-1) joint arthrodesis.

As the existing CAD software often consists of well-established system and powerful function modules, the engineer can design template according to almost any kind of preoperative planning result theoretically. However, the design work is quite complicated and requires for high precision; the process may be with high cost and low efficiency.

5 Computer-Aided Manufacturing for Surgical Templates

Once the designing procedure is accomplished, the surgical template can be fabricated through special mechanical positioning devices or various types of CAD-CAM technology. With the tremendous development of manufacturing techniques over the past decades, additive manufacturing (AM) technology (also called rapid prototyping or 3D printing) has brought revolution for the surgical guide production. Rapid prototyping is the process of using the materials of ceramic powder, plastic, or metal powder to print any object layer by layer based on the virtual three-dimensional computer designed model. Compared with the traditional CAD-CAM technologies, rapid prototyping allows the creation of very complex geometries and has the advantages of humanization design, low cost and carbon, high production efficiency, etc. For example, it may take several days to produce a template for iliosacral screw insertion through the centralized facility, while the whole process may only need 6–20 h through the RP technology.

In addition, with the appearance of the metal fabrication strategies, the metallic biomaterials such as pure titanium and its alloys have been most frequently used for medical applications over the past years. Titanium is a particularly suitable material for work in the medical field due to its high mechanical strength and fracture toughness, low specific weight, nonmagnetic, and good biocompatibility properties, and the compact protective film of titanium oxide (TiO_2) on the metal surface provides high corrosion resistance.

In 2006, Electron Beam Melting (EBM) was one of the first metal additive manufacturing technologies used for producing a cranial implant by the Swedish company Arcam. Besides EBM, the technologies of direct metal laser sintering (DMLS) and selective laser melting (SLM) have been developed recently for manufacturing high-quality metallic components. For example, Mazzoni et al. fabricated a customized mandible cutting guide through the DMLS to precisely reproduce the site and orientation of the osteotomies for tumor ablation from the virtual plan into the surgical environment. Table 5.1 shows the detailed classifications of additive manufacturing (rapid prototyping or 3D printing) technology using different materials: stereolithography (SLA), selective laser sintering (SLS), fused deposition modeling (FDM), laminated object manufacturing (LOM), etc. Among these methods, the SLA can achieve the highest level of precision and the STL is the most common way for

Table 5.1 The types of additive manufacturing

Type	Material	Method	Systems for instance	Accuracy
Stereolithography (SLA)	Photopolymers	Curing by UV laser	3D Systems, Rock Hill, SC, USA	+++
Selective laser sintering (SLS)	Small particles of thermoplastic, metal, ceramic or glass powders	Fusing by a high power laser	EOS GmbH, Munich, Germany	++
Fused deposition modeling (FDM)	Fused thermoplastic materials or eutectic metals	Extruding	Stratasys Inc., Eden Prairie, MN, USA	++
Laminated object manufacturing (LOM)	Layers of paper or plastic films	Gluing together and shaping by a laser cutter	Cubic Technologies, Torrance, CA, USA	+
Melt 3D printing	Powdered pure titanium and its alloys	Electron Beam Melting (EBM), direct metal laser sintering (DMLS), selective laser melting (SLM)	EOS GmbH, Germany Arcam, Sweden	++

fabricating surgical templates. Figure 5.6 shows various 3D-printed surgical templates and the adjacent tissue models using SLA technology.

6 Clinical Applications of Computer-Aided Design and Manufacturing of Surgical Templates

After all the preoperative work is accomplished, the surgeon can perform the surgery with the use of surgical template. The main clinical applications are in the subjects of nasal, oral, spine, hip, knee, metatarsophalangeal joint, etc., and the accuracy evaluations can be obtained through the comparison between the postoperative images and the preoperative planning images based on the image registration technique and statistical analysis.

As for the oral implantology, the accuracy has been improving since the early application of surgical template in 1990s due to the developing fabrication techniques. Usually, the global (apical and coronal), angular, depth, and lateral deviations are considered as the main parameters for the surgical assessment, and the depth deviation has been proven to be the extremely significant impact on the accuracy and clinical results. Cassetta et al. performed 112 cases of oral implant surgery using stereolithographic guides, and 111 implants were available for a comparison of accuracy [depth deviation]. The results showed that 45 were placed deeper to the planned implants with a mean deviation of −0.70 mm and a maximum deviation of −1.70 mm, and 66 were placed more superficially to the planned implant with a mean value of 0.78 mm and a maximum deviation of 2.29 mm. Scherer et al. recently conducted a total of 180 drilling actions of dental implants, and the mean position and angular deviations were 0.31° ± 0.17° mm and 0.53° ± 0.24°. We introduced a novel bone-tooth-combined-supported surgical template (shown in Fig. 5.7), which is designed utilizing CAPPOIS and fabricated via SLA technique using both laser scanning and CT imaging. The results show that the fixation was more stable than tooth-supported templates because laser scanning technology obtained detailed dentition information, which brought about the unique topography between the match surface of the templates and the adjacent teeth. The average distance deviations at the coronal and apical point of the implant were 0.66 mm (range 0.3–1.2) and 0.86 mm (range 0.4–1.2), and the average angle deviation was 1.84° (range 0.6–2.8°). In summary, the template-guided drilling procedure can improve accuracy on a very significant level in comparison with non-guided drilling surgery.

As for the nasal prosthesis retention surgery, surgical template can be used for craniofacial implant positioning. Ciocca et al. (2011) performed an accuracy evaluation between the planned and the placed final position of each implant, while the surgery was accomplished using a 3D printing template. The deviation values at the apex of the implants with respect to the planned position were 1.17 mm for the implant in the glabella and 2.81 and 3.39 mm, respectively, for those implanted in the maxilla, which means it has a more accurate positioning of craniofacial implants than unguided surgery.

As for the total hip arthroplasty (THA), Zhang et al. (2011) compared the accuracy between the conventional THA (control group, $n = 11$) and navigation template implantation (NT group, $n = 11$). After 1 year follow-up, the NT group showed significantly smaller differences (1.6° ± 0.4°, 1.9° ± 1.1°) from the predetermined angles (abduction angle 45° and anteversion angle 18°) than those in the control group (5.8° ± 2.9°, 3.9° ± 2.5°) ($P < 0.05$).

In the field of spine surgery, Hu et al. evaluated the accuracy of patient-specific CT-based rapid prototyping drill

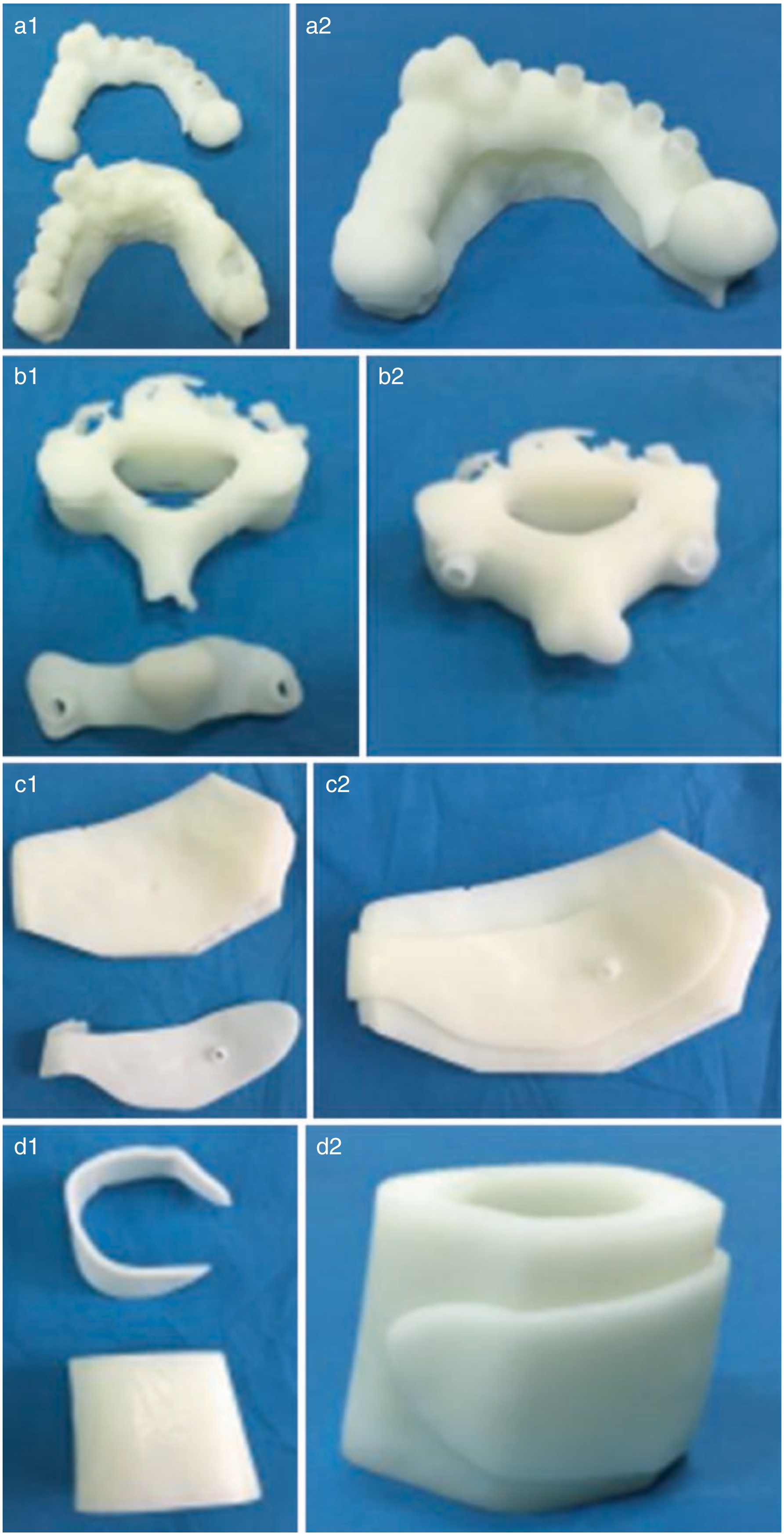

Fig. 5.6 (**a1**–**d1**) The 3D-printed surgical templates and the adjacent tissue models (**a1**, mandibular phantom; **b1**, part of cervical vertebrae phantom; **c1**, part of cervical vertebrae phantom; **d1**, part of bone phantom); (**a2**–**d2**) matching of the surgical template with the adjacent tissue models

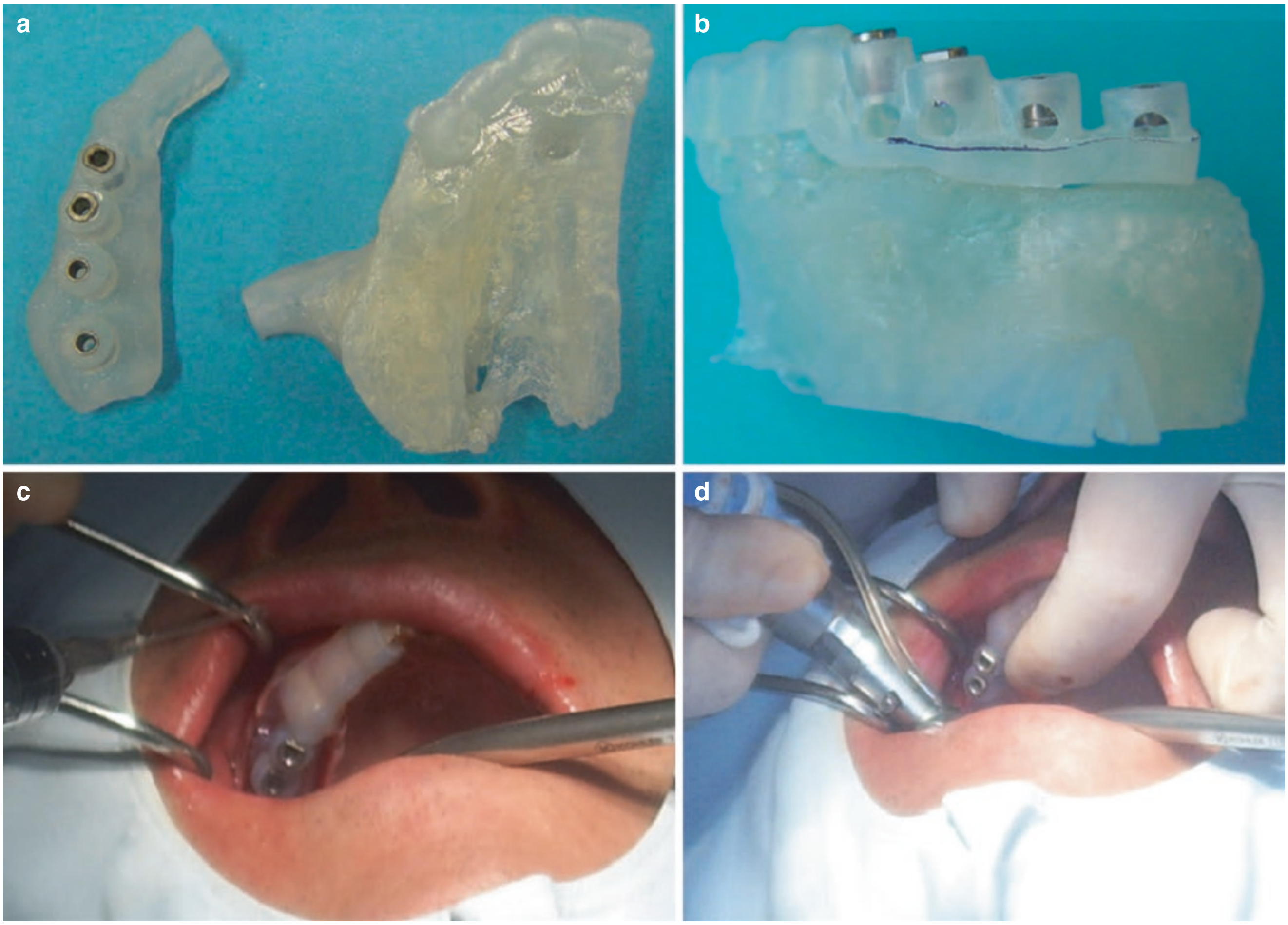

Fig. 5.7 (**a**–**d**) A novel bone-tooth-combined-supported surgical template and its clinical application, (**a**) The stereolithographic surgical template and maxillary phantom. (**b**) Matching of the surgical template with the maxillary phantom. (**c**) The template rested on the alveolar bone as well as the adjacent teeth. (**d**) The application of the template during the surgery

templates for C2 translaminar screw insertion. The results proved this technology can improve the safety profile of the fixation technique. In addition, Boonen et al. conducted 40 cases of total knee arthroplasty (TKA) using patient-specific guides. Compared with the conventional intramedullary alignment technique, the new method improved accuracy of alignment and a small reduction in blood loss and operating time.

In general, the accuracy of the surgical template applications depends on various factors such as the supporting ways of the template, the designing and fabricating methods, etc. As for the template-guided oral implantology, since the position of the implant has to be compatible with the intended final surgical restoration, there are three main types of template including bone supported, mucosa supported, and tooth supported. The oral surgery with the use of the template gets a relative highest accuracy due to several reasons as follows: (1) Template is usually placed on the tooth, which is more stable than mucosa supported in other anatomy regions (spine, nasal, etc.). (2) Many commercial or open-source preoperative planning software and template design software are available. (3) The exposed region of oral presents is larger than other regions of anatomy so that the template can achieve the optimum position.

Nevertheless, some problems and complications may exist during the period of postoperative observation, due to that the template may have the problems of supporting or assembly. Therefore, the surgeons also need to check the CT images, the manufacturing progress of the template, the fixation of the template, the substantial allowance of drill in tubes, sharpness of the drill, entry points of the drilling performance, etc.