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Development and application of rapid rehabilitation system for reconstruction of maxillofacial soft-tissue defects related to war and traumatic injuries

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Abstract

Background: Maxillofacial war injuries usually cause severe facial organ defects and deformities, handicapping the patient's daily activities, even result in a tendency to commit suicide. The application of maxillofacial prosthesis is an alternative to surgery in functional-aesthetic facial reconstruction. Computer aided design and computer aided manufacturing has opened up a new approach to the fabrication of maxillofacial prosthesis. An intelligentized rapid simulative design and manufacture system for prosthesis was developed to facilitate the prosthesis fabrication procedure.

Methods: Maxillofacial prosthesis rapid simulation design and rapid fabrication system consists of three components: digital impression, intelligentized prosthesis designing, and rapid manufacturing. The patients' maxillofacial digital impressions were taken with Structured-light 3D scanner; and then the 3D model of prostheses and their negative molds could be designed in specific software; finally, with the resin molds fabricated by rapid prototyping machine, the prostheses could be produced directly and quickly.

Results: Fifteen patients of maxillofacial defect caused by traumatic injuries received prosthesis rehabilitation provided by the established system. The contour of the prostheses coordinated properly with the appearance of the patients, and the uniform-thickness border sealed well to adjacent tissues. All the patients were satisfied with their prostheses.

Conclusions: The rapid simulative rehabilitation system of maxillofacial defects has been approaching completion. It could provide advanced technological reservation for the Army in the issue of maxillofacial defect rehabilitation.

Key words CAD/CAM; maxillofacial defect; prosthesis design; defect rehabilitation; war and traumatic injuries

Background

War and traumatic injuries may result in maxillofacial soft-tissue defects and deformities, for instance, auricular, nasal, orbital defect or multi-organ complex defects and deformities [1]. Defects in the maxillofacial region have severe and complicated impacts on the patient's physical and mental health, leading to deficits of function including mastication, speech, and deglutition; moreover, it also result in serious facial deformations, thus handicapping the patient's daily activities. Some patients suffered maxillofacial defects may show suicidal tendency, and the army morale and recruitment of new soldiers may be adversely affected. Thus, it is of great significance in the field of military medicine to rehabilitate and reconstruct the lost function and damaged appearance caused by maxillofacial war injuries, helping the patients return to the society.

Surgery was routinely adopted to reconstruct maxillofacial defects and deformities. However, the normal appearance and structure of facial region is often beyond the capability of surgery reconstruction, considering the subtle and intricate characteristics of local tissue and structures. The application of maxillofacial prosthesis is the alternative to reconstructive surgery, either because of the poor psychophysical conditions of the patient or the excessive tissue loss [2]. However, the traditional way of fabricating maxillofacial prosthesis includes several complex steps; it is a labor-intensive and time-consuming task, and the final results mainly depend on the experiences and skills of the clinician [3].

Computer aided design and computer aided manufacturing (CAD/CAM) application in this field has opened up a new approach to the fabrication of maxillofacial prosthesis [4-10]. School of Stomatology, Fourth Military Medical University has been researching on such field since 2001, and has set up an intelligentized rapid design and manufacture system for

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maxillofacial prosthesis fabrication. The system consists of three components: digital impression, simulation design of prosthesis, and rapid manufacturing of prosthesis. With this system, the fidelity precision of the prosthesis could be increased, manual labor could be simplified, fabrication time could be less spent, and the definitive rehabilitation effect of maxillofacial defects caused by war injuries could be crucially improved.

Methods

This study was carried out at the Department of Prosthodontics of School of Stomatology, the Fourth Military Medical University, Xi'an. This hospital provides treatment for both military and civilian patients. The study was approved by the Institutional Review Board of the School, and was conducted in accordance with the principles of the Helsinki declaration. A clinic assistant informed all subjects about the nature of the study. Informed consent was obtained from each subject who agreed to participate in the study.

Maxillofacial digital impression

Digital data were obtained by structured-light three-dimensional (3D) scanning system and computed tomography (CT) scanning system.

Structured-light 3D scanning

3D sensing scanning technique integrated several 3D non-contact measurement techniques, such as structured light technique, phase measurement technique, and computer vision technique. Several narrow stripes of light were projected onto the surface of the target object, and produced lines of illumination that appeared distorted from other perspectives than that of the projector, so an exact geometric reconstruction of the surface shape could be reconstructed. The 3D data of the patient's facial surface were obtained in a point-cloud format by a structured-light 3D scanner consisting of two charge-coupled device cameras and one projector connected to a personal computer (Figure 1).

Figure 1 Structured-light 3D scanner. It consists of two charge-coupled device cameras and one projector.

Before scanning, patients were asked to sit up straight and keep a stabilized facial expression with mouth naturally closed. The camera position and shutter were adjusted to the patients' face, and scanning was carried out from front and 30 degrees right and left to the patients. Data were saved as point-cloud format and imported to software allowing for optical representation of the surface and reconstruction of the 3D digital model (Figure 2).

Figure 2 3D model of the patient. Original 3-dimensional (3D) facial image of that patient was generated from data of 3D scanner.

Computed Tomography scanning

The advantage of Computed Tomography (CT) scanning is the simultaneously obtaining of accurate morphology of soft tissue and hard tissue, and thus remedying the flaw of invisible areas of ears of the structured-light 3D scanning. In China, optical scanning devices have not yet gained popularization in Medical Institutions, so CT scanning is still the dominating method in 3D data obtaining in CAD/CAM assisted prosthesis fabrication, and especially indispensable in auricular prosthesis fabrication.

Patients were asked to lie down and keep a natural facial expression with their eyes open. Condition of CT scanning should be, voltage 120 kv, current 150 mAs, thread pitch 1Q, and slice thickness 2.5 or 1.25 mm. Continuous helical scanning started from the lever of inferior margin of the chin, and stopped at the lever of calvarium with slice thickness of 1.25 mm. Scanning data were saved as DICOM format, and imported to software to reconstruct maxillofacial digital model (Figure 3).

Intelligentized simulation design of maxillofacial prosthesis

Intelligentized simulation design of maxillofacial prosthesis is the most crucial step in the whole process, and has direct correlation with the definitive prosthetic treatment outcome. Nasal, auricular, and orbital prostheses are the most commonly

Figure 3 CT scan model of the patient. Maxillofacial digital model of that patient reconstructed from CT scan data.

seen types in the clinic, and the design methods differ from each other due to diverse features. Our system has developed designing process according to every type of prosthesis, and auricular prosthesis will be taken as an example in the paper.

Mirroring of the healthy ear

The 3D head model of the patient was then oriented to the natural head position and served as references throughout the planning process [11]. The volume of auricular prosthesis and its optimal position were then simulated in software. The mid-plane was generated through nasion, pronasale, and gnathion. The 3-D image of the healthy ear was separated and mirrored to defect site to create a pattern of the lost ear.

Adjustment of the position of the mirrored ear

The optimal position of the pattern was determined in relation to the patient face with contentment of the patient and his relatives. The anteroposterior position, protrusion, inclination, and level of the pattern must be compared with the normal ear, the prostheses were viewed from the front and side of the defect, rear, and top to assess symmetry with the contra-lateral ear; the tragus and the external meatus were also could be used as references at this moment.

Design of the prosthesis pattern

The covering range of the prosthesis was defined by drawing a closed spline on the defect area, and separated from the soft tissue model. Another spline was then generated inside with a 0.5 mm distance from the first spline. The triangles between these two splines were selected out and offset 0.2 mm upwards, and then the outer boundary of the offsetting triangles was connected with the boundary of the covering range. The inner boundary of the offset triangles was projected onto the primitive pattern to generate a closed boundary line. On the pattern, the triangles encircled by this boundary line were selected out; then this boundary was connected with the inner boundary of the offset triangles, after that the stair between these triangular patches was ground. The definitive pattern was created, with a smooth margin that was exactly designed 0.2 mm in thickness and 0.5 mm in width (Figure 4).

Figure 4 Auricular prosthesis pattern. Definitive prosthesis pattern was created in system software with smooth margin, which was exactly designed in width and thickness.

Design of the negative mould

The ear pattern was transferred to a negative volume in the software. The outer boundary of the adhesive region was expanded outwards 10 mm on the defect area. The inner boundary of the adhesive region was connected to the internal surface of the prosthesis pattern, and the border of the expanded area was extruded 10 mm forward along the transverse axis; after closing the extruded bottom, the lower piece of the negative mould was obtained. The polygons of the expanded area were duplicated and bridged with the boundary of the external surface, and then the outer border of those polygons was extruded 40 mm backward along the transverse axis; the upper piece of the mould was obtained after closing the boundary. The prosthesis mould was separated to three parts just like the conventional three-piece mould in flask, and the reference mortise and tenon joints were added to guarantee a secure seal of the three-parts mould during the silicone processing procedures. These pieces were saved in STL format (Figure 5).

Rapid fabrication of maxillofacial prosthesis

After the virtual design of maxillofacial prosthesis and its negative mould, definitive prosthesis needed to be fabricated. Our system adopted the method of direct fabrication of silicone elastomer prosthesis by resin negative mould. Resin negative mould was made and then silicone elastomer could be filled into the negative mould to acquiring the definitive prosthesis. Resin pieces of the mould were fabricated with a selective laser sintering (SLS) rapid prototyping machine. As the flask of the conventional method, the negative mould was used to fabricate

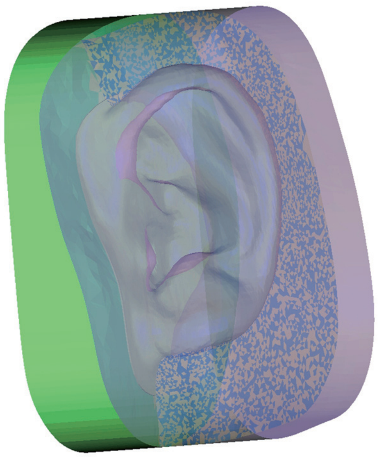

Figure 5 Three pieces negative mold. Lower and upper pieces of negative mold were designed; internal space for auricular prosthesis was shown after assembling these pieces.

Figure 7 Final result of rehabilitation. Definitive silicone prosthesis was generated after extrinsic coloring and applied to that patient.

the definitive silicone elastomer auricular prosthesis (Figure 6). At last, extrinsic coloring was finished, and the definitive silicone prostheses were applied to the patients (Figure 7). Sufficient retention was obtained using a prosthetic adhesive (Daro Adhesive Extra Strength, Factor II, Ariz, US).

Establishment of the 3D nasal morphological database

In the prosthesis design of the bilateral symmetry organs, the mirrored data of healthy side could be easily used; however, it is hard to find a proper data source for the nasal defect. A 3D model database of normal nasal shapes was established in the system, to meet the need of nasal prosthesis design.

Figure 6 Silicone elastomer prosthesis before extrinsic coloring. Resin pieces of mould were fabricated with RP machine. Silicone prosthesis was obtained using routine procedures.

Acquisition of 3D nasal morphological data

1000 nasal models were collected by 3D reconstruction of the existed CT scan data, and 200 nasal models were collected by Structured-light 3D scanning. All the models were saved as. STL file.

Development of database software

Based on Microsoft Office Access, the database software was written by Microsoft Visual C++. OpenGL were used to realize the visualization of 3D data. Multiple nasal shape classifications were integrated to develop the database, so that nasal models could be imported into the database accompanied with their morphological features, and the proper models for certain needs could also be easily found.

Application of the database

The feature classifications of the patient's nose were defined according to the photographs taken before injury. After the corresponding classifications were inputted into the search field of the database, the proper nasal model could be selected out automatically for nasal prosthesis design. Usage of the database was an efficient solution to the lack of data source, and an indispensable step in nasal prosthesis design.

Results

Between 2009 and 2013, maxillofacial prostheses were made with the intelligentized rapid design and manufacture system for 15 patients, included 9 men (60%) and 6 women (40%). Age ranged from 23 to 59 years, with a mean of 49.3±11.6 years. Facial defects were primarily the result of tumor resection (n=6, 40%); 33% were the result of congenital defects (n=5), and 27% were the result of acquired trauma (n=4). The location of the facial prostheses was distributed between auricular prostheses (*n*=6, 40%), orbital prostheses (*n*=5, 33%), and nasal prostheses (*n*=4, 27%). All patients chose to accept an adhesive retained prosthesis.

The total clinical times used for each patient were only 4 hours on average over 2 appointments. The patients' maxillofacial digital impressions were taken at the first appointment, and then primitive prosthesis pattern could be created and modified. Patient could confirm his or her acceptance of aesthetic effect at the very beginning. The next appointment is extrinsic coloring and distribution. In addition to this time, about 10 hours on average were needed to complete the design and fabrication processes. With the specific software, design of the definitive prostheses and their negative molds could be accomplished in about 3 hours. The remained time was used for resin mould Rapid Prototyping fabrication and silicone processing.

The contour of the prostheses coordinated properly with the appearance of the patients, and the border were sealed well to adjacent tissue with uniform thickness. All the patients were satisfied with the appearance of the prostheses designed and fabricated with this system.

Discussion

The traditional way of fabricating prosthesis involves taking facial impression, measurement, sculpting wax pattern, try-in and adjustment, flasking, inner and outer coloration of the prosthesis, and *et al*. The complicated processes demand prolonged fabrication period and increased visits to the clinic, and hence restricting the development and popularization of the prosthesis fabrication technique. In the 1980s, the emergence of CAD/CAM has brought revolutionary transformation to the manufacturing industry, and tremendously increased the productivity. This technique has been gradually introduced to the field of maxillofacial defect rehabilitation since the 1990s, enabling simulative design and prosthesis rapid manufacturing, and thus remarkably enhanced production efficiency and treatment effects [12-14]. CAD/CAM assisted prosthesis manufacturing procedure does not involve uncomfortable facial impression taking, and reduced the complexity of wax pattern sculpting. Therefore, the production efficiency is improved with guaranteed treatment effect, and hopefully this technique should be as a regular method in maxillofacial prosthesis producing.

Digital impression of maxillofacial soft tissue is fundamental to intelligentized simulative design of prosthesis. With the help of current digital impression taking method, data was collected easily and safely, without traumatic effects or discomfort on the patient. The mirrored data of the normal side or the proper data from the database could be used to produce the prosthesis pattern, as the result, the difficulty of the sculpting work could be reduced greatly. Otherwise, the precision of 3D model of the patient's defect area and adjacent normal region is another crucial issue in the whole treatment procedure, and is closely related to the final outcome. The 3D model reconstructed by the digital impression data has accurate morphology, and is full accord with the actual morphology of the defect area and adjacent normal tissue. As the result, the prostheses could contact closely with the skin surface of the patients. In addition, color information of the soft tissue could also be acquired, making the simulation of prosthesis treatment effect more realistic in the design procedure, thereby improving the accuracy of the prosthesis design.

Researchers have been working on the simulative design and manufacture of maxillofacial prosthesis since the 1990s [4-10,12-17]. In the early methods, it was only involved to mirror the data of the normal side to the defect side [4,6,12-15]. The surface configuration of the defect area was not considered totally in the design, therefore, large modification of the wax pattern during the try-in procedure was always needed to adjust the contact area and the surface detailed characteristics, after that the definitive prosthesis was also completed by the traditional way. With further development, the surface data of the defect area was integrated in the design of wax pattern, as a step forward of this technique [8,9,16,17]. These methods can solve the problem of compromised rehabilitation outcome by handmade prosthesis due to the weak ability in sculpting of the prosthodontists. However, recontouring of the margin and flasking of the mould were also need to be carried out by handwork after the wax patterns try–in step. Though the facial impression is eliminated from the traditional method, and the complexity of wax pattern sculpturing is reduced, the advantages of CAD/CAM are not sufficiently incarnated. Before the invention of direct fabrication of silicone prosthesis by Computer Numerically Controlled Machine or Rapid Prototyping Machine, fabrication of prosthesis through resin negative mould fabricated by CAD/CAM is the easiest way undoubtedly. Thin margins of the prosthesis were represented as the cavity in the negative mould, so that the frangibility of the pattern edge could be avoided completely. With CAD/CAM negative molds, conventional flasking and investing procedures could be eliminated totally, and the border seal between the prosthesis and skin could be improved. As the result, use the system can eliminate the try in procedure, reduce patient's visits, minimize manual labor, shorten the fabrication time, and finally improve the prosthetic treatment effect.

Meanwhile, higher requirement is raised with regard to the detailed surface features design. Realistic surface detailed feature is an important factor in the evaluation criteria of prosthesis, as well as the morphology that is in high accordance with the patient facial characteristics. It is recommended that the design of prosthesis detailed surface features be brought into consideration, like the contour of the palpebral, the facial wrinkles (especially in the canthus area), the texture of the skin, and *et al*. This is the aspect that this system needs to be improved in the future.

After the main question of simulative design and manufacture of the contour and shape of prosthesis has been resolved, color individualized simulation is another indispensable feature of high-simulative maxillofacial prosthesis. Our team has also set out to explore the computer aided printing technique for the extrinsic coloring of maxillofacial prosthesis, aiming to further improve the fidelity, reduce the fabrication time, and simplify the manufacturing procedure.

The limitation to the study should be considered when evaluating this new system. Until now, our works were focused on how to establish the whole system, make operation more simple and convenient, rely less on personal experience, spend less time to obtain a more imitated prosthesis. All the patients were satisfied with the appearance of their prostheses. However, there is still need to investigate objectively whether or not the changes brought by the new technique could make patients more satisfied and prostheses more functional. It is extremely important for future works to perform objective control study on patient satisfaction and functional improvement. We will design more objective and reliable satisfaction questionnaire for future study.

Conclusion

CAD/CAM has brought a huge revolution to the field of Prosthetics. The rapid simulative rehabilitation system of maxillofacial defects related to war and traumatic injuries has been approaching completion. It could provide advanced technological reservation for the Army in the issue of maxillofacial wound and defect rehabilitation.

Abbreviations

CAD/CAM: computer aided design and computer aided manufacturing; CT: computed tomography; SLS: selective laser sintering.

Competing interests

All authors have no financial interests that may be relevant to the submitted work.

Authors' contributions

Dr. Bai drafted the manuscript and obtained the funding. SB, ZF and YB designed the system and analyzed the data. RG, YD, GW and XC collected data. ZF, RG, YD, YB, GW and XC contributed to administrative, technical or material support. All authors had full access to all the data and take responsibility for the integrity of the data. All authors read and approved the final manuscript.

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