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Reverse modeling and solid free-form fabrication of sternum implant

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Abstract The paper presents a case where an implant for a part of the sternum (with costal cartilages) affected by cancer was created and implanted by using the specific reverse modeling method and solid free-form fabrication. The method provides surgeons with a fast and reliable tool for tissue engineering and implantation and therefore improves the quality of life for patients. Digital images of healthy sternum samples were used to develop a reverse modeling algorithm that semi-automatically generates a necessary and sufficient simplification of the tissue geometry to be fabricated in an inexpensive and applicable manner. In this particular case, the redesign of the missing part of the sternum in CAD software took three designerhours. At the same time, the suitable simplification of the geometry affects the fabrication of simpler and less expensive casting molds. Furthermore, the core of the developed algorithm for the reverse modeling of sternum can be applied in the reverse modeling improvement of other tile (or plate-like) bones.

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Introduction

Human bone-joint system is susceptible to injuries, fractures and diseases (e.g., tumors). It is, therefore, necessary to perform surgical intervention in a very short time in many cases. A key factor for the success of a surgical intervention is planning and preparation of operations.

Adequate preparation of the surgical intervention will shorten the duration of the operation and minimize the probability of occurrence of intraoperative complications (unexpected problems during surgery). Also the quality of fixation depends on the adaptation of implants to morphological features of bones.

The geometry of each bone in the human skeletal system is unique. In the case that a part of a bone has to be substituted by an implant, the application of the reverse modeling ensures that implant matches the shape of the affected part of the bone [1-3]. On this basis, it is necessary to perform the fast reverse modeling method that is adapted to that unique bone. On the other hand, it is very important to use the technology (in this case solid freeform technology) that would simplify and reduce time and costs of fabrication of casting molds for implant manufacturing.

The paper reports a case of using a specific reverse modeling method, 3D printing and casting technology for sternum implant manufacturing.

Despite many published papers in the field of application of computer aided technologies (CAD/CAM), medical

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imaging and rapid prototyping in different fields of medicine (orthopedics, dentistry, oral and maxillofacial surgery, craniofacial surgery, bone tissue engineering, etc.) there is a lack of research on their application in thoracic surgery. Reverse modeling and rapid prototyping are used for customized design and manufacturing of chin implants [4], patient-specific craniofacial bio-implants [5], models for education and training and geometrically optimal standard and customized orthopedic implants and prosthesis [6] as well as for modeling, designing, simulation and manufacturing of biological tissue and organ substitutes [7, 8], implant-based restoration design and fabrication and for manufacturing replicas in forensic pathology [9].

Case report

The patient was a 54-year-old male who was admitted to a pulmonology department because of cough with hemoptyses and suffering pain in thorax. The invasive and noninvasive diagnostic techniques were performed including FNAB (fine needle aspiration biopsy). Concerning that preoperative diagnosis was tumor of sternum with infiltration to anterior segment of right superior lobe the operative treatment was indicated. The plan for the operative treatment was resection of sternum and second and third cartilages on both sides. The plan included cuneiform resection of anterior segment of right superior lobe, also. In order to obtain structural consistency of thorax after resection of sternum (in the length of 100 mm) it was decided to apply patient-customized implant. Concerning the complexity of 3D geometry of such an implant, that is very difficult to shape manually, the reverse engineering was appeared as suitable solution. Radiology images of the case are shown in Fig. 1.

Material

Besides the CT scan of affected sternum, other five healthy sternum samples were used for the geometry analysis of the sternum and reverse modeling of the affected part of the sternum. The samples were scanned by Toshiba's Aquilion 64-slice computer tomography system at isotropic resolution of 0.5 mm. During the scanning, the patients were lying down with their hands in abduction. The samples were from men of the same age (54), approximate height, weight and thoracic volume and from the same population as the patient. These images were exported from CT in DICOM format and further processed and edited in medical image processing 3D software package for 3-dimensional design and modeling. It generates and modifies tessellated surface 3D models from stacked medical images such as Computed Tomography (CT), through image segmentation done in the STL format.

Segmentation masks are used to highlight regions of interest. Many advanced segmentation functions like thresholding (select a region of interest by defining a range of gray values), regional growing, editing (draw, erase or restore parts of images with a local threshold value and helps in eliminating artifacts and separate structures), dynamic region growing (segments an object based on the connectivity of gray values in a certain gray value range) are used to create and modify these masks.

In this particular case, the medical image processing and editing of CT scans of affected sternum lasted 1 h. At the end of the process image files were exported to STL format. The STL file holds the coordinates of each point in the cloud of points, which represents raw data that has to be imported into appropriate CAD (computer aided design) software (Dassault CATIA V5) for the reverse modeling.



Fig. 1 Radiology images of the case demonstrating the sternal tumor



Fig. 2 Cloud of points of whole thorax (*left*) and part of it, near the sternum (*right*)

Reverse modeling

The procedure for the reverse modeling of bone geometry is performed in six steps [10] using CAD software CATIA V5 R19. The reverse modeling starts with importing of the cloud of points (Fig. 2). Additional cleaning and spatial aligning of the cloud of points is what follows in order to provide an easier and thorough creation of the polygonal model.¹

The polygonal model (Fig. 3) is used for identifying referential geometrical entities (RGEs) of the bone as well as a base for the geometry redesign.

The RGEs are important because they usually indicate how the geometry of the bone should be redesigned [10]. What is specific for each bone from the human skeletal system is that each one has its own RGEs (Fig. 4). Because of that, it is important to analyze the geometry of each bone to identify the minimal set of necessary RGEs in order to develop an efficient algorithm of the reverse modeling of the geometry of that bone [10]. The geometrical analyze of the bone is performed by identifying the similarities between the specific morphologic units of the bone and CAD features (that are specific geometrical primitives). In order to analyze and validate the algorithms for the reverse modeling of a bone, one needs to have a library of digital images of healthy samples of the bone. In addition, these samples are used as kind of a geometry pattern for the redesign of missing or unhealthy parts of the bone. This was exactly the case with the part of the sternum affected by cancer. It is very difficult to assess the time needed for the process of geometrical analysis and validation of the algorithms for the reverse modeling of a bone. It depends on prior experience and creativity of the designer. In this



Fig. 3 Polygonal model of the healthy sternum region (*left*) and more detailed/closer insight (*right*)



Fig. 4 Identification of RGEs (images are captured from geometrical analysis of healthy samples)

particular case, the redesign team needed 16 designerhours.

The body of the sternum is a flat bone that is connected to the manubrium by a cartilaginous joint. Looking from the sagittal plane (of the human body) the geometry of the sternum at this joint is characterized with the sternal angle between the manubrium plate and the plate of the sternum body [11] (Fig. 4).

Considering that the part of the sternum affected by cancer was exactly that juncture area, i.e. the cartilaginous joint, the challenge was to match the missing geometry to preserve structural consistency for the thoracic cage [12] but also to simplify the geometry sufficiently in order to fabricate the one-direction opening casting mold. This is the mold consisting of two mold plates that lean each on other over a separating surface and allow the mold to be dismantled by lifting the one plate in just one direction (Figs. 14, 15). This feature (one-direction opening) makes it possible to fabricate simpler casting molds that can be done more easily and inexpensively than the molds that has to be opened in two or more directions.

¹ This polygonal model is CAD software native and is not the same one that is obtained through medical image processing and recorded in STL format.

In this particular case, the procedure for the reverse modeling of a part of the sternum started with the identification of the second and third juncture points of the costal cartilage (facets) as well as the 3D guiding curves of the ribs. For this purpose, at least two characteristic orthogonal directions of view were used (Fig. 5a, b). The first one is define by the cartilaginous joint plane-inferior aspect (Fig. 5a). Another one is defined by the plane orthogonal to cartilaginous joint plane-anterior aspect (Fig. 5b). The corresponding projections of the ribs and their boundary edges (that are spatial curves) were used for the creation of series of rib slices that are normal to these edges. In the next step, the mass-center points of these slices became the interpolation points for 3D guiding curves of the second and third pair of ribs (Fig. 6). At the end of this part of the procedure, 3D guiding curves of ribs and their updated slices were used for the modeling of a multi-section volume of the ribs and their costal cartilage extensions to the sternum (Fig. 6).

Concerning the sternum itself, the redesign procedure started with the creation of a longitudinal guiding curve of the body of the sternum. As in the case of ribs redesigning, the series of sternum slices had to be created. These slices were parallel to the transverse plane of the human body. The mass-center points of the slices became the interpolation points for the spatial guiding curve of the sternum. Finally, the spatial guiding curves of the sternum and its updated slices (Fig. 7) were used for the modeling of a multi-section volume of the body of the sternum (Fig. 8) and the manubrium. The missing part of the sternum, affected by cancer, was redesigned in accordance with the virtual model of the sternum.



Fig. 6 CAD feature (type: multi-section volume feature) that approximately remodels second rib and its costal cartilages in the region of affected sternum





Fig. 5 Two characteristic directions of views on second and third rib in the process of reverse modeling: a inferior aspect; b anterior aspect

Fig. 7 Creation of sternum slices and its mass-center points that are used for interpolation of guiding curve of the sternum and virtual outer surface



Fig. 8 CAD feature (type: multi-section volume feature) that approximately remodels sternum (including the missing part) in accordance to the geometry of healthy sternum samples, substituting the missing RGEs with RGEs of similar healthy sternum samples



Fig. 9 Simplified geometry model of the affected part of the sternum (*right*) matches the scanned geometry in the sufficient extent (*left*)

This virtual model of the sternum was generated from preceding geometrical analyses of the healthy samples of the sternum that were geometrically and dimensionally similar to the diseased one. The RGEs of the sternum affected by cancer (planes, sternum arc radius, width, length) are used to identify similar healthy sternum sample. The geometrical analyses of healthy samples were used for generating the characteristic shape pattern of the transversal and sagittal cross-sections of the sternum as well as to identify the specific geometrical and dimensional constraints and relations between the geometrical entities (e.g. sternal angle, cartilaginous joint arc radius, overall dimensions of specific transversal cross-sections on the second and third costal cartilage facets, etc.). All these constraints and relations were embedded into the set of design rules that could be executed semi-automatically and help the designer to easily adjust the missing part of the bone to the shape (geometrical entities) of the virtual sample.

During the process of redesign and adjustment of the missing part of the sternum to the shape of the virtual model, the geometry simplification ran simultaneously. The simplification included removing the burrs, little bumps and holes as well as all the other unnecessary details that negatively affect the manufacturability of the model (Fig. 9).

The final adjustments of the sternum model involved rounding and chamfering of the model sides in order to obtain the implant that can be cast in one-direction opening casting molds (Fig. 10).

Applying the previously developed algorithm for reverse modeling of the sternum redesign process of the missing part of the sternum in CAD software took three designer-hours.

Free-form fabrication

The next step involved the fabrication of the core prototype (core cavity of the mold) and sternum implant prototype using the solid free form fabrication technology (3D printing), based on the 3D models obtained by the reverse modeling. The core prototype was used for the fabrication



Fig. 10 Defining the outer wall and splitting surface of the mold (*left*) and extraction of the core of the mold (*right*)



Fig. 11 Loading and preparing the remodeled part of the sternum for 3D printing in ZPrint software

of the casting mold for the sternum implant manufacturing, while the sternum implant prototype was used for visualization in preoperative treatment planning.

The machine used for making prototypes was a 3D printer ZCorporation ZPrinter 310 System. ZCorporation is a company founded in 1994 producing solid free form fabrication systems based on 3D printing technology, headquartered in Burlington, MA, USA. The 3D model loaded in ZPrint software is shown in Fig. 11.

The material system used for 3D printing was ZP130 powder with ZB58 binder. The former is plaster-based powder, and the latter is binding liquid (the details on material ingredients are trade secret). Considering the complex geometry of the models, the selected layer thickness was 0.088 mm. Models were positioned in the working volume in a way that maximizes surface quality and strength of finished parts.

Prototype in the phase of fabrication is shown in Fig. 12.

The printing process took more than 2 h (not including 45 min of hardening before removing the powder). To achieve better mechanical properties and shorten the drying time, the prototypes were put into an oven at 100°C for



Fig. 12 Prototype of the affected part of the sternum in 3D printing process



Fig. 13 The core prototype (*left*) and sternum implant prototype produced by 3D printing process

90 min. This is a regular procedure recommended by ZCorporation to increase tensile strength of finished part up to 20 MPa. The sternum implant prototypes are shown in Fig. 13.

Since the prototypes made from 3D printing material were not suitable for direct use in prosthetic purposes [13] it was necessary to fabricate an implant from the approved medical prosthetic material. It is possible to use different autologous or heterologous materials. The most commonly used autologous materials are: fascia lata graft and various bone grafts (tibia, fibula, iliac crest) a heterologous are preserved human materials (pericardium) and preserved animal materials. Synthetic materials for the stabilization of the chest wall are: plates and supporters (metal–stainless steel and tantalum) and synthetic materials: plates and meshes (Teflon mesh and patch, Nylon, propylene, Prolene, Vicryl mesh), solid prostheses (acrylic, Teflon, silicone) and composite materials (Marlex mesh combined with methyl methacrylate). In this particular case it was decided



Fig. 14 Upper and lower plates of the casting mold (*left*) and filling the mold cavity with prosthetic material (*right*)

fabricate implant from polymethylmethacrylatto PMMA. Polyurethane foam was used to manufacture the casting mold, which is suitable for casting acrylic materials. It is significant because acrylates are the main ingredients of the prosthetic material (75% methacrylat methylstyrene-copolymer and 15% polymethylmethacrylat). It is important to note that standard prosthetic material (bone cement) is used for casting. Mechanical properties can vary depending on the bone cement manufacturer, usually within the following range of values: compressive strength 74-81 MPa; flexural modulus 2.54-2.60 GPa; flexural strength 65-73 MPa; bending strength 80 MPa. This material is used in regular surgery practice. The surgeon usually manually shapes it and no additional verification of this biomaterial is required. Precise geometry, improved part homogeneity and surface quality (arithmetical mean roughness of a surface $Ra = 7.4 \mu m$) was obtained compared to standard manual procedure, following finished precise casting process. The upper and lower plates of the casting mold and filling the mold cavity [14] with prosthetic material are shown in Fig. 14.

The prepared prosthetic material, after 4 min mixing, was applied in the mold cavity and it completely filled the cavity by mechanical compression of the mold. Upon the expiration of time provided for the solidification and partial cooling of the prosthetic material (about 8 min in PU foam mold), the implant (Fig. 15) was removed from the mold.

In the final phase, the implant was subjected to post processing and sterilization. The post processing consisted mainly of trimming excess material of the implant, using rotational sanding tool. The implant was sterilized by exposure to 30 kGy dose of electron beam radiation.

Implantation

In accordance to the plan, the resection of the sternum in the length of 100 mm and second and third cartilages on both sides including cuneiform resection of anterior



Fig. 15 Implant in the lower casting mold plate before removing and post processing

segment of right superior lobe was done. The implant was fixed to the proximal fragment of the manubrium and distal part of the body of sternum with K-wires. In addition, artificial costal cartilages of the implant were matched and connected to the patient's second and third thoracic rib with K-wires (Fig. 16). The surgery lasted around 3 h. Geometrical compatibility of the customized implant enabled more efficient implantation, whereby the structural consistency was preserved for the thoracic cage.

Results and discussion

Postoperative recovery was satisfactory and patient was discharged seven days after surgery, without any complications.

One year after surgery, control multislice CT (MSCT) of the chest of the patient, showed that the implant is in an ideal position and that there was no displacement of it. The recovery was not followed by septic complications and there was no any sign of rejection of the implant. The periodically controls that were performed during the last year showed the excellent results in the regard to chest wall stability, pulmonary function (protection of the endothoracic organs from trauma and infection), revascularization and musculature recovery. Figure 17 shows the control chest X-ray image of a patient.

From a functional point of view the final outcome was satisfactory and the patient was able to resume his normal daily activities.

The conventional operative techniques in the similar chest wall reconstructions are based on using sandwiched Marlex and stainless-steel mesh with metacylate as a material for the reconstruction [15, 16], free and pedicled bone grafts (ribs), periosteal flaps, strips of fascia lata, fascia lata flaps and pedicled muscle flaps [17], polypropylene mesh-resin sandwich [18, 19], or titanium micromesh covered with Marlex mesh [20]. In these cases, the prostheses are shaped by hand during the operation without taking into account the geometry that preceded the illness. These kind of procedures are complex and some of them use expensive materials.



Fig. 17 Control chest X-ray image



Fig. 16 Embedded sternum implant (*left*), covered with mesh (*right*)

The main advantage of the procedure that is presented in this case originates from the reverse modeling approach. The reverse modeling enables fabrication of the anatomically customized implant that fits the geometry of patient's thorax. Exactly that makes the operative treatment fast, simpler and easier than conventional one. This kind of implant provides required structural consistency and stability of thorax and in that way necessary protection of endothoracic organs and pulmonary function. Furthermore, customized implant enables application of less expensive materials. Concerning it matches the geometry of the particular patient sternum it does not disturb revascularization and musculature recovery of the treated region. Finally, this kind of implant brings good cosmetic integrity concerning the minimal destruction of the region.

Conclusion

We report a case of successful sternal reconstruction using computer-aided-design and solid (free-form) fabrication technologies in custom implant manufacturing. The application of presented method is expected to increase efficiency and quality of surgery as well as patient outcomes.

The particular observation (the conclusion that distinguishes itself) is that the usefulness of CAx technologies largely depends on the level of the development of the reverse modeling procedure for each individual bone (or tissue or part of tissue).

The precisely defined procedure for the reverse modeling of tissue geometry essentially affects acceleration and quality of surgery preparation, which also includes the efficient fabrication of an implant or fixator.

The core of the developed algorithm for the reverse modeling of the sternum can be applied in the reverse modeling improvement of other tile bones. Considering the observations from this case, further research will focus on the development of parametric geometrical models and corresponding reverse modeling methods for each bone of the human bone system, as well as on the development of new materials and corresponding (free-form) fabrication technologies.

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