Accurate Heart Model for Pacemaker Development via SFF

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ABSTRACT

Medical imaging combined with SFF techniques were used to create detailed CAD and physical heart models for commercial development of Pacemakers. Using a data set of 2D optical slice images of the human heart at 1mm spacing obtained from the Visible Human Project, a 3D CAD model was constructed by masking the features of interest in each slice. Normals on the resulting .stl file were inverted to create a single-piece mold, which was built in starch using 3D Printing. Flexible silicone was cast into this mold, and the starch was dissolved away to produce the final physical heart model. The resulting model simulates the mechanical properties of an actual heart, with medically accurate internal and external details including major veins & arteries, coronary sinus, etc.

INTRODUCTION

Solid Freeform Fabrication holds enormous promise for the field of biomedical engineering. The manufacture of objects from multiple materials with extremely complex geometries lends itself to the creation of customized implants as well as complex scaffolds, which will be key to future tissue engineering applications. In the shorter term, biomedical engineering companies are already going beyond the use of SFF for design visualization and development of surgical tools. There are numerous cases of SFF being used to create physical models of a specific patient's anatomy. Surgeons can physically handle these models and use them to prepare for complex operations. Also, these models can be used as patterns to make specialized implants, specific for the patient at hand.

The majority of this work has involved using CT images as the input data for hard tissue such as bone. In these cases, the data segmentation is relatively simple and is generally performed automatically. When one introduces soft tissue that has less grey-scale differentiation from the surrounding tissue, the process becomes much more complicated. This paper presents a case study to illustrate both the potential and the current issues with using SFF to create geometrically and mechanically realistic physical models from medical images of soft tissue. The human heart provides a good example, as it is both a critical organ for biomedical engineering research/product development as well as an extremely complex, organic geometry which pushes the limits of current manufacturing technology. Cal Poly has recently completed a project for St. Jude Medical to create a medically accurate rubber model of the human heart to be used for the development of pacemakers.

HEART MODEL CASE STUDY

Motivation

An Implantable Cardioverter Defibrillator (ICD) is an implantable device similar to a pacemaker that is also capable of providing a defibrillating shock as necessary. The thin wires extending from the device (Figure 1), through the veins, and anchored into the heart wall are the *leads*. Leads are extremely complex devices, and are the focus for much of ICD product development. Product development of an ICD, like any other product, requires fit checks, mockups and prototypes. Unfortunately, for a heart this means using the prototype device with either animal models (such as dogs) or cadavers. Both require complex procedures to use and are ultimately expensive, and neither is entirely suitable for the work associated with early product development efforts. As a result, the early design optimization of an ICD is often limited. Designs are quite mature by the time they are tested within the context of an actual heart geometry, which is clearly not the best way to do product development.

What is required is a CAD model of the heart for studies such as geometry/fit checks and Finite Element Analysis of performance, and also physical models which accurately simulate the geometry and mechanical properties of the heart. Physical models are especially desirable, as they can ultimately be used to evaluate new or novel implantation procedures for optimal ease of lead insertion. This physical model could also potentially be used in both marketing and training efforts, to help surgeons understand and evaluate the use of a new lead design or implantation procedure. For these benefits to be realized, it is important that the heart be anatomically and mechanically correct and have a realistic texture, especially the interior surface of the chambers of the heart.

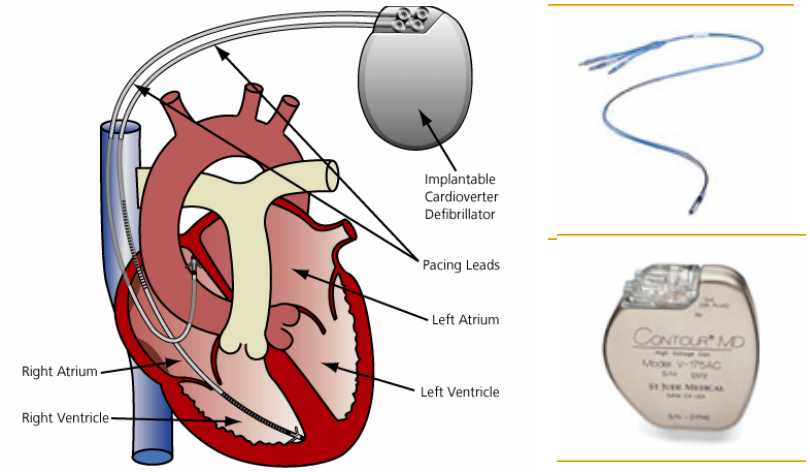

Figure 1. Implantable Cardioverter Defibrillator (ICD)

Data Set: The Visible Human Project®

The data set used for the heart model was obtained from the Visible Human Project® (http://www.nlm.nih.gov/research/visible), created by the National Library of Medicine (NLM). This data set consists of transverse CT, MRI, and optical cryosection images (optical images of the sliced cadaver) of a representative male and female cadaver at one-millimeter (male) and 1/3 millimeter (female) intervals. The corresponding sections of the three imaging modalities are in the same planes, enabling comparison of individual features.

For the male, the CT data consists of axial data of the entire body taken at 1 mm intervals, with a resolution of 512 by 512 pixels, each pixel with 12 bits of grey tone. The axial optical cryosection images are 2048 pixels by 1216 pixels, with each pixel containing 24 bits of color. Each cryosection image is approximately 7.5 megabytes. The cryosection cross-sections are also at 1 mm intervals, coinciding with the CT scans. There are 1871 cross-sections for both the CT scans and the anatomical images. Pixel resolution in the cross section (x-y plane) is 0.33 mm by 0.33 mm. The entire human body is thus represented by a data set comprised of 5,189 anatomical images which can be viewed as 0.33 x 0.33 x 1 mm resolution voxels in 3 medical image modalities.

Figure 2 illustrates the three imaging modalities. Note that MRI and Optical may at first glance look similar if both are viewed in grayscale, but the actual imaging is very different: MRI is density map, while the optical image is reflection of light. They thus pick up different features and are complementary. As can be seen in Figure 2, the heart is not very detailed in the CT images. CT is an ideal imaging technique for bones, but is poor at picking up the details of soft tissue. MRI images would work as a data set for the heart, but the resolution of the MRI images contained in the Visible Human Project is 4mm voxels, which is too low for this effort. The optical images the heart region were thus selected as the input dataset.

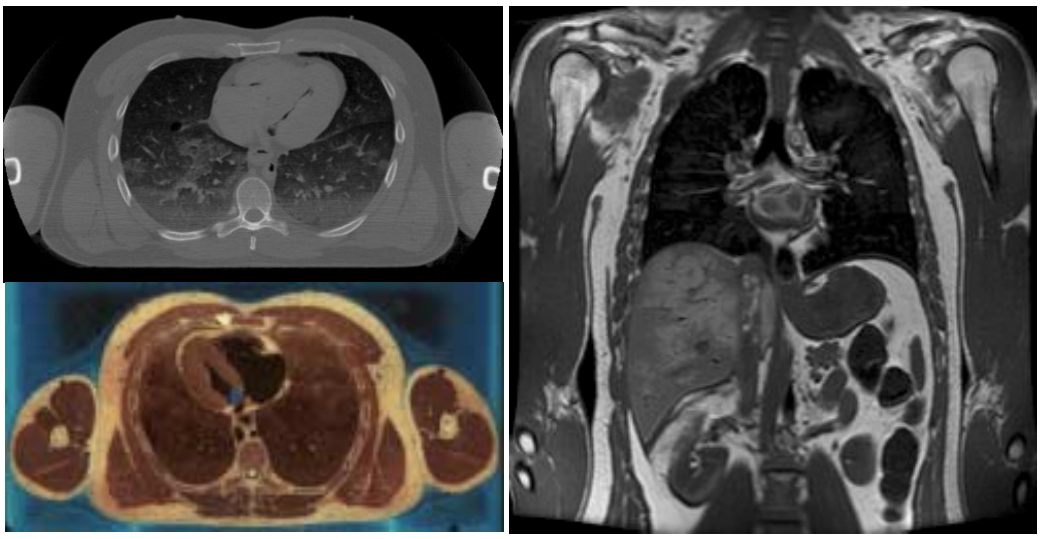

Figure 2. Visible Human male's thorax. CT (top left), MRI (right), Optical Cryosection image (lower left)

Data Segmentation

Segmentation is the process of differentiating the tissue of interest from the surrounding tissue, identifying and marking features of interest in each layer such that software can later interpolate between layers to create a 3D image or CAD data file. This involves viewing each of the cross-sectional images and isolating the areas of density that indicate the type of tissue to be modeled.

There are a number of commercial software packages available for both performing data segmentation and converting from a series of CT/MRI images to .stl files. MIMICS from Materialise (www.materialise.com) was used for this project. Most segmentation processes involve a thresholding technique that allows the user to highlight pixels depending on their gray scale values. For most applications involving isolation of bone, the thresholding tool is the primary tool used. Thresholding enables a mask to be created by defining a grey scale range. By specifying the upper and lower threshold boundaries, all the pixels with a grey scale value that fall within the boundary values are highlighted. The thresholding tool is especially useful in segmenting tissues with a comparatively low or high threshold, like bone, which show up as white in CT images.

The use of optical data requires manual marking of tissue of interest, because there is no "single color" of the heart -- the heart tissue to be isolated does not differ greatly in color or brightness from the surrounding tissues, making the segmentation process more complicated. A significant amount of operator interaction was required to identify and mark the heart tissue within each optical image, layer-by-layer (~180 layers total). The pericardium (the membrane sac which contains the heart) provided a convenient visible boundary between similar looking tissue and fat, and was used as the outer boundary to define the heart. The pericardium was seen as an extremely thin dark band separating layers of identically colored fat. Figure 3 shows this process, as well as the resulting .stl heart model.

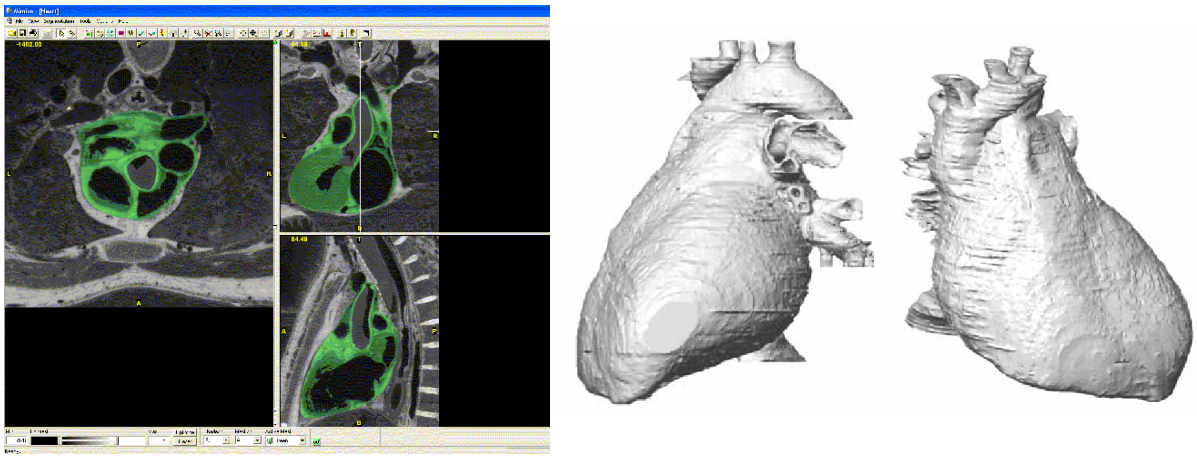

Figure 3. Left: Axial (left), transverse (upper right), and longitudinal (lower right) views as seen in Mimics. Green areas are areas highlighted to create a mask representing the heart model. Right: three-dimensional representation (STL file) of heart model in Mimics.

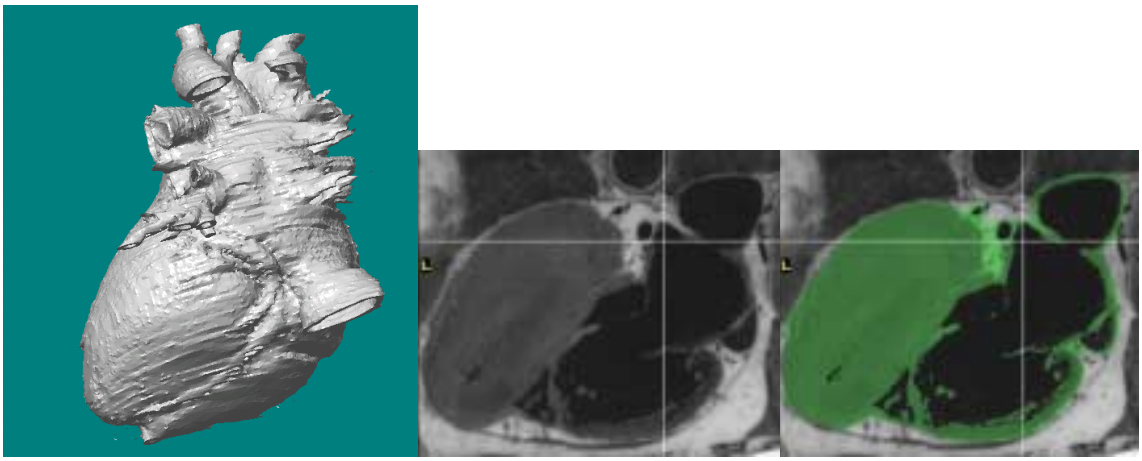

Figure 4. Coronary Sinus, seen in lower center of this view of the heart model.

Note that surface of heart looks smooth, as opposed to having the expected network of veins and arteries on the surface. This is because you are actually looking at the outside of the pericardium, which is smooth. The veins are present, but below the surface of the CAD model.

There were some difficulties in the segmentation process. Veins and arteries were difficult to segment, because there is no clear outer boundary for the vessels, only an inner boundary. It was very challenging to obtain a consistent width of the vessel wall, and therefore to have a smooth outer boundary representing the external wall of the vessels. Also, because the initial thresholding is performed in the axial view corresponding to the orientation of the data set, the vessels that run in the other two directions were not represented as clearly as those that ran axially. The coronary sinus (lower center in Figure 4) is of great interest to developers of ICDs, but is not visible in the CAD model – it is actually just below the surface as described previously, although it is a complete, open channel. A portion of the surface of the heart had to actually be "erased" layer-by-layer to remove the pericardium and expose the surface of the coronary sinus.

After the segmentation was completed, the resulting series of layers could be interpolated in MIMICS and exported as an .stl file. A solid model was also desired to assist in ICD product development efforts (to perform simple geometry and clearance checks), and to be used in finite element analysis (FEA) studies. For these uses, the model was output as set of contours in IGES format (Figure 5), and manipulated with ProEngineer.

The resulting .stl file was 80 MB, which is a difficult file size to manage. In order to reduce the file size, the resolution in the XY plane was reduced by three times. This was done by averaging over 9 pixels (0.33 x 0.33 mm) to create a representative grey scale value for the new larger pixel (1 x 1 mm). Instead of 0.33 x 0.33 x 1 mm voxels, the lower resolution file had 1 x 1 x 1 mm voxels. This yielded a file that was only 14 MB, which was a more appropriate size to manipulate. The lower resolution also provided more smoothing for better on-screen visual representation. The full resolution .stl file was used for physical model creation via Solid Freeform Fabrication

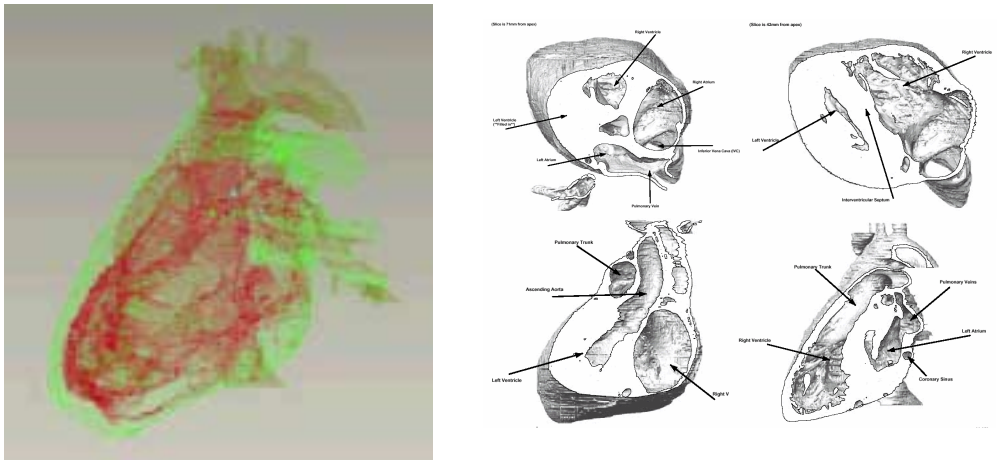

Figure 5. IGES file used for finite element analysis.

Physical Model

It was determined that no existing commercial RP machine would be suitable to create the heart directly, because of the specific required elastomeric properties of the material combined with the complex geometry of the heart. Thus the selected method was to use 3D Printing to create a pattern, perform a secondary polyurethane casting process to create a mold, and then use this mold to cast the final model in a suitable RTV silicone rubber. The system used for this project was the Z Corporation ZPrinter 310 model (http://www.zcorp.com). 3D Printing is an ideal system for a project such as this, because the unbound powder provides support for the extremely complex organic geometry.

The heart has many inner chambers and an interior texture that make it impossible to mold as a single unit. Therefore, the computer model had to be sectioned into pieces that could individually be successfully molded. Even so, each of the sections still had significant overhangs/undercuts such that rigid patterns would be impossible to remove from the cast polyurethane mold material. This challenge was overcome by the use of sacrificial patterns that could be dissolved after casting the mold. Starch-based powder (ZP14), without any post-processing, was used as the build material, with the intention of dissolving it away after casting a flexible polyurethane mold around the pattern. Once the mold was created and the pattern removed by dissolving, the final cast rubber heart sections were removable from the

Figure 6. Left: Exploded view of four sections. Right: Expendable pattern

polyurethane mold, because both components were flexible enough that the final cast piece could be pried out of the mold. Figure 6 illustrates the chosen sections, as well as a representative starch pattern.

After casting, the four resulting cast RTV rubber sections were glued together to create the final heart model. Interior and exterior detail, as well as basic mechanical properties, were sufficient for the intended use of the physical model as a tool for ICD product development. This method, however, was not entirely satisfying because of the need to create individual sections. As an alternative approach to casting such a complex geometry, an expendable starch mold was built directly on the 3D Printer. To create the mold geometry, the .stl normals of the heart model were flipped, and the result was Boolean joined with a block to produce the mold (Figure 7). This mold was built on the 3D Printer in the starch material, and again did not receive any post-processing so that it would be easily removable after casting the RTV.

It was extremely difficult to remove the unbound powder from deep, thin cavities such as the heart walls without damaging the fragile starch mold. The results of this method of casting were promising, but showed numerous areas of missing material on the surface of the resulting RTV heart, due to unbound powder remaining in the deep, thin cavities of the mold which prevented complete filling. Current efforts are focused on using a power/binder system which is more compatible with the methodology of directly creating expendable molds (e.g. sugar bound with a water-resistant binder).

An additional ongoing study which resulted from this project is the creation of separate models of the coronary sinus along with the associated vasculature (Figure 8). Detailed physical models of vasculature systems will be useful for fluid flow studies. For example, it is possible to create "disease states" in CAD (e.g. draw a 2mm layer of plaque), produce a physical model with appropriate mechanical properties using the above method, and instrument it for use in fluid flow testing. The results of such testing would be complementary to FEA fluid dynamic analyses, and would provide access to an unlimited range of geometries to simulate age, disease, etc.

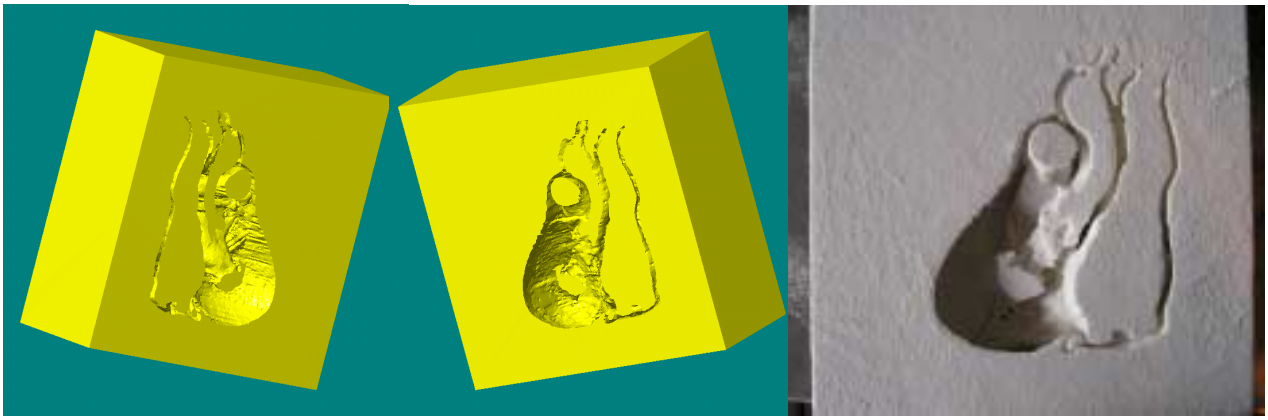

Figure 7. Expendable mold.

Figure 8. Isolated heart vein structure for physical testing.

ACKNOWLEDGEMENTS

The authors would like to acknowledge St. Jude Medical for their support of this project.