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Measurement and Reconstruction of the Leaflet Geometry for a Pericardial Artificial Heart Valve

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Abstract

This research was prompted by the fact that artificial heart valve bioprotheses do not provide long life durability comparable to the natural heart valve, together with the anticipated benefits associated with defining the valve geometries, especially the leaflet geometries for the bioprosthetic and human valves, in order to create a replicate valve fabricated from synthetic materials. Our method applies the concept of reverse engineering in order to reconstruct the freeform surface geometry.

A Brown & Shape Coordinate measuring machine (CMM) equipped with a HyMARC laser digitizing system was used to measure the leaflet profiles of a Baxter Carpentier-Edwards pericardial heart valve. The computer software product, Polyworks was used to post-process the raw data obtained from the scanning, which included merging images, eliminating duplicate points, and adding interpolated points. Three methods, creating a mesh model from cloud points, creating a freeform surface from cloud points, and generating a freeform surface by B-splines are presented in this paper to reconstruct the freeform leaflet surface. The mesh model created using Polyworks can be used for rapid prototyping and visualization. To fit a freeform surface to cloud points is straightforward but the rendering of smooth surface is usually unpredictable. A surface fitted by a group of B-splines fitted to cloud points was found to be much smoother. This method offers the possibility of manually adjusting the surface curvature, locally. However, the process is complex and requires additional manipulation.

A method to represent the leaflet geometry using equations and parametric design is introduced in this paper, and will be discussed in detail in a subsequent study.

Keywords: Artificial Heart Valve, Coordinate Measuring Machine, Laser Scanning, Surface Reconstruction, Reverse Engineering

1. Introduction

A common solution to heart valve disease is to replace the defective natural valve with an artificial valve. Currently, two kinds of prostheses, mechanical heart valves and bioprosthetic heart valves, are commercially available. Due to the difference of leaflet material, the bioprosthetic valves are categorized as pericardial valves and porcine valves. For pericardial heart valves, the leaflets were made of tissue harvested from the pericardial envelope around the heart of a cow. The porcine valve consists of a frame-mounted porcine aortic heart valve that has been chemically treated to render it inert [1]. An equally effective bioprosthetic valve involves shaping the flat pericardial tissue from the hearts of cows to create a tri-leaflet prosthesis.

Although the significant benefit of bioprosthesis is to avoid the use of long-term anti-coagulants, their lower durability makes them suitable only for the elderly population (over 65) and some special circumstances such as implantation during pregnancy. It has been reported that bioprosthetic valves have a compromised short fatigue life, typically 30% to 60% failure within 13 years of implantation [2].

The design of a synthetic, tri-leaflet heart valve, composed of subtle, durable materials is very appealing. This design concept would avoid the stiffening of the leaflets during the chemical treatment while also reducing the stress and abnormal deformation that occurs at the free edge which contributes to the tearing and calcification. Researchers have tried to design the leaflet surface with various geometries [3-9], but the durability of the heart valve still cannot compare with the natural heart valve. Thus, to replicate the geometry of the natural heart valve and apply it to the design of an artificial heart valve is an idea that could significantly improve the durability of replicated bioprosthetic valves since the geometry has been optimized over many generations of human evolution. A Computer Aided Design (CAD) model of the natural heart valve does not exist. An extensive effort is required to build a CAD model of the valve leaflet geometry in order to accomplish this reverse engineering process.

The first intermediary step is to map the leaflet geometries of the tri-leaflet bioprosthetic valve, which will be addressed in this paper. This can be accomplished using a Coordinate Measuring Machine (CMM) with a laser scanning system (3D Digital Corp., 3D Scanners, Cyberware); or other digitizing system, such as Digibotics or Cyber F/X [10, 11]. We chose the former method since the equipment was readily available to us.

Obviously the preferred valve to replicate is the human valve. However, the leaflets of the natural human aortic valves and the porcine bioprosthetic valves are translucent with some hidden features on the surface which makes them difficult to map. Therefore, a Baxter Carpentier-Edwards® pericardial heart valve, 2700 Aortic [12, 13] was chosen in this paper as the suitable valve geometry for reverse engineering, since its leaflets are opaque and the geometry of the leaflets is simpler. Fig.1 is a schematic assembly drawing, which shows the components of a Baxter pericardial heart valve, three identical leaflets, one stent, and one sewing ring. The Dacron® cloth is removed and is not shown in this drawing. The complex geometry of the leaflets is revealed, with different curvatures in the circumferential direction (i.e. parallel to leaflet free edge), and radial direction (i.e. perpendicular to the circumferential direction).

The second task of this paper is to reconstruct the 3D freeform leaflet surface based on the laser scanned profile. The common way to do this involves two main steps, image processing and freeform surface modeling.

In this paper, a Brown & Shape Validator 8202 CMM with an attached HyMARC Hyscan 45C laser digitizing system was used to scan the surface profile of the selected pericardial heart valve. A software package called Polyworks was used to perform the image processing. Three methods were investigated to create the 3D freeform leaflet surface. The method of parametric design was introduced and would be performed in future research.

Fig.1. Schematic drawing of a Baxter pericardial heart valve. It contains three identical leaflets, one stent and one sewing ring. The Dacron® cloth which envelops the stent and the sewing ring is removed and is not shown.

2. Geometry Measurement

The Brown & Shape Validator 8202 Coordinate Measuring Machine (CMM), shown in Fig.2 was used to navigate the laser digitizing system in a two dimensional path. It has two measurement systems, Touch Trigger Probe (TTP) and HyMARC Hyscan 45C laser scanning sensor.

Fig.2. Brown & Shape Validator 8202 coordinate measuring machine (CMM), and two measuring systems, touch trigger probe (TTB) and HyMARC Hyscan 45C laser scanning sensor

The mounting fixture of the pericardial artificial heart valve is shown in Fig.3. A Baxter Carpentier-Edwards® pericardial heart valve that was used as the sample in this study, was positioned in the central hole of an aluminum plate using two clasps. The plate was

connected by a shaft to a collet mounted in an indexing head (CIH), which can rotate about its axis for 360 degrees. Images of the heart valve from different viewpoints can be obtained when the CIH is incremented at predefined angles. No one image was acceptable, since each viewpoint contained hidden surfaces and “dead corners” which prevented the proper mapping of the freeform geometry. The problem was solved by merging additional images taken from different viewpoints.

Fig.3. Mounting fixture of the heart valve. The heart valve was mounted in the center of the aluminum plate with two clasps and the plate was connected to the shaft of the collet index head (CIH), which can rotate about its axis for 360 degrees. The three spheres are datum reference points.

Calibration of the CMM/laser scanning system was the first step of the measurement process. The purpose of the calibration is to ensure that whenever the camera was rotated to a new viewpoint or the heart valve rotated to a new position, then the image data points have the same coordinates with respect to a common origin. Two calibration methods were used together in this study: 1). Specimen rotates, register with TTP. As shown in Fig.3, three spheres on the cylindrical surface of the aluminum plate were used as the datum reference frame due to their fixed displacement with respect to the heart valve specimen. When the specimen was rotated to a new position, the datum reference would be registered again by probing (touching) the three spheres with the TTP; and 2). Camera rotates, calibrate with the large sphere. The other method to calibrate the system used the laser digitizing system to scan the large sphere (76.25mm in diameter), shown in Fig.2. From different viewpoints, different images are achieved. The relative displacement between the camera and the large sphere is computed in order to register the images.

Using this laser scanning system, the surface of the heart valve was scanned by sequential columns as shown in Fig.4. A set of cloud points was obtained and the Cartesian coordinates (x, y and z) were saved. The sampling rate, feed rate and step width used in this study was 10,000pt/s, 1mm/s and 0.25mm respectively.

The laser scanning process was performed five times in this study, with the CIH incremented to five predefined angles. Cloud points from the five different viewpoints were merged in order to represent the complete geometry of the sample heart valve.

Fig.4. Scanning path and scanning parameters. Sampling rate, feed rate and step width used in this study was 10,000pts/s, 1 mm/s and 0.25mm respectively.

3. Geometry Reconstruction

Since the heart valve leaflet contains a complex 3D geometry, a single scan from one specific viewpoint provides only part of the features as some regions are hidden from the viewpoint. In this study, five images taken from five viewpoints (valve rotates to five locations) were merged using Hyscan software. Fig.5 shows the model of cloud points after five images were merged. In order to show the geometry of heart valve clearly, the profiles of the aluminum plate and clasps have been deleted. This process was done by using I-Deas, a 3D CAD software by SDRC®, now part of EDS® [14].

Fig.5. Model of cloud points for heart valve after the images from five viewpoints have been merged. The profiles of the aluminum plate and the two clasps have been deleted.

3.1). Creating a mesh model from cloud points

Fig.6 is a mesh model of the heart valve geometry from the downstream viewpoint created using a software package called Polyworks, by InnovMETRIC software [15]. Duplicated points have been deleted and interpolated points generated to patch the holes in the surfaces. This triangle-linked surface is of the original leaflet geometries. This surface mesh model could be used for successive processes, such as stereolithography rapid prototyping, visualizations and stress analysis.

Fig.6. Mesh model for heart valve profile viewed from the downstream viewpoint. Duplicated points have been deleted and interpolated points were added.

3.2). Creating a freeform surface from cloud points

Raw data obtained from the laser scanning process after image processing contains a unique set of cloud points which defines the leaflet surface. The cloud points were then imported into Unigraphics, a 3D CAD software by EDS® [16]. A freeform surface, which is as seen in Fig.7, was rendered from this set of cloud points using the freeform feature forming functions provided by Unigraphics. This freeform surface needs to be trimmed along the rim of the original leaflet, which could be extracted from the cloud points. Only the trimmed surface inside the rim could be used as the leaflet surface. The process of rim extraction from cloud points is not discussed in this paper because it is beyond the scope of this study.

Fig.7. Freeform leaflet surface rendered by fitting to a set of cloud points.

3.3). Generating a freeform surface by B-splines.

The freeform surface representation of the leaflet was created by the method of B-splines, which were built upon the cloud points. The difference from the previous method is that the surface is not built directly from the cloud points.

The first step is to import the set of cloud points into I-Deas and to partition the set into a few sections for the entire surface. For each partition, a freeform surface was created from the cloud points using the previous method. The next step is to cut each of the fitted surfaces with a plane, which is approximately parallel to the free edge of the leaflet. The set of curves constitute the intersection of the cut plane and the fitted surfaces. Along the intersection a group of from 15 to 46 control points were sampled, depending upon the location of the intersection with the leaflet surface. By incrementally translating the cut plane from near the free edge location to near the base location, groups of control points are sampled. B-splines are fitted to match the control points. One B-spline fitted to a group of control points was used to represent the intersection of the cut plane and the leaflet surface. This step was repeated until all the groups of control points were fitted to individual B-splines. In this study, a total of 15 B-splines were fitted along circumferential direction of each leaflet as shown in Fig.8.

Finally, a CAD model of freeform surface for the 15 B-splines was created using the LOFT function of I-Deas, which is a commonly used function to create a freeform surface from a set of curves.

Fig.8. Freeform surface rendered by B-spline curves fitted along circumferential directions. B-splines and control points are also shown. Additional operations, such as trim and surface extension were used to create the CAD model for the leaflet. Two inflexion points, R and W are observed on the surface.

The 3D CAD model of the leaflet could be created by using the SHELL command of I-Deas, in which a uniform thickness of $200\mu\text{m}$ was applied to the freeform surface shown in Fig. 8. The 3D leaflet solid volume was then trimmed using the stent to the required size and was fitted inside the stent to form a leaflet for pericardial heart valve.

A replicate heart valve consisting of the three leaflet geometries derived from above procedure is shown in Fig.9.

Fig.9. Design concept of a pericardial heart valve, which contains three identical leaflets with reconstructed geometry.

4. Conclusions and Discussion

The surface profile from the downstream viewpoint of a commercial pericardial heart valve was measured using laser profile scanning. It was observed that the set of cloud points agree well with the original geometry of the pericardial heart valve. The point density is sufficient to represent the surface geometry, regardless of the variation in curvature at different locations. The leaflet surface was reconstructed by using different 3D freeform surface modeling methods. A smooth surface was successfully reconstructed, which could be used for subsequent solid volume modeling.

A surface mesh model created by using Polyworks is straightforward. Although this model can be used for stereolithography rapid prototyping and for visualization, it is not suitable for geometry modeling in 3D CAD software. The generation of a freeform surface from a set of cloud points can be accomplished using CAD commercial software, such as Unigraphics. However the ability to manipulate the model is very limited. Whether a surface can be generated depends upon the capability of the CAD system and the accuracy of the scanned cloud points. Scanning errors can adversely affect the smooth contour of the rendered surface.

The method, which constructs a freeform surface by a group of B-splines is complex requiring additional effort for maneuvering points, curves, planes and surfaces. However, the local curvature of each B-spline can be adjusted by re-locating, interpolating or removing the control point(s). A smoother surface was created upon this operation, which is as shown in Fig.10. In this model, Inflexion points, W and R in Fig.8 are eliminated. By smoothness, we consider the perfect smooth surface without inflexion point.

Fig.10. A smoother surface is rendered after maneuvering the control points of B-splines, comparing with that as shown in Fig.8. Inflexion points, W and R are eliminated.

For the pericardial heart valve in the static condition, the leaflet surface usually has a surface of conicoid. Fitting a quadric surface to the cloud points would yield a mathematical equation to represent the geometry. The specific type of conicoid would be revealed and the smooth surface could be created using the equation for future leaflet design. Furthermore, fitting control points into quadratic curves instead of B-splines would reveal the surface curvatures along the circumferential direction. Similar fittings could be done to generate the surface curvatures along radial direction. Using the fitted mathematical equations for the leaflet surface and the curves along circumferential/radial directions, the original leaflet design could be evaluated and the concept of parametric designs implemented. Meanwhile, the reconstruction of the leaflet surface does not have to be limited to the original scanned profiles. The surface shape can be adjusted by changing specific parameters in the equations. This would offer a method to implement alternative designs, and to explore design optimization. We reported the implementation of parametric representation and parametric design elsewhere [17].

This paper presents a method for measuring and reconstructing the leaflet geometry with a uniform thickness for pericardial heart valves. We have shown that the B-spline method can be applied to reconstruct a surface model which can be transformed into a 3D solid volume model of the leaflet.

However, the porcine bioprosthetic heart valve and the natural human aortic valve, have three leaflets with different shapes, wrinkles and varying thickness. In addition, the translucency of the leaflets makes the laser scanning process ineffective. We are exploring an alternative method and will report the results in the future.

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