

Simulation of Aortic Valve Replacement Surgery

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ABSTRACT

Surgery of aortic valve covers all ages and includes an extensive range of pathologic anatomies and surgical techniques. Achieving cardiac surgical proficiency may takes years of practice and on-the-job experience. Cardiac trainees need to develop technical competence in order to gain improved quality of care and patient safety. It is crucial to provide appropriate and efficient educational opportunities to gain the essential awareness, judgement and technicalities. Simulation plays a progressively significant role in the educational process and for cardiac surgical trainees and residents to develop the essential skills and confidence using synthetic but realistic platforms. In this study, we illustrate aortic valvotomy and replacement and briefly review surgical relief of other forms of left ventricular outflow obstruction. Then, the synthetic platform designed and developed for the simulation of aortic heart valve is discussed in detail. The technology and platform proposed here have the potential to be applied to all cardiovascular related reconstructive surgeries.

INTRODUCTION

The incident of severe aortic stenosis in adults is remarkably high [1]. Suitable timing of aortic valve replacement may avoid early and late fatal events and result in improved functional status. Early diagnosis and treatment will preserve regular ventricular function or may return irregular function to regular.

Why Valve Replacement: It is very important to understand how the regular function and structure of the left ventricle, the aortic valve, and the ascending aorta can be affected by an appropriately timed and performed valve replacement which is the basis for the decision to proceed with a surgical intervention. Aortic stenosis is typically a progressive disease. A more severe stenosis leads to a higher resistance to the left ventricle outflow. In order for the left ventricle to compensate this high resistance and maintain with a normal systemic pressure and cardiac output, a higher left ventricular pressure is generated. This elevated pressure is achieved by concentric ventricular hypertrophy. Simply the left ventricle wall gets thickened and its mass is increased. Although this might be a temporary solution for a while, but the left ventricle will eventually exceed the limit of concentric hypertrophy and begin to dilate in order to maintain left ventricular pump function. This dilation leads to change in shape of the left ventricle and may significantly and negatively affect its function. Factors such as ejection fraction and fiber shortening mean velocity might eventually be reduced leading to congestive heart failure. Both phases, i.e., cardiac hypertrophy and ventricular wall dilation, might affect the hemodynamic and metabolic alternations. As the ventricular wall dilates progressively and hypertrophy increases, the end-diastolic and pulmonary venous pressure increase which may lead to the increase of shortness of breath. Also, more oxygen is required as the myocardial wall tension increases due to hypertrophy. Given that the oxygen supply remains the same, myocardial ischemia and the symptom of angina pectoris might occur. Excessive dilation of the left ventricle might lead to chronic congestive heart failure. This is due to the alteration in ventricular shape and dynamics that create a vicious cycle that might be fatal. Aortic valve replacement will provide a significant reduction of symptoms and enhancement in ventricular dysfunction in most patients. Even in the cases of congestive heart failure and noticeable ineffectiveness of ventricular function, aortic valve replacement may lead to improvement in symptoms and ventricular function, resulting in the reversibility of the ventricular dysfunction and improved survival. Hemodynamic assessment of the valve stenosis involves determination of the valvular gradient and estimation of the aortic valve area and the aortic valve area index. If ejection fraction and cardiac output are normal, severe aortic stenosis is detected by the gradient of pressure across the valve being 50 mmHg or more or aortic valve area index being less than $0.75 \text{ cm}^2/\text{m}^2$ [1]. If cardiac output is lower than normal, valve area index needs to be taken into account and not the gradient of pressure because the pressure gradient across the valve can be minimal for low amount of cardiac outflow. Aortic valve replacement is recommended even in the presence of a left ventricular ejection fraction is

less than 25% or for symptomatic patients with moderate aortic stenosis in which aortic valve area is in the range of 0.7 to 1.2 cm² [1]

Problem Statement: An artificial platform which can be used to simulate the aortic heart valve replacement does not exist. Possible options are based on nonrealistic synthetic models or animal models which are either not realistic enough or not available for repetitive practice. It should be noted that, there are multiple limitations in using animal models which is not the case with our proposed synthetic models.

Our Strategy: We design and develop synthetic models of ascending aorta which have similar mechanical properties and geometry to those of porcine tissue. The aortic valve, the root, and other sections, which are made all in one piece, look and are physically the same as those of the porcine ascending aorta tissue. Also, our proposed models feel like tissue so that when sutures are performed it resembles a realistic platform as experienced in an actual surgical operation.

METHOD

In this study, a polymeric ascending aorta made of hydrogel-based biomaterials is proposed. To design the geometry of the root, an advanced surfacing technique based on the de Casteljau method (for developing Bezier surfaces) is applied. The Three-Dimensional (**3D**) geometry is developed using Two-Dimensional (**2D**) images obtained from the axial dissection of an adult porcine aortic root. The biomaterial used for the aortic valve is a biocompatible hydrogel made of Polyvinyl Alcohol (**PVA**) reinforced by Bacterial Cellulose (**BC**) natural nanofibers in a combination of 15% PVA and 0.5% BC, by weight fraction. The biomaterial used for the root is only 10% PVA. The tensile properties of the synthesized PVA-BC that are measured are close to those of the porcine aortic valve leaflet tissue in the two principle directions, i.e., radial and circumferential. We obtained a close match of the stress-strain curves for the aorta in the circumferential and axial directions and anisotropic 10% PVA with 75% initial strain after cycle 3 [2]. A cavity mold is designed and manufactured and the proposed polymeric valve is then fabricated. An extensive finite element analysis was performed in order to optimize the final product (please see the appendix). The proposed model may be further used for animal trials.

Preparation of the Hydrogel Biomaterial

Hydrolyzed PVA, 99+% (*Sigma-Aldrich*) with a molecular weight of 146,000-186,000 is used as the main ingredient for the solution preparation. A suspension of 0.877 wt% BC in distilled water is then added to the PVA solution. The BC solution is produced in shake flasks by fermentation process using the bacterium *Acetobacterxylinum*. The BC suspension was prepared and then added to the PVA solution. The new solution contains 15% PVA and 0.5% BC by weight fraction while the rest is distilled water as shown in Figure. 1[3].

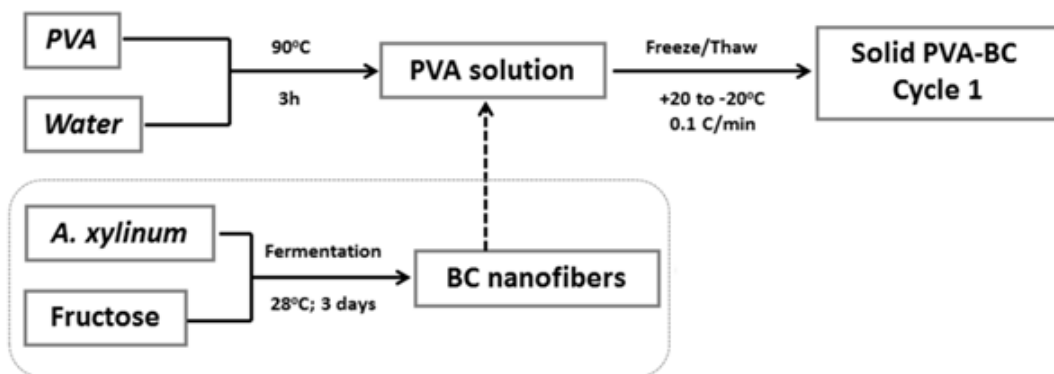


Figure 1: The proposed platform as to the PVA-BC nanocomposite preparation for the newly designed ascending aorta.

The final solution was dispensed into 3 metallic molds and placed in a heated/refrigerated circulator (15L Heating Bath Circulator Model SD15H170-A11B). The molds were cycled once between 20°C and -20°C at 0.1°C/min so the solution can solidify and gain a deterministic shape (cycle 1). In order to impose anisotropy to the samples, 75% strain was applied to all 3 samples while they were placed back into the mold to reach the maximum anisotropy [3]. The direction of stretch would be the direction with higher stiffness. One sample is kept non-stretched as control. The molds were cycled using the freeze-thaw procedure, and each time one mold was removed at the end of each cycle. The freeze/thaw process continues for 6 cycles. The above procedure and PVA-BC were applied for the preparation of the hydrogel implemented in the leaflet structure because leaflets are much stiffer than the aortic wall. For the aortic wall, a similar procedure was applied with one major difference that only 10% PVA was used only (BC fibers were not used). This is because less stiffness is required for the aortic wall.

Tensile Testing: The results of experimental tensile tests are reported in the form of load versus extension. These values are converted into stress-strain values using the samples dimensions and the initial gauge length after preconditioning. Given that the samples undergo large deformation, the stress-strain curves obtained for all samples are nonlinear and hyperelastic. To fit the data obtained, an appropriate constitutive model is applied such that [2], $\sigma = \gamma_0 + A \exp(B\varepsilon)$, where σ is true stress, ε is true strain, and γ_0 , A, and B are constants.

The tensile properties are measured by a servohydraulic testing machine (INSTRON 8872) with a precise load cell with a maximum capacity of 1 kg. In order to be consistent with the realistic bio-environment of the samples, all measurements are carried out inside a water container filled with distilled water at the body temperature. The strain rate for the performed tensile tests is set to a strain rate of 40 mm/s to a maximum of 60% strain. The preconditioning test was achieved for all samples in 10 cycles with amplitude of 5 cm and frequency of 2 cycles/sec [5,6]. The mechanical

properties obtained for the aortic valve and the ascending aorta are shown in Figs. 2a to 2d. An evaluation of all the anisotropic PVA samples and the porcine aorta was achieved in order to set up a conceivable match of the mechanical properties for tissue replacement applications. Figure. 2e indicates the stress–strain curves of the aorta in both directions and the anisotropic pure PVA sample after cycle 3 at initial strain of 75%.

The Design and Fabrication of the Ascending Aorta

For the design of the geometry of both the ascending aorta and the aortic valve, an advanced and novel surfacing technique based on the de Casteljau method is applied on the Bezier-based surfaces. The 3D geometry was developed by stacking 2D images obtained by the axial dissection of an adult human aortic root and aortic valve. It should be mentioned that the valve used for this purpose was Mitroflow bioprosthetic valve. The 2D images are digitized and converted into a finite number of control points. This is realized by mapping the 2D geometry of each section using a Coordinate Measuring Machine (**CMM**) with a laser scanning system such as 3D Digital Corp, 3D scanner cyberware.

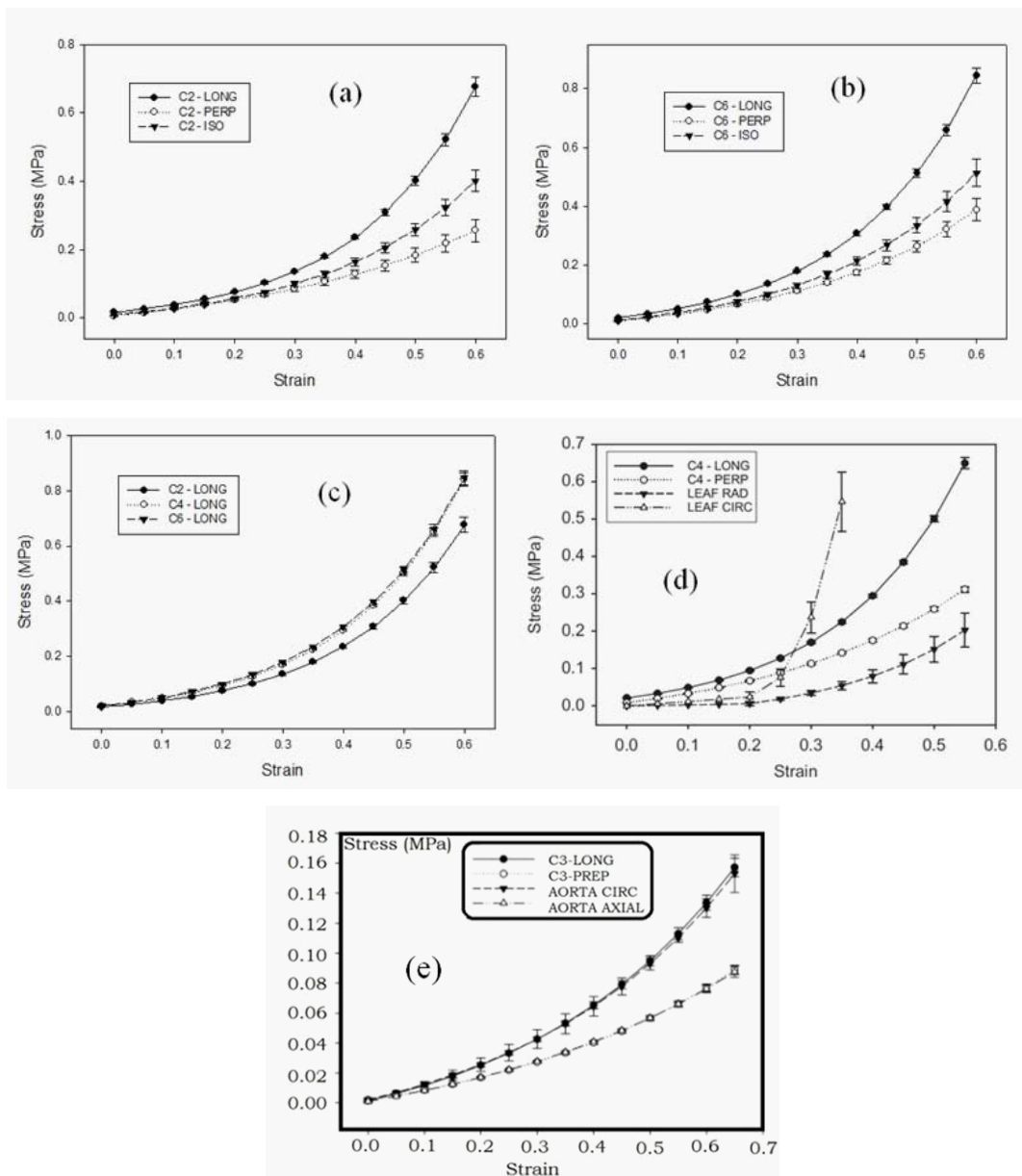


Figure 2: (a) The utilized anisotropy after cycle 2 at 75% initial strain, (b) the utilized anisotropy after cycle 6 at 75% initial strain, (c) the stress-strain curves in the longitudinal direction in cycle 2, 4, and 6 at 75% initial strain, and (d) tensile properties of the developed hydrogel, C4 is cycles 4, LONG is longitudinal, PERP is perpendicular, LEAF RAD is porcine aortic leaflet in the radial direction, LEAF CIRC is porcine aortic leaflet in the circumferential direction, and the physiological domain represents the physiological loading condition of the valve, and (e), Closest match of the tensile stress–strain curves of aorta in both directions obtained from the anisotropic PVA at 75% initial strain after cycle 3 (Mohammadi 2011).

Then the control points are applied to construct the corresponding Bezier curves to complete the 2D images digitization. These curves are the bases for the production of the final Bezier surfaces. The main advantage of this technique is that the final surface obtained is easily and quickly tunable. In order to increase the surface quality and apply any desired changes, Bezier curves are accustomed through a trial and error procedure by removing, relocating, or interpolating the initial control points. The final surfaces are brought to a CAD software environment by using a command as known as shell, e.g., command Shell of I-Deas. Because we are developing 3D and physical models, thicknesses of the valve leaflets and ascending aortic wall and their variation is of particular importance. For this purpose two surfaces are independently designed to form the top surfaces of the male and female parts of the mold for each model. Even though the produced shells of the Bezier surfaces individually have uniform thicknesses but the final products are 3D with variable thicknesses exactly the way it is meant to be [6-8].

The thickness of the model is provided by the gap defined between these two surfaces in the final design of each mold. We used Mechanical Desktop V2013i CAD software for the perfection of the models all throughout. As mentioned earlier, the geometry of the proposed aortic valve here is inspired by a design modification on the Mitroflow bioprosthetic valve.

The major advantage of this new design is that the leaflets are considered with variable thickness (0.7 mm on the free edge and 1.2 mm on the attachment with the stent) defined by applying a comprehensive finite element structural analysis and the related optimized computational methods (see the appendix). The final model of the proposed valve consists of three identical cusps whose leaflets are symmetrical about their own midlines. The fabricated model and the final prototype made of PBS thermoplastic material for the proposed aortic valve prosthesis are shown in Figure. 3. The valve is then added to the ascending aortic wall model so that a complete synthetic model (made of PBS thermoplastic material) including the sinuses, two outlets for the right and left coronary arteries and the valve is developed in only one piece. The final model of the ascending aorta is shown in Figure. 4.

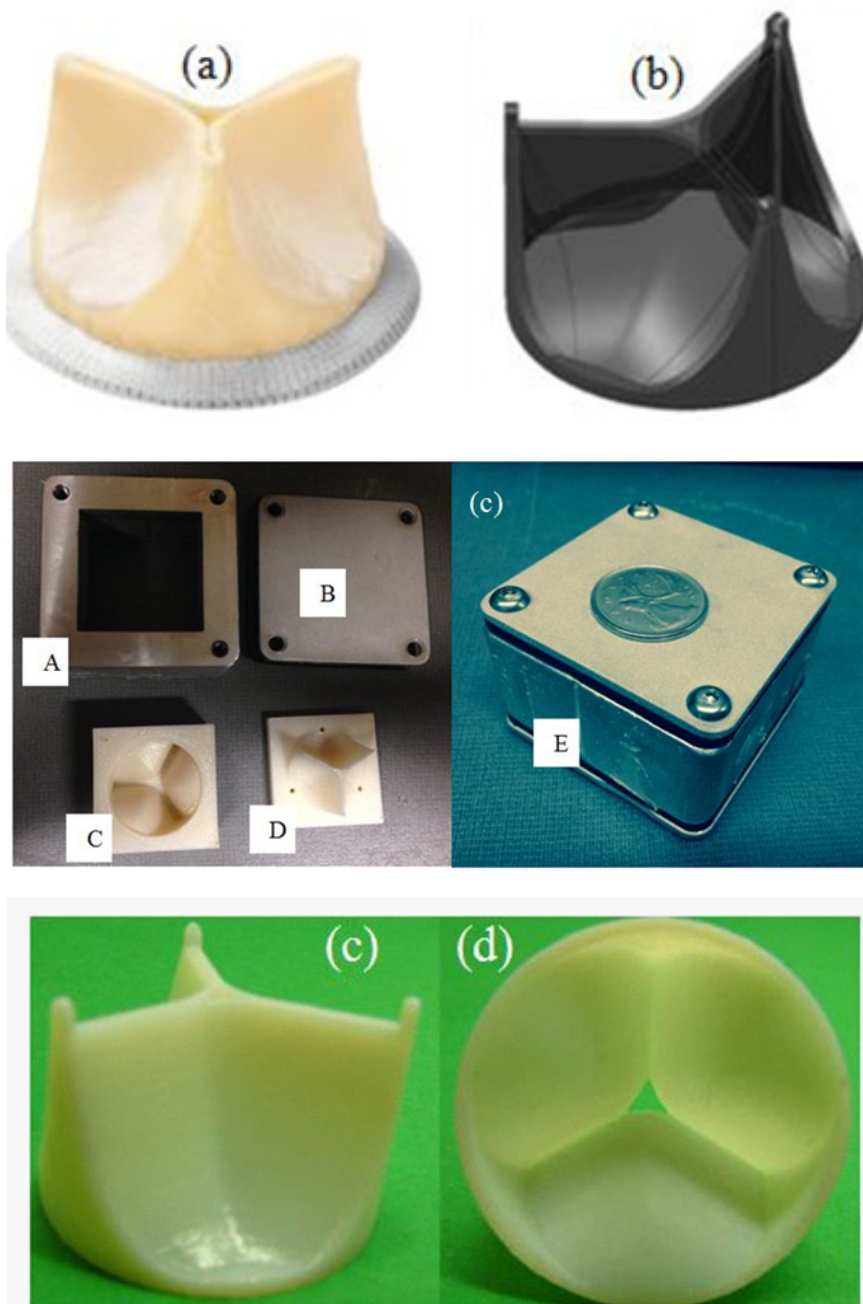


Figure 3: (a) The mitroflow bioprosthetic valve of which the design of the proposed valve is inspired, (b) the final CAD model of the proposed valve, (c) the designed and fabricated mold and its parts for the new design of the PVA-BC polymeric trileaflet valve. A: casing, B: caps x2, C: main female part, D: main male part, E: the assembled mold, (c) and (d) are the first prototypes of the valve made of PBC thermoplastic material.

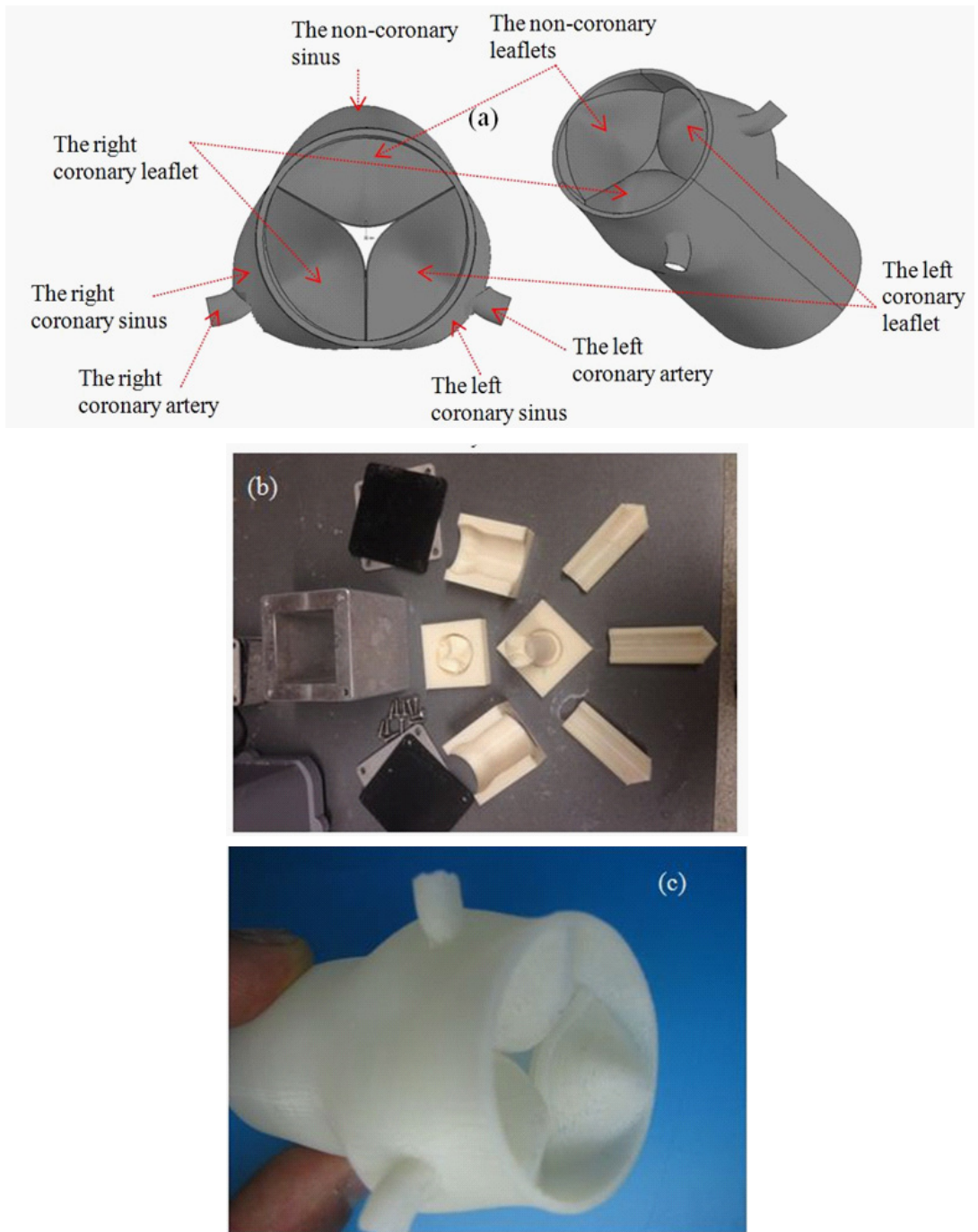


Figure 4: (a) The 3D CAD model of the ascending aorta, (b) the fabricated mold and its part of the proposed final CAD model, (c) the prototype of the ascending aorta made of PBC thermoplastic material including the left and right coronary arteries, the sinuses and the aortic valve all in only one piece.

Final Models Made of the Proposed Hydrogel

The developed material which is close in mechanical properties to those of ascending aortic wall and the porcine heart valve leaflet tissue are implemented for the final models. The designed and fabricated molds are now filled with the proposed hydrogels (PVA-BC for the valve leaflet and PVA only for the aortic wall) and the final models are manufactured. These models are similar in geometry and mechanical properties to that of native tissues and can be an excellent model to be used for the simulation of aortic heart valve surgery (Figures. 5).

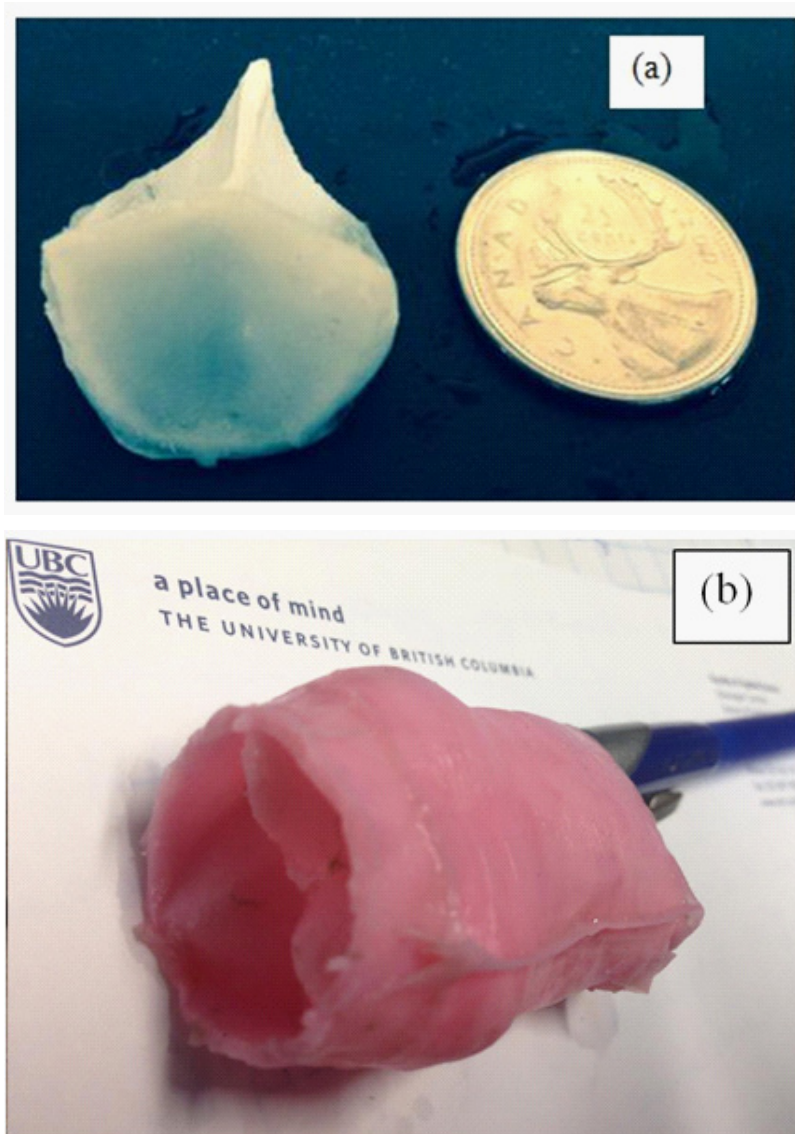


Figure 5: (a) The final aortic valve made of PVA-BC and (b) the final aortic root including the valve and sinuses with similar mechanical properties and geometry to that of the native tissue.

RESULTS AND DISCUSSION (APPLICATION)

Case 1 – Aortic Valve Replacement (Surgical Anatomy)

The anatomy of the aortic valve is shown in Figures.1 and 2. Figure. 1 shows the valve from above, with the orientation as usually seen through a standard transverse aortotomy [9].

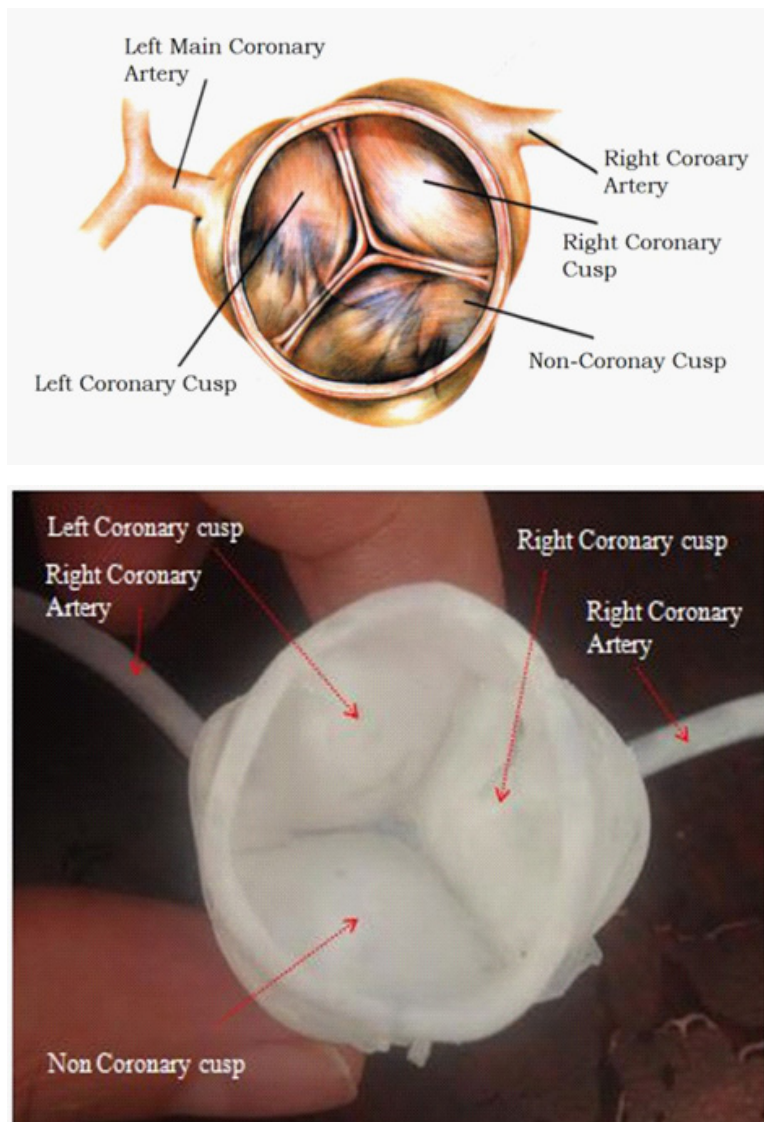


Figure 6: The anatomy of human aortic valve including the right-, left-, and non- coronary cusps (leaflets) and the main branches of left- and right- coronary arteries – top view. The top image is a typical diagram of the ascending aorta and the lower image is the synthetic ascending aorta proposed in this study which is one piece of the aortic root including the valve and coronary outlets.

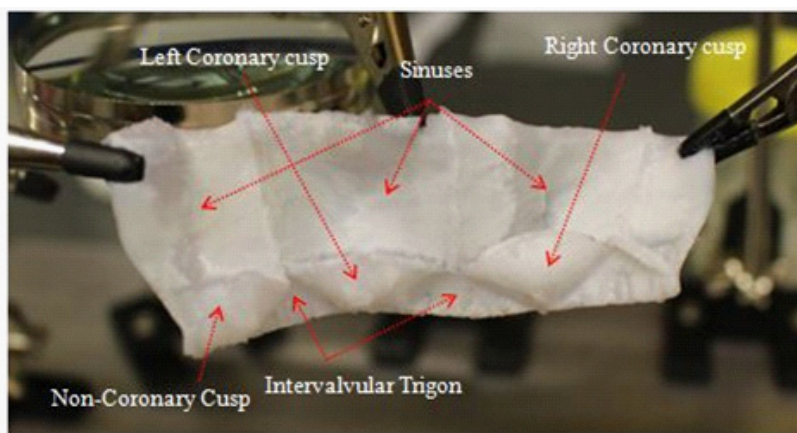
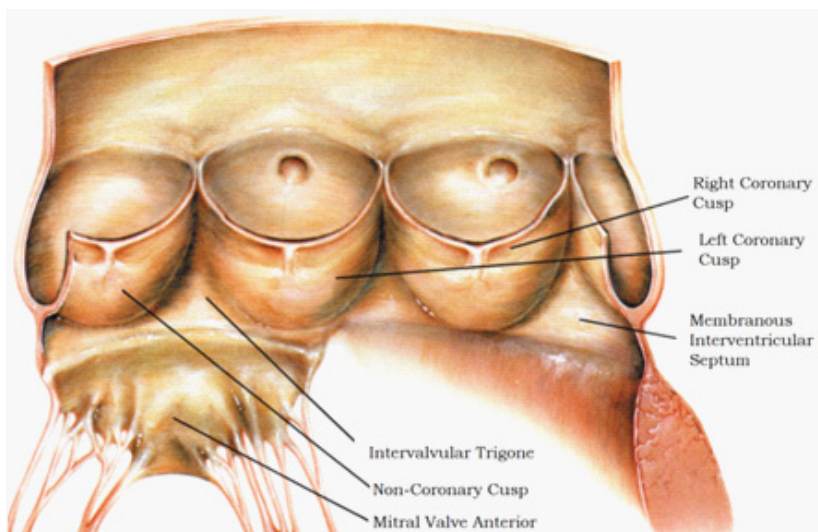


Figure 7: Demonstration of an opened-out view of the aortic valve to illustrate the subvalvular anatomy. Because the left ventricle has a common inlet and outlet, the anatomy of the aortic valve and mitral valve is intimately related. The top image is a typical diagram of the opened out ascending aorta including the aortic valve and the lower image is the synthetic ascending aorta proposed in this study which is one piece of the aortic root including the valve and coronary outlets.

Surgical procedure: A transverse aortotomy is made. An incision is normally made about 15 mm above the level of the right coronary artery. This is because if it is lower, the right coronary artery might be jeopardized leading to technical complications in valve seating and aortotomy closure. Erring on the high side is not very important because the aortotomy can easily be angled downward, and the anterior lip caused by a high incision can be quickly pulled back. The aortotomy is suggested to be extended to about 10 mm above the commissure between the left and right coronary leaflets and to a similar distance above the commissure between the left and the noncoronary leaflets [9].

After retractors are located and the valve can be seen and the approach for excision is identified, then the calcified tissues are completely excised, while care must be taken to not cause injury to bundle of His and the aortic wall. In many severely calcified valves, leaflets are free of calcification at the site of attachment prior to annulus. If so, the incision line could exactly be on the calcium-free ribbon near the annulus. If a calcium-free near the annulus does not exist, excision can be made on a hypothetical ribbon relatively close to the annulus. This is because such severe calcification might damage a portion of the annulus and part of it might be inadvertently excised. A polymer aortic valve prosthesis is designed and fabricated which is slightly smaller (normally 1 to 2 mm smaller) in diameter than the diameter of the patient annulus. The sinuses are removed in a way that only a rim of aortic wall above the cusps is left. Three sutures are placed through the prosthesis and the patient annulus (Figure. A2, B2). The prosthesis is then lowered into the patient's annulus and inverted into the left ventricle (Figure. B3). The sutures should be then run toward each commissure and firmly tied. The suture line is kept at slightly below the patient's annulus. In the case of bioprosthesis, special care must be taken to avoid the conduction tissue under the commissure between the right coronary and the noncoronary cusps which is obviously not the case but for the polymeric valve. The valve is then everted and the sutures start at the low points of the sinuses and are brought up to the commissures (Figure. A4-A5 and B4-B6) [9].

Case 2 - Congenital Aortic Stenosis

The left and right cusps are fused together at the commissure which is considered as a relative underdevelopment of the right coronary leaflet (cusp). The orifice is typically a cut between the left- and non- coronary cusps. The commissure between these two cusps is typically well developed but the other commissure may be different in degree of development and be only a primitive raphe. A simple incision is usually made in one (or two) commissure(s) of the right coronary cusp. Incision of the other commissure, however, depends on its degree of development and the enlargement and depth of the right coronary leaflet (cusp).

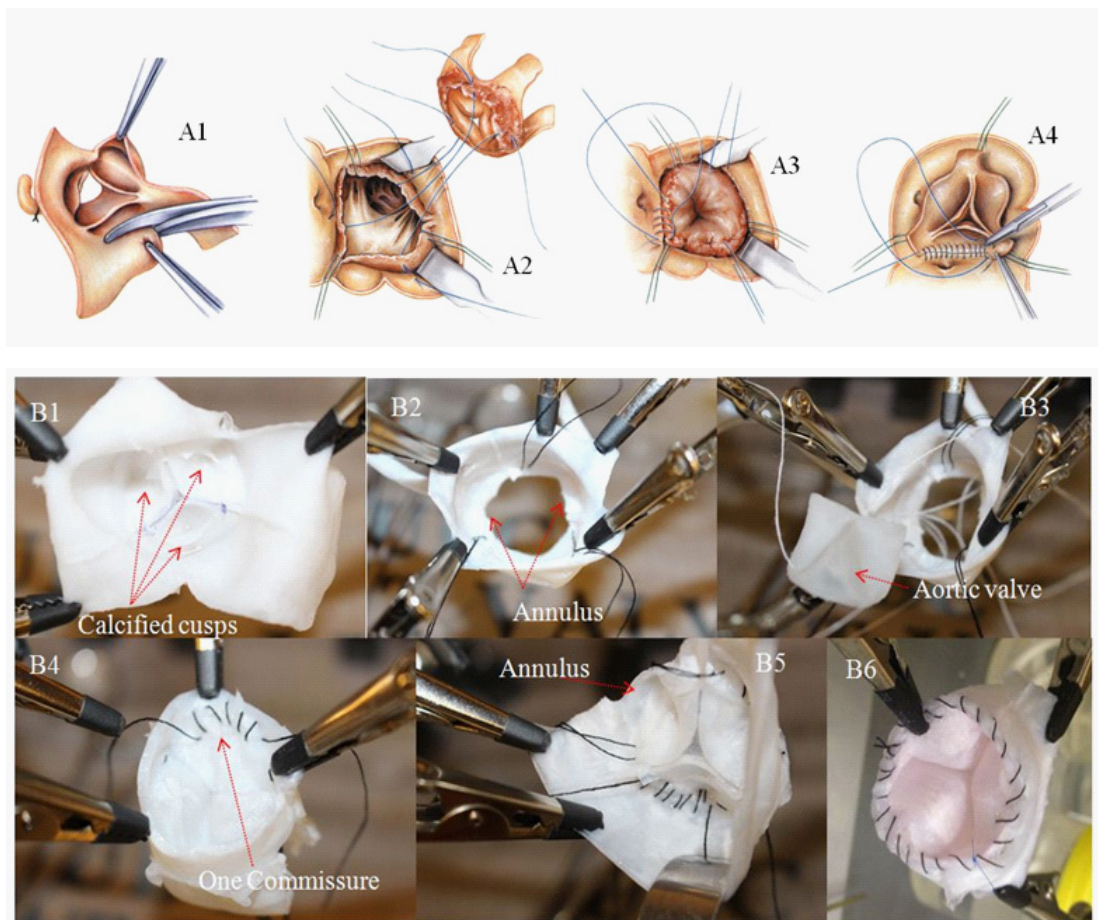


Figure 8: Anastomosis procedure of the prosthetic aortic valve and the ascending aorta built in this study. (1) The sinuses are removed in a way that only a rim of aortic wall above the cusps is left as shown in A1 and B1, (2) the calcific leaflets are removed as described above (B2), (3) three sutures are placed through the prosthesis and the patient annulus for guiding the valve into the right place in annulus, (4) valve is anchored to the annulus. As shown almost one commissure is attached (A3, A4 and B4, showing the attachment from the aortic side, B5, showing the attachment from the ventricular side) and sutures are carried around to complete the anastomosis (B6).

Surgical Procedure: In the first step a transverse aortotomy is prepared and then the valve is uncovered with small cusp retractors. Forceps are used to hold the leaflets and then an incision is made on the well-developed commissure all the way back to the annulus (Figures. 9A1, 9A2). The assessment is carefully made on the depth of support and degree of development of the right coronary leaflet. Because the right coronary leaflet make a coaptation area with the other leaflets (and not prolapse), the other commissure is carefully incised. In the last step, the subvalvular area is carefully checked to make sure there is no subvalvular stenosis underneath. The procedure on the proposed synthetic model is shown in Figures. 9B1 to 9B4.

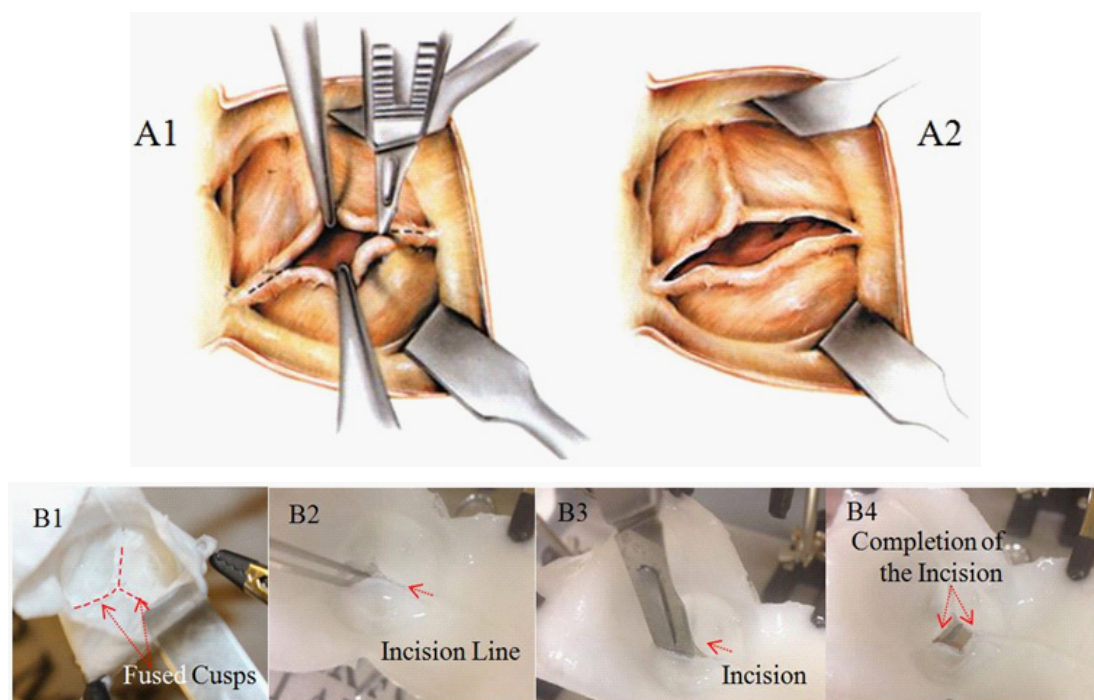


Figure 9: The exposure of the valve and incision of the well-developed commissure all the way back to the annulus (A1, A2) – top view. In the synthetic model initially all 3 cusps are fused together. The practice is make the main incision as discussed in the manuscript, (1) valve is exposed (B1), (2) the incision line is determined (B2), (3) the incision is made all the way back to the annulus (B3), and (4) the incision is completed (B4).

CONCLUSION

This chapter summarizes a novel emerging technology by which a complex surgery can be accurately simulated. We proposed a novel model of ascending aorta made of synthetic material which is similar in mechanical properties and geometry to that of native tissue. A complicated heart valve replacement surgery can be simulated step by step.

It is known that available surgical simulators lack fidelity, or are not correctly lifelike, though in this chapter a high fidelity platform was designed and fabricated. This platform may be used by young surgical residents or cardiac surgeons to develop expertise on the matter. More platforms will be developed so that other valve or ascending aorta related surgeries such as Yacobi, David, or Bentall procedures can be precisely simulated.

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