

CLAIMS

What is claimed is:

1. A method for manufacturing a personalized naturally designed mitral valve prosthesis to precisely fit a specific patient for which the valve prosthesis is made for, said method comprising:

measuring size and shape of a native mitral valve of the specific patient by using imaging means;

providing data of a material from which the personalized mitral valve prosthesis is made of;

building a 3D model of the personalized mitral valve prosthesis based on the size and shape of the native mitral valve of the specific patient and the data of the material;

optimizing the 3D model using finite element method (FEM) method;

and

fabricating the personalized mitral valve prosthesis based on the optimized FEM model.

2. The method of claim 1, further comprising visualizing the personalized mitral valve prosthesis model after the optimizing operation;

wherein said imaging means comprising: 2D or 3D echocardiography, computed tomography (CT), Cardiac magnetic resonance (CMR) or any combination thereof; or

wherein measuring size and shape of a native mitral valve of a patient comprising measuring mitral valve related parameters comprising: annular ring circumference (AC), annulus area (AA), anterior-posterior (A-P) diameter, anterolateral-posteromedial (AL-PM) diameter, commissural diameter (C-C), anterior leaflet length (AL), posterior leaflet length (PL), mitral valve shape, and length of chordae tendineae (ACL and PCL).

~~3. The method of claim 1 or 2, wherein said imaging means comprise: 2D or 3D echocardiography, computed tomography (CT), Cardiac magnetic resonance (CMR) or any combination thereof.~~

~~4. The method of any one of claims 1-3, wherein measuring size and shape of a native mitral valve of a patient comprises measuring mitral valve related parameters comprising: annular ring~~

~~circumference (AC), annulus area (AA), anterior-posterior (A-P) diameter, anterolateral-posteromedial (AL-PM) diameter, commissural diameter (C-C), anterior leaflet length (AL), posterior leaflet length (PL), mitral valve shape, and length of chordae tendineae (ACL and PCL).~~

53. The method of ~~any one of the preceding claims~~claim 1 or 2, further comprising collecting physical information of the specific patient to predict the geometry of a heart after implantation of the personalized mitral valve prosthesis, said physical information comprising: body height, body weight, age, race and gender.

64. A personalized mitral valve prosthesis comprising a flexible annular ring dimensioned to match the native mitral annulus of a specific patient, a flexible anterior leaflet and a flexible posterior leaflet dimensioned to match the native mitral leaflets of the specific patient, said leaflets connected to the annular ring, and chords dimensioned to match the native mitral leaflets of the specific patient, said chords connected to the flexible anterior leaflet and the flexible posterior leaflet, said chords further configured to connect the flexible anterior leaflet and the flexible posterior leaflet with papillary muscles of the heart, said personalized mitral valve prosthesis formed by:

measuring size and shape of a native mitral valve of the specific patient by using imaging means;

providing data of a material from which the personalized mitral valve prosthesis is made of;

building a 3D model of the personalized mitral valve prosthesis based on the size and shape of the native mitral valve of the specific patient and the data of the material;

optimizing the 3D model using FEM method; and

fabricating the personalized mitral valve prosthesis based on the optimized FEM model by cutting the material into the annular ring, the flexible anterior leaflet and the flexible posterior leaflet and the chords and connecting the flexible anterior leaflet and the flexible posterior leaflet to the annular ring, and connecting the chords to the flexible anterior leaflet and the flexible posterior leaflet.

75. The personalized mitral valve ~~prosthetic-prosthesis~~ of claim 64, wherein the personalized mitral valve ~~prosthetic-prosthesis~~ may be further formed by visualizing the personalized mitral valve prosthesis model after the optimizing operation; or

wherein said imaging means comprising: 2D or 3D echocardiography, computed tomography (CT), Cardiac magnetic resonance (CMR) or any combination thereof; or

wherein measuring size and shape of a mitral valve of a patient comprising measuring mitral valve related parameters comprising: annular ring circumference (AC), annulus area (AA), anterior-posterior (A-P) diameter, anterolateral-posteromedial (AL-PM) diameter, commissural diameter (C-C), anterior leaflet length (ALL), posterior leaflet length (PLL), mitral valve shape, and length of chordae tendineae (ACL and PCL).

~~8. The personalized mitral valve prosthesis of claim 6 or 7, wherein said imaging means comprise: 2D or 3D echocardiography, computed tomography (CT), Cardiac magnetic resonance (CMR) or any combination thereof.~~

~~9. The personalized mitral valve prosthesis of any one of claims 6-8, wherein measuring size and shape of a mitral valve of a patient comprises measuring mitral valve related parameters comprising: annular ring circumference (AC), annulus area (AA), anterior-posterior (A-P) diameter, anterolateral-posteromedial (AL-PM) diameter, commissural diameter (C-C), anterior leaflet length (ALL), posterior leaflet length (PLL), mitral valve shape, and length of chordae tendineae (ACL and PCL).~~

~~106.~~ The personalized mitral valve prosthesis of ~~any one of claims 6-9~~claim 4 or 5, further comprising collecting physical information of the specific patient to predict the geometry of a heart after implantation of the personalized mitral valve prosthesis, said physical information comprising: body height, body weight, age, race and gender.

~~117.~~ The personalized mitral valve prosthesis of claim ~~95~~, wherein the measuring comprises measuring the annular ring circumference (AC) as a combination of an anterior leaflet annular ring circumference (AAC) that is a top edge of the anterior leaflet, and a posterior leaflet annular ring circumference (PAC) that is a top edge of the posterior leaflet based on equation (iii):

$$AC(2) = \left[2\pi \frac{A-P \text{ diameter} - 2d}{2} + 4 \left(\frac{AL-PM \text{ diameter} - 2d}{2} - \frac{A-P \text{ diameter} - 2d}{2} \right) \right] \times (1 - \lambda)$$

further wherein said annular ring is formed into a multi-layered reinforced structure by folding or overlapping the top edge of each of the anterior leaflet and posterior leaflet.

~~128.~~ The personalized mitral valve prosthesis of claim ~~117~~, wherein the top edge of each of the anterior leaflet and the posterior leaflet is straight or curved for properly fitting the personalized mitral valve prosthesis to the natural geometry of the left ventricle of the specific patient; or

wherein connecting comprises joining the edge of the anterior leaflet with the edge of the posterior leaflet such to create a coaptation between the anterior leaflet and posterior leaflet; or
wherein calculating the annular ring circumference (AC) of the prosthesis is based on a ratio (λ) in equation (iii).

~~13.—The personalized mitral valve prosthesis of claim 11, wherein connecting comprises joining the edge of the anterior leaflet with the edge of the posterior leaflet such to create a coaptation between the anterior leaflet and posterior leaflet.~~

~~149.~~ The personalized mitral valve prosthesis of any one of claims ~~6-134-8~~, wherein connecting comprises joining the flexible anterior leaflet and the flexible posterior leaflet together thereby forming two commissures, wherein the two commissures incline inward in cone angle (δ_1) to create a cone shape to the personalized mitral valve prosthesis to fit in a native left ventricle of the specific patient;

wherein the cone angle (δ_1) is determined by an inclined angle (δ_0) of each commissure edge of the flexible anterior leaflet and the flexible posterior leaflet based on equation (x):

$$\delta_1 = \arctan \left[\frac{2 \sin(\delta_0)}{\pi \cos(\delta_0)} \right]; \text{ or}$$

wherein connecting comprises connecting the anterior leaflet to the posterior leaflet by connecting anterolateral side to anterolateral side and connecting posteromedial side to posteromedial side;

wherein connecting the anterior leaflet to the posterior leaflet comprises stitching.

~~15.—The personalized mitral valve prosthesis of claim 14, wherein the cone angle (δ_1) is determined by an inclined angle (δ_0) of each commissure edge of the flexible anterior leaflet and the flexible posterior leaflet based on equation (x):~~

$$\delta_1 = \arctan \left[\frac{2 \sin(\delta_0)}{\pi \cos(\delta_0)} \right]$$

16. ~~The personalized mitral valve prosthesis of any one of claims 6-15, wherein connecting comprises connecting the anterior leaflet to the posterior leaflet by connecting anterolateral side to anterolateral side and connecting posteromedial side to posteromedial side.~~

17. ~~The personalized mitral valve prosthesis of claim 16, wherein connecting the anterior leaflet to the posterior leaflet comprises stitching.~~

1810. The personalized mitral valve prosthesis of claim 138, wherein the measuring comprises measuring: size and shape of a native annular ring of the specific patient, commissure height (CH) inclined angel (δ_0), anterior leaflet length (ALL) and posterior leaflet length (PLL), and coaptation height (Coapt H) for calculating length of each leaflet edge based on equation (xi):

$$\text{Length of free edge} = \left\{ 2\pi \times (ALL \text{ (or PLL)} - CH \times \cos(\delta_0) - Coapt H) + 4 \left[\frac{1}{2} AAC \text{ (or PAC)} - CH \times \sin(\delta_0) - (ALL \text{ (or PLL)} - CH \times \cos(\delta_0) - Coapt H) \right] \right\} \div 2.$$

1911. The personalized mitral valve prosthesis of ~~any one of claims 11-13~~ claim 7 or 8, wherein the reinforced annular ring height is between 1 mm and 4 mm or between 2 mm and 3 mm.

20. ~~The personalized mitral valve prosthesis of any one of claims 11-13, wherein the reinforced annular ring height is between 2 mm and 3 mm.~~

2112. The personalized mitral valve prosthesis of ~~any one of claims 11-13~~ claim 7 or 8, wherein the annular ring circumference (AC) is a function of the anterior-posterior diameter (A-P) and the anterolateral posteromedial diameter (AL-PM) based on equation (iii):

wherein measuring comprises measuring the anterior-posterior diameter (A-P) and the anterolateral posteromedial diameter (AL-PM) is performed when the mitral valve closes during left ventricular systole.

~~22. The personalized mitral valve prosthesis of claim 21, wherein measuring comprises measuring the anterior-posterior diameter (A-P) and the anterolateral posteromedial diameter (AL-PM) is performed when the mitral valve closes during left ventricular systole.~~

~~23. The personalized mitral valve prosthesis of any one of claims 11-13, wherein calculating the annular ring circumference (AC) of the prosthesis is based on a ratio (λ) in equation (iii).~~

~~24~~13. The personalized mitral valve prosthesis of claim ~~6~~4, wherein the annular ring is asymmetrical and further wherein said annular ring is formed from a combination of an anterior leaflet annulus and a posterior leaflet annulus, wherein an anterior leaflet annular circumference (AAC) is smaller than a posterior leaflet annular circumference (PAC), and the ratio (R) between AAC/PAC is between 49/51 and 30/70.

~~25~~14. The personalized mitral valve prosthesis of claim ~~24~~13, wherein ratio (R) between AAC/PAC is between 35/65 and 42/58; or

wherein ratio (R) between AAC/PAC is 40/60; or

wherein ratio (R) between AAC/PAC is between anterior leaflet length (ALL) and posterior leaflet length (PLL).

~~26. The personalized mitral valve prosthesis of claim 24, wherein ratio (R) between AAC/PAC is 40/60.~~

~~27. The personalized mitral valve prosthesis of claim 24, wherein ratio (R) between AAC/PAC is between anterior leaflet length (ALL) and posterior leaflet length (PLL).~~

~~28~~15. The personalized mitral valve prosthesis of any one of claims ~~6-27~~4-14, wherein building the 3D model of the personalized mitral valve prosthesis comprises calculating an anterior leaflet annular circumference (AAC) and a posterior leaflet annular circumference (PAC) based on suture positions A and B; or

wherein building the 3D model of the personalized mitral valve prosthesis comprises calculating the anterior leaflet length (ALL) and posterior leaflet length (PLL) based on: (a) an anterior-posterior diameter (A-P) that is a theoretical minimum distance for coaptation; (b) a ratio

(r) between ALL to PLL; (c) coaptation depth (Cd); (d) the coaptation height (Coapt H); and (e) chord length (Lc) based on equations (viii) and (ix):

$$ALL = (A - P \text{ diameter}) \div 2 + 10 \text{ (In millimetre)}$$

$$PLL = (A - P \text{ diameter}) \div 2 + 5 \text{ (In millimetre)}.$$

29. — The personalized mitral valve prosthesis of claim 18, wherein building the 3D model of the personalized mitral valve prosthesis comprises calculating the anterior leaflet length (ALL) and posterior leaflet length (PLL) based on: (a) an anterior-posterior diameter (A-P) that is a theoretical minimum distance for coaptation; (b) a ratio (r) between ALL to PLL; (c) coaptation depth (Cd); (d) the coaptation height (Coapt H); and (e) chord length (Lc) based on equations (viii) and (ix):

$$ALL = (A - P \text{ diameter}) \div 2 + 10 \text{ (In millimetre)}$$

$$PLL = (A - P \text{ diameter}) \div 2 + 5 \text{ (In millimetre)}.$$

3016. The personalized mitral valve prosthesis of any one of claims 6-294-15, wherein connecting comprises connecting the anterior leaflet and the posterior leaflet together to form a body of the personalized mitral valve prosthesis; or

wherein each of the anterior leaflet and each of the posterior leaflet comprises two sets of chords: anterolateral chords and posteromedial chords, wherein each of the anterolateral chords and posteromedial chords comprises three sub-chords, wherein the cords are uniformly distributed along at least 3/8 of each edge from each side.

31. — The personalized mitral valve prosthesis of any one of claims 6-30, wherein each of the anterior leaflet and each of the posterior leaflet comprises two sets of chords: anterolateral chords and posteromedial chords, wherein each of the anterolateral chords and posteromedial chords comprises three sub-chords, wherein the cords are uniformly distributed along at least 3/8 of each edge from each side.

3217. The personalized mitral valve prosthesis of claim 3416, wherein building the 3D model comprises calculating a length of each, wherein calculating the length of each chord is based on parameters comprising: leaflet length, coaptation height, and coaptation depth.

~~3318.~~ The personalized mitral valve prosthesis of any one of claims ~~6-324-17~~, wherein measuring comprises measuring distance from a papillary muscle apex to a coaptation edge to denote the prosthesis chord length, further comprising on-site measuring and adjusting of a pledget like chord cap into which the chords are integrated and merged at an end of each set of chords.

5 ~~3419.~~ The personalized mitral valve prosthesis of any one of claims ~~6-334-18~~, wherein building the 3D model comprises providing calculated geometry and dimensions of the annular ring, the anterior leaflet, the posterior leaflet and the chords per the specific patient as inputs for an engineering drawing software or drawing tool;

10 wherein said engineering drawing software or drawing tool output a template for manually cutting the leaflets of the valve prosthesis; or

wherein said engineering drawing software or drawing tools output a template for machine cutting the leaflets.

~~35.—The personalized mitral valve prosthesis of claim 34, wherein said engineering drawing software or drawing tool output a template for manually cutting the leaflets of the valve prosthesis.~~

15 ~~36.—The personalized mitral valve prosthesis of claim 34, wherein said engineering drawing software or drawing tools output a template for machine cutting the leaflets.~~

~~3720.~~ The personalized mitral valve prosthesis of any one of claims ~~6-364-19~~, further comprising packing, labelling and sterilizing the personalized mitral valve prosthesis before release for usage; or

20 further comprising assembling the personalized mitral valve prosthesis onto a valve holder before packaging; or

further comprising implanting the personalized mitral valve prosthesis into the specific patient.

25 ~~38.—The personalized mitral valve prosthesis of any one of claims 6-37, further comprising assembling the personalized mitral valve prosthesis onto a valve holder before packaging.~~

39. ~~The personalized mitral valve prosthesis of any one of claims 6-38, further comprising implanting the personalized mitral valve prosthesis into the specific patient.~~