

CLAIMS

1. A method for manufacturing personalized mitral valve prosthesis , comprising the steps of:
 - 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 an annular ring, a flexible anterior leaflet, a flexible posterior leaflet and chords;
 - 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, the chords further configured to be connectable with papillary muscles of the heart;
 - wherein measuring size and shape of a mitral valve of the specific 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),

where an annular ring circumference (AC) of the personalized mitral valve prosthesis is 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, wherein the annular ring circumference (AC) of the personalized mitral valve prosthesis is calculated is based on equation (iii):

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

wherein d is the width of the flexible annular ring's edge and λ is the ratio of AC reduction from native annular ring circumference to the flexible annular ring of the personalized prosthesis.

2. The method of claim 1, wherein said flexible 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.

3. The method of claim 1, 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.

4. The method of claim 1 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.

5. The method of claim 3, wherein the measuring further comprises measuring: size and shape of a native annular ring of the specific patient, commissure height (CH) inclined angle (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.

6. The method of claim 1, wherein 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.

7. The method of claim 1, wherein the flexible annular ring is asymmetrical and wherein the flexible annular ring has a ring circumference comprising an anterior leaflet annular circumference (AAC) and a posterior leaflet annular circumference (PAC), wherein the AAC is smaller than the PAC, and a ratio (R) between AAC/PAC is between 49/51 and 30/70 of the ring circumference.

8. The method of claim 7, 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 corresponds to a ratio between an anterior leaflet length (ALL) and a posterior leaflet length (PLL).

9. The method of any one of claims 1-8, 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, the suture positions A and B selected based on a location of each of two papillary muscles that define the anterior leaflet and the posterior leaflet.

10. The method according to claim 5, 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 (vi) and (vii):

$$ALL = f(A - P \text{ diameter}, r, Cd, Ch, Lc)$$

$$PLL = f(A - P \text{ diameter}, r, Cd, Ch, Lc) \quad .$$

11. The method of any one of claims 1-10, wherein connecting comprises connecting the anterior leaflet and the posterior leaflet together to form a body of the personalized mitral valve prosthesis.

12. The method of any one of claims 1-11, 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 chords are uniformly distributed along at least $\frac{3}{8}$ of each free edge of the anterior leaflet and the posterior leaflet respectively.

13. The method of claim 12, wherein building the 3D model comprises calculating a length of each chord, wherein calculating the length of each chord is based on parameters comprising: leaflet length, coaptation height, and coaptation depth.

14. The method of any one of claims 1-13, 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.

15. The method of any one of claims 1-14, wherein building the 3D model comprises providing calculated geometry and dimensions of the flexible 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;

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.

16. The method according to claim 1, wherein the ratio of AC reduction ranges from 0% to 20% and is determined by existing clinical diagnosis.