tems in mitral position. Valve replacement by the percutaneous route or by minimally invasive surgery is becoming an increasingly common practice for the aortic and pulmonary valves, but cannot be used as yet for the mitral valve.

As explained above, the mitral annulus differs from the aortic annulus in not being circular, especially in a patient with a mitral annuloplasty ring. The available transcatheter prostheses are always tricuspid, and if they are not perfectly circular after expansion (due to an irregular expansion of the stent) they tend to reduce the degree of coaptation of the valve leaflets, resulting in prosthetic insufficiency. Since the aortic annulus is practically circular, transcatheter valves almost always work well, unless the stent is distorted during implantation owing to the presence of dystrophic calcification of the annulus and the valve leaflets. The risk of insufficiency in the mitral position, which is not circular, is very considerable, since the mitral annulus does not offer any resistance during the expansion of the prosthesis, thus leading to over-dilation and consequent loss of coaptation between the three valve leaflets.

Embodiments of the present invention seek to provide a heart valve prosthesis which can at least partially overcome the problems of the prior art described above.

According to a first aspect of the invention, there is provided ~~a heart~~ an atrio-ventricular valve prosthesis comprising a ring-shaped supporting structure to be anchored at the valve annulus, and a single extended valve leaflet of flexible material floatingly supported by said supporting structure, wherein said supporting structure comprises a support wall portion at which a root end of the valve leaflet is connected, and a complementary wall portion opposite said sup

port wall portion, which supports a static or quasi-static coaptation surface adapted to be sealingly engaged by a free end of the valve leaflet, and extending in a direction substantially parallel to the

direction of movement of the free end of the valve leaflet at the coaptation surface; and said free end of the valve leaflet is connected to said support wall portion or to said complementary wall portion preferably in their lateral portions by means of at least one traction member of flexible material, dimensioned to such a length that the movement of the free end of the valve leaflet is stopped at said coaptation surface~~.~~; and wherein the supporting structure has a D-shaped cross section, in particular in the area where said valve leaflet is contacting said structure.

According to a second aspect, there is provided a prosthesis having a supporting structure, a support wall portion, a complementary wall portion and a single extended valve leaflet supported by said supporting structure, wherein said complementary wall portion supports a static or quasi-static coaptation surface adapted to be sealingly engaged by a free end of the valve leaflet~~.~~; wherein the supporting structure has a D-shaped cross section, in particular in the area where said valve leaflet is contacting said structure; and wherein said prosthesis is adapted to be used as an atrio-ventricular valve.

Embodiments of the invention were developed on the basis of an examination of the prior art in the field of heart valve repair.

As explained by Carpentier, the aim of mitral valve repair is to restore a good coaptation surface in order to provide satisfactory mitral valve function (Carpentier A. Cardiac valve surgery – the "French correction." J Thorac Cardiovasc Surg 1983; 86: 323-37). Conventionally, the repair of a posterior leaflet prolapse consists in the resection of the leaflet followed by annuloplasty using a ring, and this has been shown to have excellent long-term durability. Typically, echocardiographic findings

after mitral valve repair show a posterior leaflet with reduced mobility or no mobility at all, which hangs vertically from the annulus and forms, as demonstrated experimentally and clinically (Cohn, L.H., Couper, G.S., Aranki, S.F., et al. Long-term results of mitral valve reconstruction for regurgitation of the myxomatous mitral valve. J Thorac Cardiovasc Surg 1994; 107: 143-51), a support against which the anterior leaflet bears in apposition. These conclusions were developed further by Perier (Perier, P., Hohenberger, W., Lakew, F., Batz, G., Urbanski, P., Zacher, M., and Diegeler, A. Toward a new paradigm for the reconstruction of posterior leaflet prolapse: midterm results of the "respect rather than resect" approach. Ann Thorac Surg 2008 Sep; 86(3): 718-25), who deliberately converted the bicuspid mitral valve into a monocuspid valve by the apposition of the an

The at least one traction member is preferably attached to lateral portions of the supporting structure.

The lateral portions are the two sides of the supporting structure which include the utmost ends of the anterior side and the posterior side. The anterior side and the posterior side preferably relate to the complementary wall portion and the support wall portion. The attachment of the traction member can be anywhere along the lateral portions.

When the traction members are arranged at the lateral portions, their interference with the movement of the valve is minimized as the valve leaflet preferably opens in an anterior posterior direction.

According to a third aspect, there is provided a delivery device comprising a prosthesis as described herein.

According to a fourth aspect, there is provided a method for manufacturing a heart valve prosthesis, ~~preferably a prosthesis as described herein,~~ comprising the steps of

- providing a supporting structure, ~~preferably a D-shaped support structure with~~ wherein the supporting structure has a D-shaped cross section, and a support wall portion and a complementary wall portion,
- assembling a valve leaflet of flexible material in the supporting structure,

wherein the valve leaflet is connected with a root end to the support wall or the complementary wall~~, preferably through stitching,~~

and a free end of the valve is attached to the other wall portion, complementary wall portion or support wall portion through a traction member.

CLAIMS

1. ~~A heart~~ An atrio-ventricular valve prosthesis comprising a ring-shaped supporting structure to be anchored at the valve annulus, and a single extended valve leaflet of flexible material floatingly supported by said supporting structure, wherein

said supporting structure comprises a support wall portion at which a root end of the valve leaflet is connected, and a complementary wall portion opposite to said support wall portion, which supports a static or quasi-static coaptation surface adapted to be sealingly engaged by a free end of the valve leaflet, and extending in a direction substantially parallel to the movement direction of the free end of the valve leaflet at the coaptation surface;

said free end of the valve leaflet is connected to said support wall portion or to said complementary wall portion by means of at least one traction member of flexible material, which is dimensioned to such a length that the movement of the free end of the valve leaflet is stopped at said coaptation surface~~.~~; and wherein the supporting structure has a D-shaped cross section, in particular in the area where said valve leaflet is contacting said structure.

2. A prosthesis according to claim 1, wherein said coaptation surface extends in the direction parallel to the movement direction of the free end of the valve leaflet for a width (h) of at least 5 mm.

3. A prosthesis according to one of the claims 1 or 2, wherein said coaptation surface is formed by an inner face of said complementary wall portion of the supporting structure.

4. A prosthesis according to one of the claims 1 or 2, wherein said coaptation surface is formed by a quasi-static coaptation leaflet which comprises a root end connected to said complementary wall portion, and a free end connected to said support wall portion or to said complementary wall portion by means of at least one traction member of flexible material which is dimensioned to such a length that said coaptation leaflet is kept bent towards said complementary wall portion.

5. A prosthesis according to any of the preceding claims, wherein said supporting structure comprises a skeleton constituted by a valve stent, which is capable to assume a delivery configuration wherein the stent is collapsed, and an implantation configuration wherein the stent is expanded.

6. A prosthesis according to any of the preceding claims, wherein said supporting structure is configured for a sutureless implantation on the valve annulus.

7. A prosthesis according to any of the preceding claims, wherein said at least one traction member is connected to a post portion of said support wall portion or said complementary wall portion, said post portion axially protrude

ing from the blood outflow side of said supporting structure.

8. A prosthesis according to any of the preceding claims, wherein at least one predetermined area of said supporting structure is provided with a positioning marker of material opaque to radiation of a predetermined wavelength.

9. A prosthesis according to any of the preceding claims, wherein there is a plurality of said traction members having different lengths that are connected to a plurality of sites distributed along the edge of the free end of the valve leaflet.

10. A prosthesis according to any of claims 1 to 8, wherein said traction member constitutes an integral extension of the valve leaflet, and extends transversely along the entire edge of the free end of the valve leaflet.

~~11. A prosthesis according to any of the preceding claims, wherein the supporting structure has a D-shaped cross section.~~

~~12~~11. A prosthesis according to ~~claim 11~~ any of claims 1 to 10, wherein the straight part of the D shape is the support wall portion or the complementary wall portion and the bent part of the D shape is the other wall portion, complementary wall portion or support wall portion, respectively.

~~13~~12. A prosthesis according to any of the preceding claims, wherein the valve and the at least one traction member are constructed as a single piece~~, preferably as a single piece~~ made of pericardium.

~~14~~13. A prosthesis according to any of the preceding claims, wherein the at least one traction member is attached to lateral portions of the supporting structure.

~~15~~14. A prosthesis according to any of the preceding claims, wherein ends of the supporting structure are flared outwardly with respect to a blood flow direction.

~~16~~15. A prosthesis according to claim ~~15~~14, wherein the flared ends are flared differently such that ~~one end, preferably~~ an inflow end~~,~~ is flared with a wider angle with respect to the blood flow direction than ~~an opposite end, preferably~~ an outflow end.

~~17. A prosthesis having a support structure and at least one valve leaflet supported by said support structure, preferably according to any of the preceding claims, wherein a supporting structure has an asymmetric arrangement such that one side, preferably the anterior side is axially shorter than an opposite side, preferably the posterior side.~~

~~18. A prosthesis having a support structure and at least one valve leaflet supported by said support structure, preferably according to any of the preceding claims, wherein ends of the supporting structure are curvilinearly flared with respect to a blood flow direction.~~

~~19. A prosthesis having a support structure and at least one valve leaflet supported by said support structure, pref~~

~~erably according to any of the preceding claims, wherein ends of the supporting structure are asymmetrically flared such that one side, preferably an anterior side, is flared with wider angle with respect to a blood flow direction than an opposite side, preferably a posterior side.~~

~~20~~16. A prosthesis having a supporting structure, a support wall portion, a complementary wall portion and a single extended valve leaflet supported by said supporting structure, wherein said complementary wall portion supports a static or quasi-static coaptation surface adapted to be sealingly engaged by a free end of the valve leaflet~~.~~; wherein the supporting structure has a D-shaped cross section, in particular in the area where said valve leaflet is contacting said structure; and wherein said prosthesis is adapted to be used as an atrio-ventricular valve.

~~21~~17. A prosthesis according to ~~claim 20~~ any of the preceding claims, wherein ~~the~~ said supporting structure has ~~a D-shaped cross section.~~an asymmetric arrangement such that the anterior side is axially shorter than the posterior side.

~~22~~18. A prosthesis according to ~~anyone~~ any of the ~~previous~~ preceding claims~~ which is adapted to be used as a mitral valve.~~, wherein ends of the supporting structure are curvilinearly flared with respect to a blood flow direction.

19. A prosthesis according to any of the preceding claims, wherein ends of the supporting structure are asymmetrically flared such that the anterior side is flared with a smaller angle with respect to a blood flow direction than the angle present in the flare of the posterior side.

~~23~~20. A delivery device comprising a prosthesis according to ~~one of the claims 1 to 22~~any of the preceding claims.

~~24~~21. A method for manufacturing a heart valve prosthesis, ~~preferably a prosthesis according to one of the claims 1 to 22,~~ comprising the steps of

- providing a support~~ing~~ structure, ~~preferably~~ wherein the supporting structure has a D-shaped ~~support structure~~cross section and ~~with~~ a support wall portion and a complementary wall portion,
- assembling a valve leaflet of flexible material in the supporting structure,

wherein the valve leaflet is connected with a root end to the support wall or the complementary wall, ~~preferably through stitching,~~and a free end of the valve is attached to the other wall portion, the complementary wall portion or the support wall portion through a traction member.

22. A method according to claim 21, wherein the valve leaflet is connected with a root end to the support wall or the complementary wall through stitching.

~~25~~23. A method according to claim ~~24~~21, wherein the valve and the traction member are constructed as a single piece~~, preferably a single piece~~ made of pericardium.