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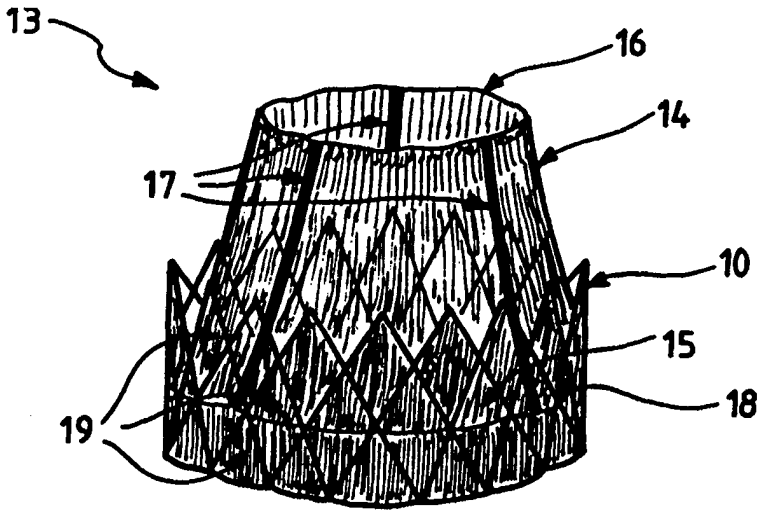
(57) Abstract

The present invention is aimed to provide a valve prothesis (IV) especially used in case of aortic stenosis, which structure is capable of resisting the powerful recoil force and to stand the forceful balloon inflation performed to deploy the valve and to embed it in the aortic annulus. A valve prothesis (13) for implantation in a body channel according to the invention comprises a collapsible valvular structure (14) and an expandable frame (10, 10') on which said valvular structure (14) is mounted. The valvular structure (14) is composed of a valvular tissue compatible with the human body and blood, the valvular tissue being sufficiently supple and resistant to allow said valvular structure (14) to be deformed from a closed state to an opened state. Said valvular tissue forms a continuous surface and is provided with guiding means (17) formed or incorporated within, said guiding means creating stiffened zones which induce said valvular structure (14) to follow a patterned movement in its expansion to its opened state and in its turning back to its closed state. The valvular structure can be extended to an internal cover (19) which is fastened to the lower end (15) of the valvular structure to prevent from regurgitation.



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VALVE PROSTHESIS FOR IMPLANTATION IN BODY CHANNELS

The present invention relates to a valve prosthesis for implantation in body channels, more particularly but not only to, cardiac valve prosthesis to be implanted by a transcutaneous catheterization technique.

The valve prosthesis can be also applied to other body channels provided with native valves, such as veins or in organs (liver, intestine, urethra,...).

The present invention also relates to a method for implanting a valve prosthesis, such as the valve according to the present invention.

Implantable valves, which will be indifferently designated hereafter as "IV", "valve prosthesis" or "prosthetic valve", permits the reparation of a valvular defect by a less invasive technique in place of the usual surgical valve implantation which, in the case of valvular heart diseases, requires thoracotomy and extracorporeal circulation. A particular use for the IV concerns patients who cannot be operated on because of an associated disease or because of very old age or also patients who could be operated on but only at a very high risk.

Although the IV of the present invention and the process for implanting said IV can be used in various heart valve diseases, the following description will first concern the aortic orifice in aortic stenosis, more particularly in its degenerative form in elderly patients.

Aortic stenosis is a disease of the aortic valve in the left ventricle of the heart. The aortic valvular orifice is normally capable of opening during systole up to 4 to 6 cm^2, therefore allowing free ejection of the ventricular blood volume into the aorta. This aortic valvular orifice can become tightly stenosed, and therefore the blood cannot anymore be freely ejected from the left ventricle. In fact, only a reduced amount of blood can be ejected by the left ventricle which has to markedly increase the intra-cavitary pressure

to force the stenosed aortic orifice. In such aortic diseases, the patients can have syncope, chest pain, and mainly difficulty in breathing. The evolution of such a disease is disastrous when symptoms of cardiac failure appear, since 50 % of the patients die in the year following the first symptoms of the disease.

The only commonly available treatment is the replacement of the stenosed aortic valve by a prosthetic valve via surgery: this treatment moreover providing excellent results. If surgery is impossible to perform, i.e., if the patient is deemed inoperable or operable only at a too high surgical risk, an alternative possibility is to dilate the valve with a balloon catheter to enlarge the aortic orifice. Unfortunately, a good result is obtained only in about half of the cases and there is a high restenosis rate, i.e., about 80% after one year.

Aortic stenosis is a very common disease in people above seventy years old and occurs more and more frequently as the subject gets older. As evidenced, the present tendency of the general evolution of the population is becoming older and older. Also, it can be evaluated, as a crude estimation, that about 30 to 50% of the subjects who are older than 80 years and have a tight aortic stenosis, either cannot be operated on for aortic valve replacement with a reasonable surgical risk or even cannot be considered at all for surgery.

It can be estimated that, about 30 to 40 persons out of a million per year, could benefit from an implantable aortic valve positioned by a catheterization technique. Until now, the implantation of a valve prosthesis for the treatment of aortic stenosis is considered unrealistic to perform since it is deemed difficult to superpose another valve such an implantable valve on the distorted stenosed native valve without excising the latter.

From 1985, the technique of aortic valvuloplasty with a balloon catheter has been introduced for the treatment of subjects in whom surgery cannot be performed at all or which could be performed only with a

prohibitive surgical risk. Despite the considerable deformation of the stenosed aortic valve, commonly with marked calcification, it is often possible to enlarge significantly the aortic orifice by balloon inflation, a procedure which is considered as low risk.

However, this technique has been abandoned by most physicians because of the very high restenosis rate which occurs in about 80% of the patients within 10 to 12 months. Indeed, immediately after deflation of the balloon, a strong recoil phenomenon often produces a loss of half or even two thirds of the opening area obtained by the inflated balloon. For instance, inflation of a 20 mm diameter balloon in a stenosed aortic orifice of 0.5 cm^2 area gives, when forcefully and fully inflated, an opening area equal to the cross sectionnal area of the maximally inflated balloon, i.e., about 3 cm^2. However, measurements performed a few minutes after deflation and removal of the balloon have only an area around 1 cm^2 to 1.2 cm^2. This is due to the considerable recoil of the fibrous tissue of the diseased valve. The drawback in this procedure has also been clearly shown on fresh post mortem specimens.

However, it is important to note that whereas the natural normal aortic valve is able to open with an orifice of about 5 to 6 cm^2 and to accommodate a blood flow of more that 15 l/min. during heavy exercise for instance, an opening area of about 1.5 to 2 cm^2 can accept a 6 to 8 l/min blood flow without a significant pressure gradient. Such a flow corresponds to the cardiac output of the elderly subject with limited physical activity.

Therefore, an IV would not have to produce a large opening of the aortic orifice since an opening about 2 cm^2 would be sufficient in most subjects, in particular in elderly subjects, whose cardiac output probably does not reach more than 6 to 8 l/min. during normal physical activity. For instance, the surgically implanted mechanical valves have an opening area which is far from the natural valve opening that ranges from 2 to 2.5 cm^2,

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