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(54) Self-expanding Heart-Valve Prosthesis for Implantation into the Human Body by Means of a Catheter system

(57) It concerns a compressed, self-expanding, heart-valve prosthesis with anchoring supports, which is characterized in that it can be introduced, by means of a catheter, into a heart-valve position through a femoral artery. After expansion in a beating heart, the prosthesis is independently anchored using anchoring barbs, so that replacement of a heart valve can be performed without opening up the thorax.

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Description

Prior art to date

For the replacement of human heart valves, only biological or mechanical valve models are available at present, which are surgically sewn tightly through an opening in the thorax after removing the diseased heart valve at the heart-valve seat. Thus a heart valve can be sewn in, but the patient's circulation must be maintained by a heart-lung machine. Heart stoppage is induced, and the heart-valve prosthesis is sewn in while the heart is stopped. The drawback to such a procedure is obvious: it involves very serious surgical intervention with corresponding risks for the patient and a long post-operative treatment phase. The operation is consequently restricted to younger patients and patients who are as healthy as possible. Very old patients and patients with severe cardiac insufficiency can no longer be considered for this operation.

Because the heart can be very easily reached here from the outside through the large blood vessels without the thorax having to be opened, it is natural to develop a foldable heart valve that is self-anchored after expansion and which replaces the diseased heart valve without having to open up the thorax.

Presentation of the invention

The invention proposed in the patent claim is based on the problem of fastening a foldable, self-expanding, anchoring device so that a more secure fit is ensured after expansion. This problem will be solved by means of the features listed in the patent claim.

To anchor a biological prosthesis, for example, a glutaraldehyde-fixed, swine-heart valve or an artificial heart valve made of polyurethane, a 6-10–cm, self-expanding, steel stent (vessel support) consisting of 2-3 segments of 5 cm each, is used. This stent has small barbs on the outside. A glutaraldehyde-fixed, swine-heart valve is sewn into the area of the side facing the heart (**Fig. 1**). The 6-10–cm long stent is bent into a curve of 5-30 degrees (depending on the patient), in order to accomplish a push forward through the curve of the aorta. After its expansion, the stent has a diameter of 30-50 mm (depending on the anatomical circumstances of the patient) (**Fig. 2**). The stent / heart-valve system is folded by a funnel and is guided in a 24 French (8-mm inside lumen) catheter by means of a flexible guide wire (**Fig. 3**). This catheter is brought forward in the ascending aorta through a puncture in the patient's femoral artery. Gaps in the area of the stent which mark the coronary ostia are indicated by means of X-ray markers. The system is lined up in the ascending aorta, whereby the internal X-ray markers that mark the coronary ostia in the stent have to match X-ray markers on the catheter. Based on alignment of the system, by means of a second catheter lying in the inner lumen, the proximal portion of the stent with the heart valve is expelled by pulling the stent catheter back. The stent is thereby unfolded and anchored together with the diseased heart valve by supporting it on the aorta wall (**Fig. 4**). The diseased aortal valve is thereby pulled out to the side. After the correct fit of the catheter, the distal portion of the stent is also expelled and is anchored in the aorta wall, so that a constant, tight fit of the heart-valve stent configuration is possible. In aortal-valve stenoses, a valvuloplasty must be performed before the implantation.

Compared with heart valves implantable to date with a catheter, the following invention is distinguished in:

1. that a self-expanding stent with anchoring barbs is used,
2. that the system can be reduced in size in the folded state, which makes its introduction possible using the femoral arteries.
3. that a gap exists in the region of the coronary ostia in the anchoring stent, which is portrayed by X-ray marking,
4. that the alignment of the stent for the coronary ostia is facilitated such that the coronary gap markings are also introduced at the expulsion of the catheter,
5. that the implantation of the heart valve in a beating heart can occur because the material ejected from the heart chamber is only insignificantly impeded during implantation of the system.

Embodiment examples of the invention are represented in Figs. 1-4.

Fig. 1: the aortal bioprosthesis or artificial aortal valve is sewn into the proximal portion of the self-expanding stent,

Fig. 2: the aortal bioprosthesis or artificial aortal valve in the proximal portion of the multi-component, self-expanding stent,

Fig. 3: the compressed, aortal bioprosthesis or artificial aortal valves with the folded, self-expanding stent is in a 6-8–mm thick catheter. The valve is unfolded by pulling the stent out and is anchored in the desired position by the barbs.

Fig. 4: the aortal bioprosthesis or artificial aortal valve with the self-expanding stent is pushed out by pulling the catheter back toward the inside of the catheter and is thereby unfolded.

Patent claims

1. A self-expandable heart-valve prosthesis and anchoring supports for the replacement of heart valves by introducing it using a heart catheter system without opening up the thorax, **characterized in**
   1. that a anchoring support (stent) is used as an anchoring system for a glutaraldehyde-fixed bioprosthesis or polyurethane heart-valve, 6-10 cm long, 20-50 mm in diameter, which exhibits barbs 0.5-1 mm long on its outside .
2. The device according to claim 1, characterized in that gaps are provided in the area of the anchoring supports for the coronary-artery ostia, and these are portrayed by X-ray markings.
3. The device according to claim 1 or 2, characterized in that the heart-prosthesis segment is bent 5-30 degrees.
4. The device according to claim 1, 2, or 3, characterized in that a heart catheter is used into which the prosthesis and anchoring segment is introduced, which indicates on the outside, by means of X-ray markings, the alignment of the compressed heart-valve prosthesis.
5. The device according to claim 1 through 4, characterized in that the heart-valve anchoring segment consists of 2-3 self-expanding segments.
6. The device according to claim 1 through 5, characterized in that implantation can occur in a beating heart because obstruction of the blood flow during the implantation is only minor.

Herewith 2 pages of drawings

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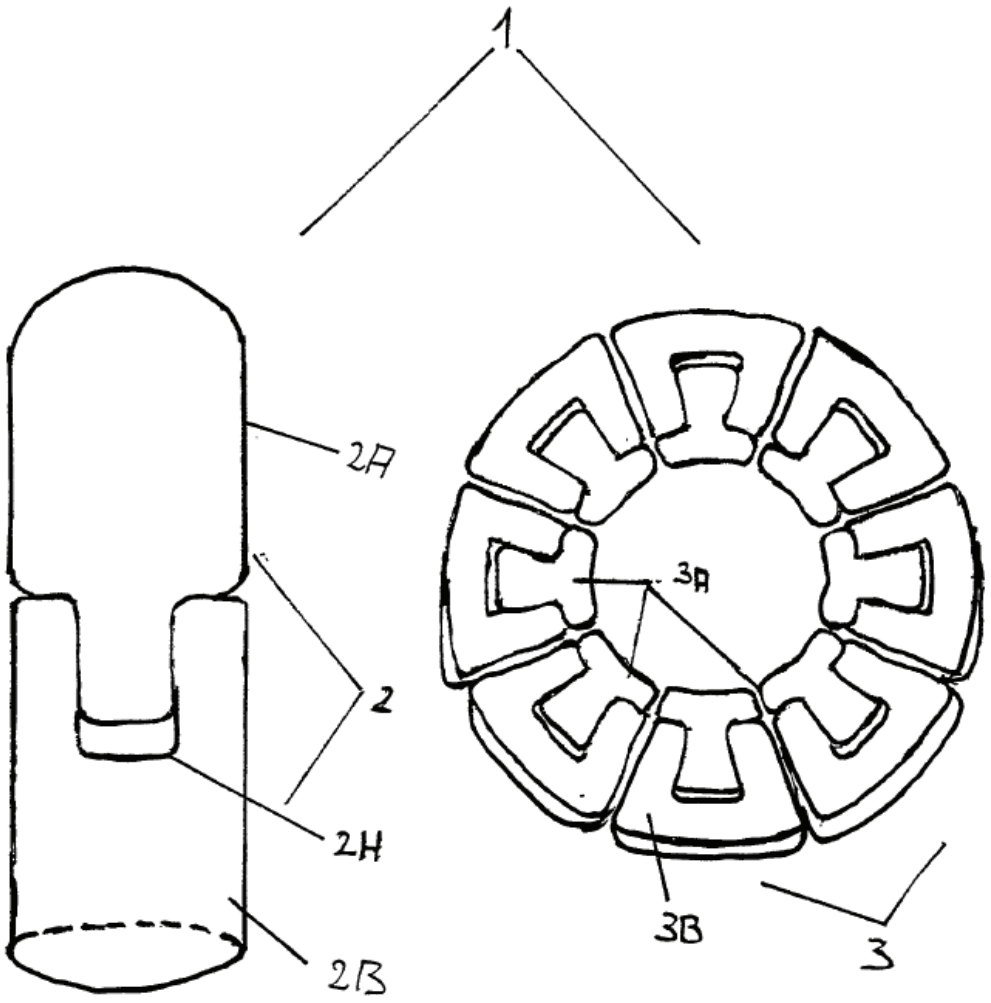

Fig. 1

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