US 20030149476A1

(19) United States

(12) Patent Application Publication

Damm et al.

(10) Pub. No.: US 2003/0149476 A1

(43) Pub. Date: Aug. 7, 2003

(54) ANCHORING SYSTEM FOR IMPLANTABLE HEART VALVE PROSTHESES

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(21) Appl. No.: **10/204,918**

(22) PCT Filed: **Feb. 28, 2001**

(86) PCT No.: **PCT/DE01/00836**

(30) **Foreign Application Priority Data**

Feb. 28, 2000 (DE).................................... 100 10 073.2

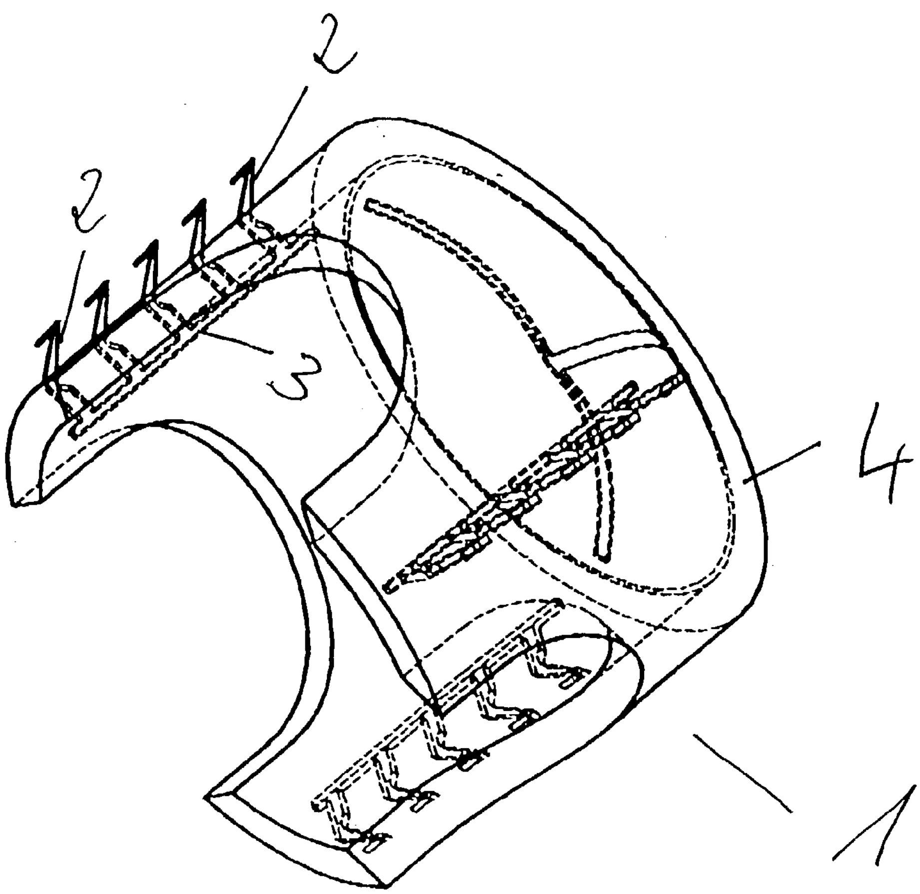
Publication Classification

(51) **Int. Cl.**^{7} **A61F 2/24**; A61F 2/06

(52) **U.S. Cl.** **623/2.1**; 606/151; 623/1.14; 623/1.36

(57) **ABSTRACT**

The invention relates to an anchoring system for heart valve prostheses which can be implanted by introduction via the aorta without any major surgical operation. With the heart valve prosthesis according to the invention it shall be achieved that this can be safely and quickly guided through the aorta toward the heart, and can be fixed there. With this, hook-shaped elements are secured to the commissures of the heart valve prosthesis the hooks of which are guided in an outward direction through the heart valve prosthesis material.



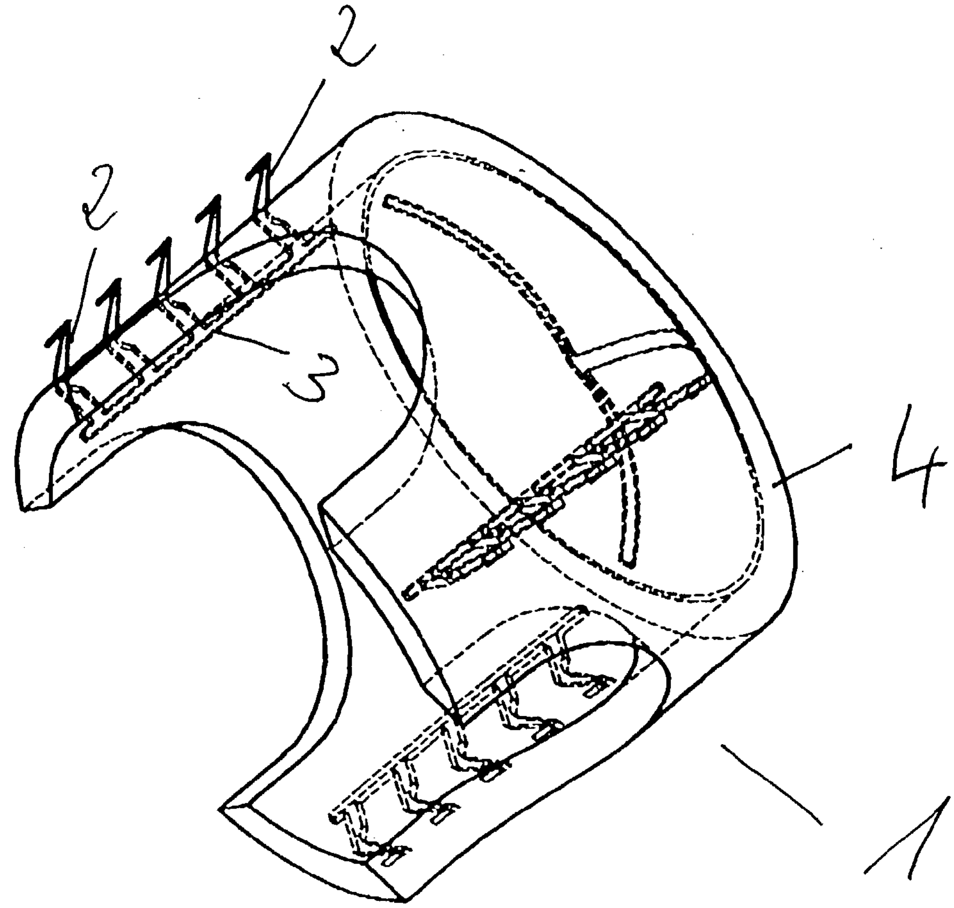


Figure 1

ANCHORING SYSTEM FOR IMPLANTABLE HEART VALVE PROSTHESES

[0001] The invention relates to an anchoring system for heart valve prostheses which is implantable via the aorta by introduction without any major surgical operation wherein in conventional manner complete opening of the thorax has been required.

[0002] In the past the most different attempts have been made and solutions have been offered as well wherein heart valve prostheses should be guided through the aorta towards the heart, and be fixedly implanted there after a deploying and stretching over operation.

[0003] Thus, in U.S. Pat. No. 5,855,601 i.a. is described a so-called stent to which a heart valve prosthesis can be secured. This stent is essentially formed of a wire-shaped form storage metal which represents a cylindrical structure within a grid structure. The form storage metal can be folded at temperatures below of 37° C., and shall be guided by means of a catheter via the aorta towards the heart, and there it shall take up the memorized shape after a cooling system has been switched off and a temperature of about 37° C. has been achieved, and shall closely fit in the respective deployed condition on the inside aorta wall.

[0004] Due to the limitations of the form storage metal, however, it is difficult for such a stent to be miniaturized and folded up so far in order to be guided through the aorta problem-free, and also to be dimensioned in the deployed state such that then it closely fits on the inside aorta wall, and will be safely supported as well.

[0005] Moreover, manufacturing an anchoring support which is constructed and designed in such a manner and made of conventional form storage metal (e.g. Nitinol) being suitable in the required temperature range is encountered with problems and requires an appropriate high manufacturing amount since as a rule such a body is cut out of solid material by laser beam cutting.

[0006] Hence, it is an object of the invention to suggest a possibility wherein heart valve prostheses are allowed to be guided via the aorta towards the heart, and be fixed there.

[0007] According to the invention this object is solved with the features of claim 1. Advantageous embodiments and improvements of the invention result from the features mentioned in the subclaims.

[0008] According to the invention, hook-shaped elements are secured immediately to the commissures of a biological heart valve prosthesis which can be removed from a pork heart, e.g., or otherwise to an artificial heart valve prosthesis, which hooks thereof are guided outside through the heart valve prosthesis material, and which in the implanted condition are sticked into the aorta wall and piercing the aorta wall, respectively such that the heart valve prosthesis can be safely secured to the aorta wall.

[0009] Further additional hook-shaped elements can also be secured to the outer ring of the heart valve prosthesis.

[0010] On that occasion, the hook-shaped elements can be sewn on to the heart valve prosthesis.

[0011] However, it is simplier and requires less amount for the hook-shaped elements to be introduced from the inside into the heart valve prosthesis, and at least for the hooks to be pushed through the heart valve prosthesis material wherein it is proper for the hook-shaped elements to be formed on a ridge or with a base element whereby it will be assured that merely the hooks of the hook-shaped elements protrude from the heart valve prosthesis, and the remaining portion having a respective size maintains the retention inside the heart valve prosthesis.

[0012] Thus, for example, a ridge can be in the form of a flat bar and an elongated plate, respectively, on which at least two hook-shaped elements are designed.

[0013] A base element, for example, can be designed in a plate-shaped manner of a circular form, wherein the cross-sectional area of the circle can prevent the heart valve prosthesis material from being pierced.

[0014] The hook-shaped elements which are arranged on ridges and base elements, respectively, are allowed to be substantially formed in a pin-shaped manner. On that occasion, one or a plurality of barbs are formed on the pin-shaped portion for anchoring in the aorta wall which interlock in or behind the aorta wall after pressing-in.

[0015] On that occasion, the barb shape can be memorized into a form storage metal such that the barbs protrude outwardly directed above the transition temperatures only, and so cutting-in and piercing the aorta wall is facilitated.

[0016] If ridges are used on which the hook-shaped elements are formed or secured to, these are allowed to be secured to the commissures of a heart valve prosthesis such that they are aligned in the longitudinal direction of the aorta in the implanted state.

[0017] However, it can also be particularly advantageous for the ridges to be designed in a helical manner such that they are adapted to the inner contour of the aorta due to the helical shape, and closely fit immediately to this by means of the hooks wherein a greater circumferential area of the inner aorta wall can be covered and an increased degree of closeness can be achieved due to the helical shape.

[0018] If individual hook-shaped elements being otherwise separated from each other are used with base elements these should also be arranged over the commissures in a distributed manner wherein a configuration following the helical shape or a configuration of two counterwound spirals is possible as well.

[0019] If ridges having hook-shaped elements are used these ridges should have a length which is at least as large as the length of the commissures of the heart valve prosthesis.

[0020] The ridges secured to the different commissures are not connected to one another.

[0021] For introducing the heart valve prosthesis with the anchoring system secured thereto it is also favourable if at least the hook-shaped elements are made of a form storage metal which maintains that the hook-shaped elements sit flat during the phase of introduction, and only low resistance of introduction and low volume are obtained and the desired shape and erecting the hooks for anchoring in the aorta wall only occur at the site of implantation.

[0022] The effective height of the hook-shaped elements then at least should be 2 mm such that they protrude from the heart valve prosthesis in this height, and penetrate into the aorta wall and pierce it, respectively.

[0023] It is also advantageous to bend the hooks of the various hook-shaped elements in different directions such that a secure fixation of the anchoring system according to the invention can be achieved while taking into account the conditions inside the aorta, pressure and flow conditions in the vicinity of the heart as well.

[0024] Advantageously, the adjacent hook-shaped elements can be bent directed towards each other, and such a position can be memorized, respectively, with the use of form storage metal. That results in cramping of the adjacent hook-shaped elements inside the aorta wall with reaching and exceeding the transition temperature, respectively.

[0025] Further, inside the heart valve prosthesis in the area of the outer ring thereof an additional annular member is allowed to be secured which can also be pressed during the phase of introduction through the aorta, and which demands a smaller volume. For this, an elastomer material such as for example a suitable plastic and rubber, respectively, provided with a helical spring as the case may be or only a helical spring as well or a form storage metal can be used.

[0026] The heart valve prosthesis provided with the anchoring system according to the invention can be introduced into the aorta by means of a catheter on which a corresponding mechanism is formed wherein the mechanism should maintain deploying the heart valve prosthesis and releasing the heart valve prosthesis placed in the desired position.

[0027] It is also possible to employ a balloon catheter wherein the heart valve prosthesis provided with the anchoring system according to the invention can be plonked on and introduced in this position into the aorta. If the site of implantation is reached the balloon is pressurized then, and the heart valve prosthesis is pressed with the hook-shaped elements against the aorta wall, and then the hooks are allowed to be anchored inside the aorta wall wherein using the form storage metal the balloon catheter can also be used for required cooling.

[0028] The surface of the balloon of such a catheter can be appropriately contoured such that, e.g. the base elements and the ridges, respectively, are safely supported in the phase of passing through the aorta due to the elasticity of the balloon and the appropriately designed contour of the ridges and base elements, respectively, and this retention can be released.

[0029] However, a catheter having a self-deploying mechanism can also be used which in turn consists of a form storage metal as well, to ensure the attachment of the heart valve prosthesis with the anchoring system according to the invention.

[0030] In each case, however, in the phase of passing through the aorta it is appropriate to envelope the heart valve prosthesis in order to avoid undesired injuries of the aorta wall before arriving at the site of implantation, and also to ensure an appropriate thermal insulation with the required cooling as well. After arriving at the site of implantation this enclosure can be teared, and a dislocking mechanism can be activated, respectively, and removed again along with the catheter from the aorta.

[0031] If a deploying mechanism made of a form storage metal is used, as already mentioned, this is allowed to be designed as an annular element which is secured to the heart valve prosthesis in the area of the outer ring thereof. Such an annular element is allowed then to ensure the stability of the implanted heart valve prosthesis, and an increased sealing function.

[0032] In the text that follows the invention will be explained in more detail according to an embodiment in which

[0033] **FIG. 1** shows an embodiment of the anchoring system according to the invention on a heart valve prosthesis.

[0034] With the embodiment of an anchoring system according to the invention for a heart valve prosthesis **1** as shown in **FIG. 1** there are hook-shaped elements **2** formed on ridges **3**, and such each ridge **3** is located on a commissure of the heart valve prosthesis **1**, and is secured there.

[0035] With this embodiment, both the ridges **3** and the hook-shaped elements **2** are made of a form storage metal as it is available e.g. under the designation of Nitinol. For the attachment the ridges **3** are introduced from the inside into the heart valve prosthesis **1** and simply pressed through the commissures of the heart valve prosthesis **1** such that this will be pierced.

[0036] The form storage metal can be memorized into the shape as shown in **FIG. 1** which will be taken up after the transition temperature of 37° C. has been exceeded. In the phase of introduction of the heart valve prosthesis **1**, however, the hook-shaped elements **2** should be inclined almost 90° in the direction towards the longitudinal axis of the ridges **3** as far as possible such that they require a relatively small volume and slightly protrude such that introducing is facilitated, and injuries of the aorta wall can be avoided.

[0037] With the embodiment as shown herein, five hook-shaped elements each are formed on the ridge **3**. Altogether, at least fifteen hook-shaped elements should be used, however.

[0038] However, the number of the hook-shaped elements **2** can be readily varied, and moreover it is possible for a plurality of such ridges **3** having hook-shaped elements **2** to be secured to a commissure of the heart valve prosthesis **1**.

[0039] On that occasion, the ridges **3** are allowed to be aligned inclined with an angle which is not shown here, wherein two such ridges **3** can also be inclined opposite to each other.

[0040] In the form which is not shown, an additional annular element can be secured to the heart valve prosthesis **1** in the area of the outer ring **4** thereof.

[0041] In addition, barbs can be formed on the hook-shaped elements **2** and the hooks thereof, respectively, to improve fastening.

1. An anchoring system for implantable heart valve prostheses, characterized in that

hook-shaped elements (**2**) are secured to the commissures of the heart valve prosthesis (**1**) the hooks of which are guided in an outward direction through the heart valve prosthesis material.

2. An anchoring system according to claim 1, characterized in that

additional hook-shaped elements (**2**) are secured to the outer ring of said heart valve prosthesis (**1**).

3. An anchoring system according to claim 1 or claim 2, characterized in that

said hook-shaped elements (**2**) are sewn on to said heart valve prosthesis (**1**).

4. An anchoring system according to claim 1 or claim 2, characterized in that

said hook-shaped elements (**2**) push through said heart valve prosthesis (**1**), and are supported inside by means of a ridge (**3**) or a base member.

5. An anchoring system according to any one of claims 1 to 4, characterized in that

a plurality of hook-shaped elements (**2**) are arranged on a common ridge (**3**), and at least one said ridge (**3**) each is secured to one commissure.

6. An anchoring system according to claim 5, characterized in that

at least two said hook-shaped elements (**2**) are each located on said one ridge (**3**).

7. An anchoring system according to any one of claims 1 to 6, characterized in that

said ridges (**3**) are aligned in the longitudinal direction of the aorta.

8. An anchoring system according to any one of claims 1 to 6, characterized in that

said ridges (**3**) are designed in a helical shape.

9. An anchoring system according to any one of claims 1 to 8, characterized in that

said ridges (**3**) at least are as long as said commissures.

10. An anchoring system according to any one of claims 1 to 9, characterized in that

at least said hook-shaped elements (**2**) are made of a form storage metal.

11. An anchoring system according to any one of claims 1 to 10, characterized in that

for anchoring in the aorta wall said hook-shaped elements (**2**) have an effective height of at least 2 mm in the deployed condition wherein they protrude from said heart valve prosthesis (**1**).

12. An anchoring system according to any one of claims 1 to 11, characterized in that

said hook-shaped elements (**2**) are designed in a pin-shaped manner and with barbs provided thereon.

13. An anchoring system according to any one of claims 1 to 12, characterized in that

said hooks of said hook-shaped elements (**2**) are bent into various directions.

14. An anchoring system according to any one of claims 1 to 13, characterized in that

an annular element is secured inside said heart valve prosthesis (**1**) in the area of said outer ring.

15. An anchoring system according to claim 14, characterized in that

said annular element is made of an elastomer material or a form storage metal.

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