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REPUBLICATION

(54) **METHODS AND CONDUITS FOR FLOWING BLOOD FROM A HEART CHAMBER TO A BLOOD VESSEL**

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(60) Provisional application No. 60/099,719, filed on Sep. 10, 1998.

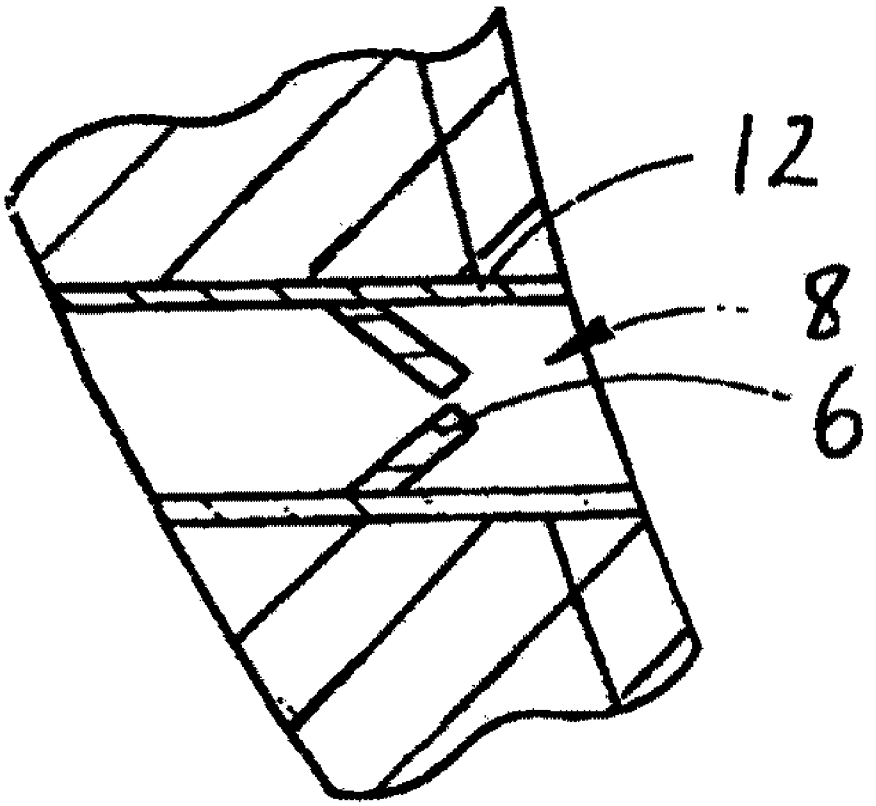
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(57) **ABSTRACT**

Disclosed is a conduit that provides a bypass around an occlusion or stenosis in a coronary artery. The conduit is a tube adapted to be positioned in the heart wall to provide a passage for blood to flow between a heart chamber and a coronary artery, at a site distal to the occlusion or stenosis. The conduit has a section of blood vessel attached to its interior lumen which preferably includes at least one naturally occurring one-way valve positioned therein. The valve prevents the backflow of blood from the coronary artery into the heart chamber.



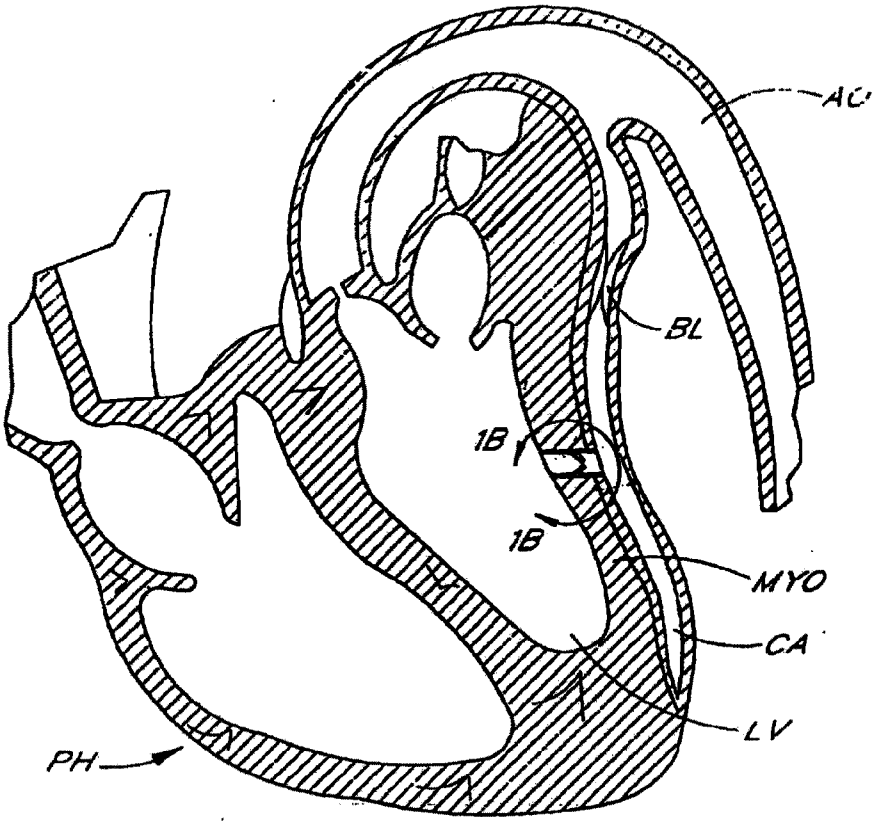


FIG. 1A

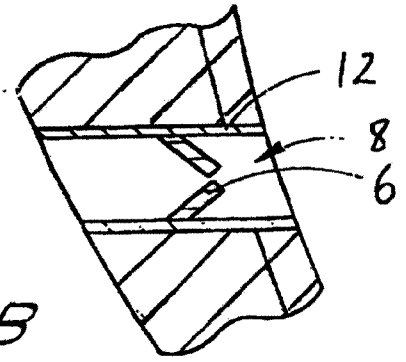


FIG. 1B

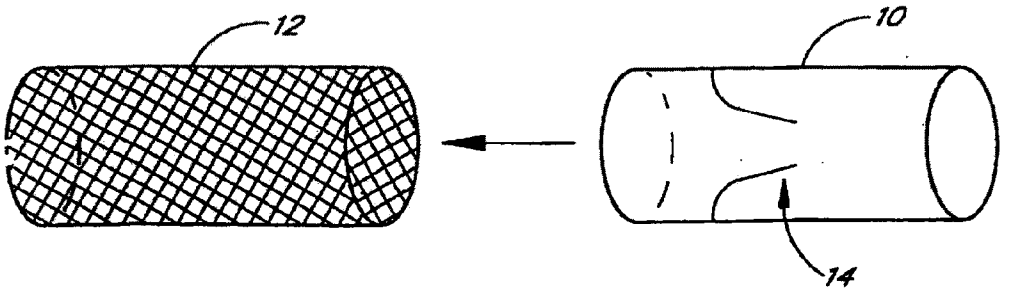


FIG. 2

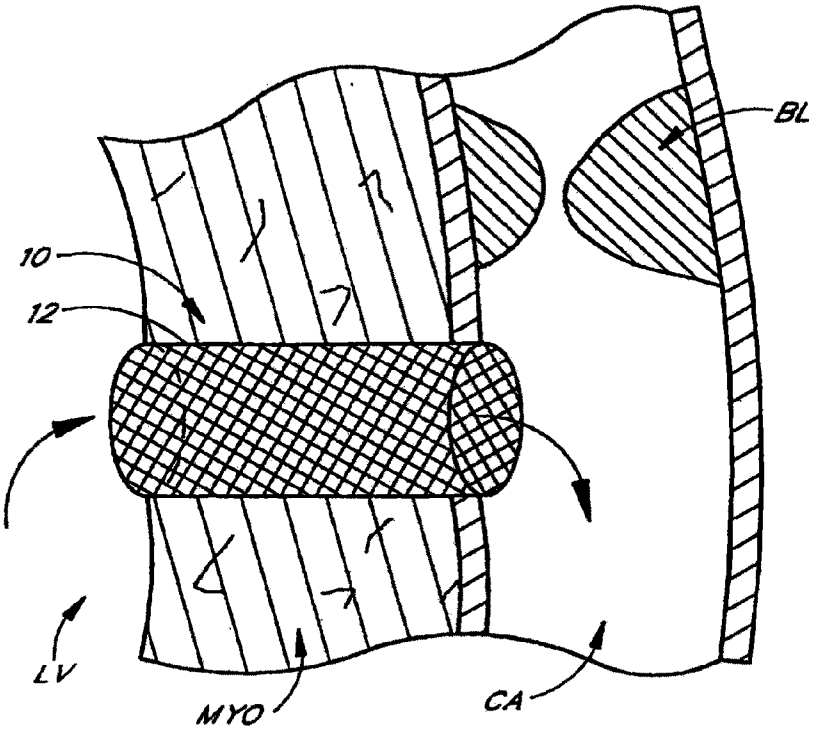


FIG. 3

METHODS AND CONDUITS FOR FLOWING BLOOD FROM A HEART CHAMBER TO A BLOOD VESSEL

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This is a continuation application of U.S. application Ser. No. 12/149,901, filed May 9, 2008, which is a divisional of U.S. application Ser. No. 10/928,190, filed Aug. 30, 2004, now U.S. Pat. No. 7,704,222, which is a continuation of U.S. application Ser. No. 09/828,794, filed Apr. 10, 2001, now U.S. Pat. No. 6,881,199, which is a continuation of U.S. application Ser. No. 09/369,061, filed Aug. 4, 1999, now U.S. Pat. No. 6,254,564, which claims the benefit of U.S. Provisional Application Ser. No. 60/099,719, filed Sep. 10, 1998, the entire disclosures of each being incorporated by reference herein.

FIELD OF THE INVENTION

[0002] This invention relates to apparatus and method for implanting a conduit to allow communication of fluids from one portion of a patient's body to another; and, more particularly, to a blood flow conduit to allow communication from a heart chamber to a vessel or vice versa, and/or vessel to vessel. Even more particularly, the invention relates to a left ventricular conduit and related conduit configurations having a blood vessel graft incorporated therein for controlling the flow of blood through the conduit to achieve bypass of an occluded or stenosed coronary artery.

BACKGROUND OF THE INVENTION

[0003] Coronary artery disease is a major problem in the U.S. and throughout the world. Coronary arteries as well as other blood vessels frequently become clogged with plaque which, at the very least, can reduce blood and oxygen flow to the heart muscle (myocardium), and may impair the efficiency of the heart's pumping action, and can lead to heart attack (myocardial infarction) and death. In some cases, these coronary arteries can be unblocked through noninvasive techniques such as balloon angioplasty. In more difficult cases, a surgical bypass of the blocked vessel is necessary.

[0004] In a coronary bypass operation, one or more venous segments are inserted between the aorta and the coronary artery, or, alternatively, the distal end of an internal mammary artery is anastomosed to the coronary artery at a site distal to the stenosis or occlusion. The inserted venous segments or transplants act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than 500,000 bypass procedures are performed in the U.S. every year.

[0005] Such coronary artery bypass graft (CABG) surgery, however, is a very intrusive procedure which is expensive, time-consuming, and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and that the patient be placed on a heart lung bypass pump so that the heart can be operated on while not beating. A saphenous vein graft is harvested from the patient's leg, another highly invasive procedure, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence are prolonged. Furthermore, many patients are poor surgical candidates due to other concomitant illnesses.

[0006] As mentioned above, another conventional treatment is percutaneous transluminal coronary angioplasty (PTCA) or other types of angioplasty. However, such vascular treatments are not always indicated due to the type or location of the blockage or stenosis, or due to the risk of emboli.

[0007] Thus, there is a need for an improved coronary bypass system which is less traumatic to the patient.

SUMMARY OF THE INVENTION

[0008] The present invention addresses the need in the previous technology by providing a coronary bypass system which avoids a sternotomy, and other intrusive aspects associated with coronary bypass surgery. It also frees the surgeon from having to perform multiple anastomoses, as is necessary in the current process.

[0009] The present device provides a conduit for diverting blood directly from a heart chamber, such as the left ventricle of the heart, to the coronary artery distal to the blockage or stenosis, thereby bypassing the blocked portion of the vessel. The conduit comprises a tube adapted to be positioned in the heart wall and having a section of blood vessel attached to the interior of the conduit, to provide a passage for blood flow which is similar to the body's own blood vessels.

[0010] The conduit device is delivered through the coronary artery to a position distal the blockage or stenosis. At that position, the coronary artery and the wall of the left ventricle, including the myocardium, are pierced to provide an opening or channel completely through from the coronary artery to the left ventricle of the heart. The conduit is then positioned in the opening to provide a permanent passage for blood to flow between the left ventricle of the heart and the coronary artery, distal to the blockage or stenosis.

[0011] The conduit is sized so that one open end is positioned within the coronary artery, while the other open end is positioned in the left ventricle. Prior to implantation of the conduit, a section of vein or other blood vessel is obtained from the patient, from another human donor, or from a nonhuman animal. The vein or other blood vessel is sized so as to fit within the interior of the conduit. The hollow lumen of the conduit with the blood vessel graft inserted therein provides a passage for the flow of blood.

[0012] If desired, the section of blood vessel inserted into the conduit may include one or more naturally occurring one-way valves. The valve prevents the backflow of blood from the myocardium into the left ventricle. For example, a section of vein having a valve therein can be used. Alternatively, the pulmonic valve or aortic valve obtained from a nonhuman animal, such as a fetal pig or piglet, can be used to provide a one-way passage for the flow of blood through the conduit.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. **1**A is a schematic, cross-sectional view of a human heart, showing a conduit in the myocardium of the heart for forming a bypass between the left ventricle and a coronary artery;

[0014] FIG. **1**B is an enlarged view of the bypass conduit of FIG. **1**A;

[0015] FIG. **2** is an exploded view of a vein graft incorporated into a heart conduit in accordance with the preferred arrangement;

[0016] FIG. **3** is a close-up, cross-sectional view of a blockage or stenosis in the coronary artery, illustrating the conduit of the preferred arrangement positioned so as to bypass the blockage or stenosis.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0017] As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. Oxygenated blood that has returned from the lungs to the heart then flows from the heart to the aorta. Some blood in the aorta flows into the coronary arteries, and the remainder of blood in the aorta flows on to the rest of the body. The coronary arteries are the primary blood supply to the heart muscle and are thus critical to life. In some individuals, atherosclerotic plaque, aggregated platelets, and/or thrombi build up within the coronary artery, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death. The presence of coronary vasospasm, also known as "variant angina" or "Prinzmetal's angina," compounds this problem in many patients.

[0018] As used herein, the term "heart chamber" primarily refers to the interior, or lumenal, aspect of the left or right ventricle or the left or right atrium. The term "conduit,""stent," and "tube" herein refer to physical structures, preferably primarily artificial, that can be positioned between two or more chambers or vessels, to allow blood flow from one chamber or vessel to another. A "shunt" is any natural or artificial passage between natural channels, such as heart chambers or blood vessels. The conduit in the preferred arrangement can be made of a variety of materials, including various metals, such as nitinol, or plastics.

[0019] As used herein, the term "heart wall" comprises any one or more of the following portions or layers of the mammalian heart: the epicardium, myocardium, endocardium, pericardium, interatrial septum, and interventricular septum.

[0020] The principles of the present invention are not limited to left ventricular conduits; and include conduits for communicating bodily fluids from any space within a patient to another space within a patient, including any mammal. Furthermore, such fluid communication through the conduits is not limited to any particular direction of flow and can be antegrade or retrograde with respect to the normal flow of fluid. Moreover, the conduits may communicate between a bodily space and a vessel or from one vessel to another vessel (such as an artery to a vein or vice versa). Moreover, the conduits can reside in a single bodily space so as to communicate fluids from one portion of the space to another. For example, the conduits can be used to achieve a bypass within a single vessel, such as communicating blood from a proximal portion of an occluded coronary artery to a more distal portion of that same coronary artery.

[0021] In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit communicates from the left ventricle, through the myocardium, into the pericardial space, and then into the coronary artery. However, other preferred embodiments are disclosed, including direct transmyocardial communication from a left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other nonmyocardial and even noncardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, septum, etc.

[0022] The bypass which is achieved with certain preferred embodiments and related methods is not limited to a complete bypass of bodily fluid flow, but can also include a partial bypass which advantageously supplements the normal bodily blood flow. Moreover, the obstructions that are bypassed may be of a partial or complete nature, and therefore the terminology "bypass" or "occlusion" should not be construed to be limited to a complete bypass or a complete occlusion but can include partial bypass and partial occlusion as described.

[0023] The preferred conduits and related methods disclosed herein can also provide complete passages or partial passages through bodily tissues. In this regard, the conduits can comprise stents, shunts, or the like, and therefore provide a passageway or opening for bodily fluid such as blood. Moreover, the conduits are not necessarily stented or lined with a device but can comprise mere tunnels or openings formed in the tissues of the patient.

[0024] The conduits of the present invention preferably comprise both integral or onepiece conduits as well as plural sections joined together to form a continuous conduit. The present conduits can be deployed in a variety of methods consistent with sound medical practice including vascular or surgical deliveries, including minimally invasive techniques. For example, various preferred embodiments of delivery rods and associated methods are disclosed. In one embodiment, the delivery rod is solid and trocar-like. It may be rigid or semi-rigid and capable of penetrating the tissues of the patient and thereby form the conduit, in whole or in part, for purposes of fluid communication. In other preferred embodiments, the delivery rods may be hollow so as to form the conduits themselves (e.g., the conduits are preferably self implanting or self inserting) or have a conduit mounted thereon (e.g., the delivery rod is preferably withdrawn leaving the conduit installed). Thus, the preferred conduit device and method for installation is preferably determined by appropriate patient indications in accordance with sound medical practices.

[0025] In order to restore the flow of oxygenated blood through the coronary artery, the preferred arrangement provides for the shunting of blood directly from the heart to a site in the coronary artery which is distal the blockage or stenosis.

[0026] Although the specification herein will describe the conduit primarily with reference to the left ventricle, the preferred arrangement can be used with any of the four heart chambers, and with any coronary artery, including the left main coronary artery, the right coronary artery, the left anterior descending artery, the left circumflex artery, the posterior descending artery, the obtuse marginal branch or a diagonal branch.

[0027] A tunnel or opening is formed through the wall of the coronary artery and the myocardium and into the left ventricle of the heart which lies beneath, or deep to, the coronary artery. A conduit is positioned in the opening to keep it open.

[0028] The conduit may be introduced into the myocardium in a variety of ways, including by a catheter threaded through the femoral artery into the aorta and thence into the left ventricle and, if necessary, the left atrium; or by a catheter threaded through the femoral vein into the inferior vena cava and thence into the right atrium and right ventricle. Alternatively, the conduit may be introduced through a surgical incision in chest wall (thoracotomy) or sternum (sternotomy).

[0029] Further details regarding conduits and conduit delivery systems are described in patent applications entitled, DESIGNS FOR LEFT VENTRICULAR CONDUIT, U.S. application Ser. No. 09/369,048, filed Aug. 4, 1999, VALVE DESIGNS FOR LEFT VENTRICULAR CONDUIT, U.S. application Ser. No. 09/368,393, filed Aug. 4, 1999, LEFT VENTRICULAR CONDUITS TO CORONARY ARTERIES AND METHODS FOR CORONARY BYPASS, U.S. application Ser. No. 09/534,038, filed Mar. 24, 2000, and BLOOD FLOW CONDUIT DELIVERY SYSTEM AND METHOD OF USE, U.S. application Ser. No. 09/368,644, filed Aug. 4, 1999, and U.S. Pat. Nos. 6,261,304, 5,429,144 and 5,662,124, the disclosures of which are all hereby incorporated by reference in their entirety.

[0030] The opening through the heart wall (including endocardium, myocardium, and epicardium) and coronary artery can be formed in a variety of ways, including by knife or scalpel, electrocautery, cryoablation, radiofrequency ablation, ultrasonic ablation, and the like. Other methods will be apparent to those of ordinary skill in the art.

[0031] The conduit is provided with a section of vein or other blood vessel positioned within its interior lumen. The section of vein or other blood vessel is obtained from the patient, from a donor, or from an animal. Prior to implantation of the conduit. a segment of blood vessel sized to fit with the lumen of the conduit is inserted into the conduit. The conduit with the graft therein provides a passage for the flow of blood which is similar to the natural human blood vessels. The segment of vein or other blood vessel harvested to fit within the conduit may include one or more of the valves which naturally occur in the human body. These valves act to prevent the backflow of blood. In the conduit, these naturally occurring venous valves prevent the blood from flowing back into the left ventricle of the heart from the coronary artery. The segment of vein is preferably inserted into the conduit prior to the conduit's deployment into the human body by any of various surgical or catheter-guided techniques known to those of skill in the art.

[0032] Referring now to FIGS. **1**A and **1**B, a coronary artery bypass is accomplished by disposing a conduit **12** (FIG. **1**B) in a heart wall or myocardium MYO of a patient's heart PH (FIG. **1**A). The conduit **12** preferably extends from the left ventricle LV of heart PH to a clogged coronary artery CA at a point downstream of a blockage BL to create a passageway **8** therethrough. Conduit **12** is preferably made of a biocompatible material such as stainless steel or nitinol, although other materials such as Ti, Ti alloys, Ni alloys, Co alloys and biocompatible polymers may also be used. In one embodiment, conduit **12** has a one way valve **6** to allow blood to flow from the left ventricle LV to the coronary artery CA. Although the conduit **12** may elastically deform under the contractive pressure of the heart muscle during systole, the stent remains open to allow blood to pass from the patient's left ventricle LV into the coronary artery CA. During diastole, the blood pumped into coronary artery through passageway **8** is blocked by one-way valve **6** from returning to left ventricle LV.

[0033] As shown in FIG. **2**, a preferred embodiment involves the use of a vein graft **10** taken from the patient. Prior to preparing the conduit **12** for placement in the patient, a section of vein **10** is obtained from the patient (e., an autologous graft or autograft). Of course, a blood vessel taken from another human donor (i.e., an allogeneic graft or allograft) or nonhuman animal species (i.e., a heterologous graft or xenograft) could also be used. The vein **10** is preferably taken from the saphenous vein in the leg of the patient. Alternatively, a donor vein could be used, or a fetal pig or piglet can be obtained and dissected to remove a section of the pulmonary artery having a pulmonic valve therein, or a section of the aorta having an aortic valve therein, or a similar vessel having a naturally occurring valve system. In other embodiments, the endothelial lining of a vein and/or a valve may be grown from one or more tissue cultures, utilizing cloning of donor cell lines or other genetic engineering techniques (or "tissue engineering") known to those of skill in the art. Thus, as used herein, "a section of blood vessel" may include one or more of the following: a surgically resected segment of a blood vessel, with or without one or more valves; the endothelial lining of a blood vessel, taken from an in vitro or in vivo specimen; and one or more venous valves, taken from in vitro or in vivo specimens.

[0034] As noted above, the section of vein **10** or other blood vessel harvested preferably contains one or more valves **14**, which occur naturally in the veins. The section of vein **10** may also not have a valve. The vein section **10** is sized so as to be the same length as the conduit **12**. The vein section **10** is placed within the interior lumen of the conduit **12** and attached to the inside of the conduit **12** by suturing or other attachment methods. The natural vein graft **10** is biocompatible and therefore reduces problems associated with rejection of the conduit **12** and clotting around or in the conduit **12**. In addition, the vein **10** provides a natural valve system **14** that is already used throughout the human body to prevent the backflow of blood. In the case of a xenograft, treatment of the graft with chemicals, such as glutaraldehyde, may be undertaken to remove living cells, including antigenic materials, from the connective tissue framework of the graft so as to reduce thrombogenicity and antigenicity.

[0035] Referring now to FIG. **3**, a self-expanding conduit **12** having a section of vein **10** therein is introduced into the wall of the myocardium MYO as follows. A conduit delivery catheter (not shown), having the compressed conduit **12** mounted on its distal end, is advanced over a puncture mechanism and into the wall of the myocardium MYO at a site distal to the blockage or stenosis BL in the coronary artery CA. When the conduit **12** is properly seated in the myocardial wall MYO, its retaining sheath is withdrawn, allowing the conduit **12** to expand and open a passageway, or maintain patency of the passageway, from the left ventricle of the heart LV to the coronary artery CA. This allows oxygenated blood to flow directly from the left ventricle of the heart LV through the conduit **12** and to the coronary artery CA, bypassing the section of coronary artery CA that is blocked BL, as shown by the arrows in FIG. **3**.

[0036] The conduit **12** may include attachment mechanisms not limited to hooks, barbs, large collars, and/or other

methods to ensure that a seal is created between the coronary artery CA and the wall of the heart wall MYO, to prevent hemorrhaging and to prevent the threat of or actual conduit migration. When positioning and securing of the conduit **12** is completed, the remaining catheter assembly is removed, leaving the conduit **12** with the vein graft therein, in place in the body.

[**0037**] The present vascular conduit having a blood vessel graft incorporated therein provides significant improvements in the present treatment of blockages or stenoses in the coronary artery. Although the invention has been described in its preferred embodiments in connection with the particular figures, it is not intended that this description should be limited in any way by the foregoing.

What is claimed is:

1-35. (canceled)

36. A method of treatment, comprising:

placing a conduit adjacent a left ventricle and an arterial blood-containing vessel such that upon implantation of the conduit a first end of the conduit is continuously open towards the left ventricle, a second end of the conduit is continuously open towards and positioned in the arterial blood-containing vessel, and at least a portion of the first open end faces at least a portion of the second open end;

wherein the conduit includes a substantially lattice structure adjacent each of the first and second ends and extending therebetween and wherein a valve is attached to the conduit within an interior of the conduit between the first and second ends to control a backflow of blood from the arterial blood-containing vessel to the left ventricle during diastole.

37. The method of claim 36, further including enlarging an opening between the left ventricle and the arterial blood-containing vessel and thereafter placing the conduit within the opening.

38. The method of claim 36, further including placing the conduit onto a catheter so that the conduit is in a compressed state, and introducing the catheter into an aorta.

39. The method of claim 38, further including introducing the catheter into a femoral artery before introducing the catheter into an aorta.

40. The method of claim 36, further including placing the conduit onto a catheter so that the conduit is in a compressed state, and introducing the catheter into a vein.

41. The method of claim 36, wherein the valve is an aortic valve.

42. The method of claim 36, wherein the valve is formed from tissue engineering techniques.

43. The method of claim 36, wherein the first end is a distalmost end of the conduit and the second end is a proximalmost end of the conduit, and each of the distalmost and the proximalmost ends is expandable.

44. The method of claim 36, wherein upon implantation of the conduit the first end of the conduit is positioned in the left ventricle.

45. The method of claim 36, wherein the conduit is a metal conduit.

46. The method of claim 36, wherein the conduit is a plastic conduit.

47. The method of claim 36, wherein a section of tissue is further attached within the interior of the conduit adjacent the first end.

48. A method of treatment, comprising:

placing a conduit adjacent a left ventricle and an arterial blood-containing vessel such that upon implantation a first end of the conduit is continuously open towards the left ventricle, a second end of the conduit is continuously open towards and positioned in the arterial blood-containing vessel, and a substantially straight line intersects at least a portion of the first end and at least a portion of the second end;

wherein the conduit includes a substantially lattice structure adjacent each of the first and second ends and extending therebetween and wherein a valve is attached to the conduit within an interior of the conduit between the first and second ends to control a backflow of blood from the arterial blood-containing vessel toward the left ventricle during diastole.

49. The method of claim 48, further including placing the conduit onto a catheter so that the conduit is in a compressed state, and introducing the catheter into an aorta.

50. The method of claim 49, further including introducing the catheter into a femoral artery before introducing the catheter into an aorta.

51. The method of claim 48, further including placing the conduit onto a catheter so that the conduit is in a compressed state, and introducing the catheter into a vein.

52. The method of claim 48 further including enlarging an opening between the left ventricle and the arterial blood-containing vessel and thereafter placing the conduit within the opening.

53. The method of claim 48, wherein the first end is a distalmost end of the conduit and the second end is a proximalmost end of the conduit, and each of the distalmost and the proximalmost ends is expandable.

54. The method of claim 53, wherein upon implantation of the conduit the first end of the conduit is positioned in the left ventricle.

55. The method of claim 53, wherein the valve is an aortic valve.

56. The method of claim 53, wherein the valve is formed from tissue engineering techniques.

57. The method of claim 53, wherein the conduit is a metal conduit.

58. The method of claim 53, wherein the conduit is a plastic conduit.

59. The method of claim 53, wherein a section of tissue is further attached within the interior of the conduit adjacent the first end.

60. The method of claim 48, wherein the conduit includes a longitudinal axis that is substantially straight between the first and second ends.

61. A method of treatment, comprising:

introducing a catheter into an aorta, wherein a conduit having a tissue valve attached to the conduit is coupled to the catheter so that the conduit and valve are each in a compressed state;

implanting the conduit adjacent a left ventricle and an arterial blood-containing vessel such that upon implantation a distalmost end of the conduit is continuously open towards the left ventricle, a proximalmost end of the conduit is continuously open towards and positioned in the arterial blood-containing vessel, and at least a

portion of the distalmost open end faces at least a portion of the proximalmost open end;

wherein the conduit includes a substantially lattice structure adjacent each of the distalmost and proximalmost ends and extending therebetween and the valve is attached to the conduit within an interior of the conduit between the distalmost and proximalmost ends to control a backflow of blood from the arterial blood-containing vessel toward the left ventricle during diastole.

62. The method of claim 61, further including expanding the distalmost end and the proximalmost end.

63. The method of claim 61, further including enlarging an opening between the left ventricle and the arterial blood-containing vessel and thereafter placing the conduit within the opening.

64. The method of claim 61, further including introducing the catheter into a femoral artery before introducing the catheter into an aorta.

65. The method of claim 61, wherein upon implantation of the conduit the distalmost end of the conduit is positioned in the left ventricle.

66. The method of claim 61, wherein the conduit includes a substantially straight longitudinal axis and the distalmost and proximalmost ends intersect the longitudinal axis.

67. The method of claim 61, wherein the valve is an aortic valve.

68. The method of claim 61, wherein the conduit is a metal conduit.

69. The method of claim 61, wherein the conduit is a plastic conduit.

70. The method of claim 61, wherein a section of tissue is further attached within the interior of the conduit adjacent the first end.

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