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(12) **United States Patent**
Gross

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(54) **PRESSURE-ENHANCED BLOOD FLOW TREATMENT**

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See application file for complete search history.

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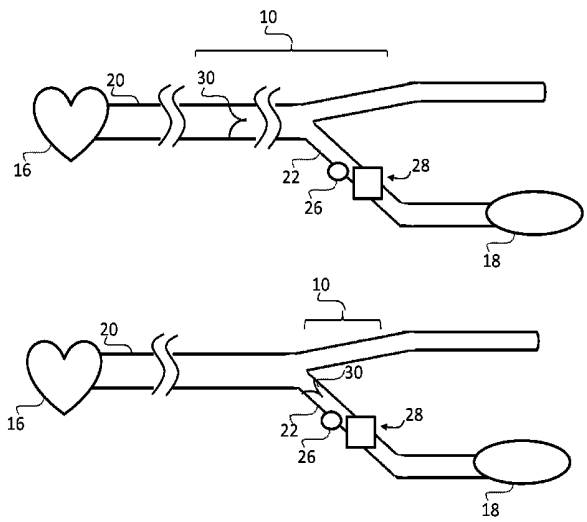
(57) **ABSTRACT**

Apparatus and methods are provided, including a sensor, configured to sense a cardiac cycle of a patient and to generate a signal in response thereto. A pressure mechanism is coupled to a site of an artery of the patient, and, in response to the signal, enhances blood flow of the patient in a downstream direction by compressing the artery. A valve is implanted upstream of the site, and inhibits blood flow in an upstream direction due to operation of the pressure mechanism. Other applications are also described.

6 Claims, 4 Drawing Sheets



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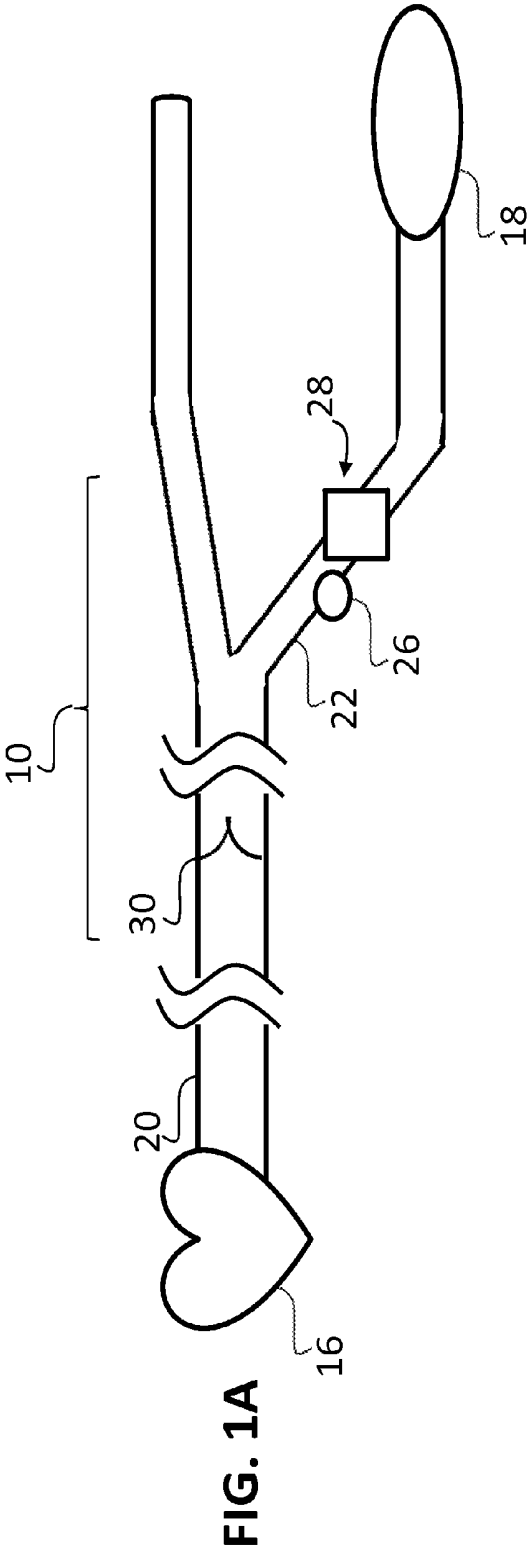

FIG. 1A

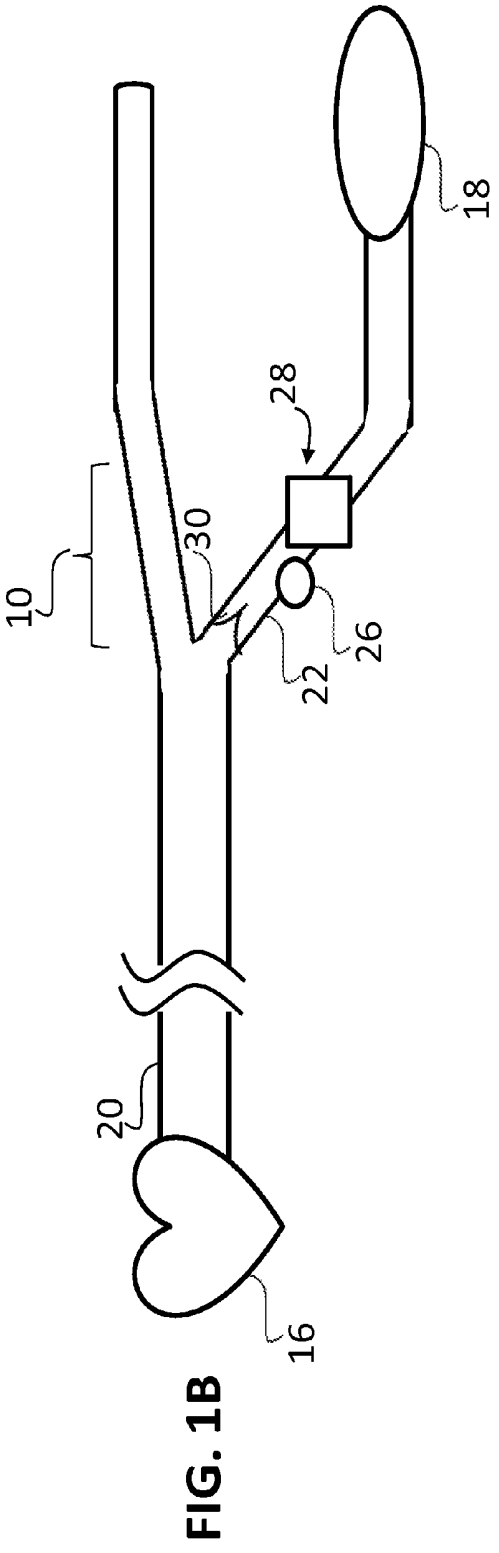

FIG. 1B

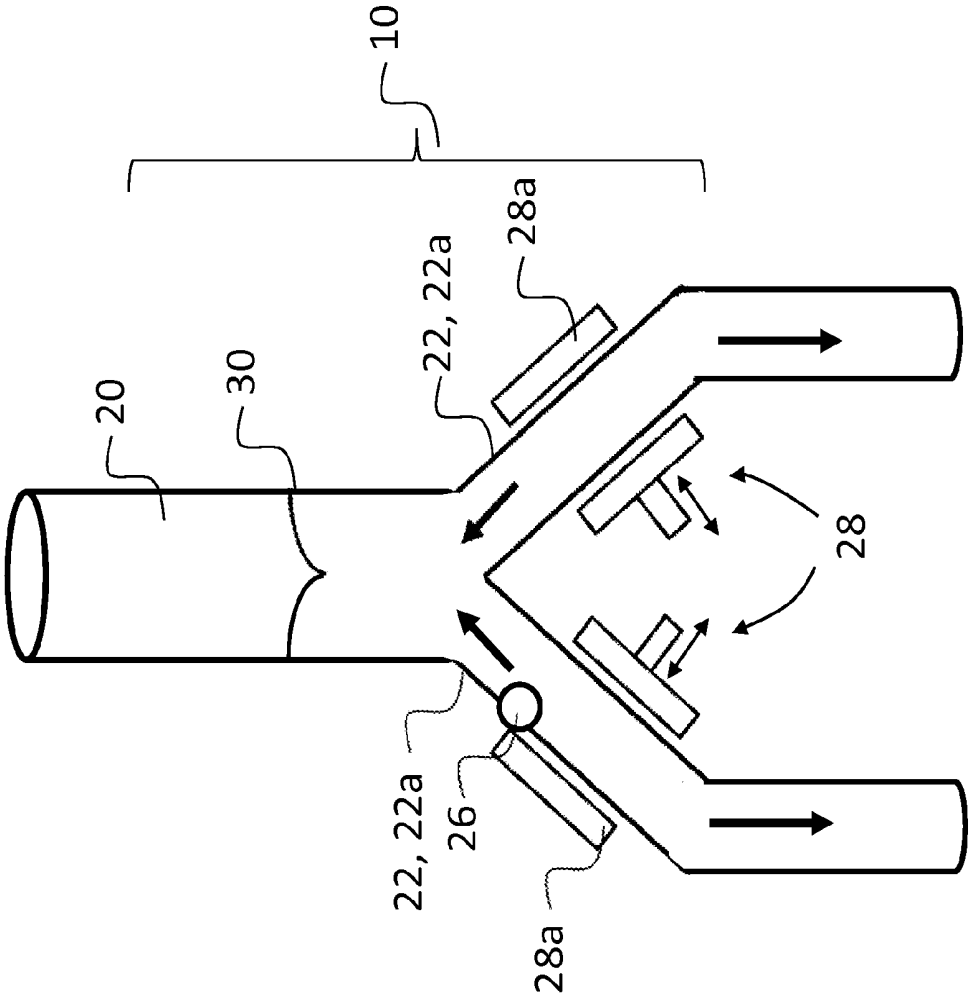

FIG. 2

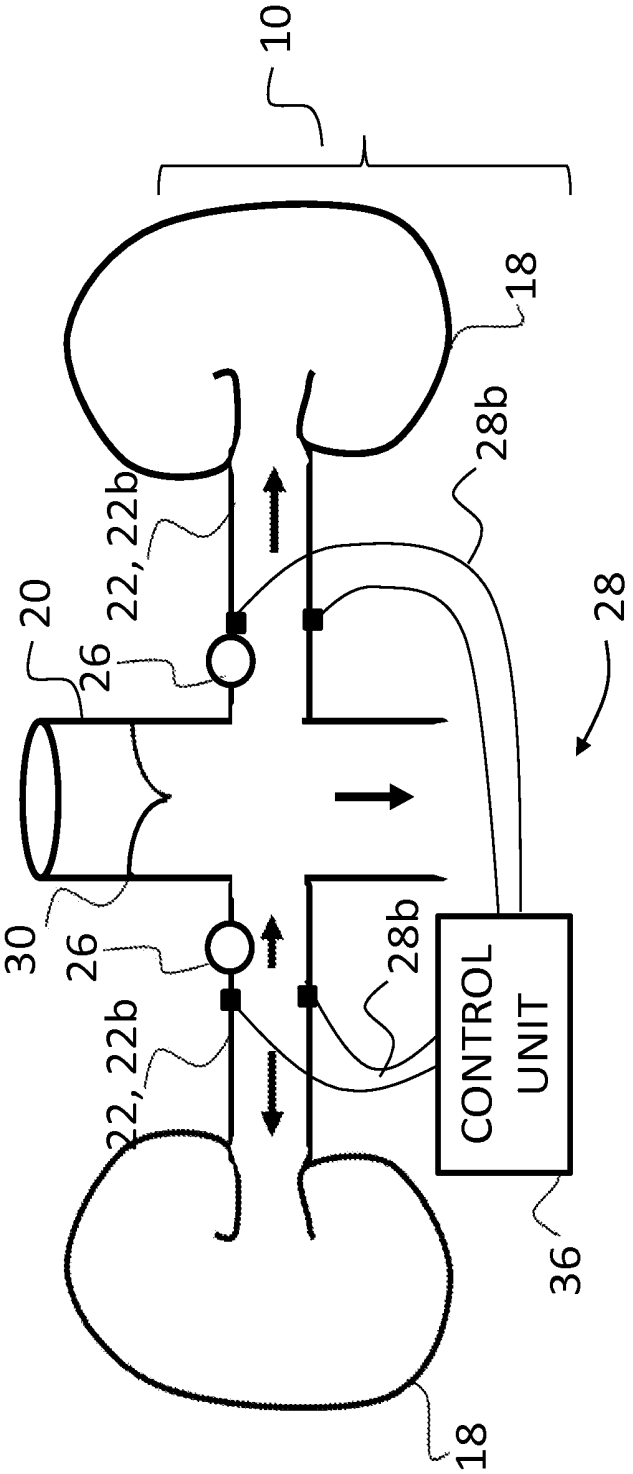

FIG. 3

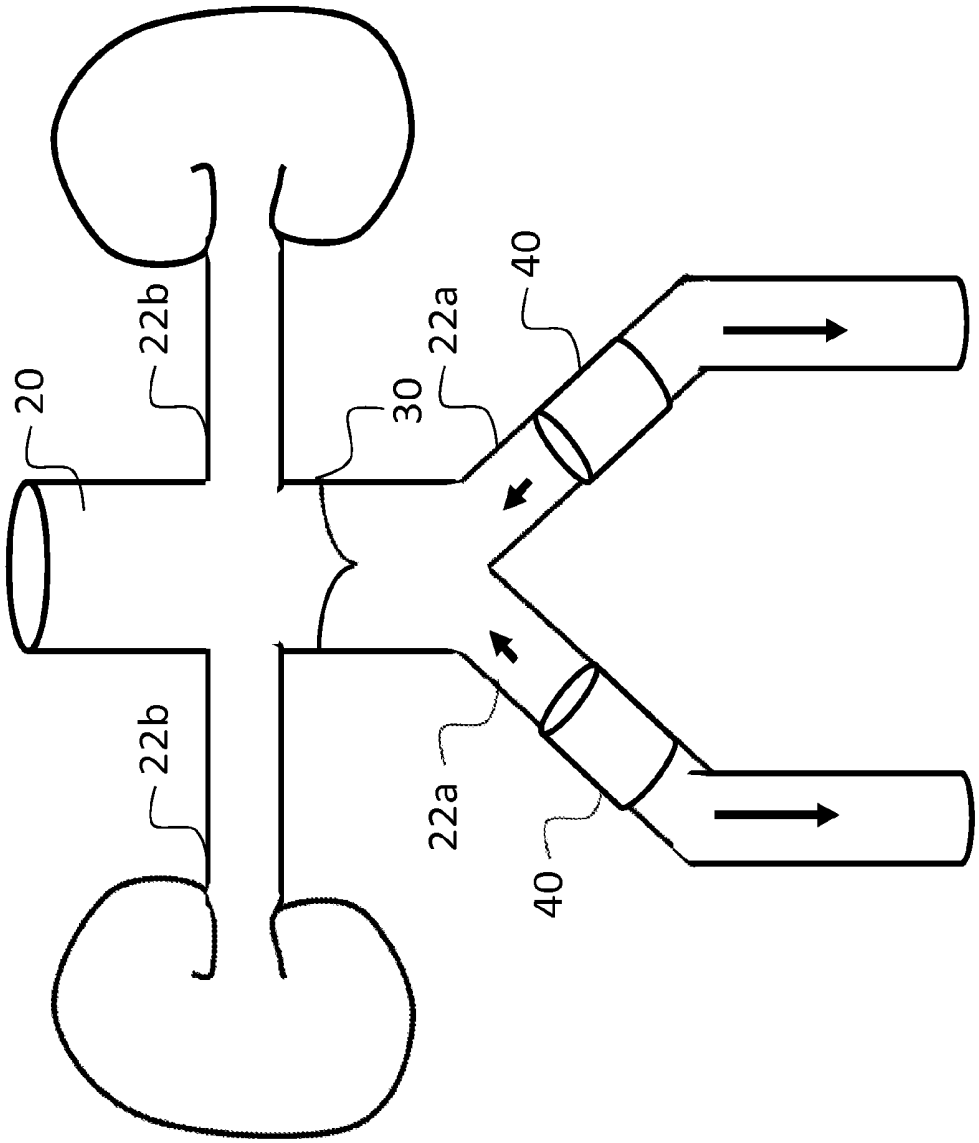

FIG. 4

PRESSURE-ENHANCED BLOOD FLOW TREATMENT

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application claims the benefit of U.S. Provisional Patent Application 61/593,915 to Gross, filed Feb. 2, 2012, entitled "Pressure-enhanced blood flow treatment," which is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to a medical device, and specifically to methods and apparatus that enhance blood flow in a blood vessel.

BACKGROUND

The narrowing or blockage of arteries, which results in obstructions to blood flow, may cause an insufficient supply of oxygen to body tissues, which may ultimately lead to loss of function of these tissues. These obstructions may occur when a blood clot or a fatty deposit arrive from a first artery through the bloodstream (e.g., from the aorta) and settle in a portion of a second artery, thereby causing narrowing or blockage of the second artery. Alternatively, an obstruction may be generated from the formation of a blood clot in the artery itself, usually where the artery has been damaged due to a disease of the artery. Causes for such damage may be a medical procedure, atherosclerosis, inflammation of the artery, or an aneurysm.

In addition, blood flow in an artery may be low due to a patient having a weak heart, e.g., due to the patient suffering from heart failure, due to nerve damage, or due to other factors.

SUMMARY OF APPLICATIONS

For some applications of the present invention, a system for enhancing blood flow in a blood vessel of a patient comprises a sensor, a pressure mechanism and a valve. Typically, but not necessarily, the valve is obtained from a source of commercially-available aortic valves. For some applications of the present invention, the valve is implanted at least five centimeters downstream of the native aortic valve site, for example between the renal artery and the bifurcation of the aorta with the iliac arteries.

According to one application of the present invention, the blood vessel of the patient is an artificial blood vessel (i.e., a graft), configured to be inserted into a peripheral arterial site, which, in the context of the present application, comprises any arterial site downstream of the implanted valve.

For some applications, a portion (e.g., a 10-40 cm portion) of the femoral artery may be excised and replaced with a blood vessel graft in at least one leg of the patient. (For example, a graft may be placed in each leg.) Alternatively, the blood vessel is a natural vessel of the patient.

For some applications of the present invention, the sensor is configured to sense a cardiac cycle of the patient and to generate a signal in response to that signal. For some applications of the present invention, the pressure mechanism is coupled to a site on the blood vessel of the patient, and is configured to respond to the generated signal by compressing the blood vessel during diastole and releasing the compression during systole, thereby enhancing blood flow of the patient in the downstream direction.

The valve is typically implanted upstream of the arterial site to which the pressure mechanism is coupled, thereby inhibiting blood flow in an upstream direction due to the operation of the pressure mechanism. Typically, the valve is not physically coupled to the pressure mechanism, i.e., the valve is not part of one integrated assembly with the pressure mechanism. Alternatively, the valve and the pressure mechanism comprise one integrated assembly. In one application of the present invention, the valve is configured to be implanted in the artery upstream to the arterial site to which the pressure mechanism is coupled. In another application of the present invention, the valve is configured to be implanted in an artery other than the arterial site to which the pressure mechanism is coupled, e.g., in the aorta of the patient.

For some applications of the present invention, the pressure mechanism comprises one or more electrodes, configured to be placed in contact with the artery. These electrodes are coupled to a control unit, which is configured to drive the electrodes to drive a contraction-inducing current into the site of the artery during diastole, and to withhold driving the electrodes to drive such a current during systole. Alternatively, the pressure mechanism comprises a mechanical compressor, a cuff, a pump or a solenoid. Other pressure mechanisms may also be used (e.g., extracorporeal pressure mechanisms, such as an external cuff, or pressure-application pants which are typically configured for applying external counterpulsation).

For some applications of the present invention, the graft is implanted downstream of the valve. For some applications of the present invention, the graft is compliant, and changes its cross-sectional area according to the cardiac cycle of the patient. For example, the graft expands during systole, and contracts during diastole. Typically, the diastolic contraction of the graft squeezes out blood that is in the contracting area of the graft. According to one application of the present invention, the implanted valve inhibits the upstream flow of blood from the contracting graft, therefore enhancing the blood flow in a downstream direction due to the contraction of the graft. Although typically the valve is implanted in the aorta, for some applications, the valve may be implanted in an artery which is smaller in diameter than the aorta.

According to one application of the present invention, the graft expands during systole without any change in the shape of the graft (e.g., both the pre-expansion and post-expansion shapes of the graft may be circular). Alternatively, the graft changes its cross-sectional shape from an ellipse in diastole to a circle in systole. The cross-sectional area thus goes up substantially during systole.

For some applications of the present invention, the valve is physically coupled to the graft. Alternatively, the valve is implanted in a different artery than the graft.

It is noted that the scope of the present invention includes implanting the valve before the pressure mechanism, as well as implanting the valve after the pressure mechanism.

There is therefore provided, in accordance with an application of the present invention, apparatus, including:

a sensor, configured to sense a cardiac cycle of a patient and to generate a signal in response thereto;

a pressure mechanism, configured to be coupled to a site of an artery of the patient, and, in response to the signal, to enhance blood flow of the patient in a downstream direction by compressing the artery; and

a valve, configured to be implanted upstream of the site, and to inhibit blood flow in an upstream direction due to operation of the pressure mechanism.

For some applications, the pressure mechanism includes:

one or more electrodes; and

a control unit, couplable to the one or more electrodes.

For some applications, the electrodes are configured to be placed in contact with the artery.

For some applications, the control unit is configured to drive the electrodes to drive a contraction-inducing current into the artery during diastole.

For some applications, the control unit is configured to withhold driving the electrodes to drive a current into the artery during systole.

For some applications, the pressure mechanism includes a cuff, configured to be placed around the artery, a mechanical compressor, a pump, or a solenoid.

For some applications, the sensor is configured to generate the signal in response to detecting diastole. For some applications, the pressure mechanism is configured to respond to the generated signal by compressing the artery during diastole and releasing the compression during systole.

For some applications, the pressure mechanism is configured to increase a blood pressure in the artery by at least 30 mmHg, by compressing the artery.

For some applications, the valve is configured to be at least 1 cm upstream from the pressure mechanism.

For some applications, the pressure mechanism is configured to compress an artery that has an outer diameter between 0.5 and 2 mm, or between 2 and 10 mm.

For some applications, the valve is configured to be implanted in the artery, upstream of the site.

For some applications, the valve is configured to be implanted in an artery other than the artery to which the pressure mechanism is coupled.

For some applications, the valve is not physically coupled to the pressure mechanism.

There is further provided, in accordance with an application of the present invention, a method, including:

facilitating sensing of a cardiac cycle of a patient by coupling a sensor to the patient;

coupling a pressure mechanism, configured to respond to a signal from the sensor, to an artery of the patient; and

implanting a valve at an arterial location of the patient, downstream of a native aortic valve site of the patient, the coupling of the pressure mechanism and the implanting of the valve being such that the implanted valve is upstream of the pressure mechanism.

For some applications, coupling the pressure mechanism to the artery of the patient includes implanting the pressure mechanism.

For some applications, coupling the pressure mechanism to the artery of the patient includes maintaining the pressure mechanism at an extracorporeal site, while it is coupled to the artery.

For some applications, facilitating the sensing includes coupling the sensor to a site of the artery of the patient.

For some applications, the pressure mechanism includes one or more electrodes, and coupling the pressure mechanism to the artery of the patient includes placing the one or more electrodes in contact with the artery.

For some applications, the pressure mechanism includes a cuff, and coupling the pressure mechanism to the artery of the patient includes placing the cuff around the artery.

For some applications, the pressure mechanism includes a mechanical compressor, and coupling the pressure mechanism to the artery of the patient includes placing the mechanical compressor around the artery.

For some applications, the pressure mechanism includes a pump, and coupling the pressure mechanism to the artery of the patient includes coupling the pump to the artery.

For some applications, the pressure mechanism includes a solenoid, and coupling the pressure mechanism to the artery of the patient includes coupling the solenoid to the artery.

For some applications, coupling the pressure mechanism to the artery includes coupling the pressure mechanism to an artery that has an outer diameter between 0.5 and 2 mm or between 2 and 10 mm.

For some applications, implanting the valve upstream of the pressure mechanism includes implanting the valve in the same artery to which the pressure mechanism is coupled.

For some applications, implanting the valve upstream of the pressure mechanism includes implanting the valve in an artery other than the artery to which the pressure mechanism is coupled.

For some applications, implanting the valve upstream of the pressure mechanism includes implanting a valve that is not physically coupled to the pressure mechanism.

There is further provided, in accordance with an application of the present invention, a method, including:

sensing a cardiac cycle of a patient;

enhancing blood flow in a downstream direction in an artery of the patient, by compressing the artery in response to the sensing of the cardiac cycle; and

inhibiting blood flow in an upstream direction due to the compression of the artery.

For some applications, inhibiting the blood flow includes performing the inhibiting at an aortic site between a renal artery and an aortic bifurcation of the patient.

For some applications, inhibiting the blood flow in the upstream direction includes inhibiting the blood flow in the upstream direction using a valve. For some applications, inhibiting the blood flow in the upstream direction using the valve includes inhibiting blood flow in the upstream direction using a valve that is at least 1 cm upstream from a site of the compression of the artery. For some applications, inhibiting the blood flow in the upstream direction using the valve includes inhibiting the blood flow in the upstream direction using a valve that is physically separated from a site of the compression of the artery.

For some applications, sensing includes sensing diastole of the patient, and wherein compressing the artery includes compressing the artery in response to the sensing of diastole. For some applications, sensing further includes sensing systole of the patient, and compressing the artery includes withholding compressing the artery in response to the sensing of systole.

For some applications, sensing includes sensing diastole of the patient, and compressing the artery includes driving a contraction-inducing current in to the artery in response to the sensing of diastole. For some applications, sensing further includes sensing systole of the patient, and compressing the artery includes withholding driving a contraction-inducing current to the artery in response to the sensing of systole.

For some applications, compressing the artery includes compressing an artery that has an outer diameter between 0.5 and 2 mm or between 2 and 10 mm.

There is further provided, in accordance with an application of the present invention, a method, including:

identifying a patient as suffering from a vascular disease; and

in response to identifying as suffering from a vascular disease, implanting a valve in an aorta of the patient, at least 5 cm downstream of a native aortic valve site of the patient.

For some applications, implanting the valve includes implanting the valve at an aortic site located between a renal artery and an aortic bifurcation of the patient. For some appli-

cations, implanting the valve in the aorta includes implanting the valve within 5 cm of an aortic bifurcation.

For some applications, the method includes implanting an artificial blood vessel downstream of an implantation site of the valve. For some applications, implanting the artificial blood vessel includes implanting two artificial blood vessels, at contralateral sites of the patient.

For some applications, implanting the artificial blood vessel includes implanting an artificial blood vessel that is configured to increase its cross-sectional area by at least 20 percent during systole.

For some applications, implanting the artificial blood vessel includes implanting an artificial blood vessel that is configured to change its cross-sectional shape from elliptical to circular, during systole.

The present invention will be more fully understood from the following detailed description of applications thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A-B are schematic illustrations of respective configurations of a system for enhancing blood flow in a blood vessel, in accordance with some applications of the present invention;

FIG. **2** is a schematic illustration of a system for enhancing blood flow in a blood vessel, in accordance with some applications of the present invention;

FIG. **3** is a schematic illustration of another system for enhancing blood flow in a blood vessel, in accordance with some applications of the present invention; and

FIG. **4** is a schematic illustration of another system for enhancing blood flow in a blood vessel, in accordance with some applications of the present invention.

DETAILED DESCRIPTION OF APPLICATIONS

Reference is made to FIG. **1**A, which is a schematic illustration of medical apparatus **10**, comprising a sensor **26**, a pressure mechanism **28** and a valve **30**. A heart **16** of a patient supplies blood to an artery **20** that is coupled to, and supplies, an artery **22**. Artery **22** may be a native artery, or it may comprise an arterial graft (either made of natural materials or artificial materials). In accordance with some applications of the present invention, sensor **26**, in response to detecting diastole, sends a signal to pressure mechanism **28**, which is coupled to artery **22** of the patient. Pressure mechanism **28** is configured to respond to the generated signal from sensor **26** by compressing the artery during diastole, thereby enhancing blood flow to a downstream organ **18**, and releasing the compression during systole. Compression of artery **22** typically generates a blood pressure of at least 140 mmHg, e.g., above 170 mmHg, but below 250 mmHg. The increase in blood pressure in the artery due to the compression, relative to the diastolic pressure within artery **22** in the absence of compression being applied, is typically at least 30 mmHg, e.g. at least 40 mmHg and/or less than 90 mmHg.

According to one application of the present invention, artery **22** has an outer diameter between 0.5 and 2 mm. According to another application of the present invention, artery **22** has an outer diameter between 2 and 10 mm.

According to some applications of the present invention, valve **30** is implanted in an artery **20**, upstream of artery **22** to which pressure mechanism **28** is coupled, thereby inhibiting blood flow in an upstream direction due to the operation of pressure mechanism **28**. For example, the valve may be implanted in the aorta and the pressure mechanism may be coupled to the renal artery, the iliac artery, and/or the femoral artery. According to some applications of the present invention, valve **30** is not physically coupled to pressure mechanism **28**, and is, for example, at least 1 cm upstream from pressure mechanism **28** (e.g., more than 10 cm, less than 50 cm, and/or 10-50 cm upstream from pressure mechanism **28**).

Reference is now made to FIG. **1**B, which is a schematic illustration of medical apparatus **10**, comprising generally the same components as shown in FIG. **1**A, except that valve **30** is implanted upstream of pressure mechanism **28** in artery **22** to which pressure mechanism **28** is coupled, thereby inhibiting blood flow in an upstream direction due to the operation of pressure mechanism **28**. For example, both the valve and the pressure mechanism may be coupled to the aorta, the renal artery, the iliac artery, and/or the femoral artery.

Reference is now made to FIG. **2**, which is a schematic illustration of medical apparatus **10**, comprising generally the same components as shown in FIG. **1**. According to one application of the present invention, artery **22**, as seen in FIG. **1**, comprises an iliac or a femoral artery **22***a*. According to one application of the present invention, pressure mechanism **28**, as seen in FIG. **1**, comprises a mechanical compressor **28***a*. Pressure mechanism **28***a* may also comprise a cuff, a pump or a solenoid, configured to cyclically press a compressing element against artery **22**.

Reference is now made to FIG. **3**, which is a schematic illustration of medical apparatus **10**, comprising generally the same components as shown in FIG. **1**. According to one application of the present invention, artery **22**, as seen in FIG. **1**, comprises a renal artery **22***b*. According to one application of the present invention, pressure mechanism **28**, as seen in FIG. **1**, comprises one or more electrodes **28***b* coupled to a control unit **36**. According to one application of the present invention, sensor **26** sends a signal to control unit **36**, which is configured to drive electrodes **28***b* to drive a contraction-inducing current to artery **22**, in response to the sensor signal. The control unit sets parameters of the current to be such as to induce contraction of muscle of the artery, and to thereby enhance blood flow in the artery leading to a kidney **18**. For example, suitable parameters include inducing contraction during diastole.

Reference is now made to FIG. **4**, which is a schematic illustration of valve **30**, configured to be implanted in an aorta of the patient. For example, as shown in FIG. **4**, valve **30** may be implanted at a site located between a renal artery **22***b* and an aortic bifurcation of the patient (where the aorta bifurcates into the two iliac arteries **22***a*), e.g., within 5 cm of the bifurcation. According to one application of the present invention, a graft **40** is implanted in communication with iliac artery **22***a* or in communication with the femoral artery, replacing a damaged portion of iliac artery **22***a*. Typically, graft **40** is implanted downstream of valve **30**. For some applications, two grafts **40** are implanted (as shown in FIG. **4**), at contralateral sites.

It is noted that the application of the invention shown in FIG. **4** typically operates without any active, powered elements. As described hereinabove, for some applications of the present invention, graft **40** is compliant, and changes its cross-sectional area according to the cardiac cycle of the patient. For example, the graft expands during systole, and contracts during diastole. Typically, the diastolic contraction of the graft squeezes out blood that is in the contracting area of the graft. According to one application of the present invention, the implanted valve inhibits the upstream flow of blood from the contracting graft, therefore enhancing the blood flow in a downstream direction due to the contraction of the graft. Although typically the valve is implanted in the

aorta, for some applications, the valve may be implanted in an artery which is smaller in diameter than the aorta.

According to one application of the present invention, the graft expands during systole without any change in the shape of the graft (e.g., both the pre-expansion and post-expansion shapes of the graft may be circular). Alternatively, the graft changes its cross-sectional shape from an ellipse in diastole to a circle in systole. The cross-sectional area thus goes up substantially during systole.

For some applications of the present invention, the valve is physically coupled to the graft.

It is noted that, although certain combinations of implantation locations, grafts and pressure mechanisms are described with reference to FIGS. **1-4**, the scope of the present invention includes combining the implantation locations, grafts, and pressure mechanisms with each other, as would be obvious to one skilled in the art upon reading the above description. For example, the scope of the present invention includes placing an electrode-based pressure mechanism (as described with reference to FIG. **3**), in the femoral artery (FIG. **2**), or the aorta, or placing a mechanical pressure mechanism (FIG. **2**) in the renal artery (FIG. **3**), or in the aorta. In addition, the scope of the present invention includes coupling a graft to an artery other than the iliac artery or the femoral artery and placing a valve at an upstream location therefrom, in accordance with the techniques described hereinabove.

The implantation of apparatus shown in FIGS. **1-4** may be performed in open surgery, or minimally invasively.

It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof that are not in the prior art, which would occur to persons skilled in the art upon reading the foregoing description.

The invention claimed is:

1. A method, comprising:

facilitating sensing of a cardiac cycle of a patient by coupling a sensor to the patient;

coupling a pressure mechanism, configured to respond to a signal from the sensor, to an artery of the patient; and

implanting a valve at an arterial location of the patient, downstream of a native aortic valve site of the patient, the coupling of the pressure mechanism and the implanting of the valve being such that the implanted valve is upstream of the pressure mechanism.

2. The method according to claim **1**, wherein the pressure mechanism includes one or more electrodes, and wherein coupling the pressure mechanism to the artery of the patient comprises placing the one or more electrodes in contact with the artery.

3. The method according to claim **1**, wherein the pressure mechanism includes a mechanical compressor, and wherein coupling the pressure mechanism to the artery of the patient comprises placing the mechanical compressor around the artery.

4. The method according to claim **1**, wherein implanting the valve upstream of the pressure mechanism comprises implanting the valve in the same artery to which the pressure mechanism is coupled.

5. The method according to claim **1**, wherein implanting the valve upstream of the pressure mechanism comprises implanting the valve in an artery other than the artery to which the pressure mechanism is coupled.

6. The method according to claim **1**, wherein implanting the valve upstream of the pressure mechanism comprises implanting a valve that is not physically coupled to the pressure mechanism.

* * * * *

专利名称(译)	增压血流治疗		
公开(公告)号	US9386991	公开(公告)日	2016-07-12
申请号	US13/755662	申请日	2013-01-31
[标]申请(专利权)人(译)	瑞博医疗器械集团		
当前申请(专利权)人(译)	RAINBOW MEDICAL LTD.		
[标]发明人	GROSS YOSSI		
发明人	GROSS, YOSSI		
IPC分类号	A61B17/00 A61F2/24 A61N1/36 A61B17/12 A61F2/06 A61B5/00 A61B5/02 A61N1/362 A61N1/365		
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代理机构(译)	萨格鲁MION，PLLC		
优先权	61/593915 2012-02-02 US		
其他公开文献	US20130204292A1		
外部链接	Espacenet USPTO		

摘要(译)

提供了装置和方法，包括传感器，被配置为感测患者的心动周期并响应于此产生信号。压力机构耦合到患者的动脉部位，并且响应于该信号，通过压缩动脉来增强患者在下游方向上的血流。在该部位的上游植入瓣膜，并且由于压力机构的操作而抑制上游方向的血流。还描述了其他应用。