(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 511 443 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
01.08.2012 Bulletin 2012/31

(21) Application number: **03757358.1**

(22) Date of filing: **06.06.2003**

(51) Int Cl.:
A61F 2/00 *(2006.01)* ***A61F 2/06*** *(2006.01)*
A61B 5/103 *(2006.01)*

(86) International application number:
PCT/US2003/017755

(87) International publication number:
WO 2003/103539 (18.12.2003 Gazette 2003/51)

(54) **ENDOVASCULAR GRAFT WITH SENSORS**

ENDOVASKULÄRE PROTHESE MIT SENSOREN

GREFFE ENDOVASCULAIRE MUNIE DE DETECTEURS

(84) Designated Contracting States:
DE FR GB IE

(30) Priority: **07.06.2002 US 165763**

(43) Date of publication of application:
09.03.2005 Bulletin 2005/10

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Printed by Jouve, 75001 PARIS (FR)

Description

BACKGROUND OF THE INVENTION

[0001] This invention relates to the treatment of body lumens and, more particularly, to the endovascular placement of a prosthetic graft within vasculature for the purpose of repairing the same.

[0002] Ruptured abdominal aortic aneurysms (AAA) are a leading cause of death in the United States. Treatment options to repair AAA include conventional open surgery and implantation of an endovascular graft. Conventional open surgical repair of AAA involves major abdominal surgery with associated high rates of morbidity. Endovascular grafts have been developed to endoluminally bypass abdominal aortic aneurysms through minimally invasive surgery. Many patients that are unacceptable surgical risks for open repairs are eligible for endovascular graft implantation. Deployment of transfemoral, endovascular grafts to treat AAA is appealing for many reasons: avoidance of an abdominal incision, lack of aortic cross clamping, the potential for regional anesthesia, and a shortened hospital stay.

[0003] Untreated AAA have been shown to continue to expand until rupture, with an associated high mortality rate. Implantation of endovascular grafts have also been associated with high complication rates, including perioperative death, conversion to open repair, the need for further intervention, the need for hemodialysis, a failure to cure the AAA, and wound complications.

[0004] The inability to obtain or maintain a secure seal between the vessel wall and the endovascular graft is a complication unique to endovascular aneurysm exclusion. Because the term "leak" has been associated with aneurysm rupture following conventional surgery, the term "endoleak" has been proposed as a more definitive description of this complication. It is believed that persistent endoleaks result in continued aneurysm expansion, which may eventually lead to aneurysm rupture. Aneurysms that have been successfully excluded have shown a tendency towards a reduction in aneurysm diameter. Failure to properly exclude the aneurysm from systemic arterial blood pressure keeps the patient at risk of impending rupture. Endoleaks have been classified according to the source of the leaks. Current classifications of endoleaks include four categories. Type I endoleaks are "perigraft" or "graft-related" leaks that involve a persistent channel of blood flow due to inadequate or ineffective sealing at the ends of the endovascular graft, or between overlapping components of a modular system. Type-II endoleaks are retrograde flow into the aneurysm sac from patent lumbar arteries, the inferior mesenteric artery, or other collateral vessels. Type III endoleaks result from fabric tears, graft disconnection, or graft disintegration. Finally, Type IV endoleaks are flow through the graft fabric associated with graft wall porosity or permeability. It has been recognized that preoperative patent side branches are not a good predictor of postoperative endoleaks.

[0005] There have been a number of reported cases of aneurysm rupture following implantation of an endovascular graft. Some of the ruptures occurred in patients without a documented endoleak.

[0006] A number of studies have focused on measurement of pressure within the aneurysm sac following implantation of an endovascular graft, both in the human patient, an animal model, or an in vitro model. Properly implanted endovascular grafts have been shown to reduce the pressure within the aneurysm sac while an endoleak, with or without detectable blood flow, continues to pressurize the sac at pressures equivalent to the systemic arterial pressure. Animal studies utilizing a predictable rupturing aneurysm model have shown that non-excluded aneurysms will rupture. Thrombosed aneurysm sacs may still receive pressurization from a sealed endoleak and this continued pressurization keeps the aneurysm at risk for rupture.

[0007] Current methods of patient follow-up include arteriography, contrast-enhanced spiral computed tomography (CT), duplex ultrasonography, abdominal X-ray, and intravascular ultrasound. All of these methods are costly and involve invasive procedures with associated morbidity that may need to be performed in a hospital. None of the imaging methods are completely successful in detecting endoleaks. Therefore, the potential exists for an endoleak to go undetected until eventual rupture. An increase in aneurysm diameter is detectable, and should be considered an indication of endoleak. To avoid aneurysm rupture an increase in diameter must be detected in a timely fashion to identify patients in need of corrective endovascular procedures.

[0008] An endovascular graft with the ability to measure pressure within the aneurysm sac and provide feedback to the physician could provide acute confirmation of a procedure and identify those patients with persistent pressurization of their aneurysm, and subsequent risk of rupture. Some physicians are advocating that the follow-up examinations of AAA patients focus on pressure measurements, but that this is not currently clinically fusible. Furthermore follow-up examinations may be performed in the physician's office as opposed to a hospital. Moreover clinicians will have a new method to study pathology of post-endovascular treated BAA disease.

[0009] Accordingly there exists a need for an endovascular graft that facilitates non-invasive measurements of pressure, as well as other pertinent parameters, within the aneurysm sac and along the endovascular graft itself as a means for confirming the success of a procedure as well as identifying patients at risk for aneurysm rupture after the endovascular graft is implanted.

[0010] WO 9942176 describes an apparatus comprising an endoluminal implant, a RF coupling coil coupled to the endoluminal implant, a therapeutic transducer electrically coupled to the RF coupling coil, and physically coupled to the endoluminal implant. The RF coupling coil supplies electrical power to the therapeutic transducer.

The therapeutic transducer has a capability for delivering energy to lumen disposed within the endoluminal implant in response to signals coupled via the RF coupling coil.

[0011] US 5609627 describes an introducer for delivering into the vasculature a straight or bifurcated stent or prosthesis; a method for delivering into the vasculature a straight or bifurcated stent or prosthesis; a method of treating and angeological disease using a bifurcated stent; an endoluminal stent having perpendicular hoop members, each hoop member formed of wire in a sinuous configuration.

[0012] US 6140740 describes a miniature piezoelectric transducer element is provided, comprising a cell element having a cavity; a flexible piezoelectric layer attached to the cell member; a first electrode attached to the external surface and a second electrode attached to the internal surface of the piezoelectric layer.

[0013] US 6077298 describes a retractable intraluminal medical device for treating tissues in a patient, the device comprising an elongate radially expandable/ retractable tubular stent having an interior luminal portion and an opposite exterior portion along a longitudinal stent axis.

[0014] US 6053873 describe implantable apparatus for measuring a fluid flow in the body of the subject, including a stent, having a generally cylindrical radial outer wall and a central lumen. A flow parameter sensor is fixed to the stent, and, measures a parameter relating to the rate of blood flow trough the stent

[0015] US 6206914 describes an implantable system, including a carrier and eukaryotic cells, which produce and release a therapeutic agent, and a stimulating element for stimulating the release of the therapeutic agent. The system can also include a sensing element for monitoring a physiological condition and triggering the stimulating element to stimulate the delivery device to release the therapeutic agent.

[0016] US 2001/0026111 describes an acoustic biosensor which is provided for deployment at an implantation site within a body, such as an abdominal aortic aneurysm. The biosensor includes a sensor element for measuring a physiological condition.

[0017] US 6475170 describes an acoustic biosensor that is provided for deployment at an implantation site within a body, such as an abdominal aortic aneurysm. The biosensor includes a sensor element for measuring a physiological condition at the implantation site, and for generating an information signal representative of the physiological condition.

[0018] However providing devices on an endovascular graft to facilitate the measurement of pertinent parameters poses problems. The measurement device increase bulk, which can significant effect the delivery profile of the endovascular graft and increase the force necessary to deploy the device, such as jacket or release wire retraction forces. Increased bulk is a significant issue for an endovascular graft. Furthermore, attachment of measurement devices to an endovascular graft may require sutures and the suture knots not only provide increased bulk, but are also potential graft wear points. Additionally, tissue growth around a measuring device attached to an implanted endovascular graft may interfere with its function and inaccurate data may result. The present invention addresses these problems and other needs.

SUMMARY OF THE INVENTION

[0019] Briefly and in general terms, the present invention is embodied in an endovascular graft with sensors attached thereto. The endovascular graft has the ability to be delivered endovascularly and measure pertinent parameters within the lumen in which it is implanted. The endovascular graft has the ability to transmit data about intra-lumen parameters to an external monitoring device. Confirmation of a successful implant procedure is quickly and easily obtained. Patient follow-up is less costly (conducted in the physician office), non-invasive, and more accurate, allowing prompt intervention in those patients most at risk for acute AAA rupture. The invention would also allow for more frequent patient follow-up, increasing the potential to diagnose and treat aneurysms at risk before acute rupture. The invention is defined by the features of claim 1.

[0020] In one aspect of the invention, a modular endovascular graft having a main body component and one or more limb components is provided. One or more sensors are attached to the limb component(s). By attaching at least one sensor near the superior end of the limb component and sizing the main body component such that the sensor is adjacent to the aneurysm sac when the endovascular graft is implanted, measurement of pertinent parameters within the aneurysm sac is facilitated. The meaning of the term "adjacent" as used herein encompasses the sensor being located within the aneurysm sac or at a location where the parameters or properties being detected indicate conditions within the aneurysm sac. Measurements of pertinent parameters within the aneurysm sac may allow early confirmation of a successful procedure and identification of areas of the patient's vasculature at risk for aneurysm rupture, thrombus formation, infection, inflamation or other anomalies without the need for invasive procedures.

[0021] An antenna or other data transmitter and a power source also may be attached to the limb component adjacent to the aneurysm sac, allowing a physician or technician to monitor graft and vessel health without the need for an invasive procedure. The transmitter transmits measurements made by the sensors to a receiver located outside the patient's body. With the main body component unencumbered with sensors, transmitters or power sources, the bulk of the main body component is minimized and thereby, catheter diameter, jacket retraction and deployment complications are kept to a minimum.

[0022] In another aspect of the invention, an endovascular graft is provided that has attached thereto at least

one integrated sensor/transmitter device capable of measuring a pertinent parameter and transmitting the measurements to an external monitoring device. Although having more bulk than a sensor, the integrated sensor/transmitter device has less total bulk than a sensor and independent transmitter device, thereby facilitating less total bulk for the endovascular graft.

[0023] Furthermore, the integrated sensor/transmitter device may be designed to allow one or more "satellite" sensors, having no function other than measurement, to be connected thereto. A single integrated sensor/transmitter device and smaller "satellite" sensors facilitate a smaller total bulk than multiple integrated sensor/transmitter devices. Attaching the integrated sensor/transmitter at a central location such as the graft crotch and "satellite" sensors at various locations on the endovascular graft facilitates measurement and transmission to an external monitoring device of pertinent parameters at multiple locations along the endovascular graft and within the lumen. The "satellite" sensors allow a complete profile of pertinent parameters to be obtained and may provide more accurate identification of anomalies. Measurement of pertinent parameters at multiple locations along the endovascular graft or within the aneurysm sac may allow early detection of a defective seal between endovascular graft components, graft wear or changes in aneurysm geometry. The smaller "satellite" sensors may also allow pertinent parameters to be measured from locations on the endovascular graft where local graft bulk is a constraint of the design, such as the graft contra limb or near the superior attachment system that holds the graft in the patient's aorta.

[0024] Additionally, it is contemplated that "satellite" sensors may be attached directly to the lumen of a patient. The integrated sensor/transmitter device also may be attached directly to the lumen or attached to an implanted endovascular graft.

[0025] Moreover, it is contemplated that passive devices, or monuments, which perform no sensing function may be attached to the implanted endovascular graft or directly attached to the aneurysm sac. By tracking the location of the monuments with a monitoring device, changes in the position of the endovascular graft within the lumen or changes in the geometry of the tissue outside the endovascular graft may be detected without the problems of encapsulation or thrombus isolation associated with the measurement of pertinent parameters. Such changes may provide early detection of endovascular graft displacement or aneurysm re-dilation due to an endoleak.

[0026] Sensors with pressure measurement capability may be used to detect pressure changes in the aneurysm sac indicative of graft failure or endoleak due to an inadequate seal between the endovascular graft and the vasculature. Sensors with temperature measurement capability may be used to detect temperature differentials associated with "hot spots" related to inflamation, infection or thrombus formation in the vessel. Sensors with the capability to measure oxygen and other blood constituents such as enzymes, proteins, and nutrients, may be used to detect minute blood flow indicative of endoleak. Sensors with the capability to measure electrical potential or magnetic fields may be used to detect differences in potential associated with areas of the vessel at risk for thrombus formation. Sensors also may be provided to facilitate other sensing applications such as blood oxymetry, blood glucose, blood or fluid flow, biochemical or hormonal balance, blood chemistry, positional data, dynamic displacement data, ocular pressure, respiration, electro physiology, tissue stress, venous return and body acoustics.

[0027] According to the invention, sensors are attached to an endovascular graft using one continuous suture. Starting at one location on the sensor, a running stitch around the sensor is used to attach the sensor to the graft fabric, thereby minimizing the number of knots necessary for attachment, in this case a single knot. It is contemplated that the running stitch may start at any location on the sensor depending on the location of the sensor on the endovascular graft. Minimizing the number of knots is advantageous because knots are potential graft wear points and add bulk. Additionally, a single knot attachment design may allow the sensor to be placed close to the graft crotch due to the lack of a knot at the end closest the crotch.

[0028] In an additional aspect of the invention, the sensors may be covered in a coating that either inhibits tissue growth or promotes a known or controlled amount and/or type of tissue growth. Because tissue growth may interfere with the ability of a sensor to perform its measurement function, inhibiting tissue growth or restricting tissue growth to a known type and/or amount may increase the reliability of measurements obtained.

[0029] The invention is applicable to all applications of endovascular grafts to treat aneurysmal segments of blood vessels. Furthermore, the invention disclosed herein may be applied any time it is desired to measure intraluminal parameters in a non-invasive manner. It is contemplated that the invention may be used with all shapes of endovascular grafts known within the art.

[0030] Other features and advantages of the present invention will become apparent from the following detailed description taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031]

FIG. 1 is a partial cross-sectional view of one embodiment of the invention showing a partially assembled bifurcated endovascular graft implanted across an aneurysm sac;

FIG. 2 is a perspective view of another embodiment

of the present invention showing a bifurcated graft with an integrated sensor/transmitter device and "satellite" sensors;

FIG. 3 is a perspective view of a typical integrated sensor/transmitter device of the present invention;

FIG. 4 is a partial cross-sectional view of an alternate embodiment of the invention shown in FIG. 2 showing a bifurcated graft implanted across an aneurysm sac into which an integrated sensor/transmitter device and "satellite" sensors have been attached;

FIG. 5 is a schematic view of another embodiment of the present invention showing an endovascular graft with monuments attached thereto implanted in a patient's body and an external source/receiver; and

FIG. 6 is an enlarged view of a portion of graft fabric showing a sensor of the present invention attached using a single suture and running stitch.

DETAILED DESCRIPTION OF THE REFERRED EMBODIMENTS

[0032] As shown in the exemplary drawings and for purposes of illustration, the invention is embodied in a prosthetic endovascular graft having the ability to measure pertinent parameters inside the lumen into which it is implanted and transmit the measurements to a receiver located external to the patient.

[0033] Referring to FIG. 1, an embodiment of the invention is shown in which a modular bifurcated endovascular graft 10 of the type known within the art is implanted in a body vessel 40 across an aneurysm sac 42 in the area of the contra-lateral 44 and ipsi-lateral 46 iliac arteries using methods known within the art (only the contra-lateral limb is shown). The bifurcated endovascular graft 10 may be assembled in-vivo from a tubular trunk component 20 and two limb components 30. The trunk component 20 has a superior end 22 adapted to be secured above the aneurysm and an inferior end 24 adapted to accept the limb components 30. The limb component 30 has a transmitter 12, power source 14, and sensors 16 attached external the graft material. The transmitter 12, power source 14 and sensors 16 can be integrated into one device as described below. The limb component 30 has a superior end 32 adapted to mate with the trunk component 20 inferior end 24 and an inferior end 34 adapted to be secured to the ipsi-lateral 44 iliac artery.

[0034] The sensors 16 measure pertinent parameters outside the endovascular graft 10 and the power source 14 provides power for the transmitter 12 which transmits the measurements to a receiver (not shown) located outside the patient's body. The transmitter 12, power source 14 and receiver (not shown) may be of any type known in the art of surgical implants or other systems utilizing miniaturized power sources and transmitters. The power source 14 and transmitter 12, for example, may be of the type used in pacemaker technology or passive power sources such as ultrasonic chargeable capacitors.

[0035] One or more sensors 16 are located near the superior end 32 of the limb component 30 but inferior the attachment/sealing area 26 between the trunk component 20 and limb component 30 such that the seal between the trunk component 20 and limb component 30 is not jeopardized. Note that the attachment/sealing area 26 is such that one or more of the sensors 16 on the limb component 30 is adjacent the aneurysm sac 42, thereby facilitating measurement of pertinent parameters within the aneurysm sac 42 without encumbering the trunk component 20 with sensors 16. Note also that the transmitter 12 and power source 14 are attached to the limb component 30 such that they are also adjacent the aneurysm sac 42. Minimizing the bulk of the trunk component facilitates a smaller delivery profile for the endovascular graft 10.

[0036] The sensors 16 may measure pressure, with the measurements used as an aid in endovascular graft 10 placement or to identify anomalies that occur after endovascular graft 10 implantation but before aneurysm rupture occurs. The sensors 16 may detect changes in pressure resulting from blood leakage between the endovascular graft 10 and the vessel wall 40, an endoleak resulting from an inadequate seal between them. Furthermore, the sensors 16 may detect changes in pressure resulting from leakage from an endoleak between the trunk 20 and vessel wall 40. Because sensors 16 are located in the area of the aneurysm sac 42, there may be multiple sensors 16 disbursed over the graft material outer wall since local thrombus or calcification may shield one or more of the sensors 16 from blood flow and render their measurements erroneous. Moreover, the sensors 16 may allow pressure differences throughout the "excluded" aneurysm sac 42 to be mapped. It is contemplated that pressure measurements in the aneurysm sac may be obtained to an accuracy range of +/- 1 to 30 mm Hg and preferably of +/- 10 mm Hg.

[0037] Alternatively, the sensors 16 may measure temperature. Differences in temperature may identify "hot spots" associated with infection, inflammation, thrombus formation or other anomalies that indicate an increased risk for aneurysm rupture. Methods known in the art of pathology and physiology may be used to relate temperature to changes in the vessel walls within which the endovascular graft is implanted.

[0038] Alternatively, the sensors 16 may detect blood flow by measuring oxygen or other constituents, such as enzymes, proteins and nutrients, which are altered by the presence of blood flow. Such sensors may allow detection of minute blood flow, often missed by conventional imaging modalities, and, therefore, allow endoleaks to be detected earlier. One method is to obtain a baseline of the constituents upon implantation of the endovascular graft. Thereafter, changes in the amount of the measured

constituents may be used to identify anomalies.

[0039] Alternatively, the sensors 16 may measure electrical potential or magnetic field strength. Changes in electrical potential may identify areas of the patient's vasculature that are at risk for thrombus formation. Induced magnetic fields indicate motion at a charged portion of the aneurysm such as would occur from pulsatile pressure.

[0040] Sensors also may be provided to facilitate other sensing applications such as blood oxymetry, blood glucose, blood or fluid flow, biochemical or hormonal balance, blood chemistry, positional data, dynamic displacement data, ocular pressure, respiration, electro physiology, tissue stress, venous return and body acoustics.

[0041] Although shown external the limb component 30 in FIG. 1, it is contemplated that the transmitter 12, power source 14 and sensors 16 may be located internal the graft material of the limb component 30. It is further contemplated that the number of transmitters 12, power sources 14 and sensors 16 shown in FIG. 1 may be varied to meet the requirements of the individual patient. It is further contemplated that sensors 16 which measure different pertinent parameters may be used together. Moreover, the invention shown in FIG. 1 may be utilized in any type of endovascular graft implant known in the art.

[0042] Referring to FIG. 2, another embodiment of the invention is shown in which an integrated sensor/transmitter 50 is attached to the endovascular graft 110 and "satellite" sensors 52 are attached at various locations on the endovascular graft 110. The integrated sensor/transmitter 50 is capable of measuring a pertinent parameter as well as transmitting measurements to a receiver (not shown) outside that patient's body. The "satellite" sensors 52 only measure pertinent parameters and their measurements are transmitted by the integrated sensor/transmitter, to which they are connected by leads 54. The "satellite" sensors 52 may provide a complete profile of pertinent parameters over the surface of the endovascular graft 110 and, therefore, facilitate better identification of anomalies.

[0043] Because the "satellite" sensors 52 are smaller than the integrated sensor/transmitter 50, the overall bulk of the endovascular graft 110 is smaller than if multiple integrated sensor/transmitter devices 50 were utilized. Furthermore, the smaller "satellite" sensors 52 may be placed such that measurements may be obtained from multiple locations, such as near the superior attachment area or within the aneurysm sac 42. Moreover, the smaller "satellite" sensors 52 facilitate measurements from places on the endovascular graft 110 where local graft bulk is a constraint of the design, such as the contra limb, or near the superior attachment system that holds the graft in the patient's aorta.

[0044] A separate power source 114 may be provided. The power source can be integrated into the sensor/transmitter as described previously and further below. The leads 54 which connect the integrated sensor/transmitter 50 to the "satellite" sensors 52 may be woven into the graft fabric or attached external to the endovascular graft 110.

[0045] It is contemplated that the location and number of integrated sensor/transmitter devices 50, power sources 114 and "satellite" sensors 52 shown in FIG. 2 may be varied to meet the requirements of the individual patient. In the embodiment shown, the integrated sensor/transmitter device 50 is located at the crotch, thereby allowing it to be near the center of the aneurysm sac 42 (see FIG. 2) while still being located furthest away from the aneurysm wall during shrinkage. It is further contemplated that the invention shown in FIG. 2 may be utilized in any type of endovascular graft implant known in the art.

[0046] Moreover, the integrated sensor/transmitter 50 and "satellite" sensors 52 may be of any type known in the art used to measure pressure, temperature, oxygen and other blood constituents, electrical potential or any other pertinent parameter indicative of endovascular graft or lumen health. One such integrated sensor/transmitter 50 to measure pressure is disclosed in U.S. Pat. Application Publication No. 2002/0045921 (Wolinsky et al.), the contents of which are hereby incorporated by reference. Again, other sensing applications may be supported such as blood oxymetry, blood glucose, blood or fluid flow, biochemical or hormonal balance, blood chemistry, positional data, dynamic displacement data, ocular pressure, respiration, electro physiology, tissue stress, venous return and body acoustics.

[0047] FIG. 3 shows a typical integrated sensor/transmitter 50 for use with the present invention. The integrated sensor/transmitter 50 includes a control chip 55 with a transmitter/receiver, energy exchanger 56, capacitor 57 and sensor 58. An external receiver (not shown) may contain a transducer, computer, LCD display and measurement display devices, such as barometers if the sensor 58 measures pressure. In operation, the transducer in the external receiver charges the capacitor 57 using ultrasonic energy and activates the sensor 58 to measure a pertinent parameter and ultrasonically transmit the measured parameter. The external receiver receives the transmitted pertinent parameter, assesses the measurement and displays the measurement, for example, as a pressure pulse curve.

[0048] Although FIG. 2 shows an integrated sensor/transmitter 50 and "satellite" sensors 52 connected by leads 54 and attached to the endovascular graft 110, alternate embodiments of the invention may utilize an integrated sensor/transmitter 50 as the sole implant. Furthermore, the "satellite" sensors 52 may be attached to the vessel 40 with the integrated sensor/transmitter 50 either attached to the vessel 40 or attached to the endovascular graft 110. FIG. 4 shows an endovascular graft 110 implanted across an aneurysm sac 42 into which an integrated sensor/transmitter 50 connected to "satellite" sensors 52 by leads 54 have been attached. It is contemplated that pressure measurements in the aneurysm sac 42 may be obtained to an accuracy range of +/- 1 to

30 mm Hg and preferably +/- 10 mm Hg utilizing either an integrated sensor/transmitter 50 alone or in conjunction with one or more "satellite" sensors 52 or integrated sensor/transmitters 50.

[0049] In an alternate embodiment of the invention illustrated in FIGS. 2 and 4, micro devices having the capability to sense their location relative to each other are either attached to the endovascular graft 110 or attached to the vessel 40. The micro devices may be excited by an external energy source, sense their relative location and transmit the data to a receiver located outside the patient's body. The data may then be interpreted to determine if displacement of the endovascular graft 110 or changes in the geometry of the vessel 40 has occurred. Such changes may provide early detection of endovascular graft 110 displacement or aneurysm 42 re-dilation due to an endoleak. Additional micro devices could be provided for better resolution. Detecting location of the micro devices rather than measuring a pertinent parameter minimizes reliability problems due to encapsulation or thrombus isolation. It is contemplated that the micro devices may be an ultrasonic crystal attached or integral to a MEM chip having the ability to read, interpret and transmit data. The micro devices also may be ultrasonic or other energy reflectors utilized in conjunction with an energy source. Using ultrasound to show or image reflector location would be much easier than creating an ultrasound image of the tissue.

[0050] In a further embodiment of the invention illustrated in FIGS. 2 and 4, devices or monuments which perform no sensing function may be attached to the implanted endovascular graft 110 or directly attached to the aneurysm sac 42. The location of the monuments may be tracked with a monitoring device to detect changes in the position of the endovascular graft 110 within the vessel 40 or changes in the geometry of the tissue outside the endovascular graft 110. It is contemplated that the monitoring device may be located external the patient's body or attached to an implanted endovascular graft. FIG. 5 illustrates an external monitoring device 64 being used to sense the location of an endovascular graft 310 having monuments 60 attached thereto which has been implanted in a patient's body. It is contemplated that the monuments may be electrically passive devices or magnetic sensors. The use of RF or magnets to sense the position of monuments is contemplated.

[0051] In one example, the position of magnetic sensors attached to the aneurysm sac 42 are measured using an external magnet of known magnetic field strength and shape. By moving the external magnet to multiple positions and orientations outside the body and polling the magnetic sensors with ultrasound, a baseline of magnetic sensor positions is established. Subsequent polling of the magnetic sensor positions allows changes in aneurysm sac 42 geometry to be detected.

[0052] In yet another embodiment of the invention shown in FIG. 6, sensors 16 or integrated sensor/transmitters 52 are attached to the endovascular graft 110 fabric using one continuous suture 70 with a running stitch, from a starting point 72 on sensor 16, which continues around the sensor 16 and back to an end point 74 (the dashed lines in FIG. 6 indicate where the suture 70 is on the inner diameter of the endovascular graft 110 fabric). Suture loops 71 are provided on the sensor 16 to facilitate attachment. A single knot 75 may be used to join the ends of the suture 70. It is contemplated that the running stitch may start and end at either end of the sensor and utilize more or less stitches depending on the location of the sensor 16 on the endovascular graft 110 and the attachment requirements. Minimizing the number of knots not only reduces bulk but also reduces potential graft wear points and may allow the sensor to be placed close to the graft crotch due to the lack of a knot at the distal end. It is further contemplated that the continuous suture 70 attachment method may be utilized with sensors 16 having suture holes or any other attachment mechanism.

[0053] In yet another embodiment of the invention, the sensors 16 may be covered in a coating, such as Teflon or heparin, to inhibit tissue growth or covered in a coating, such as Thrombin, to promote a known or controlled amount of tissue growth. Inhibiting or controlling tissue growth, which may interfere with performance, increases the reliability of the measurements made by the sensors 16.

[0054] While several particular forms of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the scope of the invention as defined in the claims. Accordingly, it is not intended that the invention be limited, except as by the scope of the appended claims.

Claims

1. A modular endoluminal prosthesis for repairing an aneurysm in vasculature, comprising
   a first endovascular graft component (20);
   a second endovascular graft component (30) for attachment to the first endovascular graft component (20), the second endovascular graft component (30) having one or more sensors (16, 50, 52) attached thereto, each sensor (16, 50, 52) configured to provide information regarding a pertinent parameter inside the vasculature;
   wherein
   at least one sensor (16, 50, 52) is located on the second endovascular graft component (30) such that the sensor (16, 50, 52) is adjacent the aneurysm when the first (20) and second (30) endovascular graft components are implanted within the vasculature;
   wherein each sensor (16, 50, 52) is attached to the endovascular graft (10, 110, 310) by one continuous suture (70) with a running stitch, from a starting point (72) on the sensor (16, 50, 52), which continues

around the sensor (16, 50, 52) and back to an end point (74).
wherein each sensor (16, 50, 52) comprises suture loops (71); and
at least one receiving device (64) located outside a patient's body, each receiving device (64) capable of receiving the information provided by the one or more sensors (16, 50, 52) and transmitted by one or more transmitters.

2. The prosthesis of claim 1, further comprising:

one or more power sources (14, 114) attached to the second endovascular graft component (30); and
one or more transmitting devices (12, 50) attached to the second endovascular graft component (30), each transmitting device (12, 50) capable of transmitting signals containing the parameters measured by one or more sensors (16, 50, 52) to a location outside a patient's body.

3. The prosthesis of claim 2, wherein the power sources (14, 114) and transmitting devices (12, 50) are adjacent the aneurysm when the first (20) and second (30) endovascular graft components are implanted within the vasculature.

4. The prosthesis of claim 1, wherein one of the first (20) and second (30) endovascular graft components is generally tubular and each has a superior end (22, 32), an inferior end (24, 34) and a midsection.

5. The prosthesis of claim 4, wherein one or more sensors (16, 50, 52) are located on the second endovascular graft component (30) at a midsection thereof.

6. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) measure pressure.

7. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) measure temperature.

8. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) measure fluid flow.

9. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) measure blood flow.

10. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) measure blood chemistry.

11. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) measure fluid chemistry.

12. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) measure position.

13. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) detect motion.

14. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) measure acoustics.

15. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) measure a constituent altered by the presence of minute amounts of blood flow.

16. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) measure electrical potential.

17. The prosthesis of claim 1, wherein at least one of the sensors (16, 50, 52) measure magnetic fields.

18. The prosthesis of claim 1, wherein one or more sensor(s) (16, 50, 52) are located on the external surface of the second endovascular graft component (30).

19. The prosthesis of claim 1, wherein one or more sensor(s) (16, 50, 52) are located on the internal surface of the second endovascular graft component (30).

Patentansprüche

1. Modulare endoluminale Prothese für die Reparatur eines Aneurysmas in einer Gefäßanordnung, umfassend
eine erste endovaskuläre Prothesenkomponente (20);
eine zweite endovaskuläre Prothesenkomponente (30) zum Anbringen an der ersten endovaskulären Prothesenkomponente (20), wobei die zweite endovaskuläre Prothesenkomponente (30) einen oder mehrere Sensor(en) (16, 50, 52) aufweist, die daran angebracht sind, wobei jeder Sensor (16, 50, 52) ausgestaltet ist, Informationen zu einem relevanten Parameter im Innern der Gefäßanordnung bereitzustellen;
wobei
sich mindestens ein Sensor (16, 50, 52) an der zweiten endovaskulären Prothesenkomponente (30) befindet, sodass der Sensor (16, 50, 52) benachbart zum Aneurysma ist, wenn die ersten (20) und zweiten (30) endovaskulären Prothesenkomponenten innerhalb der Gefäßanordnung implantiert sind;
wobei jeder Sensor (16, 50, 52) an der endvaskulären Prothese (10, 110, 310) durch eine fortlaufende Naht (70) mit einem fortlaufenden Nahtstich angebracht ist, die von einem Anfangspunkt (72) an dem Sensor (16, 50, 52) um den Sensor (16, 50, 52) herum und zurück zu einem Endpunkt (74) verläuft;
wobei jeder Sensor (16, 50, 52) Nahtschlaufen (71) umfasst; und
mindestens eine Empfangsvorrichtung (64), die sich

außerhalb eines Patientenkörpers befindet, wobei jede Empfangsvorrichtung (64) in der Lage ist, Informationen zu empfangen, die von dem einen oder mehreren Sensor(en) (16, 50, 52) bereitgestellt und von einem oder mehreren Transmittern übertragen werden.

2. Prothese nach Anspruch 1, überdies umfassend:

eine oder mehrere Stromquellen (14, 114), die an der zweiten endovaskulären Prothesenkomponente (30) angebracht ist/sind; und
eine oder mehrere Übertragungsvorrichtungen (12, 50), die an der zweiten endovaskulären Prothesenkomponente (30) angebracht ist/sind, wobei jede Übertragungsvorrichtung (12, 50) Signale, die Parameter enthalten, die von einem oder mehreren Sensor(en) (16, 50, 52) gemessen wurden, an einen Ort außerhalb eines Patientenkörpers übertragen kann.

3. Prothese nach Anspruch 2, wobei die Stromquellen (14, 114) und die Übertragungsvorrichtungen (12, 50) dem Aneurysma benachbart sind, wenn die ersten (20) und zweiten (30) endovaskulären Prothesenkomponenten in der Gefäßanordnung implantiert sind.

4. Prothese nach Anspruch 1, wobei eine, die erste (20) oder zweite (30) endovaskulären Prothesenkomponenten, im Allgemeinen rohrförmig ist und jeweils ein höheres Ende (22, 32) und ein unteres Ende (24, 34) und einen Mittelabschnitt aufweist.

5. Prothese nach Anspruch 4, wobei sich ein oder mehrere Sensor(en) (16, 50, 52) auf der zweiten endovaskulären Prothesenkomponente (30) auf einem Mittelabschnitt derselben befinden.

6. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) Druck misst.

7. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) Temperatur misst.

8. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) Fluidstrom misst.

9. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) Blutstrom misst.

10. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) chemische Blutzusammensetzung misst.

11. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) chemische Fluidzusammensetzung misst.

12. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) Position misst.

13. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) Bewegung feststellt.

14. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) Akustik misst.

15. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) einen Bestandteil misst, der durch das Vorhandensein einer kleinen Menge Blutstrom verändert wird.

16. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) elektrisches Potential misst.

17. Prothese nach Anspruch 1, wobei mindestens einer der Sensoren (16, 50, 52) Magnetfelder misst.

18. Prothese nach Anspruch 1, wobei sich ein oder mehrere Sensor(en) (16, 50, 52) auf der äußeren Oberfläche der zweiten endovaskulären Prothesenkomponente (30) befinden.

19. Prothese nach Anspruch 1, wobei sich ein oder mehrere Sensor(en) (16, 50, 52) auf der inneren Oberfläche der zweiten endovaskulären Prothesenkomponente (30) befinden.

Revendications

1. Prothèse endoluminale modulaire pour réparer un anévrysme dans le système vasculaire, comprenant :

un premier composant de greffon endovasculaire (20) ;
un second composant de greffon endovasculaire (30) pour la fixation au premier composant de greffon endovasculaire (20), le second composant de greffon endovasculaire (30) muni d'un ou de plusieurs capteurs (16, 50, 52) fixés à celui-ci, chaque capteur (16, 50, 52) étant configuré pour fournir des informations relatives à un paramètre pertinent à l'intérieur du système vasculaire ;
dans lequel
au moins un capteur (16, 50, 52) est localisé sur le second composant de greffon endovasculaire (30), de telle sorte que le capteur (16, 50, 52) est adjacent à l'anévrysme lorsque les premier (20) et second (30) composants de greffon endovasculaire sont implantés à l'intérieur du système vasculaire ;
dans lequel chaque capteur (16, 50, 52) est fixé

au greffon endovasculaire (10, 110, 310) par une suture continue (70) avec un point devant, depuis un point de départ (72) sur le capteur (16, 50, 52) qui se poursuit autour du capteur (16, 50, 52) et revient vers un point final (74), dans lequel chaque capteur (16, 50, 52) comprend des boucles de suture (71) ; et
au moins un dispositif de réception (64) localisé à l'extérieur du corps d'un patient, chaque dispositif de réception (64) étant capable de recevoir les informations fournies par un ou plusieurs capteurs (16, 50, 52) et transmises par un ou plusieurs émetteurs.

2. Prothèse selon la revendication 1, comprenant en outre :

une ou plusieurs sources d'alimentation (14, 114) fixées au second composant de greffon endovasculaire (30) ; et
un ou plusieurs dispositifs de transmission (12, 50) fixés au second composant de greffon endovasculaire (30), chaque dispositif de transmission (12, 50) étant capable de transmettre des signaux contenant les paramètres mesurés par un ou plusieurs capteurs (16, 50, 52) à un emplacement situé à l'extérieur du corps d'un patient.

3. Prothèse selon la revendication 2, dans laquelle les sources d'alimentation (14, 114) et les dispositifs de transmission (12, 50) sont adjacents à l'anévrysme lorsque les premier (20) et second (30) composants de greffon endovasculaire sont implantés à l'intérieur du système vasculaire.

4. Prothèse selon la revendication 1, dans laquelle un des premier (20) et second (30) composants de greffon endovasculaire est généralement tubulaire et chacun présente une extrémité supérieure (22, 32), une extrémité inférieure (24, 34) et une section médiane.

5. Prothèse selon la revendication 4, dans laquelle un ou plusieurs capteurs (16, 50, 52) sont situés sur le second composant de greffon endovasculaire (30) sur une section médiane de celui-ci.

6. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) mesure la pression.

7. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) mesure la température.

8. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) mesure l'écoulement fluidique.

9. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) mesure le flux sanguin.

10. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) mesure la chimie sanguine.

11. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) mesure la chimie fluidique.

12. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) mesure la position.

13. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) détecte le mouvement.

14. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) mesure l'acoustique.

15. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) mesure un constituant modifié par la présence d'infimes quantités de flux sanguin.

16. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) mesure le potentiel électrique.

17. Prothèse selon la revendication 1, dans laquelle au moins un des capteurs (16, 50, 52) mesure les champs magnétiques.

18. Prothèse selon la revendication 1, dans laquelle un ou plusieurs capteurs (16, 50, 52) sont localisés sur la surface externe du second composant de greffon endovasculaire (30).

19. Prothèse selon la revendication 1, dans laquelle un ou plusieurs capteurs (16, 50, 52) sont localisés sur la surface interne du second composant de greffon endovasculaire (30).

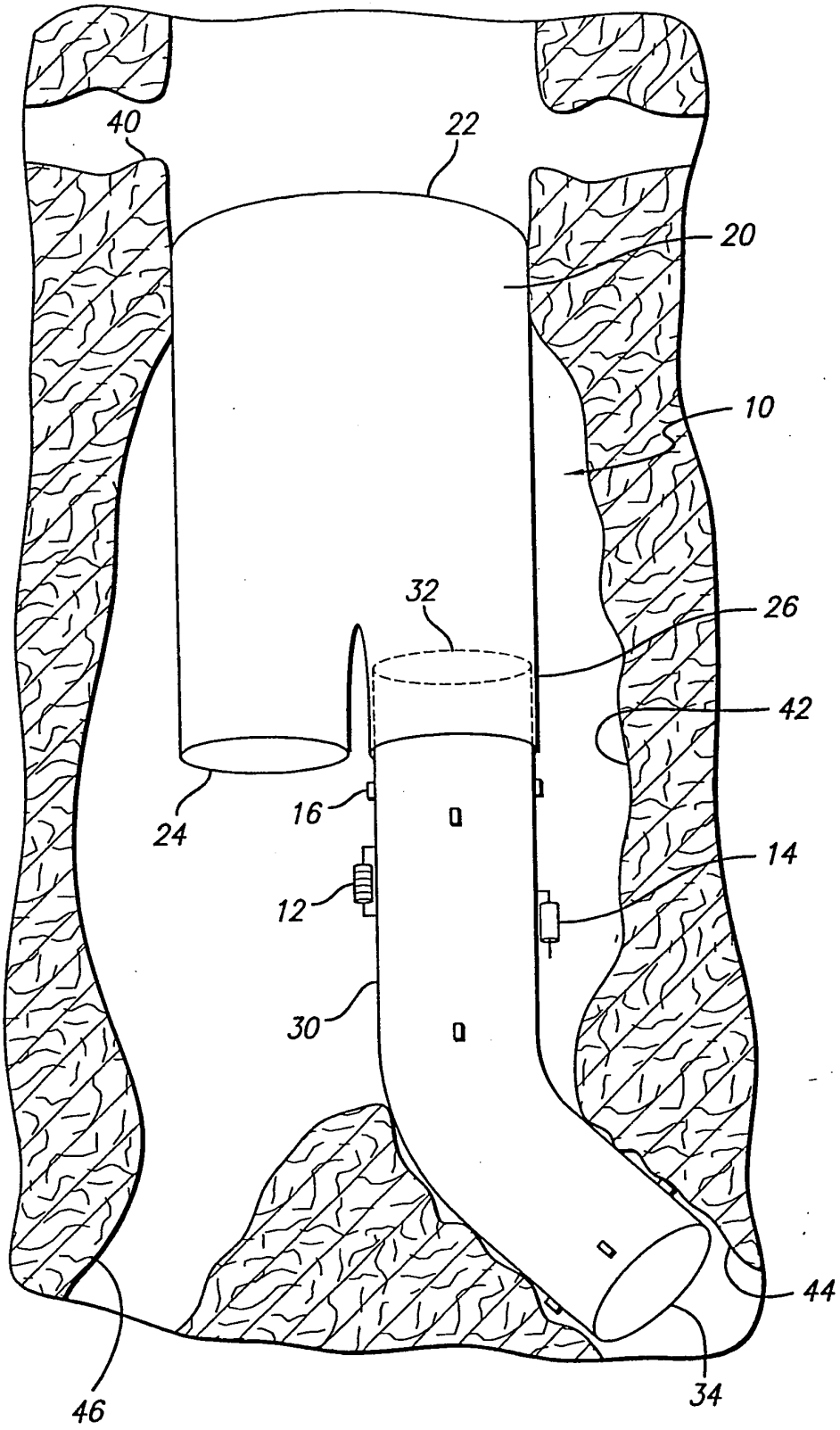


FIG. 1

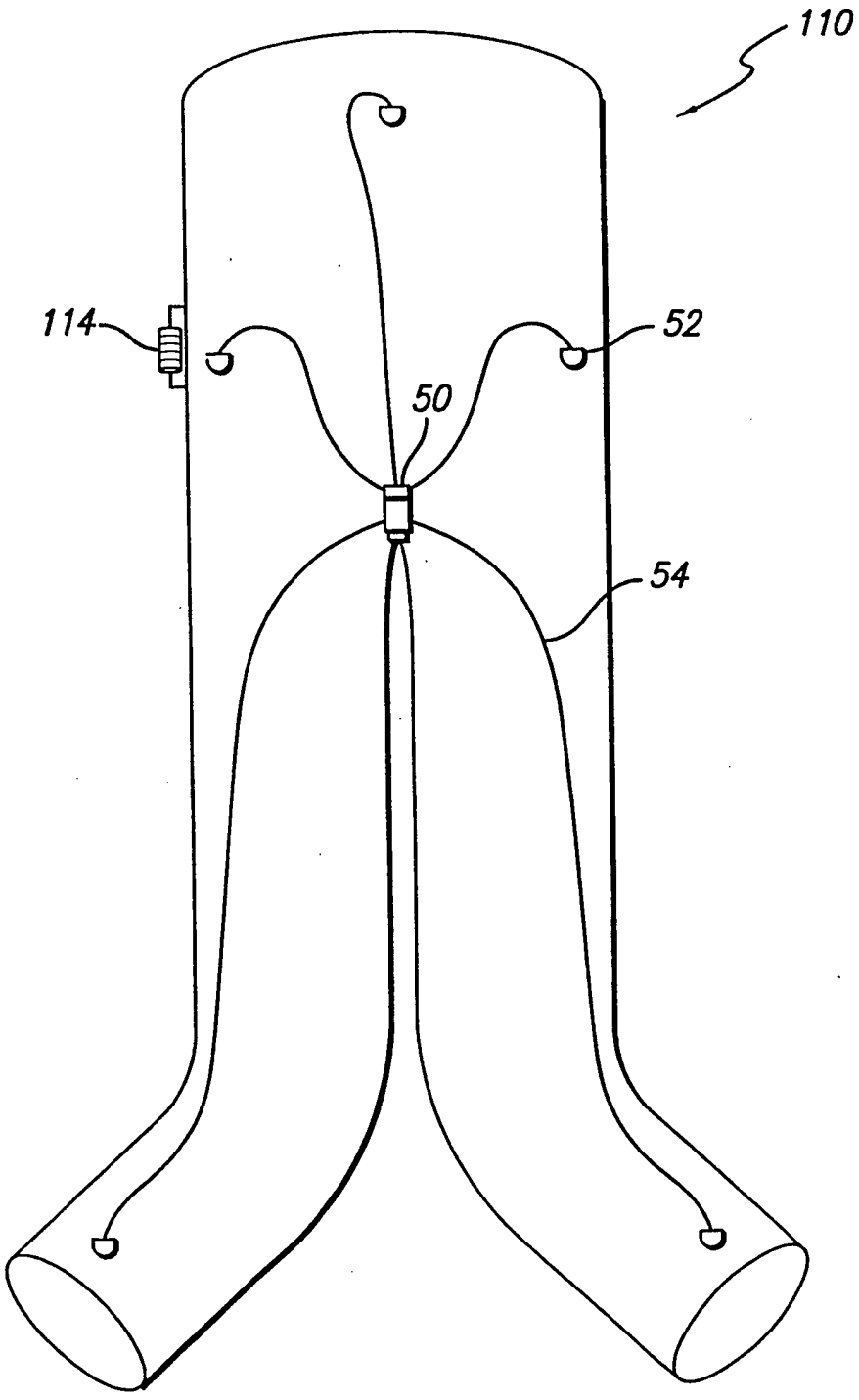
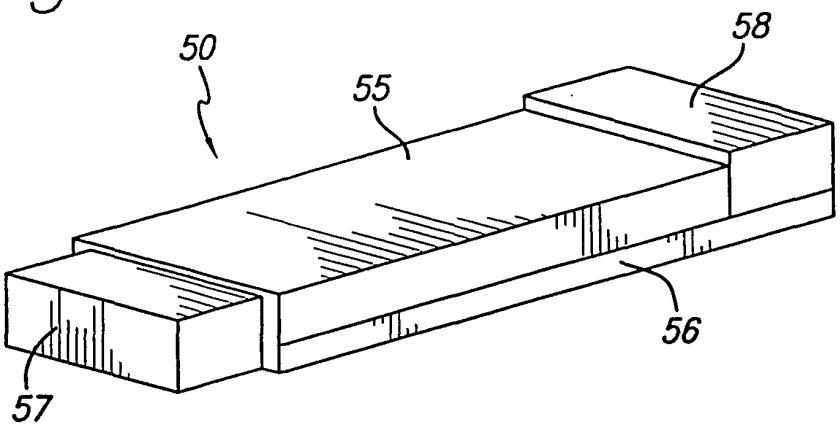


FIG. 2

FIG. 3



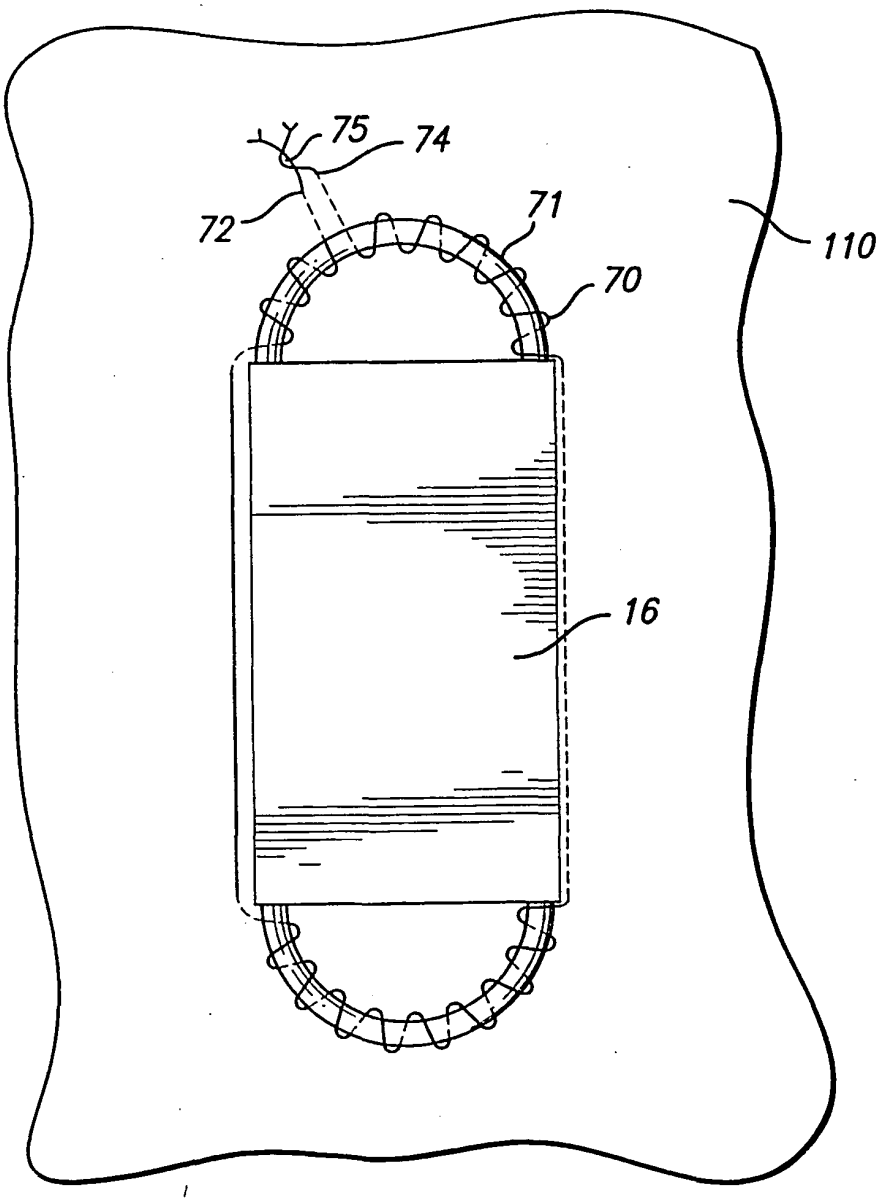


FIG. 6

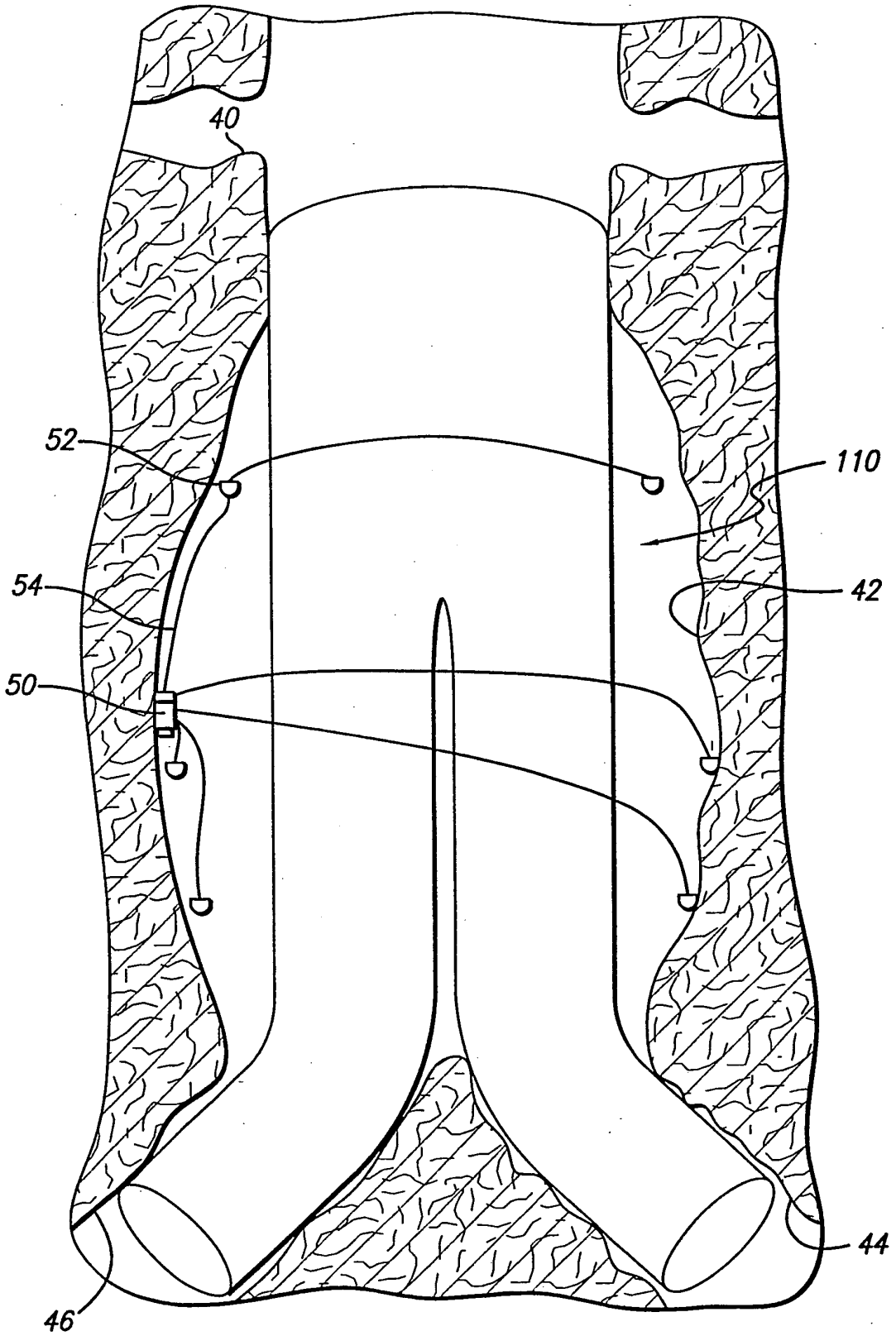


FIG. 4

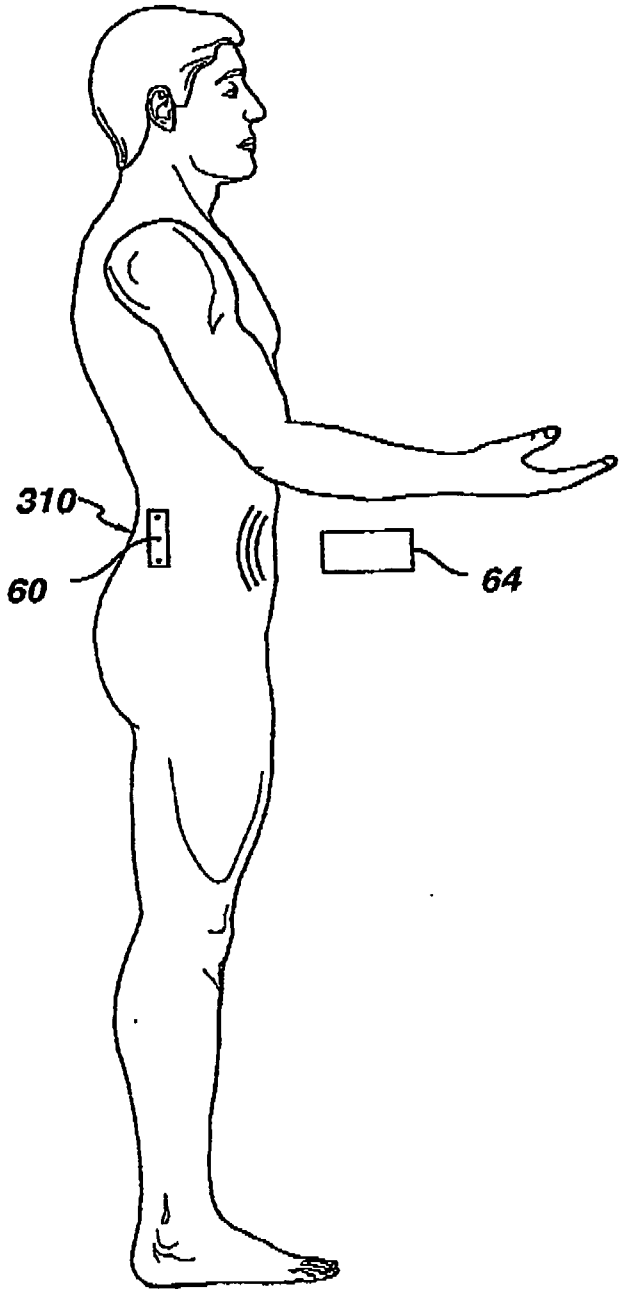


FIG. 5

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	带有传感器设计和附着方法的血管内移植物		
公开(公告)号	EP1511443A4	公开(公告)日	2009-07-08
申请号	EP2003757358	申请日	2003-06-06
[标]申请(专利权)人(译)	血管内TECH		
申请(专利权)人(译)	血管内TECHNOLOGIES，INC.		
当前申请(专利权)人(译)	血管内TECHNOLOGIES，INC.		
[标]发明人	BROWN PETER S LEMERE MARK T BARKMAN KIMBERLY KOVAC TIM		
发明人	BROWN, PETER, S. LEMERE, MARK, T. BARKMAN, KIMBERLY KOVAC, TIM		
IPC分类号	A61B5/00 A61F2/02 A61F2/06 A61F2/00 A61B5/103		
CPC分类号	A61B5/076 A61B5/0028 A61B5/0031 A61B5/02007 A61B5/02014 A61B7/001 A61B2560/0219 A61F2/07 A61F2002/065 A61F2002/067 A61F2250/0002		
优先权	10/165763 2002-06-07 US		
其他公开文献	EP1511443B1 EP1511443A1		
外部链接	Espacenet		

摘要(译)

一种血管内移植物，其具有附接到其上的传感装置，以便于测量移植物植入其中的脉管系统内的相关参数。电源和发射器可以连接到移植物上，以便于将测量结果传输到患者体外的接收装置。传感装置可以是具有测量和传输能力的电无源或集成装置。传感装置可以附接到移植物材料上的特定位置或附接到腔，从而从脉管系统内的关键点提供相关参数，或者可以分散在移植物材料的表面上或腔内，以提供轮廓。相关参数。可以使用运行针脚通过一次缝合将感测装置附接到移植物材料以使移植物体积最小化并且可以用材料涂覆以抑制或控制组织生长。

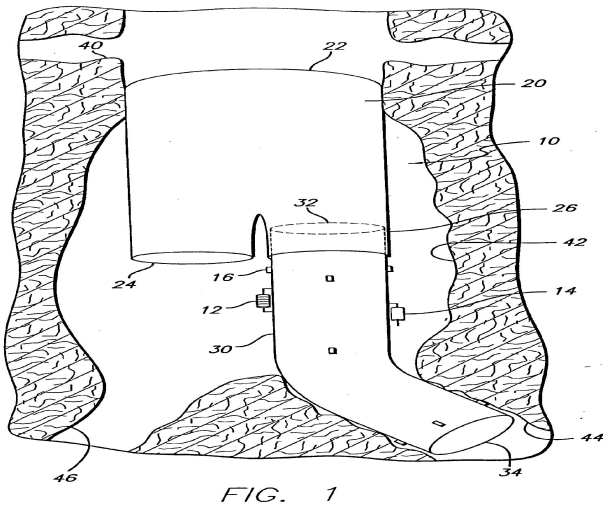

FIG. 1