Title: NON-OCCLUSIVE VASCULAR BYPASS SURGICAL METHODS AND INSTRUMENTS

Abstract: The present invention includes non-occlusive vascular bypass methods that can be accomplished in either an open or a laparoscopic setting. The inventive methods of vascular bypass surgery involve implanting a novel graft prosthesis in a patient, while not occluding the patient’s blood vessel, or at least one of either the donor or recipient vessels, depending on the particular bypass surgery. The novel graft section is attached as desired at both its ends, one or two vessel wall pieces are sectioned while retained with a novel vessel wall grasping means, also provided, sectioned with the excimer laser, circular scalpel, aortic punch or some other suitable means, and removed with the grasping means.
NON-OCCUSIVE VASCULAR BYPASS SURGICAL METHODS AND INSTRUMENTS

Related Application

This application claims the benefit of U.S. Provisional Application Serial No. 60/151,646 filed August 31, 1999, the entire disclosure of which is incorporated by reference herein.

Field of the Invention

The present invention pertains generally to methods for vascular bypass surgery and related apparatuses for accomplishing the same. More particularly, the invention includes methods for accomplishing a vascular bypass surgery, either by an open procedure or through a less-invasive laparoscopic approach. Either method is fully achievable without clamping and occluding the blood vessel or vessels, depending on the bypass surgery, to secure and implant the novel graft lumen section, or prosthesis. The invention also relates to improved biocompatible graft lumen sections with one or two integral sidearms and optional graft extenders, a modified laser catheter device, and vessel wall grasping and sectioned vessel wall piece removal tools, necessary for accomplishing the surgical techniques.

Background of the Invention

Surgical methods for all types of vascular bypass surgery have traditionally been performed by making an open incision, or incisions, in the patient large enough for the surgical team to gain access and perform the procedure with hand instruments. These conventional open vascular bypass procedures involve clamping of the patient's blood vessel or vessels, and are well known for their significant post-operative morbidity and recovery times. Such surgeries involving clamping of one or two of the patient's blood vessels are unavailable to certain patients of advanced age or preexisting medical conditions.

Percutaneous transluminal balloon angioplasty and intravascular stenting have been rapidly developed and widely applied in recent years as less morbid alternatives to conventional open vascular bypass procedures. However, significant restenosis and complication
rates can occur in these endovascular methods. Open surgery continues to be the gold-standard definitive treatment of functionally significant arterial occlusive diseases and often serves as the optimal salvage treatment of failed endovascular procedures. Interruption of blood flow in both donor and recipient vessels has always been necessary in conventional bypass procedures. This maneuver always confers the inherent risk of significant tissue ischemia and other unfavorable physiologic effects.

Laparoscopic (or endoscopic, thorascopic, etc., hereinafter collectively referred to as "laparoscopic") surgical methods have advanced in many surgical fields, offering far less invasion of the patient's body, and corresponding shortened recovery periods and hospital stays. This equates to significantly reduced healthcare costs and the decrease of unsightly scars. Unfortunately, laparoscopic methods for vascular surgery have not advanced so far as in other fields.

Conventional open vascular bypass surgery, as well as any laparoscopic methods developed so far for vascular surgery, require clamping and occlusion of the blood vessel or vessels to be bypass operated on to prevent bleeding. This has the dramatic effect of making some surgeries completely unavailable to certain patients, due to the higher than allowable risk to the patient of temporarily stopping such blood flow. In addition, clamping has been known to cause adverse physiologic changes and even death to some patients. An example is in aorto-renal bypass surgery. Clamping of the aorta is known to cause patient morbidity and mortality, especially in the population of patients with suboptimal cardiovascular status. Also, in other surgeries, such as in brain surgeries, clamping of the blood vessels causes dangerous extended ischemic periods.

U.S. Patent Nos. 5,211,683; 5,304,220 and 5,452,733 all describe methods of different types of vascular surgery where clamping of the blood vessels operated on is a necessary means to stop any bleeding while the bypass operation takes place. U.S. Patent Nos. 5,330,490 and 5,634,941 describe vascular graft apparatus to be inserted inside a diseased blood vessel, or to be used in connection with a typical bypass operation. Clamping of the vessels is necessary for their insertion and attachment.

Laparoscopic methods found in the literature for vascular surgery have all required blood vessel clamping, similar to the traditional open surgical methods. The following articles all


All of the surgical methods described above require open surgical methods and/or clamping of the blood vessel or vessels.

30 **Summary of the Present Invention**

The present invention overcomes these and other disadvantages of the prior art, while providing novel methods that can be adapted for nearly all types of vascular bypass surgeries in both the open and in the laparoscopic settings. In addition, novel graft prostheses and extenders are provided, as well as a novel laser catheter device for performing the procedures using either laparoscopy or open surgical methods. Vessel wall section grasping and wall piece removal tools are also provided.

The present invention relates generally to novel, non-occlusive
vascular bypass methods in either an open or a laparoscopic setting. Both inventive methods of vascular bypass surgery involve implanting a graft prosthesis in a patient, while not occluding the patient’s blood vessel, or at least one of either the donor or recipient vessels, depending on the particular bypass surgery (for example, certain bypass surgeries may require an end-to-end anastomosis, thereby requiring clamping at that vessel, because of the size of either the donor or recipient vessel in such vascular bypass surgeries involving both a donor and a recipient vessel). Access is gained to a patient, either laparoscopically or in an open surgical setting, a graft section is attached as desired at both its ends, one or two vessel wall pieces are retained with the vessel wall grasping means, sectioned with the excimer laser, circular scalpel, aortic punch or some other suitable means, and removed with the grasping means. Details of the operation of the tools and surgical procedures are found below.

Two important needs are met by the methods described above:

1. The conventional open vascular bypass procedures involving occluding the blood vessel or vessels are well known for their significant postoperative morbidity and recovery time, which increase patient hospital stay and health care costs. Laparoscopy, or a similarly performed open surgery wherein the blood vessel or vessels are not occluded, would be able to reduce the significance of these variables in a clinical setting.

2. The conventional open vascular bypass requires occlusion of donor vessel blood flow to prevent bleeding. The avoidance of clamping of donor (or recipient, or same) blood vessel (thus, no interruption of blood flow) in performing the novel vascular technique helps to avoid the adverse physiologic changes that occur as a consequence of clamping. For example, this method can be used in aorta-renal artery bypass without the need for clamping aorta. (Clamping of aorta is known to produce physiologic responses resulting in patient morbidity and mortality, especially in the population of patients with suboptimal cardiovascular status).

Existing laser catheters in the market are different from that described in the device/method proposed above (use of annular balloons, typically saline filled, to prevent bleeding, everted tipped laser for optimal circular hole cut in vessel wall, etc.). Also, no vessel wall traction grasping and removing devices, similar to those described above, are known to exist in the market or
literature.

The role of laparoscopy in vascular surgery has been virtually nonexistent, and only a few anecdotal cases (a total of less than 10) exist in the literature (see articles mentioned above). All the 5 cases described were performed with the conventional vascular surgical method - including clamping of the donor vessel. The method(s) proposed will be the first laparoscopic bypass that does not require interruption of donor (or recipient, or same) vessel blood flow, which is highly desirable, especially in cases involving 10 important vessels such as aorta and inferior vena cava.

In the literature, vessel wall tunneling with excimer laser has been performed by only one group of investigators - the Tullekin Group in the Netherlands (see articles mentioned above). Their technique, first described more than five years ago, has been used only in a small number of carotid artery surgery in open surgical setting. The proposed method/materials here differ from those of the Dutch group in several important and novel aspects:

(1) The proposed method can be laparoscopic/endoscopic in nature; not in an open surgical setting (though could be performed in the open surgical manner as well).

(2) The attachment of the graft to donor and recipient vessel surface (before wall tunneling) is performed with laparoscopic techniques (such as EndoStitch or VCS device - U.S. Surgical or hand suturing) optionally followed by reinforcement with fibrin glue (to prevent blood leakage). It is not done by the traditional surgical suturing.

(3) The proposed method can be used in most vessel types inside a body cavity, especially in the abdominal cavity where most laparoscopic/endoscopic procedures are performed. The Dutch method was entirely restricted to carotid arteries.

(4) The proposed method allows end-to-side anastomosis between graft and donor vessel as well as between graft and recipient vessel (or in a regular bypass operation in the same blood vessel). The Dutch method was restricted to end-to-side anastomosis on only one end of the interposition venous graft.

(5) The laser catheter proposed has special everted fiber ends to allow smooth transition at vascular anastomotic site, an intraluminal lumen to accommodate a vessel wall removing/grasping device (to avoid embolization by the vessel wall piece after laser circumferential ablation), and a balloon on its exterior surface or sheath to prevent
back bleeding. These features of the excimer laser use are different from those of the Dutch group.

(6) The grafts proposed are synthetic with two (or one) pre-made side arms (possibly made of Gore-Tex, a registered trademark of W.L. Gore and Associates, or of another synthetic biocompatible material), which are different from the venous (human/animal tissue from other parts of that human/animal) interposition grafts with hand-sewn modification used by the Dutch group. Of course, the graft sections can be fabricated on the bench from sewn, straight, tubular materials.

(7) All the devices used in this proposal are specially designed to be able to pass through laparoscopic trocars, such as a trocar of approximately 10 mm in diameter.

Brief Description of the Drawings

FIGs. 1A and 1B are partial side views of the laser catheter device of the present invention with a deflated and an inflated external mounted balloon, respectively.

FIGs. 1C and 1D are enlarged end and side views, respectively of the laser catheter device of FIGs. 1A and 1B.

FIGs. 2A and 2B are partial side views of an alternative embodiment of the inventive laser catheter device.

FIG. 3A - 3C illustrate an inventive embodiment of a vessel wall remover according to the present invention.

FIGs. 3D - 3E illustrate an alternative embodiment of a portion of the FIGs. 3A - 3C embodiment.

FIGs. 4A - 4C illustrate an optional exterior mounted balloon deflated, inflated and within a central lumen of an inventive laser catheter, for the vessel wall removal tool of the present invention, respectively.

FIGs. 5A - 5C illustrate an optional inventive obturator for the vessel wall removal tool of the present invention.

FIGs. 6A - 6C illustrate an optional sheath mount configuration for the vessel wall removal tool of the present invention with an external mounted balloon in a deflated, inflated and inflated within a laser catheter device position, respectively, according to the present invention.

FIGs. 7A - 7E illustrate an optional vessel wall grasper tool according to the present invention.
FIG. 8 illustrates a single sidearm embodiment of a novel graft prosthesis according to the present invention.

FIG. 9 illustrates a double sidearm embodiment of a novel graft prosthesis according to the present invention.

FIGS. 10A - 10D illustrate two graft extender embodiments according to the present invention.

FIGS. 11A - 11I illustrate a surgical method according to the present invention.

FIGS. 12A - 12H illustrate an additional embodiment of a surgical method according to the present invention.

FIGS. 13A - 13D illustrate another embodiment depicting a laparoscopic version of an inventive vascular bypass surgical method.

**Detailed Description**

Referring now to the figures, which are for purposes of illustrating the present invention and not for limiting same, FIGS. 1A - 1D depict the novel end section of a vessel wall tunneling device, in this case an excimer laser catheter device, in accordance with an embodiment and the principles of the present invention, shown generally at 10. As will be further explained below, a circular scalpel or an aortic punch device, modified to punch out a circular section of a vessel wall in one stroke, each having a central lumen are also possible vessel wall tunneling means contemplated within the scope of the present invention (neither is shown). The details of its use in the inventive vascular bypass surgical methods will be further explained below.

Excimer lasers are pulsed lasers operating in the ultraviolet range of the electromagnetic spectrum. They are different from other types of medical lasers in that tissue ablation occurs through photodecomposition with high precision and without tissue thermal injury.

The excimer laser catheter device 10 of the present invention has an exteriorly mounted balloon 12 mounted near the end 14 of the laser catheter device 10. In Fig. 1A the balloon is shown deflated. In Fig. 1B, the balloon is shown inflated such as with saline solution to prevent back-bleeding within a graft lumen that is already attached at an end to a blood vessel wall (an anastomotic site as will be described below). Figs. 1C and 1D show an enlarged view of the end 14 of the laser catheter device 10. A single
circumferential, or annular, row, or ring, of laser fibers 18 (Fig. 1D) or a plurality of such rows of laser fibers 18 (two rows shown in Fig. 1C) are provided. In a preferred embodiment, the laser fibers 18 are everted near end 14 such as in region A as shown in Fig. 1D. The everted tips of the laser fibers 18 will provide a cleaner, fuller ablated out section of vessel wall, as will be described more fully infra. The laser catheter device 10 has a central lumen 16 to facilitate the surgical techniques, as also described infra.

In an alternative embodiment depicted in Figs. 2A and 2B, the laser catheter device 10 is carried inside a flexible sheath 20, which sheath 20 would allow the laser catheter 10 to slide through its lumen 22. Similarly, a balloon 12 is mounted exteriorly to the flexible sheath 20 to help prevent back-bleeding during the vascular bypass graft section through which the laser catheter and sheath are inserted, as will be described below. Figure 2A shows the balloon 12 inflated whereas balloon 12 is deflated in the Fig. 2B depiction.

Other possible versions of the laser catheter device 10 that are contemplated as within the scope of the present invention include one without an everted tip (not shown) and one with an elliptical projecting angled end (not shown) to make such elliptical ablations on a blood vessel wall and corresponding angled anastomoses of a tubular graft section with the blood vessel. A suitable non-everted tipped excimer laser can be a Spectranetics excimer laser catheter (Model 500-012, Spectranetics, Colorado Springs, CO) with a tip outer diameter of 14.5 Fr, tip inner diameter of 10.2 Fr. full length (40 cm) central lumen and 1-row of 101 peripheral laser fibers (diameter: 100 microns, depth penetration: 0.05 mm/pulse); capable of delivering 40 pulses/sec. with 200 nsec/pulse duration and providing energy of 60 mili-Joules/mm²). Of course, either of these embodiments would preferably have either an exteriorly mounted balloon mounted near their respective ends (similar to Figs. 1A and 1B) or would be carried within a sheath which could have an exteriorly mounted balloon (similar to Figs. 2A and 2B).

Any of the inventive embodiments of the laser catheter device could be used in either an open or a laparoscopic vascular bypass surgical setting, as will be more fully explained below. In any case, the laser fibers will ablate the blood vessel wall that comes in contact in a circumferential manner, which results in a circular (or elliptical, in the case of the angled version) vessel wall tunnel and a circular (or elliptical) piece of vessel wall that must be
removed to prevent embolization.

With any of the above-described instruments, there is an intact circular vessel wall piece centered at the end 14 of the laser catheter 10 (or other central lumen in the case of a circular scalpel 5 or aortic punch device) after laser ablation (or other sectioning means, such as by the circular scalpel or the punch device described above) that is removed by a grasper device, such as 40 in Figs. 3A through 7E. Of course, the grasping tool 40 is in place within the central lumen 16 of the laser catheter device 10 while the vessel wall piece is being sectioned, to prevent embolization of the removed wall piece.

A blood vessel wall removing device 40 can have different features. Others skilled in the art may determine another suitable way to grasp and retain the vessel wall piece to be ablated or otherwise sectioned against the sectioning means, such as the end 14 of the excimer laser catheter device 10 (Fig 7E, e.g.), in addition to those described below. Any such means are contemplated as within the scope of the present invention. In one embodiment, this grasping device 40 is as shown in Figures 3A-C. A hollow needle 41 having a central lumen 42 is provided within the central lumen 16 of the laser catheter device 10 to penetrate the blood vessel wall, after which aspiration of blood through this needle can confirm its proper intravascular position. Any such needle and corresponding aspiration of blood can be used as a first step to confirm the intravascular position for the insertion of a wall tractioning and wall piece removal tool 44. After confirmation of the intravascular position of the needle 41 tip 45, the wall piece removal and grasping tool is moved forwardly (see directional arrow in Fig. 3B) from within the central lumen 42 of the needle 41 (Fig. 3B). In one embodiment, as depicted in Figs. 3B-3C, one or more (three are shown) self-expanding hooks (such as spring hooks) 46 are provided. One or more barbed or barbless hooks 46 is passed through the needle 41, behind the vessel wall 100 to grasp the intravascular surface 104 of the vessel wall piece to be. After opening of the self-expanding hooks 46 and upon slight retraction of the wall tractioning and wall piece removal tool 44, hooks 46 contact the interior surface 104 of the blood vessel wall 100. This is to ensure the vessel wall piece to be sectioned has its exterior surface 102 in good contact with the end 14 of the excimer laser catheter device 10 (Figs. 1A-2B and Fig. 4C) or other sectioning means, such as circular scalpel or modified aortic punch
device discussed supra.

As can be seen in Figs. 3D and 3E, the needle 41 can inserted with a novel triggering, or firing, means to ensure penetration of a blood vessel wall, while at the same time not punching through the vessel entirely. In Fig. 3D, needle 40' is depicted in its loaded state, with tip 48 substantially contacting the exterior surface 102 of the target blood vessel 100. The triggering mechanism may be a simple spring operated mechanism with a very short throw length, just enough to ensure satisfactory penetration of a vessel wall without penetrating completely through the target vessel to be operated on. In Fig. 3E, the needle tip 48 is depicted as already fired and through vessel wall 100 into its intravascular position.

Optionally, but preferably, an embodiment of vessel wall removing device 40 includes a centering balloon 43 located near distal end 45 of needle 41, as shown in Figs. 4A-4C. The inflatable balloon 43 can be mounted on the exterior of the distal end 45 of the needle 41. The balloon is helpful to prevent bleeding through the lumen 16 of the laser catheter (see Figure 4A-4C). A deflated balloon 43 is shown mounted directly to the needle 41 near its distal end 45 in Fig. 4A. In Fig. 4B, the balloon 43 is shown inflated. In Fig. 4C, the inflated balloon 43 surrounding the needle 41 is shown inside the central lumen 16 of a laser catheter device 10.

The vessel wall piece is removed after laser catheter tunneling (or sectioning via the circular scalpel or punching via the aortic punch) is completed. The removal of this circular vessel wall piece is essential to prevent embolization phenomenon. This vessel wall removing device 40 can be built within the laser catheter device 10 or can be mounted inside the lumen 16 of the laser catheter device 10 as a separate entity, in which case it can be positioned appropriately inside the catheter lumen 16 with the inflatable balloon 43 to ensure its central positioning (see Figure 4A-4C) and to prevent bleeding through the central lumen 16 of the laser catheter device 10, as described above.

Figures 5 - 5B illustrate an optional obturator 47 that can be used with wall removal tool 40 to help pierce the vessel wall (such as 100 in Fig. 3A) in the embodiment of wall piece removal tool 40 shown in Figs. 3A-3C without the triggering mechanism. The obturator has a tapered, or pointed, tip 49 mounted on a thin wire. It is simply inserted though the central lumen 42 of the hollow needle 41 to ensure the vessel wall is pierced. It is then removed from the
needle 41. The hook grasper, or other means (such as the balloon tool 60 with balloon 62, described below) is then inserted through hollow needle 41 to function as above-described.

As illustrated in Figs. 6A-6C, the balloon 43 can be optionally mounted on a flexible sheath 50 covering the needle 41 (similar to the concept depicted for the laser catheter device 10 in Figs. 2A-2B and described above). The sheath 50 would allow the needle 41 to slide through the lumen 52 of the sheath 50. Again, the balloon 43 would be useful for centering the needle 41 within the lumen 16 of the laser catheter 10, and helpful to prevent back-bleeding through the lumen 16 of the laser catheter device 10.

Figures 7A - 7E illustrate alternate means for removing the vessel wall piece that was ablated. Instead of spring type self-expanding hooks (46 in Figs. 3B and 3C), a simple inflatable balloon vessel wall grasping and removal device 60 is provided within vessel wall removal device 40'. A similar hollow needle 41 is first (again, preferably inflatable with saline solution to help prevent embolization in the event of balloon 62 puncture) pierced through vessel wall 100 (Fig. 7A). Next vessel wall grasping and removal device 60 is inserted through hollow needle 41 such that balloon 62 is in an intravascular position behind vessel interior wall 104 (Figs. 7B and 7C). The balloon 62 is then inflated (Fig. 7D). When it is slightly retracted (as in Fig. 7E) the vessel wall section to be ablated, or otherwise sectioned, comes into good contact with the everted tipped excimer laser catheter 10. Upon ablation, the vessel wall section is simply removed along with the laser catheter device 10 and the wall removal tool 40' with the balloon 62 still inflated.

Alternative means for vessel wall grasping and removal, such as vacuum suction similar to that described by some of the Tulleken articles above, are similarly contemplated and within the spirit of this invention.

Special synthetic graft prostheses with one or two integral side arms (110, 120 in Figs. 8 and 9, respectively) and optional graft extenders 131, 132 are provided (Figs. 10A - 10D). Each side arm 114, 126 and 128 allows passage via openings 116, 127 and 129, respectively, of the vessel wall-tunneling and removal devices described above to come in contact with the blood vessel wall surface to allow vessel wall tunneling, as will be more fully described infra. The single side arm graft 110 is used if either the donor or the recipient vessel is of a small diameter that does not allow wall-
tunneling, in which case an end-to-end anastomosis is performed between the graft (the end without side arm) and the small vessel (the transected end that must be temporarily occluded such as with a clamp). If both the donor and recipient vessels (or the single vessel) are of sufficient diameter to allow wall-tunneling, then a double side arm device 120 can be used to allow wall-tunneling on both vessels with end-to-side anastomoses.

In either case, the distance between the two vessels to be connected can be accommodated either by using grafts 110, 120 or desired pre-made lengths or with the addition of the graft extenders 131, 132 for graft sections 110 and 120 (Figs. 10A-10D). The graft - graft extender anastomosis can be augmented with a single or a double ring-groove mechanism 134, 136, respectively, shown in 10B and 10D, respectively, to ensure fit and simplify installation.

An alternate version of the double sidearm graft prostheses 120' is shown in Figure 9B, and contemplated for normal or routine bypass operations within a single blood vessel due to blockage 121 of blood flow 123, weakening, disease and the like. These graft sections 110, 120, 120' are preferably a single piece and are conceived to come in a variety of sizes for different surgical uses and locations. The grafts 110, 120, 120' and extenders 130, 140 are made of biocompatible materials, such as extended polytetrafluoroethylene (ePTFE) or Goretex® (W.L. Gore and Associates - Flagstaff, AZ). Optionally, a graft prosthesis according to the present invention can be manufactured on the bench from straight tubular biocompatible graft material stock and hand-sewn (or otherwise attached) sidearms.

Although described with reference to certain preferred and alternate embodiments, certain modifications and variations of the general principles of the invention which may be apparent to those of skill in the art are all within the scope of the invention as defined by the accompanying claims and equivalents thereto. These methods and devices are contemplated to be available for nearly any vascular surgery in people or animals.

Laparoscopic Or Open Bypass Procedure Involving a Donor and a Recipient Vessel

1) If both donor and recipient vessels DV, RV, respectively, (the method described herein presumes such a bypass technique as an
aortorenal procedure where there exists a donor and a recipient blood vessel, otherwise a modified graft section can be used as shown in Figure 9B, for normal bypass operations within a single blood vessel following the technique described below, similarly) are of sufficient diameter to allow vessel wall tunneling or sectioning, the following technique may be used:

After gaining surgical access, whether via open or laparoscopic techniques, via preparation (not shown), including anesthesia, site preparation, surgical incisions, such as for the placement of laparoscopic devices/instruments, such as trocars for access, cameras, etc., placement of those devices/instruments into the patient, and passing a graft section through a trocar--such as a 10 mm trocar:

(A) Referring now to Fig. 11A, attach the two respective open ends (such as 122, 124 in Fig. 9) of a synthetic graft 120 with two side arms 126, 128 to the exterior surface of both blood vessels DV, RV with laparoscopic techniques (to make the anastomoses as at 200). Suitable laparoscopic techniques include, but are not meant to be limited to, means such as by free-needle suturing, Endostitch - U.S. Surgical, VCS vascular clip application device - U.S. Surgical, or a combination thereof. Additionally, Fibrin glue, which is a mixture of fibrinogen and plasminogen and is widely known to the vascular surgical community, can be optionally used to seal the anastomotic sites and facilitate good endothelialization.

(B) Referring now to Fig. 11B, pass a vessel wall-tunneling device, such as laser catheter device 10 (with or without a catheter and or one or more balloons to prevent back-bleeding -- balloon, such as 12, not shown in Fig. 11B) through the side arm 126 closer to the donor vessel DV and create a tunnel; based on the modified excimer laser catheter 10 described above (or using an aortic punch-like tool, or using a circular scalpel).

Next, the following steps need to be performed (see Fig. 11C):

(1) Place the laser catheter end 14 with laser fibers 18 and wall grasper 40 next to the target vessel surface 102, (2) inflate the balloon 12 outside the laser catheter 10 to occlude the space between the graft 120 and the catheter 10, (3) referring now to Fig. 11D, penetrate the vessel wall 100 into intravascular space with the hollow needle 41 of the vessel wall grasping device 40, (4) aspirate through the needle with a syringe extracorporeally--presence of blood confirms intravascular position of the needle 41 tip 48, (5)
referring now to Fig. 11E, pass an expandable hook device 44 (or optional balloon grasper such as 60 -- see Figs. 7A-7E) through the needle 41 into vessel lumen, behind the circular wall piece to be removed after wall-tunneling, and secure the wall piece from the interior surface 104 of the blood vessel with the hooks 46 (see Fig. 11F), (6) fire laser fibers 18 to ablate and tunnel the vessel wall 100 in direct contact with the fibers 18 (or cut or punch the vessel wall), (7) referring now to Fig. 11G, advance laser catheter 10 slowly and penetrate the full thickness of vessel wall 100 (Note: traction exerted by the hook(s) 46 pressing the vessel wall 100 into contact with the laser fibers 18 also helps to allow full penetration of vessel wall 100), (8) remove the circular wall piece 106 with vessel wall grasping device 44 and hooks 46 after full penetration of vessel wall 100 in a circular fashion by laser catheter 10 -- the vessel wall piece, grasping device, and laser catheter (or circular scalpel or aortic punch) can all be removed together through the side arm 126 of the graft 120, and (9) clamp with clamps 140 the graft side arm 126 used and the graft lumen 120 distal to the side arm 126 to prevent bleeding. Note: if force is encountered during attempted removal, the wall piece may be partially attached. The laser should be rotated slightly (in case some fibers are not working properly) and the tissue ablated again, until easy retraction of the vessel wall piece 106 occurs. Note also: the grasping means disclosed are just the preferred embodiments -- alternate means such as the suction method described in the above-mentioned Tulleken articles could also be used, as could others and still be within this invention.

(C) Remove the wall-tunneling device from the side arm - after which the side arm and the graft lumen distal to the side arm are occluded with a vascular clamp device 140, such as bulldogs, (the sidearm 126 can be transected and sewn shut or otherwise permanently sealed after confirmation of a good anastomosis by known methods, including suturing, Endostitch, laparoscopic EndoGIA stapler, etc.).

(D) Repeat the same steps (B and C above) for the recipient vessel (RV) to graft 120 anastomosis -- the other opposing graft side arm (such as 128 -- Fig. 11A) that is closer to the recipient vessel RV is used for passage of tunneling devices 10 for this series of steps.

(E) Remove the temporary occlusion device 140 on the synthetic graft lumen, which allows free communication between the donor and the recipient blood vessels through the graft.
2) If one of the 2 vessels involved (donor or recipient) is of insufficient diameter to allow vessel wall tunneling, then a single-arm graft (such as 110 in Fig. 8) is used, and an end-to-end anastomosis will be performed between the small vessel (with its transected end requiring temporary clamping) and the graft 110 (the end without the side arm). The tunneling of the larger vessel wall with the formation of end-to-side anastomosis is the same as that described above in (1).

10 Laparoscopic Or Open Bypass Procedure Involving an Occlusion in a Single Vessel

Whether in an open (Figs. 12A-H) or in a laparoscopic setting (Figs. 13 A-D), the method for conducting a bypass operation for an occlusion or otherwise defective section of a blood vessel, is substantially the same as that described above for bypass operations involving a donor and a recipient blood vessel. After gaining surgical access, whether via open (Figs. 12A-H) or laparoscopic (Figs. 13A-D) techniques, via preparation (not shown), including anesthesia, site preparation, surgical incisions, such as for the placement of laparoscopic devices/instruments through the abdominal wall W of the patient (see Fig. 13B-D), such as trocars 150 for access, cameras, etc., placement of those devices/instruments into the patient, and passing a graft section, such as graft 120', through a trocar 150 -- such as a 10 mm trocar:

(A) Referring now to Figs. 12A, 12H and shown connected in 13 B, attach the two respective open ends (such as 122', 124' in Fig. 9B) of a synthetic graft 120' with two side arms 126', 128' to the exterior surface of the blood vessel on opposite sides of the occlusion or blockage 121. Optional biocompatible rings 151 can be used to ensure graft section open ends 122', 124' remain open and circular for attachment (Fig. 12A). Either laparoscopic techniques, as described above, or open techniques including those described above and otherwise known in the art, can be used to make the anastomoses 200.

(B) Steps (B) through (E) from above are essentially repeated, as needed, whether in the open or the laparoscopic setting.

(F) Optionally, bulldog clamp the vessel on opposite sides of the blockage 121 with clamps 140 (see Fig. 9B). The blockage may then be transected and the cut ends suture ligated or otherwise
permanently sealed as described above (not shown).

(G) Remove the temporary occlusion device, such as bulldog clamps 140 on the vessel.
CLAIMS

We claim:

1. A method for vascular bypass surgery within a body comprising the steps of:
   a) making one or more incisions in a patient to gain surgical access for the bypass surgery;
   b) providing a novel tubular graft prosthesis having a central lumen between an open proximal end and an open distal end, a first tubular side arm adjacent said proximal end and a second tubular sidearm adjacent said distal end;
   c) placing the tubular graft prosthesis such that said proximal end is in contacting relation with the exterior of a side-wall of a first blood vessel location where desired and such that said distal end is in close proximity to a side wall of a second blood vessel location where desired;
   d) affixing said proximal end of said graft prosthesis to the side-wall of the first blood vessel location thereby making an end-to-side anastomosis;
   e) temporarily occluding said graft prosthesis central lumen approximately mid-way between said proximal and distal ends and between said side-arms;
   f) inserting a sectioning means having a central lumen through said side arm adjacent said proximal end and inserting a vessel wall securing and removing means through said central lumen of said sectioning means;
   g) securing the vessel wall at the first blood vessel location with the vessel wall securing and removing means such that an end of the sectioning means is substantially held adjacent to a first vessel wall piece to be sectioned;
   h) sectioning the first vessel wall piece still secured by said vessel wall securing and removing means;
   i) removing said sectioning means and said vessel wall securing and removing means with the sectioned first vessel wall piece secured thereto;
   j) quickly and permanently occluding said side-arm adjacent said proximal end;
   k) affixing said distal end of said graft lumen section to the side-wall of the second blood vessel location thereby making an end-to-side anastomosis;
1) inserting a sectioning means having a central lumen through said side arm adjacent said distal end and inserting a vessel wall securing and removing means through said central lumen of said sectioning means;

m) securing the vessel wall at the second blood vessel location with the vessel wall securing and removing means such that an end of the sectioning means is substantially held adjacent to a second vessel wall piece to be sectioned;

n) sectioning the second vessel wall piece still secured by said vessel wall securing and removing means;

o) removing said sectioning means and said vessel wall securing and removing means with the sectioned second vessel wall piece secured thereto;

p) quickly and permanently occluding said side-arm closely adjacent said distal end; and

q) removing said temporary occluding means to allow bypass blood flow through said graft lumen section from the first blood vessel location to the second blood vessel location.

2. The method of vascular bypass surgery of claim 1 that is accomplished wholly by laparoscopic, endoscopic, thoracoscopic, or the like, means.

3. The method of vascular bypass surgery of claim 1 wherein the step of inserting a vessel wall securing and removing means through said central lumen of said sectioning means further comprises the steps of:

a) positioning said vessel wall securing and removing means such that an end having a hollow needle tip is substantially coincident with an end of the sectioning means proximate the vessel wall and centered within said central lumen of said sectioning means;

and

b) inflating a balloon attached around a flexible sheath that surrounds said vessel wall securing and removing means inside said central lumen of said sectioning means and adjacent said end of the sectioning means proximate the vessel wall to prevent back-bleeding.

4. The method of vascular bypass surgery of claim 1 wherein the vessel wall securing and removing means comprises a hollow needle device having a hollow rigid pointed tip for penetrating the vessel wall and a hook device for securing the vessel wall piece to be sectioned that can be moved fore and aft along the length and out the
tip of the hollow needle.

5. The method of vascular bypass surgery of claim 1 wherein the vessel wall securing and removing means comprises a hollow needle device having a hollow rigid pointed tip for penetrating the vessel wall and a balloon device for securing the vessel wall piece to be sectioned that can be moved fore and aft along the length and out the tip of the hollow needle.

6. The method of claim 1 further comprising the steps of:
   a) slowly extending a hollow needle device having a hollow rigid pointed tip from within a flexible sheath surrounding said vessel wall securing and removing means into the blood vessel, while simultaneously aspirating blood from the needle to confirm the desired intravascular position of said needle tip;
   b) extending a vessel wall entrapment device through said hollow needle into the intravascular space;
   c) slightly withdrawing said vessel wall entrapment device such that it contacts and holds the vessel wall piece to be sectioned against said end of said sectioning means.

7. The method of claim 6 wherein said vessel wall entrapment device has at least one self-expandable hook.

8. The method of claim 6 wherein said vessel wall entrapment device comprises an inflatable balloon.

9. The method of claim 1 further comprising the steps of:
   a) rapidly extending a hollow needle device having a hollow rigid pointed tip a desired distance from within a sheath surrounding said vessel wall securing and removing means and into the blood vessel, using a triggering mechanism, such that the desired intravascular position of said needle tip is achieved;
   b) extending a vessel wall entrapment device through said hollow needle into the intravascular space;
   c) slightly withdrawing said vessel wall entrapment device such that it contacts and holds the vessel wall piece to be sectioned against said end of said sectioning means.

10. An excimer laser catheter device for use in performing controlled vessel wall tunneling or tissue ablation in vascular surgery or the like, comprising:
   a) an elongate catheter, substantially in the form of a hollow tube having an inner and an outer wall, and having an open proximal lasing end and a distal control end;
   b) one or more rows of laser fibers circumferentially
disposed around said inner wall such that a hollow center, or central lumen, for passing other medical instruments is maintained, said laser fibers each having an everted tip substantially terminating at and coincident with said open lasing end; and

5 c) means for lasing controlled pulses of energy through said laser fibers to said everted tips to tunnel or ablate vessel wall tissue or the like, said means for lasing electronically connected to said distal control end.

11. The excimer laser catheter device of claim 10 having an external flexible tubular sheath substantially encasing said excimer laser catheter device along the length of said elongate catheter substantially from said open proximal lasing end to said distal control end.

12. The excimer laser catheter device of claim 11 wherein said flexible sheath has an externally mounted and circumferentially disposed balloon attached thereto closely adjacent said proximal lasing end to provide a seal against bleeding upon inflation; said balloon having a means for controlled inflation and deflation, using sterile saline solution or the like, connected thereto.

13. The excimer laser catheter device of claim 10 designed and adapted to be used in laparoscopic surgical procedures, and the like, wherein said elongate catheter can be either flexible, bent, angled or radiused to allow said lasing end to be positioned circumferentially flush against the vessel wall tissue to be tunneled or ablated.

14. The excimer laser catheter device of claim 10 wherein said open lasing end is angled such that when held flush against a blood vessel's side-wall to tunnel or ablate a section therefrom, an elliptical, or oblong, piece will be removed.

15. A flexible, biocompatible and substantially tubular graft prosthesis sized and adapted for use in vascular bypass surgery comprising:

an open proximal end,

an open distal end,

a central lumen section for passing blood or the like,

a first substantially tubular integral sidearm adjacent said proximal end, and

a second substantially tubular integral sidearm closely adjacent said distal end,
said sidearms each having a substantially circular open end and an end opposite said circular open end that is integral with and open to said central lumen section for passing medical instruments and the like therethrough.

16. The graft prosthesis of claim 15 made of expanded polytetrafluoroethylene.

17. The graft prosthesis of claim 15 designed and adapted for use in a laparoscopic surgical procedure, or the like, said graft prosthesis able to be inserted into a patient’s body through a 10mm surgical trocar.

18. A flexible, biocompatible and substantially tubular graft prosthesis sized and adapted for use in vascular bypass surgery comprising:
   an open proximal end;
   an open distal end;
   a central lumen section for passing blood or the like;
   a substantially tubular integral sidearm adjacent said proximal end;
said sidearm having a substantially circular open end and an end opposite said circular open end that is integral with and open to said central lumen section for passing medical instruments and the like therethrough.

19. A vessel wall securing and removing means for use in vascular bypass surgery, comprising:
   an elongate hollow needle having a central lumen, an open pointed end for penetrating a blood vessel’s side-wall, or the like, and an open distal end for passing other instruments therethrough, said needle sized and adapted to fit within said central lumen of an excimer laser catheter designed for laparoscopically performing vascular bypass surgery;
   a flexible tubular sheath for loosely encasing said needle having an open sheath end, said sheath designed such that said needle can slidably extend and withdraw relative to said open sheath end, and from within said sheath;
   means for extending and withdrawing said needle relative to said sheath to penetrate a blood vessel’s wall, or the like, and locate said open pointed end in the blood vessel’s intravascular space;
   a doughnut shaped balloon, fixedly attached around said sheath and closely adjacent said open end;
means for inflating and deflating said balloon using sterile saline solution, or the like, to both position said elongate needle radially centered within a central lumen of another medical device and to prevent back bleeding between said needle and such other medical device; and a vessel wall securing means that can extend from said open pointed end into the intravascular space and, upon slight withdrawal of said needle and said vessel wall securing means, secure a section of vessel wall.

20. The vessel wall securing and removing means of claim 19 wherein the means for extending and withdrawing said needle relative to said sheath to penetrate a blood vessel's wall further comprises an aspiration means, to continually aspirate and check for the presence of blood to confirm the desired intravascular position of said tapered pointed end.

21. The vessel wall securing and removing means of claim 19 wherein the means for extending and withdrawing said needle relative to said sheath to penetrate a blood vessel's wall further comprises an obturator; said obturator having a sharp conical pointed end and a maximum diameter slightly less than the diameter of said open proximal tapered pointed end, such that said obturator effectively fills said pointed end thereby aiding in vessel wall penetration, said obturator designed to be removed once desired vessel wall penetration is confirmed.

22. The vessel wall securing and removing means of claim 19 wherein the means for extending and withdrawing said needle relative to said sheath to penetrate a blood vessel's wall comprises a triggering mechanism designed and adapted to force said open pointed end into the intravascular space of a blood vessel by penetrating such blood vessel's wall.

23. The vessel wall securing and removing means of claim 19 wherein said vessel wall securing means comprises a self-expandable, multi-pronged hook device and means for extending into the intravascular space.

24. The vessel wall securing and removing means of claim 19 wherein said vessel wall securing means comprises a vessel wall entrapment device having a deflated intravascular balloon at an end, means for inserting said deflated balloon through said hollow needle and extending into the intravascular space, and means for inflating said intravascular balloon, said intravascular balloon sized to
secure a circular area of vessel wall, that once inflated and slightly withdrawn, is less than such a vessel's cross-sectional area.

25. A method for vascular bypass surgery within a body comprising the steps of:
   a) making one or more incisions in a patient to gain surgical access for the bypass surgery;
   b) providing a novel tubular graft prosthesis having a central lumen between an open proximal end and an open distal end, and a tubular side arm adjacent said proximal end;
   c) placing the tubular graft prosthesis such that said proximal end is in contacting relation with the exterior of a sidewall of a first blood vessel where desired and such that said distal end is in close proximity to a transected end of a second blood vessel where desired;
   d) affixing said proximal end of said graft prosthesis to the side-wall of the first blood vessel thereby making an end-to-side anastomosis;
   e) temporarily occluding said graft prosthesis central lumen approximately mid-way between said proximal and distal ends;
   f) inserting a sectioning means having a central lumen through said side arm adjacent said proximal end and inserting a vessel wall securing and removing means through said central lumen of said sectioning means;
   g) securing the vessel wall at the first blood vessel with the vessel wall securing and removing means such that an end of the sectioning means is substantially held adjacent to a first vessel wall piece to be sectioned;
   h) sectioning the first vessel wall piece still secured by said vessel wall securing and removing means;
   i) removing said sectioning means and said vessel wall securing and removing means with the sectioned first vessel wall piece secured thereto;
   j) quickly and permanently occluding said side-arm adjacent said proximal end;
   k) affixing said distal end of said graft lumen section to the transected end of the second blood vessel thereby making an end-to-end anastomosis;
   l) removing said temporary occluding means to allow bypass blood flow through said graft lumen section from the first
blood vessel location to the second blood vessel location.