

[54] **GRAFT TUBES**

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[22] Filed: **June 18, 1973**

[21] Appl. No.: **370,861**

Related U.S. Application Data

[60] Continuation of Ser. No. 241,190, April 5, 1972,
abandoned, which is a division of Ser. No. 101,031,
Dec. 23, 1970, Pat. No. 3,710,777, said Ser. No.
241,190, Continuation-in-part of Ser. No. 175,914, is
a division of Ser. No. 823,287, May 9, 1969, Pat. No.
3,625,198, which is a continuation-in-part of Ser. No.
655,838, July 25, 1967, Pat. No. 3,514,791.

[52] **U.S. Cl.**..... **3/1, 3/DIG. 1**

[51] **Int. Cl.**..... **A61f 1/24**

[58] **Field of Search**..... **3/1, DIG. 1; 128/334 R,
128/334 C, 1 R**

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Assistant Examiner—Ronald L. Frinks

Attorney, Agent, or Firm—Lee R. Schermerhorn

[57] **ABSTRACT**

The invention is illustrated and described in connec-
tion with the growing of a femoro-popliteal artery
graft. A tunneling tube is inserted through an incision
above the inguinal ligament in the groin area adjacent
an upper portion of the femoral artery and thrust
downward subcutaneously through the thigh to a point
below the knee on the inner or medial side of the leg
adjacent a lower portion of the popliteal artery. A
flexible silicone mandrel assembly having two layers of
knitted Dacron on a flexible silicone rod is inserted in
the tunneling tube. Then the tunneling tube is re-
moved and the incision closed. The patient resumes
his normal activity for a number of weeks during
which time an ingrowth of connective tissue incorpo-
rates itself in the Dacron mesh, making an autogenous
artery graft grown in the place where it is to be used.

In a second operation, a new incision is made below
the inguinal ligament to expose the upper end of the
graft tube containing the mandrel and an incision is
made below the knee to expose the lower end of the
graft tube containing the mandrel. Both ends of the
graft and mandrel are cut off and the mandrel is
pulled out. The graft is then anastomosed to the
femoral artery above and the popliteal artery below,
using the end-to-side method of anastomosis. The
closing of the two incisions completes the operation
with the graft providing a shunt for the
femoro-popliteal artery extending from the groin to a
point below the knee.

5 Claims, 19 Drawing Figures

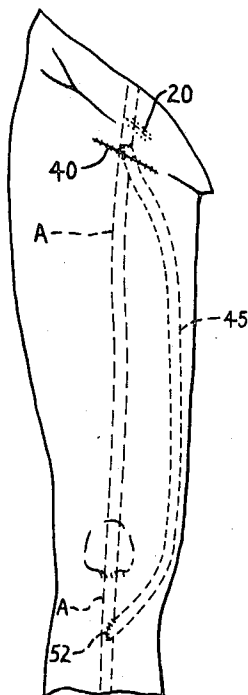


Fig 1

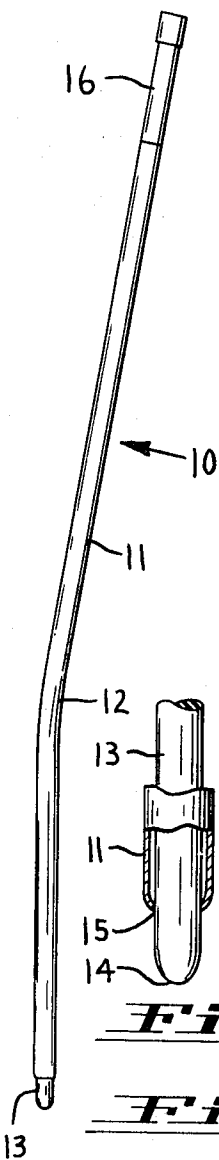


Fig 2

Fig 7

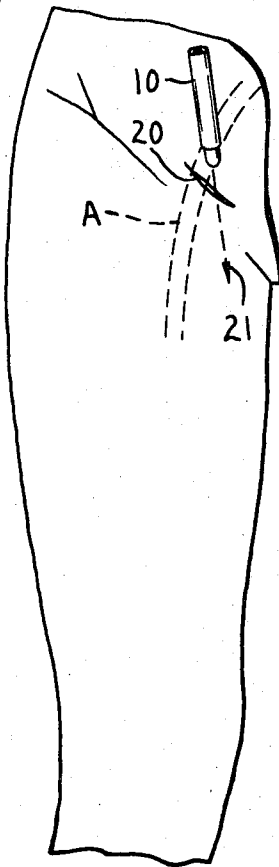
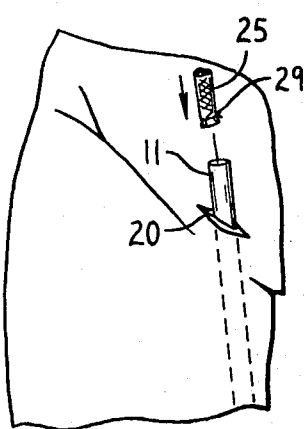


Fig 3

Fig 4

Fig 8

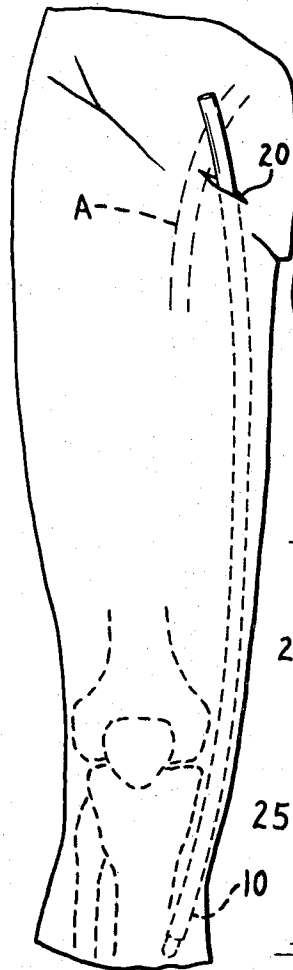
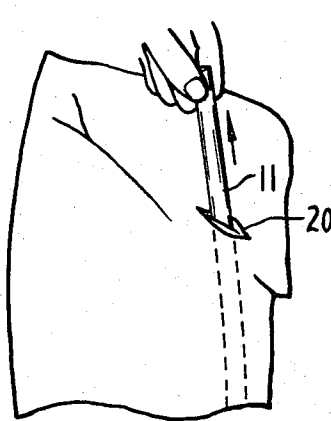


Fig 9

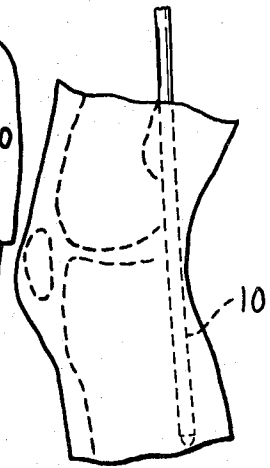


Fig 5

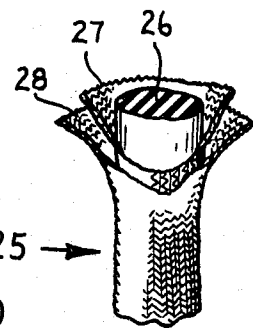
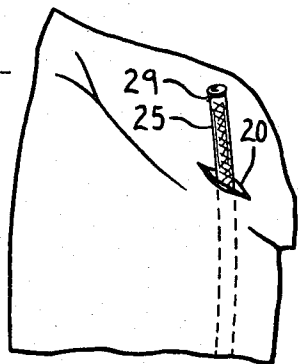


Fig 6



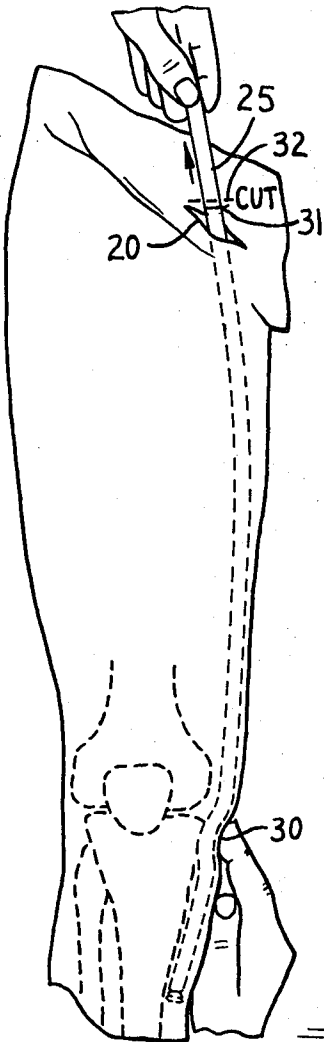


Fig. 10

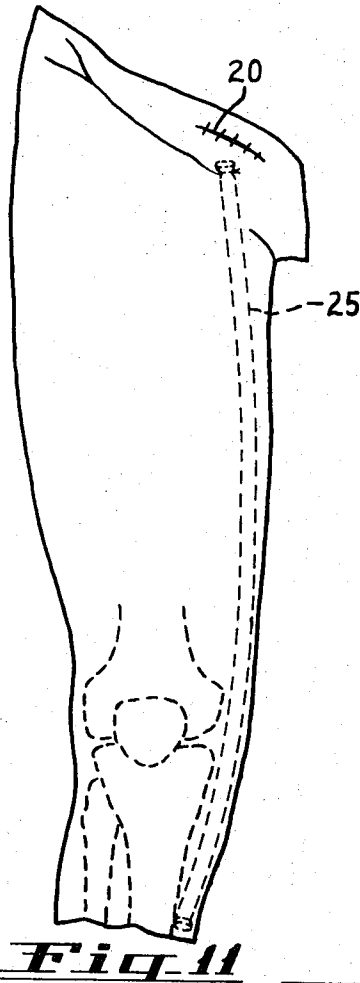


Fig. 11

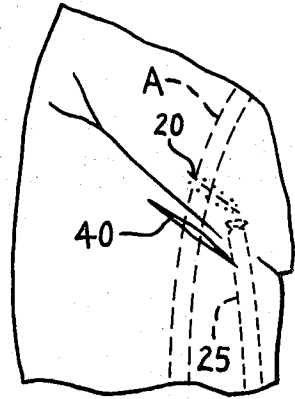


Fig. 12

Fig. 15

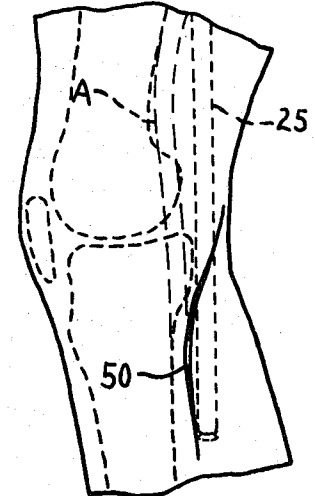


Fig. 16

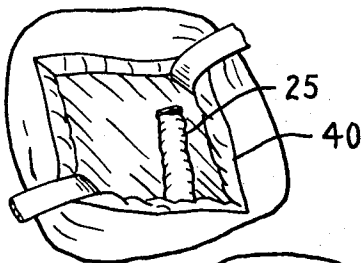


Fig. 13

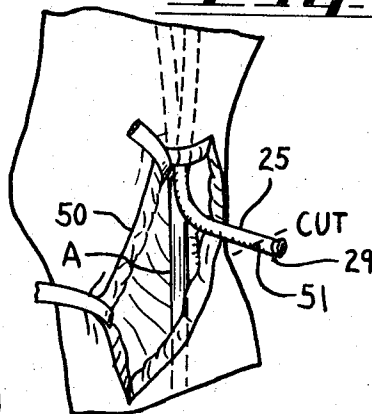


Fig. 14

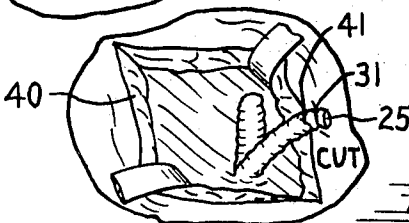


Fig 17

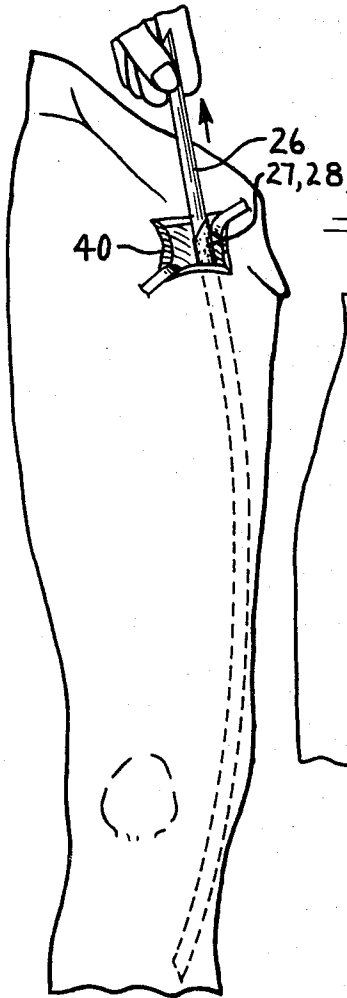


Fig 18

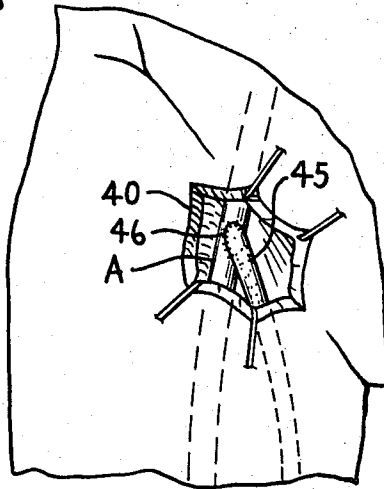
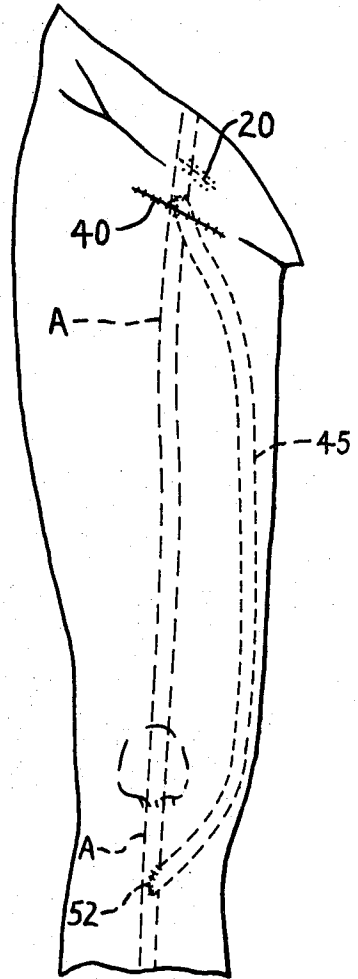


Fig 19



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GRAFT TUBES

CROSS-REFERENCES TO RELATED APPLICATIONS

This is a continuation of application Ser. No. 241,190, filed Apr. 5, 1972, on GRAFT TUBES, now abandoned, which is in turn a division of Ser. No. 101,031, filed Dec. 23, 1970, on METHOD AND APPARATUS FOR GROWING GRAFT TUBES IN PLACE, now U.S. Pat. No. 3,710,777, said Ser. No. 241,190 also being a continuation-in-part of Ser. No. 175,914, filed Aug. 30, 1971, on GRAFT MEMBER GROWN IN A LIVING BODY, now U.S. Pat. No. 3,710,400; which is a division of Ser. No. 823,287, filed May 9, 1969, on DIE AND HOLDER FOR IMPLANTING IN A LIVING BODY TO GROW TISSUE GRAFTS, now U.S. Pat. No. 3,625,198; which is a continuation-in-part of Ser. No. 655,838, filed July 25, 1967, on TISSUE GRAFTS, now U.S. Pat. No. 3,514,791.

BACKGROUND OF THE INVENTION

This invention relates to method and apparatus for growing graft tubes in place.

Although artery grafts have been grown successfully in one part of the body for use in another part of the same body, they have a number of disadvantages. They require the implantation and removal of dies and a relatively long growing time in the dies. They require surgical operations on the two different parts of the body involved. This entails a relatively long operating time and a degree of pain to the patient which it is desirable to minimize. The extent of the surgical operations enhances the danger of infection. Die grown grafts must establish a blood supply after implantation. When a long graft tube is needed, it is usually necessary to anastomose several short tubes together.

Vein grafting also has many disadvantages. Quite often an adequate vein is not available and frequently there is a serious question as to whether an available vein is adequate to carry arterial pressure. In the usual saphenous vein graft, multiple incisions and a large amount of dissection must be done to remove the vein. This, again, increases the time of the operation and the danger of infection. Also, the vein graft is devascularized and requires time to reestablish its blood supply.

Objects of the invention are, therefore, to provide an improved method and apparatus for growing graft tubes, to provide a method and apparatus for growing autogenous graft tubes in place, to provide a method that will grow strong grafts which have established their own blood supply during growth, to provide a method which minimizes incisions and dissection and which accordingly reduces the operating time and danger of infection, to provide an autogenous graft tube which is tougher and stronger than any other known autogenous graft tube, and to provide apparatus for carrying out the method which is well tolerated by the body.

SUMMARY OF THE INVENTION

In the present method a tunneling tube is inserted in a small incision and thrust through the body in such direction as to occupy the position desired for the graft tube. A mandrel assembly comprising a plurality of layers of knitted mesh on a flexible plastic mandrel is inserted in the tunneling tube and then the tunneling tube

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is withdrawn and the incision closed. The patient can resume his normal routine of life while the graft tube is growing as a result of the ingrowth of connective tissue into the mesh of the knitted tubes. After a number of weeks the natural process is complete, resulting in a graft tube which has established its own blood supply.

In a second operation the mandrel is withdrawn and the ends of the graft tube are connected to the intended natural tube or tubes. The second operation requires only two incisions, at the opposite ends of the graft tube, with a minimum of discomfort and convalescent time on the part of the patient and a greatly reduced possibility of infection.

The invention will be better understood and additional objects and advantages will become apparent from the following description of the preferred method and apparatus with reference to the accompanying drawings. Various changes may be made in the details of the method and apparatus and certain features may be used without others. All such modifications within the scope of the appended claims are included in the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevation view of the tunneler used in practicing the method of the invention;

FIG. 2 is an enlarged view of the distal end portion of the tunneler with parts in section;

FIG. 3 is a front view of a patient's right leg and groin showing the step of inserting the tunneling tube for a femoro-popliteal artery graft;

FIG. 4 is a view similar to FIG. 3 showing the tunneling tube fully inserted;

FIG. 5 is a side view of a portion of the leg in FIGS. 3 and 4 showing the position of the tunneling tube relative to the knee;

FIG. 6 is a fragmentary perspective view showing the mandrel assembly;

FIG. 7 is a front view similar to FIG. 3, showing the step of inserting the mandrel assembly into the tunneling tube;

FIG. 8 is a view similar to FIG. 7, showing the step of removing the tunneling tube;

FIG. 9 is a view similar to FIG. 8, showing the tunneling tube removed;

FIG. 10 is a view similar to FIG. 4, showing the mandrel and knitted coverings stretched preparatory to ligating them and cutting them to length;

FIG. 11 is a view similar to FIG. 10, showing the completion of the first operation with the incision closed and the mandrel assembly in position to grow a graft tube;

FIG. 12 is a view similar to FIGS. 7, 8 and 9, showing a new incision made in a second operation after a graft tube has grown on the mandrel;

FIG. 13 is a view of a portion of FIG. 12, showing the new incision opened to expose the upper end of the mandrel assembly;

FIG. 14 is a view similar to FIG. 13, showing the step of cutting off the upper end of the graft and mandrel for removal of the mandrel;

FIG. 15 is a side view similar to FIG. 5, showing a new incision below the knee;

FIG. 16 is a similar view showing the step of cutting off the lower end of the graft and mandrel;

FIG. 17 is a front view, showing the step of removing the mandrel from the graft tube;

FIG. 18 is a similar view showing the anastomosis of the upper end of the graft tube to an upper portion of the femoral artery; and

FIG. 19 is a front view showing the completion of the second operation.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention will be described by way of example in connection with the growing of a femoro-popliteal artery graft in situ. FIGS. 3 and 4 are front views of a human right leg having femoral artery A which has become partially incompetent. The method is carried out in two relatively simple surgical operations on the patient several weeks apart.

The First Operation

The first operation involves the use of the tunneling tube 10 shown in FIGS. 1 and 2. The tunneling tube comprises a metal tube 11 which for the present purpose has a slight bend at 12. Tube 11 contains a removable flexible core rod 13 preferably made of a suitable plastic such as Teflon or Lexan. Core rod 13 has a rounded distal end portion 14 which protrudes from the distal end of tube 11. The distal end of tube 11 is slightly intumed at 15 to provide a snug sliding fit on the rod 13 which insures that the end of the tube will be completely closed by the rod without leaving any crevice or opening between the tube and the rod.

The proximal end of rod 13 is equipped with a handle portion 16 which abuts against the proximal end of tube 11 when the parts are assembled as shown in FIGS. 1 and 2. The bend in the tube and the snug fit against the rod at 15 provides sufficient friction to hold the rod securely in the tube while at the same time permitting the rod to be withdrawn from the tube. The purpose of rod 13 is to provide a plug for the distal end of tube 11 which is removable from its proximal end.

The first step of the first operation is to make an incision 20 in the groin above the inguinal ligament and approximately overlying the position of artery A as shown in FIG. 3. Tunneling tube 10 containing core rod 13 is inserted in incision 20 and forced downward through the subcutaneous tissue of the leg in spaced relation to artery A as indicated by arrow 21. The tunneling tube is guided so that it will pass along the inside of the leg on the inside and somewhat to the rear of the knee joint as shown in FIGS. 4 and 5 with the distal end of the tube extending a short distance below the knee. Then the core rod 13 is withdrawn leaving tube 11 in the leg.

The next step is to insert mandrel assembly 25, in FIG. 6, into tube 11 as shown in FIG. 7. Mandrel assembly 25 comprises a flexible and elastic rod or mandrel 26 having a smooth surface and made of a suitable plastic such as silicone rubber. Overlying the mandrel are an inner coarse mesh fabric tube 27 and an outer fine mesh fabric tube 28. These tubes are preferably knitted from a suitable synthetic fiber such as Dacron.

By way of example for the present purpose, inner tube 27 may be knitted on a sixteen needle knitting head using 70 denier Dacron thread, and outer tube 28 may be knitted on a 22 needle knitting head using the same thread. After knitting, both tubes 27 and 28 are dipped in a xylene suspension of silicone rubber and hung to dry. The rubber coats and impregnates the thread but does not close the mesh openings in the fabric.

Tube 27 is then stretched on a polished steel rod having a diameter approximately 0.020 inch greater than the diameter of mandrel 26, and tube 28 is stretched on a polished steel rod having a diameter approximately 0.052 inch larger in diameter than mandrel 26. The two rods are placed in an oven to vulcanize the silicone rubber contained in and on the Dacron thread. Upon removal from the rods, the tubes 27 and 28 do not change in length or diameter, the vulcanized rubber imparting a starched effect to the fabric.

Tube 27 is then placed on mandrel 26 and tube 28, which has an inside diameter about 0.012 inch greater than the outside diameter of tube 27, is placed over the latter tube forming the mandrel assembly 25 shown in FIG. 6. A silk ligature 29 is used to tie fabric tubes 27 and 28 onto both ends of mandrel 26. This prevents slippage and also prevents runs forming in the knitted material.

Mandrel assembly 25 is inserted in tunneling tube 11 as shown in FIG. 7. Then tunneling tube 11 is withdrawn, as shown in FIG. 8, leaving mandrel assembly 25 in the leg as shown in FIG. 9.

By applying exterior pressure on the skin over the mandrel assembly at point 30 in the region of the knee as shown in FIG. 10, the fabric tubes 27 and 28 and the silicone mandrel 26 are stretched upward and a third silk ligature 31 is applied as shown, allowing the excess length of tubes 27 and 28 and the silicone mandrel 26 to be cut off at 32. The upper ends of tubes 27 and 28 and the silicone mandrel 26 in FIG. 10 will then pull back into the incision by their elasticity and the incision 20 may be sutured closed as shown in FIG. 11.

Since the incision 20 in the first operation just described amounts to little more than a stab wound, it heals quickly and the patient may leave the hospital in a day or so and resume his normal activities while a graft tube is growing on mandrel 26. The mandrel has approximately the same flexibility as a normal femoral artery under arterial pressure whereby the mandrel assembly does not impede movements of the knee joint or interfere with any other activity of the patient.

Connective tissue grows into the fabric tubes 27 and 28, filling the space between tube 27 and mandrel 26, and filling the space between tubes 27 and 28, forming a strong, soft, flexible, reinforced tissue tube with a wall thickness of approximately 0.025 inch to 0.030 inch in 5 to 8 weeks. The presence of the coarse mesh tube 27 within the fine mesh tube 28 provides space for the growth of an adequate thickness of tissue inside the outer tube 28 to insure against rupture when the graft is put into use. Thus, a tube of tissue grows in the coarse mesh of tube 27 within the outer fabric tube 28. Inner tube 27 serves as a spacer to hold outer tube 28 away from the mandrel. Outer tube 28 is the primary strength imparting element. The lining surface of the tissue which forms against the smooth surface of mandrel 26 is smooth and shiny as desired for an artery lumen.

The Second Operation

When the graft has matured, the patient returns to the hospital and in a second operation a new incision 40 is made below the inguinal ligament and overlying the femoral artery A as shown in FIG. 12. Incision 40 is opened to expose the upper end of mandrel assembly 25 as shown in FIG. 13, and the end of the graft and

mandrel are cut off on an angle as indicated at 41 in FIG. 14.

An incision 50 is made below the knee as shown in FIG. 15 and the lower end of the graft and mandrel are cut off on an angle as indicated at 51 in FIG. 16. Mandrel 26 is withdrawn from tubes 27, 28 and the graft structure as shown in FIG. 17. The remaining graft tube is identified by numeral 45 in FIG. 18 wherein the upper end of the graft tube has been connected in an end-to-side anastomosis at 46 with femoral artery A.

In FIG. 19 the part of the operation below the knee is completed with the lower end of graft tube 45 connected with artery A in an end-to-side anastomosis and both incisions 40 and 50 having been closed.

Graft tube 45, being completely vascularized and mature, provides a shunt which is immediately functional to bypass the incompetent portion of artery A and provide an adequate supply of blood to the lower leg. Again, the patient may be released from the hospital in a very short time and requires only a convalescent period at home sufficient to heal the new incisions 40 and 50.

The first operation described above requires about 10 minutes and the second operation about 1 and ½ hours. They are both simple operations, the first requiring only one incision and the second, two incisions. This compares with a difficult three and one-half to four hour operation with multiple incisions according to the conventional practice of removing and reversing a saphenous vein as a replacement for an incompetent femoral artery.

The method and apparatus of the invention may also be used to connect one artery with another artery. For example, the common femoral arteries on opposite sides have been interconnected in selected instances of obstruction of one iliac artery with the opposite one patient. A tunnel is made between the two groins in the subcutaneous layer of the lower abdominal wall. A graft tube is grown in the tunnel and anastomosed end-to-side to each common femoral artery.

In another example an axillary artery (in the arm pit) has been connected to the common femoral artery on the same side by a graft tube grown in situ in a tunnel. In this patient the aorta and iliac arteries in the abdomen were so severely diseased or embedded in scar tissue as to make it impossible or impractical to reestablish blood supply through them to the lower extremity. This in essence takes part of the blood supply to the arm and diverts it to the leg.

It is also within the scope of the invention to use the

present graft tubes for other purposes such as veins, esophagus, ureters, bile ducts and trachea. Further, the invention is not limited to growing graft tubes in situ. The mandrel assembly in FIG. 6 is equally well adapted for growing transplantable graft tubes which may be autogenous, homologous or heterologous. For example, autogenous graft tubes have been grown in tunnels in the subcutaneous layer of the chest wall using this mandrel assembly, the graft being removed and transferred to another part of the body for use. Graft tubes grown in this way have been used to replace a segment of the aorta and to replace the iliac arteries.

In this connection the mandrel assembly in FIG. 6 may be implanted with or without the use of the tunneling tube in FIG. 1 and, in the latter case, the mandrel assembly may be made in Y configuration to grow a bifurcation graft. By making the smaller limbs of the Y less than half the diameter of the large limb, the smaller limbs of the mandrel may be withdrawn through the large limb of the graft tube. Such a bifurcation graft has been used for replacement of the lower abdominal aorta and iliac arteries, for example.

What is claimed is:

1. An autogenous graft tube comprising an ingrowth of connective tissue from a living body in the permanently implanted part of a mandrel assembly having a temporarily implanted part and a permanently implanted part, said temporarily implanted part comprising a flexible mandrel capable of bending with body movements, and said permanently implanted part comprising a fabric tube on said mandrel impregnated with a stiffening agent and a layer of material inside of said fabric tube holding said fabric tube spaced away from said mandrel, the entire outer surface of said fabric tube being exposed to said ingrowth of connective tissue, said ingrowth of connective tissue having a smooth cast lumen formed by said mandrel, and said graft tube having a permanent blood supply established during the ingrowth of said connective tissue.

2. A graft tube as defined in claim 1, said mandrel being made of silicone rubber.

3. A graft tube as defined in claim 1, said layer of material comprising a second fabric tube.

4. A graft tube as defined in claim 3, said second fabric tube being of coarser mesh than said first fabric tube.

5. A graft tube as defined in claim 3, both of said fabric tubes being impregnated with silicone rubber vulcanized in situ.

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