United States Patent [19]

Kornberg

[11] **Patent Number: 4,562,596**

[45] **Date of Patent: Jan. 7, 1986**

[54] **AORTIC GRAFT, DEVICE AND METHOD FOR PERFORMING AN INTRALUMINAL ABDOMINAL AORTIC ANEURYSM REPAIR**

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[21] Appl. No.: **603,800**

[22] Filed: **Apr. 25, 1984**

[51] **Int. Cl.**[4] **A61F 1/24;** A61F 1/22; A61B 17/00

[52] **U.S. Cl.** ..... **623/1;** 128/334 R; 128/325

[58] **Field of Search** ..... 3/1.4, 1; 128/334 R, 128/334 C, 343, 1 R, 325

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[57] **ABSTRACT**

An aortic graft that is specifically constructed for intraluminal insertion and comprising a flexible hollow, tubular material, having a generally cylindrical shape with an upper end and lower end and having a minor and major axis, and having disposed along its major axis a plurality of parallel struts, the struts having angled hooks with barbs at their upper ends, the upper ends of the struts extending beyond the upper end of the tubular material, thus allowing the graft to be securely attached to the inside of the aorta above the aneurysm. A tubular device for inserting the graft is also disclosed.

9 Claims, 10 Drawing Figures

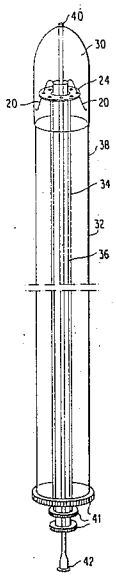


FIG. 1

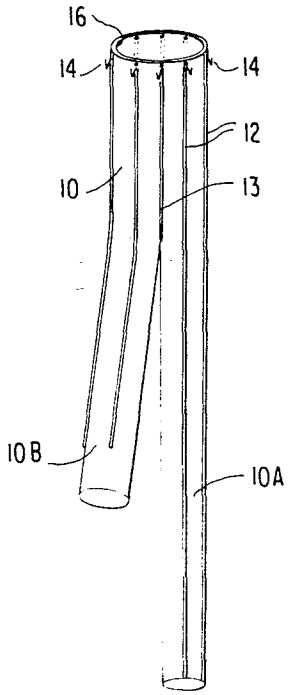


FIG. 2

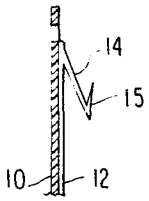


FIG. 5

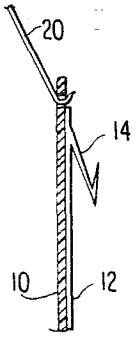


FIG. 3

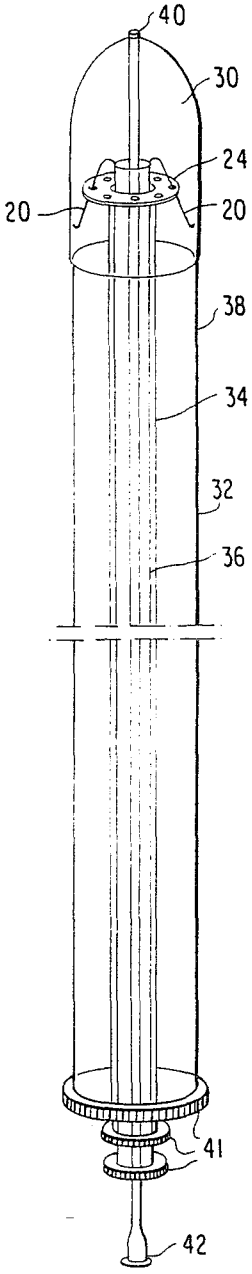


FIG. 4

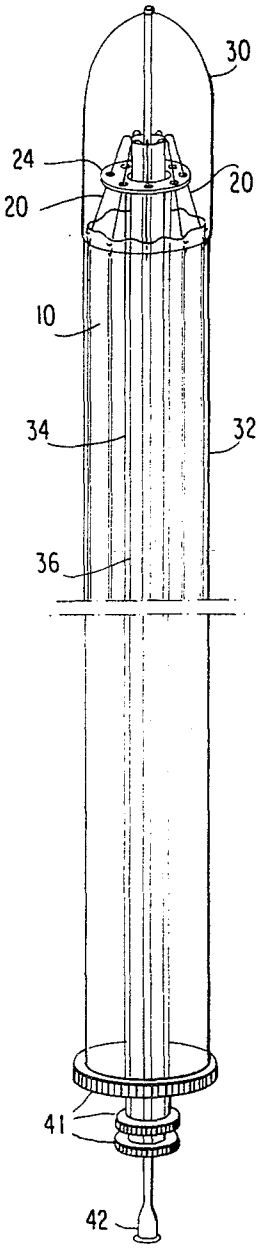


FIG. 6

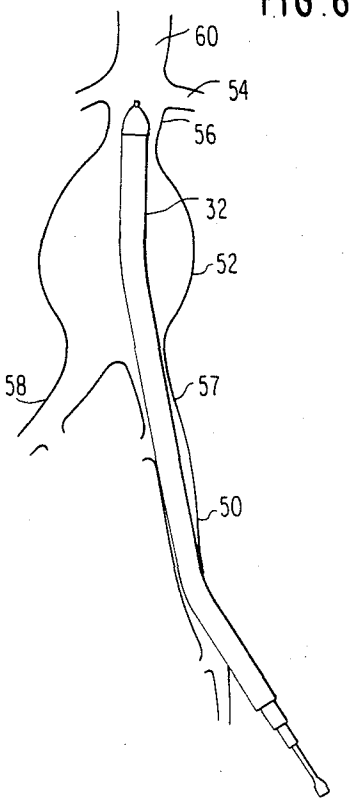
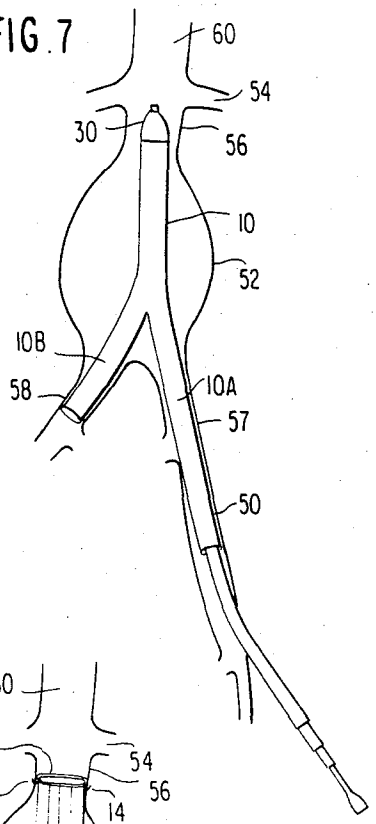


FIG. 7



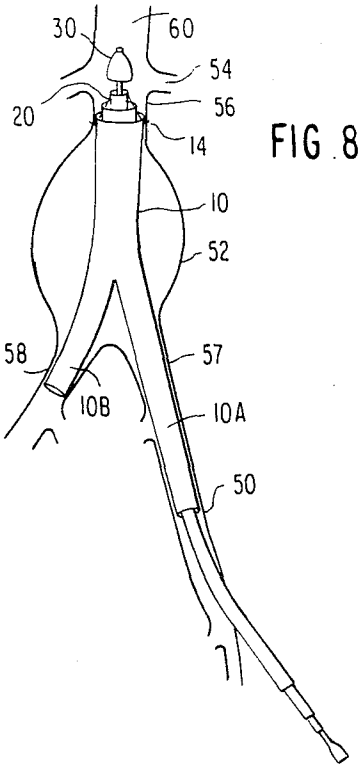


FIG. 8

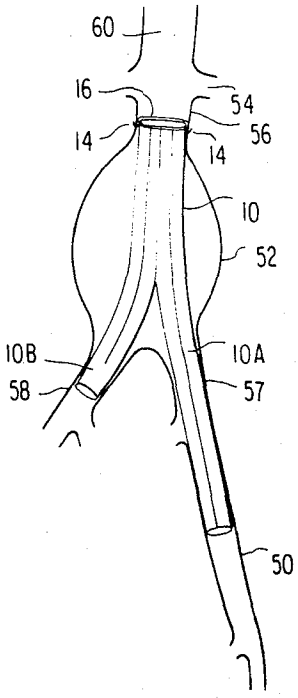


FIG. 9

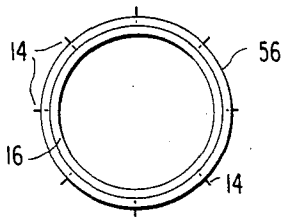


FIG. 10

AORTIC GRAFT, DEVICE AND METHOD FOR PERFORMING AN INTRALUMINAL ABDOMINAL AORTIC ANEURYSM REPAIR

The invention concerns an aortic graft, a device and method for the intraluminal repair and treatment of abdominal aortic aneurysms.

An abdominal aortic aneurysm is a sac caused by an abnormal dilation of the wall of the major artery of the body as it passes through the abdomen. The abdomen is that portion of the body which lies between the thorax and the pelvis. It contains a cavity, known as the abdominal cavity, separated by the diaphragm from the thoracic cavity and lined with a serous membrane, the peritoneum. The aorta is the main trunk from which the systemic arterial system proceeds. It arises from the left ventricle of the heart, passes upward, bends over and passes down through the thorax and through the abdomen to about the level of the fourth lumbar vertebra, where it divides into the two common illiac arteries.

The aneurysm usually arises in the infrarenal portion of the arteriosclerotic diseased aorta, i.e. below the kidneys. When left untreated, the aneursym will eventually cause rupture of the sac with ensuing fatal hemorrhaging in a very short time. The high mortality associated with the rupture has lead to the present state of the art and the transabdominal surgical repair of abdominal aortic aneursyms. Surgery involving the abdominal wall, however, is a major undertaking with associated high risk. There is considerable mortality and morbidity associated with this magnitude of surgical intervention which in essence involves replacing the diseased and aneurysmal segment of blood vessel with a prosthetic device which is a synthetic tube, usually fabricated of either Dacron (a polyester), polytetrafluoroethylene, or other suitable material.

If the aneurysmal segment of the aorta can be functionally excluded from the pressures of the blood flow then the condition can be treated even without excising the diseased segment of aorta.

It is therefore the object of this invention to provide a method to exclude the aneurysmal segment of abdominal aorta from the circulation without the need for major abdominal surgery.

A further object of this invention is to reduce the mortality and morbidity associated with an extensive abdominal operation and the need for a general anesthetic in patients who usually have other associated diseases.

A still further object of this invention is to allow for the emergency stabilization of patients with ruptured abdominal aortic aneurysms.

A still further object of the invention is to provide a method for treatment of abdominal aortic aneurysms without the need for surgical intervention through the abdominal wall.

A further object of the invention is to provide a device for repair of abdominal aortic aneurysms which will reduce the mortality and morbidity associated with major abdominal surgery.

In achieving these and other objects, one feature of the invention resides in a method whereby a vascular graft of a new configuration is inserted into the inside of the aorta through a cutdown in the femoral artery. In this way, the aneurysmal segment of the abdominal aorta is excluded from the circulation system. A cutdown is a creation of a small, incised opening, especially over a vein or other critical vessel.

A further feature of the invention resides in a method employing a tubular device having mounted therein a new vascular graft and comprising forming an opening in a femoral artery, inserting a vascular graft into the artery and moving the graft in an upwardly direction into the aorta without the need for general anesthetic.

A still further feature of the invention resides in a device made of a plurality of tubes having a generally cylindrical configuration and having mounted therein the new vascular graft structure, which device is designed for easy operation in positioning the graft in the desired location in the damaged artery.

Additionally, a feature of the invention resides in a tubular graft material having a plurality of struts or stays equipped with hooks for rapid and secure attachment within the desired location of the damaged artery.

The nature and characteristic features of the present invention will be better understood through the following detailed description and accompanying drawings wherein:

FIG. **1** shows an aortic bifurcation graft used in accordance with the invention. The graft is equipped with a circumferential row of hooks and a plurality of longitudinal struts.

FIG. **2** shows an enlarged view of the upper end of a strut and hook.

FIG. **3** shows the tubular device of the invention used to insert a graft.

FIG. **4** shows the tubular device of the invention containing the graft encased within it and ready for intraluminal insertion.

FIG. **5** shows a portion of the means for holding the graft inside the tubular device.

FIG. **6** shows the device with the encased graft being inserted inside the aorta through a femoral artery cutdown.

FIG. **7** shows the strut supported graft being positioned into the other illiac artery and above the aneurysm.

FIG. **8** shows the deployment and attachment of the graft proximally to the aorta above the aneurysm.

FIG. **9** shows the graft in place and excluding the aneurysm from the circulation.

FIG. **10** is a cross sectional view through the proximal end of the graft and aorta showing the circumferential attachment of the graft to the aorta.

The invention will now be described in further detail with reference to the drawings.

In FIG. **1**, the bifurcated graft **10** with its supporting struts **12** is illustrated. Since the purpose of this invention is to permanently place the vascular graft intraluminally to exclude the aneurysm from the blood flow, then the graft must have support along its length, so that the blood flow does not dislodge it, over the lifetime of the patient. The flexible conduit **10** which constitutes the bifurcated graft of this invention is sufficiently flexible to be capable of conforming to the interior contour of the wall portion of the artery into which it is inserted. The graft is a generally cylindrical, hollow, bifurcated sleeve with longitudinal supporting and reinforcing members called struts **12** running along the major axis of the cylindrical sleeve. The struts assure proper orientation of the graft within the artery. The bifurcated graft **10** has two legs, with one leg thereof **10A** generally being longer than the other **10B**.

A variety of different configurations may be used so that the number of circumferential located strengthening struts or ribs **12** attached or formed in the wall of the graft may vary from a minimum of four up to twelve or more, preferably eight. The upper limit on the number of struts is not critical provided that no more are used than is necessary. Of course with more struts, the graft becomes increasingly more rigid.

The struts or strays may be formed of any suitable material, surgical steel being an example of one such substance. Being preferably formed of steel, the struts permit the graft to be readily observed by X-ray visualization techniques during deployment in the artery. The degree of flexibility of the struts can vary provided that the vascular graft is sufficiently rigid to perform in accordance with the method of the invention.

The struts can run the length of each leg or only part of the entire length of each leg of the graft. Typically, the struts will run essentially the entire length of each leg or a majority of the distance along each leg. Generally, each graft will have three different size of struts; namely, a long strut for the long leg **10**A, a shorter strut for the shorter leg **10**B, and an even shorter strut **13** which will extend from the circular opening **16** at the top of the graft to the point of bifurcation.

The material of the graft may typically be fabricated from flexible natural or synthetic polymeric substances such as polyester fabric (DACRON), polytetrafluoroethylene and the like. Other substances such as Mylar, rayon, cellulose acetate, cellulose butyate may also be used. These substances may be specially woven and/or treated textile fabric material inert to body fluids and compatible therewith. Many such biologically compatible materials are known in the art and may be used for purposes of this invention. Typically, these materials are very thin, on the order of 0.5 mm.

Generally, the graft is prepared and packaged under aseptic conditions to avoid contamination. It is further contemplated that the graft may be treated with non-wettable substance such as liquid silicone or wax. It may also be cleaned with an antibiotic prior to use. Further, it may be treated with an anticoagulant. All such techniques are known in the art and may be used according to the present invention as desired or necessary.

The length of each leg of the graft can be determined by experience and will vary somewhat depending on the patient. The graft is characterized by **3** important dimensions; namely, the length of the single tube of the graft before the point or bifurcation, the length of the short leg **10**B and the length of the long leg **10**A. Generally, the upper tubular section will range from 5 to 10 cm, the short leg **10** will range from 5 to 15 cm and the longer leg will range from 15 to 20 cm. The lengths of the long and short leg can be tailored in the operating room to fit the intended patient. It is for this reason that the struts may not go to the complete end of each leg; that is, in order to enable the surgeon to cut off a short piece of the end of the leg to tailor it to the specific patient.

The proximal attachment of the graft **10** to the inside wall of the aorta is accomplished by the hooks **14** which are located at the upper end of each strut **12**. The row of hooks **14** forms a ring around the outer circumference of graft **10** and are oriented downwardly at an angle of about 10°–45° C. with respect to the vertical. Each hook **14** has a barb **15** located at the lower end of the hook so as to inhibit upward movement which might tend to dislodge the graft after it is positioned and attached to the aorta wall. While FIG. **1** shows a hook **14** at the upper end of each strut **12**, it is to be understood that the hooks could be fewer in number than the number of struts; e.g. the hooks could be attached to every other strut.

A flexible ring **16** located at the upper end of the graft **10** functions to exclude the multiple punctures in the aorta, where the hooks **14** pierce the blood vessel, from the blood flow after the graft is set in position. The ring **16** may be fabricated of flexible, resilient plastic or rubber which is in the compressed, or partially open state prior to positioning in the damaged artery. Once in place, the ring will spring open and snug up against the walls of the artery covering the punctures in the arterial wall made by the hooks **14**. It is contemplated that a graft could also be made without the resilient ring **16**.

The graft has struts **12** that run for essentially the length of the strut along its longest leg **10**A as well as midline struts **13** which extend only to the bifurcation of the graft **10**. This gives added longitudinal support to the graft when it is in place. It also gives more flexibility to the other or shorter graft limb **10**B, so that it can be positioned more easily into the other side. The struts may be formed of any biologically acceptable material such as surgical steel or even plastic of sufficient rigidity and preferably radiologically opaque to permit visualization during the positioning of the graft in the patient.

In FIG. **2**, the upper end of the strut **12** is shown with the hook **14** coming off at about a 30 degree angle. At the uppermost end of strut **12**, there is formed an eyelet or opening to permit temporary engagement with other holding means to be described below. Preferably, the barb **15** on the lower end of hook **14** is oriented parallel to the strut **12**. This allows a firm anchoring into the tissues and also lessens the risk of damaging surrounding organs. Although the preferred embodiment of the invention includes the formation of the hook **14** as shown in FIG. **2**, it is contemplated that other fastening means may be suitably used for this purpose such as clips, needles or any permanent suture material. The barb **15** at the end of the hook **14** is only a fraction of the length of the hook, typically 2 to 8 mm. Because the barb **15** is preferably parallel to the strut, it lies in a safe manner parallel to any other organs so as to prevent damage thereto and to further limit cutting back through aorta. The hook **14** and barb **15** may be formed of the same material as the strut **12**.

In FIG. **3**, the tubular positioning device **32** of the invention is shown without the graft in place. The device comprises a plurality of concentrically arranged sliding tubes including an outer casing or tube **38** fitted with a separable bullet shaped upper top **30** and which together form a cylindrical hollow outer housing. Outer casing **38** is removed by slipping or pulling it off prior to deployment. Contained within the outer hollow tubular housing **38** is hollow, generally cylindrical tube **36**, the major axis of which coincides with the major axis of the housing **38**. At the upper end of tube **36** are fastened a plurality of arms **20**. Only two of such arms **20** are shown in FIG. **3** but it is to be understood that the number of arms **20** coincide with the number of hooks **14** eyelets. The arms **20** are shaped so as to readily engage with the eyelet formed at the top end of strut **12**.

A second hollow, generally cylindrical tube **34** is in sliding engagement over the first, or inner, tube **36**. A fenestrated collar or ring **24** is attached at the upper end of the outer tube **34**. Tube **34** in the position shown in FIG. **3** is located somewhat below the top of inner tube

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