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**(71) Applicant:** ST. JUDE MEDICAL, INC. [US/US]; One Lillehei Plaza, St. Paul, MN 55117 (US).

**(72) Inventors:** SCHANKERELI, Kemal ; 7979 Neal Avenue North, Stillwater, MN 55082 (US). BRUHNDING, Dean, A. ; 372 Nottingham Drive, Circle Pines, MN 55014 (US).

**(74) Agents:** APOLZON, Lawrence, E. et al.; Neuman, Williams, Anderson & Olson, 77 West Washington Street, Suite 2000, Chicago, IL 60602 (US).

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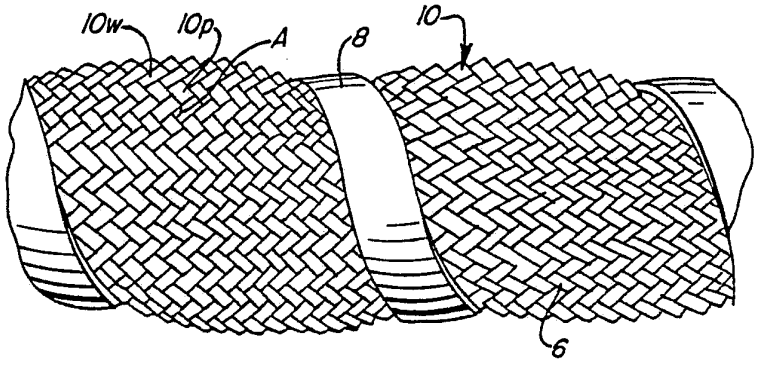


**(57) Abstract**

A prosthesis for the replacement of diseased autogenous blood vessels in humans and of a tubular textile construction. The prosthesis includes a braided yarn substrate (6) which is non-crimped and is compacted. The graft also includes an external polypropylene support (8) which wraps around the substrate (6). A method of manufacture is also disclosed.

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# Braided Polyester Vascular Prosthesis and Method

## Background of the Invention

### Field of the Invention

This invention relates to prostheses for the replacement of diseased autogenous blood vessels in humans and methods of making such prostheses. The prosthesis of the preferred embodiment of this invention is of a tubular, textile construction and in particular, is constructed in a braided manner and is of variable length and diameter.

Various diseases can affect the cardiovascular system. While some diseases affect the heart itself, others primarily affect blood vessels. For instance, atherosclerosis is a major disease that affects blood vessels resulting in stenosis or the narrowing of the internal lumen of the vessel. Such stenosis impedes and reduces blood flow. In addition to stenosis, as the vessel thickens the vessel wall loses the ability to expand and contract and the vessel also becomes weakened and susceptible to bulging. This is known as aneurysm. Under certain conditions such as hypertension or elevated blood pressure, aneurysms will frequently cause the weakened vessel to dissect and ultimately rupture. In major arteries where aneurysms and stenosis have become

extensive and the vessel is no longer reliable, such vessels must usually be replaced by a graft of some sort.

While autografts can be harvested from the patient's body, e.g. the long vein in the leg called the saphenous vein, such harvesting can be a tedious surgical task, does not always result in the best quality graft and is often not therapeutically recommended.

As a result of the above-stated problems with autografts, synthetic grafts are being developed for coronary artery by-pass as well as for other blood vessel replacement. Work is also being done in the area of polytetrafluoroethylene (PTFE) grafts but long-term results are uncertain and such grafts are rigid resulting in technical difficulties. Also, because the PTFE tears easily, there is a problem with suture retention. In the past, both Teflon® and Dacron® (polyester) fibers have been commonly employed materials for synthetic grafts because they are biocompatible. More recently, however, Dacron polyester because of its good implant history has become one of the preferred synthetic materials being used in the manufacture of arterial prostheses. Dacron polyester material can also be configured in such a manner so as to be flexible.

Another benefit of Dacron polyester prostheses is that under certain porosity conditions, they can be penetrated from the outside of the graft through pores in the graft walls by perigraft tissues thereby fastening the prosthesis to surrounding perigraft tissues and making the prosthesis blood tight. Polyester grafts are therefore potentially capable of being completely integrated with the patient's own tissues. Alternatives to such complete integration or "complete healing" exist such as the use of

pharmacologic agents to suppress thrombus formation, but only "complete healing" provides long term freedom from thrombotic occlusion.

In light of the above-mentioned benefits from "complete healing", which can be defined as incorporation of the entire graft within a fibrous tissue matrix whose flow surface is covered with pseudointima and with endothilium cells at the anastomatic lines, "complete healing" is a desirable objective in graft technology. Another object is to avoid profusion or leakage of blood out of the graft. One way of avoiding such leakage is to preclot the graft. Preclotting a graft must be done at the time of the implant and involves perfusing blood into the lumen of the graft and massaging the graft rigorously until the blood passes through the pores and clots. Such preclotting introduces additional risks to the implant procedure. At porosities below 100 ml/min-$cm^2$ at 120 mm Hg, preclotting can be eliminated. Above such porosities preclotting is necessary but in the range of 100 to about 500 ml/min-$cm^2$ at 120 mm Hg, preclotting, while required, can be accomplished more efficiently or effecively, i.e., blood is less likely to profuse from the graft after the preclotting procedure.

Vascular prostheses which are currently available and made of Dacron polyester can be either braided, as shown in U.S. Patent 4,441,215 issued to Kaster for Vascular Graft, woven or knitted. Mechanical support for such prostheses can be provided by crimping the prosthesis itself or supporting it externally with a sleeve or wrap of plastic material such as polypropylene.

Other available prostheses can be made of PTFE as discussed above and wrapped with a polypropylene monofilament for support.

The braided graft shown in the above referenced U.S. Patent 4,441,215 issued to Kaster is covered with a sleeve. While this sleeve prevents the outward profusion of blood, such a graft is less flexible than the saphenous vein and is not readily elongated or tailored to a shorter length. Also, because of the external sleeve, tissue ingrowth cannot be accomplished, thereby making "complete healing" impossible. With tightly woven polyester grafts or with microporous PTFE the porosity is relatively low or zero and preclotting may not be necessary. Under such circumstances however, because of the small interstices, predictable and healthy ingrowth of healing tissue cannot be assured. Also, woven grafts are generally crimped for support purposes and they are not compliant compared to natural arteries. Alternatively, knitted Dacron polyester grafts can be used to increase porosity and thereby provide larger interstices and subsequent ingrowth, but preclotting becomes necessary. Thus, with available grafts, preclotting is necessary if "complete healing" or complete integration is a major objective.

It is therefore desirable to have a vascular prosthesis that has a smooth blood flow surface and has a porosity that can be readily controlled to increase the efficiency of preclotting and yet allow for tissue ingrowth and complete healing. It is also desirable to have a vascular prosthesis which is externally supported in such a manner so that the substrate can be flexed through a small radius without kinking but the internal surface is smooth. In addition, it is desirable to have a

vascular prosthesis with improved bursting strength so as to further strengthen the walls of the prosthesis. Moreover, it is desirable to have a prosthesis which meets the above requirements which can be readily manufactured and that can have a diameter that can be closely controlled.

It is an object of this invention to provide an improved vascular prosthesis which meets the aforestated requirements and desirable characteristics.

It is another object of this invention to provide a vascular prosthesis that has a smooth blood flow surface.

It is yet another object of this invention to provide vascular prosthesis with a porosity that can be controlled to increase the efficiency of preclotting.

It is another object of this invention to provide an improved vascular prosthesis which can be externally supported and yet can be flexed through a small radius without kinking.

It is a further object of this invention to provide a method of manufacturing vascular prostheses that have controllable porosity.

Further and additional objects of this invention will appear from the following description, accompanying drawings and appended claims.

## SUMMARY OF THE INVENTION

In accordance with one embodiment of this invention the aforementioned requirements and objects are satisfied through a tubular textile substrate constructed in a braided manner and of variable length (60-100 cm.) and diameter (6-24 mm) such that it can be used for the

replacement of diseased autogenous blood vessels in humans. The vascular prosthesis includes a braided polyester yarn substrate which is non-crimped to provide a smooth internal surface. The substrate is also compacted. In addition to the braided compacted non-crimped polyester substrate, the vascular graft includes an external polypropylene support which wraps around the substrate and is heat fused thereto.

In a preferred embodiment of the invention, the braided substrate is in the form of two plys of 40 or 70 denier type 56 polyester yarn. Where 70 denier is used, 54 smaller filaments at 1-10 twists per inch are used to make the yarn and where 40 denier yarn is used, 27 filaments at 1-10 twists per inch make the yarn. While single ply or more than two ply yarn is acceptable for purposes of this invention, two ply yarn is preferred where two plys or yarn portions are wound together to form a yarn. The multiple ply yarn provides a means of controlling porosity as do the denier and number of filaments as well as the compacting. It should be understood that it is not necessary for each yarn in a single substrate to be of the same denier or be made up from the same ply or plys. In this manner, the characteristics of the substrate can be varied by varying the nature of the yarns used in a single substrate.

The yarn can also be texturized so as to give the yarn bulk causing the yarn to bloom thus facilitating tissue ingrowth. The extent of texturizing provides additional means of controlling porosity.

The polyester substrate for the vascular graft can be made with the use of a braiding unit such as a 96 carrier unit which is capable of making sleeve-like

substrates via the over and under construction of warp and pic yarns. The angle of incidence where the warp and pic yarns cross is less than 90° relative to the longitudinal and radial (circumferential) directions of the substrate.

After the substrate is formed, it is subjected to a scouring cycle to remove dirt. Subsequent to the scouring cycle, a preselected length and diameter of the substrate is compacted so as to mechanically shrink the substrate and reduce the porosity. To assure a given desired lumen size, the substrate is placed on a mandrel of the desired diameter before it is compacted. Compaction can be accomplished in a heated chamber filled with a halogenated hydrocarbon, preferably one which has been chlorinated, such as methylene chloride. Alternatively, compaction can be accomplished in a steam atmosphere. The compaction process provides a desirable method of exactly controlling the porosity for a given substrate diameter.

After the compaction process and additional substrate processing, e.g. removing the methylene chloride from the surface of the substrate material, the substrate is ready to be wrapped with the polypropylene monofilament support. Depending upon the extent of support desired, the entire compacted substrate can have a single helical wrap placed around it or alternatively a double helix. The ends of the externally supported substrate are then cauterized to prevent fraying, dry packaged and sterilized in the package by radiation or other conventional means.

The packaged and sterilized vascular graft is then ready for implant by removing it from the packaging, cauterizing it to a desired length and attaching its ends

to the areas of implant by standard suturing procedures. When the porosity of the graft is above 100 ml/min-$cm^2$ at 120 mm Hg, preclotting is necessary.

## DESCRIPTION OF THE DRAWINGS

For a more complete understanding of this invention reference should be made to embodiments illustrated in greater detail in the accompanying drawings and described below by way of example of the invention.

Figure 1 is a schematic side perspective view of a preferred embodiment of a vascular graft embodying teachings of this invention;

Figure 2 is an enlarged section view of the graft taken along line 2-2 of Figure 1 showing the ends of the braided Dacron polyester yarns and the polypropylene support;

Figure 3A is an enlarged section of the surface of the graft shown in Figure 1 showing the braided configuration and a single helical external support;

Figure 3B is an enlarged section of the surface of a graft embodying teachings of this invention showing the substrate in phantom lines and an alternative configuration of the external support;

Figure 4 is an enlarged section of one end of a polyester substrate of a graft embodying teachings of this invention without a polypropylene support;

Figure 5 is an enlarged partial perspective view of a 2-ply yarn thread;

Figure 6 is a view of two substrates on two mandrels immersed in a compaction chamber containing a halogenated hydrocarbon where the compaction chamber has been sectioned to expose the substrates and mandrels; and

Figure 7 is an end enlarged view of a vascular graft embodying teachings of this invention in which the ends have been cauterized and the graft is ready for implanta ion.

It should be understood that the drawings are not necessarily to scale and that the embodiments shown are sometimes illustrated in part by phantom lines and fragmentary views. In certain instances details of the actual structure which are not necessary for the understanding of the present invention may have been omitted. It should be understood, of course, that the invention is not necessarily limited to the particular embodiments illustrated herein.

## DETAILED DESCRIPTION

### DESCRIPTION OF PREFERRED GRAFTS

Figure 1 illustrates a vascular graft 2 constructed of braided polyester yarns 10 (see Fig. 3A) to form a tubular substrate 6 in accordance with this invention. E. I. DuPont de Nemours and Company of Wilmington, Delaware makes polyester yarn under the above mentioned trademark Dacron. The substrate 6 has been compacted as described in greater detail below under the section entitled Description of Preferrred Methods of Manufacture. A polypropylene external support 8 in the form of a substantially round monofilament 9 is wrapped

around the substrate 6 in a helical manner and is heat fused to the external surface of the substrate. A preferred diameter of the monofilament is 0.015 inches to 0.020 inches. The polypropylene support 8 prevents the tubular structure from collapsing or being crushed under certain conditions and its helical configuration leaves the graft pliable so that it can be flexed or bent without kinking. As shown in Figure 4, without the support, the substrate 6 collapses.

The length of the vascular graft and inside diameter can be varied depending upon the size of the vessel being replaced. The length can be varied from about 60 to 100 centimeters and the diameter can be varied from about 6 millimeters to 24 millimeters. While the graft of the subject invention is intended primarily for medium to large bore prostheses, i.e., greater than 6 mm in diameter, it is anticipated that with further technological advancements, a substrate employing the teachings of this invention may be suitable, in conjunction with appropriate coating technology to enhance biocompatability and patency, for peripheral blood vessels as those below the elbow and knee which are smaller than 6 mm in diameter.

The graft is non-crimped so that it can be flexed through a small radius without kinking and still have a smooth interior surface. The ability to flex through a small radius without kinking is desirable to prevent blockage of the graft. The smooth interior surface provided by the non-crimped design is desirable as it reduces the likelihood of thrombus formation.

Figure 3A shows an enlarged section of the graft 2 shown in Figure 1 with the external support 8 heat fused to the substrate 6 such that surface of the substrate is slightly constricted by the monofilament of polypropylene. In Figure 3A, the monofilament is wrapped in a helical manner. In Figure 3B, a double helix wrap 8' of monofilament is used for additional support. The substrate 6 is shown in phantom lines to further illustrate the configuration of the double helix wrap 8'. It should be understood that other configurations of the polypropylene wrap can be used depending upon the desired support and that the configurations can be varied along the length of the substrate e.g., so that the support at the ends can be less extensive so as to facilitate working with the graft for implant purposes.

Figure 3A also shows a plurality of polyester yarns 10 which are braided in an over and under construction of warp yarns 10w and pic yarns 10p. As shown best in Figure 4, the angle of incidence A defined by the crossing of the warp and pic yarns is less than 90° relative to the longitudinal and radial (circumferential) directions.

The use of a braiding configuration enables the vascular graft to be compliant such that the graft can radially expand and contract back to its original size. With such a structure, the bursting strength (also known as the burst pressure) as measured by probe intrusion, as described below, can be increased up to 750-900 p.s.i. The procedure used by the applicants for measuring bursting strength known as the Modified Burst Test is reported in the Association for the Advancement of Medical Instruments (A.A.M.I.) document 30 AAMI VP20-3/86 entitled

"Standard For Vascular Graft Prostheses (Proposed)," dated March, 1986 Revision beginning at page 20. This procedure, which is known in the art includes, placing a representative flat sample of material over a hole in the base of the test apparatus as described in the above referenced A.A.M.I. procedure. A metal plate, containing a hole of the same size, is placed over the sample. A rounded rod or probe is traversed, at a constant rate of 125 mm/min through the sample and the maximum breaking load is recorded. The burst pressure is measured by the applicants in "p.s.i." and is calibrated through the use of a standard testing foil having a burst pressure of 100.2±3 p.s.i.

The braided and compacted configuration also provides for a structure with a porosity where the efficiency of preclotting can be high, i.e., the effectiveness of preclotting to avoid leakage of blood is high. The braided and compacted substrate is also useful as to improving suture retention. With the present invention, suture retention of the cauterized graft ranges from approximately 1.5-2.8 kg. Suture retentions above 2.0 are most desirable. Such suture retention can be measured by taking a Prolene suture of size 3-0 and passing it 3 mm from the cauterized end of the graft. A tensile pull test with any tensile tester is conducted in the longitudinal direction until the suture separates out of the fabric.

A warp yarn 10w used for the braided construction of this invention is illustrated in Figure 5. The pic yarns 10p used are about the same length as the warp yarn 10w because the yarns are braided. The warp yarn 10w shown in Figure 5 is two ply in that it includes

two yarn portions 10wa, 10wb of polyester twisted together. Each yarn portion 10wa, 10wb is made of type 56 Dacron polyester. The yarn denier can vary from 100 to 40. For 100 denier, 96 yarn filaments are recommended. It is recommended that such filaments be twisted 1 to 10 twists per inch. For 40 denier, 27 yarn filaments are recommended at the same twist. At a yarn denier between 40 to a 100, the number of filaments varies between 27 and 96, e.g. 70 denier at 54 filaments. Figure 2 shows these filaments 11 of each yarn 10. A Z-twist or an S-twist can be used to process the yarn.

Additionally, texturization gives the yarn bulk to decrease porosity and facilitates tissue ingrowth. Such texturization can be accomplished by the use of a heated rotating texturization cannister.

It is important to understand that it is not necessary for each warp and pic yarn used in the graft of this invention to have the same ply, denier, number of filaments, twist type and extent of texturization. In fact, it has been found that the properties of a vascular prosthesis such as bursting strength and porosity can be further varied by the characterization of the yarns to be used. Therefore, it is contemplated that the vascular grafts of this invention may include yarns which are not identical.

By using multiple-ply yarns, the porosity of the surface formed by the braiding can be further controlled. It has also been found that the use of multiple plies of yarn increases the bursting strength. Such an increase is important because a prosthesis with a low bursting

strength may ultimately experience aneurysm and fail. With this invention, a bursting strength up to almost 900 p.s.i. can be obtained with a two-ply yarn substrate.

It has been found that with the configuration described above and where the substrate has been compacted the porosity of the graft has been reduced to as low as about 340 ml/min-cm$^2$ at 120 mm Hg, thereby reducing the outward profusion of blood to the extent that the efficiency of preclotting is high. Moreover, with such a compacted braided configuration it is believed that porosities at least as low as 100 ml/min-cm$^2$ at 120 mm Hg could be obtained by manipulating various parameters such as the characterization of the yarn, the use of multiple ply and the extent of compaction. With such porosities below 100 ml/min-cm$^2$ at 120 mm Hg , preclotting can be eliminated. Also, it is believed that at this porosity the suture retention can be further increased. It is further believed that with this invention the porosity of the substrate will not greatly exceed about 600 ml/min-cm$^2$ at 120 mm Hg, which also enables efficient preclotting.

A method of measuring porosity or permeability is reported in the aforementioned A.A.M.I. document AAMI VP20-3/86 beginning at page 13. The applicants follow a similar procedure. In particular, permeability is measured by placing a representative flat sample of material which was degassed for 30 minutes under a vacuum in water over a hole of a test apparatus. The test apparatus includes a plexiglass water inner tube having a height calibrated to provide a pressure of 120 mm Hg and a pump to maintain the height of the column at a pressure of 120 mm Hg. An outer tube functions as an overflow from the inner tube. The bottom of the calibrated tube

contains a pipe about 6" in length with an on-off valve driven by a solenoid with a timer. A top plate is located below the valve and solenoid and has a hole 0.5 $cm^2$ in area. The calibration of 120 mm Hg. is from the top of the inner tube to the bottom of this top plate. The sample is placed on a lower plate having a hole in its upper portion also 0.5 $cm^2$ in area which is aligned with the hole of the top plate. A pipe or spout leads from the base of this hole in the lower plate and at the end of the spout is a graduated cylinder to measure water in "ml." In operation, the fabric is placed between the holes of the two plates, the solenoid is actuated by a timer set for 15 seconds thereby allowing water to pass through the sample for that period. The water passed through the sample and out the lower plate and spout is collected in the graduated cylinder. As a result the applicants obtain a value of "V" ml. of water per 15 seconds per 0.5 $cm^2$ where "V" is the reading on the graduated cylinder. The applicants multiply "V" times 8 to obtain the porosity reading in "ml/min-$cm^2$ at 120 mm Hg."

With the braided configuration, however, and the texturization of the yarn, tissue ingrowth still occurs and complete healing of the patient results. While single ply yarn can be used and the porosity controlled in other manners as previously discussed such as texturization and also by the use of compaction as discussed below, the porosity can be controlled very effectively by the use of multiple ply yarn.

DESCRIPTION OF PREFERRED METHODS OF MANUFACTURE

The method of manufacturing the vascular graft of this invention for implant involves preparation of the braided substrate, processing the substrate, attaching the external support, packaging the graft and sterilizing it for shipment.

Preparing the substrate involves methods of braiding yarns into a seamless sleeve-like configuration which are well known in the art. With the substrate of the present invention, a 96 carrier braiding unit which has the ability to braid up to 96 yarns at a time can be used. Single or multiple ply yarns of various deniers, filaments and texturizations can be used. As previously discussed, such variations provide a basis for controlling porosity.

After the substrate is prepared, it is ready for further processing. For interim storage or to facilitate handling, the substrate can be rolled in a collapsed state at a preselected diameter onto a spool and is ready for processing into a vascular graft.

When the substrate is received, for example, on a spool, it is in the form of textile greige goods and needs to be cleaned. A predetermined length of substrate can be cut from the spool and subjected to a cleaning process first by hand cleaning the exterior with a brush followed by scouring in a nonheated ultrasonic cleaner with detergent and/or sodium bicarbonate for about 30 minutes. Problem areas can be further scoured by a hand brush. The substrate is then thoroughly rinsed with water and dried on a mandrel as in a dryer at 100°C for 1-2 hours. This scouring process is important as it removes dirt from the griege goods.

After the scouring cycle, the substrate is ready for compaction. As previously discussed, compaction provides additional means of controlling porosity so that preclotting can be eliminated or reduced. Some porosity as in the range of 50 to several thousand ml/min-$cm^2$ at 120 mm Hg is desirable so that cell ingrowth can occur and "complete healing" where the graft remains patent, results. With this invention, the porosity can be controlled by compaction while at the same time maintaining a selected diameter of the substrate. As a result, exact diameters can be provided to the surgeon for various porosities.

While various methods of compaction are envisioned, one method of accomplishing such compaction is shown in Figure 6. Figure 6 shows a cutaway view of a compaction chamber 100 containing two braided substrates 102 of a predetermined diameter which have been cut to a preselected length and slid over mandrels 104 of a corresponding diameter. The compaction chamber shown in cross section in Figure 6 is cylindrical and has a chamber portion 106 and a top portion 108, each with corresponding threaded portions so that the top portion 108 can be fixed with the chamber portion 106. The chamber portion 106 has a disc having openings in its base to accommodate a plurality of mandrels 104 each with a substrate 102. The compaction chamber 100 shown in Figure 6 has been filled with methylene chloride which induces mechanical shrinkage of the polyester substrate. For this purpose, various other halogenated hydrocarbons will suffice, particularly chlorinated hydrocarbons. Once the mandrel has been placed in the chamber and the top portion screwed on, the chamber is then placed in an oven set at about 300°F for

about 30 minutes to 1 hour. During this period, the internal temperature goes up to about 226°F and the substrate shrinks in an axial direction. Shrinkage in the radial direction is determined by the diameter of the mandrel. In this manner, the porosity of the substrate can be reduced through shrinkage of the braided substrate in accordance to the diameter of the mandrel.

At the end of 30 minutes to an hour in the 300°F oven, the compaction chamber is removed and is cooled. In particular, the entire chamber is quickly cooled by immersion in a cool water bath for about fifteen minutes. After cooling, the chamber 100 is then opened by removing the top portion 108 and each mandrel 104 with a substrate 102 is removed. It is important that after being heated in methylene chloride, that the substrate be removed from the methylene chloride quickly so that its effect on the substrate can be terminated. Such quick removal is satisfied as just described. Other methods of heating and cooling the substrate with the methylene chloride are envisioned such as the use of a heating band on the compaction chamber or an immersion heater for heating or the use of a cooling jacket on the compaction chamber for cooling. The substrate is left on the mandrel and the residual methylene chloride is removed from the surface of the substrate by rinsing in water. The substrate is then dried by placement into a drying oven at 100°C for 30-60 minutes.

It should be understood that the internal temperature of the chamber can be varied and range from about 200°F-280°F and the time of heating can be varied to modify the extent of compaction. For example, higher internal temperatures or longer times of exposure to

methylene chloride increase the amount of shrinkage and thereby reduce porosity. Such changes would enable the porosity to be controlled further.

It should also be understood that other means of compaction are envisioned. For instance, the substrate on a mandrel can be subjected to a steam atmosphere and then dried. All methods of compaction which are envisioned here involve the use of a mandrel with a substrate of a corresponding diameter slid over the mandrel where the substrate is then subjected to a shrinkage process so that the substrate shrinks longitudinally or axially and shrinkage in the radial direction is determined by the diameter of the mandrel.

After compaction, the substrate, still on the mandrel, is ready for the application of the external support in the form of a polypropylene monofilament of 0.015 to 0.020 inches in width. To apply the polypropylene wrap helically as shown in Figure 3A, the mandrel with the substrate is placed on a winding machine which slowly rotates the mandrel and substrate. The monofilament is tied to one end of the mandrel and as the mandrel rotates, the monofilament is spirally wound along the length of the substrate, resulting in a helical pattern of 3-15 turns or winds per inch. When the monofilament helix covers the entire substrate, it is cut and tied to the other end of the mandrel. The mandrel is then placed in an oven at about 190°C-205°C for about 5-15 minutes so that the monofilament is heat fused to the external surface of the substrate. The resulting bond is such that the support can be lifted from the substrate without tearing the substrate. This may be desirable especially at the ends so that the surgeon can readily

remove the external support to the extent that the ends of the substrate must be made clear and pliable for suturing the substrate to the tissue. Alternatively, a higher heat or longer exposure time bonds the monofilament more thoroughly to the substrate such that it cannot be removed without tearing the surface of the substrate.

If additional rigidity is needed, as at areas where the graft is more susceptible to being crushed, a double helix can be formed as shown in Figure 3B. To form the double helix, the mandrel and substrate with the single helix can be repositioned on the winding machine so that a reverse helix is formed by the application method described above. Heat fusing of both helixes can then be performed.

It is contemplated that another method of heat fusing the monofilament to the substrate can be accomplished by using the standard winding machine discussed above with an infrared lamp overhead the mandrel containing the substrate wound with the monofilament which follows the monofilament as it contacts the substrate so that fusing occurs simultaneously with the application of the monofilament.

After the external support is fused to the substrate, the substrate is removed from the mandrel and the ends are cut to a standard length with a cauterizing knife to prevent fraying. The resulting prosthesis is then ready for dry packaging as in a tube of cellulose propionate. The prosthesis in the package is then sterilized by gamma or beta radiation or other conventional means.

For implant, the sterilized graft is removed from the package and cauterized to the implant length. An end view of the cauterized graft 110 is shown in Figure 7. Where the porosity is above 100 ml./min-cm$^2$ at 120 mm Hg, preclotting is necessary and can be accomplished by shooting the patient's blood into the lumen of the graft and massaging it through the interstices of the walls and permitting the blood to clot, thereby preventing outward profusion of the blood but allowing tissue ingrowth. Implant can then follow pursuant to normal procedures known in the art. It should be noted that the polypropylene wrap can be removed from the ends of the graft so that the surgeon can work more freely during the suturing procedure.

Thus with this invention, a vascular graft having a smooth inner surface which is externally supported and is completely free of crimping is provided which can be readily manufactured. Furthermore, the diameter of the graft can be controlled very accurately and a porosity can be obtained at the same time that provides for highly efficient preclotting but facilitates tissue ingrowth so that complete healing can result. In addition, the graft of this invention can be flexed through a small radius without kinking and at the same time has improved bursting strength.

EXAMPLE

One example of the above described invention is as follows. A substrate having a diameter of 8 mm and length of 100 cm was obtained from a spool. The substrate was in the form of braided 2 ply both plys being of 70

denier 54 filament type 56 Dacron polyester yarns. The substrate was made on a 96 carrier braiding unit. The cutting and cleaning procedures were followed as already described. The substrate was then compacted. For compaction, the substrate was slid over a mandrel of 8 mm diameter. The mandrel and substrate were then placed in a compaction chamber which was filled with methylene chloride. After the chamber was closed it was placed in an oven set at 300°F for about 45 minutes. At that time, the compaction chamber was removed and cooled in a cold water bath at 40-60°F for 15 minutes. The substrate, still on the mandrel, was then removed from the chamber and was rinsed under water and dried on the mandrel at 212°F for 60 minutes. The dried substrate was then removed from the mandrel for porosity, bursting strength and suture retention measurements. The methods of measurement of each of these properties has already been described. The resulting porosity was approximately 340 ml./min-$cm^2$ at 120 mm Hg, the bursting strength was 800 p.s.i. and the suture retention was approximately 2.0 kg.

Such a substrate would be suitable for having the polypropylene wrap applied as described earlier (for instance, at 5 winds per inch), cauterized, dry packaged, sterilized and ready for implant.

Thus an improved vascular graft has been provided which meets the aforestated objects of this invention.

While a specific embodiment of this invention has been shown, it will be understood, of course, that the invention is not limited thereto since modifications may be made and other embodiments of the principles of this invention will occur to those skilled in the art to which

this invention pertains. Therefore, it is contemplated by the appended claims to cover any such modification and other embodiments as incorporate those features of this invention within the true spirit and scope of the following claims.

What is claimed is:

1. A prosthesis for the replacement of autogeneous blood vessels in human beings comprising a substrate including a plurality of braided yarns so as to form a smooth blood flow surface and a monofilament support wrapped around said substrate wherein the porosity of said substrate is no greater than about 500 ml./min-cm$^2$ at 120 mm Hg.

2. The invention of claim 1 wherein a predetermined number of said yarns are multiple plies of type 56 polyester yarns.

3. The invention of claim 2 wherein said multiple plies of yarn have a denier ranging from 100 denier to 40 denier and ranging from 96 yarn filaments for 100 denier to 27 yarn filaments for 40 denier.

4. The invention of claim 1 wherein a predetermined number of said yarns are texturized.

5. The invention of claim 1 wherein the bursting strength of said substrate is at least 750 p.s.i.

6. The invention of claim 1 wherein said substrate has a cauterized end having a suture retention of at least 2.0 kg.

7. The invention of claim 1 wherein the porosity of said substrate is such that preclotting of the prosthesis is not necessary for implantation into a human being.

8. The invention of claim 1 wherein said monofilament support wraps around said substrate to form a helix.

9. The invention of claim 1 wherein said monofilament supports wraps around said support to form a double helix.

10. A method of making a prosthesis for the replacement of autogenous blood vessels in human beings comprising:

preparing a substrate of braided yarn into a sleeve-like configuration; and

processing the substrate including cutting the substrate to a preselected length and compacting the substrate.

11. The method of claim 10 wherein the compacting comprises placing the substrate in a halogenated hydrocarbon at a predetermined temperature for a predetermined time period.

12. The method of claim 10 further comprising applying an external monofilament support to said substrate.

13. A method of compacting a substrate of braided yarn for a vascular prosthesis of a preselected diameter comprising:

placing said substrate having said preselected diameter on a mandrel of about equal diameter;

placing said substrate on a mandrel in a halogenated hydrocarbon;

elevating the temperature of said halogenated hydrocarbon to at least 200°F for a predetermined length of time; and

quickly cooling said mandrel and substrate in the halogenated hydrocarbon to room temperature.

14. A method of applying a monofilament polypropylene support to a substrate of braided yarn to form a supported vascular shaft comprising:

placing said substrate on a mandrel;

affixing a monofilament of polypropylene to a first end of said mandrel;

rotating said substrate and mandrel;

spirally winding said monofilament along the length of the rotating substrate;

affixing the monofilament to a second end of said mandrel; and

heating said mandrel and substrate with monofilament to at least 190°C for at least 5 minutes.

FIG. 1

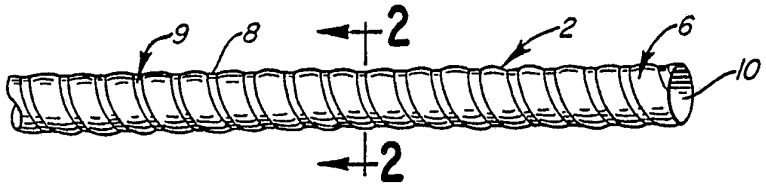



FIG. 2

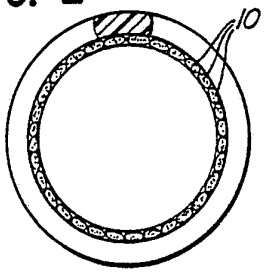
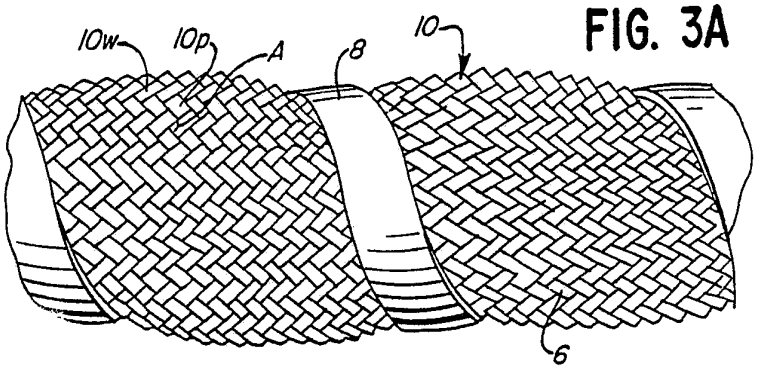



FIG. 3A



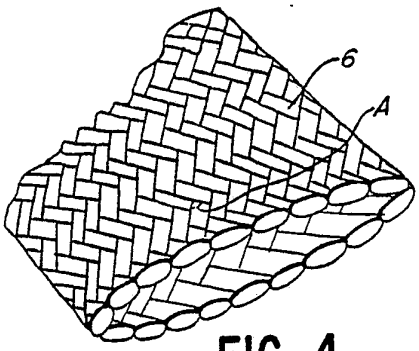




FIG. 4

FIG. 3B

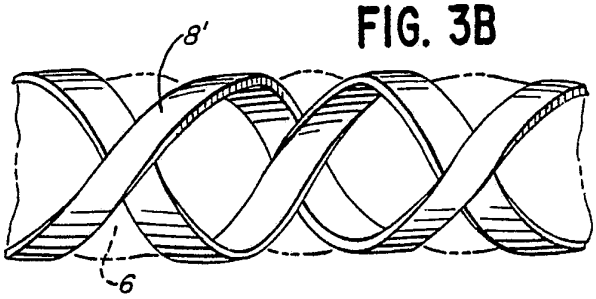



FIG. 5

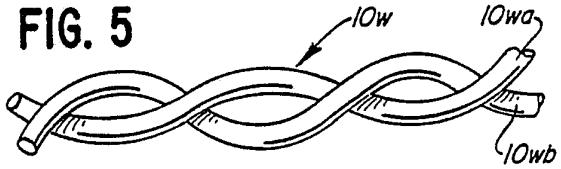



FIG. 6

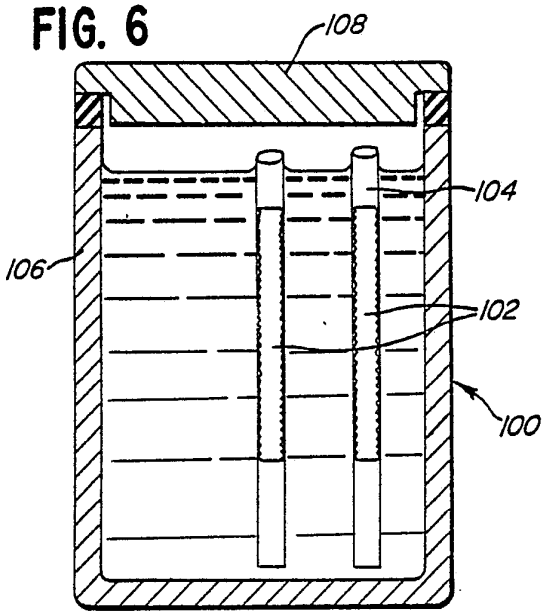
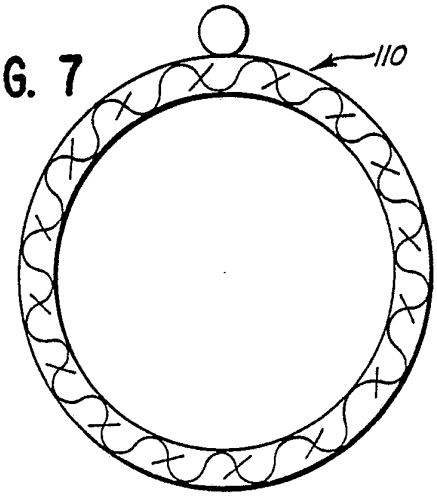



FIG. 7



# INTERNATIONAL SEARCH REPORT

International Application No PCT/US87/01869

## I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC: (4) A61F 2/06
U.S. Cl. 623/1

## II. FIELDS SEARCHED

Minimum Documentation Searched [4]

| Classification System | Classification Symbols |
|---|---|
| U.S. | 623/1, 12,66 128/334R |

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

## III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

| Category * | Citation of Document, [16] with indication, where appropriate, of the relevant passages [17] | Relevant to Claim No. [18] |
|---|---|---|
| Y | US,A, 4,191,218 (CLARK ET AL.) 04 March 1980 See col. 2, l. 37-38 | 10-12 |
| Y | US,A, 4,441,215 (KASTER) 10 April 1984 See col. 6, l.1-17 | 6 |
| Y | US,A, 4,517,687 (LIEBIG ET AL.) 21 May 1985 See col. 2, l.37; col. 2, l.53-54; col. 3, l.25-29; col. 3, l.59-63 | 3,4,7,10 |
| Y | US,A, 3,479,670 (MEDELL) 25 November 1969 See col. 2, l. 29-35; col. 2, l.36-39; col. 3, l.9-11; col. 3, l.14-18 | 1,8,9,13,14 |

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

## IV. CERTIFICATION

| Date of the Actual Completion of the International Search [2] | Date of Mailing of this International Search Report [2] |
|---|---|
| 25 September 1987 | 15 OCT 1987 |
| International Searching Authority [1] ISA/US | Signature of Authorized Officer [20] A. Cannon |