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VASCULAR PROSTHESES

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This invention relates to prosthetic articles.

More particularly, this invention relates to vascular prosthetics having a pre-determined porosity.

Prosthetics are known and are commonly manufactured from Dacron (proprietary name for polyethylene terephthalate) or Teflon (proprietary name for polytetrafluoroethylene) fibers. Such articles are available in essentially four types of construction:

- (1) Seamless knitted arterial grafts;
- (2) Seamless woven arterial grafts;
- (3) Seamless knitted bifurcations; and
- (4) Seamless woven bifurcations.

Of the foregoing, the knitted type is highly resistant to fraying on the cut edges. In the woven type greater care must be taken in handling cut edges and each suture placed well back from the cut edge. A seamless knitted graft, the most widely used, as the more open weave allows the blood to penetrate the interstices of the fabric, permits subsequent ingrowth of fibrous tissue to produce firm attachment of the new intima lining on the inner surface. Seamless woven grafts are relatively non-porous and their use is indicated in certain conditions where the clotting mechanism has been temporarily altered by heparinization. From the above it is noted that the seamless knitted grafts are undoubtedly preferred under all the usual conditions and that porosity of the graft is important.

It is an object of this invention to provide prosthetics of pre-determined porosity and a simple method of manufacturing the same.

It is a further object of the invention to provide a vascular prosthetic of the foregoing characteristics and made from fibers well known to be suitable for such articles.

The foregoing objects are achieved by this invention which essentially comprises winding a fiber on a form of suitable configuration so that the fibers overlap, and fusing the fibers where they are in contact. The winding operation controls porosity and the fusing step forms the wound fibers into an integral article.

To fabricate a vascular prosthetic according to this invention, a fiber, for example of Dacron, having a suitable diameter, is wound on a mandrel. The diameter of the mandrel will determine the inside diameter of the finished article and will depend on the size of the vessel to be repaired. The fiber can be wound back and forth along the mandrel in a number of winding patterns, and the number of turns per unit length plus the thickness of the wound material will determine the porosity. The closeness of turns is easily regulated by ordinary apparatus, such as a universal winder of the type usually found in textile mills.

The wound fabric is then fused by means of adhesion between the crossed threads to form an integral article. Various adhesives can be used for this purpose and the Versamids (proprietary name for a series of polyamide resins produced by the condensation of polycarboxylic acids with polyamines) are one suitable type of adhesive. The fusing step, when the foregoing polyamide resin is employed, can be accomplished by simply curing the heat-setting adhesive.

Ultrasonic techniques may also be employed to fuse the fiber. Polyethylene terephthalate is known to be sealable by this technique. See "Ultrasonic Splicing of Polyethylene Terephthalate Fibers," by F. P. Alles, appearing in

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the Journal of the Society of Motion Picture and Television Engineers.

The following example illustrates a preferred embodiment of carrying out the invention, but it is to be understood that this example is given by way of illustration and not limitation.

Example

Dacron fiber was wound from a bobbin onto a mandrel having a diameter of approximately 0.20". The mandrel is part of a universal winder and is supported in a chuck driven by an electric motor. A fiber feeding device is mounted in a carriage movable parallel to the axis of the mandrel. A variable speed and reversible electric motor drives the carriage and feeding device. By varying the speeds of the electric motors, an infinite variety of winding patterns can be achieved. A brush roller coating device is also mounted on the carriage and is adapted to apply a thin coating of a Versamid resin adhesive (Versamid "400") to the Dacron fiber. Adhesive is not applied to the fiber until a layer of fiber has been first wound on the mandrel to prevent the fiber from sticking to the mandrel. While the mandrel is turning, the carriage is caused to traverse the length of the mandrel several times. The fibers of each layer overlap underlying layers and form a porous hollow tube. For a given number of turns per inch and a given number of layers (which establishes wall thickness) the porosity of the resultant article can be readily determined by experimentation. Once a suitable value is obtained, the process parameters of turns per inch and wall thickness are established. An article having that porosity can thereafter be rapidly fabricated.

To set the resin and thereby render the article integral, the wound fiber is gently heated to cure the resin while still on the mandrel. Curing agents known in the art as suitable catalysts for this reaction may be employed to facilitate the process. A convenient method of heating the article is to employ a steam jacketed mandrel. Hot water or steam circulated through the mandrel efficiently sets the resin. Other heating apparatus, such as heat lamps, may be used.

Rather than employ a brush-coating technique, the resin may be applied by other means such as roller coating or dip coating.

The process lends itself to mass production techniques and can employ the usual type of winding equipment. For this reason, no expensive or unusual equipment is necessary.

We claim:

1. A method of fabricating a vascular prosthetic article of pre-determined porosity comprising winding a non-absorbable fiber filament suitable for vascular prosthetic use onto a form in a first direction to provide a first helically wound layer of filament on said form, winding said filament in a second opposite direction to provide a second helical layer of filament disposed over said first layer to thereby form a plurality of points of intersection of said filament and to increase the thickness of the wall of the hollow article so formed while at the same time reducing the porosity of said wall, continuing said winding by repeating winding in alternating opposite directions a pre-determined number of times to provide an article of pre-determined wall porosity which porosity renders said article suitable for prosthetic use, and fusing the fiber filaments together at said points of intersection to provide an integral vascular prosthetic article.

2. A method of fabricating a vascular prosthetic article of pre-determined porosity comprising winding a non-absorbable fiber filament suitable for vascular prosthetic use onto a rotating cylindrical form to provide a first helically wound layer of said fiber on said form, con-

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tinuing said winding by providing a second helically wound layer over and of opposite hand with respect to said first layer to form a plurality of points of intersection between filaments of said first and second layers and to increase the thickness of the wall of the hollow cylindrical article so formed while simultaneously reducing the porosity of said wall, continuing said winding by providing a pre-determined number of further helically wound layers over said second layer each further layer having a hand opposite to that of the underlying layer to provide a vascular prosthetic article of pre-determined porosity which porosity renders said article suitable for vascular prosthetic use, the fiber of said second and following layers being coated prior to winding with a heat setting adhesive, and heating said vascular prosthetic article to cure set adhesive and to fuse said fiber at said points of intersection to form an integral vascular prosthetic article.

3. A method according to claim 2 wherein said fiber is polyethylene terephthalate and said adhesive is a polyamide resin.

4. A vascular prosthetic comprising a hollow tubular article having a wall comprising a plurality of layers of a fiber filament suitable for vascular prosthetic use and wound in the form of a helix, each helical layer being of opposite hand such that a plurality of points of intersection of fibers is present between each helical layer, said article having a pre-determined porosity suitable for vas-

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lar prosthetic use and being established by the number of helical layers constituting said wall, and the fiber of each layer being fused to each adjacent layer only at said points of intersection.

5. A vascular prosthetic article as claimed in claim 4 wherein said fiber is polyethylene terephthalate.

6. A vascular prosthetic article as claimed in claim 5 wherein a heat-set polyamide resin adhesive is present at each point of intersection to fuse fibers of said adjacent layers.

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