

United States Patent [19]
Sauvage

[11] **3,878,565**
 [45] **Apr. 22, 1975**

- [54] **VASCULAR PROSTHESIS WITH
 EXTERNAL PILE SURFACE**
 [75] Inventor: **Lester R. Sauvage**, Seattle, Wash.
 [73] Assignee: **Providence Hospital**, Seattle, Wash.
 [22] Filed: **July 25, 1973**
 [21] Appl. No.: **382,631**

Related U.S. Application Data

- [63] Continuation of Ser. No. 168,786, July 14, 1971,
 abandoned.
 [52] U.S. Cl. 3/1; 3/DIG. 1; 66/169;
 66/194; 128/334 R
 [51] Int. Cl. A61f 1/24; D04b 1/02; D04b 9/12
 [58] Field of Search 66/169, 170, 191, 194,
 66/9 R, 9 B; 28/72 P; 26/2 R; 139/387 R;
 3/1, DIG. 1; 128/334 R, 334;
 138/121, 123-125

[56] **References Cited**
UNITED STATES PATENTS

2,752,953	7/1956	Schmidt	138/125
2,804,762	9/1957	Kameda	66/170
2,944,588	7/1960	Sannipoli et al.	66/170 UX
3,094,762	6/1963	Jeckel	139/387 R
3,096,560	7/1963	Liebig	139/387 R
3,108,357	10/1963	Liebig	139/387 R
3,316,557	5/1967	Liebig	3/1

3,463,158	8/1969	Schmitt et al.	128/334 R
3,479,670	11/1969	Medell	3/1
3,561,441	2/1971	Lombardi	66/194 X
3,571,815	3/1971	Somyk	66/170 X
3,588,920	6/1971	Wesolowski	3/1

OTHER PUBLICATIONS

Knitting Spare Parts for Human Bodies, Textile Industries, December, 1959.
 Prosthetic Reconstruction of the Trachea, Surgery, March, 1969, Vol. 65, No. 3, pp. 462-469.
 Artificial Skin, Vol. XII, Trans. Amer. Soc. Artif. Int. Organs, 1966, pp. 340-343.

Primary Examiner—James Kee Chi
 Attorney, Agent, or Firm—C. E. Martine, Jr.

[57] **ABSTRACT**

A tubular textile synthetic cardio-vascular prosthesis manufactured from polyester or other synthetic fibers and provided externally with a thin resilient mat surface defined by a multiplicity of fiber loops capable of enhancing the ability of the graft to retain clotted blood and improve the rate of growth of tissue within its confines while permitting free passage of unclotted blood therethrough.

4 Claims, 6 Drawing Figures



Edwards v. Aortic Innovations
 U.S. Patent 11,389,310
Edwards Ex. 1135

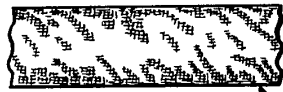


FIG. 1A

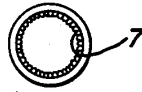


FIG. 1B



FIG. 1C



FIG. 2A

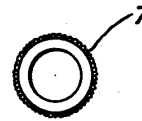
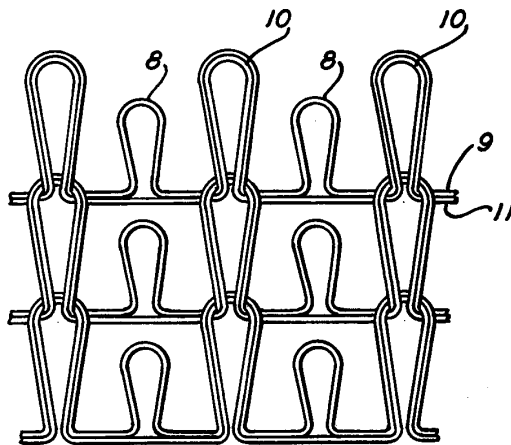


FIG. 2B

FIG. 3



INVENTOR.
LESTER R. SAUVAGE

BY

W. Carlton Howard

VASCULAR PROSTHESIS WITH EXTERNAL PILE SURFACE

This application is a continuation of copending application Ser. No. 168,786 filed July 14, 1971 by Lester R. Sauvage, now abandoned.

This invention relates generally to new and useful improvements in synthetic vascular prostheses or grafts and particularly seeks to provide a velour graft having its outer surface especially formed to retain clotted blood while permitting free passage of unclotted blood.

One type of synthetic graft that is being used for this purpose is formed as a continuous tube knitted from a polyester or other synthetic thread or yarn and axially compacted to define a multiplicity of transverse corrugations, as shown in Jeckel U.S. Pat. No. 3,337,673. These corrugations greatly increase the surface area per unit length of the graft and the ridges and hollows of its inner surface tend to hold any clotted blood within the confines of the length of the graft until the clots become dissolved while permitting the free passage of unclotted blood therethrough.

Although this type of synthetic graft has been quite successful, it is believed that it would function more efficiently if more positive means could be found to hold clotted blood within the confines of the length thereof, thereby further reducing the possibility of blood clots entering the blood stream before they can be dissolved.

The literature in this field shows that braided, woven or knitted cardiovascular prostheses should, in general, be at least partially permeable and should be so textured as to promote healing with minimum danger of thrombus formation. Velour-type fabrics have been experimentally bonded to luminal surfaces of impermeable prostheses to anchor autologous layers of fibrin in a position to form pseudointimas, covering the plastic and interfacing with the blood (SURGERY, Jan. 1969, Vol. 65, pp. 70-77). Such fabrics, with the pile loops on the inside, have also been used alone, with some success but with the disadvantage that the healing and endothelialization on the inner surface reduce the size of the lumen and thus require use, initially, of over-size grafts to achieve a desired final result.

According to the present invention, a tubular prosthesis is knitted with pile loops on the inside, as is customary with available knitting machines, and is then turned inside out. Finishing operations preferably include axial compression on a mandrel, as suggested in Tapp U.S. Pat. No. 2,836,181, but to only a slight extent (e.g. 30 percent or less), producing loose random corrugations without flattening the pile, followed by setting in any customary manner to give some dimensional stability. In small sizes, for some applications, the crimping or corrugating step may be omitted.

Therefore, an object of this invention is to provide a synthetic graft having a velour exterior surface formed to enhance the retention of clotted blood and improve the rate of growth of tissue within the confines of the length thereof.

Another object of this invention is to provide a synthetic graft of the character stated which is formed as a continuous tube knitted from two or more polyester or other inert threads or yarns and of diverse forms.

Another object of this invention is to provide a synthetic graft of the character stated in which the continuous tube thereof is knitted from two or more yarns, one of which is inwardly displaced to define a loop at

each knitting point thereby forming a resilient mat-like surface over the entire inside of said tube, the tube being then turned inside out and loosely crimped or corrugated.

With these and other objects, the nature of which will be apparent, the invention will be more fully understood by reference to the drawing, the accompanying detailed description and the appended claims.

FIG. 1A represents an elevation of a knitted velour tube for synthetic graft constructed without transverse corrugations, provided externally with a thin resilient mat surface defined by a multiplicity of fiber loops;

FIG. 1B represents an end elevation of the knitted tube of FIG. 1A having a resilient mat surface on the inside of the tube, before being turned inside out;

FIG. 1C represents an end elevation of the knitted tube of FIG. 1A, having the resilient mat surface on the outside of the tube;

FIG. 2A represents an elevation of a knitted velour tube for synthetic graft constructed with random transverse corrugations, provided externally with a thin resilient mat surface defined by a multiplicity of fiber loops.

FIGS. 2B represents an end elevation of the knitted tube of FIG. 2A having the resilient mat surface on the outside of the tube.

FIG. 3 represents an enlarged fragmentary diagram of the knitting pattern.

The size of the loops forming mat surfaces is exaggerated in FIGS. 1B, 1C and 2B for purposes of illustration.

Referring to the drawing in detail, the invention as illustrated is embodied in a synthetic graft formed from a continuously knit tube 6.

The entire inner surface of the tube 6 is covered by a thin resilient mat, generally indicated at 7, defined by a multiplicity of internally directed thread loops 8 that are formed by a loop thread 9 (see FIG. 3) and concatenated with the jersey knit loops 10 formed from a body thread 11.

The tube 6 with its loop mat 7 is knitted on a jersey knit circular knitting machine that has been modified to accept and properly position the loop thread 9 so that a loop is formed in it for enclosure by and concatenation with each new loop of the body thread 11, all of the mat-forming loops 8 being on the inside of the tube, as originally knitted.

To further explain, if for a given size artificial artery a 66 needle circular knitting machine is used then there would be 66 wales and each of the body thread loops 10 in each course would contain a concatenated loop of the thread 9, each mat-forming loop 8 being formed by the operation in a suitable manner of jacks alternating with the needles.

After the internally matted tube 6 has been knitted it is further processed by being turned inside out (FIG. 1C) followed by controlled axial compaction and heat treatment to form a multiplicity of random transverse corrugations (FIGS. 2A and 2B) the mat-covered surface being capable of enhancing the ability of the graft to retain clotted blood and improve the rate of growth of tissue where desired while permitting free passage of unclotted blood therethrough.

In the normal operation of the circular knitting machine referred to above the loops 8 are formed on the inside of the tube, as stated, resulting in the tube shown in FIG. 1B. Important advantages have been noted in

3

the use of synthetic grafts having the "velour" or mat surface on the outside (FIGS. 1C and 2B), and such tubes can most conveniently be made merely by turning inside out the tubes as produced on the machine.

It will of course be understood that the mat-forming loops 8 need not be formed between each pair of the body loops 10, but may be formed in any desired sequence so long as the mat 7 is well defined. However, at the present time and with the presently used types of polyester or other inert fiber threads, it appears preferable to have a mat-forming loop with each body loop.

A presently preferred polyester for use as described above is "Dacron;" "Teflon" also appears to be practical and desirable under some circumstances.

By the use of the random crimp or corrugation (FIG. 2A) there is no crushing of the loops which occurs if the spiral wound corrugation of Jeckel U.S. Pat. No. 3,367,673 is resorted to. Loops on the inside reduce the area of the lumen, as noted, whereas placing the loops on the exterior leaves the interior of the tube smooth and full size while healing takes place over the entire exterior surface, not merely at the points of anastomosis, as commonly noted in presently used grafts.

In actual use of these prostheses in man, no long-term observations are available but short term observations are very significant. In experimental use during the past year such grafts have been implanted in more than 75 patients, some of whom required difficult arterial repairs and the distal bed being often quite restricted. At the outset it was found that ease of suturing was a great advantage, and the external velour surface provided a high degree of filamentousness which facilitated pre-clotting of the prosthesis and minimized blood loss.

Observation for periods up to 6 months showed impressively the apparent benign incorporation of the

4

prosthesis into the surrounding tissues, with which they blend in a manner contrasting sharply with the fibrotic reaction around conventional grafts with relatively smooth outer walls. In previously known grafts the fibrous tissue ingrowing from the end of the artery, adjacent the anastomosis, was not thrombogenic, whereas that growing in from the perigraft sources was undesirably thrombogenic compacted fibrin. No such thrombogenicity has been observed in the grafts disclosed herein.

What I claim is:

1. A tubular knitted textile synthetic vascular graft comprising a tubular body provided with a multiplicity of knitted fibrous loops projecting outwardly from the outer surface of said body and presenting a pile mat of filamentary material receptive to tissue ingrowth on said outer surface, said loops being effective to improve the rate of growth of tissue within said graft.

2. The synthetic graft of claim 1 in which said knitted tube is formed from one continuous thread and the loops of said resilient mat are formed from a second continuous thread.

3. The synthetic graft of claim 1 in which said knitted tube has been axially compacted to define a multiplicity of circumferential corrugations, along its length.

4. A tubular knitted textile synthetic vascular graft comprising a seamless tubular body provided with a multiplicity of knitted fibrous loops projecting outwardly from the outer surface of said body and presenting a relatively open pile mat of filamentary material receptive to tissue ingrowth on said outer surface, said tubular body controlling the passage of tissue elements therethrough.

* * * * *

40

45

50

55

60

65