

April 17, 1962

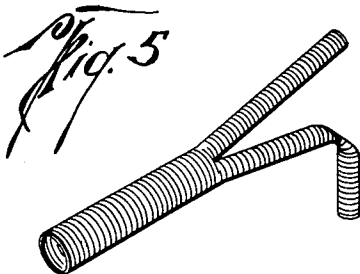
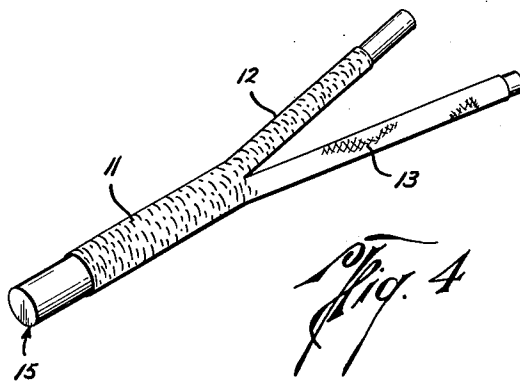
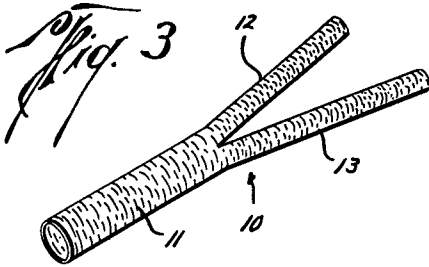
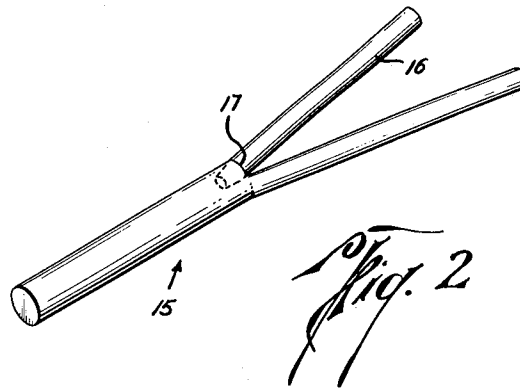
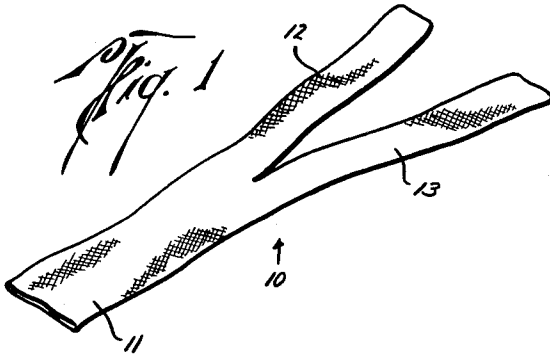
E. E. STARKS

3,029,819

ARTERY GRAFT AND METHOD OF PRODUCING ARTERY GRAFTS

Filed July 30, 1959

2 Sheets-Sheet 1



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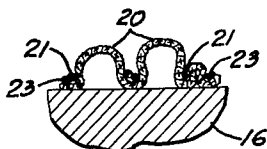
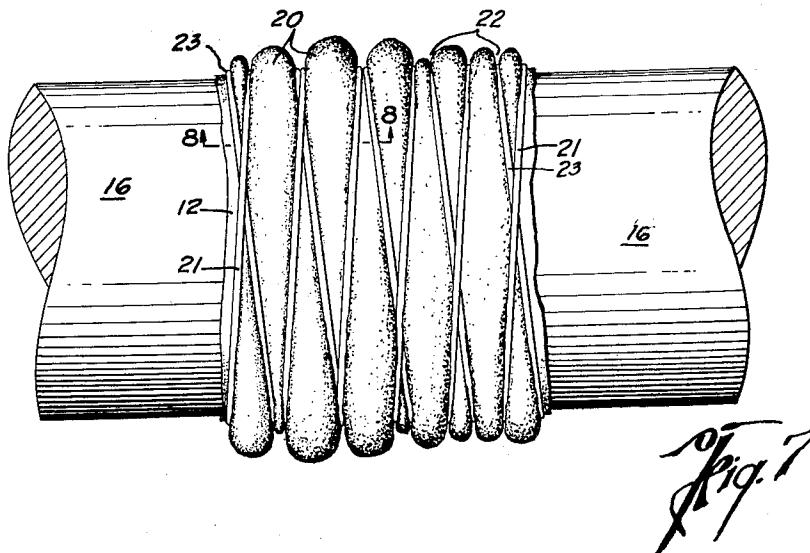
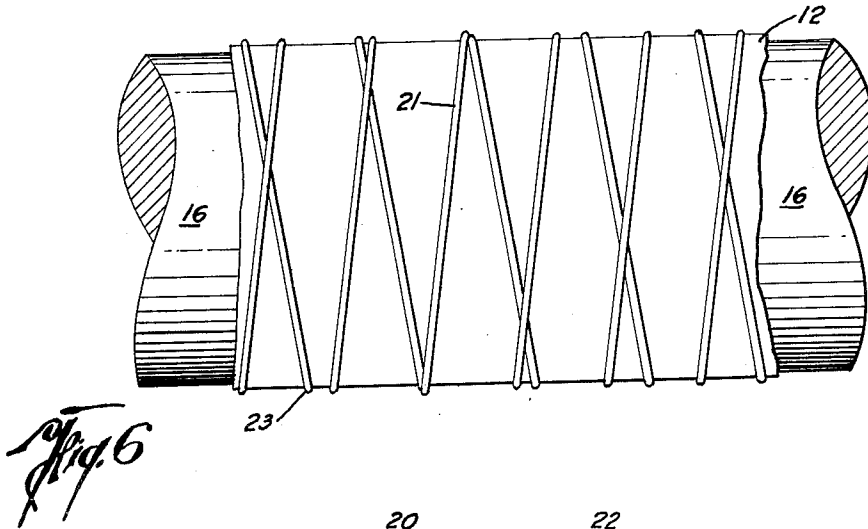
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ARTERY GRAFT AND METHOD OF PRODUCING ARTERY GRAFTS

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2 Sheets-Sheet 2



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1

3,029,819

ARTERY GRAFT AND METHOD OF PRODUCING ARTERY GRAFTS

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7 Claims. (Cl. 128—334)

This invention relates to artificial or substitute arteries and more particularly to an improved artery graft and a method of making such artery graft.

It frequently occurs that, for one reason or another, a portion of an artery must be removed from either man or other animal, and some graft or substitute must be inserted to replace the removed portion. Nylon warp loom fabric tubes have been used for the purpose. While such tubes are porous, it has been found that, when the tube has been sewed in place, the body naturally forms a film or some sort of seal of the pores in the fabric and, in approximate effect, reconstructs a new artery about the nylon fabric tube as a base or foundation structure.

But the nylon tubes have several disadvantages. In use, it is usually necessary to bend the artery graft, and it is absolutely necessary that the graft not kink as all tubing tends to do upon bending. Also, in use it frequently occurs that the grafts are stretched lengthwise; in grafts previously known such lengthwise stretching causes a substantial reduction of the diameter of the graft, and/or causes a twisting of the graft, both of which have obvious disadvantages when the tube is used in grafting an artery of certain blood carrying capacity and when being secured to the ends of artery tissue of the patient.

A partial answer to some of these and other problems has been experimentally arrived at—to preset in the nylon fabric a series of annular ridges, as by placing the tubular fabric upon a ribbed or threaded mandrel, winding the grooves or thread with wire and placing in an acid bath until the fabric takes on a permanent set. But this solution has proved impractical because of the varying internal diameters, twists, rough surfaces, and remaining kink tendency, and for other reasons.

Grafts resulting from those experiments have now been substantially completely replaced by those of this invention.

Accordingly, an object of this invention is to provide an improved artery graft.

Another object of this invention is to provide an artery graft of insignificant diameter change upon lengthwise extension of the graft.

Further objects of the invention are to provide a graft having good resistance to kinking and to twisting, having a properly fine porosity, resilience, and stretch.

Still another object of this invention is to provide a method of and apparatus for making artery grafts by which bifurcated grafts of uniform quality and characteristics throughout their length including completely up to the bifurcation, may be readily made.

Other objects are apparent from the following description and accompanying drawings.

These objects are accomplished in accordance with preferred embodiments of this invention, by among other things, the placing of artery graft fabric upon a smooth mandrel and winding thereof as hereinafter described, followed by appropriate heating to cause the fabric to take on the set dictated by the mandrel and winding.

FIGURE 1 is an illustration of a typical limp woven bifurcated sleeve of the type which may be used in this invention.

FIGURE 2 is a pictorial illustration of a mandrel conveniently used as a part of this invention.

FIGURE 3 illustrates pictorially a typical artery graft produced by and constituting this invention.

2

FIGURE 4 illustrates pictorially a mandrel, as of FIGURE 2, sheathed in a fabric sleeve as of FIGURE 1, and partially wound and wrinkled in accordance with this invention.

FIGURE 5 illustrates a kink of the type that frequently occurs when tubular sleeves are bent and of a type this invention seeks to avoid in artery grafts.

FIGURE 6 is a fragmentary side elevational view, greatly enlarged, of a portion of the leg 12 of the article shown in FIGURE 4, but illustrating the same before axial compression.

FIGURE 7 is a fragmentary side elevational view, matching FIGURE 6, but illustrating the portion of the article after extensive, but incomplete, axial compression.

FIGURE 8 is a sectional view taken on line 8—8, FIGURE 7.

In FIGURE 1, there is illustrated a typical piece of cloth 10, woven into bifurcated tubular sleeve form, lying flat and limp as it naturally tends to do. For convenience of reference we may refer to the portions thereof as the main sleeve 11, a first leg 12 and a second leg 13. While a straight tubular graft might have been shown the bifurcated one is chosen for illustration here.

The fabric of the woven sleeve is preferably of a weave necessitating all threads to kink and turn continuously, as a knit weave. Weaves of a large number of warp threads running about as much longitudinally of the sleeve as around it and without weft threads running more directly around the sleeve are not preferred as such weaves tend more to reduce in diameter upon lengthwise stretching.

Soft fibrous crimped yarn of polyethylene terephthalate (e.g., Dacron, E. I. duPont de Nemours & Co., Wilmington, Delaware) has been found to be superior to most other materials out of which to weave the cloth. Many yarns cannot be made to work at all in this invention.

A critical feature of this invention is the use of a smooth surfaced mandrel 15 such as that illustrated in FIGURE 2, as distinguished from a mandrel of earlier experiments with threads or other annular or approximately annular helical grooves therein.

In accordance with the method of a preferred embodiment of this invention, the mandrel 15 is inserted into the woven sleeve 10. In bifurcated mandrels, such as that illustrated, one of the legs such as the leg 16 may be detached from the remainder of the mandrel, as by unscrewing it, to facilitate the insertion and removal of the mandrel into and from the sleeve 10. In FIGURE 2, the joint between the leg 16 and the remainder of the mandrel is illustrated at 17, and a male and female screw arrangement, not shown, is positioned on the axis of the leg 16 and in the body of the mandrel to serve as the detachable securing means for the leg 16.

Once the sleeve is on the mandrel, the mandrel is wound an appropriate number of turns per inch of length of the mandrel, as for example 10 turns per inch, in a helical wind advancing along the mandrel. This is preferably followed by a counter-wind of helical form. Viewed from one end of the mandrel, one wind will be with right hand helix and the other with left hand helix. Preferably the second wind is of a slightly different number of turns per inch, for example 8 turns per inch.

Thread of about .008 inch diameter and made of nylon has been found preferable for the winding, though such size is not at all critical. With such thread it is apparent that much more space is left between the threads at 8 or 10 turns per inch, than is covered by the threads, and this leaving-of-more-space-than-is-covered-by-thread is important to best results.

In fact, if the number of turns per inch is significantly

less than 5 or more than 20 turns per inch, the artery graft is rendered so inferior to that obtainable with a proper number of turns, as to make it surgically unacceptable though perhaps technically still operable. For such a number of turns (8 and 10 per inch) the helix angle of the thread-winds, after wrinkling as below defined, is in the less than 25° range.

One of the significant and preferred features is the use of two separate winds of threads of opposite helical form. When the wind or winds are of the same helix, a stretch upon the resulting graft causes the ends thereof to tend to twist. While some slight twisting can be occasionally tolerated it is never preferred. Hence, the double wind of reverse helix is of importance to the best artery graft and often in this work only the best is good enough.

Also, the reverse helix appears to impart to the resulting artery graft a greater resistance to kinking (as in FIG. 5) upon bending of the artery graft, and of course a maximum resistance to kinking is imperative in artery grafting work.

After the winding as aforesaid, the sleeve 10, or if it be a bifurcated sleeve then the various arms 11, 12 and 13 thereof, are pushed up on the mandrel until small wrinkles are formed throughout the length of the sleeve (or each arm or leg throughout the length of such arm or leg). Means for holding the sleeves up in the wrinkled condition may be attached to the mandrel if desired.

It is significant that the mandrel be enough smaller than the sleeve itself, to permit this wrinkling of the sleeve upon the mandrel, while at the same time leaving no more space than is necessary for this wrinkling. However, the tolerance of variation between sleeve diameter and mandrel diameter is much greater in this invention, than when threaded mandrels are used.

FIGURE 4 illustrates a sleeve on a mandrel with main sleeve 11 and first leg 12 wound and wrinkled, while the second leg 13 remains yet to be wound and wrinkled. A portion of the wound and wrinkled leg 12, greatly enlarged, is illustrated in FIGURE 7, and FIGURE 6 provides a graphic reference by which the dispositions of the fabric tube and its windings, after axial compression of the tube, can be compared with the dispositions thereof before axial compression.

After the sleeve is wrinkled, the mandrel-with-sleeve-and-nylon-thread-wind thereupon is placed in an oven for appropriate baking—enough to give to the fabric a permanent set. Many materials will not take an effective set within convenient baking tolerances—they either take no set or burn up or become weakened. When polyethylene terephthalate (Dacron) is used and the mandrel is average room temperature at the commencement of the baking procedure, a nine minute bake in a 450° oven has been found effective to raise the Dacron itself to a setting temperature, perhaps 360°. It will be understood that, polyethylene terephthalate being thermoplastic, with a melting point on the order of 480°, such baking is effective to soften the fabric of the sleeve and that, after being again cooled to room temperature, the fabric will retain that form in which it was baked.

The mandrel is then cooled, the thread removed, the leg 16 unscrewed if a bifurcated artery graft is being made, and the entire sleeve removed from the mandrel. The improved artery graft of FIGURES 3 and 6-8 is the result.

While it is impossible to illustrate in absolute detail in a drawing the nature of the ridges and wrinkles and texture of the surface of the improved graft, it can be understood that the improved graft of FIGURES 3 and 6-8 has a character of flexibility rather than the loose dish rag limpness of the raw woven sleeve of FIGURE 1. The outside surface is covered with wrinkles extending helically, while the inside surface is free of protrusions, ridges and grooves. Thus, the artery graft can be characterized as having closely adjacent, outwardly bulging wrinkles in the form of helical convolutions, indicated at 20, FIG-

URES 7 and 8, the wrinkles being defined by edges formed by winding 21, FIGURE 7. The helical wrinkles 20 are interrupted by helical depressions indicated at 22, FIGURE 7, formed by winding 23 which extends counter to the helical direction of the wrinkles. Since mandrel portion 16 has a smooth cylindrical surface, and since the valleys which define the edges of the wrinkles, and the depressions which interrupt the wrinkles, are formed respectively by windings 21 and 23, the edges of the wrinkles and the bottoms of the depressions interrupting the wrinkles all lie in a common cylindrical surface and the wrinkles, bulging outwardly, lie wholly outside of that common surface.

The improved artery graft tends to hold its cylindrical form, to be stretchable without either twisting or objectionable change in diameter, to afford when under blood pressure high resistance to kinking when being bent through short radius curves.

Further, the inside of the artery graft has a surface texture varying from tight and very smooth to porous and of the smoothness of the raw untreated sleeve fabric material—the totality of which is a surface smooth and substantially free from ridges, grooves and the like. When the improved graft is stretched longitudinally grooves in the inside surface reappear but in the relaxed unstretched condition there are no grooves in any substantial sense in the inside surface. This is by marked contrast with prior art experimental grafts in which the inside surface of the grafts have ridges, grooves, and the like therein, comparable to those on the outside.

Modifications may be made in the invention as above described for illustrative purposes without departure from the scope of some phases of the invention. For example, metal thread (wire) may be used rather than nylon thread for the winding without departing from the scope of the new graft invention. And a material other than Dacron and which can be induced by acid to take an appropriate set may be used. Accordingly, the foregoing description is to be construed as exemplary only and is not to be construed as any limitation upon the invention as defined in the following claims.

I claim:

1. A woven artery graft comprising an exteriorly wrinkled fabric tube of a material having at least the general characteristics of polyethylene terephthalate, the fabric of said tube being disposed in side-by-side, helically extending, outwardly bulging wrinkles interrupted by helical depressions, said depressions extending helically in the opposite direction with respect to said helically extending wrinkles, the edges of said wrinkles and the bottoms of said depressions all lying in a common cylindrical surface and said wrinkles lying wholly outside of said cylindrical surface, said artery graft being capable of being stretched axially substantially without twisting and of recovering its initial form when released after axial stretching.

2. A woven artery graft in accordance with claim 1 and wherein the helix of said wrinkles and the helix of said depressions have different numbers of turns per inch.

3. The method for producing an artery graft comprising placing on a mandrel having a smooth surface a fabric tube formed of a yarn having at least the general characteristics of polyethylene terephthalate; winding a fine strand helically about the mandrel-supported fabric tube to provide a first winding consisting of spaced helical convolutions; then winding a fine strand helically about the mandrel-supported fabric tube to provide a second winding consisting of spaced helical convolutions, one of said windings being in the form of a right-hand helix and the other being in the form of a left-hand helix, the convolutions of said second winding crossing those of said first winding, each of said windings having at least 5 and not more than 20 turns per inch and the diameter of the fine strand of each winding being such that substantially more of the surface of the fabric tube is left uncovered than is covered by said windings; compressing the wound fabric

5

6

tube axially and thereby causing the convolutions of each of said windings to be shifted toward each other and those portions of the fabric of the tube which are not covered by said windings to assume a wrinkled disposition; heating the wound and axially compressed fabric tube, while maintaining the same in its axially compressed condition, to a temperature such that, after cooling, the fabric will have assumed a permanent set in the condition to which it is constrained by said windings and such axial compression; and then cooling the fabric tube, removing said windings and recovering the fabric tube in the form of an exteriorly wrinkled flexible tube capable of being stretched axially substantially without twisting and of recovering its initial form when released after axial stretching.

4. The method for producing an artery graft in accordance with claim 3 and wherein one of said windings has a different number of turns per inch than does the other of said windings.

5. The method for producing an artery graft in accordance with claim 3 and wherein said fabric is of a soft, crimped yarn of polyethylene terephthalate and the strand diameter of said windings is on the order of .008 inch.

6. The method for producing an artery graft in accordance with claim 3 and wherein one of said windings has on the order of 8 turns per inch and the other of said windings has on the order of 10 turns per inch.

7. The method for producing an artery graft comprising placing on a mandrel having a smooth surface a fabric tube formed of a soft fibrous yarn capable of being shaped to a given configuration and then treated to cause the same to retain that configuration as its normal disposition; winding a fine strand at least substantially helically about the mandrel-supported fabric tube to provide a first winding consisting of spaced convolutions; then

winding a fine strand at least substantially helically about the mandrel-supported fabric tube to provide a second winding consisting of spaced convolutions, said windings extending counter to each other with the convolutions of said second winding crossing those of said first winding, each of said windings having at least 5 and not more than 20 turns per inch and the diameter of the fine strand of each winding being such that substantially more of the surface of the fabric tube is left uncovered than is covered by said windings; compressing the wound fabric tube axially and thereby causing the convolutions of each of said windings to be shifted toward each other and those portions of the fabric of the tube which are not covered by said windings to assume a wrinkled disposition; heating the wound and axially compressed fabric tube to cause the same to be set in the wrinkled condition resulting from said step of axially compressing the wound fabric tube; removing said windings and recovering the fabric tube in the form of an exteriorly wrinkled flexible tube capable of being stretched axially substantially without twisting and of recovering its initial form when released after axial stretching.

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