

1

3,094,762

TETRAFLUOROETHYLENE RESIN TUBING
Norman Charles Jeckel, Glens Falls, N.Y., assignor to
United States Catheter & Instrument Corporation,
Glens Falls, N.Y., a corporation of New York
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This invention relates to improvements in knitted "Teflon" prosthesis and is more particularly concerned with a knitted "Teflon" blood vessel graft having minimal porosity.

The recent expansion of vascular surgery has increased the need for blood vessel substitutes, particularly arteries, and artery banks have been established for this purpose. Homografts (natural blood vessels) have been used to a certain extent but such use is greatly restricted by limited supply, time and expense that is connected therewith. Since the supply of homografts is limited, it is extremely difficult to match the varieties of size and shapes of blood vessels that may be necessary during surgery, the size of which may not be known prior to surgical entry.

The normal blood vessel is an extremely tough and resilient organ which must be flexible and elastic but at the same time strong and non-collapsible. The varied properties of the normal blood vessel is particularly emphasized at the joints, having an extensive range of movement, e.g., the hip joint between the legs and the primary body trunk. In fact one of the common but difficult locations for blood vessel substitution has been the aortic bifurcation where the aorta divides into the iliac arteries to supply each leg.

It was only natural that attempts be made to secure synthetic blood vessels to be used on a surgical basis. Many materials have been suggested but nylon (polyhexamethylene adipamide) appears to be the first to have been utilized on a commercial basis. Since that time other materials have been developed or suggested, including "Dacron" (Du Pont trademark for polyethylene glycol terephthalate), "Orlon" (Du Pont trademark for polyacrylonitrile) and "Teflon" (Du Pont trademark for tetrafluoroethylene resin). Various other materials have been suggested, but these have been the leading ones.

Of these presently used materials, it has been found that Teflon causes the least tissue reactivity, retains greater strength over a period of time, heals more rapidly as a graft, exhibits a lower rate of thrombosis and occlusion and causes formation of a thinner fibrous layer in the internal bore, than any of the other materials. Thus, at the present time, Teflon is by far the preferred material.

A woven or braided graft can be tightly woven so that the porosity is minimal and thus avoid external preclotting of the graft before insertion into place. However, the woven and braided grafts are not fray-resistant at cut edges and thus offer more difficulty in suturing, as the stitches must be farther removed from the cut edges. It has been found that knitted grafts are much more fray-resistant at cut edges and are thus preferable for suturing, as the stitches may be made relatively close to the cut edge. However, a knitted graft is relatively porous so that external preclotting was advisable to avoid loss of blood after insert of a graft.

It is an object of this invention to provide a knitted tube for a prosthesis which is impervious to blood and other body fluids and a method for forming such a tube.

It is also an object of this invention to provide a knitted "Teflon" tube for blood vessel grafts that has been heat treated to shrink the tube and reduce the porosity thereof.

I have found that a tube knitted of Teflon filaments can be heated over a period of time up to a point below the fusion point of Teflon which will decrease the tube diameter and reduce the size of the minute wall openings, re-

2

sulting in a final tube that will not leak blood when placed in the vascular system.

With the above objects and others in view, the nature of which will be more apparent, the invention will be more fully understood by reference to the accompanying detailed description and the appended claims.

This invention, as will be described here in detail, is embodied in a knitted Teflon tubing to be utilized as a blood vessel prosthesis.

A bleached Teflon knitted tube is baked for four hours at 610° F. which reduces the diameter from an initial 1" to a final 0.8", i.e., about 20% and the minute openings in the wall are similarly reduced. Such a heat-shrunk tube does not permit blood to pass through the walls.

The following table shows the percentage reduction of tube diameter when heated at 610° F.

Table 1

Time in hours:	Percent diameter reduction
1	14
4	20
8	27
10	30

Thus it will be noted that the shrinkage is relatively greater during the earlier heating period and tapers off considerably after one hour. The melting point of Teflon is 621° F. so that 610° is about the upper margin if fusion is to be avoided. The heating may be at a lower temperature although it is too slow below about 350° F. to be practical. The heating period can extend up to 30 hours but this reaches the point where there is very little additional shrinkage.

This heat treatment is applicable to tubes formed from white (bleached) or brown Teflon, but we prefer the bleached Teflon tubing for prosthesis for medical reasons.

Although blood vessel prostheses are the primary concern of this heat shrinking process, it may be used on any knitted Teflon tube or fabric where it is desired to reduce the porosity thereof.

I claim:

1. A process for reducing the porosity of a knitted tetrafluoroethylene blood vessel prosthesis having a tubular shape with a substantially circular cross-section comprising heating said prosthesis at a temperature range between 350° F. and immediately below the fusion point of tetrafluoroethylene.

2. A process as claimed in claim 1 wherein said heating is up to 30 hours.

3. A process as claimed in claim 1 wherein said heating is about 4 hours at about 610° F.

4. The process as claimed in claim 1 wherein said heating is continued until the original tube diameter is reduced about 20%.

5. A blood vessel prosthesis made in accordance with the process of claim 1.

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