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T. J. FOGARTY
EMBOLECTOMY CATHETER

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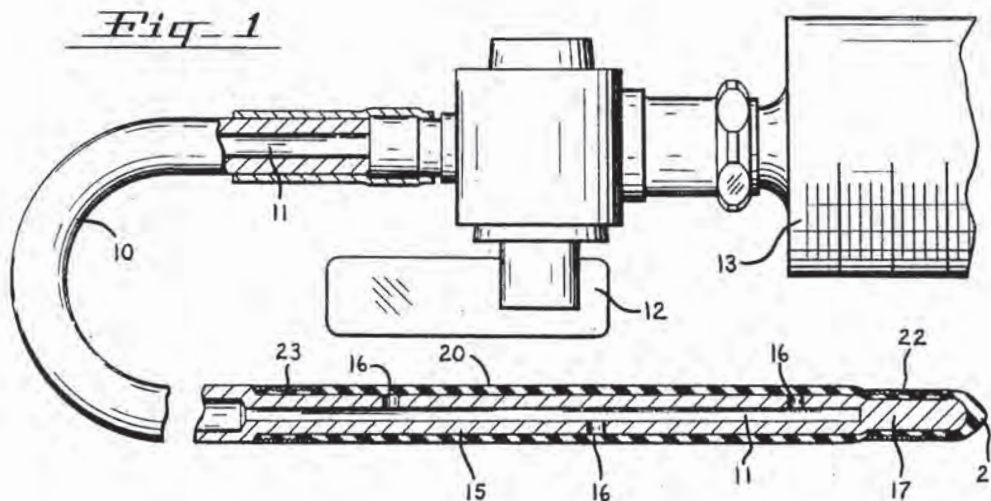
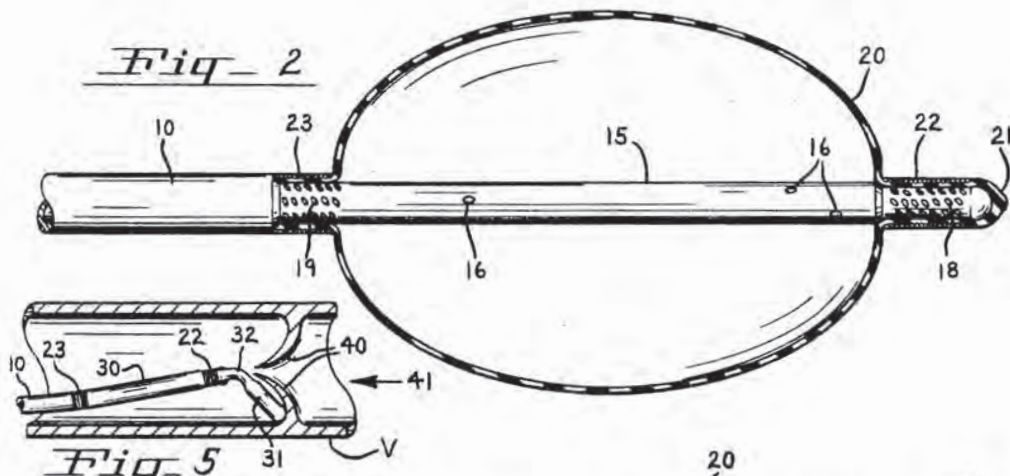
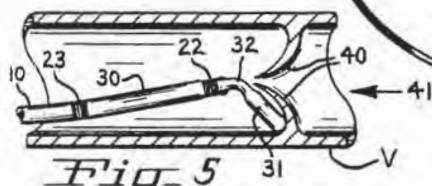
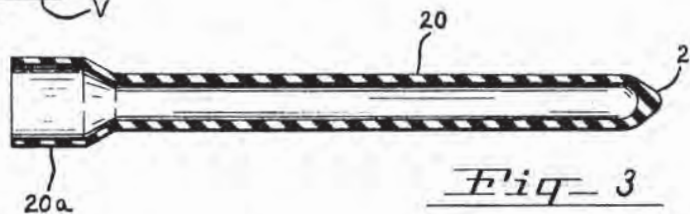
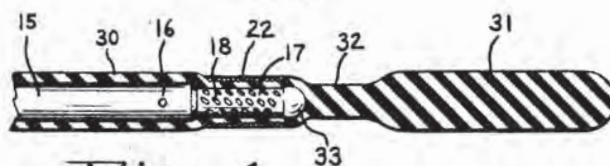


Fig. 5



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EMBOLECTOMY CATHETER

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18 Claims

ABSTRACT OF THE DISCLOSURE

A balloon catheter in which the balloon material is longitudinally stretched when deflated causing the balloon to contract circumferentially and smoothly hug the catheter body. A venous thrombectomy catheter having a soft and highly flexible tip portion capable of doubling back against the catheter body for upstream passage through the valve leaflets in a vein.

This invention relates to improvements in a balloon catheter for embolectomy purposes.

This application is a continuation-in-part of my co-pending application titled, "Method of Vascular Surgery or the Like and Instrument Thereof," Ser. No. 208,967 filed July 10, 1962, now abandoned.

In the use of a balloon catheter to remove a blood clot, the location of the clot is first determined and then an incision is made in the vessel containing the clot or in some branch of the vessel which communicates therewith. The nearest point of access where such incision may be made may in some cases be at a considerable distance from the clot, depending upon the part of the body where the clot is located. The catheter is inserted through the incision and threaded through the vessel or branch leading to the clot. With the balloon deflated, the tip of the catheter is pierced through the clot and the threading movement continued until the balloon portion of the catheter has passed entirely through the clot. Then the balloon is inflated on the remote side of the clot. The catheter may then be withdrawn, the balloon behind the clot acting as a drag to push the clot ahead of it until the clot reaches the region of the incision where it can be readily withdrawn.

Emboli can occur to many vessels of the body. These vessels may be relatively normal or diseased. Atherosclerosis is by far the most common disease affecting these vessels. When affected by this process, vessels become quite tortuous and have regions of marked angulation and narrowing. Under such conditions clots occurring in the vessels resist the passage of conventional relatively straight and stiff catheters. If undue force is exerted, the catheter may pass through the vessel wall or cause disruption of atherosclerotic material.

Many difficulties attend the removal of clots with balloon catheters. After the catheter has pierced through the clot, the balloon is inflated and the clot removed along with the catheter. During the dragging of a clot along the vessel, there is a tendency for the resistance to removal to cause the balloon portion of the catheter to slide over the tip of the catheter. Sometimes it is necessary to reduce the inflation of the balloon during removal and during such deflation this distal end portion of the balloon may become caught on the catheter tip causing the tip to angulate acutely, inflating fluid being trapped in the distal end portion of the balloon so that it does not deflate as desired.

Other problems also exist. Arteries and veins because of their specific individual functions possess certain ana-

tomical differences. Arteries, performing an efferent circulatory function, are relatively thick walled vessels without valves. Veins, having as their main function the return of blood to the heart, in contrast, are thin walled vessels containing numerous valves. Consequently, the type of clot forming in these two structures is significantly different. An arterial embolus is firmer and of greater density than the clots occurring in the veins.

Because of these differences and, also, for the sake of efficiency, the structure and design of catheters for the extraction of clots from such type of vessel must also differ. The catheters designed for the extraction of venous thrombi must be of a more pliable nature in order to avoid perforation of the venous wall. In addition, some mechanism must be available to enable a catheter to pass through the venous valves which offer obstruction to catheters not specifically designed for this purpose. Particularly, for the extraction of venous clots from peripheral portions of the body, the catheter must be designed so that the instrument can be atraumatically conducted past the valves.

The general object of the present invention is, therefore, to provide improved balloon catheters for embolectomy purposes which will overcome these problems and which will overcome the deficiencies and shortcomings of conventional catheters. Other objects are to provide improved forms of balloon structure which will not stretch beyond the tip of the catheter, which will not trap air in the distal portion of the balloon when it is desired to deflate the balloon and to provide different forms of constructions for catheters to be used in arteries and veins in order to meet the particular problems encountered in each case.

In the present catheters, the danger of passing the catheter through the wall of the vessel or causing disruption of atherosclerotic material is avoided by covering the distal extremity with soft pliable material.

In the case of the catheter for venous thrombectomy, a very pliable tip is provided extending forward from the distal end of the balloon. The pliability of the tip is of such degree that the obstruction offered by the valvular face causes acute angular deformity of the tip. The force necessary to cause this acute angulation is far below the force required to cause valvular or wall damage to the venous system. As the tip yields, it doubles back to such a position that it falls through the valvular orifice. The catheter may then be continued on until another valve is met and the procedure repeated.

The invention also includes improvements in the manner of attaching the balloon to the catheter body and the arrangement of fluid passages through the catheter body for inflating and deflating the balloon so that all parts of the balloon are insured of deflating when desired.

Still other objects and advantages will become apparent and the invention will be better understood with reference to the following description of two preferred embodiments of the catheter illustrated on the accompanying drawing. Various changes may be made, however, in the details of construction and arrangement of parts and all such modifications within the scope of the appended claims are included in the invention.

In the drawing:

FIGURE 1 is a general view of a catheter embodying the features of the invention for arterial thrombectomy with certain parts shown in section;

FIGURE 2 is a view of the distal end of the catheter of FIGURE 1 with the balloon inflated and shown in section;

FIGURE 3 is a sectional view of the balloon of FIGURES 1 and 2 in relaxed condition before installation; FIGURE 4 is a longitudinal sectional view of the distal

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end portion of a catheter for venous thrombectomy; and FIGURE 5 is a longitudinal sectional view through a vein showing manipulation of the catheter of FIGURE 4 to pass it through a valvular opening.

The arterial catheter tube 10 in FIGURE 1 is composed of flexible plastic material and contains a lumen or bore 11 to convey fluid for inflating and deflating the balloon. The proximal end of the tube is connected to one side of the valve 12 and the other side of the valve is connected to a syringe 13.

At its distal end the tube 10 has a reduced portion 15 provided with radial openings 16 staggered around the tube and a still further reduced extremity 17 beyond the end of bore 11. The surface of the tube is provided with minute projections at 18 and 19 for securing end portions of the balloon 20. The openings 16 extend along substantially the entire length of the balloon to a point close to the solid extremity 17.

As shown in FIGURE 3, the balloon 20 is manufactured as a closed end rubber tube having a thickened end portion 21 which is soft and pliable. In assembly, the balloon is drawn over the end of the catheter tip by gripping the skirt 20a of the balloon and pulling tightly, forcing the catheter end portion 17 into the balloon and imparting considerable longitudinal stretch to the material of the balloon. With the balloon held in this position, a layer of thread 22 is wound around the end portion 17, squeezing the rubber of the balloon tightly against and between the projections 18, causing these projections firmly to grip the material of the balloon. The stretch of the balloon and tension of the thread in winding beginning at the distal end of the winding area forces the rubber to compress to a smaller diameter. As the winding progresses in a proximal direction, the tension of the thread forces additional stretch to occur under the winding with the result that the outside diameter of the wound thread is slightly smaller than the final deflated diameter of the balloon and the main body of the catheter tube 10.

With the balloon still held in longitudinally stretched condition as described, a proximal binding 23 is applied in a similar manner over the projections 19. Just prior to termination of the binding 23 in proximal direction, excess balloon material including the skirt 20a is cut off so that the last few turns of the thread cover up any ragged edges of the balloon material. A suitable air drying cement or the like is then soaked into both of the bindings 22 and 23 for sealing and locking the bindings in place and providing a smooth surface thereon. Thus, the balloon in FIGURE 1 is not in a relaxed condition while deflated but is stretched in a longitudinal direction, causing it to shrink in diameter and hug closely and smoothly the smooth surface of the reduced catheter tube portion 15. The binding 23 compresses the balloon material so that the outside diameter of the binding is no larger in diameter than the main portion of the tube 10 and the outside diameter of the longitudinally stretched and deflated balloon between the bindings 22 and 23 is the same.

The taper and the softness of tip 21 prevents damage to the wall of the artery as the catheter is threaded therein. Thus, the distal end of the catheter may be pierced through a clot and the balloon inflated on the remote side of the clot, preferably by means of a liquid expressed from syringe 13. When inflated, the balloon assumes a sausage shape as shown in FIGURE 2. Then, by closing valve 12 and withdrawing the catheter with the balloon inflated, the clot may be moved along the artery ahead of the balloon and pulled out of the incision where the catheter was inserted.

In case there are constrictions in the artery, the balloon undergoes a progressive contraction in passing through each constriction. The openings 16 are distributed in different radial directions along the entire length of tube portion 15 which is within the balloon to permit free interflow of the inflating fluid from one end of the balloon to the other. Thus, even though the balloon may be con-

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stricted for a short interval tightly against the tube portion 15, a pocket of inflating fluid cannot be trapped in the distal end of the balloon to stop the withdrawal movement of the balloon. Inflating fluid from the extreme distal end of the balloon can pass through the most distal opening 16 to a more proximal portion of the balloon which has already passed through the constriction. The inflating fluid has free interflow between opposite ends of the balloon through openings 16 under all conditions.

In this way the balloon readily adjusts itself to cross sectional variations in the lumen of the artery so as to pass relatively freely through constricted sections and maintain contact with the wall of the lumen to keep the clot moving ahead of the balloon. This insures against the balloon moving past the clot and leaving the clot in the artery when a severe constriction is encountered. In a similar way the balloon progressively conforms to changing cross sectional shape of the lumen in the artery to maintain full circumferential contact with the wall of the lumen at all times during withdrawal of the balloon and clot.

FIGURE 4 illustrates a modification for venous thrombectomy. In this case the balloon 30 is provided with an elongated soft and floppy end 31 extending beyond the tip 17 of catheter tube 10. In order to make the end 31 even more yieldable to bending, it is provided with a reduced neck at 32 adjacent the end of tip 17. Preferably, the end of tip 17 is slightly enlarged to a bulbous shape as indicated at 33. Balloon 30 is secured in a stretched condition the same as balloon 20 in FIGURE 1. It is sausage shaped when inflated and performs in the same manner as balloon 20.

The mode of operation of end extension 31 is shown in FIGURE 5. Here the problem is to thread the catheter through valve leaflets 40 in a vein V in opposition to the direction of the flow of blood through the vein as indicated by the arrow 41. These valve leaflets are inclined in a downstream direction and present no obstruction to a catheter which is being threaded in a downstream direction. However, when the catheter is being threaded in an upstream direction, as shown in FIGURE 4, the valve leaflets 40 present an obstruction which deflects the tip of the catheter away from the valve orifice and towards the wall of the vein.

When this happens with the present catheter, the end 31 merely angulates and shifts the neck portion 32 into a more centralized position in the vein in line with the valve orifice. Then, as the catheter is pushed forward, end portion 31 doubles back and neck 32 leads the catheter through the orifice in looped configuration. When end 31 is clear of the valve, it straightens out in a forward direction and assumes its original shape until the next is encountered and then the described operation is repeated. In order to function in this manner the end portion 31 forward from neck 32 should not be longer than approximately half the inside diameter of the vein at the valve or valves which will be encountered.

Notwithstanding the soft and floppy texture of end 31, it is still capable of piercing a clot in the vein. If it does not proceed straight forward through the clot, it is free to double back and pass through the clot in such configuration just as it passes through a valve obstruction in FIGURE 4.

The catheter in FIGURE 4 gives the surgeon the option of approaching the clot from either direction whereas heretofore it was only possible to approach in a downstream direction in the case of a venous clot. When it is impossible to approach in a downstream direction, the present catheter gives the surgeon means for removing a clot which could not heretofore be removed. Also, by approaching the clot in an upstream direction, there is the advantage of withdrawing it in the downstream direction whereby it is much more easily moved through the valves at intervals along the vein.

Although the material of main body portions 10, 15 and

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17 is described as flexible, it is relatively stiff and hard in comparison with the parts 20, 21, 30, 31 and 32 made of the very soft balloon material. The main body portions must be rigid enough to support the balloon and hold it in elongated sausage shape when inflated, to sustain the tension of the stretched balloon material when it is deflated and to push the forward portions of the catheter through all irregularities and angulations in the lumen of the vessel approaching the clot when the balloon is deflated.

The longitudinally stretched and tensioned condition of the balloon material when deflated, whereby the balloon material smoothly and constrictively hugs the supporting body portion 15, and the smooth transitions from balloon 20 to binding 23 to tube 10 in FIGURE 1, provides a uniform, smooth external surface capable of being inserted into a restricted incision in a vessel and through regions of angulation and constriction of the lumen of the vessel without excessive friction and without frictionally deforming the balloon section. In passing through restrictions, the deflated balloon material does not tend to gather and bunch up at its trailing end so as to enlarge the diameter of the catheter and impede its free sliding movement. This tendency has been found highly objectionable in conventional balloon catheters.

Having now described my invention and in what manner the same may be used, what I claim as new and desire to protect by Letters Patent is:

1. A catheter comprising a flexible tube, a balloon surrounding an end portion of said tube, openings in said tube distributed along the length of said balloon for the passage of fluid in inflating and deflating the balloon, and means securing opposite end portions of the balloon to said tube with the balloon material stretched longitudinally between said securing means and smoothly hugging said tube when the balloon is deflated, said balloon having a closed end enclosing the end of said tube for a short distance beyond said securing means at the distal end of the balloon, said closed end of the balloon having a thickened portion relatively softer than said tube overlying and projecting beyond the end of said tube and forming a soft tip on the catheter.

2. A catheter as defined in claim 1, said securing means comprising a winding such as thread.

3. A catheter as defined in claim 1, said tube having protuberances under said securing means to grip said end portions of the balloon.

4. A catheter as defined in claim 1, including a syringe and a valve on the opposite end of said tube for inflating and deflating the balloon.

5. A catheter comprising a flexible tube, a balloon surrounding an end portion of said tube, openings in said tube distributed along the length of said balloon for the passage of fluid in inflating and deflating the balloon, and means securing opposite end portions of the balloon to said tube with the balloon material stretched longitudinally between said securing means and smoothly hugging said tube when the balloon is deflated, said tube having a portion of reduced diameter within said balloon and said securing means so that the maximum diameter of said securing means and deflated balloon does not exceed the diameter of the main portion of said tube, said reduced diameter portion of said tube being further reduced within said securing means at the distal end of the balloon.

6. A catheter as defined in claim 5, including a soft and floppy tip end portion on the catheter.

7. A catheter as defined in claim 6, said tip end portion projecting forward from a flexible reduced neck portion which permits said tip end portion to double back against the catheter in a return bend.

8. A catheter comprising a flexible tube, a balloon surrounding an end portion of said tube, openings in said tube distributed along the length of said balloon for the

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passage of fluid in inflating and deflating the balloon, and means securing opposite end portions of the balloon to said tube with the balloon material stretched longitudinally between said securing means and smoothly hugging said tube when the balloon is deflated, a soft and floppy tip end portion on the catheter, said tip end portion comprising a part of the balloon.

9. A catheter comprising a flexible tube having an end portion of reduced diameter, a balloon surrounding said portion of reduced diameter, said balloon having a closed end covering the end of said tube and forming a tip on the catheter, openings in said tube distributed along the length of the balloon for inflating and deflating the balloon, means securing end portions of the balloon to said tube, and projections on the surface of said tube under said securing means for gripping the balloon material, said balloon material being stretched longitudinally between said securing means and smoothly hugging the surface of said tube when the balloon is deflated.

10. A catheter comprising an elongated hollow main body made of flexible plastic material which is stiff enough to be pushed through the lumen of a vascular vessel, said body having a uniform outside diameter throughout a substantial portion of its length, said body having a relatively short distal end portion of said plastic material of reduced diameter, said end portion having radial passages through the wall thereof, and an elastic tubular balloon normally in a longitudinally elongated condition attached to and covering said reduced end portion, the proximal end of said balloon being tightly engaged to the proximal end of said reduced portion by a banding means, the distal end of said balloon being closed by a substantially hemispherical thickened end portion of the balloon material, said balloon being tightly engaged near its distal end by a banding means to form an integrated catheter which throughout its length provides a uniform, smooth external surface capable of being inserted into a restricted surgically formed opening without excessive friction and without frictionally deforming said balloon section as it passes into or is withdrawn from said restricted opening.

11. A catheter as defined in claim 10, including a source of fluid pressure adapted for connection with the proximal end of the catheter for inflation of said balloon.

12. A catheter as defined in claim 10, said radial passages being staggered longitudinally and circumferentially around said reduced portion to a point close to the distal end of the balloon.

13. A catheter comprising a flexible tube, a balloon surrounding an end portion of the tube, and an inflation passageway in said tube for inflating and deflating the balloon, said balloon having a non-inflatable tip end portion projecting beyond the end of said tube and forming a soft and highly flexible and resilient tip end portion on the catheter capable of freely doubling back in a return bend.

14. A catheter as defined in claim 13, said tip end portion of the balloon having a reduced neck portion to enhance its bendability.

15. A catheter comprising a flexible tube having a lumen therein, a balloon surrounding a distal end portion of said tube, balloon inflation openings in said tube within said balloon communicating with said lumen, and means securing opposite end portions of said balloon to said tube, said tube having a portion of reduced diameter within said balloon and said securing means so that the maximum diameter of said securing means and deflated balloon does not exceed the diameter of the main portion of said tube, said reduced diameter portion of said tube having a further reduced end portion within said securing means at the distal end of said balloon, said balloon having a closed distal end enclosing said further reduced end portion of said tube, said lumen terminating at the point where said further reduced end portion begins.

16. A catheter as defined in claim 15, said distal end of said balloon projecting beyond the end of said tube and

forming a soft and highly flexible tip end portion on the catheter capable of freely doubling back in a return bend.

17. A catheter comprising a flexible tube having a co-axial lumen therein, said tube being continuous to the distal end of the catheter and said distal end being closed, a balloon surrounding the distal end portion of said tube, said balloon having a closed end covering said distal end of said tube and forming a soft tip on the catheter, balloon inflation openings in said tube communicating with said lumen at longitudinally spaced points along said balloon, a winding securing the proximal end of said balloon to said tube, a winding securing a distal end portion of said balloon to said tube at a point close to said distal end of said tube, and surface irregularities on said tube under said windings distorting and gripping the balloon material, said balloon material being stretched longitudinally between said windings and smoothly hugging the surface of said tube when the balloon is deflated.

18. A catheter as defined in claim 17, said closed end of said balloon projecting beyond the end of said tube and forming a soft and highly flexible tip end portion on the catheter capable of freely doubling back in a return bend.

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U.S. Cl. X.R.

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