MANUFACTURE OF PLASTIC CATHETER
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ABSTRACT OF THE DISCLOSURE
The method of making a plastic catheter, the significant aspect of which is a novel and improved method for securing the inflatable plastic balloon or sac to the catheter shaft, said method comprising use of heated molds that surround opposite ends of the balloon after the latter has been slid over the catheter shaft, the method further comprising the introduction of pressure into the catheter to cause the catheter to expand into pressurized contact with the molds to cause the ends of the balloon to fuse to the catheter shaft.

BACKGROUND OF THE INVENTION
Catheters of the urethral or retention type have been in use for many years and traditionally comprise a flexible and resilient tubular body portion having an elongated drainage and infusing lumens extending longitudinally therethrough. An opening is provided in the catheter wall extending into communication with the infusing lumen, and an inflatable sac or balloon is secured to the catheter in overlying relation with respect to the infusing opening wherein introduction of fluid pressure through the infusing lumen will cause the sac or balloon to distend. The distal end of the catheter is normally closed off and rounded, and a drainage eye is provided in the catheter wall in communication with the drainage lumen, said eye being located intermediate the balloon and the catheter distal end. At the proximal end of the catheter, funnel portions are provided in communication with the infusing and drainage lumens, respectively, the tubular body normally being bifurcated adjacent its proximal end, whereupon the proximal ends of the infusing and drainage lumen extend angularly from each other. Catheters of this general type are illustrated in U.S. Pat. Nos. 2,248,934 and 2,308,484.

Catheters of the general type described supra have been conventionally made of rubber, the usual manufacturing technique involving a series of latex dips, much in the manner described in U.S. Pat. No. 2,320,157, for example. Although rubber or latex catheters of this type have proven to be quite satisfactory in operation and use, it has been found that certain advantages are achieved by making catheters of this type of clear plastic material. More specifically, in urethral catheters constructed of latex, it has been found that after a certain degree of usage there is a build-up of calcium salts in the drainage lumen of the catheter, which build-up serves to reduce the drainage capacity of the catheter and, in extreme cases, might even occlude the catheter so as to completely block off drainage. By constructing the catheter of a nontraumatic, flexible and nontoxic plastic, the catheter will function substantially as effectively as the conventional latex catheter and will resist the undesirable build-up of calcium salts mentioned above, thus permitting a smaller drainage lumen to be used, which in turn permits the catheter shaft to be of smaller diameter.

In addition, by making the catheter of a clear, transparent plastic, added advantages are obtained in that the catheter can be visually inspected to insure that proper drainage is taking place, etc.

SUMMARY OF THE INVENTION
Since it is not possible to manufacture a plastic catheter by means of the same techniques used in connection with the manufacture of a latex catheter, it is a primary object of the present invention to provide a method of manufacturing plastic catheters of the urethral or retention type.

One of the principal problems that has existed in the manufacture of plastic catheters is the provision of suitable means for securing or sealing the inflatable plastic sac or balloon on the catheter shaft so that the balloon will be securely sealed to the shaft and at the same time free to distend, and so that the outer surface of the shaft, and particularly that portion where the balloon is located, will be substantially smooth and unobstructed, thus facilitating insertion of the catheter in use. It is therefore a most important object of the instant invention to provide a technique whereby an inflatable plastic balloon may be securely sealed to a catheter so that the aforesaid problems are overcome.

A further object of my invention is the provision of a method for securing an inflatable plastic balloon to a catheter, which method is relatively simple and economical to perform, and which results in the provision of an effective end product.

Other objects, features and advantages of the invention will become apparent as the description thereof proceeds when considered in connection with the accompanying illustrative drawings.

DESCRIPTION OF THE DRAWINGS
In the drawings which illustrate the best mode presently contemplated for carrying out the present invention:

FIG. 1 is a side elevational view, partly in section, of a catheter manufactured by means of the instant invention;

FIG. 2 is an enlarged fragmentary elevational view illustrating one of the steps performed pursuant to the instant invention;

FIG. 3 is an enlarged fragmentary elevational view, partly in section, illustrating a subsequent step in my method;

FIG. 4 is an enlarged fragmentary elevational view, in section, illustrating the means by which the inflatable balloon is sealed to the catheter shaft;

FIG. 5 is an enlarged fragmentary elevational view, in section, illustrating a catheter constructed in accordance with my method after the balloon has been sealed thereto; and

FIG. 6 illustrates the catheter shown in FIG. 5 with the balloon in distended position.

DESCRIPTION OF THE INVENTION
Referring now to the drawings, and more particularly to FIG. 1 thereof, there is shown a catheter 10 constructed of a suitable nontraumatic, flexible and nontoxic plastic, such as polyvinylchloride. The catheter 10 com-
prises a shaft 12 having a drainage lumen 14 and an inflating lumen 16 extending longitudinally therethrough. At its proximal end, the catheter 10 is bifurcated so that the drainage lumen 14 and inflating lumen 16 extend angularly from each other, the drainage lumen terminating at a funnel portion 18, and the inflation lumen terminating in a funnel portion 20. At its distal end, the catheter 10 is provided with a closed, gently rounded tip 22, near which there is provided a drainage eye 24, see FIGS. 5 and 6. Secured to and extending around the shaft 12 is an inflatable balloon 26, whereby it is intended that the sac 26 is located near the distal end of the catheter but spaced sufficiently therefrom so that drainage eye 24 may be located between the sac and the tip 22 of the catheter. An inflation eye 28 is formed in the wall of the shaft 12 in communication with the inflating lumen 16 and the interior of balloon 26, whereby the introduction of fluid pressure through the inflating lumen will cause the balloon to distend, as shown in FIG. 6.

The method of securing balloon 26 to shaft 12 will now be described. The first step is to provide the shaft 12 having the longitudinally extending drainage and inflating lumens therein. The shaft may be made by any suitable means, such as extruding, and the tip 22 is formed at the distal end by any suitable means. The inflation eye 28 is formed in the wall of shaft 12 in communication with inflating lumen 16, but it is important to note that the drainage eye is not provided at yet. The next step is to coat the shaft 12 at the portion thereof that is to be covered by the inflatable balloon with a release agent 30, such as Baymal or Silica, so that there will be no subsequent undesirable adhesion between that portion of the catheter shaft and the inner surface of the balloon. A relatively thin vinyl sleeve 32 (approximate wall thickness of .012" to .018") is slid over the distal end of the catheter so that the coated portion of the catheter shaft 30 is approximately centered with respect thereto, it being understood that the inflation eye 28 will also be approximately centered between the ends of sleeve 32. It will be understood that the sleeve 32 makes a snug fit around shaft 12 and that the length of said sleeve is substantially longer than the length of the area that has been coated with release agent 30.

The catheter shaft, with the sleeve 32 therearound, as illustrated in FIG. 3, is then inserted into a heated mold comprising a pair of ring elements 34, 36 that surround the end portions of the sleeve 32, as illustrated in FIG. 4. It is important to note that the inner surface of the rings 34 and 36 is tapered, as at 38, it being understood that the rings make pressurized contact with the end portions of sleeve 32. Where the catheter is constructed of polyvinylchloride, it has been found that best results are obtained where the ring molds are maintained at a temperature of 300-340° F. In order to establish sufficient pressure between the ring molds and the ends of sleeve 32 against catheter shaft 12 so as to obtain good fusion between the latter, fluid pressure is introduced through drainage lumen 14; and since the drainage eye 24 has not as yet been provided, the catheter shaft 12 will expand so as to make sufficient pressurized engagement with the ring molds to insure that good fusion takes place between the end of sleeve 32 and the outer surface of shaft 12. It has been found, however, that when pressure is introduced into drainage lumen 14, there is a tendency for inflating lumen 16 to collapse, thus raising the possibility and even probability that the wall of the inflating lumen will fuse to the outer wall of shaft 12 at the location of ring mold 34. This problem is overcome by plugging the proximal end of inflating lumen 16, as by means of a plug 40, before introducing pressure to drainage lumen 14. The plug 40 functions to maintain an air cushion in lumen 16 that prevents the aforesaid undesirable collapsing of the lumen from taking place.

Thus, the combination of the internal pressure in drain-
ge lumen 14 and the heated ring molds 34 and 36 result in a secure sealing between the end portions of the sleeve 32 and the outer wall of shaft 12. The tapered inner surface of the ring molds causes the fused ends of sleeve 32 to blend smoothly and gradually with the outer surface of shaft 12, as clearly illustrated in FIGS. 4 through 6. Once proper fusion has taken place the catheter has been removed from the ring molds, the drainage eye 24 is then cut into the wall of shaft 12; and, as aforesaid, the eye is located intermediate balloon 26 and the distal tip 22 of the catheter.

It has been found that better fusion of the sac to the catheter shaft, and at lower fusion temperatures, is possible if a thin coating of vinyl plastisol is applied to the edges of sleeve 32 before insertion into the molds 34, 36. It has also been found that best results are obtained when air pressure is introduced to drainage lumen 14 within the range of two to eight pounds per square inch.

The coating of shaft 12 with release agent 30, as aforesaid, is desirable, but not essential, to successful operation of this process. It will be understood that the thickness of the coating 30 is exaggerated for purposes of illustration in FIGS. 2 and 3 of the drawings. In actual practice, this is a thin coating, and the sleeve 32 makes intimate contact with the outer surface of shaft 12 prior to fusing.

Where the catheter and balloon are made from polyurethane, (Estane type), the same general process as aforesaid may be performed, except that since polyurethane fuses more readily than polyvinylchloride, somewhat lower fusion temperatures are necessitated; and, specifically, in the range of 290-310° F. The air pressure introduced into drainage lumen 14 must be more closely controlled, and it has been found that best results are obtained where the pressure is in the range of two to five pounds per square inch. Where the catheter is being made from polyurethane, lower fusion temperatures may be used if the edges of the sac are coated with a high boiling solvent, such as N-methyl-2-pyrrolidone.

While the above is described herein certain specific examples of the practice of this invention, the invention is not limited to the specific details, or materials, or proportions or conditions herein specified, and the invention may be modified according to individual preference or conditions without departing from the spirit thereof, except as indicated by the scope of the appended claims.

What is claimed is:

1. The method of making a catheter comprising the following steps:

(a) forming an elongated flexible shaft having drainage and inflating lumens extending longitudinally therethrough;

(b) forming a tip to close the distal end of said shaft;

(c) forming an inflation eye through the wall of said shaft in communication with said inflating lumen near the distal end of said shaft;

(d) sliding a resilient sleeve snugly over said shaft so that said sleeve overlies said inflation eye;

(e) inserting said shaft into a heated mold having circular portions in contact with the opposite ends of said sleeve;

(f) plugging the inflation lumen adjacent its proximal end;

(g) introducing pressure into said drainage lumen to cause expansion of said shaft in order to force said shaft and the end portions of said sleeve outwardly into pressurized contact with said circular portions to cause said sleeve end portions to fuse to said shaft; and

(h) forming a drainage eye through the wall of said shaft in communication with said drainage lumen adjacent its distal end.

2. The method of claim 1 further characterized in that prior to step (d) the shaft is coated with a release agent
at that portion of the shaft that will eventually be in contact with the free inner surface of said sleeve to prevent sticking therebetween.

3. The method of claim 1 further characterized in that said shaft and sleeve are of polyvinylchloride.

4. The method of claim 3 further characterized in that prior to step (e) the ends of said sleeve are coated with vinyl plastisol.

5. The method of claim 3 further characterized in that the mold in step (e) is heated to 300–340° F.

6. The method of claim 3 further characterized in that the pressure in step (g) is air pressure of two to eight pounds per square inch.

7. The method of claim 1 further characterized in that said shaft and sleeve are of polyurethane.

8. The method of claim 7 further characterized in that prior to step (e) the ends of said sleeve are coated with a high boiling solvent.

9. The method of claim 7 further characterized in that the mold in step (e) is heated to 290–310° F.

10. The method of claim 7 further characterized in that the pressure in step (g) is air pressure of two to five pounds per square inch.

References Cited

UNITED STATES PATENTS

2,930,634 3/1960 Merritt 156—293 X
3,047,910 8/1962 Downs 156—293 X
3,152,592 10/1964 Foley.
3,467,103 9/1969 McKinstry et al.

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