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(54) CATHETER

(71) We, HOSPAL LTD., a Swiss Body Corporate, of 62 Missionsstrasse, 4002 Basle, Switzerland, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a catheter. More particularly, the invention relates to a catheter for placement in an artery, vein or fistula vessel of a patient, through which blood may be withdrawn from and/or delivered to a patient.

The catheter of the invention is particularly intended for use in blood dialysis, where it is of high importance to achieve optimal blood flow rates to and from the patient. In view of the need to employ catheters of limited cross-sectional size, the catheter is normally the element in the entire extracorporeal blood flow path which plays the greatest role in limiting blood flow rates which can be achieved. This is particularly true in single needle dialysis, and there is indeed still some prejudice against employing the single needle dialysis technique for this reason.

Various catheters for effecting dialysis are available. These catheters normally comprise an open-ended length of catheter defining a lumen, about one to one and a half inches long, and a removable trocar located coaxially in the lumen with its point protruding beyond the distal end of the catheter. The trocar normally fits snugly against the inner wall surface of the catheter along its length but not so tightly that the trocar cannot be removed after placement of the catheter. The same applies to catheters intended for single needle dialysis, the removable trocar and catheter in this case being of somewhat larger cross section.

It has now been found that the flow rate of blood through catheters of the type described above can be significantly increased by modifying the form of the catheter, or rather the shape of the lumen defined by the catheter. Alternatively spoken, the same flow rate of blood can be achieved through the modified catheter when applying a significantly lower pressure differential to blood being withdrawn or returned to a patient.

The modification of the invention has wide application and may be employed in various types of catheters through which blood may be withdrawn from or delivered to a patient. Catheters of various types to which the modification of the invention has been applied will be described below, more particularly with reference to the accompanying drawings.

In accordance with the invention, there is provided a catheter for placement in an artery, vein or fistula vessel of a patient, through which blood may be withdrawn from and/or delivered to the patient, which catheter has a catheter wall provided with at least one aperture therein at a distal end region of the catheter to allow passage of blood radially into or out of the catheter and an axial opening at the distal end of the catheter to allow passage of blood through the axial end of the catheter, the catheter wall having an inner surface defining the radially outermost extent of a lumen, which lumen has a cross-sectional area which is less at the said distal end region than at a proximal end region of the catheter, the said inner surface of the catheter wall having at least a portion thereof, interrupted by the or at least one said aperture at the distal end region which tapers progressively towards the distal end of the catheter, and the thickness of the catheter wall being progressively greater from the proximal end region where the cross-sectional area of the lumen is larger to the distal end region where it is smaller.

The cross-sectional area of the lumen most preferably diminishes substantially uniformly from the proximal end region of larger cross-sectional area to the distal end region of smaller cross-sectional area. However, the cross-sectional area may diminish in step-wise fashion.

In a preferred catheter embodying the invention, from 2 to 6 inclusive of the said apertures are provided in the circumferential wall of the catheter. The apertures may be in pairs and two to three pairs of apertures may be provided, the two apertures of each pair preferably being in diametrically opposed relationship, each pair of apertures then being longitudinally spaced away from the adjacent pair. Adjacent pairs of such diametrically opposed apertures are preferably arranged at right angles to one another so that weakening of the distal end region of the catheter is minimised.

In one embodiment of a catheter in accordance with the invention, the total area of the apertures in the circumferential wall of the catheter, together with the area defined by the axial opening at the distal end of the catheter, should be at least as great as the smallest cross-sectional area of the lumen through which blood may be passed. In another embodiment, the total area of the apertures in the circumferential wall of the catheter (without the axial opening defined by the distal end of the catheter) should be at least as great as the smallest cross-sectional area of the lumen.

For ease of insertion of the catheter, the outer diameter of the catheter most preferably diminishes to a minimum outer diameter at the distal end at least from a position distal to the distally most extreme aperture in the circumferential wall of the catheter. Similarly, the cross-sectional area of the lumen most preferably diminishes to a minimum at least from the same position.

The proximal end of the catheter may be coaxially connected to a hub having a bore of cross-sectional area at least as large as the largest cross-sectional area of the lumen, the hub in turn being coaxially connected to a hollow cylindrical body having a closure at its free end.

The hollow cylindrical body may have a hollow cylindrical side arm leading into the side of the hollow cylindrical body. The free end of the side arm may be provided with means for connection to a blood line or the free end of the side arm may alternatively be sealed closed by a resealable plug through which a needle may be passed.

The catheter may be provided with a hollow needle (or removable trocar) which passes through the closure at the free end of the hollow cylindrical body and coaxially through the hollow cylindrical body, through the hub and through the catheter so that the point of the needle protrudes beyond the distal end of the catheter. This hollow needle may be provided with female luer means at its proximal end for receiving the nose of a syringe.

The closure at the free end of the hollow cylindrical body may comprise a flexible tube coaxially connected to the free end of the hollow cylindrical body, and a removable resealable plug sealing closed the free end of the flexible tube and through which the needle passes.

The invention is applicable to catheters having a double lumen construction, for example, those described in our copending UK Patent Application No. 30553/79 (Serial No. 1 578 153).

In one such construction of a catheter in accordance with the invention, the hollow needle is not intended to be withdrawn and hence defines the inner lumen of a double lumen construction. In this construction, the hollow needle defines an inner lumen and the catheter with the outside surface of the needle defines an annular outer lumen. So as to avoid that the sharp end of the needle protrudes beyond the distal end of the catheter, which is conveniently of Teflon ("Teflon" is a Registered Trade Mark), the hollow needle may be retractable over a short distance so that the point of the needle may be retracted after placement of the catheter. In the retracted position of the needle, the catheter seals against the wall of the needle and around the point thereof.

Locator means, conveniently comprising a displacement element mounted on the proximal end region of the needle and front and back stops, may be provided for locating the needle in a catheter placement position (in which the point of the needle protrudes beyond the distal end of the catheter) and for locating the needle in said retracted position.

The thickness of the catheter side wall is progressively greater from the region where the cross-sectional area of the lumen is larger to the region where the cross-sectional area of the lumen is smaller. In this manner a minimum outer diameter of the catheter in the proximal end region can be achieved.

The inner diameter of the catheter may range from about 0.02 to about 0.07 inches, preferably from about 0.03 to about 0.06 inches. The inner diameter of the needle may range from about 0.02 to about 0.05 inches, preferably from about 0.03 to about 0.04 inches.

The invention will now be described with reference to the accompanying drawings showing by way of example, catheters involving the modification of the invention.

In the drawings:

Figure 1 shows a cross-sectional side ele-

vation of a catheter in which a removable trocar is provided;

Figure 2 shows a cross sectional side elevation of a double lumen catheter in which a needle defining an inner lumen is provided;

Figure 3 shows a cross-sectional side elevation of a double lumen catheter comprising first and second tubular elements, one located coaxially within the other and a removable trocar passing through the lumen defined by the inner tubular element.

Referring to Figure 1 of the drawings, reference numeral 10 refers generally to a catheter comprising a catheter wall 12, the inside surface of which defines a lumen 14. The lumen 14 has a cross-sectional area in a proximal end region 16 of the catheter which is larger than the cross-sectional area of the lumen 14 defined in a distal end region 18 of the catheter. A pair of diametrically opposed apertures 20 are provided in the circumferential wall 12 of the catheter so as to interrupt a portion of the inner surface of the catheter wall at the distal end region 18, which portion tapers progressively towards the distal end of the catheter. It will be noted that the cross-sectional area of the lumen 14 diminishes substantially uniformly from the proximal end region 16 (of larger cross-sectional area) to the distal end region 18 (of smaller cross-sectional area).

Reference numeral 22, in Figure 1, refers to a hollow needle or trocar which is removable. The distal end of the inside surface of the catheter wall 12 defines an axial end opening 24 when the trocar 22 is removed. With the trocar 22 removed, blood may be passed into and out of the lumen when the catheter is placed in an artery, vein or fistula vessel of a patient by means of a monitoring and blood pump device (not shown).

The pair of apertures 20 in the wall 12 of the catheter are in a region where the cross-sectional area of the lumen 14 is diminishing towards the distal end of the catheter. The total area of the apertures 20 in the circumferential wall 12 of the catheter, together with the area of the axial opening 24 defined by the distal end of the catheter (with trocar 22 removed), should be at least as great as the smallest cross-sectional area of the lumen 14.

Still referring to Figure 1, the proximal end 26 of the catheter is coaxially connected to a hub 28 having a bore 30 which is as large as the largest cross-sectional area of the lumen 14 (in the proximal end region 16). The hub 28 is in turn coaxially connected to a hollow cylindrical body 32 having a hollow cylindrical side arm 34 leading into its side. A flexible tube 36 carrying a removable resealable plug 38 is connected to the end of the hollow cylindrical body 32. The removable trocar 22 passes through the plug 38, through the flexible tube 36, coaxially through the hollow cylindrical body 32, through the hub 28 and through the catheter so that the point of the trocar protrudes beyond the distal end of the catheter.

A female luer 40 is mounted at the proximal end of the trocar 22, which is kept closed by a removable closure cap 42. The female luer defines a bore 43 into which the nose of an infusion syringe may be fitted.

A short length of flexible tubing 44, carrying a closure cap 46, is connected to the end of the side arm 34.

The catheter embodying the invention shown in Figure 1 is suitable both for so-called single needle dialysis and for double needle dialysis. For double needle dialysis, the catheter may be somewhat smaller in cross-section, and a resealable plug similar to resealable plug 38 is then conveniently provided to close off the end of the side arm 34. Such resealable plug may serve as an infusion point.

Referring now to Figures 2 and 3 of the drawings, reference numerals 10 to 46 refer to the same integers of the catheter as in Figure 1.

Referring now particularly to Figure 2 of the drawings, the needle 22 is not removable as in the trocar of Figure 1. Furthermore, the needle terminates at the end of the hollow cylindrical body 32 and is sealed at this end to the wall of the hollow cylindrical body 32 by means of a seal 48. The female luer 40, instead of being mounted on the needle as in Figure 1, is somewhat different in form and is fitted into the end of the flexible tube 36. The end of the female luer adjacent the closure cap 42 is connectable at 50 to a blood line. Another difference between the catheter shown in Figure 2 and that shown in Figure 1 is the form of the catheter towards its distal end region 18. Thus, the wall 12 of the catheter is spaced away from the outer surface of the needle 22 in said distal end region. Four apertures 20 are provided in the circumferential wall 12 of the catheter so as to interrupt a portion of the inner surface of the catheter wall at the distal end region 18, which portion tapers towards the distal end of the catheter. The portion converges more steeply at the distal end to seal against the outer wall of the needle. Blood may thus pass into the lumen 14 through apertures 20. In this construction two pairs of diametrically opposed apertures 20 are provided, the one pair being at right angles to the other.

Figure 3 comprises features common to both Figures 1 and 2. Thus, the removable trocar 22 of Figure 1 is provided, and the needle 22 of Figure 2 (which is not removable) is replaced by an inner tubular element 52 which, when the trocar 22 is removed, defines an inner lumen. The

lumen 14 in Figure 3 is in the form of an annular outer lumen which is defined between the outer surface of the inner tubular element 52 and the inner surface of an outer tubular element 12. In this construction, three pairs of diametrically opposed apertures 20 are provided, each pair being arranged at right angles to one another.

In the embodiments shown in both Figures 2 and 3, the cross-sectional area of the bore 30 of the hub 28 is at least as great as the sum of the outer cross-sectional area of the needle 22 (in Figure 2) or the inner catheter 52 (in Figure 3) and the largest cross-sectional area of the annular outer lumen 14 (in both Figures 2 and 3).

In operation of the embodiment shown in Figure 1, the vein, artery or fistula vessel is punctured by means of the trocar 22, and the catheter is inserted into the vessel to a point near the proximal end region 16. Infusion may be effected through the trocar 22 during this placement. The trocar is then partly withdrawn, and blood is allowed to fill the lumen 14, hollow cylindrical body 32 and flexible tube 36. The trocar is then completely withdrawn, the flexible tube 36 clamped closed, the removable resealable plug 38 removed and the end of the flexible tube 36 connected up to a blood line leading to the monitoring and blood pump device (not shown). Similarly, the short length of flexible tubing 44 connected to the side arm 34 is clamped closed, the cap 46 removed and connected up to a blood line leading from the monitoring and blood pump device.

In operation of the embodiment shown in Figure 2, the catheter is similarly placed in an artery, vein or fistula vessel of a patient, but in this case the needle 22 is not withdrawn since it serves the function of defining an inner lumen through which blood may be returned to the patient, blood being withdrawn through the lumen 14 (outer) and to the monitoring and pump device through the side arm 34.

Operation of the embodiment shown in Figure 3 is similar to that of Figure 2, excepting that the trocar 22 is removed and connection up to the blood line is effected as described in relation to Figure 1.

WHAT WE CLAIM IS:—

1. A catheter through which blood may be withdrawn from and/or delivered to a patient, which catheter has a catheter wall provided with at least one aperture therein at a distal end region of the catheter to allow passage of blood radially into or out of the catheter and an axial opening at the distal end of the catheter to allow passage of blood through the axial end of the catheter, the catheter wall having an inner surface defining the radially outermost extent of a lumen, which lumen has a cross-sectional area which is less at the said distal end region than at a proximal end region of the catheter, the said inner surface of the catheter wall having at least a portion thereof, interrupted by the or at least one said aperture, at the distal end region which tapers progressively towards the distal end of the catheter, and the thickness of the catheter wall being progressively greater from the proximal end region where the cross-sectional area of the lumen is larger to the distal end region where it is smaller.

2. A catheter according to claim 1, in which the cross-sectional area of the lumen diminishes substantially uniformly from the proximal end region of larger cross-sectional area to the distal end region of smaller cross-sectional area.

3. A catheter according to claim 1 or 2, in which from two to six said apertures are provided in the wall of the catheter at the said distal end region thereof.

4. A catheter according to claim 3, in which two or three pairs of said apertures are provided in the wall of the catheter, the two apertures of each pair being in diametrically opposed relationship, and each pair of apertures being longitudinally spaced away from the adjacent pair.

5. A catheter according to claim 4, in which adjacent pairs of diametrically opposed apertures are arranged at right angles to one another.

6. A catheter according to any one of the preceding claims in which the total area of the aperture or apertures in the wall of the catheter together with the area of the axial opening at the distal end of the catheter is at least as great as the smallest cross-sectional area of the lumen through which blood may be passed.

7. A catheter according to claim 6, in which the total area of the aperture or apertures in the wall of the catheter is at least as great as the smallest cross-sectional area of the lumen through which blood may be passed.

8. A catheter according to any one of the preceding claims in which the outer diameter of the catheter diminishes to a minimum outer diameter at the distal end from a position distal to the aperture or, when more than one said aperture is provided, the distally most extreme aperture in the wall of the catheter.

9. A catheter according to any one of the preceding claims, in which the inner diameter thereof ranges from 0.02 to 0.07 inches inclusively.

10. A catheter according to claim 9, in which the inner diameter thereof ranges from 0.03 to 0.06 inches inclusively.

11. A catheter according to any one of the preceding claims, which catheter includes a removable needle disposed coax-

ially within the catheter so that the point of the needle protrudes beyond the distal end of the catheter.

12. A catheter including an outer tubular element comprising a catheter as claimed in any one of claims 1 to 10, and, secured within the outer tubular element, an inner tubular element coaxial with the outer tubular element, the outer surface of the inner tubular element and the inner surface of the outer tubular element together defining the said lumen and the inner surface of the inner tubular element defining an inner and second lumen.

13. A catheter according to claim 12 which further includes a removable needle disposed coaxially within the said second and inner tubular element so that the point of the needle protrudes beyond the distal end of each said tubular element.

14. A catheter according to claim 12, wherein the inner tubular element is a tubular needle secured relative to the catheter so that the point of the needle protrudes beyond the distal end thereof.

15. A catheter according to any one of claims 1 to 11, the proximal end of which catheter is coaxially connected to a hub having a bore, which bore has a minimum cross-sectional area at least as large as the largest cross-sectional area of the lumen, the hub in turn being coaxially connected to a hollow cylindrical body having a closure member at its free end.

16. A catheter according to claim 15, in which the hollow cylindrical body has a hollow cylindrical side arm leading thereinto.

17. A catheter according to claim 16, in which the free end of the side arm is provided with means for connection to a blood line.

18. A catheter according to claim 16, in which the free end of the side arm is sealed closed by means of a removable resealable plug through which a needle may be passed.

19. A catheter according to any one of claims 15 to 18 when appendant to claim 11 in which said hollow needle passes through the closure member at the free end of the hollow cylindrical body and coaxially through the hollow cylindrical body, through the hub and through the catheter so that the point of the needle protrudes beyond the distal end of the catheter.

20. A catheter according to claim 19, in which the hollow needle is provided with a female luer at its proximal end for receiving the nose of a syringe.

21. A catheter according to claim 19 or claim 20, in which the closure member at the free end of the hollow cylindrical body comprises a flexible tube coaxially connected to the free end of the hollow cylindrical body, and a removable resealable plug sealing closed the free end of the flexible tube through which the needle passes.

22. A catheter according to any one of claims 19 to 21, in which the inner diameter of the needle is from 0.02 to 0.05 inches inclusive.

23. A catheter according to claim 22, in which the inner diameter of the needle is from 0.03 to 0.04 inches inclusive.

24. A catheter according to any one of the preceding claims substantially as herein described with reference to and as illustrated in Figure 1, 2 or 3 of the accompanying drawings.

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1578152 COMPLETE SPECIFICATION

2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 1

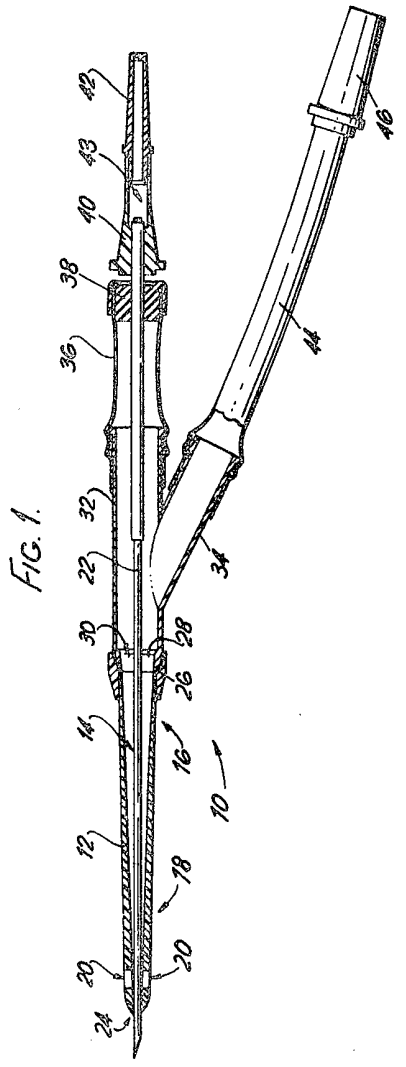

FIG. 1.

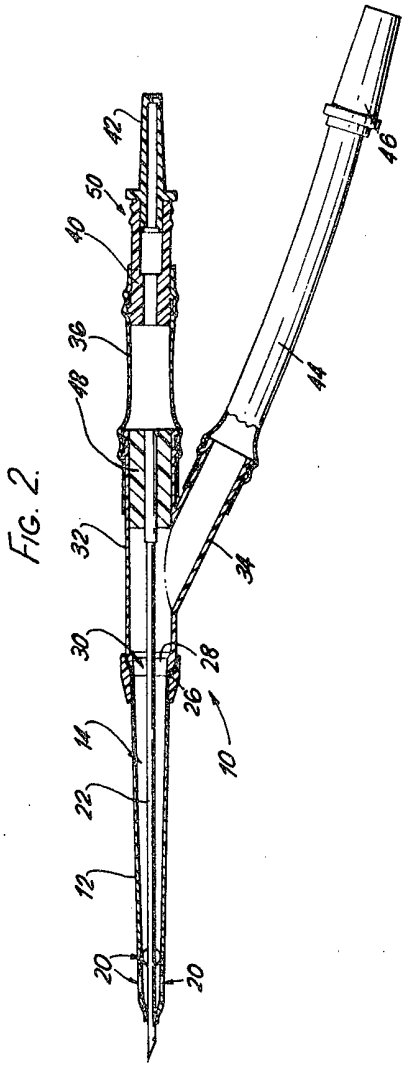

FIG. 2.

1578152 COMPLETE SPECIFICATION

2 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheet 2

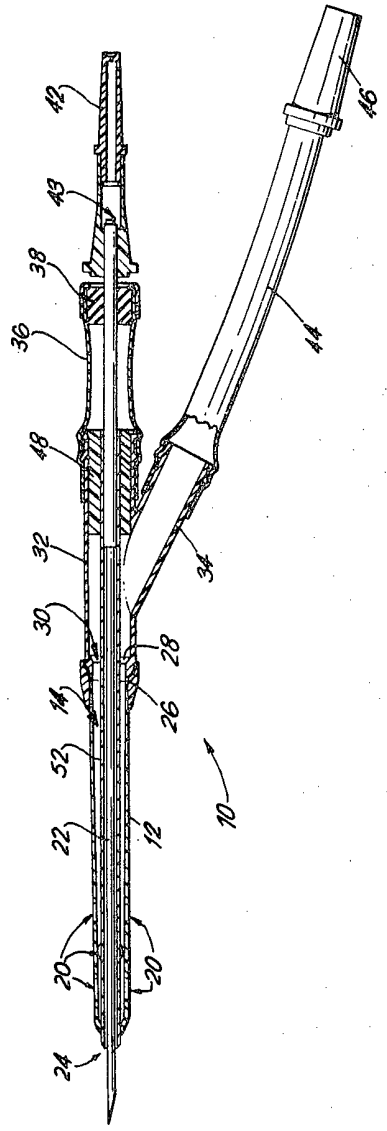

FIG. 3.