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(54) **CATHETER FOR PERCUTANEOUS TRANSRADIAL APPROACH**

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(57) **ABSTRACT**

A preshaped tubular catheter for percutaneous transradial approach to catheterization, comprises a distal bridge shaped portion having a distal arch defining a primary curve, a top defining a secondary curve, and a proximal arch defining a tertiary curve. The proximal arch is connected to a straight shaft. The shaft is stiff and the bridge shaped portion has a flexibility extending at least up to and including the primary curve and a stiffness extending at least up to and including the tertiary curve.

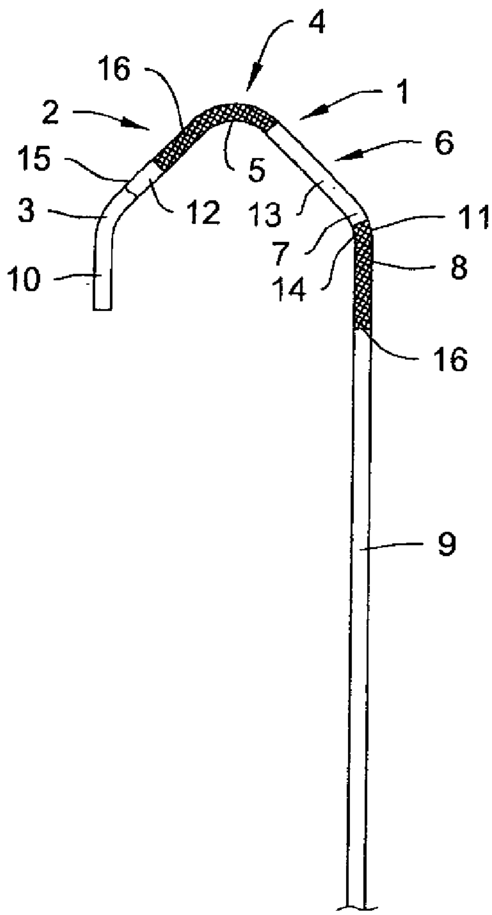


Fig. 1

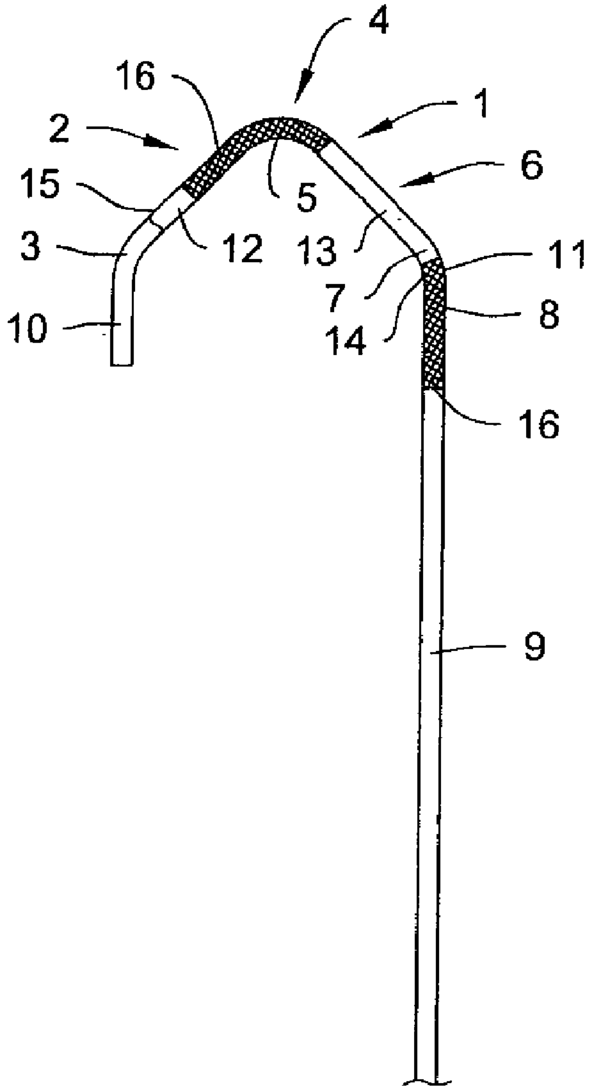


Fig. 2

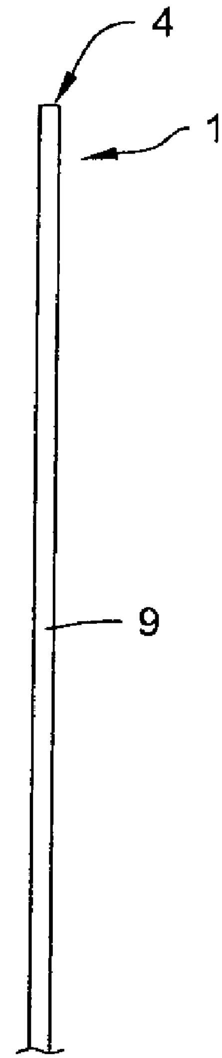


Fig.3

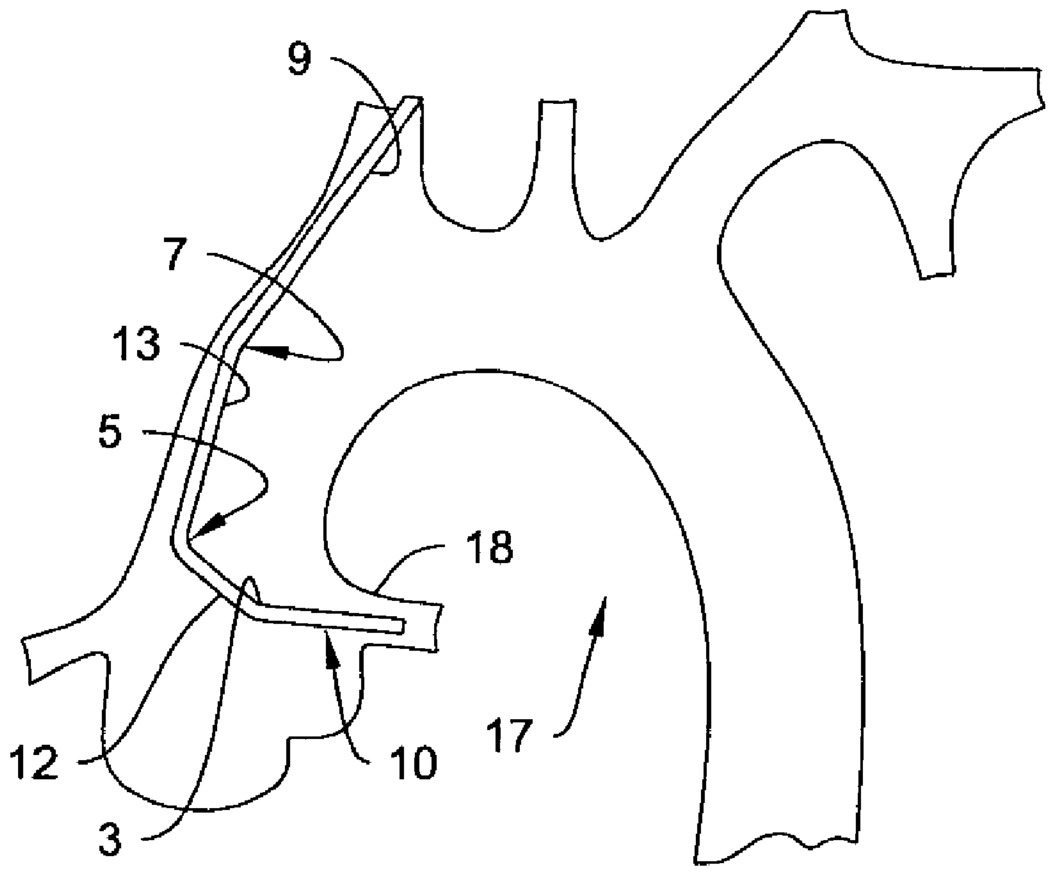


Fig.4

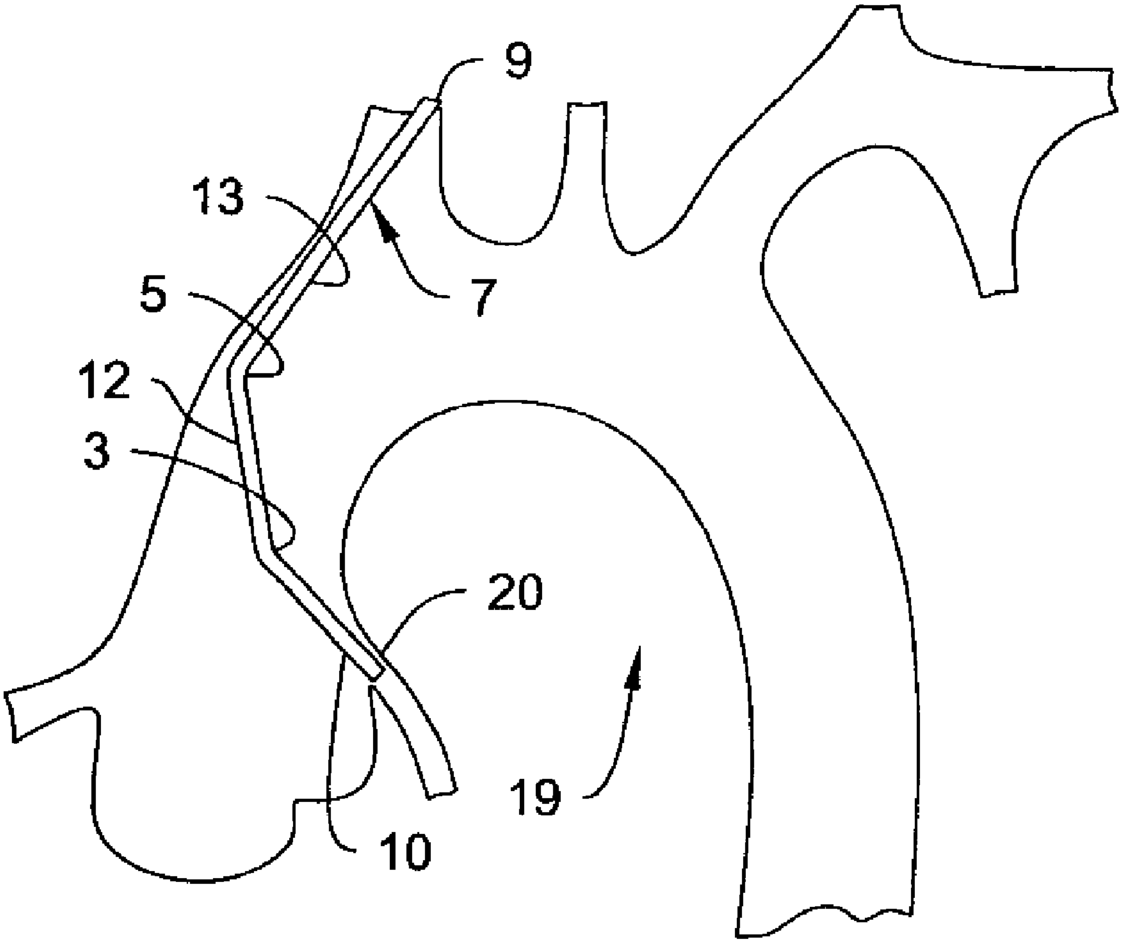


Fig.5

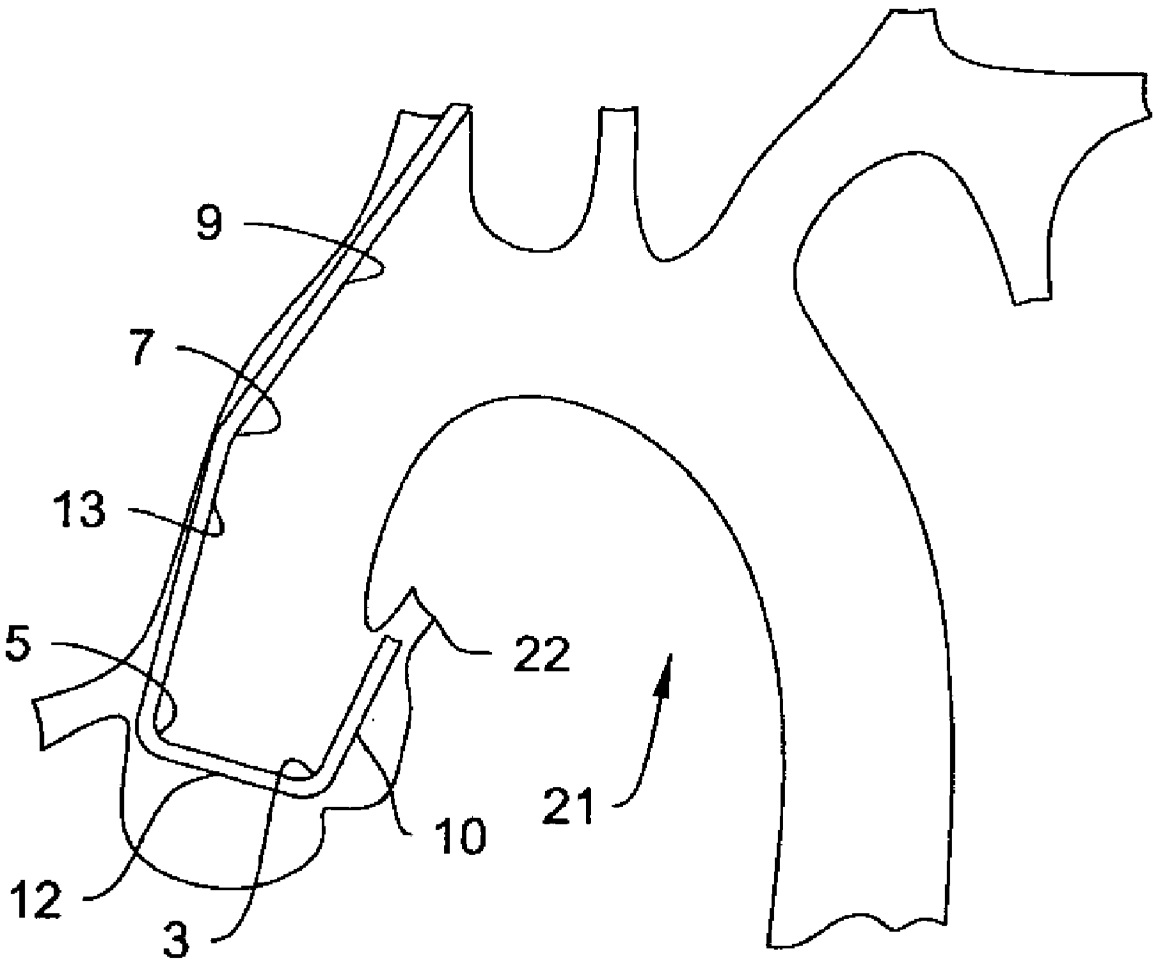
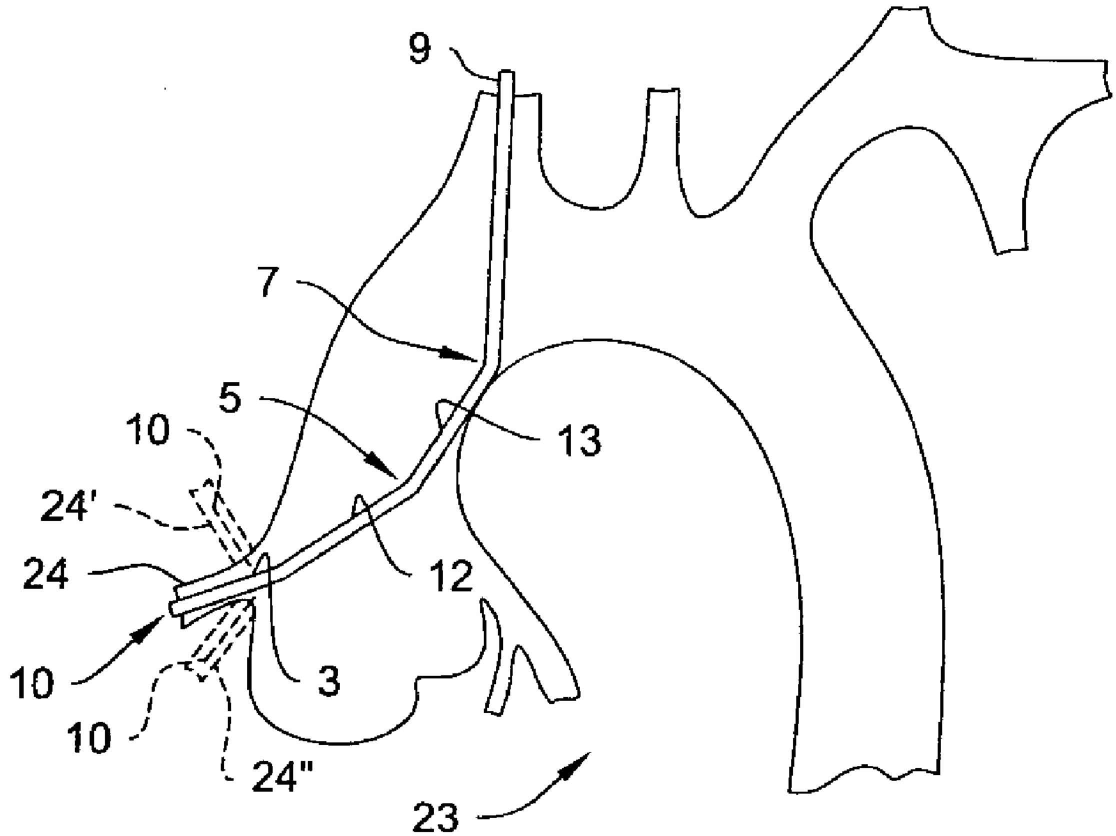


Fig.6



CATHETER FOR PERCUTANEOUS TRANSRADIAL APPROACH

[0001] This application is a continuation of U.S. application Ser. No. 10/792,432, filed Mar. 3, 2004, which is a continuation of U.S. application Ser. No. 10/246,270, filed Sep. 18, 2002, now U.S. Pat. No. 6,723,083, which is a continuation of U.S. application Ser. No. 09/901,401, filed Jul. 9, 2001, now U.S. Pat. No. 6,620,150, which is a continuation of U.S. application Ser. No. 09/356,830, filed Jul. 19, 1999, now U.S. Pat. No. 6,273,881, which is a continuation of U.S. application Ser. No. 08/899,083, filed Jul. 23, 1997, which is a continuation of U.S. application Ser. No. 08/560,251, filed Nov. 21, 1995.

BACKGROUND OF THE INVENTION

[0002] This invention relates to preshaped tubular catheters for percutaneous transradial approach to catheterization.

[0003] Preshaped catheters are commonly used for medical procedures such as diagnosis or such as coronary angioplasty or coronary stent implantation in which they serve to guide other catheters such as pressure measuring or balloon or stent loaded balloon catheters. In these procedures, a femoral approach is currently used in which the preshaped catheter is introduced into the aorta via the femoral artery, and the catheter is then manipulated at its proximal end, by push or pull and/or torque motions, for steering its distal end into the lumen of the selected vessel. To assist in advancing the catheter through the cardiovascular system, a relatively stiff guidewire is inserted into the catheter to straighten it out and bring the tip of the catheter in the direction of origin of the selected artery prior to actual cannulation. After the catheter is inserted into the artery, the guidewire is withdrawn, and the catheter may serve for a diagnosis procedure or for the guidance of another catheter such as a balloon catheter or a stent loaded balloon catheter.

[0004] In order to properly achieve its guiding function, the preshaped catheter should have an efficient backup or stability in the region where it is placed in order to withstand the efforts and motions of the pulsating environment as well as the stresses and deformations caused by the passage of the balloon catheter or other catheter or other equipment which it guides. It should also assure a good coaxiality for proper alignment with the ostium of the artery to avoid loss of push force on the guided catheter or the risk of trauma caused by a stent loaded balloon catheter entering the vessel in a misaligned condition. Furthermore, the preshaped guiding catheter should have some automatic configurational adaptability to easily find its way through the vascular system with a minimal amount of manipulations to whenever possible reduce the load of positioning travels for the patient. It should also have an appreciable capacity to deal with a variety of take-offs or angular positions which the left coronary artery, the right coronary artery or venous by-pass grafts may have with respect to the aortic arch. And when in the selected position, the catheter should lock in place and be releasable only under longitudinal tension from the operator.

[0005] Accordingly, the preshaped guiding catheters should have a configuration of lines, curves and/or angles which precisely match the environmental context in which they will have to be used and it is therefore practically impossible to simply foresee the effects of changes made to the catheter shape.

[0006] A great number of preshaped catheters have been designed over the years for the transfemoral catheterization.

[0007] For instance, the most commonly used catheter for left coronary arteries, namely the catheter referred to as the "left Judkins" which comprise an elongated straight shaft portion followed by a distal end portion consisting of a straight portion extending from the shaft portion and followed by a curved portion for approximately 180.degree. followed by a straight portion forming a small angle with the straight portion extending from the shaft portion, this last straight portion terminating in a tip portion substantially perpendicular thereto. This catheter is often made of a plastic material, and most of the catheters of that kind have a flexibility which is unmodulated along their length. They are also supplied in canted configurations to meet particular take-off requirements. This kind of catheter cannot be applied to right coronary arteries and, therefore, another catheter has been designed for right coronary arteries, namely the catheter referred to as the "right Judkins", also made of a plastic material, which comprises an elongated shaft portion having the shape of an elongated S terminating in a tip portion substantially perpendicular to the distal end of the S shaped shaft portion. Most of the catheters of that kind also have a flexibility which is unmodulated along their length.

[0008] Other preshaped catheters made of a plastic material, most of which have a flexibility which is unmodulated along their length have been designed, for example the catheters described in the document WO 92/12 754 the purpose of which is to improve over the "Judkins" catheters. According to a first embodiment, intended for left coronary arteries, the catheter comprises a first straight shaft portion followed by a distal end portion comprising a second straight portion extending at an angle to the first straight portion, followed by a curved portion for approximately 180.degree. followed by a third straight portion substantially parallel to the second straight portion, and a tip portion extending from and at an angle from the third straight portion, this tip portion extending behind the first straight shaft portion; this catheter is adapted for use with a relatively stiff wire inserted therein. A second embodiment, also intended for left coronary arteries and for use with a stiff wire inserted therein comprises an elongated first straight shaft portion followed by a distal end portion consisting of a second straight portion extending at an angle to the first straight shaft portion, a curved portion extending from the second straight portion for approximately 180.degree., a third straight portion extending from the curved portion at an angle to the second straight portion, and a tip portion extending at an angle to the third straight portion and parallel to the second straight portion, the tip portion extending behind the first straight portion. A third embodiment, also intended for left coronary, arteries and use with a stiff guiding wire, and more particularly for left coronary arteries which are angularly displaced posteriorly from their normal distance (a situation referred to as posterior take-off), comprises a first straight portion extending from the proximal end of the catheter, and a distal end portion consisting of a second straight portion extending at an angle to the first straight portion and followed by a curved portion extending for approximately 180.degree., the curved portion being followed by a third portion terminating in a tip portion; in this catheter, the first and third straight portions are bent out of the plane formed by the second straight portion and the curved portion. A fourth embodiment intended for use with a stiff guidewire in a right coronary artery that is angularly displaced from its normal position and has an anterior take-off, comprises a first straight portion and a distal end portion formed by a second straight portion extending from the first straight portion at an angle in a first plane which is between 50.degree. and 700 and at an angle in a second plane which is perpendicular to the first plane which is between 20.degree. and 40.degree., a third straight tip portion extends from the second straight portion at an angle which is between 20.degree. and 30.degree. in the first plane and at an angle between 40.degree. and 50.degree. to the second straight portion. A fifth embodiment, intended for use with a stiff guidewire in a venous by-pass connecting the aorta to the distal segment of the right coronary artery, comprises a first straight shaft portion and a distal end portion consisting of a first curved portion extending the first straight portion, a second curved portion extending the first curved portion oppositely thereto and followed by a straight tip portion parallel to the first straight portion.

[0009] Still other preshaped catheters are available on the market such as, for instance, the catheter referred to as the "left Amplatz" or the "right Amplatz" which is constructed on variations of a basic shape having a straight elongated shaft followed by a first curve in a first direction followed by a second curve in the opposite direction, or the catheter referred to as the "Multipurpose" which bases on a shape having a substantially straight shaft portion followed by a curve, most of which have a flexibility which is unmodulated along their length.

[0010] A percutaneous transradial approach to catheterization is now being investigated because of favorable anatomical relations of the radial artery to its surrounding structures and the double blood supply to the hand. Potential benefits of this approach are safe transarterial coronary interventions combining rapid mobilization of the patient after intervention, with the resulting reduced hospitalization, and easy, safe, and effective hemostasis leading to a marked reduced incidence of access-site related major complications.

[0011] So far, there are, however, no specific catheters available for this technique. Typically, catheters such as those referred to hereinabove, which are specific to percutaneous transfemoral catheterization approach, have been used, however with relative lack of success on backup and coaxiality in alignment with the artery. Furthermore, they usually require a straightening wire for bringing the tip of the catheter in the direction of the ostium of the artery. And a plurality of catheters is needed to meet the various take-off configurations; and even so, they need some tricks to be properly used.

[0012] It is therefore an object of the present invention to improve the percutaneous transradial approach to catheterization by proposing a catheter specific to transradial catheterization. It is a further object of the invention to provide a catheter for transradial approach which avoids the drawbacks of the catheters for femoral approach used for transradial approach. Still a further object of the invention is to provide a catheter for transradial approach which is simple to manufacture with available techniques, and which avoids unnecessary costs as well as complex stock supply or ordering procedures.

SUMMARY OF THE INVENTION

[0013] Accordingly, the combination of a flexible primary curve with stiff structures provides modulated flexibility and allows selective cannulation of right coronary arteries, left coronary arteries, and venous by-pass grafts. It also permits dealing with a variety of take-off conditions of the right coronary artery, the left coronary artery and venous by-pass grafts. As it permits to bring the tip of the catheter in the direction of the origin of the coronary artery prior to any cannulation, there is an improved coaxiality of the catheter. Deep intubation across sharp curves of coronary irregularities is also possible. The stiff structures assure support on contralateral aortic sinus and extra support against aortic wall; they optimize the torque and kink resistance during catheter manipulations; they also optimize the support for easier manipulation and change of angles of the primary curve; and once the catheter is positioned they assure full backup to the catheter.

[0014] As a result, there is no need for a guidewire to bring the tip of the catheter in the direction of the origin of the coronary, prior to cannulation. There is a smooth passage of stents by reduced friction at the site of the catheter curves. The success of stent delivery is thus greatly improved and stent implantation may become a current procedure, not only for elective cases, and without the need to exchange guiding catheters.

[0015] A further advantage is that the catheter has a multipurpose capacity for dealing with right coronary arteries, left coronary arteries, and venous by-pass grafts, without the necessity to exchange catheters during a muitivessel procedure, thereby preventing artery spasm and discomfort, potential loss of distal access in case of extreme tortuosity, long procedural and fluoro time, as well as unnecessary costs and heavy stbck procedures.

[0016] And of course the catheter has compatibility for percutaneous transluminal coronary angioplasty, perfusion, stent delivery and diagnostic.

[0017] In sum, the present invention relates to a preshaped tubular catheter for percutaneous transradial approach to catheterization, having a distal bridge shaped portion having a distal arch defining a primary curve, a top defining a secondary curve, and a proximal arch defining a tertiary curve. The proximal arch is connected to a distal end of a straight and stiff shaft, and the bridge shaped portion has a flexibility extending at least up to and including the primary curve and a stiffness extending at least up to and including the tertiary curve. The distal bridge shaped portion may have a first distal straight portion, a primary curve extending from the first distal straight portion, the primary curve having a concavity oriented towards a proximal end of the bridge shaped portion, a second straight portion extending from the primary curve, the second straight portion being inclined towards the proximal end of the bridge shaped portion, a secondary curve extending from the second straight portion, the "secondary curve having a concavity oriented between the first distal straight portion and the proximal end of the bridge shaped portion, a third straight portion extending from the secondary curve, the third straight portion being inclined towards the proximal end of the bridge shaped portion, and a tertiary curve extending from the third straight portion, the tertiary curve having a concavity oriented towards the first distal straight portion, and the tertiary curve having a proximal end connected to the distal end of the straight shaft. The flexibility of the bridge shaped portion may extend at least over the first distal straight portion, the primary curve, and a distal portion of the second straight portion. The secondary curve may extend over about 90.degree., and the tertiary curve may extend over about 45.degree. The second straight portion and the third straight portion may be essentially the same length. The first distal straight portion may be substantially parallel to the straight shaft.

[0018] The above and other objects, features and advantages of the invention will become readily apparent from the following detailed description with reference to the accompanying drawings which show, diagrammatically and by way of example only, a preferred but still illustrative embodiment of the invention.

DESCRIPTION OF THE DRAWINGS

[0019] FIGS. **1** and **2** are side and front views, respectively of a portion of the catheter according to the invention.

[0020] FIGS. **3**, **4** and **5** are, respectively, cross sectional views of a portion of a cardiovascular system with the catheter inserted in the left coronary artery.

[0021] FIG. **6** is a cross sectional view of a portion of a cardiovascular system with the catheter inserted in the right coronary artery.

DESCRIPTION OF PREFERRED EMBODIMENTS

[0022] The catheter shown in FIGS. **1** and **2** is tubular and comprises a distal bridge shaped portion **1** having a distal arch **2** defining a primary curve **3**, a top **4** defining a secondary curve **5**, and a proximal arch **6** defining a tertiary curve **7**. The proximal arch **6** is connected to a distal end **8** of a straight shaft **9** the proximal end of which is fitted with the usual handling connector (not shown). The shaft **9** is stiff and the bridge shaped portion **1** has a flexibility extending at least up to and including the primary curve **3** and a stiffness extending at least up to and including the tertiary curve **7**.

[0023] More specifically, the bridge shaped portion **1** comprises a first distal straight portion **10**, a first primary curve **3** extending from said first straight portion **10**, which primary curve has a concavity oriented towards the proximal end **11** of the bridge shaped portion **1**. A second straight portion **12** extends from primary curve **3** and is inclined towards the proximal end **11** of the bridge shaped portion **1**. A secondary curve **5** extends from the second straight portion **12** and said secondary curve has a concavity oriented between the first distal straight portion **10** and the proximal end **11** of bridge shaped portion **1**. A third straight portion **13** extends from the secondary curve **5**, and said straight portion **13** is inclined towards the proximal end **11** of bridge shaped portion **1**. A tertiary curve **7** extends from third straight portion **13**, and said tertiary curve has a concavity oriented towards the first distal straight portion **10**; a proximal end **14** of said tertiary curve is connected to the distal end **8** of the shaft **9**.

[0024] The shaft **9** is stiff and, preferably, the flexibility of the bridge shaped portion **1** extends over the first distal straight portion **10**, the primary curve **3** and a distal portion **15** of second straight portion **12** while the proximal part of second straight portion **12**, the secondary curve **5**, the third straight portion **13** and the tertiary curve **7** are stiff. Stiffness may be obtained, for example, by a braiding **16** embedded in the plastic material forming the catheter or otherwise, for example, by quality of the material at the appropriate regions.

[0025] Preferably, the secondary curve extends over about 90.degree. and the tertiary curve extends over about 45.degree. However, these data may be selected otherwise.

[0026] In a preferred embodiment, the second straight portion **12** and the third straight portion **13** are essentially of the same length. Another choice is however possible, for instance the second and third straight portions may have a differing length.

[0027] The first distal straight portion **10** may be, as shown, substantially parallel to the straight shaft **9**. However, this first distal straight portion **10** may be selected at an angle opening in the direction of straight shaft **9**.

[0028] Instead of extending up to the distal portion **15** of second straight portion **12**, the flexibility of the bridge shaped portion **1** may extend closer to the primary curve **3** or proximally beyond the distal portion **15** of second straight portion **12**.

[0029] The distal end of first distal straight portion **10** may be fitted with a soft tip to be fully atraumatic.

[0030] FIG. **3** shows a cardiovascular system **17** in which the left coronary artery **18** has a horizontal take-off. As may be seen, the tertiary curve **7** rests on the aortic wall; upon pulling the catheter, the secondary curve **5** will deflect the primary curve **3** so that the first straight portion **10** coaxially engages the ostium of the artery.

[0031] FIG. **4** shows a cardiovascular system **19** in which the left coronary artery **20** has a downward take-off. In this situation a pull on the catheter will modify the support conditions of secondary and tertiary curves **5** and **7** to re-direct primary curve **3** and first straight portion **10** in the direction of the ostium of the artery.

[0032] FIG. **5** shows a cardiovascular system **21** in which the left coronary artery has a vertical take-off. In such a condition, the catheter will need a push so that the tertiary curve **7** lies deeper in the root whereby the secondary curve **5** will divert the primary curve **3** to have it take a more vertical position to secure coaxiality of the first straight portion **10** with the ostium of the artery.

[0033] FIG. **6** shows a cardiovascular system **23** in which the right coronary artery is shown in a horizontal take-off **24**, respectively in upward take-off **24'**, respectively in a downward take-off **24"**. As may be seen, the tertiary curve **7** and secondary curve **5** assure a correct directioning of primary curve **3** and first straight portion **10** in coaxial alignment with the artery. To achieve engagement into the upward take-off **24'** a push on the shaft **9** of the catheter will give an upward deflection of primary curve **3** and the corresponding upward directioning of first straight portion **10** to coaxially engage the artery. Engagement into the downward take-off **24"** will require a pull on shaft **9** of the catheter so that the primary curve **3** will take a more downward deflection which will re-direct downwardly the first straight portion **10** to properly engage the ostium coaxially.

[0034] As may be seen, in all these conditions, the catheter has a strong back-up due to the supporting condition of the tertiary curve, and/or secondary curve, and/or third straight portion.

What is claimed:

1. A preshaped catheter, comprising:

a tubular, generally straight end segment;

a plurality of generally straight segments proximal of the end segment; and

a plurality of curved segments; and

means for permitting the end segment to coaxially intubate a lumen of a left coronary artery having an ostium, whether the left coronary artery has a horizontal take-off, an upward take-off, or a downward take-off, while a portion of the catheter rests on a portion of a wall of an aorta when the end segment is intubated in the lumen.

2. The catheter of claim 1, wherein the portion of the catheter is adapted to rest on a portion of the wall of an aorta generally opposite the wall having the ostium of the left coronary artery.

3. The catheter of claim 1, wherein the plurality of generally straight segments and the plurality of curved segments are configured to permit the end segment to coaxially intubate a lumen of a right coronary artery having an ostium, whether the right coronary artery has a horizontal take-off, a vertical take-off, an upward take-off, or a downward take-off, and are configured so that a portion of the catheter rests on a portion of a wall of an aorta when the end segment is intubated in the lumen of the right coronary artery.

4. The catheter of claim 3, wherein the portion of the catheter is adapted to rest on a portion of the wall of an aorta generally opposite the wall having the ostium of the right coronary artery.

5. The catheter of claim 1, further comprising a generally straight proximal segment, and wherein a portion between the proximal segment and the end segment is more flexible than the proximal segment or the end segment.

6. The catheter of claim 1, wherein the distal end segment and the proximal segment are generally parallel when the catheter is in an unconstrained position.

7. The catheter of claim 1, wherein the plurality of curved segments extend over a corresponding plurality of angles, and wherein the plurality of angles total about 180 degrees.

8. The catheter of claim 1, wherein the plurality of curved segments extend over a corresponding plurality of angles, and wherein the plurality of angles exceed about 180 degrees.

9. The catheter of claim 1, wherein the end segment is more flexible than the plurality of generally straight segments.

10. The catheter of claim 1, wherein the plurality of curved segments comprise a primary curve, a secondary curve, and a tertiary curve.

11. The catheter of claim 10, wherein the primary curve extends through an angle of about 45 degrees.

12. The catheter of claim 10, wherein the secondary curve extends through an angle of about 90 degrees.

13. The catheter of claim 10, wherein the tertiary curve extends through an angle of about 45 degrees.

14. The catheter of claim 10, wherein the plurality of generally straight segments comprise a first segment disposed between the primary and the secondary curve and a second straight segment disposed between the secondary and the tertiary curve.

15. The catheter of claim 14, wherein the first segment and the second segment are essentially the same length.

16. A catheter, comprising:

a distal bridge portion including a first straight region, a second straight region, a third straight region, a primary curve disposed between the first and second straight regions, a secondary curve disposed between the second and third straight regions, a tertiary curve disposed proximal to the third straight region;

a proximal shaft portion connected to the tertiary curve; and

means to co-axially align the first straight region within a coronary artery, whether the coronary artery has a horizontal take-off, an upward take-off, or a downward take-off.

17. The catheter of claim 16, wherein the coronary artery is a left coronary artery.

18. The catheter of claim 16, wherein the coronary artery is a right coronary artery.

19. The catheter of claim 16, wherein the catheter is configured so that a portion of the catheter may rest against a wall of the aorta opposite the coronary artery when the first straight region is within the coronary artery.

20. The catheter of claim 16, wherein a distal portion of the bridge portion is more flexible than a proximal portion of the bridge portion.

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