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(54) **LUBRICOUS AND READILY BONDABLE CATHETER SHAFT**

GLEITFÄHIGER LEICHT HAFTBARER KATHETERSCHAFT

CORPS AXIAL DE CATHETER, GLISSANT ET A FIXATION FACILE

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## Description

### BACKGROUND OF THE INVENTION

**[0001]** This invention relates to catheters for performing intravascular procedures such as percutaneous transluminal coronary angioplasty (PTCA) and more specifically to elongated shafts for such catheters.

**[0002]** PTCA is now one of the most widely used treatment modalities for heart disease. The procedure basically comprises advancing a dilatation catheter, having an inflatable balloon on its distal extremity, into the patient's coronary anatomy over a guidewire until the balloon of the dilatation catheter is properly positioned across the lesion to be dilated. Once properly positioned, the dilatation balloon is inflated with liquid to a predetermined size at relatively high pressures, e.g. up to 20 atmospheres or more, to expand the arterial passageway. Generally, the inflated diameter of the balloon is approximately the same diameter as the native diameter of the body lumen being dilated so as to complete the dilatation but not overexpand the artery wall. After the balloon is finally deflated, blood flow resumes through the dilated artery and the dilatation catheter can be removed therefrom.

**[0003]** In most PTCA procedures, a guiding catheter having a preshaped distal tip is first percutaneously introduced into the cardiovascular system of a patient by means of a conventional Seldinger technique and advanced therein until the preshaped distal tip of the guiding catheter is disposed within the aorta adjacent to the ostium of the desired coronary artery. The guiding catheter is twisted or torqued from its proximal end, which extends out of the patient, to guide the distal tip of the guiding catheter into the desired coronary ostium. Once the guiding catheter is in proper position within the patient's vasculature, the dilatation catheter with a guidewire slidably disposed within an inner lumen of the dilatation catheter is positioned within the inner lumen of the guiding catheter. The guidewire is first advanced out the distal tip of the guiding catheter seated in the coronary ostium into the patient's coronary artery and directed to the region of the patient's coronary anatomy where the procedure is to occur. A torque may be applied to the proximal end of the guidewire, which extends out of the proximal end of the guiding catheter, to guide the curved or otherwise shaped distal end of the guidewire into a desired branch of the coronary artery. The advancement of the guidewire within the selected artery continues until it crosses the lesion to be dilated. The dilatation catheter is then advanced over the previously advanced guidewire, until the balloon on the distal extremity of the dilatation catheter is properly positioned across the lesion which is to be dilated.

**[0004]** Current intravascular catheter designs are limited by the need to incorporate conflicting characteristics. For example, most dilatation catheters are designed to be introduced into a body lumen over an in-place guidewire which is slidably received within an inner lumen within the catheter. As such, it is desirable to minimize the friction between the guidewire and the surface of the inner lumen of the catheter by constructing the catheter from a lubricous material such as a high density polyethylene. However, lubricous polymeric materials frequently lack other desirable properties, including, for example, the ability to readily bond to incompatible polymeric materials such as polyethylene terephthalate and nylon. Due to the high inflation pressures (up to 300 psi or more) associated with coronary balloon angioplasty, it is imperative to provide a strong bond between one or more ends of the dilatation balloon and the catheter shaft. Polyolefin balloons can be effectively fusion bonded to a polyethylene shaft but balloons made of nylon and other polyamide materials, and balloons made of polyesters such as polyethylene terephthalate do not easily bond to polyolefinic materials. Nylon and polyethylene terephthalate balloons usually require surface treatment and the use of a suitable adhesive to bond to polyolefin materials such as polyethylene. The additional manufacturing steps of surface treatments and incorporating and curing an adhesives, greatly complicate the manufacturing process and can introduce significant quality control problems. A catheter shaft should also have adequate strength for pushability and resistance to buckling or kinking. As another example, it may be desirable to provide a catheter shaft with elastomeric properties to improve flexibility. However, most lubricous materials are not elastomeric.

**[0005]** United States Patent No. 5,304,134 to Kraus et al., which is hereby incorporated in its entirety by reference, attempts to provide a solution to the poor bonding of lubricous by providing the catheter shaft with an inner tubular member having a lubricous proximal portion and a non-lubricous, bondable distal portion. However, this approach does not represent a complete solution, because the lubricous proximal portion must still be bonded to the non-lubricous distal portion. The Kraus et al. system also requires that some portion of the guidewire lumen be formed from a non- lubricous material which restricts guidewire movement within the lumen.

**[0006]** A different approach involves forming the dilatation balloon as an integral portion of the catheter shaft itself, but this requires the balloon and the shaft to be formed from the same material, which is not always desirable because the property requirements for the balloon and the shaft can be quite different, particularly for dilatation catheters for PTCA .

**[0007]** Accordingly, there remains a need to provide a catheter shaft having a lubricous inner surface defining a guidewire lumen while allowing an easy, secure bond with a dilatation balloon or other catheter components formed of non-lubricous polymeric materials. The present invention satisfies these and other needs.

## SUMMARY OF THE INVENTION

**[0008]** The present invention is directed to an intraluminal catheter as claimed in Claim 1 and to a balloon dilatation catheter as claimed in Claim 15 which are suitable for performing angioplasty procedures.

**[0009]** Preferred embodiments of these catheters are subject of the dependent claims.

**[0010]** In accordance with the present invention, the catheter shaft or catheter shaft segment is formed of a polymeric blend comprising at least 30% by weight, preferably at least 50% by weight of a lubricous polymeric component, not more than 60%, preferably not more than 40% of a bonding polymeric component and up to 30%, preferably not more than 10% of a polymeric component for compatiblizing the lubricous and bonding components. Optionally, up to 25% by weight, usually not more than 10% by weight of the blend should be a catalytic material to facilitate cross linking the shaft material after forming the product. The lubricous component and the bonding component must be compatible or capable of being made compatible. As used herein the term "compatible" and words of similar import mean that two polymer materials readily form an intimate mixture when they are melt processed together. Usually, they are miscible when both are in a molten condition.

**[0011]** In one presently preferred embodiment, the catheter or catheter segment is formed of a blend of 50% to 80% polyethylene (a lubricous component), up to 50% of a copolyester such as Hytrel® (the bonding component) and up to 30% of a compatiblizing agent such as an acrylate. The polymer components are intimately mixed and extruded into a tubular product which is utilized as the inner tubular member of an intravascular catheter. The surface defining an inner lumen of the tubular member has a kinematic frictional coefficient of 0.08 to 0.3 on a smooth glass. A balloon formed of PET readily fusion bonds to the outer surface of the tubular member.

**[0012]** These and other advantages of the invention will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0013]**

Fig. 1 is an elevational view, partially in section, of an over-the-wire dilatation catheter having an inner tubular member embodying features of the invention.

Fig. 2 is a transverse cross section of the embodiment shown in Fig. 1 taken along the lines 2-2.

Fig. 3 is an elevational view, partially in section, of the distal section of a rapid exchange type dilatation catheter having an inner tubular member embodying features of the invention.

Fig. 4 is a transverse cross section of the embodiment shown in Fig. 4 taken along the lines 4-4.

Fig. 5 is an elevational view, partially in section, of an alternative embodiment wherein the distal section of the catheter shaft is formed of an extrusion of a polymer blend.

Fig. 6 is a transverse cross section of the embodiment shown in Fig. 6 taken along the lines 6-6.

## DETAILED DESCRIPTION OF THE INVENTION

**[0014]** Reference is made to Figs. 1 and 2 which illustrate a balloon dilatation catheter 10 embodying features of the invention. Generally, the catheter 10 comprises an outer tubular member 11, an inner tubular member 12, a dilatation balloon 13 on a distal portion of the catheter and an adapter 14 on the proximal end of the catheter. The inner tubular member 12 has a guidewire receiving inner lumen 15 which slidably receives guidewire 16. The outer surface of the inner tubular member 12 and the inner surface of the outer tubular member 11 define an annular inflation lumen 17 which is in fluid communication with the interior of balloon 13 and side arm 18 of adapter 14.

**[0015]** The distal skirt 20 of balloon 13 is bonded, preferably fusion bonded, to the exterior of the inner tubular member 12 and the proximal skirt 21 is fusion bonded to the exterior of the outer tubular member 11. The fusion bonds are preferably formed by applying laser energy to the exterior of the skirts 20 and 21 which causes the interface between the skirts and the exterior of the outer and inner tubular members 11 and 12. In one presently preferred embodiment, both the outer and inner tubular members 11 and 12 are formed of a polymer blend in accordance with the invention.

**[0016]** Figs. 3-4 depict another embodiment of the invention directed to a rapid exchange type dilatation catheter 30. The catheter 30 includes a relatively stiff proximal shaft 31 formed of hypotubing and a relatively flexible distal shaft section 32. The distal shaft section 32 includes an inner tubular member 33, an outer tubular member 34 and a dilation balloon 35. The inner tubular member 33 has a guidewire receiving inner lumen 36 which is in fluid communication with a distal guidewire port 37 in the distal end of the catheter 30 and a proximal guidewire port 38 disposed a short distance, e.g. 10 to 45 cm from the proximal end of the balloon 35. The proximal shaft 31 comprises a metallic hypotube 40 (e.g. stainless steel or NiTi alloys) and an outer polymer jacket 41 formed of suitable polymer material such as high density polyethylene. The distal end 32 of the hypotube 40 is truncated and fits into the interior of the outer tubular member 34 and bonded thereto by suitable adhesive 42. Support tube 43, preferably formed of polyimide, is disposed between the inner and outer tubular members 33 and 34 and defines inflation lumen.44. As shown in more detail in Fig. 4, the outer tubular member is partially bonded to the inner tubular member 33 and

partially to the support tube 43. A filler material 46, such as 75/25 high density/low density polyethylene, is disposed between the outer tubular member 34 and the support tube 43.

**[0017]** In the embodiment of Figs. 3-4 the inner tubular member 33 is formed of a polymer blend in accordance with the present invention. The distal skirt 47 of balloon 35 is fusion bonded to the exterior of the inner tubular member 33 as in the previously discussed embodiment shown in Figs. 1 and 2. The proximal skirt 48 of the balloon 35 forms the outer tubular member 34 and is formed of essentially the same material as the balloon. In an alternative embodiment not shown the outer tubular member 34 may be a member separate and distinct from the balloon and formed of a polymer blend in accordance with the present invention. In this latter case the proximal skirt of the balloon 35 is fusion bonded to the exterior of the outer tubular member.

**[0018]** Figs. 5 and 6 illustrate yet another embodiment of the invention wherein the catheter 50 has a distal shaft 51 which is of a dual lumen construction and is formed by extruding a polymer blend in accordance with the present invention. A tubular extension 52 extends through the interior of the dilatation balloon 53 and has a distal guidewire port 54 in its distal end. The balloon 53 has a distal skirt 55 fusion bonded to the distal end of the tubular extension 52 and a proximal skirt 56 fusion bonded to the distal shaft 51 as shown in the drawings.

**[0019]** A presently preferred polymer blend includes about 65% high density polyethylene, about 30% Hytrel® (available from Dupont) and about 5% ethylene methyl acrylate such as Lotryl 24MA005 (available from Elf ATOCHEM). This blend readily fusion bonds to polyethylene terephthalate and has a coefficient of friction of about 0.1-0.2.

**[0020]** Although individual features of embodiments of the invention may be shown in some of the drawings and not in others, those skilled in the art will recognize that individual features of one embodiment of the invention can be combined with any or all the features of another embodiment.

## Claims

1. An intraluminal catheter having an elongated shaft which has proximal and distal portions and which has at least a catheter shaft segment thereof formed of a polymeric blend comprising at least 30% by weight of a lubricous polymeric component and not more than 60% by weight of a bonding polymeric component, said polymeric blend being capable of bonding to another catheter component.

2. The intraluminal catheter of claim 1 wherein said another catheter component is formed of a non-lubricous polymeric material.

3. The intraluminal catheter of Claim 2 wherein said another catheter component is a balloon.

4. The intraluminal catheter of Claim 1 wherein said bonding polymeric component is compatiblized with the lubricous polymeric component by means of a compatiblizing agent.

5. The intraluminal catheter of Claim 4 wherein said compatiblizing agent is an acrylate.

6. The intraluminal catheter of Claim 5 wherein said compatiblizing agent is an alkyl acrylate having from 2 to 5 carbon atoms.

7. The intraluminal catheter of Claim 1 wherein said lubricous polymeric component is polyethylene.

8. The intraluminal catheter of claim 1 wherein said polymeric bonding component is a copolyester.

9. The intraluminal catheter of Claim 4 wherein said polymeric blend comprises up to 30% by weight of said compatiblizing agent.

10. The intraluminal catheter of claim 4 wherein said polymeric blend comprises not more than 10% by weight of said compatiblizing agent.

11. The intraluminal catheter of Claim 1 wherein said polymeric blend comprises at least 50% by weight of said lubricous polymeric component.

12. The intraluminal catheter of Claim 1 wherein said polymeric blend comprises not more than 40% by weight of said polymeric bonding component.

13. The intraluminal catheter of Claim 4 wherein said polymeric blend comprises 65% by weight of high density polyethylene as said lubricous polymeric component, 30% by weight of Hytrel® copolyester as said polymeric bonding component, and 5% by weight of ethylene methyl acrylate as said compatiblizing agent.

14. The intraluminal catheter of Claim 1 wherein said polymeric blend further comprising a catalytic material to facilitate cross linking in the catheter shaft segment.

15. A balloon dilatation catheter comprising:

    a) an elongated shaft which has proximal and distal portions and which has at least a catheter shaft segment thereof formed of a polymeric blend comprising at least 30% by weight of a lubricous polymeric component and not more than 60% by weight of a bonding polymeric

component; and

(b) a dilatation balloon formed of a non-lubricous material having at least a distal skirt bonded to said catheter shaft segment.

**16.** The catheter of Claim 15 wherein the distal skirt is fusion bonded to the catheter shaft segment.

**Patentansprüche**

**1.** Intraluminaler Katheter mit einem gestreckten Schaft, welcher nahe und entfernte Bereiche aufweist und bei welchem wenigstens ein Katheterschaftsegment desselben aus einer polymerischen Mischung gebildet ist, welche wenigstens 30 Gew.-% einer gleitfähigen polymerischen Komponente und nicht mehr als 60 Gew.-% einer bindenden polymerischen Komponente aufweist, wobei die Polymermischung in der Lage ist, an einem anderen Katheterbestandteil zu haften.

**2.** Intraluminaler Katheter gemäß Anspruch 1, wobei das andere Katheterbestandteil aus einem nichtgleitfähigen polymerischen Material gebildet ist.

**3.** Intraluminaler Katheter gemäß Anspruch 2, wobei die andere Katheterkomponente ein Ballon ist.

**4.** Intraluminaler Katheter gemäß Anspruch 1, wobei die bindende polymerische Komponente mittels einem Kompatibilisierungsmittel mit der gleitfähigen polymerischen Komponente kompatibel gemacht ist.

**5.** Intraluminaler Katheter gemäß Anspruch 4, wobei das Kompatibilisierungsmittel ein Acrylat ist.

**6.** Intraluminaler Katheter gemäß Anspruch 5, wobei das Kompatibilisierungsmittel ein Alkylacrylat mit 2 bis 5 Kohlenstoffatomen ist.

**7.** Intraluminaler Katheter gemäß Anspruch 1, wobei die gleitfähige polymerische Komponente Polyethylen ist.

**8.** Intraluminaler Katheter gemäß Anspruch 1, wobei die polymerische Bindekomponente ein Copolyester ist.

**9.** Intraluminaler Katheter gemäß Anspruch 4, wobei die Polymermischung bis zu 30 Gew.-% des Kompatibilisierungsmittels aufweist.

**10.** Intraluminaler Katheter gemäß Anspruch 4, wobei die Polymermischung nicht mehr als 10 Gew.-% des Kompatibilisierungsmittels aufweist.

**11.** Intraluminaler Katheter gemäß Anspruch 1, wobei die Polymermischung wenigstens 50 Gew.-% der gleitfähigen Polymerkomponente aufweist.

**12.** Intraluminaler Katheter gemäß Anspruch 1, wobei die Polymermischung nicht mehr als 40 Gew.-% der polymerischen Bindekomponente aufweist.

**13.** Intraluminaler Katheter gemäß Anspruch 4, wobei die Polymermischung 65 Gew.-% Polyethylen mit hoher Dichte als gleitfähige Polymerkomponente, 30 Gew.-% Hytrel® Copolyester als polymerische Bindekomponente und 5 Gew.-% Ethylenmethylacrylat als Kompatibilisierungsmittel aufweist.

**14.** Intraluminaler Katheter gemäß Anspruch 1, wobei die Polymermischung weiter ein kathalytisches Material aufweist, um das Vernetzen in dem Katheterschaftsegment zu erleichtern.

**15.** Ballon-Dehnkatheter, welcher aufweist:

a) einen gestreckten Schaft, welcher nahe und entfernte Bereiche aufweist, und bei welchem wenigstens ein Katheterschaftsegment desselben aus einer Polymermischung gebildet ist, welche wenigstens 30 Gew.-% einer gleitfähigen polymerischen Komponente und nicht mehr als 60 Gew.-% einer bindenden polymerischen Komponente aufweist; und
b) einen Ausdehnungsballon gebildet aus einem nicht-gleitfähigen Material, welcher wenigstens einen entfernten Rand aufweist, der mit dem Katheterschaftsegment verbunden ist.

**16.** Katheter gemäß Anspruch 15, wobei der entfernte Rand mit dem Katherterschaftsegment schmelzverbunden ist.

**Revendications**

**1.** Cathéter intravasculaire comprenant un corps allongé qui présente des portions proximale et distale et qui porte au moins un segment de tige de cathéter sur lui réalisé dans un mélange polymère comprenant au moins 30 % en poids d'un composant polymère lubrifiant et de pas plus de 60 % en poids d'un composant polymère de liaison, ledit mélange polymère étant apte à se lier sur un autre composant de cathéter.

**2.** Cathéter intravasculaire selon la revendication 1 dans lequel ledit un autre composant de cathéter est réalisé dans un matériau polymère non lubrifiant.

**3.** Cathéter intravasculaire selon la revendication 2

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