Further difficulty arises in peripheral arteries when attempting to cross the iliac arch where wire bending may occur as the push force is not effectively transferred to the distal part of the catheter. Attempts to reinforce the catheters using metallic inner members or stiff members have failed since the catheter must be flexible in order to travel through the arteries without damaging the vessels. Other limitations to reinforcing the balloon include the need to keep a low profile (minimize the addition of new materials or layers of tubing) and the need to have short inflation/deflation times (maximizing the area of the inflation lumen to allow rapid liquid flow into the balloon during inflation and out of the balloon during deflation).

[0006] Thus, the ability of balloon catheters and especially balloon catheters with long balloons used to treat peripheral arteries (with balloon lengths up to 30 cm) to reach and cross target lesions is often limited and can prolong procedures requiring the use of excessive contrast media and radiation, both of which can be harmful to the patient.

[0007] For all of the above reasons, it would be desirable to provide improved angioplasty balloon catheters and methods for their use. In particular, it would be desirable if the balloon catheters could have improved pushability or column strength, particularly over their distal regions comprising the balloon, as well as improved torqueability, and thus be capable of being advanced through tortuous regions of the vasculature and through restricted, difficult-to-pass vascular lesions. In addition to possessing such improved column strength and torsional stiffness, it is desirable that the flexibility of the distal region of the catheter, particularly that comprising a balloon, remain sufficiently high to that the balloon remains sufficiently conformable to be delivered around tight bends and through tortuous regions of the vasculature. At least some of these objectives will be met by the inventions described below.

[0008] 2. Description of the Background Art. Patents describing balloon angioplasty catheter constructions include U.S. Patent Nos. 7,491,213; 7,635,347; 7,273,470; 7,022,106; 6,030,405; and 5,827,231.

BRIEF SUMMARY OF THE INVENTION

[0009] Embodiments of tThis invention providediscloses a balloon catheter with improved ability to deliver torque and push throughout the device, including the relatively weak balloon segment of a catheter, to the distal end of the catheter. The balloon catheter typically includes a rotatable asymmetric tip and a reinforced shaft with an improved ability to transmit torque to rotate and realign a leading edge of the tip to facilitate passage through an obstruction. The tip is

preferably asymmetric around its axis, usually being beveled, and the reinforced catheter shaft is capable of transmitting rotation and push force to the catheter tip while maintaining flexibility and deployment performance. When an obstacle is encountered rotation of the catheter allows the tip to pass through the obstacle.

[0010] A particularly advantageous feature of the present invention is referred to as a "slide lock mechanism" which provides intra-balloon support while maintaining flexibility and uniform inflation. This can be achieved through extending a support lumen thru the inflatable part of the balloon to fit inside or close to the distal balloon leg. Attempts to provide full intra-balloon support tubes which are anchored at both ends to the catheter can cause the balloon to deform and assume a non-cylindrical configuration when fully inflated (as shown in Fig. 2). By decoupling the two ends of the balloon from the shaft while providing support tube throughout the full length of the balloon, as achieved with the present invention, such balloon deformation can be avoided. The particular slide lock mechanism of the present invention is also able to provide for both increased column strength (catheter pushability) and torsional rigidity (the ability to rotate the proximal end of the catheter shaft about its axis and cause a comparable rotation of the distal end of the shaft even when the shat is passing through tortuous regions of the vasculature), which are advantageous in catheter placement. Increased column strength and torsional rigidity allow improved transmission of both turning and translation of the shaft from the proximal end so that such motions are accurately reflected in the distal end of the catheter and can allow crossing of tight, long and diffuse lesions that currently are very difficult to treat and may eventually lead to amputation.

[0010a] According to a first aspect of the present invention, there is provided a balloon catheter comprising: an inner member having a proximal end, a distal end, and a guidewire lumen extending therethrough; a distal tip at the distal end of the inner member; a reinforcement sleeve disposed coaxially over the inner member, said sleeve having a proximal end and a distal end and providing an inflation lumen between an outer surface of the inner member and an inner wall of the sleeve; an inflatable balloon having a distal end secured to the distal tip and/or distal end of the inner member and a proximal end secured to the reinforcement sleeve so that the balloon can receive an inflation medium from the inflation lumen, the inflatable balloon further having a distal leg proximal of the distal end and a distal taper proximal of the distal leg; wherein, when the balloon is deflated, the distal end of the reinforcement sleeve is held in place by pressure and/or friction applied from the distal leg and will engage a proximal surface of the distal tip to transfer pushing forces to said tip, the proximal surface being adjacent or distal to the distal leg and, wherein, when the balloon is inflated, the distal end of the reinforcement sleeve can separate from the proximal surface of the distal tip to enhance flexibility and limit deformation of the inflated balloon.

[0011] In embodimentsa ~~first aspect~~ of the present invention, the balloon catheter comprises a shaft having an inner member a proximal end, a distal end, and a guide wire lumen extending therethrough. When the guide wire lumen extends fully through the inner member, the catheter will have an "over-the-wire" configuration where the guide wire passes through the entire length of the catheter. When the guide wire lumen passes through only a portion of the inner member or other structure of the shaft, the catheter can have a "rapid exchange" configuration where only a short length of the guide wire, typically from 10 cm to 35 cm, is received through the catheter and passes through the catheter balloon.

[0012] The catheter maywill further include a distal tip disposed at the distal end of the catheter shaft. The tip could be symmetric or the distal tip will have an asymmetric configuration, typically being beveled at an angle in the range from 30 degrees to 60 degrees, usually being about 45 degrees, so that a leading edge of the tip can be oriented relative to a luminal obstruction to facilitate passing that obstruction. Usually, the distal tip will be a separate

component attached to a distal end of the inner member of the catheter shaft. In other instances, particularly when a distal end is not beveled, a distal tip may be formed integrally in the inner member or other portion of the shaft itself.

[0013] The balloon catheter according to embodiments of the present invention further comprises a reinforcement sleeve which is disposed coaxially over the inner member. The reinforcement sleeve has a proximal end and a distal end and, when in place over the inner member, provides an annular inflation lumen between an outer surface of a shaft and inner wall of the sleeve.

[0014] The balloon catheter further includes an inflatable balloon, typically a non-distensible balloon formed of a conventional balloon material such as nylon or pebax or other materials known in the arts. The balloon has a distal end and a proximal end where the distal end is secured directly or indirectly to the distal tip and/or to the distal end of the inner member. The proximal end of the balloon is secured to the reinforcement sleeve, typically near the distal end of the reinforcement sleeve. As at least the distal end of the reinforcement sleeve will be free to move relative to the inner member, as described in more detail below, the distal end of the balloon will be able to move relative to the proximal end of the balloon as the balloon is inflated, reducing the risk that the balloon will deform from the desired cylindrical configuration as it is inflated.

[0015] In the preferred constructions, a distal end of the extended outer shaft maywill directly couple or engage the distal tip of the catheter when the balloon is deflated and the catheter is being advanced through the vasculature. By engaging or otherwise being coupled to the distal tip, the reinforcement sleeve is able to transmit both axial force (i.e., increase the overall column strength of the catheter) as well as torsional force from the proximal end of the catheter to the distal end. The enhanced column strength and torsional rigidity are achieved during the catheter advancement, which is when they are most needed. Moreover, the torsional rigidity and column strength of the reinforcement sleeve are provided in addition to the strength and rigidity of the catheter shaft itself so that the overall column strength and torsional rigidity are the sum of the contributions of each component.

[0016] While the distal end of the reinforcement sleeve maywill engage or otherwise be coupled to the distal tip (or the distal end of the balloon) while the balloon is deflated during catheter advancement, the reinforcement sleeve will not be attached to the catheter tip so that the reinforcement sleeve will be able to move or retract in a proximal direction in response to balloon elongation when the balloon is inflated. Thus, two ends of the balloon will be able to move apart from each other and the stress on the balloon which would result from the balloon

ends being anchored is eliminated. Thus, the balloon maywill be able inflate with less risk of the deformation than if the balloons were both attached to the balloon shaft.

[0017] The distal end or region of the reinforcement sleeve maywill have one or more ports or passages formed therethrough in order to permit balloon inflation. An inflation medium can be introduced into the annular lumen between the sleeve and the shaft, typically through an inflation port on a proximal hub of the catheter. The inflation medium can travel the length of the catheter through the annular lumen. The distal region of the sleeve may be generally cylindrical so that the annular lumen continues the entire length of the catheter to reach the distal tip. With such a fully extending sleeve, the inflation ports can be formed along the length of the sleeve at multiple locations within the balloon. Alternatively, in order to produce the crossing profile of the balloon, the sleeve can be tapered so that it lies immediately over the outer surface of the distal end of the inner member, thus eliminating the inflation medium over a distal region of the balloon. In such cases, the holes maywill need to be located in the proximal area of the balloon before the out shaft if fully tapered.

[0018] The inner member may have any conventional angioplasty balloon shaft structure, typically comprising a hypotube or other metal body portion over at least a portion of its length. Alternatively, the inner member could be a polymeric body over at least a portion of its length, typically being reinforced with a braid, mesh, embedded wires, or the like, in order to increase column strength and torsional rigidity.

[0019] The reinforcement sleeve maywill typically comprise a polymer tube over at least a portion of its length, where the polymer may be reinforced with meshes, braids, wires, or the like, in order to increase both its column strength and torsional rigidity.

[0020] In a specific embodiment of the catheter, the balloon maywill include at a distal constriction (distal leg) which does not inflate with introduction of the inflation medium. This distal restriction is spaced apart from the inner member so that a channel is created which receives the distal end of the reinforcement sleeve. Usually, the channel maywill be sufficiently long so that the reinforcement sleeve remains in the channel even when it is fully retracted in its proximal direction when the balloon is fully inflated.

[0020a] According to a second aspect of the present invention, there is provided a method for dilatating a lesion in a blood vessel, said method comprising: providing a catheter having an inner member, a distal tip, a reinforcement sleeve, and an inflatable balloon connected at a distal end to the inner member and at a proximal end to the reinforcement sleeve, wherein, when the balloon is deflated, a distal end of the reinforcement sleeve engages a proximal surface of the distal tip located adjacent or distal to a distal leg of the inflatable balloon, and the distal leg is distal to a distal taper of the inflatable balloon and applies pressure and/or friction to hold the distal end of the reinforcement sleeve in place; advancing the catheter through a patient's vasculature by pushing a proximal end of the inner member to transmit force to the distal tip through both the inner member and the reinforcement sleeve, while both the inner member and distal end of the reinforcement sleeve remain engaged with the distal tip, to position the balloon at the lesion; and inflating the balloon within the lesion such that the balloon radially expands and elongates and the distal end of the reinforcement sleeve separates from the proximal surface of the distal tip to accommodate such balloon elongation.

[0021] In embodiments of~~a second aspect,~~ the present invention, ~~t provides a method for dilatating a body lumen, typically dilatating a lesion in a blood vessel. T~~he method comprises providing a catheter having an inner member, a distal tip (area distally to the inflatable balloon), a reinforcement sleeve (outer shaft), and an inflatable balloon connected at a distal end to the inner member and at a proximal end to the reinforcement sleeve. The catheter is advanced

through a patient's vasculature by pushing a proximal end of the catheter shaft to transmit a push force to the distal tip of the catheter through both the inner member and the reinforcement sleeve. While the catheter is being advanced by pushing, the distal ends of the both the inner member and the outer shaft remain engaged against the distal tip of the catheter in order to facilitate positioning of the balloon at the lesion or other target site. Once at the lesion or other target site, the balloon is inflated so that the balloon radially expands and elongates. As the balloon elongates, the reinforcement sleeve separates from the distal tip to accommodate such balloon elongation, whereby stresses and constricting forces which could deform the balloon are greatly reduced. Usually, while a balloon is being advanced, it is also being rotated, where the rotational torque is transmitted to the distal tip through both the inner member and the reinforcement sleeve, both of which remain engaged against the tip during catheter advancement. Usually, the distal will have a beveled or other asymmetric end which may be reoriented relative to an obstruction in the vasculature in order to help pass the obstruction as the catheter is advanced and rotated.

[0022] In embodiments~~another aspect~~ of the present invention, the catheter inner member may utilize reinforced tubes allowing rotation and push force transmission. This reinforcement is achieved by use of braided shafts where a braid of thin metallic or polymer ribbons that increase the inner member torque and push force transmission without compromising the shafts flexibility. The braided shafts can be the external shaft or the internal shaft (inner member) or both. The internal shaft is connected to the balloon distal end and the external shaft is connected to the balloon proximal end, often these two are not connected. Reinforcing those shafts, especially the inner shaft, greatly improves the operators control over the balloon throughout the catheters length all the way to the tip, mainly torque and pushability.

[0023] In embodiments~~yet another aspect~~ of the present invention, the catheter shaft may utilize reinforced tubes or support material in the internal shaft, and/or external shafts and the two are connected at an anchoring area near the proximal end of the balloon, allowing enhanced control of the balloon by the operator.

[0024] In embodiments~~still another aspect~~ of the present invention, an inner construction of the balloon comprises a continuation of the distal shaft/ inflation lumen that extends through the balloon all the way to the balloon distal leg or tip. This elongated distal shaft could be bonded at the balloon distal end or can be stabilized by pressure applied from the balloon leg. To provide effective inflation/deflation the inflation lumen that extends throughout the balloon contains