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(71)(72) Applicant and Inventor: TRUCKAI, Csaba [US/US]; 627 Alberta Avenue, Sunnyvale, CA 94087 (US).

(74) Agents: HAVERSTOCK, Thomas, B. et al.; Haverstock & Associates, Suite 420, 260 Sheridan Avenue, Palo Alto, CA 94306 (US).

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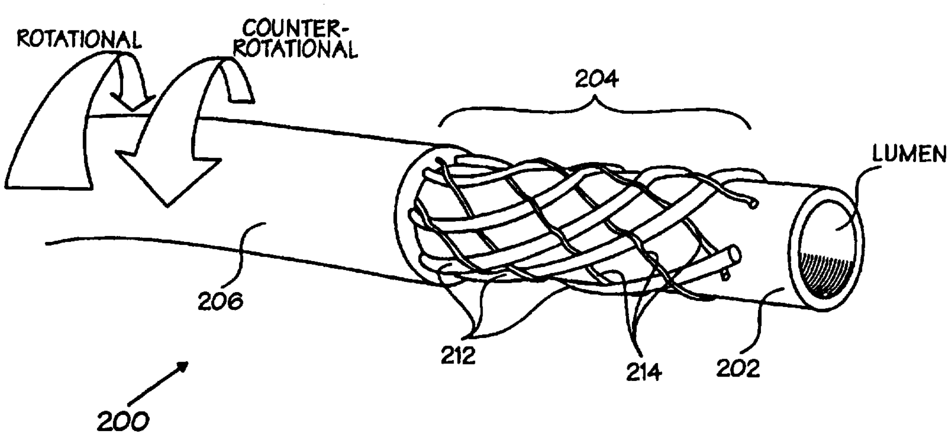

(57) Abstract

A flexible catheter comprising a reinforcement sheath made of helically disposed reinforcement elements. Different elements made of different material and having different thickness are used in different winding directions. By braiding thicker elements in a rotational direction, and by braiding substantially thinner elements in a counter-rotational direction, the kink-resistance, torsional stiffness and axial stiffness of the resulting catheter will be increased without increasing the catheter wall thickness. Thus, the same mechanical characteristics of catheters having thick catheter walls can be achieved in thin-walled catheters, greatly increasing the possible lumen diameter of the catheters. An even thinner catheter wall can be formed when the reinforcement elements are partially embedded into the wall of the inner tubular member.

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THIN-WALLED AND BRAID-REINFORCED CATHETER

FIELD OF THE INVENTION

The present invention generally relates to intravascular catheters, such as guiding catheters or diagnostic catheters used during percutaneous transluminal coronary angioplasty or microinvasive neuroradiology procedures, and any other catheters that can be introduced into a vasculature.

BACKGROUND OF THE INVENTION

With the advent of technology and surgical techniques, complicated surgical procedures such as transluminal coronary angioplasty and microinvasive neuroradiology have almost become routine for cardiologists and neuro-surgeons. In order to perform these procedures, as well as others such as laser angioplasty, angioscopy or intra-coronary atherectomy, it is necessary to introduce a catheter into an artery of the patient, and subsequently advance the catheter along the course of the artery or the other blood vessels to engage the target tissues. Surgical or diagnostic devices are often introduced within the catheter.

Conventional catheters, however, have a small lumen diameter, thus limiting the size and complexity of the surgical or diagnostic devices that can be introduced. Those catheter bodies are typically made of an inner plastic tube surrounded by and reinforced with a braided stainless steel mesh, and covered with an outer plastic sleeve. As shown in Figure 1, the braided steel mesh comprises helically disposed braid elements in both rotational and counter-rotational winding directions. Examples of such designs are disclosed in U.S. Patents 3,485,234 and 3,585,707. Those catheters are often manufactured by extruding a plastic tubing, and then braiding metal fibers or strands over the plastic tubing to form a braided tube. The plastic tubing must be sufficiently thick to act as a base around which the braid is woven. A second extruded layer of plastic is then applied over the braided tube. Those catheters, however, while providing desirable mechanical characteristics, usually lack desirable wall thickness and lumen diameter.

In order to develop catheters having a larger lumen diameter, catheter walls must be made as thin as possible. However, thin, under reinforced plastic tubing lacks desirable mechanical characteristics such as kink resistance, torsional stiffness and axial stiffness. An improved torsional stiffness permits torque to be better transmitted from a proximal end of the catheter to a distal tip to facilitate advancement of the catheter through the branching blood vessels of the patient. A high kink resistance is also desirable because, once a catheter kinks, it will lose its functionality. In additional, a high axial stiffness is desirable because an axial force is sometimes necessary to push the catheter through long and winding blood vessels to engage the target tissue.

Attempts have been made to optimize these mechanical characteristics. For example, in U.S. Patent 5,057,092 (Webster), a catheter comprising a flexible inner wall surrounded by a braided reinforcing mesh and a flexible plastic outer wall is disclosed. In Webster, the braided reinforcing mesh is interwoven with longitudinal wrap members having a low modulus of elasticity to increase axial stiffness. Such a braided reinforcing mesh can increase torque and or axial stiffness of the catheter. However, a major drawback of such a design is that as more reinforcing elements are involved, catheter wall thickness is necessarily increased, thus reducing the lumen diameter. Furthermore, that mesh design does not enhance the torque performance or pushability of the catheter, since identical braid members are used in both winding directions.

Other examples include U.S. Patents 5,176,660 and 5,019,057, both authored by the applicant herein. In those patents, the applicant discloses a flexible catheter comprising a resilient, tubular layer in telescopic relation with a tubular sheath made of helically disposed strands. In that design, at least one of the helically disposed strands that are comprised of the tubular sheath is flat and has a width that substantially exceeds its height. Furthermore, to increase axial stiffness, the catheter also requires at least one axial reinforcing element. However, although such a braid reinforcement element can enhance torque response and axial stiffness of the catheter, that design does not reduce the wall thickness. Furthermore, it is important to note that the braided structure disclosed in these two patents comprises a plurality of flat and round elements that are wound in both rotational and counter-rotational directions. Because of this disposition of braid elements, such a design does not increase the torque response and pushability of the catheter.

Attempts have also been made to reduce wall thickness of prior art devices by reducing the thickness of the reinforcing elements and increasing their tensile strength. However, decreasing the diameter of the reinforcing elements will also decrease the kink resistance of the catheter.

The relationship between the kink-resistance of a catheter and the diameter of the reinforcing elements can be described in the formula below:

For a round reinforcing element:

$$I_{round} = D^4 \times \pi / 64$$

where D is the diameter of a round reinforcing element, and I_{round} is the kink resistance of the braided reinforcing sheath. And, for a rectangular reinforcing element:

$$I_{rectangular} = A^3 \times B / 12$$

where A and B are the dimensions of a rectangular reinforcing element.

Thus, decreasing the diameter or cross-sectional area of the reinforcing elements will reduce the kink resistance of the catheter. The increased tensile strength cannot compensate for the reduced kink-resistance of these constructions, and therefore, when sharply bent, a catheter constructed with thin reinforcing elements only will become excentric (collapse), reducing its torque performance. The catheter may also kink and lose its functionality.

Other prior art devices attempted to reinforce the catheter with coil-like structures. However, coils tend to have good torque transmission only in one direction (in the winding direction). A rotational force applied opposite to the coil's winding direction tends to open the coil structure, and therefore, the rotational force is not transmitted. Coil structures do not provide sufficient torque transmission capability because the reinforcing members are not interlaced with other reinforcing members. As a result, if a torque is applied to a proximal end of the coil structure, the coil will increase or decrease its nominal diameter depending on the direction of the torque, rather than transmitting the torque to a distal end.

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