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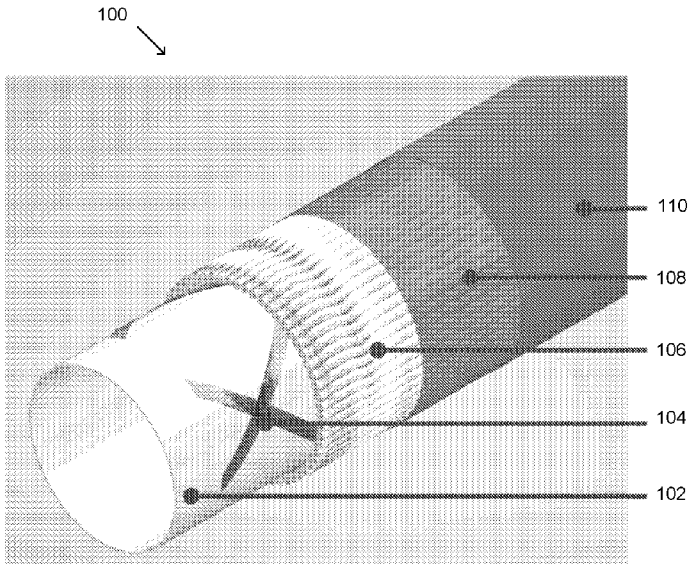


FIG. 1

(57) Abstract: The disclosure provides for a variable stiffness catheter. The catheter may include an inner layer forming an inner lumen, a middle layer surrounding the inner layer, and an outer layer surrounding the middle layer. The middle layer may include an annular lumen and a plurality of strings within the annular lumen, and the plurality of strings may be connected to the inner layer. Applying a vacuum and evacuating the annular lumen of the middle layer alters a frictional force between the inner layer and the outer layer and thereby changes the catheter's flexural rigidity.

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VARIABLE STIFFNESS CATHETER AND METHODS THEREOF

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority under 35 USC § 119(e) to U.S. Patent Application Ser. No. 62/965,525, filed on January 24, 2020, the entire contents of which are hereby incorporated by reference.

FIELD

[0002] The present disclosure is directed to a temporally variable stiffness catheter and methods of use thereof.

BACKGROUND

[0003] Over the last few decades, advancements in visceral peripheral arterial, neurovascular arterial, and venous branch cannulations have evolved with the evolution of available endovascular devices. Currently difficulties exist in highly tortuous and angulated vascular systems. This leads to the need for the use of multiple catheters and sheaths that are advanced into one another to provide staged stiffness and an axial system for advancement of devices to distal target vessels. Current branch vessels of the peripheral vasculature that are challenging to primarily catheterize include but are not limited to the celiac artery, renal artery, superior mesenteric artery/vein, splenic artery/vein, gastroduodenal artery/vein, hepatic artery/vein, tortuous femoral arteries/veins, distal tibial arteries/veins, and branches of the profunda femoris artery/vein. Similarly, catheterization of the neurovascular tree can be quite challenging in terms of accessing the internal and external carotid arteries and their intracranial branches, as well as the vertebral arteries.

[0004] Currently, surgeons use a coaxial system of catheters to offer navigation and support during surgeries. A floppy intermediate guide catheter is introduced surrounding a guidewire to navigate the vasculature. Once the guide catheter is in place, a larger, stiff sheath is pushed coaxially along the outside to provide support for the system to send a medical device to the brain or peripheral vascular tree. This leads to herniation,

which occurs when the stiffer sheath dislodges the floppy guide catheter from its path as it is moved coaxially to cover the guide catheter. Herniation can also occur if no sheath is used for support during intervention - the medical device will cause the guide catheter to herniate into the ascending or descending aortic arch when it passes through the guide catheter. Another problem with current catheters is buckling. Buckling occurs when a medical device kinks the catheter or creates a turn that is too sharp to travel through.

[0005] Accordingly, there remains a need for a variable stiffness catheter to be flexible enough to navigate the vasculature from radial, ulnar, femoral, popliteal, carotid, jugular, and pedal access and stiff enough to provide support for medical devices passed through the catheter.

BRIEF SUMMARY

[0006] The disclosure provides for a variable stiffness catheter. The variable stiffness catheter may include an inner layer forming an inner lumen, a middle layer forming an annular lumen and surrounding the inner layer, the annular lumen being fluidly connected to a vacuum source, and an outer layer surrounding the middle layer. Applying the vacuum and evacuating the annular lumen of the middle layer alters a frictional resistance or adhesion between the inner layer and the outer layer and thereby changes the catheter's flexural rigidity. The middle layer has a low flexural rigidity or shear resistance when the vacuum is not applied and a high flexural rigidity or shear resistance when the vacuum is applied, and the catheter has a variable stiffness along a length of the catheter between a proximal end and a distal end of the catheter. In some aspects, evacuation of the annular lumen of the middle layer changes the flexural rigidity or adhesion of the middle layer. Evacuation of the annular lumen of the middle layer causes an increase in the frictional resistance or adhesion that enables the inner layer, the middle layer, and the outer layer to flex as if they were a single layer, thereby increasing the flexural rigidity of the inner layer, the middle layer, and the outer layer beyond a sum of their flexural rigidities. There may be variable frictional resistance or adhesion between contacting surfaces of the inner layer and the outer layer on the middle layer. The lower flexural rigidity or shear resistance may be from continuous full

microfluidic patency of the annular lumen connecting to the vacuum source and the high shear rigidity of the catheter may be from the friction or adhesion arising when the vacuum source is applied/activated. The catheter may have a variable stiffness on a portion of the length of the catheter. The catheter may have a variable stiffness along a length of the catheter between a proximal end and a distal end of the catheter. The catheter may have a variable stiffness along a portion or more than one portion of the length of the catheter. The location of the portion of the catheter having variable stiffness may be optimized for a specific surgical procedure, including the treatment of a stroke, physiological monitoring, thrombectomy, atherectomy, stenting, ballooning, embolization, ablation, implantation of devices, diagnostic evaluation, PE, arterial/venous thrombus, aneurysm treatment, treating dam-aged arteries and veins, neurologic disorders to treat stroke, Parkinson's, control-ling hemorrhage, and/or dialysis access treatment. The middle layer may include a plurality of strings within the annular lumen. The plurality of strings may be in a spiral formation or linear formation along the length of the inner layer. The plurality of strings may be placed, distributed, or oriented asymmetrically. The catheter may have a variable stiffness from the proximal end to the distal end of the catheter. Additionally, the variable stiffness aspect may be asymmetric (e.g. on side of the catheter) on a portion of a catheter to enable preferential bending or straightening when manipulated. The catheter may have a variable stiffness that is asymmetric or helical along of one portion or more than one portion of the length of the catheter. The structuring may be so as to induce bending of the catheter that augments anchoring, curvature, or torsion of the catheter over a defined region. The anchoring, curvature, or torsion of the catheter may be actuated by release of the vacuum in the middle layer.

[0007] In another aspect, the variable stiffness catheter may include an inner layer forming an inner lumen, a middle layer surrounding the inner layer, the middle layer having an annular lumen and a plurality of strings within the annular lumen, and an outer layer surrounding the middle layer. The variable stiffness catheter may be operable to have a low stiffness configuration and a high stiffness configuration upon actuation of a vacuum to the middle layer. The catheter may have a variable stiffness on a portion of the catheter. The location of the portion of the catheter having variable

stiffness is optimized for a specific surgical procedure, including the treatment of a stroke, physiological monitoring, thrombectomy, atherectomy, stenting, ballooning, embolization, ablation, implantation of devices, diagnostic evaluation, PE, arterial/venous thrombus, aneurysm treatment, treating dam-aged arteries and veins, neurologic disorders to treat stroke, Parkinson's, control-ling hemorrhage, and/or dialysis access treatment. The inner layer may be relatively non-compliant and the outer layer may be relatively compliant. The plurality of strings are in a spiral formation or linear formation along the length of the inner layer. The plurality of strings may be placed, distributed, or oriented asymmetrically. In some aspects, the inner layer may further comprise a braid on its outer surface. In additional aspects, the outer layer may include a coating. In further aspects, the variable stiffness catheter may further comprise a vacuum source fluidly connected to the annular lumen of the middle layer. The variable stiffness catheter is in the low stiffness configuration when the vacuum source is not actuated and is in the high stiffness configuration when the vacuum source is actuated. The inner layer, the plurality of strings, and the outer layer may be compressed together in the high stiffness configuration. The inner lumen is operable to receive a neurovascular, body vascular, or pulmonary vascular medical device. The variable stiffness catheter may be operable to reduce herniation and buckling in the vasculature when inserted radially.

[0008] The disclosure also provides methods of providing transradial interventions. The method may include inserting a variable stiffness catheter through a radial, ulnar, femoral, popliteal, carotid, jugular, or pedal artery of a patient and navigating the variable stiffness catheter through the patient's vasculature when the variable stiffness catheter has a low flexural rigidity or shear resistance. The method may further include fluidly connecting a vacuum source to the annular lumen of the variable stiffness catheter and applying the vacuum to the annular lumen to compress together the inner layer, the plurality of strings, and the outer layer, creating high flexural rigidity or shear resistance. In some aspects, the method may further include inserting a medical device through the inner lumen of the variable stiffness catheter. The medical device may be a neurovascular, body vascular, or pulmonary vascular medical device. The inner layer of the variable stiffness catheter may be relatively non-compliant and the outer layer of the

variable stiffness catheter may be relatively compliant. The inner layer of the variable stiffness catheter may further comprise a braid on its outer surface and/or a casing surrounding the outer layer. In some aspects, the variable stiffness catheter may be operable to reduce herniation and buckling in the vasculature when inserted radially.

[0009] Additional embodiments and features are set forth in part in the description that follows, and will become apparent to those skilled in the art upon examination of the specification or may be learned by the practice of the disclosed subject matter. A further understanding of the nature and advantages of the disclosure may be realized by reference to the remaining portions of the specification and the drawings, which forms a part of this disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The description will be more fully understood with reference to the following figures and data graphs, which are presented as various embodiments of the disclosure and should not be construed as a complete recitation of the scope of the disclosure, wherein:

[0011] **FIG. 1** is an illustration of the variable stiffness catheter, in one example.

[0012] **FIG. 2** shows a portion of a cross-section of the variable stiffness catheter, in one example.

[0013] **FIG. 3A** shows a cross-section of the variable stiffness catheter in a low stiffness configuration, in one example.

[0014] **FIG. 3B** shows a cross-section of the variable stiffness catheter in a high stiffness configuration, in one example.

DETAILED DESCRIPTION

[0015] The disclosure may be understood by reference to the following detailed description, taken in conjunction with the drawings as described below. It is noted that, for purposes of illustrative clarity, certain elements in various drawings may not be drawn to scale. Several variations of the device are presented herein. It should be understood that various components, parts, and features of the different variations may be combined together and/or interchanged with one another, all of which are within the

scope of the present application, even though not all variations and particular variations are shown in the drawings. It should also be understood that the mixing and matching of features, elements, and/or functions between various variations is expressly contemplated herein so that one of ordinary skill in the art would appreciate from this disclosure that the features, elements, and/or functions of one variation may be incorporated into another variation as appropriate, unless described otherwise.

[0016] Several definitions that apply throughout this disclosure will now be presented. As used herein, "about" refers to numeric values, including whole numbers, fractions, percentages, etc., whether or not explicitly indicated. The term "about" generally refers to a range of numerical values, for instance, ± 0.5-1%, ± 1-5% or ± 5-10% of the recited value, that one would consider equivalent to the recited value, for example, having the same function or result.

[0017] The term "comprising" means "including, but not necessarily limited to"; it specifically indicates open-ended inclusion or membership in a so-described combination, group, series and the like. The terms "comprising" and "including" as used herein are inclusive and/or open-ended and do not exclude additional, unrecited elements or method processes. The term "consisting essentially of" is more limiting than "comprising" but not as restrictive as "consisting of." Specifically, the term "consisting essentially of" limits membership to the specified materials or steps and those that do not materially affect the essential characteristics of the claimed invention.

[0018] Endovascular catheters must navigate to the target site within a patient, and once at the target site, the catheter (or catheter system) must provide enough support for medical devices such as stents, balloons, thrombectomy devices, intrasaccular aneurysm occlusion devices, coils, and hemodynamic monitoring devices to reach the target site. If an intervention is performed using a compliant catheter system, the catheter(s) are likely incapable of providing adequate support. Stiff, supportive catheters are thus necessary for performing intervention, and they are especially important for delicate, precise surgeries such as those performed by neurovascular surgeons, vascular surgeons, cardiologists, interventional radiologists, and other interventionalists. That being said, increasing a catheter's stiffness, or stability, decreases its ability to successfully navigate through the arterial and venous vasculature.

[0019] When a sufficient external force acts on compliant catheters, they may deform by way of kinking, buckling, or herniating. Stiff catheters provide stable platforms to advance medical devices through their lumen, but are difficult to steer due to their increased rigidity.

[0020] Disclosed herein is a catheter with temporally variable stiffness. The variable stiffness catheter has a low stiffness configuration and a high stiffness configuration to prevent herniation and buckling in the vasculature but also provide structure for advancing medical devices. Vacuum actuation may be used to alter the inertial properties of the catheter and maximize the change in its flexural rigidity or shear resistance, thus providing variable stiffness between a low stiffness configuration (e.g. a floppy state or non-actuated state) and a high stiffness configuration (e.g. a stiff state or actuated state) on demand. The variable stiffness may allow for the catheter to be used through radial access by being floppy/flexible enough to navigate the vasculature and stiff enough to provide support for medical devices passed through the catheter. In various embodiments, the catheter may be used in transradial neurovascular, body vascular, or pulmonary vascular interventions. For example, the catheter may begin in its low stiffness configuration to navigate the vasculature and reach the brain. Then, the catheter may be actuated by a surgeon with an indeflator, or other negative pressure device or vacuum device found in standard operating suites, to reach the desired change in stiffness to support the medical device. The catheter may be used for endovascular applications, neurovascular applications and non-neurovascular applications. In some non-limiting examples, the catheter may be used for cerebrovascular, pulmonary artery, peripheral vascular applications, or used in other arterial and venous structures that range from 1 mm to 25 mm in diameter.

[0021] In an embodiment, the variable stiffness catheter **100** may include a supported inner layer **102**, a compliant outer layer **108**, and a middle layer **106** of "strings" **105** disposed in an annular lumen **107** between the inner and outer layers, as seen in **FIG. 1**. In some examples, the catheter may further include a coating **110** surrounding the outer layer **108**. The catheter **100** may have a low stiffness configuration and a high stiffness configuration that may be changed based on actuation of a vacuum on the middle layer.

[0022] For example, the variable stiffness catheter **100** includes an inner layer **102** forming an inner lumen, a middle layer **106** surrounding the inner layer **102**, and an outer layer **108** surrounding the middle layer **106**. The middle layer **102** may form an annular lumen. The annular lumen of the middle layer **106** may be fluidly connected to a vacuum source such that the middle layer has a low flexural rigidity or shear resistance when the vacuum is not actuated and a high flexural rigidity or shear resistance when the vacuum is actuated. There may be variable frictional resistance or adhesion between contacting surfaces of the inner layer and the outer layer on the middle layer. Thus, applying the vacuum and evacuating the annular lumen of the middle layer alters the frictional resistance or adhesion between the inner layer and the outer layer and thereby changes the catheter's flexural rigidity. The middle layer has a low flexural rigidity or shear resistance when the vacuum is not applied and a high flexural rigidity or shear resistance when the vacuum is applied. The lower flexural rigidity or shear resistance may be from continuous full microfluidic patency of the region connecting to the vacuum source in the catheter and the high flexural rigidity or shear resistance may be from the friction or adhesion arising when the vacuum source is applied or activated. These aspects may allow the catheter to have a variable stiffness along a length of the catheter between a proximal end and a distal end of the catheter. In some examples, the catheter may have variable stiffness along a portion or segment between its proximal and distal ends, and in other examples, the catheter may have variable stiffness along its entire length from its proximal to distal end.

[0023] The inner layer **102** may provide the initial structure of the catheter by forming an inner lumen with a diameter of about 1.5 mm to about 2 mm. In at least one example, the inner lumen may have a diameter of about 1.78 mm. In additional examples the inner layer **102** may form an inner lumen with a diameter of about 0.70 mm to about 0.72 mm. The inner lumen may be operable to receive a neurovascular medical device, including but not limited to embolic agents, coils, balloons, stents, medications, catheters, neuromodulation devices, pressure monitoring, and/or catheter ablation devices. The catheter and/or neurovascular device may be used for the treatment of a stroke, physiological monitoring, thrombectomy, atherectomy, stenting, ballooning, embolization, ablation, implantation of devices, diagnostic evaluation, PE,

arterial/venous thrombus, aneurysm treatment, treating damaged arteries and veins, neurologic disorders to treat stroke, Parkinson's, controlling hemorrhage, and/or dialysis access treatment.

[0024] The inner layer **102** may reduce friction and support the strings **105** from the middle layer **106**. In some examples, the inner layer **102** may be non-compliant or relatively non-compliant. The inner layer may be made of materials including but not limited to nylon, polyether block amide (e.g. Pebax®), PTFE, PU, and other plastic polymers. In some examples, the inner layer **102** is thin and non-deforming when a vacuum is applied to the annular lumen **107**. However, as described below, in certain embodiments, the inner layer may be collapsible. Accordingly, the inner layer **102** may also be made from a material including but not limited to latex, polyether block amide (e.g. Pebax®), and/or silicone. The inner layer **102** may have a thickness of about 0.02 mm to about 0.05 mm. In at least one example, the inner layer **102** has a thickness of about 0.036 mm. The inner layer **102** may be supported, for example, with a braid **104** on the outer diameter of the inner layer **106**. The braid **104** may be a thin layer that supports the inner layer **102** against buckling. In some examples, the braid **104** may be arranged in a crossing pattern to aid in the support of the inner layer **102**, as seen in **FIG. 1**. The braid **104** may have a thickness of about 0.01 mm to about 0.04 mm. In at least one example, the braid **104** has a thickness of about 0.025 mm. The braid **104** may be made of nitinol in some examples.

[0025] The middle layer **106** may include an annular lumen **107** with an array of thin tubes or strings **105** that surround the inner layer **102**. The strings **105** may add stiffness and maximize the thickness of the catheter **100** when the catheter is in an actuated state. The strings **105** may extend the longitudinally along the length of the annular lumen **107**, and may attach to the proximal and distal ends of the inner layer **102**. In some examples, the strings **105** may be in a spiral configuration along the length of the annular lumen **107**. In at least one example, the strings **105** may be placed side by side in a linear formation to encase the inner layer **102** with a single sheet of strings **105**. In other examples, the strings **105** may be placed, distributed, or oriented asymmetrically. The middle layer **106** may include between about 40 strings and about 170 strings, depending on the diameter of the strings. In various examples, the

maximum number of strings may be up to 47 strings, up to 71 strings, up to 80 strings, up to 88 strings, up to 150 strings, or up to 163 strings. In at least one example, the middle layer **106** may include about 60 strings. The distance between each string **105** may range from about 0 mm to about 0.02 mm. In some examples, the strings **105** may be nitinol wires or synthetic threads. Non-limiting examples of threads include metallic threads, monofilament threads, and fibers. The strings **105** may have a radius of about 0.05 mm to about 0.2 mm. In various examples, the strings **105** may have a radius of about 0.056 mm, 0.083 mm, 0.108 mm, or 0.167. In at least one example, the strings **105** have a radius of about 0.0825 mm. The density and diameter of the strings **105** may affect the rigidity of the catheter **100**.

[0026] The outer layer **108** may be a compliant or relatively complaint layer that surrounds the middle layer **106** and inner layer **102** of the catheter **100**. In some examples, the outer layer **108** is thin and tear-resistant, such that it can withstand the vacuum/suction applied to the middle layer. When the catheter **100** is actuated, air within the annular lumen **107** is evacuated, and the outer layer **108** collapses down to compress the inner layer **102** and strings **105** as one unified body. Alternatively, the collapsible layer may comprise the inner (as opposed to the outer) layer of the catheter. Accordingly, in an embodiment, when the catheter **100** is actuated, air within the annular lumen **107** is evacuated, and the inner layer **102** collapses outward to compress the strings **105** and the outer layer **108** as one unified body. In this alternative embodiment, the outer layer **108** forms a non-compliant structure. The activated state is mathematically stiffer than the original state. The material used to form the outer layer **108** (and the inner layer **102** described above) will depend on whether or not the layer is intended to be collapsible. In some examples, the outer layer **108** may be made of a material including but not limited to latex, polyether block amide (e.g. Pebax®), and/or silicone. Alternatively, if the outer layer is non-compliant, it may be made from materials such as nylon, polyether block amide (e.g. Pebax®), PTFE, PU, and other plastic polymers. In some examples, the outer layer **108** is thin and non-deforming when a vacuum is applied to the annular lumen **107.** In various embodiments, the outer layer **108** is opaque. The outer layer **108** may have a thickness of about 0.01 mm to about 0.03 mm. In at least one example, the outer layer **108** has a thickness of about 0.0175

mm. The outer layer **108** may be further surrounded by a coating **110** in some examples. The coating may be a hydrophilic coating. The coating **110** may have a thickness of about 0.01 mm to about 0.03 mm. In at least one example, the coating **110** has a thickness of about 0.0175 mm.

[0027] **FIG. 2** shows a cross section of the layers of the catheter **100**, in one example. The catheter **100** may have an inner diameter ranging from about 1.5 mm to about 7 mm. In various examples, the catheter **100** has an inner diameter of about 1.778 mm, 2.235 mm, 5.333 mm, 5.667 mm, 6.0 mm, 6.333 mm, or 6.667 mm. In at least one example, the catheter **100** has an inner diameter of about 1.778 mm. Alternatively, the catheter **100** may have an inner diameter ranging from about 0.70 mm to 0.72 mm. The catheter **100** may have an outer diameter ranging from about 1.6 mm to about 8 mm in the actuated state. In various examples, the catheter **100** has an outer diameter of about 2.0 mm, 2.667 mm, 6.0 mm, 6.667 mm, or 7.333 mm. In at least one example, the catheter **100** has an outer diameter of about 2.1 mm. The catheter **100** ranges in size from 5 French to 26 French. In various examples, the catheter **100** may have a size of about 5 French, 6 French, 7 French, 8 French, 9 French, 10 French, 11 French, 12 French, 13 French, 14 French, 15 French, 16 French, 17 French, 18 French, 19 French, 20 French, 21 French, 22 French, 23 French, 24 French, 25 French, or 26 French. For example, the catheter **100** may have a size of 6 French or 20 French. When the layers of the catheter **100** are compressed, the catheter **100** may have a thickness of about 0.1 mm to about 0.2 mm. In at least one example, the catheter **100** has a thickness of about 0.127 mm to 0.161 mm. The catheter **100** thickness may include the thickness of the inner layer **102**, braid **104**, strings **105**, outer layer **108**, and/or coating **110**, as seen in **FIG. 2**.

[0028] The catheter may include a connector at its proximal end for connecting a vacuum source. The vacuum source may be fluidly connected to the annular lumen of the middle layer. In some examples, the vacuum source may be an indeflator or a syringe. The catheter may include an atraumatic distal end to prevent luminal dissection.

[0029] Evacuation of the annular lumen **107** of the middle layer changes the flexural rigidity or shear resistance of the middle layer. This may enable the catheter **100** to

assume two different stiffness configurations: a low stiffness configuration (vacuum not applied/actuated) and a high stiffness configuration (vacuum applied/actuated). **FIG. 3A** shows an example cross section of the catheter in the low stiffness or low flexural rigidity configuration. In the low stiffness or low flexural rigidity configuration, the annular lumen **107** defined between the inner and outer layers is maintained at approximately atmospheric pressure, enabling the adjacent surfaces of the inner and outer layers, as well as the plurality of strings, to slide freely relative to one another, such that each of these three elements functions essentially independently with respect to structural stiffness of the catheter. **FIG. 3B** shows an example cross section of the catheter in the high stiffness or high flexural rigidity configuration. In the high stiffness or high flexural rigidity configuration, the annular lumen is evacuated under negative (vacuum) pressure, causing the collapse of the annular lumen and accompanying close contact of the adjacent surfaces of the inner and outer layers and strings. In the high stiffness or high flexural rigidity configuration, the inner and outer layers and strings function essentially as a single composite structure with significantly enhanced stiffness. For example, evacuation of the annular lumen of the middle layer causes an increase in the frictional resistance or adhesion that enables the inner layer, the middle layer, and the outer layer to flex as if they were a single layer, thereby increasing the flexural rigidity or shear resistance of the inner layer, the middle layer, and the outer layer beyond a sum of their flexural rigidities. The transition between the low and high stiffness configurations is controlled by the application and removal of a vacuum source from the annular lumen.

[0030] The catheter may have a flexural rigidity of about 1.4 Nm^2 to about 6 Nm^2 when in the low stiffness configuration. For example, the catheter may have a flexural rigidity of about 1.4 Nm^2 to about 2 Nm^2, about 2 Nm^2 to about 4 Nm^2, and about 4 Nm^2 to about 6 Nm^2 when in the low stiffness configuration. The catheter may have a flexural rigidity of about 6 Nm^2 to about 15 Nm^2 when in the high stiffness configuration. For example, the catheter may have a flexural rigidity of about 6 Nm^2 to about 8 Nm^2, about 8 Nm^2 to about 10 Nm^2, and about 10 Nm^2 to about 15 Nm^2 when in the high stiffness configuration.

[0031] The catheter **100** may have a length from about 10 cm to about 100 cm, from

about 10 cm to about 90 cm, from about 10 cm to about 80 cm, from about 10 cm to about 70 cm, from about 10 cm to about 60 cm, from about 10 cm to about 50 cm, from about 10 cm to about 40 cm, from about 10 cm to about 30 cm, or from about 10 cm to about 20 cm. The catheter **100** may have a length from about 20 cm to about 100 cm, from about 20 cm to about 90 cm, from about 20 cm to about 80 cm, from about 20 cm to about 70 cm, from about 20 cm to about 60 cm, from about 20 cm to about 50 cm, from about 20 cm to about 40 cm, or from about 20 cm to about 30 cm. The catheter **100** may have a length from about 30 cm to about 100 cm, from about 30 cm to about 90 cm, from about 30 cm to about 80 cm, from about 30 cm to about 70 cm, from about 30 cm to about 60 cm, from about 30 cm to about 50 cm, from about 30 cm to about 40 cm. The catheter **100** can have a length of from about 40 cm to about 100 cm, from about 40 cm to about 90 cm, from about 40 cm to about 80 cm, from about 40 cm to about 70 cm, from about 40 cm to about 60 cm, or from about 40 cm to about 50 cm. The catheter **100** can have a length of from about 50 cm to about 100 cm, from about 50 cm to about 90 cm, from about 50 cm to about 80 cm, from about 50 cm to about 70 cm, from about 50 cm to about 60 cm. The catheter **100** can have a length of from about 60 cm to about 100 cm, from about 60 cm to about 90 cm, from about 60 cm to about 80 cm, or from about 60 cm to about 70 cm. The catheter **100** can have a length of from about 70 cm to about 100 cm, from about 70 cm to about 90 cm, or from about 70 cm to about 80 cm. Alternatively, the catheter **100** can have a length of from about 80 cm to about 100 cm or from about 80 cm to about 90 cm. Alternatively, the catheter **100** can have a length of from about 90 cm to about 100 cm. For example, the catheter can have a length of about 30, 60, or 100 cm.

[0032] In some embodiments, the catheter may have variable stiffness capabilities along a length of the catheter between its proximal end and its distal end. For example, there may be variable frictional resistance or adhesion between contacting surfaces of the inner layer and the outer layer on the middle layer. For example, only a portion or segment or more than one portion of the length of the catheter may have the variable stiffness capabilities, and the remaining portions of the catheter may remain compliant or stiff, depending on the use and/or size of the catheter. In some examples, the location of the portion or segment of the catheter having variable stiffness is optimized

for a specific surgical procedure, including but not limited to the treatment of a stroke, physiological monitoring, thrombectomy, atherectomy, stenting, ballooning, embolization, ablation, implantation of devices, diagnostic evaluation, PE, arterial/venous thrombus, aneurysm treatment, treating dam-aged arteries and veins, neurologic disorders to treat stroke, Parkinson's, control-ling hemorrhage, and/or dialysis access treatment. This segment may be at the distal catheter, the mid catheter segment, or the proximal segment of the catheter. There may also be more than one segment of the catheter with rigidity actuation.

[0033] In another embodiment, the catheter may have a proximal end with variable stiffness capabilities, while the distal end may be compliant. In some examples, the distal most 5 to 10 cm of the catheter may be compliant without variable stiffness capabilities. In this example, the distal end of the catheter is more flexible than the proximal end, but may still overcome the problems of herniation and buckling. In other embodiments, the length of the catheter from its proximal end to its distal end may have variable stiffness. In still other embodiments, the middle third of the catheter may have variable stiffness.

[0034] In an embodiment, the catheter may have pre-formed segments tailored for known areas or arterial angulation or tortuosity. In some embodiments, the catheter may have pre-formed segments to accommodate the aortic arch, variants of the aortic arch and origins of the vertebral and carotid arteries, right atrium, abdominal aorta, iliofemoral artery/vein segments, and upper and lower extremity arterial/venous anatomy. Flexural rigidity actuation may serve to impact the rigidity of the pre-formed segment of the catheter, or segments flanking the pre-formed segment of the catheter.

[0035] In additional embodiments, the variable stiffness may be asymmetric or helical along of one portion or more than one portion of the length of the catheter. For example, the variable stiffness may be asymmetric (e.g. on a side of the catheter) on a portion of a catheter to enable preferential bending or straightening when manipulated. The structure of the asymmetric variable stiffness be operable to induce bending of the catheter that augments anchoring, curvature, or torsion of the catheter over a defined region. The anchoring, curvature, or torsion may then be actuated by release of the vacuum in the middle layer. The asymmetric variable stiffness on a side of the catheter

may allow for more efficient navigation or anchoring of a catheter for a predefined anatomic configuration once the catheter has arrived at that location. The asymmetric stiffness may be range from 1 to 99% of the circumference of the catheter. In at least one example, the asymmetric stiffness may occupy 50% of the circumference of catheter.

Examples

Example 1:

[0036] To quantify the change in stiffness, beam theory, which treats the catheter body as a beam subject to an applied moment (rotational force) was used. From the Euler-Bernoulli equation describing beam theory, the flexural rigidity (EI terms) mathematically describes the stiffness of a material, as seen in Eqn. 1

$$M = {}^{EI}/_{\rho} \qquad \text{Eqn. 1}$$

where M is the moment, E is the elastic modulus, I is the area moment of inertia for the beam cross section, and ρ is the radius of curvature.

[0037] The catheter controls the flexural rigidity by changing the moment of inertia (I) – the geometric design of the cross section – and optimizing the elastic modulus (E) – the inherent property of a material that describes its resistance to deformation. The catheter has two distinct states that are characterized by their moments of inertia in the low stiffness configuration and the high stiffness configuration. In the low stiffness configuration, before the vacuum is actuated, the inner layer, middle layer, and outer layer act independently, so the catheter has a low moment of inertia. In the high stiffness configuration, once the vacuum is actuated, all three layers act as one single layer, as if they were glued together. By pairing this change in inertial properties with the most effective materials, the flexural rigidity or shear resistance can be optimized to change by a factor of eight.

[0038] Using the methods and theory described above, the flexural rigidity of two different prototypes of the catheters described herein were determined for a 9 Fr alpha prototype and a 6 Fr alpha prototype.

[0039] Having described several embodiments, it will be recognized by those skilled in the art that various modifications, alternative constructions, and equivalents may be

used without departing from the spirit of the invention. Additionally, a number of well-known processes and elements have not been described in order to avoid unnecessarily obscuring the present invention. Accordingly, the above description should not be taken as limiting the scope of the invention.

[0040] Those skilled in the art will appreciate that the presently disclosed embodiments teach by way of example and not by limitation. Therefore, the matter contained in the above description or shown in the accompanying drawings should be interpreted as illustrative and not in a limiting sense. The following claims are intended to cover all generic and specific features described herein, as well as all statements of the scope of the present method and system, which, as a matter of language, might be said to fall therebetween.

CLAIMS

What is claimed is:

1. A variable stiffness catheter comprising:

an inner layer forming an inner lumen;

a middle layer forming an annular lumen and surrounding the inner layer, the annular lumen of the middle layer being fluidly connected to a vacuum source; and

an outer layer surrounding the middle layer,

wherein applying the vacuum and evacuating the annular lumen of the middle layer alters a frictional resistance or adhesion between the inner layer and the outer layer and thereby changes the catheter's flexural rigidity.

2. The variable stiffness catheter of claim 1, wherein the middle layer has a low flexural rigidity or shear resistance when the vacuum is not applied and a high flexural rigidity or shear resistance when the vacuum is applied.

3. The variable stiffness catheter of claim 2, wherein the low flexural rigidity or shear resistance of the catheter is from continuous full microfluidic patency of the annular lumen connecting to the vacuum source and the high flexural rigidity or shear resistance of the catheter is from the friction or adhesion arising when the vacuum source is applied.

4. The variable stiffness catheter of claim 1, wherein evacuation of the annular lumen of the middle layer changes the flexural rigidity or adhesion of the middle layer.

5. The variable stiffness catheter of claim 4, wherein evacuation of the annular lumen of the middle layer causes an increase in the frictional resistance or adhesion that enables the inner layer, the middle layer, and the outer layer to flex

as if they were a single layer, thereby increasing the flexural rigidity of the inner layer, the middle layer, and the outer layer beyond a sum of their flexural rigidities.

6. The variable stiffness catheter of claim 1, wherein there is variable frictional resistance or adhesion between contacting surfaces of the inner layer and the outer layer on the middle layer.

7. The variable stiffness catheter of claim 1, wherein the catheter has a variable stiffness along a length of the catheter between a proximal end and a distal end of the catheter.

8. The variable stiffness catheter of claim 7, wherein the catheter has a variable stiffness along a portion or more than one portion of the length of the catheter.

9. The variable stiffness catheter of claim 8, wherein a location of the portion of the catheter having variable stiffness is optimized for a specific surgical procedure.

10. The variable stiffness catheter of claim 7, wherein the variable stiffness is along an asymmetric side of one portion or more than one portion of the length of the catheter.

11. The variable stiffness catheter of claim 1, wherein a plurality of strings within the annular lumen.

12. The variable stiffness catheter of claim 11, wherein the plurality of strings are in a spiral formation or linear formation along a length of the inner layer.

13. The variable stiffness catheter of claim 1, wherein the inner layer is relatively non-compliant and the outer layer catheter is relatively compliant.

14. The variable stiffness catheter of claim 1, wherein the inner layer further comprises a braid on its outer surface.

15. The variable stiffness catheter of claim 1, further comprising a casing surrounding the outer layer.

16. A method of providing transradial interventions, the method comprising:

inserting the variable stiffness catheter of claim 1 through a radial artery of a patient; and

navigating the variable stiffness catheter through the patient's vasculature, wherein the variable stiffness catheter has a low flexural rigidity.

17. The method of claim 16, further comprising:

fluidly connecting a vacuum source to the annular lumen; and

applying the vacuum to the annular lumen to compress together the inner layer, and the outer layer, creating high flexural rigidity.

18. The method of claim 17, further comprising:

inserting a medical device through the inner lumen of the variable stiffness catheter.

19. The method of claim 18, wherein the medical device is a neurovascular, body vascular, or pulmonary vascular medical device.

20. The method of claim 16, wherein the variable stiffness catheter is operable to reduce herniation and buckling in the vasculature when inserted radially.

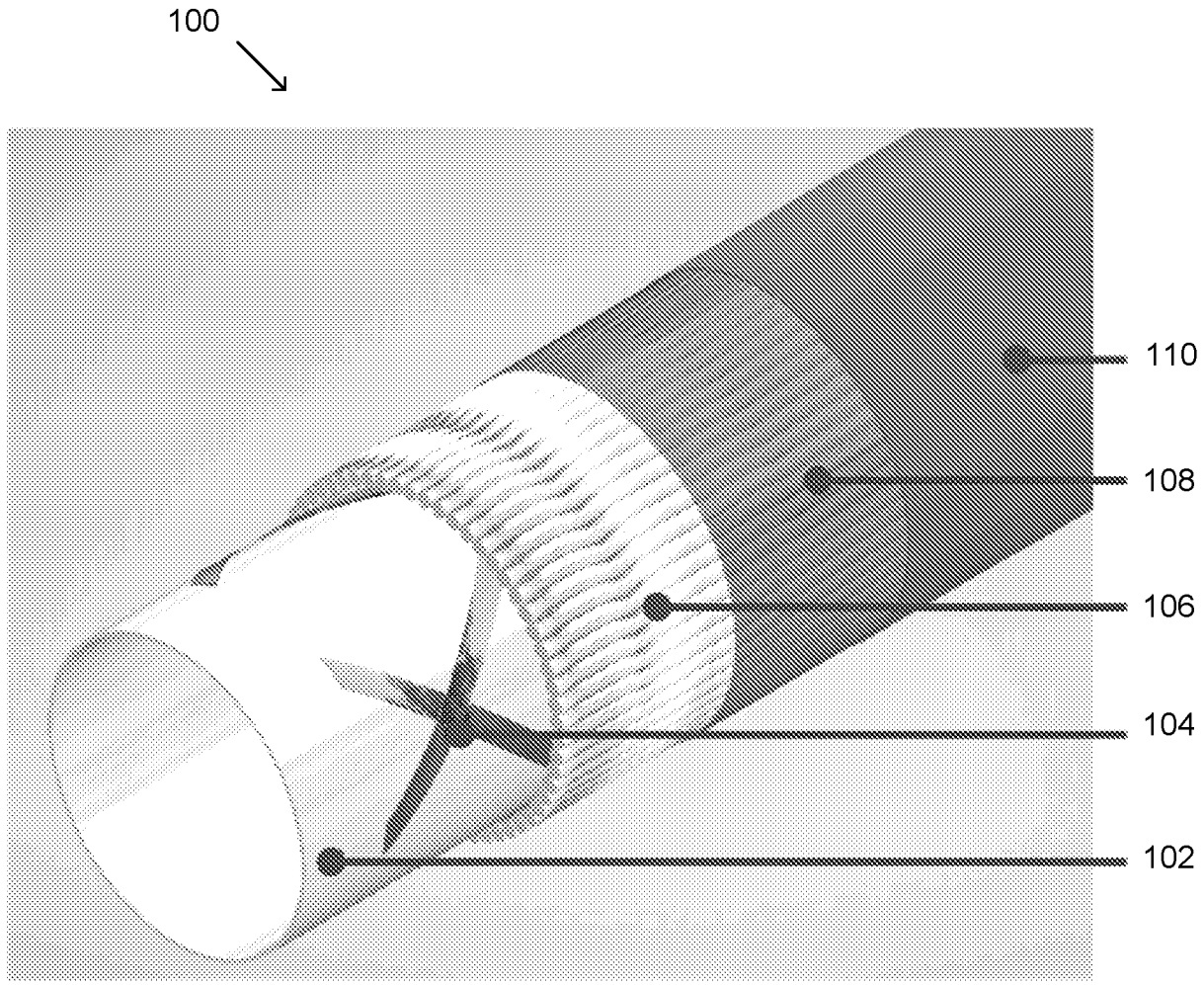


FIG. 1

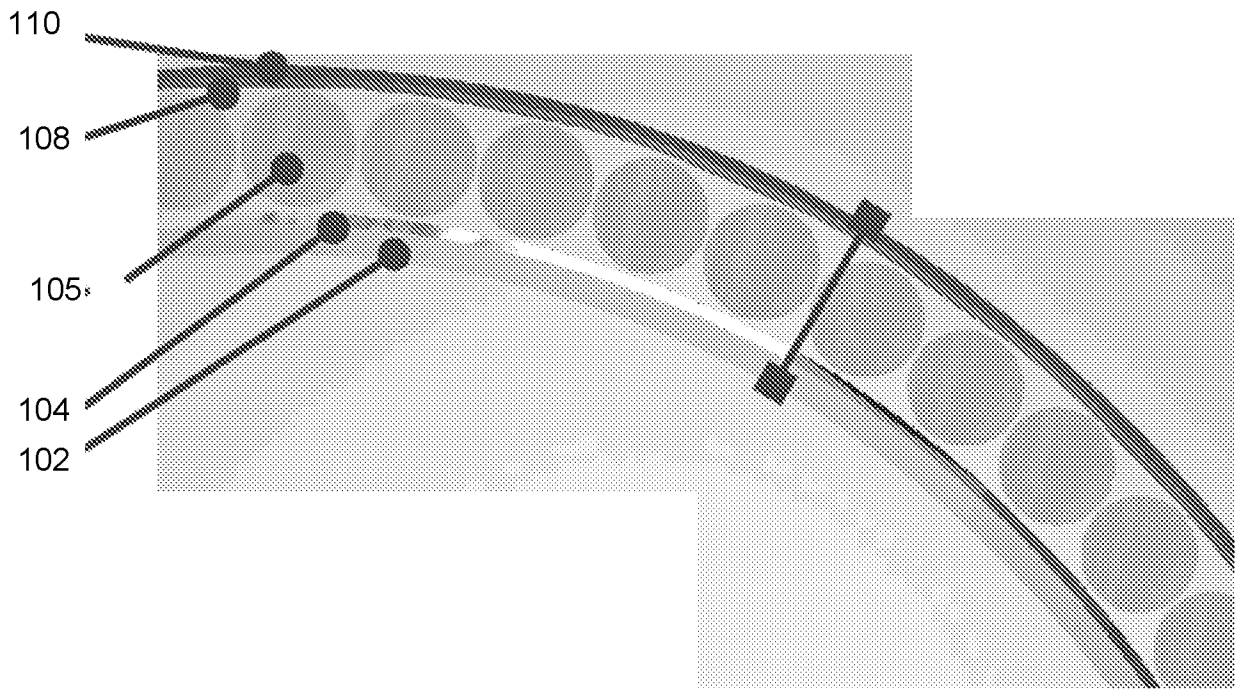


FIG. 2

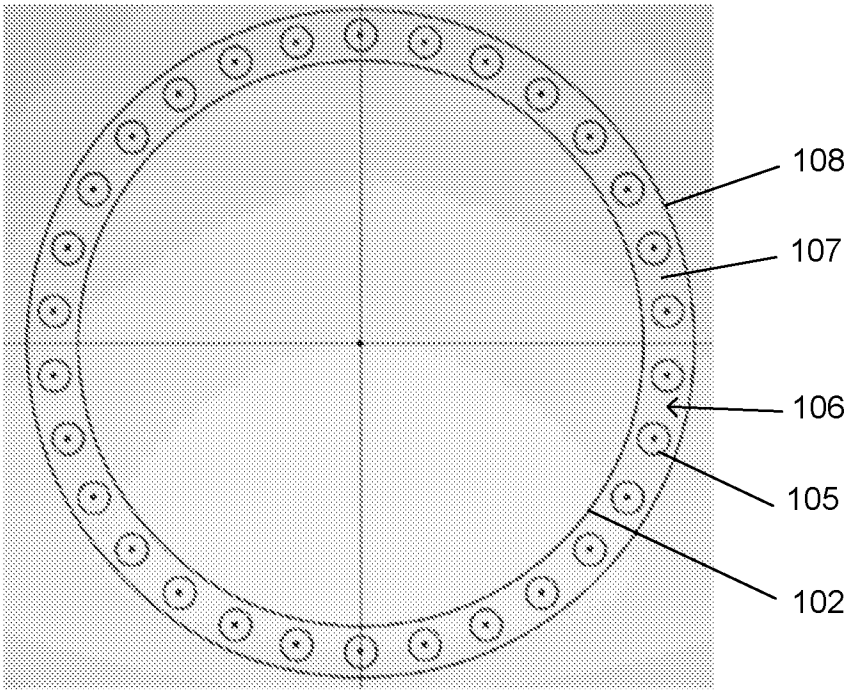


FIG. 3A

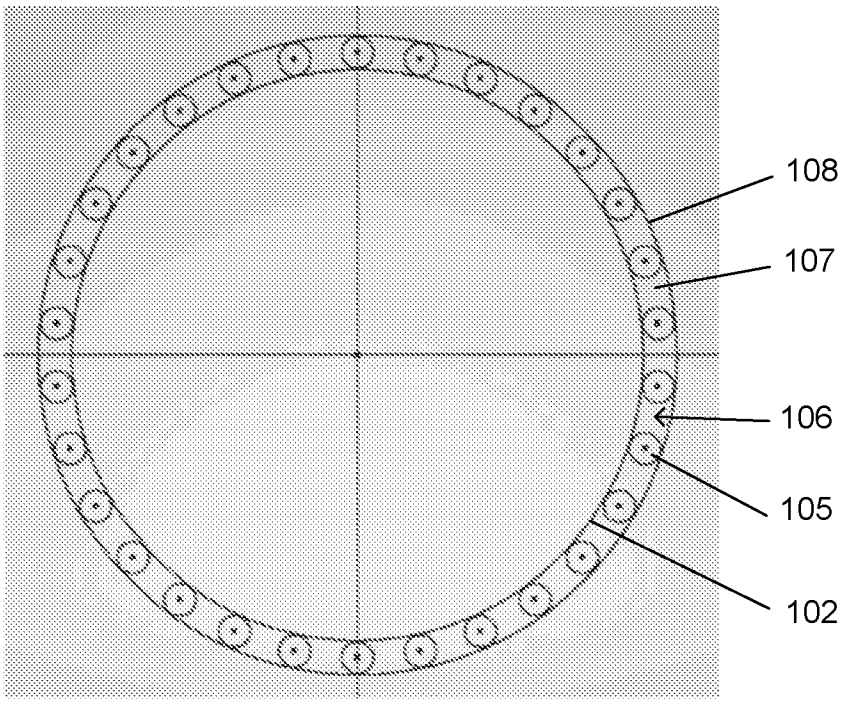


FIG. 3B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/14895

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 25/00 (2021.01)
CPC - A61M 25/0053

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2015/0216589 A1 (Medtronic CryoCath LP) 06 August 2015 (06.08.2015), entire document, especially Fig 1-3D, 7-10; para [0029]-[0039], [0043]-[0044]	1-10, 16-20
X	WO2020/018934 A1 (NEP TUNE MEDICAL INC.) 23 January 2020 (23.01.2020), entire document, especially Fig 44A-44B; para [0264]	1, 11-13, 15
Y		14
Y	US 6,217,566 B1 (Ju et al.) 17 April 2001 (17.04.2001), entire document, especially Fig 2-3; col 12, ln 38-61	14
A	US 2013/0245551 A1 (O'Day) 19 September 2013 (19.09.2013), entire document	1-20
A	US 2013/0237950 A1 (ABBOTT CARDIOVASCULAR SYSTEMS INC.) 12 September 2013 (12.09.2013), entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 March 2021 (25.03.2021)	APR 27 2021
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300