HIGH TORQUE GUIDEWIRE DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to United States Patent Application No. 17/382,271 filed July 21, 2021 entitled "High Torque Guidewire Device" which is a continuation-in-part of United States Patent Application No. 17/154,777, filed January 21, 2021 entitled "Guidewire having Enlarged, Micro-Fabricated Distal Section". This application also claims priority to and the benefit of United States Provisional Patent Application Serial 63/180,061, filed April 26, 2021 entitled "High Torque Guidewire Device". The entire contents of each of the above applications is incorporated by reference in their entireties

BACKGROUND

[0002] Guidewire devices are often used to lead or guide catheters or other interventional devices to a targeted anatomical location within a patient's body. Typically, guidewires are passed into and through a patient's vasculature in order to reach the target location, which may be at or near the patient's heart or brain, for example. Radiographic imaging is typically utilized to assist in navigating a guidewire to the targeted location. In many instances, a guidewire is placed within the body during the interventional procedure where it can be used to guide multiple catheters or other interventional devices to the targeted anatomical location.

[0003] Guidewires are available with various outer diameter sizes. Widely utilized sizes include 0.010, 0.014, 0.016, 0.018, 0.024, 0.035, and 0.038 inches, for example, though they may also be smaller or larger in diameter. Because torque transmission is a function of diameter, larger diameter guidewires typically have greater torque transmission (the ability to effectively transfer torque from proximal portions of the wire to more distal portions of the wire or "torqueability"). On the other hand, smaller diameter guidewires typically have greater flexibility.

[0004] Guidewires with good torquability are beneficial in that they provide effective navigation and good alignment between rotation at the proximal end and corresponding movement at the distal end, which can be important when navigating tortuous anatomy. Simply increasing the size of the guidewire can increase its torquability, but may overly increase the stiffness of the guidewire as well. An overly stiff guidewire can lead to difficulties in initial placement of the guidewire at the targeted treatment site. Moreover,

there are known methods for increasing guidewire flexibility, such as reducing the core wire diameter, but these often come at the expense of torquability of the device.

[0005] What is needed, therefore, is a guidewire device with dimensions suitable for various intravascular procedures (including, for example, neurovascular and cardiovascular procedures) capable of providing enhanced torquability without being excessively stiff. In other words, there is an ongoing need for guidewire devices capable of providing high levels of torsional stiffness without

BRIEF DESCRIPTION OF THE DRAWINGS

[0006] Various objects, features, characteristics, and advantages of the invention will become apparent and more readily appreciated from the following description of the embodiments, taken in conjunction with the accompanying drawings and the appended claims, all of which form a part of this specification. In the Drawings, like reference numerals may be utilized to designate corresponding or similar parts in the various Figures, and the various elements depicted are not necessarily drawn to scale, wherein:

[0007] Figure 1 illustrates an embodiment of a guidewire device having a core and an outer tube and which may utilize one or more of the components described herein;

[0008] Figure 2 illustrates an exemplary embodiment of a guidewire device with a tube that has an outer diameter that is larger than an outer diameter of a proximal section of the core;

[0009] Figure 3 is a detailed view of the distal section of the guidewire of Figure 2, with the tube structure removed to better illustrate underlying features of the device;

[0010] Figure 4 is a detailed view of the tube of the guidewire of Figure 2;

[0011] Figure 5 is a cross-sectional view of a distal section of the guidewire of Figure 2, showing alignment of the beams of a one-beam section of the tube with a flattened distal section of the core;

[0012] Figures 6 and 7 are cross-sectional views of the guidewire of Figure 2 showing that the outer diameter of the tube is greater than the outer diameter of the proximal section of the core;

[0013] Figures 8 and 9 illustrate torsional stiffness vs. sample twist for guidewire devices, comparing a guidewire device according to the present disclosure (labelled "A24 Soft") to other prior art guidewire devices, showing that the guidewire device according to the present disclosure beneficially provides higher torsional stiffness;

[0014] Figure 10 illustrates bending stiffness profiles of various guidewire embodiments according to the present disclosure (labelled as "A24 Soft", "A24 Standard", and "A24 Support") in terms of equivalent stainless-steel (304V) wire diameter; and

[0015] Figures 11-13 compare these respective bending stiffness profiles to other prior art guidewire devices, illustrating that bending stiffness is not adversely affected despite the enhanced torque provided by the presently disclosed guidewire devices.

DETAILED DESCRIPTION

Introduction

[0016] Figure 1 schematically illustrates the general components of a guidewire 100 that may utilize one or more features described in greater detail below. The illustrated guidewire 100 includes a core 102 and an outer tube 104. The core 102 includes a distal section 103 (also referred to herein as the distal core 103) that extends into the outer tube 104 as shown. The distal core 103 may be tapered, either continuously or in one or more discrete sections, so that more distal sections have a smaller diameter and greater flexibility than more proximal sections. In some embodiments, the most distal section of the core 102 may be flattened into a ribbon-like shape with a flat, rectangular, or oblong cross section. For example, the distal core 103 may be ground so as to progressively taper to a smaller diameter at the distal end.

[0017] The core 102 and the tube 104 are typically formed from different materials. For example, the tube 104 is preferably formed from a relatively flexible and elastic material such as nitinol, whereas the core 102 may be formed from a relatively less flexible and elastic material such as stainless steel. Forming the core 102 from stainless steel (or other materials with similar modulus of elasticity) may be advantageous because it allows the distal tip to hold a shape when selectively bent/shaped by an operator and because stainless steel provides sufficient modulus of elasticity to provide more responsive translational movement. While these materials are presently preferred, other suitable materials such as polymers or other metals/alloys may additionally or alternatively be utilized.

[0018] The tube 104 is coupled to the core 102 (e.g., using adhesive, soldering, and/or welding) in a manner that beneficially allows torsional forces to be transmitted from the core 102 to the tube 104 and thereby to be further transmitted distally by the tube 104. A medical grade adhesive or other suitable material may be used to couple the tube 104 to the core wire 102 at the distal end 110 of the device to form an atraumatic covering.

[0019] The outer tube 104 may include a cut pattern that forms fenestrations 106 in the tube. The pattern of fenestrations 106 may be arranged to provide desired flexibility characteristics to the tube 104, including the promotion of preferred bending directions, the reduction or elimination of preferred bending directions, or gradient increases in flexibility along the longitudinal axis, for example. Examples of cut patterns and other guidewire device features that may be utilized in the guidewire devices described herein are provided in detail in United States Patent Application Publication Nos. 2018/0193607, 2018/0071496, and 2020/0121308, the entireties of each of which are incorporated herein by this reference.

[0020] The proximal section of the guidewire device 100 (the portion extending proximally from the tube 104) extends proximally to a length necessary to provide sufficient guidewire length for delivery to a targeted anatomical area. The guidewire device 100 typically has a length ranging from about 50 cm to about 350 cm, more commonly about 200 cm, depending on particular application needs. The tube 104 may have a length ranging from about 5 cm to about 350 cm, more typically about 15 cm to about 50 cm, such as about 25 cm to about 40 cm.

[0021] The guidewire device 100 may have a diameter of about 0.010 inches to about 0.038 inches, though larger or smaller sizes may also be utilized depending on particular application needs. For example, particular embodiments may have outer diameter sizes corresponding to standard guidewire sizes such as 0.014 inches, 0.016 inches, 0.018 inches, 0.024 inches, or other such sizes common to guidewire devices. The distal section 103 of the core 102 may taper to a diameter of about 0.002 inches, or a diameter within a range of about 0.001 to 0.005 inches. In some embodiments, the distal tip may be flattened (e.g., to a rectangular cross section) to further enhance bending flexibility while minimizing reductions in cross-sectional area needed for tensile strength. In such embodiments, the cross section may have dimensions of about 0.001 inches by 0.003 inches, for example. In some embodiments, the tube 104 has a length within a range of about 3 to 350 cm.

[0022] Additional features and details regarding the foregoing components are described in further detail below. The following examples may be particularly beneficial in applications where the corresponding catheter is about sized at 0.027 inches or greater, and the guidewire is thus beneficially sized at about 0.024 inches or greater in order to limit the amount of annular space between the inner surface of the catheter and the outer surface of the guidewire, but still allow for relative movement between them. In such

implementations, the guidewires described herein are able to provide sufficient diameter in the distal sections of the device to limit the annular space, while still maintaining effective torqueability and lateral flexibility. These sizes are not limiting, however, and the same features and details described below may also be utilized in guidewires that are smaller or larger than 0.024 inches.

Distal Section Features

[0023] Figure 2 illustrates an example of a guidewire 200. Except where noted herein, the guidewire 200 may include any of the general features described above in relation to guidewire 100, with like reference numbers indicating like parts. As shown, the guidewire 200 includes a core 202 and an outer tube 204, with a distal section 203 of the core 202 inserted into the tube 204. The outer tube 204 includes a plurality of fenestrations 206. A polymer-based adhesive may form an atraumatic distal tip 210.

[0024] The core 202 also includes a proximal section 201 (also referred to herein as the proximal core 201) that is disposed proximal of the outer tube 204 and is not inserted into the outer tube 204. The proximal core 201 may comprise a friction-lowering coating, such as polytetrafluoroethylene (PTFE) and/or other suitable coating materials. The tube 204 may also include a coating, preferably a suitable hydrophilic coating and/or other suitable coating materials.

[0025] Preferably, the outer diameter of the tube 204 is slightly larger than the outer diameter of the proximal core 201. In one exemplary embodiment, the proximal core 201 has an outer diameter of about 0.018 inches, while the tube 204 has an outer diameter of about 0.024 inches. Other core and/or tube sizes may also be utilized, however. Preferably, the tube 204 has an outer diameter that is about 10% or more larger than the outer diameter of the proximal core 201, more preferably about 15% to about 80% larger, or more preferably about 20% to about 70% larger, such as about 25% to about 35% larger.

[0026] This is further illustrated by the cross-sectional views of Figures 6 and 7. As shown, the outer diameter (D1) of the proximal core 201 is less than the outer diameter (D2) of the tube 204. The ratio of D2 to D1 may be, for example, about 1.1 to about 3, more preferably about 1.15 to about 2, or about 1.2 to about 1.75.

[0027] As mentioned above, a larger outer diameter in the tube 204 can better match certain desired catheter sizes at the catheter distal tip portion and thereby reduce the amount of annular space between the guidewire and catheter during placement of the catheter over the guidewire. This is particularly beneficial at the more distal sections of

the guidewire, which are more likely to be navigated through deeper, more tortuous portions of the patient's vasculature.

[0028] However, increasing the diameter of the core 202 to match the larger diameter of the tube 204 may make the core 202 too stiff for use in certain desired applications. Thus, maintaining a smaller core 202, while increasing the size of the tube 204 relative to the core 202, allows use of the more flexible core 202 while still enabling the benefits of a larger tube 204 at the distal sections of the guidewire 200.

[0029] As explained in more detail below, however, providing a tube 204 that has a larger outer diameter than the core 202 can introduce other challenges. In particular, the difference in diameter between the outer tube 204 and the distal core 203 enlarges the annular space between the outer surface of the distal core 203 and the inner surface of the tube 204. Because the tube 204 can be more flexible than the distal core 203, as the wire navigates a bend, the distal core 203 may be positioned off-center from the center line of the tube 204. As the guidewire is moved through the vasculature, this off-centering can disrupt the smooth distal transmission of rotational movement, causing a buildup and sudden release of forces which lead the guidewire to move with a "snap" and/or "whip" to a non-desired preferential rotational location. This disruption to the tactile feel and rotational control of the guidewire can make it more difficult for the operator to rotationally position the guidewire as intended, raising the risk of interventional procedure delays, suboptimal outcomes, inability to access the target location, or even tissue injury.

[0030] The embodiments described herein beneficially provide additional features that assist in radially centering the distal core 203 within the tube 204 even though the tube 204 has a larger outer diameter than the proximal core 201. One or more centering mechanisms may be included to beneficially reduce undesirable whip and/or snap movements of the guidewire (i.e., the centering mechanisms may improve rotational control), thereby enabling a user to have greater rotational control and improved tactile handling of the guidewire.

[0031] Figure 3 illustrates an expanded view of the distal section of the guidewire 200 with the tube 204 removed in order to better visualize the distal core 203 and some of the other underlying components. As shown, the core 202 includes one or more transition zones 208 where the core 202 tapers to a smaller diameter. A distal end section 211 of the core 202 may be flattened. The one or more transition zones 208 may be discrete, with one or more sections of the core of substantially continuous outer diameter disposed between,

or the distal core 203 may have a substantially continuous taper along all or most of its length.

[0032] A bushing 212 may be included at the point forming the joint to which the proximal end of the tube 204 is attached. The bushing 212 may have an outer diameter that substantially matches the outer diameter of the proximal core 201. The bushing 212 may be formed from the same material as the tube 204 (e.g., nitinol). The bushing 212 provides for better centering between the core 202 and the tube 204 and/or reduces the amount of adhesive needed to bond the separate components. Although shown here as a tube, the bushing 212 may have alternative geometries such as a coil, braid, slotted/cut tube, etcetera.

[0033] As shown, the bushing 212 may also include a chamfered or beveled surface 214 on its proximal end to provide a smooth transition between different diameters. The distal end of the bushing 212 may also be chamfered or beveled. Even though the distal end of the bushing 212 will be covered by the tube 204, providing a bushing 212 with a chamfer/bevel on both ends can aid in manufacturing, eliminating the need to ensure proper orientation of the bushing and eliminating the potential for erroneous orientation.

[0034] The illustrated guidewire 200 includes a proximal coil 216, a distal coil 218, and a bushing coil 220 positioned over the proximal coil 216 and the distal coil 218. The distal coil 218 is preferably formed of a radiopaque material, such as platinum group, gold, silver, palladium, iridium, osmium, tantalum, tungsten, bismuth, dysprosium, gadolinium, and the like. The distal coil 218 thus preferably allows radiographic visualization of the distal end of the guidewire 200 during a procedure. The distal coil 218 may have a length of about 0.5 cm to about 20 cm, or more typically about 3 cm to about 15 cm, such as about 10 cm.

[0035] The proximal coil 216 may be formed from a non-radiopaque material such as stainless steel, other suitable metal, a suitable polymer, or other suitable material. The proximal coil 216 may be attached to the distal core 203 at a point adjacent to or near to the proximal end of the distal coil 218 and/or at any point along the coincident length of the distal core 203, most commonly at or near each end of the proximal coil 216. The proximal coil 216 may have a length of about 1 to 25 cm, or more typically about 3 to 20 cm, such as about 5 to 15 cm. Technically, the distal coil 218 could be extended further proximally to take the place of the proximal coil 216. However, materials that function well as radiopaque markers (e.g., platinum) are relatively expensive. Also, their use as a packing material to fill large portions of the annular space could cause the distal section of

the guidewire 200 to be overly bright when imaged under x-ray fluoroscopy and thus not allow the operator to visualize other areas of interest. Thus, the proximal coil 216 is preferably separate from, and formed from a different material than, the distal coil 218.

[0036] The proximal coil 216 and the distal coil 218 aid in filling some of the annular space between the distal core 203 and the tube 204. Although the coil examples illustrated herein are shown having wires with a circular cross section, it will be understood that other coil types may also be utilized. For example, centering coil(s) may be edge-wound and/or may have a ribbon, rectangular, oblong, or other non-circular shaped cross-sectional shape.

[0037] Although the proximal coil 216 and distal coil 218 aid in filling some of the annular space, additional annular space remains, particularly when a somewhat larger tube 204 is utilized. The wire size of the proximal coil 216 and distal coil 218 could be increased to fill more space. However, increasing wire size too much may introduce excessive stiffness to the device. Preferably, the wire size of the proximal coil 216 and distal coil 218 is about 0.008 inches or less, or about 0.006 inches or less, or more preferably about 0.004 inches or less, such as about 0.002 inches or less.

[0038] To aid in filling the remainder of the annular space, the guidewire 200 may include a bushing coil 220. The bushing coil 220 may be disposed over the proximal coil 216 and the distal coil 218. The bushing coil 220 may extend over the entirety of both of the proximal coil 216 and the distal coil 218. As with the proximal coil 216 and the distal coil 218, the wire diameter of the bushing coil 220 is preferably limited. For example, the wire diameter of the bushing coil, when a metal material is utilized, may be about 0.008 inches or less, or about 0.006 inches or less, or more preferably about 0.004 inches or less, such as about 0.002 inches or less. The bushing coil 220 may be formed of stainless steel and/or other suitable material, such as another metal or a polymer. In examples where a polymer material is utilized, the modulus may be much less relative to a metal material and the wire diameter of the coil may therefore be larger without overly affecting the bending stiffness. In at least some embodiments, wire diameter of one or more of the coils (e.g., the bushing coil 220) may be up to about 0.025 inches, or up to about 0.020 inches, or up to about 0.015 inches.

[0039] The use of a bushing coil 220 in addition to the proximal coil 216 and distal coil 218 aids in filling the annular space between the distal core 203 and the tube 204 without the use of over-sized coils. This aids in maintaining centering of the distal core 203 within the tube 204, which prevents the undesirable effects of misalignment that have been described above while also minimally impacting the bending flexibility of the device.

[0040] In some embodiments, the bushing coil 220 may be substantially coincident with the proximal coil 216 and the distal coil 218. Alternatively, as shown, the bushing coil 220 may extend farther proximally than the proximal coil 216. This allows the bushing coil 220 to fill in more of the annular space even at portions where the proximal coil 216 is not able. That is, because of the tapered profile of the distal core 203, certain more proximal portions of the annular space do not fit both the proximal coil 216 and the bushing coil 220, but may still be filled by the further extending proximal portion of the bushing coil 220. The bushing coil 220 preferably extends along a substantial portion of the length of the tube 204. For example, the bushing coil 220 may have a length of at least about 60% of the length of the tube 204, or at least about 75% of the length of the tube 204, or at least about 80% of the length of the tube 204, or at least about 85% of the length of the tube 204.

[0041] In preferred embodiments, the proximal coil 216 and the distal coil 218 are each wound in a first direction, while the bushing coil 220 is counter-wound in a second, opposite direction. This beneficially limits interlocking and binding of the bushing coil 220 to either of the proximal coil 216 or the distal coil 218. The bushing coil 220 may also have a pitch that is different (e.g., narrower) than that of the proximal coil 216 or the distal coil 218. For example, the proximal coil 216 and/or the distal coil 218 may have a pitch of about 0.002 inches to about 0.008 inches, or about 0.003 inches to about 0.007 inches, whereas the bushing coil 220 may have a pitch of about 0.001 inches to about 0.006 inches, or about 0.002 inches to about 0.005 inches.

[0042] The proximal coil 216, the distal coil 218, and the bushing coil 220 are preferably configured to fill a substantial portion of the volume of the annular space between the distal core 203 and the tube 204. For example, proximal coil 216, the distal coil 218, and the bushing coil 220 may be configured to fill approximately 20% or more, 35% or more, 50% or more, 60% or more, 70% or more, 80% or more, or even up to about 90% or more of the volume of the annular space. Of course, other conventional guidewires may include joints or bushings that fill up large portions of the annular space at the particular part of the guidewire they are located. However, when the entire length of the outer tube is considered, such joints and bushings fill relatively little of the volume of the overall annular space.

[0043] The centering mechanism principles described herein may be utilized with other structural configurations to provide beneficial centering effects. For example, while the above embodiments describe various centering mechanisms with a core as the “inner

member" and a microfabricated tube as the "outer member," other structures may additionally or alternatively be utilized as the outer and/or inner members along with one or more of the described centering mechanisms.

[0044] For example, the inner member may be a wire (such as a ground core as described above), a tube (e.g., metal or polymer hypotube or metal or polymer microfabricated tube), a braid, or a coil. By way of further example, the outer member may be a tube (e.g., metal or polymer hypotube or metal or polymer microfabricated tube), a braid, a coil, or a polymer tube impregnated with a braid or coil. The centering mechanism may include a set of coils such as those described above, or may additionally or alternatively include other structures for providing centering of the inner member within the outer member. For example, one or more of the coils 216, 218, 220 may be replaced by one or more tubes (e.g., metal or polymer hypotube or metal or polymer microfabricated tube), braided sections, or sets of stacked rings.

[0045] Figure 4 illustrates the tube 204 separate from the core 202 and some of the other components of the device. The tube 204 extends between a proximal end 222 and a distal end 224. The fenestrations 206 formed within the tube 204 may be made according to a variety of cut patterns. Preferably, the overall effect of the fenestrations provides a flexibility gradient across the tube 204 where more flexibility increases closer to the distal end 224. Typically, greater flexibility can be provided by removing more of the stock material, such as by increasing the depth of the cut, decreasing the space between adjacent cuts, and/or reducing the number of axially extending beams 226 connecting each of the circumferentially extending rings 228.

[0046] The illustrated embodiment, for example, may include a three-beam section 230 (three beams connecting each adjacent pair of rings) that transitions to a two-beam section 232 (two beams connecting each adjacent pair of rings) that transitions to a one-beam section 234 (a single beam connecting each adjacent pair of rings). Within each of these sections, the cut depth and/or cut spacing may also be adjusted to provide a smooth intra-section and inter-section flexibility gradient. For example, the two-beam section 232 may have progressively less distance between cuts as it advances toward the distal end 224. It may then transition to the one-beam section 234, which itself then includes progressively less distance between cuts as it advances toward the distal end 224.

[0047] The one-beam section 234 may have a length of about 0.5 cm to about 3 cm, or about 0.75 cm to about 2 cm, for example. The two-beam section 232 may have a length of about 4 cm to about 16 cm, or about 6 cm to about 12 cm, for example. The three-beam

section 230 may have a length of about 12 cm to about 36 cm, or about 18 cm to about 30 cm, for example. In other words, the three-beam section 230 may be about 2 to 5 times longer than the two-beam section 232, and the two-beam section 232 may be about 2 to 5 times longer than the one-beam section 234. Designing the tube 204 with these proportions of cut/beam sections has been found to provide effective balance of axial, lateral, and torsional stiffness for most applications.

[0048] The tube 204 may also include a distal-most section 235 that has a two-beam pattern. This section is preferably relatively short, such as about 0.5 cm or less, or about 0.25 cm or less, or about 0.15 cm or less. Providing a relatively short two-beam section at section 235 provides added surface area for an adhesive material applied at or near the distal end 224 of the tube 204 to bond, allowing a stronger coupling between the distal end 224 and any internal components bonded thereto.

[0049] Certain sections of the tube 204 may have cuts that are rotationally offset so as to avoid the formation of any preferred bending planes. For example, an angular offset may be applied after each cut or series of cuts such that the overall resulting pattern of beams 226 in the tube 204 do not align in a way that forms preferred bending planes.

[0050] Other sections of the tube 204 may include a preferred bending plane. For example, the one-beam section 234 may be aligned as shown in Figure 4, with each beam offset by about 180° from the previous beam. These beams may also be aligned with the bending plane of the flattened distal end section 211 of the core. Figure 5 illustrates, in cross-section, how the beams 226 of the one-beam section 234 are preferably aligned in the same plane as the flattened, wider section of the distal end section 211 of the core.

Effective Torque & Torque to Bend Ratios

[0051] Figures 8 and 9 illustrate that guidewire devices of the present disclosure are capable of providing higher torque (i.e., torsional stiffness) as compared to various prior art devices. In Figures 8 and 9 and elsewhere herein, the device labelled "A24 Soft" represents an example of a guidewire device as described herein, while other labels refer to other prior art devices. In particular, "A14 Soft" refers to the Aristotle® 14 Guidewire with soft profile (0.014 inch outer diameter, sold by Scientia Vascular), the "A18 Soft" refers to the Aristotle® 18 Guidewire with soft profile (0.018 inch outer diameter, sold by sold by Scientia Vascular), the "Synchro2 Soft" refers to the Synchro^2 with soft profile (0.014 inch outer diameter, sold by Stryker Neurovascular), the Chikai 14 refers to the Asahi Chikai guidewire (0.014 inch outer diameter, sold by Asahi Intecc Medical), and the

"A14 Soft CoreWire" and "A18 Soft CoreWire" are the same as the "A14 Soft" and the "A18 Soft" but only the core wire without outer tube or other components. In other figures, the label "Fathom 16" refers to the Fathom 0.016 inch outer diameter guidewire sold by Boston Scientific. The label "A14" is synonymous with "AR14", "A18" is synonymous with "AR18", and the like.

[0052] As shown, the "A24 Soft" is more effective in providing torsional stiffness than the comparative prior art devices. Table 1 summarizes the data of Figures 8 and 9 by showing the rotational stiffness (averaged over all measurement points across the 35 cm distal section) of the "A24 Soft" and some of the other prior art guidewire devices.

Table 1: Torque / Rotational Stiffness

Guidewire Device	**Avg. Rotational Stiffness (inch·pounds / degree)**	**Avg. Rotational Stiffness (N·m / rad)**
A24 Soft	2.59 E-06	1.68 E-05
A14 Soft	1.56 E-06	1.01 E-05
A18 Standard	1.99 E-06	1.29 E-05
A18 Soft	3.45 E-07	2.24 E-06
Chikai 14	7.95 E-07	5.15 E-06
Synchro2 Soft	1.04 E-06	6.73 E-06

[0053] Advantageously, the high torque provided by the disclosed guidewire device does not come at the expense of significantly reduced bending flexibility. Figure 10 illustrates profiles of bending stiffness (i.e., flexural rigidity) of various guidewire embodiments according to the present disclosure (labelled as "A24 Soft", "A24 Standard", and "A24 Support") in terms of equivalent stainless-steel (304V) wire diameter. Because bending stiffness of a beam is a constant directly related to the cross-sectional dimensions of the beam, the measured guidewire stiffness can be related to the constant in terms of a stainless-steel wire that would provide the same bending stiffness measurement.

[0054] To carry out the measurement procedure, the distal tip of the guidewire to be measured was clamped in a collet pin vise with the guidewire tip protruding out of the vise. The guidewire tip was mounted so that the flattened tip of the core (where applicable) was aligned in the horizontal orientation and the measurement was taken in the direction intended to be shaped. Additional measurement points were tested by advancing the wire

in the collet and trimming the wire as necessary so that the guidewire extends past a load cell roller midpoint.

[0055] Figures 11-13 compare these respective bending stiffness profiles to other prior art guidewire devices, illustrating that bending stiffness is not adversely affected despite the enhanced torque provided by the A24 guidewire devices. This is true even though some of the comparison devices have a smaller size and would therefore be expected to have greater flexibility in bending (i.e., less bending stiffness).

[0056] The data provided herein illustrate that guidewire devices made according to the present disclosure are capable of providing relatively high torque without significantly and detrimentally increasing the bending stiffness. Accordingly, a "torque to bend" ratio can be utilized as a useful metric that highlights the beneficial properties of the presently disclosed guidewire devices. The "torque to bend" ratio is a value indicating the relationship between torsional stiffness (as the numerator) and bending stiffness (as the denominator). The exact value may change depending on the units utilized in each of the input measures, but so long as units are selected consistently, comparisons across different devices can be made. In Table 2, the torque to bend ratio is shown in units of radians^{-1}, which results from a rotational stiffness numerator in units of ($N \cdot m^2$/rad) divided by a bending stiffness denominator in units of $N \cdot m^2$.

Table 2: Bending Stiffness & "Torque to Bend" Ratios

Guidewire Device	**Distance from Distal End (cm)**	**Bending Stiffness (equiv. SS diam.)**	**Bending Stiffness ($N \cdot m^2$)**	**'Torque to Bend' Ratio (rad^{-1})**
A24 Soft	0.5	1.74	3.5E-08	479.36
	1	2.18	8.85E-08	189.63
	1.5	2.44	1.35E-07	124.33
	2	2.81	2.38E-07	70.62
	3	3.45	5.8E-07	28.91
	4	3.45	5.52E-07	30.39
	5	3.57	6.48E-07	25.88
	6	3.65	6.84E-07	24.53
	7	4.11	1.11E-06	15.08
	8	4.47	1.53E-06	10.95
	9	4.92	2.31E-06	7.27

	10	5.38	3.27E-06	5.13
	12.5	5.42	3.34E-06	5.02
	15	5.72	4.27E-06	3.93
	17.5	5.89	4.81E-06	3.49
	20	6.00	5.17E-06	3.25
	22.5	6.86	8.78E-06	1.91
	25	7.47	1.22E-05	1.38
	27.5	8.59	2.11E-05	0.79
	30	9.99	3.86E-05	0.43
	32.5	11.73	7.34E-05	0.23
	35	14.10	0.000152	0.11
A14 Soft	0.5	2.36	1.23E-07	81.82
	1	2.42	1.37E-07	73.50
	2	2.71	2.16E-07	46.68
	3	3.15	3.95E-07	25.58
	4	3.53	6.18E-07	16.34
	5	3.85	8.74E-07	11.55
	6	4.18	1.22E-06	8.25
	8	4.85	2.2E-06	4.58
	9	4.86	2.22E-06	4.54
	10	5.03	2.56E-06	3.94
	11	5.11	2.73E-06	3.71
	12	5.12	2.76E-06	3.67
	13	5.07	2.63E-06	3.83
	14	5.10	2.71E-06	3.72
	15	5.08	2.67E-06	3.79
	16	5.25	3.04E-06	3.32
	17	5.17	2.85E-06	3.54
	18	5.09	2.69E-06	3.75
	19	5.02	2.53E-06	3.99
	20	4.87	2.26E-06	4.47
	21	5.07	2.65E-06	3.82
	22	5.01	2.52E-06	4.01
	23	5.08	2.66E-06	3.80
	25	5.08	2.66E-06	3.80
	27	5.27	3.09E-06	3.26

	29	5.21	2.94E-06	3.43
	31	6.01	5.23E-06	1.93
	33	7.91	1.56E-05	0.65
A18 Standard	0.5	2.15	8.25E-08	156.20
	1	2.28	1.06E-07	121.82
	2	3.48	5.67E-07	22.71
	3	3.68	7.14E-07	18.04
	4	3.86	8.65E-07	14.89
	5	4.15	1.15E-06	11.21
	6	4.22	1.23E-06	10.46
	7	4.44	1.51E-06	8.54
	8	4.66	1.83E-06	7.03
	9	4.77	2.01E-06	6.41
	10	5.05	2.53E-06	5.10
	12.5	5.65	3.96E-06	3.25
	15	5.96	4.89E-06	2.63
	17.5	6.01	5.07E-06	2.54
	20	6.06	5.24E-06	2.46
	22.5	6.15	5.54E-06	2.33
	25	6.75	8.08E-06	1.60
	27.5	7.84	1.47E-05	0.88
	30	9.30	2.90E-05	0.44
	32.5	10.88	5.43E-05	0.24
	35	12.19	8.58E-05	0.15
A18 Soft	0.5	1.90	5.03E-08	44.42
	1	1.88	4.88E-08	45.82
	2	3.16	3.86E-07	5.79
	3	3.61	6.56E-07	3.41
	4	3.69	7.16E-07	3.12
	5	3.90	8.99E-07	2.49
	6	3.83	8.33E-07	2.68
	7	3.98	9.72E-07	2.30
	8	4.18	1.19E-06	1.89
	9	4.31	1.34E-06	1.67
	10	4.57	1.70E-06	1.32

	12.5	5.10	2.63E-06	0.85
	15	5.31	3.08E-06	0.73
	17.5	5.28	3.02E-06	0.74
	20	5.29	3.05E-06	0.73
	22.5	5.30	3.05E-06	0.73
	25	6.09	5.33E-06	0.42
	27.5	7.31	1.11E-05	0.20
	30	9.13	2.70E-05	0.08
	32.5	10.62	4.94E-05	0.05
	35	12.36	9.05E-05	0.02
Synchro2 Soft	0.5	2.15	8.55E-08	78.73
	2.5	2.72	2.19E-07	30.73
	5	3.31	4.8E-07	14.01
	7.5	4.14	1.18E-06	5.73
	10	4.50	1.64E-06	4.10
	12.5	4.57	1.74E-06	3.86
	15	4.56	1.73E-06	3.89
	17.5	4.72	1.99E-06	3.39
	20	4.88	2.27E-06	2.97
	22.5	5.24	3.02E-06	2.23
	25	5.45	3.53E-06	1.91
	27.5	6.06	5.39E-06	1.25
	30	6.36	6.54E-06	1.03
	32.5	6.91	9.12E-06	0.74
	35	6.66	7.87E-06	0.86
	37.5	7.43	1.22E-05	0.55
	40	8.76	2.36E-05	0.29
	42.5	10.14	4.23E-05	0.16
	45	11.37	6.69E-05	0.10

[0057] The data provided in Figures 8-13 and in Tables 1 and 2 can be utilized to calculate such torque to bend ratios for the presently disclosed guidewires and for the selection of comparative devices. The guidewire devices disclosed herein beneficially provide greater torque to bend ratios than prior art devices. In some implementations, this type of comparison can be made across devices of similar size. That is, for a given

guidewire size, the presently disclosed guidewire devices provide improved torque to bend ratios, even though a differently sized guidewire may have a higher torque to bend ratio because of size differences. For example, some embodiments may have an outer diameter size of no more than about 0.024 inches.

[0058] As further illustrated by the data of Figures 8-13 and Tables 1 and 2, a guidewire device according to the present disclosure can provide a torque to bend ratio of greater than 160 rad^{-1}, or about 200 rad^{-1} or greater, or about 250 rad^{-1} or greater, or about 300 rad^{-1} or greater, or about 350 rad^{-1} or greater, or about 400 rad^{-1} or greater, or about 450 rad^{-1} or greater, at a distal 0.5 cm section of the guidewire device (e.g., at about 0.5 cm from the distal end). The other tested guidewire devices were unable to provide a torque to bend ratio at these values.

[0059] In some embodiments, a guidewire device according to the present disclosure can provide a torque to bend ratio of 80 rad^{-1} or greater, or about 100 rad^{-1} or greater, or about 120 rad^{-1} or greater, at a distal 1.5 cm section of the guidewire device (e.g., at about 1.5 cm from the distal end). The other tested guidewire devices were unable to provide a torque to bend ratio at these values.

[0060] In some embodiments, a guidewire device according to the present disclosure can provide a torque to bend ratio of 130 rad^{-1} or greater, or about 150 rad^{-1} or greater, or about 170 rad^{-1} or greater, at a distal 1.0 cm section of the guidewire device (e.g., at about 1.0 cm from the distal end). The other tested guidewire devices were unable to provide a torque to bend ratio at these values.

[0061] In some embodiments, a guidewire device according to the present disclosure can provide a torque to bend ratio of 50 rad^{-1} or greater, or about 60 rad^{-1} or greater, or about 65 rad^{-1} or greater, at a distal 2.0 cm section of the guidewire device (e.g., at about 2.0 cm from the distal end). The other tested guidewire devices were unable to provide a torque to bend ratio at these values.

[0062] In some embodiments, a guidewire device according to the present disclosure can provide a torque to bend ratio of 15 rad^{-1} or greater, or about 20 rad^{-1} or greater, or about 25 rad^{-1} or greater, at a distal 5.0 cm section of the guidewire device (e.g., at about 5.0 cm from the distal end). The other tested guidewire devices were unable to provide a torque to bend ratio at these values.

[0063] In some embodiments, a guidewire device according to the present disclosure can provide a torque to bend ratio of 8 rad^{-1} or greater, or about 9.5 rad^{-1} or greater, or

about 11 rad^{-1} or greater, at a distal 8.0 cm section of the guidewire device (e.g., at about 8.0 cm from the distal end). The other tested guidewire devices were unable to provide a torque to bend ratio at these values.

[0064] Other torque to bend ratios for the tested devices can be readily determined using the data provided by Figures 8-13 and summarized by Tables 1 and 2.

Abbreviated List of Defined Terms

[0065] While certain embodiments of the present disclosure have been described in detail, with reference to specific configurations, parameters, components, elements, etcetera, the descriptions are illustrative and are not to be construed as limiting the scope of the claimed invention.

[0066] Furthermore, it should be understood that for any given element of component of a described embodiment, any of the possible alternatives listed for that element or component may generally be used individually or in combination with one another, unless implicitly or explicitly stated otherwise.

[0067] In addition, unless otherwise indicated, numbers expressing quantities, constituents, distances, or other measurements used in the specification and claims are to be understood as optionally being modified by the term "about" or its synonyms. When the terms "about," "approximately," "substantially," or the like are used in conjunction with a stated amount, value, or condition, it may be taken to mean an amount, value or condition that deviates by less than 20%, less than 10%, less than 5%, less than 1%, less than 0.1%, or less than 0.01% of the stated amount, value, or condition. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of the claims, each numerical parameter should be construed in light of the number of reported significant digits and by applying ordinary rounding techniques.

[0068] Any headings and subheadings used herein are for organizational purposes only and are not meant to be used to limit the scope of the description or the claims.

[0069] It will also be noted that, as used in this specification and the appended claims, the singular forms "a," "an" and "the" do not exclude plural referents unless the context clearly dictates otherwise. Thus, for example, an embodiment referencing a singular referent (e.g., "widget") may also include two or more such referents.

[0070] It will also be appreciated that embodiments described herein may include properties, features (e.g., ingredients, components, members, elements, parts, and/or

portions) described in other embodiments described herein. Accordingly, the various features of a given embodiment can be combined with and/or incorporated into other embodiments of the present disclosure. Thus, disclosure of certain features relative to a specific embodiment of the present disclosure should not be construed as limiting application or inclusion of said features to the specific embodiment. Rather, it will be appreciated that other embodiments can also include such features.

CLAIMS

1. A guidewire device configured to provide high rotational stiffness without significantly increasing bending stiffness, the guidewire comprising:

a core having a proximal section and a distal section; and

a microfabricated outer tube coupled to the core such that the distal section of the core passes into and is encompassed by the outer tube,

wherein the guidewire device provides one or more of the following:

a ratio of rotational stiffness to bending stiffness of about 160 rad^{-1} or greater at a location about 0.5 cm from a distal end of the guidewire device,

a ratio of rotational stiffness to bending stiffness of about 80 rad^{-1} or greater at a location about 1.0 cm from the distal end,

a ratio of rotational stiffness to bending stiffness of about 130 rad^{-1} or greater at a location about 1.5 cm from the distal end,

a ratio of rotational stiffness to bending stiffness of about 50 rad^{-1} or greater at a location about 2.0 cm from the distal end,

a ratio of rotational stiffness to bending stiffness of about 15 rad^{-1} or greater at a location about 5.0 cm from the distal end, or

a ratio of rotational stiffness to bending stiffness of about 8 rad^{-1} or greater at a location about 8.0 cm from the distal end.

2. The guidewire device of claim 1, wherein the outer tube and the core define an annular space between an inner surface of the outer tube and an outer surface of the distal section of the core, wherein an outer diameter of the outer tube is greater than an outer diameter of the proximal section of the core.

3. The guidewire device of claim 2, further comprising a distal coil encompassing part of the distal section of the core.

4. The guidewire device of claim 3, further comprising a proximal coil disposed proximal of the distal coil and encompassing part of the distal section of the core.

5. The guidewire device of claim 4, further comprising a bushing coil disposed over at least a portion of one or both of the distal coil and the proximal coil.

6. The guidewire device of claim 3, wherein the distal coil is more radiopaque than stainless steel.

7. The device of claim 4, wherein the proximal coil is less radiopaque than the distal coil.

8. The device of claim 5, wherein the bushing coil extends farther proximally than the proximal coil.

9. The device of claim 5, wherein the bushing coil has a length of at least about 60% of the length of the outer tube.

10. The device of claim 5, wherein at least one of the proximal coil, distal coil, and bushing coil is wound in a direction opposite the other coils.

11. The device of claim 10, wherein the proximal coil and the distal coil are each wound in a first direction, while the bushing coil is counter-wound in a second, opposite direction.

12. The device of claim 5, wherein the bushing coil has a pitch that is smaller than that of the proximal coil and/or distal coil.

13. The device of claim 5, wherein the proximal coil, distal coil, and bushing coil fill 15% or more of the volume of the annular space.

14. The device of claim 1, wherein the outer diameter of the outer tube is larger than the outer diameter of the proximal section of the core by about 10% or more.

15. A guidewire device configured to provide high rotational stiffness without significantly increasing bending stiffness, the guidewire comprising:

a core having a proximal section and a distal section;

a microfabricated outer tube coupled to the core such that the distal section of the core passes into and is encompassed by the outer tube;

a distal coil encompassing part of the distal section of the core;

a proximal coil disposed proximal of the distal coil and encompassing part of the distal section of the core; and

a bushing coil disposed over at least a portion of one or both of the distal coil and the proximal coil,

wherein the outer tube and the core define an annular space between an inner surface of the outer tube and an outer surface of the distal section of the core, wherein an outer diameter of the outer tube is greater than an outer diameter of the proximal section of the core, and

wherein the guidewire device provides one or more of the following:

a ratio of rotational stiffness to bending stiffness of about 160 rad^{-1} or greater at a location about 0.5 cm from a distal end of the guidewire device,

a ratio of rotational stiffness to bending stiffness of about 80 rad^{-1} or greater at a location about 1.0 cm from the distal end,

a ratio of rotational stiffness to bending stiffness of about 130 rad^{-1} or greater at a location about 1.5 cm from the distal end,

a ratio of rotational stiffness to bending stiffness of about 50 rad^{-1} or greater at a location about 2.0 cm from the distal end,

a ratio of rotational stiffness to bending stiffness of about 15 rad^{-1} or greater at a location about 5.0 cm from the distal end, or

a ratio of rotational stiffness to bending stiffness of about 8 rad^{-1} or greater at a location about 8.0 cm from the distal end.

16. The device of claim 15, wherein the proximal coil, distal coil, and bushing coil fill 15% or more of the volume of the annular space.

17. The device of claim 15, wherein the outer diameter of the outer tube is larger than the outer diameter of the proximal section of the core by about 10% or more.

18. The device of claim 15, wherein the proximal coil and the distal coil are each wound in a first direction, while the bushing coil is counter-wound in a second, opposite direction.

19. The device of claim 15, wherein the bushing coil extends farther proximally than the proximal coil.

20. A guidewire device configured to provide high rotational stiffness without significantly increasing bending stiffness, the guidewire comprising:

a core having a proximal section and a distal section;

a microfabricated outer tube coupled to the core such that the distal section of the core passes into and is encompassed by the outer tube, wherein the outer diameter of the

outer tube is larger than the outer diameter of the proximal section of the core by about 10% or more;

a distal coil encompassing part of the distal section of the core;

a proximal coil disposed proximal of the distal coil and encompassing part of the distal section of the core; and

a bushing coil disposed over at least a portion of one or both of the distal coil and the proximal coil,

wherein the proximal coil, distal coil, and bushing coil fill 15% or more of the volume of the annular space,

wherein the outer tube and the core define an annular space between an inner surface of the outer tube and an outer surface of the distal section of the core, wherein an outer diameter of the outer tube is greater than an outer diameter of the proximal section of the core, and

wherein the guidewire device provides one or more of the following:

a ratio of rotational stiffness to bending stiffness of about 160 rad^{-1} or greater at a location about 0.5 cm from a distal end of the guidewire device,

a ratio of rotational stiffness to bending stiffness of about 80 rad^{-1} or greater at a location about 1.0 cm from the distal end,

a ratio of rotational stiffness to bending stiffness of about 130 rad^{-1} or greater at a location about 1.5 cm from the distal end,

a ratio of rotational stiffness to bending stiffness of about 50 rad^{-1} or greater at a location about 2.0 cm from the distal end,

a ratio of rotational stiffness to bending stiffness of about 15 rad^{-1} or greater at a location about 5.0 cm from the distal end, or

a ratio of rotational stiffness to bending stiffness of about 8 rad^{-1} or greater at a location about 8.0 cm from the distal end.