SLOTTED MEDICAL DEVICE

Inventors: Stephen J. Jacobsen, Salt Lake City, UT (US); Clark C. Davis, Holladay, UT (US); David Wells, Etobicoke (CA); DeWayne C. Fox, South Jordan, UT (US)

Correspondence Address:
SNELL & WILMER
ONE ARIZONA CENTER
400 EAST VAN BUREN
PHOENIX, AZ 85004-0001

Appl. No.: 10/213,123
Filed: Aug. 5, 2002

Related U.S. Application Data
Continuation-in-part of application No. 09/470,607, filed on Dec. 22, 1999, now Pat. No. 6,428,489.
Continuation-in-part of application No. 09/399,375, filed on Sep. 20, 1999, now abandoned, which is a continuation-in-part of application No. 08/568,493, filed on Dec. 7, 1995, now abandoned, and which is a continuation-in-part of application No. 09/470,607, filed on Dec. 22, 1999, now Pat. No. 6,428,489, which is a continuation-in-part of application No. 09/359,334, filed on Jul. 21, 1999, now abandoned, which is a continuation-in-part of application No. 08/856,415, filed on May 14, 1997, now abandoned, which is a division of application No. 08/568,490, filed on Dec. 7, 1995, now abandoned.

Publication Classification

Int. Cl. A61B 5/00
U.S. Cl. 600/585

ABSTRACT
A medical device configured to navigate through anatomy that may be used as a guidewire, or both. Embodiments may navigate like a guidewire, but once in place, perform many or all of the functions that a catheter may perform. The device generally has a body which may be nitinol, with a plurality of pairs of slots cut into the body to make it more flexible in bending while maintaining adequate torsional stiffness. Each longitudinally adjacent pair may be rotated an angle around the axis from the previous pair, and the angle may be less than 89 degrees and greater than 31 degrees. In some embodiments, the angle may be in the range of 70-90 degrees and the average of the angles, computed over 10 adjacent sets of cuts, may be less than 89 degrees and greater than 70 degrees.
Fig. 8

Guidewire Tensile Strength

- conventional guidewires
- NiTi micromachined guidewires .014"

Stainless Steel Wire Diameter
- .001
- .0015
- .002
- .003
- .004
- .005
- .006
- .007
- .008

Bending Stiffness (Lb-in^2)

Fig. 9

Guidewire Torsional Strength

- conventional guidewires
- NiTi micromachined guidewires .014"

Stainless Steel Wire Diameter
- .001
- .0015
- .002
- .003
- .004
- .005
- .006
- .007
- .008

Bending Stiffness (Lb-in^2)
Fig. 21
Fig. 6

Fig. 7
**Fig. 8**

*Guidewire Tensile Strength*

- **Ultimate Tensile Strength (Lb)** vs. **Bending Stiffness (Lb-in^2)**
  - Competitive guidewires
  - PVS micromachined guidewires

**Stainless Steel Wire Diameter**

- .001
- .0015
- .002
- .003
- .004
- .005
- .006
- .007
- .008

---

**Fig. 9**

*Guidewire Torsional Strength*

- **Ultimate Torsion Strength (Lb-in)** vs. **Bending Stiffness (Lb-in^2)**
  - Competitive guidewires
  - PVS micromachined guidewires
Guidewire Performance Criteria

Fig. 10

Fig. 11
Fig. 12

Fig. 13
Liner can move relative to outer tube.

Ribbon coil embedded in polymer tube.

Micromachined catheter tube.

FIG. 38
FIG. 40

CROSS-SECTION OF COIL DRAW SUPPORTED LINER

4015 POLYMER LINER

4010 METAL OR POLYMER COIL OR BRAID
FIG. 41

CROSS-SECTION OF GROOVED LINER

(FLURALITY OF CIRCULAR OR HELICAL)
FIG. 42

DETAIL OF FUSED POLYMER CYL ON LINER

FUSED AREA
FIG. 43
SLOTTED MEDICAL DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 09/399,375 filed on Sep. 20, 1999, which application is a continuation-in-part of U.S. patent application Ser. No. 08/568,493 filed Dec. 7, 1995; and is also a continuation-in-part of U.S. patent application Ser. No. 09/470,607 filed on Dec. 22, 1999, which is a continuation-in-part of U.S. patent application Ser. No. 09/359,334 filed on Jul. 21, 1999, which application is a continuation-in-part of U.S. patent application Ser. No. 08/856,415 filed on May 14, 1997, which is a division of U.S. patent application Ser. No. 08/568,490 filed on Dec. 7, 1995; the disclosures of which are hereby incorporated herein by reference.

FIELD OF INVENTION

[0002] This invention relates to medical devices for use within living bodies and methods for making and using such devices. The medical devices may be, for example, catheters, guide wires (guidewires), or hybrids of catheters and guidewires.

BACKGROUND OF THE INVENTION

[0003] Catheter guide wires (guidewires) have been used to “lead” or “guide” catheters to desired target locations in animal or human anatomy. This may be done via a body’s lumen, for example such as traversing luminal spaces defined by the vasculature to the target location. The typical guidewire may be from about 135 centimeters to 195 centimeters in length, and may be made from two primary components—a stainless steel solid core wire, and a platinum alloy coil spring. The core wire may be tapered on the distal end to increase its flexibility. The coil spring may be soldered to the core wire at its distal end and at a point where the inside diameter of the coil spring matches the outside diameter of the core wire. Platinum may be selected for the coil spring because it provides better fluoroscopic or other radiologic imaging during navigation of the guidewire in the body, and it is generally biocompatible. The coil spring may also provide softness for the tip of the guidewire to reduce the likelihood of unwanted puncture of a Luminal wall or the damaging of this or any other anatomy.

[0004] As mentioned, navigation of a guidewire through the anatomy may be achieved with the assistance of radiographic imaging. This may be done by introducing contrast media into the body lumens being traversed and viewing the guidewire in the body lumens using X-ray fluoroscopy or other comparable methods. The guidewire may be provided with a tip that may be curved or bent to a desired angle so as to deviate laterally a short distance. By rotation of the wire, the tip can be made to deviate in a selected direction from an axis of the guidewire about which it rotates. In some devices the catheter enables introduction of contrast media at the location of the distal tip to enable the visualization of a Luminal space being traversed by the catheter and guidewire. Visualization may be by fluoroscope, for example, or another device. The guidewire and catheter may be introduced into a luminal space, comprising for example a vessel or duct and advanced there through until the guidewire tip reaches a desired vessel or luminal branch. The user may then twist the proximal end of the guidewire so as to rotate and point the curved distal tip into the desired branch so that the device may be advanced farther into the anatomy via the luminal branch. The catheter may be advanced over the guidewire to follow, or track, the wire. This procedure may be repeated as needed to guide the wire and overlying catheter to the desired target location. Once the catheter has been advanced to the desired location, the guidewire may be withdrawn, depending upon the therapy to be performed. Often times, such as in the case of balloon angioplasty, the guidewire may be left in place during the procedure and can be used to exchange catheters.

[0005] From this description, it will be apparent that a guidewire having very low resistance to flexure yet relatively high torsional strength may be most desirable. As the guidewire may be advanced into the anatomy, internal resistance from the typically numerous turns, and surface contact, decreases the ability to advance the guidewire further. This, in turn, may lead to a more difficult and prolonged procedure, or, more seriously, failure to access the desired anatomy and thus a failed procedure. A guidewire with high flexibility helps overcome the problems created by internal resistance. However, if the guidewire does not also have good torque characteristics (torsional stiffness), the user will not be able to twist the proximal end in order to rotate the distal tip of the guidewire as required.

SUMMARY OF THE INVENTION

[0006] It is therefore an object of the invention to provide an improved medical device which exhibits both torsional stiffness, bending flexibility, and longitudinal strength.

[0007] Specifically, the present invention provides, in an exemplary embodiment, a medical device configured to navigate through anatomy. Some embodiments may be used as a guidewire, and may be solid or tubular. Some tubular embodiments of the device may be used as a catheter, or may be used as either a catheter or a guidewire. Some embodiments may navigate like a guidewire, but once in place, perform many or all of the functions that a catheter may perform. Other objects and uses of the present invention are described herein.

[0008] The device generally has a body with a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end. The device may also have a plurality of pairs of slots cut into the body, each of which may be substantially perpendicular to the axis, and each slot in each pair may be on substantially opposite sides of the axis. Each longitudinally adjacent pair may be rotated an angle around the axis from the previous pair, and the angle may be, for example, less than 89 degrees and greater than 31 degrees. In some such embodiments, the angle may be greater than 89 degrees. In other embodiments, however, the angle may be in the range of 70-90 degrees and the average of the angles, computed over 10 adjacent sets of cuts, may be less than 89 degrees and greater than 70 degrees.

[0009] At least some of the slots may have a cross sectional shape that may be, for example, wedge-shaped, T-shaped, or substantially circular. In some embodiments, for at least a plurality of the pairs of slots, the first slot may be at substantially the same axial location as the second slot.
There may also be a varying longitudinal spacing between adjacent pairs, which may vary from the proximal end to the distal end, for example to vary the bending stiffness of the device along its length. The slots may have been formed, for instance, by saw-cutting, grinding, laser cutting, etching, or electron discharge machining. One type of grinding that may be used is grinding with a diamond abrasive blade. The body of the device may be nitinol, which may be superelastic, and the distal end of the device may have a detectable element, such as a radiopaque element or an MRI detectable element.

Some embodiments have a tubular polymer sleeve coaxial with at least part of the body. For instance, the body may be tubular, and the sleeve may be inside the body. The sleeve may prevent leakage of liquids through the slots, for example, if the device is used as a catheter to deliver medication to a particular location. In some embodiments, a wire may be disposed inside the tubular body and slidable therein. The wire may have at least one bend formed in it, which may effect the shape of the device when the wire is inside, compared to after the wire is removed, the wire may also effect (e.g., increase) bending stiffness.

The present invention also provides, in particular an embodiment, a catheter configured to navigate through anatomy. The catheter may have a tubular body with a plurality of pairs of slots cut into the body, and each pair of slots may be on substantially opposite sides of the axis. The device may have a tubular polymer sleeve, which may be inside at least part of the body. The present invention even further provides a hollow catheter guidewire apparatus that includes a tubular nitinol body with a plurality of pairs of slots cut into the body.

A catheter guidewire apparatus in accordance with principles of the invention may be realized in a specific illustrative embodiment of a catheter guidewire formed of a thin, elongate, hollow tubular body of material, the exterior surface of which includes a plurality of pairs of cuts or slots spaced apart along the length of the body. The cuts extend generally transversely of the body and may be positioned and formed to give the guidewire flexibility while maintaining a relatively high degree of torsional stiffness. By manipulating the size, shape, spacing, and orientation of the cuts, the torsional stiffness of the guidewire relative to its flexibility or beam stiffness can be selectively altered. In one specific embodiment, the cuts may be offset from one another to provide desired flexibility without sacrificing torsional strength. The guidewire, being hollow, may also serve as a catheter itself. Slots may also be provided which extend through the sidewalls of the hollow tube to the lumen to allow discharge therethrough of fluids flowing in the lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side, fragmented, partially cross-sectional, view of one embodiment of a catheter guidewire apparatus configured in accordance with the principles of the present invention;

FIG. 2 is a side, fragmented, view of a portion of a guidewire showing different types of cuts or etchings which may be utilized in a solid or tubular guidewire in accordance with principles of the present invention;

FIG. 3 is a side, fragmented, view of the tip of a guidewire with radiopaque coil or band wrapped thereabout, in accordance with principles of the present invention;

FIGS. 4 and 5 show side, fragmented views of two embodiments of guidewires formed with cuts, in accordance with principles of the present invention;

FIG. 6 is a side, fragmented view of a tapered guidewire formed with cuts, in accordance with principles of the present invention;

FIG. 7 is a side, fragmented view of a solid guidewire formed with a coiled tip, in accordance with principles of the present invention;

FIG. 8 is a graph of guidewire tensile strength compared to bending stiffness for a micromachined guidewire in accordance with principles of the present invention;

FIG. 9 is a graph of the ultimate torsional strength of a micromachined guidewire in accordance with principles of the present invention compared to its bending stiffness;

FIG. 10 is a graph of the torsional stiffness of a micromachined guidewire in accordance with principles of the present invention compared to its bending stiffness;

FIG. 11 is a graph showing the ratio of torsional stiffness to bending stiffness of a micromachined guidewire in accordance with principles of the present invention compared to its bending stiffness;

FIGS. 12a, 12b, and 12c show cross-sectional views of guidewires disposed within lumenus of circular and elliptical catheters;

FIG. 12d shows the potential serpentine path of a guidewire through a catheter which tends to wedge the guidewire within the catheter;

FIG. 13 shows a perspective, partially fragmented, view of a guidewire in accordance with principles of the invention in another embodiment;

FIG. 14 shows a side view, partially fragmented, of a core wire of the guidewire of FIG. 13 illustrating the grind profile;

FIG. 15 shows a side view, partially fragmented, of a core wire of the guidewire of FIG. 13 with a medial stainless steel wire coil added;

FIG. 16 shows a side view, partially fragmented, of a core wire of the guidewire of FIG. 13 with a medial wire coil and distal marker coil added;

FIG. 17 shows a side view, partially fragmented, of a core wire of the guidewire of FIG. 13 with a medial wire coil and distal marker coil and proximal stainless steel coil added;

FIG. 18 shows a side view, partially fragmented, of a core wire of the guidewire of FIG. 13 with a medial wire coil, distal marker coil, proximal stainless coil and micromachined tubing added at a distal tip portion;

FIG. 19 shows a fragmentary perspective view of a portion of a micromachined tubing segment such as shown in FIG. 18, in accordance with principles of the invention;
FIG. 20 shows a cross-sectional view, taken along line 20-20 in FIG. 19 of the micromachined tube shown in FIG. 19;

FIG. 21 shows a fragmentary perspective view of a portion of a micromachined tubing segment such as shown in FIG. 19 subjected to torsional forces, illustrating deformation of the tubing;

FIG. 22 shows a cut orientation distribution progressing in an axial direction along a micromachined guidewire segment;

FIG. 23 shows a fragmentary side view of a portion of a micromachined tubing segment illustrating a cut orientation distribution in another embodiment; and

FIG. 24 shows a diagram further illustrating the cut set distribution shown in FIG. 23.

FIG. 1 is a side, fragmentated, partially cross-sectional view of a tubular guide wire formed in accordance with the present invention;

FIGS. 2A, 2B and 3 show side, fragmentated views of three embodiments of a tubular guide wire having integrally formed beams in accordance with the present invention;

FIGS. 4A and 4B is side, fragmentated views of other embodiments of a tubular guide wire formed with integrally formed beams in accordance with the present invention;

FIG. 5 is a side, fragmentated view showing two different types of cuts or etchings which is utilized in a hollow guide wire in accordance with the present invention;

FIG. 6 is a side, fragmentated view of still another embodiment of a tubular guide wire etched or cut to form interlocking teeth, in accordance with the present invention; and

FIG. 7 is a side, fragmentated view of a metal tubular guide wire or catheter, with central metal conductor, suitable for use in making electrical measurements, applying electromagnetic signals to the body, etc.

FIG. 8 is a graph of guide wire tensile strength compared to bending stiffness for the micromachined tubular guide wire of the present invention;

FIG. 9 is a graph of the ultimate torsional strength of the micromachined tubular guide wire of the present invention compared to its bending stiffness;

FIG. 10 is a graph of the torsional stiffness of the micromachined tubular guide wire of the present invention compared to its bending stiffness;

FIG. 11 is a graph showing the ratio of torsional stiffness to bending stiffness of the micromachined tubular guide wire of the present invention compared to its bending stiffness;

FIG. 12 shows cross-sectional views of guide wires disposed within the lumen of circular and elliptical catheters; and

FIG. 13 shows the potential serpentine path of a guide wire through a catheter which tends to wedge the guide wire within the catheter.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

The present invention provides, in an exemplary embodiment, a medical device configured to navigate through anatomy. Some embodiments may be used as a guidewire, and may be solid or tubular. Some tubular embodiments of the device may be used as a catheter, or may be used as either a catheter or a guidewire. Some embodiments may navigate like a guidewire, but once in place, perform many or all of the functions that a catheter may perform. Various embodiments are described herein as examples of the present invention.

As an overview, an example of a medical device in accordance with the present invention, generally has a body with a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end. The device may also have a plurality of pairs of slots cut into the body, each of which may be substantially perpendicular to the axis, and each slot in each pair may be on substantially opposite sides of the axis. Each longitudinally adjacent pair may be rotated an angle around the axis from the previous pair, and the angle may be, for example, less than 87 degrees and greater than 31 degrees. In some such embodiments, the angle may be greater than 87 degrees. In other embodiments, however, the angle may be in the range of 70-90 degrees and the average of the angles, computed over 10 adjacent sets of cuts, may be less than 89 degrees and greater than 70 degrees.

In some embodiments, at least some of the slots may have a cross sectional shape that may be, for example, square, rectangular, wedge-shaped, T-shaped, or substantially circular. In some embodiments, for at least a plurality of the pairs of slots, the first slot may be at substantially the same axial location as the second slot. There may also be a varying longitudinal spacing between adjacent pairs, which may decrease from the proximal end to the distal end, for example to vary the bending stiffness of the device along its length. The slots may have been formed, for instance, by saw-cutting, grinding, laser cutting, etching, or electron discharge machining. One type of grinding that may be used is grinding with a diamond abrasive blade. The body of the device may be nitinol, which may be superelastic, and the distal end of the device may have a detectable element, such as a radiopaque element or an MRI detectable element.

Some embodiments have a tubular polymer sleeve coaxial with at least part of the body. For instance, the body may be tubular, and the sleeve may be inside the body. The sleeve may prevent leakage of liquids through the slots, for example, if the device is used as a catheter to deliver medication to a particular location. In some embodiments, a wire may be disposed inside the tubular body and slidable therein. The wire may have at least one bend formed in it, which may effect the shape of the device when the wire is inside, compared to after the wire is removed. The wire may also effect (e.g. increase) bending stiffness.

The present invention also provides, in a particular embodiment, a catheter configured to navigate through anatomy. The catheter may have a tubular body with a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end. There may also be a plurality of pairs of slots cut into the body, and each slot may be substantially perpendicular to the axis. Each pair
of slots may be on substantially opposite sides of the axis. The device may have a tubular polymer sleeve, which may be inside at least part of the body. There may also be a re-positionable torquer and a luer adapter. The sleeve may be slidably disposed with respect to the body, and may be inside the body. The sleeve may be made, for example, of an elastomer, polyurethane, polyethylene, or Teflon.

[0054] The present invention even further provides a hollow catheter guidewire apparatus that includes a tubular nitinol body with a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end. There may be a plurality of pairs of slots cut into the body, and each slot may be substantially perpendicular to the axis and may be at substantially the same axial location as the second slot in the pair. The two slots in each pair may be on substantially opposite sides of the axis. Each longitudinally adjacent pair may be rotated an angle around the axis from the previous pair. The angle may be, for example, less than 89 degrees, and greater than 31 degrees. In some embodiments, each longitudinally adjacent pair of slots may be rotated an angle around the axis from the previous pair, and the angle may be in the range of 70-90 degrees. In some embodiments, the average of the angles, computed over 0 adjacent sets of cuts, may be, for example, less than 89 degrees and greater than 70 degrees.

[0055] There may be a tubular polymer sleeve coaxial with at least part of the body, and a detachable chuck configured to attach to the body and configured to facilitate manually rotating the body about the axis. The chuck may be configured to facilitate introduction of medications into the interior of the guidewire, and the distal end of the device may be curved to facilitate navigation through the anatomy.

[0056] Referring to FIG. 1 of the drawings, illustrated is one exemplary embodiment of a solid guidewire 200 made in accordance with the present invention. The guidewire 200 includes a proximal end 204, a distal end 208, and a midportion 210 disposed therebetween, with the proximal end being mounted in a conventional pin vise type torqueing chuck 212. The guidewire 200 may be constructed of nickel titanium alloy, and may range in size from about 0.008 inches to about 0.090 inches in diameter and from about 135 to 300 centimeters in length. The guidewire 200 could also be made of stainless steel. Four preferred diameter sizes may be 0.008 inches, 0.014 inches, 0.016 inches and 0.035 inches.

[0057] Cuts, slots, gaps or openings 216 and 220 may be formed in the guidewire 200 along the length thereof, including the midportion 210, either by saw cutting (e.g., diamond grit embedded semiconductor dicing blade), etching (for example using the etching process described in U.S. Pat. No. 5,106,455), laser cutting, or electron discharge machining. Cuts 216 may be angled to allow for a longer cut and thus greater flexibility, whereas cuts 220 may be generally perpendicular to the long dimension of the guidewire.

[0058] As will be discussed in more detail below, the cuts may be specifically configured to form transverse beams within the body of the guidewire. This configuration allows the cuts and beams to interact to provide for lateral flexibility in the guidewire, while maintaining torsional stiffness. By controlling and varying the spacing, depth and type of cuts, the flexure profile and torsional stiffness of the guidewire may be selectively and relatively independently modified. Generally, the more closely spaced the cuts and the greater their depth, the more flexible will be the guidewire. However, modification of the exact shape, orientation, and spacing of the cuts will also allow selective modification or preservation of the torsional characteristics of the cross section independent of flexibility.

[0059] The distal end 208 of the guidewire 200 may be preshaped with a curve, as shown, to allow for directing the guidewire around curves and bends. To maintain flexibility in the distal end 208, cuts may also be provided on that end. Advantageously, the tip may be rounded to minimize the chance of traumatic piercing of body tissue. Also formed on the distal end 208 may be a radiopaque marker band 224. The band 224 may be gold or platinum alloy (for X-ray fluoroscopy) or gadolinium or dysprosium, or compounds thereof (for MRI) and may be formed on the distal end 208 by deposition, wrapping or use of shape memory alloy (SMA) to “lock” the band around the end.

[0060] FIG. 2 is a side, fragmented view of a guidewire 230, showing three alternative type cuts 234, 238 and 240. These type cuts provide a kind of built-in flexure stop to prevent further flexure of the guidewire when the cut openings close to contact one another and prevent further flexure in that direction. Wedge shaped cuts 234 may be formed on opposite sides of the guidewire 230, with the greater width of the wedge being at the bottom of the cut. T-shaped cuts 238 may likewise be formed on opposite sides of the guidewire 230, with the cross piece of the T being at the bottom of the cut. Cuts 240 may be generally circular as shown. It will be apparent that other cut shapes could also be provided to meet the needs of the user. The cuts 234, 238, and 240 are shown oppositely oriented, but it will be apparent that the cuts could also be formed at circumferentially spaced locations about the guidewire, or at alternating locations such as shown and described in more detail with regard to, for example, FIG. 5.

[0061] All three types of cuts shown in FIG. 2 form an integral transverse beam section, shown in cross-hatch as areas 232, 236, and 242, respectively, between oppositely disposed cuts. This configuration may provide at least two distinct benefits. First, it allows the beam section to be longer than the gap of the flexure stop. This allows the amount of strain in the beam prior to stop engagement to be controlled by varying the ratio of beam length to gap size, allowing more flexibility, i.e. less bending resistance.

[0062] The location and shape of the beam section 232, 236, or 242 also greatly influences the torsional characteristics of the guidewire 230. As may be well known by those skilled in mechanics, torsional strength may be primarily provided by the outer portion of the cross section of a member. Thus, for illustration, a relatively thin-walled pipe will have nearly the same torsional strength as a solid bar of the same diameter because the central portion of the cross section of the solid bar contributes very little to torsional strength. Similarly, by comprising a transverse beam which crosses the entire cross-section of the guidewire 230, the beam sections 232, 236, or 242 include a significant amount of the outer portion of the cross section of the guidewire, and therefore transmit varying proportions of the torsional forces from one side to the other of the cuts 234, 238, and 240 depending on their shape.

[0063] For example, beam 232 may be relatively long (measured in the direction of the long axis of the guidewire),
but may be relatively deep (measured transverse to the long axis) and will therefore transmit a relatively large amount of torsional force. Beam 236 may be longer and thinner than beam 232, and will therefore transmit a smaller amount of torsional force across the cut 238. Of the examples given in FIG. 2, beam 240 may be the shortest and strongest of all, and will probably transmit the greatest amount of torsional force. However, given the size and shape of cuts 240, this configuration may provide the greatest flexibility. Because the small flexure stop gaps of cuts 234, 238, and 240 may be varied in width without changing the depth or overall shape of the cut, the flexibility of the guidewire section may be selectively altered without affecting the size or strength of the torsion beam section. Thus, the flexibility and torsional strength of the guidewire may be selectively and relatively independently altered.

[0064] Advantageously, longitudinally adjacent pairs of cuts may be rotated about 90 degrees around the wire from one another to provide flexure laterally and vertically. However, the cuts may transmit to provide preferential flexure between in only one, two, three, etc. directions, if that may be desired. Of course, the cuts could be randomly formed which may allow bending (flex) equally, non-preferentially in all directions or planes. This could be achieved by circumferentially spacing the cuts.

[0065] FIG. 3 shows an alternative embodiment for applying a radiopaque marker to the distal end of a guidewire 244, shown in side, fragmented view. An annular trough or channel 248 may be formed at the tip of the guidewire 244, and a radiopaque wire coil, preferably made of platinum alloy, may be wound around the guidewire in the channel. The coil 252 could be welded or soldered to itself to hold it in place at the tip of the guidewire 244. If a gold or platinum band is used with a nickel titanium alloy guidewire, the guidewire could be cooled and deformed to allow the coil to be placed on the wire and then when the guidewire were returned to room temperature, the coil would be maintained in place on the guidewire without the need for welding or soldering or other joining mechanism, except for joining the coil to itself.

[0066] FIG. 4 is a side, fragmented view of a solid guidewire 260 formed with opposing cuts 264 spaced along a portion of the guidewire, and opposed cuts 266 rotated 90 degrees from opposed cuts 268. As with cuts 266, the rotated cuts 268 may be preferably arranged in opposing pairs, with opposite cut corresponding to 268 not visible on the far side of the guidewire. Of course, the cuts could be formed to provide preferential bending (flex) in one plane, or could be positioned to allow bending in multiple planes. This could be achieved, in some embodiments, for example, by rotating adjacent pairs of cuts by 45 degrees with respect to one another or some other selected angular amount. Also shaded in FIG. 4 is the transverse beam sections 262 between adjacent opposing cuts 264. It will be apparent that the pairs of rotated cuts 268 will also form transverse beams therewith, except that these beams will be oriented at an angle of 90 degrees relative to the beam between cuts 266.

[0067] FIG. 5 is a side, fragmented view of a solid guidewire 270 formed with staggered or offset cuts 274 on opposite sides of the guidewire. A curved distal end 278 is also shown with a radiopaque marker band 280. As with the FIG. 4 embodiment, certain pairs of offset cuts could be rotated with respect to the other pairs, to thereby control direction of flexure. This configuration also presents particular advantages regarding torsional control. As may be evident from FIG. 4, opposed cuts produce thin flexure beams 262 between the bottoms of each pair of opposed cuts. The dimensions and flexure properties of these beams may be determined by the depth, separation and width of the cuts and so the flexibility of a guidewire with opposed cuts may be controlled by varying these parameters.

[0068] Offset cuts, as indicated in FIG. 5, produce much larger flexure beams 272 in the area between each pair of adjacent cuts. As will be expected, these large beams may be able to transmit a relatively large amount of torsion. Depending on the depth of the cuts 274, this section will also comprise relatively thin flexure beams 276 between the base of each cut and the opposing side of the guidewire. While these beams 276 may be relatively thin, they will nevertheless transmit a relatively large amount of torsion because they may be located toward the outside of the cross section.

[0069] It will be apparent that the flexure properties of this guidewire may be determined not only by the depth and width of the cuts (as with opposed cuts) but also by the offset (axial spacing) of the cuts. Consequently, the flexibility of a guidewire with offset cuts can be more accurately controlled by varying any or all of these parameters. Also, the flexibility could be varied simply by controlling the degree of the offset while keeping the depth and width of the cuts constant. More importantly, however, the torsional strength of the guidewire can be maintained because the beam sections which primarily resist torsional force may be more fully preserved with offset cuts.

[0070] Offset cuts provide additional advantages because it may be more practical to produce a consistent pattern of this type of cut than with opposed cuts. Very flexible sections with opposed cuts require very deep and/or wide cuts, and controlling either parameter may be problematic in some embodiments since very deep cuts could overly weaken the guidewire and very wide cuts may result in catching on and/or damaging tissue through which the guidewire may be threaded. Very flexible beams using the offset cut pattern, on the other hand, may be produced without the need for either deep or wide cuts, but rather by simply varying the distance or separation of the offset cuts, and this may be done very accurately.

[0071] FIG. 6 is a side, fragmented view of a solid guidewire 284 having an enlarged proximal section 288, which may provide more torqueability, and a narrowed distal section 292, covered by a hydrophilic polymer sleeve 294. For example, the enlarged section could be 0.014 inches in diameter whereas the narrowed section could be 0.010 inches in diameter. The distal end 296 of the guidewire 284 may be formed with cuts as earlier described. Of course, cuts could also be provided at other locations in the narrowed section 292 or in the enlarged section 288, to increase flexibility, while maintaining high torsional stiffness in many embodiments.

[0072] FIG. 7 is a side, fragmented view of a solid guidewire 300 having a tapered distal end 304 about which may be wrapped a coil 308 made, for example, of platinum alloy. Disposed at the tip of the distal end 304 of the guidewire and in the end of the coil 308 may be a solder ball 312. Cuts 316 may also be formed in the guidewire 300 as
discussed earlier. In addition to the use of cuts to control the flexure of a guidewire, nickel titanium alloy guidewires can be heat treated to vary the flexure characteristics. For example, selective annealing along the length of the wire can change stress/strain relationship of the material, and thus the flexure.

[0073] In the embodiments of a solid guidewire discussed above, the guidewires can be made “flow directable” by providing highly flexible distal ends. “Flow directability” means that the distal end of the guidewire tends to “flow” with the blood around curves and bends in a vasculature passageway. To reduce resistance to movement of a guidewire in a vasculature passageway, the surface of the guidewire may be electropolished to increase the smoothness thereof, and additionally, a lubricious coating may be applied to the surface of the guidewire—such coatings might illustratively include silicone based oil and/or polymer or hydrophilic polymers. Alternatively, a lubricious sleeve made, for example, of a hydrophilic polymer could also be provided for disposal over the guidewire.

[0074] FIGS. 8-11 provide graphical evidence of the improvement this invention provides over the prior art. These graphs depict actual test results of catheter guidewires formed according to this invention, showing the strength of the inventors’ catheter guidewires compared to the prior art, and the relative preservation of torsional strength relative to flexibility. As noted above, the prior art does include catheter guidewires with cuts or notches formed therein to increase flexibility of the distal end of the catheter. However, these cuts may be not formed so as to simultaneously preserve the torsional strength of the guidewire. With these prior art catheter guidewires, the distal end becomes very flexible, but has very poor torsion transmission characteristics. The result may be that the end of the guidewire flops around, but cannot easily be turned or rotated within a catheter or vessel.

[0075] FIG. 8 is a graph of guidewire tensile strength compared to bending stiffness for the micromachined guidewire of the present invention. The individual (square) data points represent tension test results for micromachined guidewires. The ultimate tensile strength in pounds may be indicated on the vertical axis, while the bending stiffness in psi may be given on the horizontal axis. Below the horizontal axis may be a second axis noting the size of stainless steel wire which would correspond to the respective bending stiffness shown in the horizontal axis. The solid line represents the theoretical tensile strength for equivalent solid wires.

[0076] This figure shows that micromachining cuts in the surface of the guidewire does not significantly reduce its tensile strength compared to non-machined guidewires. This may be an important consideration in the catheter field because low tensile strength could increase the likelihood of breakage of the guidewire during a procedure, or while attempting to extract the guidewire from a patient. Obviously such a situation could present a significant medical hazard.

[0077] FIG. 9 is a graph of the ultimate torsional strength of the micromachined guidewire of the present invention compared to its bending stiffness. The vertical axis shows the ultimate torsional strength of the guidewire in units of pound-inches, and the horizontal axis shows the bending stiffness in psi. As with FIG. 8, the square data points represent actual test results of micromachined catheter guidewires, and the solid line represents the theoretical results for a catheter guidewire of solid circular cross section. It will be apparent from this graph that as the bending stiffness (or size) of the guidewire decreases, the expected or theoretical torsional strength also decreases. This is depicted by the solid line. However, as the actual test results indicate, as the size or bending strength of the micromachined guidewire decreases, the torsional strength does not correspondingly decrease as would be expected. Instead, as can be seen from the divergence of the data points from the solid line, the torsional strength of the guidewire decreases at a much slower rate. This situation is depicted in a slightly different way in FIG. 10, which provides a graph of the bending stiffness of the micromachined guidewire of the present invention compared to its torsional stiffness in psi. Again, the actual results diverge from the expected results for smaller and more flexible guidewires.

[0078] The importance of this situation may be more clearly evident from FIG. 11, which is a graph showing the ratio of torsional stiffness to bending stiffness of the micromachined guidewire of the present invention compared to its bending stiffness. In this graph the vertical axis represents a ratio of torsional stiffness to bending stiffness (JG/EI), with the result that the expected relationship of bending stiffness to torsional stiffness (the solid line) may be now a horizontal line. In FIG. 11, this line is set equal to unity, in order to more graphically show the actual results of the inventors’ tests. As can be seen from these actual test results, as the flexure strength decreased, the torsional strength of the micromachined guidewires was more than 30 times more than expected.

[0079] The condition indicated by FIG. 11 represents some unexpected results. When the inventors first began micromachining catheter guidewires, as with the prior art, the goal was primarily to increase the flexibility. However, as guidewire sizes decreased and/or flexibility increased, the inventors noticed a corresponding (and expected) decrease in torsional strength. This may be a significant problem with catheter guidewires because guidewires with low torsional strength cannot be manipulated as easily, and may be more likely to become wedged or jammed into the catheter or vasculature of the patient. With a torsionally weak guidewire, when the user twists the proximal end, there may be a significant delay in the transmission of the torque to the distal end. Indeed, like axially twisting the end of a weak coil spring, most of the rotation may be not transmitted at all. Instead, the geometry of the guidewire may be likely to be deformed into a serpentine shape and wedge into the side of the catheter or vasculature in which it may be located.

[0080] FIG. 12 shows cross-sectional views of guidewires disposed within the lumen of circular and elliptical catheters. As will be apparent, when a circular catheter is advanced into the vasculature of a patient and navigates curves and other tortuous routes, the cross-sectional shape of the catheter frequently tends to flatten out in places into a more elliptical cross-section. When a guidewire 400 is disposed in catheter 402 having a circular cross-section, it would have no preference as to its location within the cross section—its position will present a state of physical equilibrium regardless of its location because all locations may be the same. However, with an elliptical catheter 404, the guidewire 400 in a central location represents a state of
unstable equilibrium, like a ball sitting on the top of another ball. The result may be that the guidewire will naturally gravitate to a point of stable equilibrium 406, in the tight corner of the catheter lumen. In this condition, it can be seen that the area of contact between the guidewire and the catheter may be much larger, resulting in large frictional forces which will hinder the easy movement of the guidewire within the catheter.

[0081] This condition will also tend to wedge the guidewire within the catheter simply by virtue of the serpentine shape. FIG. 13 shows the potential serpentine path of a torqued guidewire 420 through a catheter 422. By virtue of the deformation of the guidewire 420, when an axial driving force (denoted Fwire in FIG. 13) may be applied to the guidewire 420, it will be converted into an axial force (denoted Fxial) and a perpendicularly oriented wedging force (denoted Fwedge) which may tend to jam the guidewire within the catheter.

[0082] To prevent these problems, the inventors experimented with methods of providing cuts in catheter guidewires that would increase flexibility without reducing torsional strength as much. It was hoped that for a guidewire of a given flexibility, the torsional strength could be increased by 50% above the theoretical or predicted torsional strength. After trying many configurations, the inventors discovered that forming cuts in the guidewires so as to create beams with a particular location and configuration would allow flexibility to be increased without a correspondingly large decrease in torsional strength. The inventors were pleasantly surprised when testing the present invention to find that instead of a 50% increase of torsional strength, they had found a way to provide a more than 3000% increase in torsional strength. As a result, guidewires formed by the present method provide significantly greater torsional strength relative to their flexibility than the prior art.

[0083] With reference to FIG. 13 a guidewire 500 in accordance with principles of the invention comprises a proximal portion 502 extending from a proximal end 504 to a first transition portion 506 where the diameter of the guidewires changes. This proximal portion comprised a stainless steel core wire 501 configured as solid wire of circular cross section. The core wire in the proximal portion may be covered with a low friction coating. For example PTFE may be used to coat the proximal portion in the illustrated example. The proximal portion has a diameter as large as needed to transmit torque sufficient for the intended use of the guidewire. For coronary and some peripheral uses for example a diameter of about 14 thousandths of an inch may be appropriate, and may be used in the illustrated example.

[0084] At the first transition portion 506 the stainless steel wire may be ground to a smaller diameter, transitioning over an axial length sufficient to provide a smooth transition. This may be about 2 inches in one embodiment. Beginning at and distal of the first transition portion the guidewire 500 has a more complex configuration. A proximal coil 508 may be disposed over the stainless core wire 501. The core wire continues to the distal end 510 of the guidewire, the proximal coil overlaying the core wire as will be further explained. The proximal coil may be attached to the core wire at the first transition portion 506 by a proximal solder joint 512 at a point where the inner diameter of the coil matches the outer diameter of the core wire. The diameter of the core wire continues to decrease under the proximal coil, and beyond it in accordance with a grind profile that will be described.

[0085] At a distal end of the proximal coil 508 the guidewire 500 in an exterior aspect comprises a micromachined tubing 514 formed of a superelastic material such as NiTi alloy. This micromachined tubing may be very important to functionality of the catheter guidewire, as it transmits torque to the distal end 510 of the guidewire but may be very flexible. The micromachined tubing overlays additional structure as will be described below. The micromachined tubing may be attached to the proximal coil 508 via other underlying structure, and the core wire 501 at a medial solder and glue joint 516. The location of this joint may be important as it may be the point where the torsional force “carrying capacity” of the core wire 501 is substantially equal to that of the micromachined tubing. A force path may therefore be established which extends through the core wire from the proximal end 504 of the guidewire 500 to the medial solder and glue joint 516, then continues through the micromachined tubing 514 to the distal end 510 of the guidewire 500.

[0086] As can be appreciated, the view of FIG. 13 is fragmented, and not to scale. The outer diameter of the proximal coil 508 may be substantially the same as the proximal portion 502 of the core wire. The outer diameter of the micromachined tubing 514 at the distal tip portion 511 of the guidewire 500 may be also approximately the same, all being about 14 thousandths of an inch. In one embodiment the proximal coil is about 11 inches long and the distal tip portion comprising the micromachined tubing is about 2 inches long. The distal tip portion can be given a curved or other bent configuration.

[0087] At the distal end 150 of the guidewire 500 the micromachined tubing, underlying structure (not shown), and the core wire 501 may be attached at a distal solder and glue joint 518. The core wire has a very small diameter at the distal end, the grind profile reducing it to approximately 2 thousandths of an inch prior to reaching that point. The distal solder and glue joint comprises an adhesive 520 which may be formed into a rounded configuration at the distal end of the guidewire to form anatraumatic tip.

[0088] Turning to FIGS. 14-18 the construction of an exemplary guidewire configuration will be described in more detail. With reference particularly to FIG. 14, the core wire 501 alone may be seen to advantage, with the grind profile appreciable. The corewire has a rounded configuration at the proximal end 504 of the wire, and the proximal portion 502 may be as previously described, and may be about 65 inches in length in one exemplary embodiment. The grind profile extends about 14 inches further to the distal end 510 of the guidewire 500. In addition to the first transition portion 506, a second 522 and a third 524 transition portion may be provided. Distal of the first transition, which as mentioned may be about 2 inches in length in the exemplary illustrated embodiment, the core wire has a first reduced diameter portion 526 having a length of about 6 inches and a diameter of about seven and a half thousandths of an inch. The second transition portion may be also about 2 inches in length, and the diameter further reduces from that of the first reduced diameter portion to about five and a half thousandths of an inch. This diameter may be maintained for...
about two and a half inches, to form a second reduced diameter portion 528. At the third transition portion 524 the diameter further decreases to about two thousandths of an inch, which may be maintained to the distal end 510 as mentioned, to form a third reduced diameter portion 530. This third transition portion may be about one tenth of an inch in length, and the third reduced diameter portion may be about one and nine tenths inches in length in the illustrated exemplary embodiment. The third reduced diameter portion may be configured to be extremely flexible as will be appreciated, but retain sufficient axial strength to help prevent distal tip separation on withdrawal of the guidewire from a position where the tip may be stuck in the anatomy, and to assist in facilitating pushability of the distal tip portion 511 of the guidewire.

[0089] With reference to FIG. 15, the underlying structure mentioned before will now be described. A medial coil 532 may be attached to the core wire 501 at the third transition portion 524. The medial coil has an outer diameter substantially equal to the inner diameter of the proximal coil 508 and the inner diameter of the micromachined tubing 514. It may be attached by soldering, and this location of attachment on the third transition portion may be that of the medial solder and glue joint mentioned above. Also, it will be noted that the location may be near the proximal end of the third transition portion, so that the diameter of the core wire at this location may be substantially the same as the second reduced diameter portion 528. As the core wire transfers torque to the micromachined tubing at this location as mentioned above, the location on the grind profile may be important as it represents the “end of the line” for torque transmission through the core wire, and the diameter of the core wire may be directly proportional to the amount of torsional force that can be transmitted, the location and diameter may be chosen in conjunction with selection of the parameters of the micromachined tubing so that the “carrying capacity” for torque may be substantially equal. A mis-match represents an inefficiency in this regard and may be to be avoided unless for some design objective a discontinuity in tortuosity may be desired at this point.

[0090] The medial coil 532 may be formed of stainless steel in one embodiment, and has a proximal unwound portion 534 at its proximal end, to aid in more secure bonding to the core wire 501 as a longer length of coil wire can be bonded due to slight deformation thereby allowed to follow the grind profile. The medial coil has a distal unwound portion 536 which will be further described next.

[0091] Turning to FIG. 16, a distal coil 538 may be disposed over the third reduced diameter portion at the distal tip portion. The proximal end of the distal coil may be provided with an unwound portion 540 which cooperates with the distal unwound portion 536 of the medial coil to form a secure interlock by intertwining of the coils, then soldering. As will be appreciated the distal coil can be of slightly larger diameter wire, due to the reduced grind profile it overlays, but the outside diameter may be held to be slightly less than that of the inside diameter of the micromachined tubing (not shown) as will be described. The distal coil may be formed of a radiopaque material in the illustrated embodiment to provide enhanced fluoroscopic visibility. Materials such as platinum, gold, palladium, dysprosium, as known in the art, may be used for this purpose, and accordingly the increased diameter wire used provides more radiopacity when formed of such a material useful for this purpose. The distal coil thus acts as a marker to aid in navigation of the guidewire within the anatomy of a patient. As will be appreciated, the drawing figures may not to scale, and the distal coil can be considerably longer than the medial coil 532. The distal end of the distal coil may be soldered to the core wire 501 adjacent the distal end 510 at the location of the distal solder and glue joint 518.

[0092] With reference to FIGS. 14, 15, 16, and 17, it will be appreciated that the guidewire 500 apparatus may be assembled by attaching the medial spring 532 to the core wire, then attaching the distal (marker) coil 538 to the medial coil, then the proximal coil may be slipped over the assembly and soldered to the core wire 501 at the proximal solder joint 512 and to the medial coil 532 at the location of the medial solder and glue joint 516. The solder used throughout may be a silver or gold alloy solder or another material regulatory-approved for such use.

[0093] With reference to FIG. 18, fabrication of the catheter may be completed by placement of the micromachined tubing 514 over the distal tip portion 511. It may be fixed in place by securing it at its proximal end at the medial solder and glue joint 516 by means of a suitable adhesive such as a UV cured regulatory-approved adhesive such as Dymax, and by attaching the distal end to the distal tip of the core wire 501, and also to the distal (marker) coil by an identical or similar adhesive. As mentioned this adhesive when cured forms a rounded tip 520 to reduce trauma, and completes the distal solder and glue joint which holds together the core wire, distal marker coil, and the micromachined tubing at the distal end 510 of the guidewire.

[0094] The guidewire can further include a micromachined “barcode” identification 142 located at a convenient location such as adjacent the proximal or distal end of the guidewire. The barcode may be made by very lightly scoring the surface to form a binary code to encode identifying information regarding the catheter. This may be done by a similar process to that used to micromachine the tubing 514 or another guidewire as discussed above and as follows. The advantage of such a marking system may be that individual guidewires can be identified, enabling “lot of one” custom manufacturing and marking of one to as many as desired guidewires 500.

[0095] Turning now to FIG. 19, discussion of the micromachined tubing 514 more specifically should include mention of how the tubing may be made. In addition to the description above with regard to wires generally, and below with regard to this tubing segment specifically, further details regarding fabrication of the tubing can be found in co-pending U.S. patent application serial no., Attorney Docket No. T3681.CIP1, the disclosure of which may be hereby incorporated herein by reference.

[0096] As will be appreciated, enhanced performance may be obtained by optimization of one or more physical attributes of the guidewire. In the case of the illustrated exemplary embodiment now being discussed, a unique construction combined with optimization provides increased tortuosity while allowing flexibility, so as to be compliant with tortuous vasculature in accessing a target site within the patient’s anatomy.

[0097] For the moment digressing to review of a more general case, when a member of circular cross section may
be used to transmit a torsional force, the overwhelming majority of the force may be “transmitted” by the outer portions of the member, the capacity to resist deformation due to induced stress being maximum at the outer circumferential surface of the member. Accordingly, whether a tubular member or a solid member of circular cross-section of a given material may be used to transmit torque, relatively little increase in diameter for the tubular member may be required to transmit the same amount of torque because in fact the “middle” portion of a solid circular member contributes very little to resistance of the stresses, and hence does little to transmit them.

The present invention may be directed to maximizing torque transmission, while minimizing resistance to bending of a guidewire body, for example in the tubular member 514 shown. To do so, from the foregoing it will be apparent that only the equivalent of a tubular structure may be implicated, even though a solid member may be used. Therefore the following discussion will apply to solid wires as well, though it will be understood that this may be because an assumption may be made that the inner portion of the wire may not contribute appreciably, and the structure other than a tubular portion of it may be being ignored. In practice a tubular configuration may be advantageous as other structure can be placed inside, as in the case of the illustrated embodiment given by example herein employing a tubular micromachined tubing segment 514 at a distal tip portion 511.

One way in which the guidewire distal tip portion may be optimized may be using superelastic material, preferably formed as a tube, micromachining the tube to create a structure which maximizes torque transmission while minimizing resistance to bending. A section of micromachined tubing 514, having slot-like cuts formed therein may be shown to illustrate the structure. The cuts may be opposed cuts in the illustrated embodiment. That may be, two cuts may be made from opposite sides of the tubing at the same location along the longitudinal axis of the tubing. The depth of the cuts may be controlled to leave a segment 546 of the tubing wall extant between the cuts on each of the opposite sides (180 degrees apart) of the tubing. These segments will act as “beams” as discussed above to carry forces across the cut area at that location along the longitudinal axis 548 of the tubing. As a matter of convention such segments will be referred to as “axial beams” 546 as they carry or transfer forces in roughly an axial direction from adjacent structure on one side to adjacent structure on the opposite side. When a pair of opposed cuts 550 is made adjacent to the cuts previously described (544) the location of the cuts may be made such that the axial beam(s) 546A formed by the second set of cuts may be displaced circumferentially from the adjacent axial beam(s) 546. This of course may be done by rotation of the tube relative to the saw used to cut the tubing through some angle before cutting. This can be seen in FIG. 20. The amount of rotation may be selected with each successive cut to give a pattern calculated to facilitate torque transmission while also facilitating bending of the tube after machining. The specifics of this cutting distribution will be discussed below. With reference again to FIG. 19, what may be important to this discussion is that in addition to axial beams, other beams, which by convention we will call transverse beams 552 may be created.

The transverse beams 552 may be defined as the curved portion of the tubing wall between adjacent cuts 544, 550 and adjacent axial beams. e.g. 546 and 546A. As will be appreciated, these transverse beams carry forces from a particular set of axial beams to the two adjacent axial beams created by the adjacent set of cuts.

With reference to FIG. 21, as will be appreciated once a tube 514 has been fabricated and a torque force may be applied at one end, say the proximal end, with respect to another, say the distal end, the forces in the machined tube will tend to deform the axial and transverse beams, e.g. 546 and 552. In order to optimize the machined tube for maximum torque transmission, the goal may be to match, insofar as possible, the strain in the axial and transverse beams all along the length of the wire. This may be so that one or the other will not constitute a weak point which will fail by deformation well beyond that of the adjacent axial or transverse beams when the torqueing force may be applied. As can be appreciated, with reference to FIG. 19 this matching can be done in tubing of constant cross section by variation of several parameters, namely the location (spacing 555 between), width 556, and depth 558 of cuts (e.g. 544, 550) made. Wider spacing of cuts creates wider transverse beams, shallower cuts create wider axial beams. Likewise more closely spaced cuts create narrower transverse beams, and deeper cuts create more narrow axial beams. Wider cuts create longer axial beams. The configuration of the micromachined tubing may be defined by calculation, using well-known formulas for stress and strain. The design process can further include finite-element analysis of the configuration to give localized stress and strain values. The calculations may be repeated as necessary using incrementally changing parameters to optimize the design taking into account the concepts set forth herein.

As a practical matter in manufacturing, a saw blade of a specified width will be used. And accordingly the width of all cuts may be held to this value. In the illustrated embodiment a diamond silicon wafer cutting saw blade (as may be used in the microprocessor and memory chip manufacturing art—not shown) about one thousandth of an inch wide may be used to make the cuts (e.g. 544). While it may be possible to make wider cuts by making a first cut, then moving the wire relative to the blade by a distance up to a width of the blade, and repeating as necessary for wider cuts, speed of fabrication may be higher if a single cut may be used. Therefore, using this constant cut width, the possible variables may be depth 558 of cut and spacing 555.

Given that cut width 556 may be to be held constant, in one embodiment the other parameters may be selected as follows. The bending stiffness desired at any selected location along a length of tubing may be obtained by selecting of an appropriate spacing 555 between cuts. Given that the width of cut may be a constant, in the calculations, selection of a distance between the set of opposed cuts to be made (e.g. 546A) and the last set of opposed cuts made (e.g. 546) will define, by means of the calculations, the depth of the cuts to be made as the distance between cuts defines the width of the transverse beams, and the width of the transverse beams may be related to the width of the axial beam by the condition of equality of strain values to be obtained for a given applied torsional force 554 as mentioned.
[0104] The locations of the axial beams 546 will be set by the relative angular displacement of the adjacent sets of opposed cuts, as will be described, and hence the width and the length of the transverse beams 552 will be known. The width of the axial beams to be created depends on the depth of cut. The length of each axial beam may be the same and equal to the constant cut width (e.g. one thousandth of an inch in the illustrated embodiment). The depth of cut may be determined by comparison of the strain in the each of the resulting axial beams (they may be assumed to be the same, though in fact they may not be in all cases due to differing force distribution due to variations in geometry) and then matching the strain in the axial beam(s) (e.g. 546) with the strain in the transverse beam(s) (e.g. 552). As will be appreciated, four transverse beams may be created between each set of opposed cuts. The resulting strains may be evaluated in each of the four beams, but in one embodiment another simplifying assumption may be made that the strain in the two shorter transverse beams may be the same, and likewise the strain in the two longer transverse beams may be the same. The greater of the resulting strains in the transverse beams may be compared with the strain in the axial beams. This represents the force transmission path for transfer of the torque. The depth of cut 558 may be varied until the strains may be matched. This value may be then used in making the cuts at that location.

[0105] Other factors may be taken into consideration. For example, there may be a practical limit on the size of axial and transverse beams. Too large at the desired advantages may be lost, too small and imperfections in materials and variations within the tolerances in machining can compromise performance. This may be governed by the thickness of the tubing if tubing may be used, the size of the saw blade, accuracy of the machining apparatus, etc. Generally speaking, axial or transverse beams having dimensions on a par with or smaller than the width of the cutting blade used to micromachine them may be avoided.

[0106] The design process then, in summary, may be in one embodiment to space the cuts (e.g. 544, 550) apart along the axis 548 of the tubing so as to provide bending as desired. The cuts may be closer together to give less resistance to bending, and more spaced apart to give more resistance to bending. (See, for example FIGS. 13 and 18, where the tubing segment 514 becomes more flexible toward the distal end 510 of the guidewire 500.) The stiffness can be controlled by means of variation of the spacing 555 of the cuts, the other parameters being selected as appropriate as described above. The bending stiffness of the tubing can vary along the longitudinal axis, for example being made to gradually become less stiff toward the distal end, by gradually decreasing the spacing between cuts as in the above example.

[0107] As discussed, the depth 558 of the cuts may be calculated using stress/strain relationships to match the strain in the axial 546 and transverse 552 beams created. In one embodiment as the calculation progresses, the strain in the axial beams may be matched to that of the greatest calculated in the previously calculated transverse beams. Alternatively another method could be employed, for example comparing the strain in a given axial beam 546 to that of the transverse beams 552, 552A on either side of the axial beam along the axis 548 of the tubing 514 to match the strain. In another embodiment the average of the highest strain values in transverse beams 552, 552A, 552A (552A1 and 552A2 being of unequal length the strains may be markedly different), on either side can be used to match the strain in the axial beam 546 under consideration. As will be appreciated, varying the thickness of the axial beam(s) affects the forces transmitted to the transverse beams and therefore varies the stress and strain in the transverse beam; so, as a result, many iterations of these calculation steps can be required to optimize the design. Likewise, adjustment of the size of one set of axial and transverse beams will affect the stresses and strains in adjacent sets of axial and transverse beams, so additional calculations and re-calculations can be required to optimize by matching strain throughout all the adjacent axial and transverse beams. Practical considerations will require the use of a computer and appropriate algorithm programmed therein to optimize these design parameters.

[0108] With reference again to FIG. 20, the distribution of the orientation of adjacent cut pairs giving rise to the axial beams 546 left after the cuts are made, will now be discussed. The object may be to provide a distribution of cut orientations along the length of the tubing that minimizes “preferred” bending directions of the micromachined tubing 514 giving rise to undesirable effects collectively referred to as “whip” or a deviation of expected rotational result at the distal tip of the guidewire from that expected by the user from rotational inputs made at the proximal end of the guidewire by turning the collet fixture 512.

[0109] With reference to FIG. 22, one way of organizing the cut distribution to minimize whip is to assume a first cut pair of opposed cuts (180 degrees apart) and a second pair of opposed cuts immediately adjacent will be offset by an angle of ninety degrees. Collectively the four cuts will be referred to as a first cut set 560. A second cut set 562 of adjacent opposed cuts oriented ninety degrees apart may be subsequently made, these being oriented with respect to the first cut set (designated arbitrarily as oriented at 0 degrees) so as to be rotated 45 degrees. The next similar cut set 564 may be oriented at 22.5 degrees, and the next at 67.5 degrees, and so on in accordance with the distribution graphically illustrated in the figure. The sequence repeats every 64 cut sets (128 opposed cuts, and 256 cuts in total).

[0110] With reference to FIGS. 23 and 24, in another embodiment, the cut distribution may be defined by a helical pattern. A first cut pair 570 may be at zero degrees. A second cut pair 572 may be rotated with respect to the first through a chosen angle “x”. For example, this angle can be 85 degrees. A third cut pair 574 may be oriented by rotation through an angle equal to 2x, or 170 degrees in the exemplary embodiment. This pattern may be continued, as the next cut pair (not shown) may be oriented at 3x or 255 degrees, etc. continuing to turn, for example, in the same direction and by the same magnitude of angular rotation, x. The bending axis 576 formed by the first cut pair 570 may be oriented at 0 degrees; and the next bending axis 578 formed by the second cut pair may be oriented at 85 degrees in the example, and the third bending axis 580 at 170 degrees, and so on. This exemplary pattern will repeat after 72 cut pairs (144 total cuts) where x may be equal to 85 degrees. The orientation of any pair of cuts (and hence the bending axis) will be given by the following sequence: Pair 1=0 degrees; Pair 2=x degrees; Pair 3=2x degrees; Pair N=(N-1)x degrees. Where the increment may be 85 degrees this
may be equivalent to 0; 85; 170; 255; \ldots \ (N-1)85 \ldots degrees. This has been found to give good bending and torque transmission characteristics and low whip.

[0112] Thus, each longitudinally adjacent pair of cuts may be rotated an angle around the axis from the previous pair, and the angle may be, for example, less than 89 degrees and greater than 31 degrees. In some such embodiments, the angle may be greater than 80 degrees (e.g. 85 degrees). In other embodiments, however, the angle may be in the range of 70-90 degrees and the average of the angles, computed over 10 adjacent sets of cuts, may be less than 89 degrees and greater than 70 degrees. As an example, the angle may alternate between 90 degrees and 80 degrees, thus averaging 85 degrees. Other patents satisfying this average would be apparent to a person of skill in the art. As would also be apparent to a person skilled in the art, a 95 degree rotation is the same thing as an 85 degree rotation, the opposite direction (just a change in the direction of the helix). Thus, in this situation and as used herein, a range of 31 to 89 degrees in the rotation angle between cuts, for example, is the same as a range from 91 to 149 degrees. Similarly, a range of 70 to 90 degrees is the same as a range of 90 to 110 degrees.

[0113] With reference now to FIGS. 9, 10, 11 and 13 in comparing 0.014 inch diameter Ni Ti tubing micromachined as discussed herein to conventional guidewire configurations and stainless steel tubing, it can be seen that the micromachined tubing may be superior to conventional guidewire configurations when the diameter of the stainless steel core wire, which conventionally transmits the great-majority of the torque, drops below about 5 thousandths of an inch on the guidewire. Since no advantage may be obtained when the core wire is this diameter and larger, there may be no reason to provide micromachined tubing proximal of the point where the guidewire drops to this value. Accordingly, for example in the illustrated embodiment it will be observed that where the medial solder/glue joint (516 in the FIGS.) may be located may be substantially at the point where the guidewire drops to about 0.005 inch diameter. As explained, the Ni Ti tubing segment which has been micromachined as described above provides a superior path for transmission of torque to the distal tip 510 of the guidewire from that point while at the same time facilitating bending. Thus the exemplary embodiment illustrates that the guidewire configuration can be optimized for cost as well, the less expensive stainless steel core wire and conventional coil configuration being provided up to the point where better characteristics may be obtained with a micromachined configuration.

[0114] Other features of the guidewire can include providing lubricious coatings on components distal of the proximal portion 502 previously described as including such a coating. For example a silicone coating as may be known in the art can be applied in one of the many manners known in the art.

[0115] Another feature may be that the micromachined tubing can be deburred after micromachining if necessary. For example an acid wash etching process can be used to deburr the inner surfaces, and the tubing can be placed on a mandrel and turned while being subjected to an abrasive jet to dauber and round the micromachined edges to minimize the possibility of catching on anatomy.

[0116] In another aspect, the micromachining pattern can be altered to provide preferred bending directions. This can be useful in customizing the guidewire to reach a target location within a particular anatomical structure, or even a particular individual patient. As an example of this, a MRI or CAT scan can produce a data set from which a preferred access route, for example, vasculature to a target site, can be constructed in three dimensions. The guidewire can be micromachined to provide locally variable flexibility as needed to facilitate the traversing the last critical distance to the target site. A catheter individually customized for that patient could be made from that same data set (for example sent to the manufacturer via the Internet) and shipped out to the user very rapidly, since micromachining may be a computer-controlled automated process that could be customized based on the data set in accordance with another automated procedure. This guidewire (or catheter for that matter) could be individually identified by a bar code as described herein.

[0117] As will be appreciated the guidewire 500 system in accordance with principles of the invention enables improved performance over conventional configurations, and can be optimized for cost and performance. It may be understood that the above-described exemplary embodiments and arrangements may be only illustrative of the application of the principles of the present invention. Numerous modifications and alternative arrangements may be devised by those skilled in the art without departing from the spirit and scope of the present invention and the appended claims may be intended to cover such modifications and arrangements.

DETAILED DESCRIPTION OF EXEMPLARY TUBULAR EMBODIMENTS

[0118] FIG. 1 is a side, fragmented, partially cross-sectional view of a tubular guide wire 320 made in accordance with the present invention. A pin vise type torqueing chuck 324 is shown attached to a proximal end 328. The chuck 324 may include an opening, bore, or luer adapter 332, which may be, for example, configured to facilitate introduction of medications into the interior of the tubular guide wire 320.

[0119] Wire mandrel 333 may be insertable in the hollow of the tubular guide wire 320. Wire mandrel 333 may be made radiopaque to X-ray fluoroscopy or, if magnetic resonance imaging (MRI) were used, the wire mandrel 333 may be made of a material active for MRI detection such as gadolinium or gadolinium compound, gadolinium encapsulated in a sheath, dysprosium, or dysprosium encapsulated in a sheath. Alternatively, a radiopaque solution could be introduced into the interior of the tubular guide wire 320 or a solution visible in MRI could be used, if MRI rather than X-ray fluoroscopy were utilized. The purpose of such a wire mandrel or solutions, of course, would be to allow tracking location and/or movement of the guide wire 320 as it may be threaded into vasculature or body cavities.

[0120] The wire mandrel 333 could also be used to change the curvature of the tubular guide wire 320 as desired by the user. For example, the tubular guide wire 320 could be formed with a portion of it curved or angled (such as the curved distal end 340 to be discussed momentarily) and a straight wire mandrel 333 could then be inserted into the guide wire to straighten it out and then removed when desired to allow the guide wire to resume the curved shape.
Alternatively, the tubular guide wire 320 could be formed to be straight and the wire mandrel 333 formed with selected curves so that when the mandrel were inserted into the tubular guide wire, the mandrel would cause the guide wire to assume those same curves and when the mandrel were removed, the guide wire would again straighten. In this manner, depending upon the initial shape of the wire mandrel 333 and/or the tubular guide wire 320, the shape of the guide wire can be controlled to a certain extent while disposed in vasculature or body cavities.

[0121] Advantageously, the tubular guide wire 320 may be constructed of nickel titanium alloy and may range in size from about 0.008 inches to 0.090 inches in outside diameter, and about 0.005 inches to 0.084 inches in inside diameter, and about 175 to 300 cm in length. The tubular guide wire 320 could also be made of stainless steel, polymers or other flexible materials having suitable strength.

[0122] Cuts, slots, gaps or openings 334, 336 and 338 may be formed in the tubular guide wire 320 along the length thereof, either by saw cutting (e.g. diamond grit embedded semiconductor dicing blade); electron discharge machining, laser cutting or etching (for example using the etching process described in U.S. Pat. No. 5,106,455) anisotropically to provide for lateral flexibility in the guide wire. Cuts 334 may be generally perpendicular or crosswise to the long dimension of the guide wire and may be shown as being cut on alternate sides of the guide wire. (Various alternative cut patterns will be discussed in more detail later.) Cuts 336 may be angled to allow for a longer cut, and cuts 338, on the distal end 340 of the guide wire, may be also formed perpendicular to the guide wire.

[0123] As will be discussed in more detail below, the cuts form transverse beams within the body of the guide wire. This configuration allows the cuts and beams to interact to provide for lateral flexibility in the guide wire, while maintaining torsional stiffness. By controlling and varying the spacing, depth and type of cuts, the flexure profile and torsional stiffness of the guide wire may be selectively and relatively independently modified. Generally, the more closely spaced the cuts and the greater their depth, the more flexible will be the guide wire. In the preferred embodiment, the cuts on the distal end of the guide wire may be formed so as to allow a minimum bending radius of the distal tip of 1/2 inch or less. However, modification of the exact shape, orientation, and spacing of the cuts will also allow selective modification or preservation of the torsional characteristics of the cross section at the distal end and at various locations along the tubular member somewhat independently of flexibility.

[0124] The distal end 340 of the guide wire may be preshaped with a curve, as shown, to allow for directing the guide wire around curves and bends. The cuts 338 allow for maintaining the flexibility in the distal end 340. Advantageously, the tip may be rounded to minimize the chance of traumatic piercing of body tissue. Also formed on the distal end 340 may be a radiopaque or MRI marker or band 344. The band 344 may be gold or platinum alloy (for X-ray fluoroscopy) or gadolinium or dysprosium, or compounds thereof (for MRI), and may be formed on the distal end 340 by deposition, wrapping or use of the shape memory alloy (NiTi) effect to “lock” the band around the end. Alternatively, a radiopaque plug may be disposed in the lumen at the distal end 340 (or an MRI marker).

[0125] FIG. 2A is a side, fragmented view of a tubular guide wire 350 formed with perpendicular cuts 354, 358, 362, 366, etc., along the length thereof. The cut 354 may be formed on the top of the guide wire 350, the cut 358 may be formed on the bottom, the cut 362 may be formed on the near side of the guide wire, and the cut 366 may be formed on the far side. In effect, each cut may be rotated by 180 degrees or 90 degrees, and offset from the preceding cut. Of course, the cuts could be formed to provide preferential bending (flex) in one plane, or could be randomly formed to allow bending (flex) equally, non-preferentially in all planes. This could be achieved, for example, by circumferentially spacing the cuts. In the preferred embodiment, the cuts may be circumferentially spaced or rotated in small increments, such as 50, 100, 200, etc., in a generally random pattern so as to create a tubular member having relatively uniform flexural bending characteristics in all directions relative to the longitudinal axis of the member. This eliminates preferential bending in any one plane, which may be advantageous in many applications.

[0126] The perpendicular cuts in FIG. 2A create relatively thin flexure beams 356 between the base of each cut and the opposing side of the tubular guide wire. While these beams 356 may be relatively thin, they will nevertheless transmit a relatively large amount of torsion because they may be located toward the outside of the cross section.

[0127] FIG. 2B is a side, fragmented view of a tubular guide wire 365 formed with pairs of cuts 367 formed on opposite sides of the guide wire and staggered or offset. These cuts form beams 364 thereinbetween. The flexibility (bending stiffness), longitudinal strength and torsional stiffness of the tubular guide wire may be determined primarily by the dimensions and flexure properties of the beams formed by the cuts; e.g., beams between opposing cuts (such as beams 376, 422, 426, and 430 between cuts 374, 424, 428, and 432, in FIGS. 3 and 5 respectively); and beams between adjacent offset cuts (such as beams 356 and 364 between cuts 354, 358, 362, 366 in FIG. 2A, and 367 in FIG. 2B). These properties, in turn, may be determined by the depth, width and separation of cuts. Very flexible sections with opposed cuts (such as shown in FIG. 3) generally require that the cuts be deep and/or wide, to yield flexible beams 384.

[0128] However, it may be sometimes difficult to precisely control the depth of cuts without overly weakening the guide wire; and especially wide cuts may be impractical because they may cause the guide wire to catch or snag on body tissue. Very flexible sections with offset cuts (such as shown in FIGS. 2A and 2B) may be achieved by reducing the spacing between the cuts to yield flexible beams 364 (FIG. 2B), and this may be more accurately controlled than may be cut depths, as already discussed. Thus, the use of offset cuts allows for accurately controlling the flexibility of guide wires without the attendant risk of overly weakening them as to torsional or longitudinal strength.

[0129] Opposed cuts such as shown in FIG. 3 and FIG. 5 produce relatively thin flexure beams between the bottoms of each pair of opposed cuts on each side of the tubular member. The dimensions and flexure properties of these beams may be determined by the depth, separation and width of the cuts. Consequently, the flexibility of a guide wire with opposed cuts may be, controlled by varying these
parameters. Offset cuts, as shown in FIG. 2B, generally produce much larger flexure beams in the area between each pair of adjacent cuts. As will be expected, these larger beams may be generally able to transmit a larger amount of torsion.

[0130] It will be apparent that the flexure properties of this guide wire may be determined not only by the depth and width of the cuts (as with opposed cuts) but also by the offset (axial spacing) of the cuts. Consequently, the flexibility of a guide wire with offset cuts can be more accurately controlled by varying any or all of these parameters. Also, the flexibility could be varied simply by controlling the degree of the offset while keeping the depth and width of the cuts constant. More importantly, however, the torsional strength of the guide wire can be maintained because the beam sections which primarily resist torsional force may be more fully preserved with offset cuts.

[0131] Offset cuts provide additional advantages because it may be more practical to produce a consistent pattern of this type of cut than with opposed cuts. Very flexible sections with opposed cuts require very deep and/or wide cuts, and controlling either parameter may be problematic since very deep cuts could overly weaken the guide wire and very wide cuts may result in catching on and/or damaging tissue through which the guide wire may be threaded. Very flexible beams using the offset cut pattern, on the other hand, may be produced without the need for either deep or wide cuts, but rather by simply varying the distance or separation of the offset cuts, and this may be done very accurately.

[0132] Disposed in the tubular guide wire 350 may be a solid wire mandrel 361 having a bend 368, which will cause the tubular guide wire 350 to conform to the same bend, as previously discussed. The solid wire mandrel 361 provides stiffening for the tubular guide wire 350 for that portion in which the mandrel may be inserted. A stop 363 may be located at the proximal end of the mandrel 361 to prevent movement of the mandrel, and in particular the distal end of the mandrel, beyond a certain point in the guide wire 350, for example, to avoid puncturing tissue beyond the distal end of the guide wire by the distal end of the mandrel. Further, the mandrel 361 could have a tapered, and thus more flexible, distal end, along with (or without) a blunt or dull tip.

[0133] FIG. 3 is also a side, fragmented view of a tubular guide wire 370, also with cuts 374, 378, etc. formed therein. Cut 374 may actually be two cuts formed on the top and the bottom of the guide wire 370, whereas cut 378 comprises two cuts formed on the near side and the far side, etc. A distal end 382 of the guide wire 370 may be curved, and includes a radiopaque or MRI band 386. (The distal ends of the guide wires can also be shapeable by the clinician by heating and/or bending.

[0134] FIGS. 4A and 4B show a side, fragmented views of a tubular catheter 400 having opposed cuts 404 formed at an angle with the long direction of the guide wire, and tubular guide wire 408 having offset cuts 412 formed at an angle with the long direction of the guide wire, respectively. Of course, the cuts could be formed to provide preferential bending (flex) in one plane, or could be positioned to allow bending in multiple planes. This could be achieved, for example, by rotating adjacent pairs of cuts by 45 degrees with respect to one another or some other selected angular amount.

[0135] FIG. 5 is a side, fragmented view of a tubular guide wire 420, showing three alternative type cuts 424, 428 and 432. These type cuts may provide a kind of built-in flexure stop to prevent further flexure of the guide wire 420 when the cut openings close to contact one another and prevent further flexure in that direction. The cuts 424 may be formed on opposite sides of the guide wire 420 and may be wedge- or triangle-shaped, with the greater width of the wedge being at the bottom of the cut. The cuts 428 may be formed on opposite sides of the guide wire 420 in the form of T’s, with the crosspiece of the T being at the bottom of the cut. The cuts 432 may be generally circular as shown. Other cut shapes could also be provided to meet the needs of the user. The cuts 424, 428, and 432 may be disposed oppositely oriented, but it will be apparent that the cuts could also be formed at circumferentially-spaced locations about the guide wire, or at alternating locations such as shown and described with regard to other figures above.

[0136] All three types of cuts shown in FIG. 2 form an integral transverse beam section, shown in cross-hatch areas 422, 426, and 430, respectively, between oppositely disposed cuts. This configuration provides at least two distinct benefits. First, it allows the beam section to be longer than the gap of the flexure stop. This allows the amount of strain in the wire, respectively. Of course, the cuts could be formed to provide preferential bending (flex) in one plane, or could be positioned to allow bending in multiple planes. This could be achieved, for example, by rotating adjacent pairs of cuts by 45 degrees with respect to one another or some other selected angular amount. Other cut shapes could also be provided to meet the needs of the user. The cuts 424, 428, and 432 may be disposed oppositely oriented, but it will be apparent that the cuts could also be formed at circumferentially-spaced locations about the guide wire, or at alternating locations such as shown and described with regard to other figures above.

[0137] FIG. 5 is a side, fragmented view of a tubular guide wire 420, showing three alternative type cuts 424, 428 and 432. These type cuts may provide a kind of built-in flexure stop to prevent further flexure of the guide wire 420 when the cut openings close to contact one another and prevent further flexure in that direction. The cuts 424 may be formed on opposite sides of the guide wire 420 and may be wedge- or triangle-shaped, with the greater width of the wedge being at the bottom of the cut. The cuts 428 may be formed on opposite sides of the guide wire 420 in the form of T’s, with the crosspiece of the T being at the bottom of the cut. The cuts 432 may be generally circular as shown. Other cut shapes could also be provided to meet the needs of the user. The cuts 424, 428, and 432 may be disposed oppositely oriented, but it will be apparent that the cuts could also be formed at circumferentially-spaced locations about the guide wire, or at alternating locations such as shown and described with regard to other figures above.

[0138] All three types of cuts shown in FIG. 2 form an integral transverse beam section, shown in cross-hatch areas 422, 426, and 430, respectively, between oppositely disposed cuts. This configuration provides at least two distinct benefits. First, it allows the beam section to be longer than the gap of the flexure stop. This allows the amount of strain in the wire to stop engagement to be controlled by varying the ratio of beam length to gap size, allowing more flexibility, i.e. less bending resistance.

[0139] However, the location and shape of the beam sections 422, 426, and 430 also greatly influences the torsional characteristics of the guide wire 420. As is well known by those skilled in mechanics, torsional strength may be provided primarily by the outer portion of the cross section.
of a member. Thus, for illustration, a relatively thin-walled pipe will have nearly the same torsional strength as a solid bar of the same diameter because the central portion of the cross section of the solid bar contributes very little to torsional strength. Similarly, by forming a transverse beam which includes a significant amount of the outer portion of the cross section of the tubular guide wire, the present invention will transmit varying proportions of the torsional forces from one side to the other of the cuts 424, 428, and 432, depending on their shape.

[0140] For example, beam 422 may be relatively long (measured in the direction of the long axis of the guide wire), but may be relatively deep (measured transverse to the long axis) and will therefore transmit a relatively large amount of torsional force. Beam 426 may be longer and thinner than beam 422, and will therefore transmit a smaller amount of torsional force across the cut 428. Of the examples given in FIG. 5, beam 432 may be the shortest and strongest of all, and will probably transmit the greatest amount of torsional force. However, given the size and shape of cuts 432, this configuration may provide the greatest flexibility. Because the small flexure stop gaps of cuts 422,426, and 430 may be varied in width without changing the depth or overall shape of the cut, the flexibility, of the guide wire section may be selectively altered without affecting the size or strength of the torsion beam section. Thus, the flexibility and torsional strength of the guide wire may be selectively and relatively independently altered.

[0141] Advantageously, longitudinally adjacent pairs of cuts may be rotated about 90 degrees or other dimensional amounts around the wire from one another to provide flexure laterally and vertically. However, the cuts may be located to provide preferential flexure in only one, two, three, etc. directions, if that may be desired. Of course, the cuts could preferably be randomly formed to allow bending (flex) equally, non-preferentially in all directions or planes. This could be achieved by circumferentially spacing the cuts in relatively small angular increments.

[0142] FIG. 6 is a side, fragmented view of a tubular guide wire 500 having cuts or etchings 504 which may extend all the way through the guide wire to separate it into pieces, with the cuts or etchings being formed with teeth which interlock when the guide wire may be reassembled. When the guide wire is inserted into a vasculature passageway, the teeth in the cuts 504 may interlock to prevent relative rotation thereof and to transmit torque, but also allow significant lateral flexibility.

[0143] The tubular guide wire disclosed can be used with a catheter threaded thereover in a conventional manner, or can be used to deliver medication to a target location in a manner similar to the catheters themselves. With cuts formed along the length or at least a portion of the length of the tubular guide wires, the medication may be allowed to leak from the bore of the guide wire out into the vasculature passageway. Of course, the location of discharge of medication from the tubular guide wire can be controlled by controlling depth of the cuts as well as the location thereof. In addition, a polymer sleeve may be inserted in the lumen or bore of a tubular guide wire, and/or on the outside as well, for sealing and preventing the outflow or discharge of medication from the guide wire lumen. Controlling the length of such sleeves on the guide wire enables control of discharge points of medication from the guide wire.

[0144] In addition, a stiffening mandrel or wire can be inserted through the bore or lumen of a tubular guide wire as already discussed, and such mandrel or wire can be curved at selected locations such as location 368 in the mandrel 350 of FIG. 2, to cause a corresponding bend in the tubular guide wire. Alternatively, the tubular guide wire can be formed with one or more bends and then a substantially straight mandrel may be inserted into the hollow of the guide wire to cause it to straighten as needed. Also, the mandrel can be made of a material so that it may be visible either with X-ray fluoroscopy or MRI, depending upon the process used to view the clinical procedure.

[0145] FIG. 7 is a side, cross-sectional, fragmented view of a tubular catheter guide wire 604 made from a metallic or other electrically conductive alloy, in the lumen 608 of which may be disposed an electrically conductive wire 612 about which may be disposed an electrically insulative sheath 616. Alternatively, the interior wall of the lumen 608 could include a layer of insulation and obviate the need for the insulative sheath 616. Illustratively, the diameter of the lumen 608 could be 0.009 inches, and the diameter of the wire 612 and sheath 616 could be 0.006 inches.

[0146] The structure of FIG. 7 illustrates a use of the tubular catheter/guide wire of the present invention for making internal electrical measurements such as the detection of voltage patterns at a target location in the body. Also, the combination of FIG. 7 could be used for ablation in which a radio frequency or other signal may be transmitted over the conductor tube 604 and conductor wire 612 to the distal end to cause tissue in front of the distal end. In addition, a heating coil could join the tubular conductor 604 and the conductor wire 612 at the distal end to provide a heating element for performing thermal treatment at a target location in the body. Of course, other electrical measurements or treatments could be utilized with the structure of FIG. 7. Of course, the typical guide wires discussed earlier, being solid, could not provide this function, nor could typical catheters since they may be made of nonmetallic material.

[0147] In the embodiments of the tubular guide wire discussed above, the guide wires can be made “flow-directable” by providing highly flexible distal ends. “Flow-directability” means that the distal end of the guide wire tends to “flow” with the blood around curves and bends in a vasculature passageway. To reduce resistance to movement of a guide wire in a vasculature passageway, the surface of the guide wire can be electropolished to increase the smoothness thereof, and additionally, a lubricious coating may be applied to the surface of the guide wire—such coatings might illustratively include silicone based oil and/or polymeric or hydrophilic polymers. Alternatively, a lubricious sleeve made, for example, of a hydrophilic polymer could also be provided for disposal of the guide wire.

[0148] FIGS. 8-11 provide graphical evidence of some of the improvements the invention provides over the prior art. These graphs depict actual test results of catheter guide wires formed according to this invention, showing the strength of the inventor’s catheter guide wires compared to the prior art, and the relative preservation of torsional strength relative to flexibility. As noted above, the prior art does include catheter guide wires with cuts or notches formed therein to increase flexibility of the distal end of the catheter. However, these cuts may be not formed so as to
simultaneously preserve the torsional strength of the guide wire. With these prior art catheter guide wires, the distal end becomes very flexible, but has very poor torsion transmission characteristics. The result may be that the end of the guide wire flops around, but cannot easily be turned or rotated within a catheter or vessel.

[0149] FIG. 8 is a graph of guide wire tensile strength compared to bending stiffness for the micromachined guide wire of the present invention. The individual (square) data points represent tension test results for micromachined guide wires. The ultimate tensile strength in pounds may be indicated on the vertical axis, while the bending stiffness in psi may be given on the horizontal axis. Below the horizontal axis may be a second axis noting the size of stainless steel wire which would correspond to the respective bending stiffness shown in the horizontal axis. The solid line represents the theoretical tensile strength for equivalent solid wires.

[0150] This figure shows that micromachining cuts in the surface of the guide wire does not significantly reduce its tensile strength compared to non-machined guide wires. This may be an important consideration in the catheter field because low tensile strength could increase the likelihood of breakage of the guide wire during a procedure, or while attempting to extract the guide wire from a patient. Obviously such a situation could present a significant medical hazard.

[0151] FIG. 9 is a graph of the ultimate torsional strength of the micromachined guide wire of the present invention compared to its bending stiffness. The vertical axis shows the ultimate torsional strength of the guide wire in units of pound-inches, and the horizontal axis shows the bending stiffness in psi. As with FIG. 8, the square data points represent actual test results of micromachined catheter guide wires, and the solid line represents the theoretical results for a catheter guide wire of solid circular cross section. It will be apparent from this graph that as the bending stiffness (or size) of the guide wire decreases, the expected or theoretical torsional strength also decreases. This may be depicted by the solid line. However, as the actual test results indicate, as the size or bending strength of the micromachined guide wire decreases, the torsional strength does not correspondingly decrease as would be expected. Instead, as can be seen from the divergence of the data points from the solid line, the torsional strength of the guide wire decreases at a much slower rate. This situation may be depicted in a slightly different way in FIG. 10, which provides a graph of the bending stiffness of the micromachined guide wire of the present invention compared to its torsional stiffness in psi. Again, the actual results diverge from the expected results for smaller and more flexible guide wires.

[0152] The importance of this situation may be most clearly evident from FIG. 11, which is a graph showing the ratio of torsional stiffness to bending stiffness of the micromachined guide wire of the present invention compared to its bending stiffness. In this graph the vertical axis represents a ratio of torsional stiffness to bending stiffness (J/EI), with the result that the expected relationship of bending stiffness to torsional stiffness (the solid line) may be now a horizontal line. In FIG. 11, this line is set equal to unity, in, order to more graphically show the actual results of the inventors’ tests. As can be seen from these actual test results, as the flexure strength decreased, the torsional strength of the micromachined guide wires was more than 30 times more than expected.

[0153] The condition indicated by FIG. 11 represents some unexpected results. When the inventors first began micromachining catheter guide wires, as with the prior art, the goal was primarily to increase the flexibility. However, as guide wire sizes decreased and/or flexibility increased, the inventors noticed a corresponding (and expected) decrease in torsional strength. This may be a significant problem with catheter guide wires because guide wires with low torsional strength cannot be manipulated as easily, and may be more likely to become wedged or jammed into the catheter or vasculature of the patient. With a torsionally weak guide wire, when the user twists the proximal end, there may be a significant delay in the transmission of the torque to the distal end. Indeed, like axially twisting the end of a weak coil spring, most of the torque may be not transmitted at all. Instead, the geometry of the guide wire may be likely to be deformed into a serpentine shape and wedge into the side of the catheter or vasculature in which it may be located.

[0154] FIG. 12 shows cross-sectional views of tubular guide wires disposed within the lumen of circular and elliptical catheters. As will be apparent, when a circular catheter may be advanced into the vasculature of a patient and navigates curves and other tortuous routes, the cross-sectional shape of the catheter frequently tends to flatten out in places into a more elliptical cross-section. When a tubular guide wire 100 may be disposed in catheter 102 having a circular cross-section, it would normally have no preference as to its location within the cross-section—its position will present a state of physical equilibrium regardless of its location because all locations may be the same. However, with an elliptical catheter 104, the guide wire 100 in a central location represents a state of unstable equilibrium, like a ball sitting on the top of another ball. The result may be that the guide wire will naturally gravitate to a point of stable equilibrium 106, in the right corner of the catheter lumen. In this condition, it can be seen that the area of contact between the guide wire and the catheter may be much larger, resulting in large frictional forces which will hinder the easy movement of the guide wire within the catheter.

[0155] This condition will also tend to wedge the guide wire within the catheter simply by virtue of the serpentine shape. FIG. 13 shows the potential serpentine path of a torqued guide wire 120 through a catheter 122. By virtue of the deformation of the guide wire 120, when an axial driving force (denoted Fwire in FIG. 13) may be applied to the guide wire 120, it will be converted into an axial force (denoted F axial) and a perpendicularly oriented wedging force (denoted Wedging Force) which will tend to jam the guide wire within the catheter.

[0156] To prevent these problems, the inventors experimented with methods of providing cuts in catheter guide wires that would increase flexibility without reducing torsional strength as much. It was hoped that for a guide wire of a given flexibility, the torsional strength could be increased by 50% above the theoretical or predicted torsional strength. After trying many configurations, the inventors discovered that forming cuts in the guide wires so as to create beams with a particular location and configuration would allow flexibility to be increased without a correspond-
ingly large decrease in torsional strength. The inventors were pleasantly surprised when testing the present invention to find that instead of a 50% increase of torsional strength, they had found a way to provide a more than 3000% increase in torsional strength. As a result, guide wires formed by the present method provide significantly greater torsional strength relative to their flexibility than the prior art.

It may be to be understood that the above-described arrangements may be only illustrative of the application of the principles of the present invention. Numerous modifications and alternative arrangements may be devised by those skilled in the art without departing from the spirit and scope of the present invention and the appended claims may be intended to cover such modifications and arrangements.

Supported Catheter Liner Exemplary Embodiment

Micromachined catheter tubes require a sleeve or liner in many embodiments to prevent fluid from escaping through the micromachined slots. Unsupported polymer liners may be bonded to the micromachined tube inner wall of sufficient wall thickness that they don’t kink or collapse when the catheter is bent in a tight radius. Various embodiments of this invention provide a liner that can be extremely thin and flexible and yet not collapse when bent. Both bonded and thick-wall liners can stiffen the catheter so much that clinical performance may be degraded. The supported liner of the present invention can have a wall thickness, for example, as low as 0.001" and not collapse on bending. This may be advantageous both from flexibility and catheter lumen maximization perspectives. The liner can be bonded to the micromachined tube at the proximal and distal ends for retention without sacrificing the benefits of flexibility that this design provides. The ribbon coil can be made from metal or polymeric material. Metals such as stainless steel, platinum, and nickel-titanium could be used and polymers such as nylon, polyester, and polyimide may be used.

Further description of an exemplary embodiment of the present invention, a first polymer tube 3805 may be blown into the micromachined tube 3801 so that it may be in contact with the inner wall. The polymer can be polyethylene, Pebax, Hytrel, or other suitable material. “Blowing the tube in” refers to the process of using heat and pressure to expand the polymer tube. The coil 3810 may be constrained on a mandrel and slid into the first polymer tube 3805 and released. The coil may have a memory position at a diameter greater than the bore of the first polymer tube so it expands into contact with it when released. A second polymer tube 3815 may be then blown into the bore of the coil 3810. The coil 3810 may then be embedded between the polymer tubes 3805 and 3815 which bond to each other where they touch between loops of the coil 3810.

Collapse Resistant Liner Configurations

Steerable delivery systems based on micromachined metal tubes may require a liner, for example, liner 3905, to prevent fluid leakage through the slots 3902 in the metal tube 3901. FIG. 39, shows a cross-section of such a device. The desired characteristics of the liner 3905 may be: high lateral flexibility, resistance to kinking, high hardness and lubricity of the lumen, high burst pressure, and minimal wall thickness. It may be also beneficial to the performance of the device if the liner 3905 is not in intimate contact with the inner wall of the metal tube. Thus, in an exemplary embodiment, space 3912 exists between micromachined tube 3901 and liner 3905. In order to achieve these objectives, several features can be utilized.

One such feature illustrated in FIG. 40 is a thin polymer liner 4015 with external coil or braid support 4010. FIG. 40 shows a cross-section of this liner design. It may be similar to the embedded support coil “Supported liner disclosure”, without the outer polymer layer, described with reference to FIG. 38. The outer polymer layer 3805 may be not necessary in all cases and precise space can be saved by omitting this layer. The supporting structure 4010 can be a coil or braid of round or ribbon wire. A coil gives maximal flexibility and avoids the radial space consumed where the wires of a braid cross. On the other hand, braids have higher tensile strength and give additional axial support for assembly of the liner structure. An other alternative would be a multiple-start helical coil (possibly with multiple layers with alternating helix directions) to add tensile strength at the expense of flexibility. The wire can be made of a radiopaque material such as one of the platinum alloys, or other metals like stainless steel, or NiTiNol. It could also be constructed from a rigid polymer such as nylon, polyester, polycarbonate, high density polyethylene, or polypropylene. The inner polymer tube 4015 can be made of polymers such as Teflon, polyethylene, urethane, silicone, or various thermoplastic elastomers (TPE’s). An exemplary embodiment uses a NiTiNol ribbon coil with a ribbon thickness of 0.0006" and a width of 0.005" wound at a pitch of 0.009" over a PTFE tube with a 0.021" outer diameter and a 0.001" wall thickness. The coil/braid 4010 can be held against the outer wall of the polymer tube (liner 4015) by spring action of the coil/braid or by a thin polymer coating such as parylene, urethane, silicone, or epoxy. Alternatively, the coil/braid 4010 can be constructed to fit around the polymer tube with minimal force between them to allow some relative motion between the layers for increased flexibility. Another alternative would be to thermally fuse the coil/braid 4010 to the polymer liner 4015.

FIG. 41 is a cross-section illustrating a Grooved polymer type of liner. This embodiment may give higher flexibility and kink resistance without the additional components required for the coil/braid support embodiment described above. The polymer liner tube 4115 may be grooved (with grooves 4120) to provide thin areas that may be flexible, and ring-like areas that may be resistant to kinking. The construction can consist of a plurality of circular grooves 4120 or it can comprise one or more continuous helical grooves 4120, either single start or multi-start. The grooves 4120 can be made, for example, by grinding, machining, thermal forming or molding. Alternatively, the structure can be constructed by winding a coil of like material on the tube and thermally fusing them together as shown in FIG. 42.

The width, depth, and spacing of the grooves 4120 can be varied to optimize the characteristics of the tube (e.g. liner 4115). An exemplary embodiment uses a single helical groove with a depth of ¾ of the wall thickness, a width of approx. 1 wall thickness, on a pitch of approx. 2 wall thicknesses. The thin areas of both the grooved tube (e.g. 4115) and the coil/braid supported structures can be deformed by heat and internal pressure to give a more flexible structure similar to a bellows as shown in FIG. 43.
The lumen of any of these liner structures could be coated with a lubricious coating such as a hydrophilic coating.

One embodiment of this invention would use a polymer liner tube that may be grooved only near the distal end of the device where increased flexibility may be required. The size range of various exemplary embodiments may be lumen diameters ranging from 0.012" to 0.1" and liner wall thickness ranging from 0.0005" to 0.015".

Referring once again to FIG. 39, various embodiments of the present invention involve Liner Fixation. Generally, liner 3905 constructions may need to be anchored to the outer slotted Nitinol tube 3901 to achieve a working device. The liners 3905 would be bonded to the metal tube 3901 at the proximal and distal ends. Intermediate anchor points can also be provided to transfer tensile loads from the metal tube 3901 to the liner structure 3905. These intermediate points could be located, for example, at the proximal end of the slots in the metal tube and at the midpoints of the cuts in the metal tube.

What is claimed is:

1. A medical device configured to navigate through anatomy, the device comprising:
   a. a body having a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end;
   b. a plurality of pairs of slots cut into said body, each said slot being substantially perpendicular to said axis, each said pair comprising a first slot and a second slot, said first slot and said second slot being on substantially opposite sides of said axis;
   c. each longitudinally adjacent said pair being rotated an angle around said axis from the previous said pair;
   d. said angle being less than 89 degrees; and
   e. said angle being greater than 31 degrees.

2. The device of claim 1, said angle being greater than 80 degrees.

3. The device of claim 1 at least some of said slots having a cross sectional shape selected from the group consisting of: wedge-shaped, T-shaped, and a substantially circular.

4. The device of claim 1, for at least a plurality of said pairs, said first slot being at substantially the same axial location as said second slot.

5. The device of claim 1 having a varying longitudinal spacing between adjacent said pairs, said spacing generally decreasing from said proximal end to said distal end.

6. The device of claim 1, said slots having been formed by a method selected from the group comprising saw-cutting, grinding, laser cutting, etching, and electron discharge machining.

7. The device of claim 1, said slots having been formed by grinding with a diamond abrasive blade.

8. The device of claim 1, said body being nitinol.

9. The device of claim 1, said distal end comprising a detectable element, said detectable element being selected from the group consisting of radiopaque elements and MRI detectable elements.

10. The device of claim 1 further comprising a tubular polymer sleeve coaxial with at least part of said body.

11. The device of claim 10, said body being tubular, said sleeve being inside said body.

12. The device of claim 1, said body being tubular, the device further including a wire disposed inside said body and slidable therein.

13. The device of claim 12, said wire including at least one bend formed therein.

14. The device of claim 1, the device being a guidewire.

15. The device of claim 1, said body being tubular, the device being a catheter.

16. A catheter configured to navigate through anatomy, the catheter comprising:
   a. a tubular body having a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end;
   b. a plurality of pairs of slots cut into said body, each said slot being substantially perpendicular to said axis, each said pair comprising a first slot and a second slot, said first slot and said second slot being on substantially opposite sides of said axis;
   c. a tubular polymer sleeve inside at least part of said body;
   d. a re-positionable sleeve; and
   e. a luer adapter.

17. The catheter of claim 16, said sleeve being slidably disposed with respect to said body.

18. The catheter of claim 16, said sleeve being inside said body.

19. The catheter of claim 16, said sleeve substantially comprising a material selected from the group consisting of elastomers, polyurethane, polyethylene, and Teflon.

20. A hollow catheter guidewire apparatus comprising:
   a. a tubular nitinol body having a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end;
   b. a plurality of pairs of slots cut into said body, each said slot being substantially perpendicular to said axis, each said pair comprising a first slot and a second slot, said first slot being at substantially the same axial location as said second slot, said first slot and said second slot being on substantially opposite sides of said axis;
   c. each longitudinally adjacent said pair being rotated an angle around said axis from the previous said pair, said angle being less than 89 degrees, and said angle being greater than 31 degrees;
   d. a tubular polymer sleeve coaxial with at least part of said body;
   e. and a detachable chuck configured to attach to said body, said chuck being configured to facilitate manually rotating said body about said axis.

21. A hollow catheter guidewire apparatus comprising:
   a. a tubular nitinol body having a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end;
   b. a plurality of pairs of slots cut into said body, each said slot being substantially perpendicular to said axis, each said pair comprising a first slot and a second slot, said first slot being at substantially the same axial location as said second slot, said first slot and said second slot being on substantially opposite sides of said axis;
each longitudinally adjacent said pair being rotated an angle around said axis from the previous said pair;
said angle being in the range of 70-90 degrees; the average of said angles, computed over 10 adjacent sets of cuts, being less than 89 degrees and greater than 70 degrees.
a tubular polymer sleeve coaxial with at least part of said body;
and a detachable chuck configured to attach to said body, said chuck being configured to facilitate manually rotating said body about said axis.
22. The apparatus of claim 21:
said chuck being configured to facilitate introduction of medications into the interior of said guidewire;
said distal end being curved;
said distal end comprising a detectable element;
said detectable element being selected from the group consisting of radiopaque elements and MRI detectable elements;
said pairs having a varying longitudinal spacing;
said spacing generally decreasing from said proximal end to said distal end; and
said slots having been formed by a method selected from the group comprising saw-cutting, grinding, laser cutting, etching, and electron discharge machining.
23. The device of claim 21 further including a metal wire slidably disposed inside said body and removable therefrom.
24. A medical device configured to navigate through anatomy, the device comprising:
a body having a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end;
a plurality of pairs of slots cut into said body, each said slot being substantially perpendicular to said axis, each said pair comprising a first slot and a second slot, said first slot and said second slot being on substantially opposite sides of said axis;
each longitudinally adjacent said pair being rotated an angle around said axis from the previous said pair;
said angle being in the range of 70-90 degrees; the average of said angles, computed over 10 adjacent sets of cuts, being less than 89 degrees and greater than 70 degrees.

* * * * *