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CROSSING GUIDEWIRE WITH DEFLECTABLE TIP FOR ADVANCING THROUGH AN AORTIC VALVE

Abstract

A crossing guidewire that is adapted for use in crossing an aortic valve may include a proximal shaft segment, a distal shaft segment including a distal end, and a hinge point disposed between the proximal shaft segment and the distal shaft segment. The hinge point may be adapted to allow the distal shaft segment to pivot relative to the proximal shaft segment when the distal end of the distal shaft segment contacts the aortic valve.

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Background/Summary

CROSS REFERENCE TO RELATED APPLICATIONS [0001] This application claims the benefit of priority of U.S. Provisional Application No. 63/552,909 filed Feb. 13, 2024, the entire disclosure of which is hereby incorporated by reference.

TECHNICAL FIELD
[0002] The present disclosure pertains to medical devices and methods for using medical devices. More particularly, the present disclosure pertains to a guidewire for accessing and advancing through an aortic valve.
BACKGROUND
[0003] A wide variety of intracorporeal medical devices have been developed for medical use, for example, intravascular use. Some of these devices include guidewires, catheters, medical device delivery systems (e.g., for stents, grafts, replacement valves, etc.), and the like. These devices are manufactured by any one of a variety of different manufacturing methods and may be used according to any one of a variety of methods. Of the known medical devices and methods, each has certain advantages and disadvantages. There is an ongoing need to provide alternative medical devices as well as alternative methods for manufacturing and using medical devices.
SUMMARY
[0004] This disclosure provides design, material, manufacturing method, and use alternatives for medical devices. An example may be found in a crossing guidewire that is adapted for use in crossing an aortic valve. The crossing guidewire includes an elongate shaft and a hinge point that divides the elongate shaft into a main segment and a pivoting segment. The hinge point is adapted to allow the pivoting segment to pivot relative to the main segment when the pivoting segment contacts the aortic valve, thereby centering the hinge point relative to the aortic valve.
[0005] Alternatively or additionally, the hinge point may be adapted to allow the pivoting segment to pivot more than 45 degrees relative to the main segment.
[0006] Alternatively or additionally, the hinge point may be adapted to allow the pivoting segment to pivot more than 60 degrees relative to the main segment.
[0007] Alternatively or additionally, the hinge point may be adapted to allow the pivoting segment to pivot more than 90 degrees relative to the main segment.
[0008] Alternatively or additionally, the hinge point may function as a new distal tip when subsequently advancing the crossing guidewire through the aortic valve after the pivoting segment has pivoted relative to the main segment.
[0009] Alternatively or additionally, the hinge point may include a ball and socket, where one of the main segment and the pivoting segment has a terminus forming a socket and the other of the main segment and the pivoting segment has a terminus forming a ball that rotatably fits within the socket.
[0010] Alternatively or additionally, the hinge point may include a gap between the proximal shaft segment and the distal shaft segment, with a flexible polymeric sleeve extending over the gap.
[0011] Alternatively or additionally, the hinge point may include a kink point that will preferentially bend when the distal end of the pivoting segment contacts the aortic valve.

[0012] Another example may be found in a crossing guidewire that is adapted for use in crossing an aortic valve. The crossing guidewire includes a proximal shaft segment, a distal shaft segment that includes a distal end, and a hinge point that is disposed between the proximal shaft segment and the distal shaft segment. The hinge point is adapted to allow the distal shaft segment to pivot relative to the proximal shaft segment when the distal end of the distal shaft segment contacts the aortic valve.
[0013] Alternatively or additionally, the distal shaft segment may have a length extending between the hinge point and the distal end that is sufficient to position the hinge point at or near a midpoint of the aortic valve when the distal shaft segment pivots relative to the proximal shaft segment.
[0014] Alternatively or additionally, the distal shaft segment may have a length extending between the hinge point and the distal end that is in a range of 10 millimeters to 15 millimeters.
[0015] Alternatively or additionally, the distal shaft segment may have a length extending between the hinge point and the distal end that is about 13 millimeters.
[0016] Alternatively or additionally, the hinge point may include a ball and socket, where one of the proximal shaft segment and the distal shaft segment has a terminus forming a socket and the other of the proximal shaft segment and the distal shaft segment has a terminus forming a ball that rotatably fits within the socket.
[0017] Alternatively or additionally, the hinge point may include a gap between the proximal shaft segment and the distal shaft segment, with a flexible polymeric sleeve extending over the gap.
[0018] Alternatively or additionally, the hinge point may include a kink point that will preferentially bend when the distal end of the distal shaft segment bottoms out within the aortic valve.
[0019] Alternatively or additionally, the distal end of the distal shaft segment may include a rounded tip.
[0020] Another example may be found in a method for accessing the left ventricle through the aortic valve. The method includes advancing a first catheter through the aortic arch, the first catheter positioned with a distal end of the first catheter proximate the sinotubular junction. A crossing guidewire is advanced through the first catheter and towards the aortic valve, the crossing guidewire including an elongate shaft and a hinge point dividing the elongate shaft into a main segment and a pivoting segment. The crossing guidewire is urged distally until a distal end of the pivoting segment contacts one of the cusps of the aortic valve. The crossing guidewire is urged further distally, thereby causing the pivoting segment to pivot relative to the main segment and thereby causing the hinge point of the crossing wire to be more closely centered relative to the aortic valve. The crossing guidewire is urged further distally, thereby causing the hinge point of the crossing wire to extend through the aortic valve.
[0021] Alternatively or additionally, causing the pivoting segment to pivot relative to the main segment may include causing the pivoting segment to pivot at least 45 degrees relative to the main segment.
[0022] Alternatively or additionally, causing the pivoting segment to pivot relative to the main segment may include causing the pivoting segment to pivot at least 60 degrees relative to the main segment.
[0023] Alternatively or additionally, causing the pivoting segment to pivot relative to the main segment may include causing the pivoting segment to pivot at least 90 degrees relative to the main segment.
[0024] The above summary of some embodiments, aspects, and/or examples is not intended to describe each disclosed embodiment or every implementation of the present disclosure. The Figures, and Detailed Description, which follow, more particularly exemplify these embodiments.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The disclosure may be more completely understood in consideration of the following detailed description in connection with the accompanying drawings, in which:

[0026] FIG. **1** is a schematic view of a human heart;

[0027] FIG. **2** is a schematic view of an aorta;

[0028] FIG. **3** is a schematic superior view of the aorta of FIG. **2**, including an aortic valve;

[0029] FIGS. **4**A through **4**H are schematic views of the aorta, showing an illustrative method for reaching and passing through the aortic valve;

[0030] FIG. **5** is a schematic view of an illustrative crossing wire that may be utilized in the illustrative method shown in FIGS. **4**A through **4**H;

[0031] FIG. **6**A is a cross-sectional view taken along line **6**-**6** of FIG. **5**, with the illustrative crossing wire shown in a linear configuration;

[0032] FIG. **6**B is a cross-sectional view taken along line **6**-**6** of FIG. **5**, with the illustrative crossing wire shown in a deflected configuration;

[0033] FIG. **7** is a schematic view of an illustrative crossing wire that may be utilized in the illustrative method shown in FIGS. **4**A through **4**H;

[0034] FIG. **8**A is a cross-sectional view taken along line **8**-**8** of FIG. **7**, with the illustrative crossing wire shown in a linear configuration;

[0035] FIG. **8**B is a cross-sectional view taken along line **8**-**8** of FIG. **7**, with the illustrative crossing wire shown in a deflected configuration;

[0036] FIG. **9**A is a schematic view of an illustrative crossing wire that may be utilized in the illustrative method shown in FIGS. **4**A through **4**H, with the illustrative crossing wire shown in a linear configuration; and

[0037] FIG. **9**B is a schematic view of the illustrative crossing wire of FIG. **9**A, shown in a linear configuration.

[0038] While aspects of the disclosure are amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to limit aspects of the disclosure to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the disclosure.

DETAILED DESCRIPTION

[0039] The following description should be read with reference to the drawings, which are not necessarily to scale, wherein like reference numerals indicate like elements throughout the several views. The detailed description and drawings are intended to illustrate but not limit the present disclosure. Those skilled in the art will recognize that the various elements described and/or shown may be arranged in various combinations and configurations without departing from the scope of the disclosure. The detailed description and drawings illustrate example embodiments of the disclosure. However, in the interest of clarity and ease of understanding, while every feature and/or element may not be shown in each drawing, the feature(s) and/or element(s) may be understood to be present regardless, unless otherwise specified.

[0040] For the following defined terms, these definitions shall be applied, unless a different definition is given in the claims or elsewhere in this specification.

[0041] All numeric values are herein assumed to be modified by the term “about,” whether or not explicitly indicated. The term “about”, in the context of numeric values, generally refers to a range of numbers that one of skill in the art would consider equivalent to the recited value (e.g., having the same function or result). In many instances, the term “about” may include numbers that are rounded to the nearest significant figure. Other uses of the term “about” (e.g., in a context other than numeric values) may be assumed to have their ordinary and customary definition(s), as understood from and consistent with the context of the specification, unless otherwise specified.

[0042] The recitation of numerical ranges by endpoints includes all numbers within that range, including the endpoints (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).
[0043] Although some suitable dimensions, ranges, and/or values pertaining to various components, features and/or specifications may be disclosed, one of skill in the art, incited by the present disclosure, would understand desired dimensions, ranges, and/or values may deviate from those expressly disclosed.
[0044] As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise. It is to be noted that in order to facilitate understanding, certain features of the disclosure may be described in the singular, even though those features may be plural or recurring within the disclosed embodiment(s). Each instance of the features may include and/or be encompassed by the singular disclosure(s), unless expressly stated to the contrary. For simplicity and clarity purposes, not all elements of the present disclosure are necessarily shown in each figure or discussed in detail below. However, it will be understood that the following discussion may apply equally to any and/or all of the components for which there are more than one, unless explicitly stated to the contrary. Additionally, not all instances of some elements or features may be shown in each figure for clarity.
[0045] Relative terms such as “proximal”, “distal”, “advance”, “retract”, variants thereof, and the like, may be generally considered with respect to the positioning, direction, and/or operation of various elements relative to a user/operator/manipulator of a device, wherein “proximal” and “retract” indicate or refer to closer to or toward the user and “distal” and “advance” indicate or refer to farther from or away from the user. In some instances, the terms “proximal” and “distal” may be arbitrarily assigned in an effort to facilitate understanding of the disclosure, and such instances will be readily apparent to the skilled artisan. Other relative terms, such as “upstream”, “downstream”, “inflow”, and “outflow” refer to a direction of fluid flow within a lumen, such as a body lumen, a blood vessel, or within a device. Still other relative terms, such as “axial”, “circumferential”, “longitudinal”, “lateral”, “radial”, etc. and/or variants thereof generally refer to direction and/or orientation relative to a central longitudinal axis of the disclosed structure or device.
[0046] For the purpose of clarity, certain identifying numerical nomenclature (e.g., first, second, third, fourth, etc.) may be used throughout the description and/or claims to name and/or differentiate between various described and/or claimed features. It is to be understood that the numerical nomenclature is not intended to be limiting and is exemplary only. In some embodiments, alterations of and deviations from previously used numerical nomenclature may be made in the interest of brevity and clarity. That is, a feature identified as a “first” element may later be referred to as a “second” element, a “third” element, etc. or may be omitted entirely, and/or a different feature may be referred to as the “first” element. The meaning and/or designation in each instance will be apparent to the skilled practitioner.
[0047] Diseases and/or medical conditions that impact the cardiovascular system are prevalent throughout the world. Traditionally, treatment of the cardiovascular system was often conducted by directly accessing the impacted part of the system. For example, treatment of a blockage in one or more of the coronary arteries was traditionally treated using coronary artery bypass surgery. As can be readily appreciated, such therapies are rather invasive to the patient and require significant recovery times and/or treatments. More recently, less invasive therapies have been developed, for example, where a blocked coronary artery could be accessed and treated via a percutaneous catheter (e.g., angioplasty). Such therapies have gained wide acceptance among patients and clinicians. In some instances, these therapies may be referred to as transaortic valve implantation or transcatheter aortic valve implantation, also known as TAVI procedures. In some instances, these therapies may be referred to as transaortic valve replacement or transcatheter aortic valve

replacement, also known as TAVR procedures. The terms TAVI and TAVR may in some cases be used interchangeably to refer to a procedure in which a native aortic valve is repaired or replaced. In some instances, a TAVI or TAVR procedure may be utilized to install a second replacement aortic valve in place of a previously installed first replacement aortic valve.

[0048] FIG. **1** is a schematic view of a human heart **10**, illustrating some of the anatomy involved in accessing the interior of the heart **10** in general and in accessing the aortic valve in particular. The heart **10** includes a right atrium **12**, which receives blood via the superior vena cava **14** and the inferior vena cava **16**. Blood within the right atrium **12** passes to a right ventricle **18** via a tricuspid valve **20**. Blood within the right ventricle **18** passes through a pulmonary valve **22** and into a pulmonary artery **24** in order to go to the lungs to be oxygenated. Oxygenated blood from the lungs returns via pulmonary veins **26** and enters a left atrium **28**. A mitral valve **30** allows blood to flow from the left atrium **28** into a left ventricle **32**. Blood exits the left ventricle **32**, through an aortic valve **34**, into an aorta **36** and from there is carried throughout the body.

[0049] FIG. **2** is a schematic view of the aorta **36**. As can be seen, the aorta **36** includes an ascending aorta **38** that extends from the aortic valve **34** up to an aortic arch **40**, as well as a descending aorta **42** that extends downward from the aortic arch **40**. Several arteries extend from the aortic arch **40**. For example, a brachiocephalic artery **44** that bifurcates into a right subclavian artery and a right common carotid artery extends from the aortic arch **40**. A left common carotid artery **46** and a left subclavian artery **48** also extend from the aortic arch **40**. It will be appreciated that the aortic valve **34** may be reached by an intravascular device extending into the body via the brachiocephalic artery **44**, the common carotid artery **46**, the left subclavian artery **48** or a femoral artery (not shown). Access through the femoral artery follows a path up to the abdominal aorta (not shown), through the descending aorta **42**, the aortic arch **40** and the ascending aorta **38**. This path may be considered as moving upstream, against the normal flow of blood.

[0050] FIG. **3** is a schematic view of the aortic valve **34**, looking down on the aortic valve **34** from within the ascending aorta **38**. A small part of the ascending aorta **38** is shown, showing a portion of a right coronary artery **50** and a left main coronary artery **52**. The aortic valve **34** includes a total of three valve cusps **54**, individually labeled as **54***a*, **54***b* and **54***c*. Each of the valve cusps **54** may be considered as being bowl-shaped, particularly when closed (as shown). Each of the valve cusps **54** are attached along one side to the aorta **36** and have an opposing edge that seals against the adjoining valve cusps **54** when the aortic valve **34** is closed. It will be appreciated that trying to extend an intravascular device such as a guidewire through the aortic valve **34** may be problematic, as a distal end of the intravascular device may tend to bottom out in one of the bowl-shaped valve cusps **54**, especially if the aortic valve **34** is closed at the time that the intravascular device is extended distally.

[0051] In some instances, a crossing guidewire may be adapted to facilitate crossing the aortic valve **34**. In some instances, as will be discussed, a crossing guidewire may be adapted to have a distal end that bottoms out in, or otherwise contacts, one of the valve cusps **54**, thereby causing a distal end region of the crossing guidewire to deflect or pivot. In some instances, this may cause the deflection point or pivot point, sometimes referred to as a hinge point, to be more closely centered relative to the aortic valve **34** such that the deflection point or pivot point functions as a new distal end of the crossing guidewire and thus can more easily be extended through the aortic valve **34**. FIGS. **4**A through **4**H show an illustrative method in which a crossing guidewire that has been adapted to facilitate crossing the aortic valve **34** is used in combination with other intravascular devices to reach and extend through the aortic valve **34**.

[0052] In FIG. **4**A and FIG. **4**B, a first catheter **56** is advanced through the aorta **36** until a distal end **58** of the first catheter **56** is positioned proximate the STJ (sinotubular junction) **60**. The STJ **60** denotes the bottom of the ascending aorta **38**. In some cases, the first catheter **56** may be considered a guide catheter. In some instances, the first catheter **56** may be considered as being an AL1 catheter. Once the first catheter **56** is positioned, a crossing guidewire **62** may be advanced

within the first catheter **56** such that a distal end **64** just extends through the distal end **58** of the first catheter **56**. In some cases, the distal end **64** includes a rounded or otherwise atraumatic tip.
[0053] As seen in FIG. **4**C, the crossing guidewire **62** has been urged distally until the distal end **64** of the crossing guidewire **62** has contacted one of the valve cusps **54**. As can be seen, the crossing guidewire **62** includes a proximal shaft segment **66**, a distal shaft segment **68** and a hinge point **70** that is disposed between the proximal shaft segment **66** and the distal shaft segment **68**. The hinge point **70** may take several forms, as will be discussed. In some instances, the hinge point **70** may be considered as being a point along the crossing guidewire **62** where the distal shaft segment **68** is preferentially designed to deflect or pivot relative to the proximal shaft segment **66**. In some instances, the hinge point **70** allows better centering of the proximal shaft segment **66** once the distal shaft segment **68** bottoms out within, or otherwise contacts, one of the valve cusps **54**.
[0054] In some cases, the proximal shaft segment **66** may be considered as being a main shaft segment and the distal shaft segment **68** may be considered as being a pivoting segment. In some instances, the proximal shaft segment **66** and the distal shaft segment **68** may together be considered as defining an elongate shaft. With the distal end **64** of the crossing guidewire **62** bottomed out within, or otherwise contacting, one of the valve cusps **54**, it can be seen that the hinge point **70** is more closely centered relative to the aortic valve **34**, and is effectively a new distal end of the crossing guidewire **62**. As seen in FIG. **4**D, the crossing wire **62** may be further urged distally through the aortic valve **34** with the distal shaft segment **68** still pivoted relative to the proximal shaft segment **66**. In some cases, having the proximal shaft segment **66** helps to center the hinge point **70**.
[0055] Once the crossing wire **62** has been advanced as shown in FIG. **4**D, a second catheter **72** may be advanced over the crossing wire **62** to a point where the second catheter **72** extends through the aortic valve **34** as shown in FIG. **4**E. In some cases, the second catheter **72** may be considered as being a guide sheath. In some cases, instead of advancing the second catheter **72** over the crossing guidewire **62**, the first catheter **56** may instead be advanced distally over the crossing guidewire **62** and through the aortic valve **34**. In some instances, advancing the second catheter **72** (or alternatively, advancing the first catheter **56**) over the crossing guidewire **62** may cause the distal shaft segment **68** to become realigned axially with the proximal shaft segment **66**, thereby making it easier to subsequently advance other intravascular devices over the crossing guidewire **62**. In some cases, once the second catheter **72** (or the first catheter **56**) has been advanced distally through the aortic valve **34**, the crossing guidewire **62** may be withdrawn proximally.
[0056] As seen in FIG. **4**F, a pigtail catheter **74** may be advanced through the first catheter **56** and/or the second catheter **72**. In some cases, the pigtail catheter **74** may be advanced over the crossing guidewire **62**. In some instances, the pigtail catheter **74** may be advanced within the first catheter **56** and/or the second catheter **72** after the crossing guidewire **62** has been withdrawn. The pigtail catheter **74** may be used to inject a contrast fluid, for example. As seen in FIG. **4**G, a guidewire **76** may be advanced through the first catheter **56** and/or the second catheter **72** and through the pigtail catheter **74**. The guidewire **76** may be adapted for use in performing particular steps of a TAVI/TAVR procedure, for example. One or more additional intravascular devices may be advanced over the guidewire **76**, for example. After the guidewire **76** has been advanced through the aortic valve **34**, the pigtail catheter **74** may subsequently be withdrawn, as shown in FIG. **4**H.
[0057] The crossing guidewire **62** may take a variety of different forms, as long as the crossing guidewire **62** has the hinge point **70** that is adapted to allow the distal shaft segment **68** to deflect or pivot relative to the proximal shaft segment **66**, thereby allowing the hinge point **70** to become more closely centered relative to the aortic valve **34** and thus more likely aligned to pass through the aortic valve **34** when the crossing guidewire **62** is advanced distally. In some instances, the distal shaft segment **68** has a length extending between the hinge point **70** and the distal end **64** that is sufficient to position the hinge point **70** at or near a midpoint of the aortic valve **34** when the distal shaft segment **68** pivots relative to the proximal shaft segment **66**. In some cases, the distal

shaft segment **68** may have a length extending between the hinge point **70** and the distal end **64** that is in a range of 10 millimeters to 15 millimeters. In some cases, the distal shaft segment **68** may have a length extending between the hinge point and the distal end that is about 13 millimeters.
[0058] In some instances, the hinge point **70** may be adapted to allow the distal shaft segment (or pivoting segment) **68** to pivot more than 45 degrees relative to the proximal shaft segment (or main segment) **66**. In some instances, the hinge point **70** may be adapted to allow the distal shaft segment (or pivoting segment) **68** to pivot more than 60 degrees relative to the proximal shaft segment (or main segment) **66**. In some instances, the hinge point **70** may be adapted to allow the distal shaft segment (or pivoting segment) **68** to pivot more than 90 degrees relative to the proximal shaft segment (or main segment) **66**. In some cases, there may be a relationship between the length of the distal shaft segment **68** and the maximum angle that the hinge point **70** is capable of reaching. For example, a greater length for the distal shaft segment **68** may mean that the maximum angle for the hinge point **70** is less. As another example, a shorter length for the distal shaft segment **68** may mean that the maximum angle for the hinge point **70** is greater. Essentially, there may be a geometric relationship between the length of the distal shaft segment **68** and how far (to what angle) the distal shaft segment **68** is able to deflect.
[0059] FIG. **5** is a schematic view of an illustrative crossing guidewire **80** that may be considered as being an example of the crossing guidewire **62**. The crossing guidewire **80** includes an elongate shaft **82** that is divided into a proximal shaft segment **84** and a distal shaft segment **86** by a hinge point **88** that is disposed between the proximal shaft segment **84** and the distal shaft segment **86**. In some instances, the hinge point **88** may include a ball and socket arrangement in which one of the proximal shaft segment **84** and the distal shaft segment **86** has a terminus forming a socket and the other of the proximal shaft segment **84** and the distal shaft segment **86** has a terminus forming a ball that rotatably fits within the socket.
[0060] FIG. **6**A is a cross-sectional view taken along the line **6**-**6** of FIG. **5**. As shown, a terminus **90** of the proximal shaft segment **84** includes a rounded socket **94** and a terminus **92** of the distal shaft segment **86** includes a rounded ball portion **96** that fits within the rounded socket **94** and allows the distal shaft segment **86** to pivot within the rounded socket **94**. In some cases, a frictional fit between the rounded ball portion **96** and the rounded socket **94** may help to hold the distal shaft segment **86** in a linear relationship with the proximal shaft segment **84**, as shown in FIG. **6**A. In FIG. **6**B, which shows the crossing guidewire **80** in a deflected position, having a distal end **98** of the distal shaft segment **86** bottom out within one of the valve cusps **54** is sufficient to overcome any frictional forces between the rounded ball portion **96** and the rounded socket **94**, thereby allowing the distal shaft segment **86** to deflect or pivot.
[0061] As shown, the distal shaft segment **86** has a reduced diameter relative to that of the proximal shaft segment **84**. As an example, the distal shaft segment **86** may have a diameter that is reduced up to about 60 percent relative to a diameter of the proximal shaft segment **84**. In some cases, the distal shaft segment **86** may have a diameter that is equal to that of the proximal shaft segment **84**. In some instances, the distal shaft segment **86** has a length that is sufficient to position the hinge point **88** at or near a midpoint of the aortic valve **34** when the distal shaft segment **86** pivots relative to the proximal shaft segment **84**. In some cases, the distal shaft segment **86** may have a length that is in a range of 10 millimeters to 15 millimeters. In some cases, the distal shaft segment **86** may have a length that is about 13 millimeters.
[0062] In some instances, the hinge point **88** may be adapted to allow the distal shaft segment (or pivoting segment) **86** to pivot more than 45 degrees relative to the proximal shaft segment (or main segment) **84**. In some instances, the hinge point **88** may be adapted to allow the distal shaft segment (or pivoting segment) **86** to pivot more than 60 degrees relative to the proximal shaft segment (or main segment) **84**. In some instances, the hinge point **88** may be adapted to allow the distal shaft segment (or pivoting segment) **86** to pivot more than 90 degrees relative to the proximal shaft segment (or main segment) **84**. In some cases, there may be a geometric relationship between

the length of the distal shaft segment **86** and how far (to what angle) the distal shaft segment **84** is able to deflect.

[0063] FIG. **7** is a schematic view of an illustrative crossing guidewire **100** that may be considered as being an example of the crossing guidewire **62**. FIG. **8**A is a cross-sectional view taken along the line **8**-**8** of FIG. **7**, showing internal structure of the crossing guidewire **100**. The crossing guidewire **100** includes an elongate shaft **102** that is divided into a proximal shaft segment **104** and a distal shaft segment **106** by a hinge point **108** that is disposed between the proximal shaft segment **104** and the distal shaft segment **106**. In some cases, as shown, the hinge point **108** includes a physical gap between the proximal shaft segment **104** and the distal shaft segment **106**. A flexible polymeric sleeve **110** extends over the gap to complete the hinge point **108**.

[0064] In some instances, the flexible polymeric sleeve **110** may be formed of a heat-shrinkable material such as polyether block amides available commercially under the Pebax™ name, PET (polyethlene terephthalate), PTFE (polytetrafluoroethylene), PEF (polyethylene furanoate), PES (polyethersulfone), silicone rubber, high performance fluoroelastomers available commercially under the Viton™ name, polyolefins, PFA (perfluoroalkoxy) polymers, or PVDF (polyvinylidene fluoride). In some cases, the flexible polymeric sleeve **110** may be formed of a non-heat-shrinkable material that can form the hinge point **108**. As an example, the flexible polymeric sleeve **110** may be formed of a silicone rubber having a Young's Modulus ranging from 0.448 MPa (mega Pascal) to 145 MPa. As another example, the flexible polymeric sleeve **110** may be formed of Pebax™ 7233, which has a Young's Modulus of 510 MPa.

[0065] Absent applied forces, the flexible polymeric sleeve **110** may hold the distal shaft segment **106** in a linear or axially aligned configuration (as shown in FIG. **8**A). When a distal end **112** of the distal shaft segment **106** bottoms out within, or contacts, one of the valve cusps **54**, the flexible polymeric sleeve **110** is flexible enough to allow the distal shaft segment **106** to deflect or pivot relative to the proximal shaft segment **104**, as shown for example in FIG. **8**B.

[0066] In some cases, the proximal shaft segment **104** may include a reduced diameter section **114** that accommodates the flexible polymeric sleeve **110** without increasing an overall diameter of the crossing guidewire **100**. As an example, the proximal shaft segment **104** may have a maximum diameter of 0.965 millimeters (0.038 inches) and a minimum diameter (within the reduced diameter section **114**) of 0.254 millimeters (0.010 inches). The distal shaft segment **106** may have a diameter of 0.010 inches. In some cases, the proximal shaft segment **104** may not include the reduced diameter section **114**, in which case the flexible polymeric sleeve **110** may increase the overall diameter of the crossing guidewire **100**.

[0067] In some instances, the distal shaft segment **106** has a length that is sufficient to position the hinge point **108** at or near a midpoint of the aortic valve **34** when the distal shaft segment **106** pivots relative to the proximal shaft segment **104**. In some cases, the distal shaft segment **106** may have a length that is in a range of 10 millimeters to 15 millimeters. In some cases, the distal shaft segment **106** may have a length that is about 13 millimeters. In some instances, the hinge point **108** may be adapted to allow the distal shaft segment **106** to pivot more than 45 degrees relative to the proximal shaft segment **104**. In some instances, the hinge point **108** may be adapted to allow the distal shaft segment **106** to pivot more than 60 degrees relative to the proximal shaft segment **104**. In some instances, the hinge point **108** may be adapted to allow the distal shaft segment **106** to pivot more than 90 degrees relative to the proximal shaft segment **104**. In some cases, there may be a geometric relationship between the length of the distal shaft segment **106** and how far (to what angle) the distal shaft segment **106** is able to deflect.

[0068] FIG. **9**A is a schematic view of an illustrative crossing guidewire **120** that may be considered as being an example of the crossing guidewire **62**. The crossing guidewire **120** includes an elongate shaft **122** that is divided into a proximal shaft segment **124** and a distal shaft segment **126** by a hinge point **128** that is disposed between the proximal shaft segment **124** and the distal shaft segment **126**. In some cases, as shown, the hinge point **128** includes a reduced diameter

segment or a kink point that will preferentially bend when a distal end **130** of the distal shaft segment **126** bottoms out within, or contacts, the aortic valve. Absent applied forces, the hinge point **128** may hold the distal shaft segment **126** in a linear or axially aligned configuration (as shown in FIG. **9**A). When the distal end **130** of the distal shaft **126** bottoms out within, or contacts, one of the valve cusps **54**, the hinge point **128** will preferentially bend in order to enough to allow the distal shaft segment **126** to deflect or pivot relative to the proximal shaft segment **124**, as shown for example in FIG. **9**B.

[0069] In some instances, the distal shaft segment **126** has a length that is sufficient to position the hinge point **128** at or near a midpoint of the aortic valve **34** when the distal shaft segment **126** pivots relative to the proximal shaft segment **124**. In some cases, the distal shaft segment **126** may have a length that is in a range of 10 millimeters to 15 millimeters. In some cases, the distal shaft segment **126** may have a length that is about 13 millimeters. In some instances, the hinge point **128** may be adapted to allow the distal shaft segment **126** to pivot more than 45 degrees relative to the proximal shaft segment **124**. In some instances, the hinge point **128** may be adapted to allow the distal shaft segment **126** to pivot more than 60 degrees relative to the proximal shaft segment **124**. In some instances, the hinge point **128** may be adapted to allow the distal shaft segment **126** to pivot more than 90 degrees relative to the proximal shaft segment **124**. In some cases, there may be a geometric relationship between the length of the distal shaft segment **126** and how far (to what angle) the distal shaft segment **126** is able to deflect.

[0070] The materials that can be used for the various components of the devices and components thereof disclosed herein may include those commonly associated with medical devices. In some instances, the devices and/or other elements disclosed herein may be made from a metal, metal alloy, polymer (some examples of which are disclosed below), a metal-polymer composite, ceramics, combinations thereof, and the like, or other suitable material. Some examples of suitable metals and metal alloys include stainless steel, such as 444V, 444L, and 314LV stainless steel; mild steel; nickel-titanium alloy such as linear-elastic and/or super-elastic nitinol; other nickel alloys such as nickel-chromium-molybdenum alloys (e.g., UNS: N06625 such as INCONEL® 625, UNS: N06022 such as HASTELLOY® C-22®, UNS: N10276 such as HASTELLOY® C276®, other HASTELLOY® alloys, and the like), nickel-copper alloys (e.g., UNS: N04400 such as MONEL® 400, NICKELVAC® 400, NICORROS® 400, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R44035 such as MP35-N® and the like), nickel-molybdenum alloys (e.g., UNS: N10665 such as HASTELLOY® ALLOY B2®), other nickel-chromium alloys, other nickel-molybdenum alloys, other nickel-cobalt alloys, other nickel-iron alloys, other nickel-copper alloys, other nickel-tungsten or tungsten alloys, and the like; cobalt-chromium alloys; cobalt-chromium-molybdenum alloys (e.g., UNS: R44003 such as ELGILOY®, PHYNOX®, and the like); platinum enriched stainless steel; titanium; combinations thereof; and the like; or any other suitable material.

[0071] As alluded to herein, within the family of commercially available nickel-titanium or nitinol alloys, is a category designated “linear elastic” or “non-super-elastic” which, although may be similar in chemistry to conventional shape memory and super elastic varieties, may exhibit distinct and useful mechanical properties. Linear elastic and/or non-super-elastic nitinol may be distinguished from super elastic nitinol in that the linear elastic and/or non-super-elastic nitinol does not display a substantial “superelastic plateau” or “flag region” in its stress/strain curve like super elastic nitinol does. Instead, in the linear elastic and/or non-super-elastic nitinol, as recoverable strain increases, the stress continues to increase in a substantially linear, or a somewhat, but not necessarily entirely linear relationship until plastic deformation begins or at least in a relationship that is more linear than the super elastic plateau and/or flag region that may be seen with super elastic nitinol. Thus, for the purposes of this disclosure linear elastic and/or non-super-elastic nitinol may also be termed “substantially” linear elastic and/or non-super-elastic nitinol.

[0072] In some cases, linear elastic and/or non-super-elastic nitinol may also be distinguishable

from super elastic nitinol in that linear elastic and/or non-super-elastic nitinol may accept up to about 2-5% strain while remaining substantially elastic (e.g., before plastically deforming) whereas super elastic nitinol may accept up to about 8% strain before plastically deforming. Both of these materials can be distinguished from other linear elastic materials such as stainless steel (that can also be distinguished based on its composition), which may accept only about 0.2 to 0.44 percent strain before plastically deforming.

[0073] In some embodiments, the linear elastic and/or non-super-elastic nickel-titanium alloy is an alloy that does not show any martensite/austenite phase changes that are detectable by differential scanning calorimetry (DSC) and dynamic metal thermal analysis (DMTA) analysis over a large temperature range. For example, in some embodiments, there may be no martensite/austenite phase changes detectable by DSC and DMTA analysis in the range of about −60 degrees Celsius (° C.) to about 120° C. in the linear elastic and/or non-super-elastic nickel-titanium alloy. The mechanical bending properties of such material may therefore be generally inert to the effect of temperature over this very broad range of temperature. In some embodiments, the mechanical bending properties of the linear elastic and/or non-super-elastic nickel-titanium alloy at ambient or room temperature are substantially the same as the mechanical properties at body temperature, for example, in that they do not display a super-elastic plateau and/or flag region. In other words, across a broad temperature range, the linear elastic and/or non-super-elastic nickel-titanium alloy maintains its linear elastic and/or non-super-elastic characteristics and/or properties.

[0074] In some instances, the linear elastic and/or non-super-elastic nickel-titanium alloy may be in the range of about 50 to about 60 weight percent nickel, with the remainder being essentially titanium. In some embodiments, the composition is in the range of about 54 to about 57 weight percent nickel. One example of a suitable nickel-titanium alloy is FHP-NT alloy commercially available from Furukawa Techno Material Co. of Kanagawa, Japan. Other suitable materials may include ULTANIUM™ (available from Neo-Metrics) and GUM METAL™ (available from Toyota). In some other embodiments, a superelastic alloy, for example a superelastic nitinol can be used to achieve desired properties.

[0075] In at least some instances, portions or all of the device and/or other elements disclosed herein may also be doped with, made of, or otherwise include a radiopaque material. Radiopaque materials are understood to be materials capable of producing a relatively bright image on a fluoroscopy screen or another imaging technique during a medical procedure. This relatively bright image aids a user in determining the location of the devices and/or other elements disclosed herein. Some examples of radiopaque materials can include, but are not limited to, gold, platinum, palladium, tantalum, tungsten alloy, polymer material loaded with a radiopaque filler, and the like. Additionally, other radiopaque marker bands and/or coils may also be incorporated into the design of the devices and/or other elements disclosed herein to achieve the same result.

[0076] In some instances, a degree of Magnetic Resonance Imaging (MRI) compatibility is imparted into the devices and/or other elements disclosed herein. For example, the devices and/or components or portions thereof may be made of a material that does not substantially distort the image and create substantial artifacts (e.g., gaps in the image). Certain ferromagnetic materials, for example, may not be suitable because they may create artifacts in an MRI image. The medical device(s) or portions thereof, may also be made from a material that the MRI machine can image. Some materials that exhibit these characteristics include, for example, tungsten, cobalt-chromium-molybdenum alloys (e.g., UNS: R44003 such as ELGILOY®, PHYNOX®, and the like), nickel-cobalt-chromium-molybdenum alloys (e.g., UNS: R44035 such as MP35-N® and the like), nitinol, and the like, and others.

[0077] In some instances, the devices and/or other elements disclosed herein may be made from or include a polymer or other suitable material. Some examples of suitable polymers may include polytetrafluoroethylene (PTFE), ethylene tetrafluoroethylene (ETFE), fluorinated ethylene propylene (FEP), polyoxymethylene (POM, for example, DELRIN® available from DuPont),

polyether block ester, polyurethane (for example, Polyurethane 85A), polypropylene (PP), polyvinylchloride (PVC), polyether-ester (for example, ARNITEL® available from DSM Engineering Plastics), ether or ester based copolymers (for example, butylene/poly(alkylene ether) phthalate and/or other polyester elastomers such as HYTREL® available from DuPont), polyamide (for example, DURETHAN® available from Bayer or CRISTAMID® available from Elf Atochem), elastomeric polyamides, block polyamide/ethers, polyether block amide (PEBA, for example available under the trade name PEBAX®), ethylene vinyl acetate copolymers (EVA), silicones, polyethylene (PE), MARLEX® high-density polyethylene, MARLEX® low-density polyethylene, linear low density polyethylene (for example REXELL®), polyester, polybutylene terephthalate (PBT), polyethylene terephthalate (PET), polytrimethylene terephthalate, polyethylene naphthalate (PEN), polyetheretherketone (PEEK), polyimide (PI), polyetherimide (PEI), polyphenylene sulfide (PPS), polyphenylene oxide (PPO), poly paraphenylene terephthalamide (for example, KEVLAR®), polysulfone, nylon, nylon-12 (such as GRILAMID® available from EMS American Grilon), perfluoro (propyl vinyl ether) (PFA), ethylene vinyl alcohol, polyolefin, polystyrene, epoxy, polyvinylidene chloride (PVdC), poly(styrene-b-isobutylene-b-styrene) (for example, SIBS and/or SIBS 50A), polycarbonates, ionomers, biocompatible polymers, other suitable materials, or mixtures, combinations, copolymers thereof, polymer/metal composites, and the like. In some instances the sheath can be blended with a liquid crystal polymer (LCP). For example, the mixture can contain up to about 6 percent LCP.

[0078] In some instances, the devices and/or other elements disclosed herein may include and/or be treated with a suitable therapeutic agent. Some examples of suitable therapeutic agents may include anti-thrombogenic agents (such as heparin, heparin derivatives, urokinase, and PPack (dextrophenylalanine proline arginine chloromethylketone)); anti-proliferative agents (such as enoxaparin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid); anti-inflammatory agents (such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine); antineoplastic/antiproliferative/anti-mitotic agents (such as paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors); anesthetic agents (such as lidocaine, bupivacaine, and ropivacaine); anti-coagulants (such as D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, anti-thrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors, and tick antiplatelet peptides); vascular cell growth promoters (such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters); vascular cell growth inhibitors (such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin, bifunctional molecules consisting of an antibody and a cytotoxin); cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vasoactive mechanisms.

[0079] It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps, without exceeding the scope of the disclosure. This may include, to the extent that it is appropriate, the use of any of the features of one example embodiment being used in other embodiments. The disclosure's scope is, of course, defined in the language in which the appended claims are expressed.

Claims

1. A crossing guidewire adapted for use in crossing an aortic valve, the crossing guidewire comprising: an elongate shaft; and a hinge point dividing the elongate shaft into a main segment

and a pivoting segment; wherein the hinge point is adapted to allow the pivoting segment to pivot relative to the main segment when the pivoting segment contacts the aortic valve, thereby centering the hinge point relative to the aortic valve.

2. The crossing guidewire of claim 1, wherein the hinge point is adapted to allow the pivoting segment to pivot more than 45 degrees relative to the main segment.

3. The crossing guidewire of claim 1, wherein the hinge point is adapted to allow the pivoting segment to pivot more than 60 degrees relative to the main segment.

4. The crossing guidewire of claim 1, wherein the hinge point is adapted to allow the pivoting segment to pivot more than 90 degrees relative to the main segment.

5. The crossing guidewire of claim 1, wherein the hinge point functions as a new distal tip when subsequently advancing the crossing guidewire through the aortic valve after the pivoting segment has pivoted relative to the main segment.

6. The crossing guidewire of claim 1, wherein the hinge point comprises a ball and socket, where one of the main segment and the pivoting segment has a terminus forming a socket and the other of the main segment and the pivoting segment has a terminus forming a ball that rotatably fits within the socket.

7. The crossing guidewire of claim 1, wherein the hinge point comprises a gap between the proximal shaft segment and the distal shaft segment, with a flexible polymeric sleeve extending over the gap.

8. The crossing guidewire of claim 1, wherein the hinge point comprises a kink point that will preferentially bend when the distal end of the pivoting segment contacts the aortic valve.

9. A crossing guidewire adapted for use in crossing an aortic valve, the crossing guidewire comprising: a proximal shaft segment; a distal shaft segment including a distal end; and a hinge point disposed between the proximal shaft segment and the distal shaft segment, the hinge point adapted to allow the distal shaft segment to pivot relative to the proximal shaft segment when the distal end of the distal shaft segment contacts the aortic valve.

10. The crossing guidewire of claim 9, wherein the distal shaft segment has a length extending between the hinge point and the distal end that is sufficient to position the hinge point at or near a midpoint of the aortic valve when the distal shaft segment pivots relative to the proximal shaft segment.

11. The crossing guidewire of claim 9, wherein the distal shaft segment has a length extending between the hinge point and the distal end that is in a range of 10 millimeters to 15 millimeters.

12. The crossing guidewire of claim 9, wherein the distal shaft segment has a length extending between the hinge point and the distal end that is about 13 millimeters.

13. The crossing guidewire of claim 9, wherein the hinge point comprises a ball and socket, where one of the proximal shaft segment and the distal shaft segment has a terminus forming a socket and the other of the proximal shaft segment and the distal shaft segment has a terminus forming a ball that rotatably fits within the socket.

14. The crossing guidewire of claim 9, wherein the hinge point comprises a gap between the proximal shaft segment and the distal shaft segment, with a flexible polymeric sleeve extending over the gap.

15. The crossing guidewire of claim 9, wherein the hinge point comprises a kink point that will preferentially bend when the distal end of the distal shaft segment contacts the aortic valve.

16. The crossing guidewire of claim 9, wherein the distal end of the distal shaft segment comprises a rounded tip.

17. A method for accessing the left ventricle through the aortic valve, the method comprising: advancing a first catheter through the aortic arch, the first catheter positioned with a distal end of the first catheter proximate the sinotubular junction; advancing a crossing guidewire through the first catheter and towards the aortic valve, the crossing guidewire including an elongate shaft and a hinge point dividing the elongate shaft into a main segment and a pivoting segment; urging the

crossing guidewire distally until a distal end of the pivoting segment contacts one of the cusps of the aortic valve; further urging the crossing guidewire distally, thereby causing the pivoting segment to pivot relative to the main segment and thereby causing the hinge point of the crossing wire to be more closely centered relative to the aortic valve; and further urging the crossing wire distally, thereby causing the hinge point of the crossing wire to extend through the aortic valve.

18. The method of claim 17, wherein causing the pivoting segment to pivot relative to the main segment comprises causing the pivoting segment to pivot at least 45 degrees relative to the main segment.

19. The method of claim 17, wherein causing the pivoting segment to pivot relative to the main segment comprises causing the pivoting segment to pivot at least 60 degrees relative to the main segment.

20. The method of claim 17, wherein causing the pivoting segment to pivot relative to the main segment comprises causing the pivoting segment to pivot at least 90 degrees relative to the main segment.