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ROBOTIC ACTUATION OF ELONGATED MEDICAL DEVICES

Abstract

An elongated medical device comprises an external member defining a lumen, an internal member disposed in the lumen and coupled to a distal portion of the external member, and a linearly-actuatable element coupled to the internal member, wherein linear actuation of the linearly-actuatable element causes relative linear movement between the external member and the internal member and deformation of the distal portion of the external member.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application is a continuation application of U.S. patent application Ser. No. 18/548,599, filed Sep. 1, 2023, which is a national phase application of PCT/US 2022/077563, filed Oct. 5, 2022, which claims priority to U.S. Provisional Application No. 63/262,108, filed Oct. 5, 2021, the contents of which are incorporated herein by reference for all purposes.

FIELD

[0002] Embodiments relate generally to the field of robotic medical procedure systems and, in particular, to systems, apparatus and methods for robotically controlling the movement of one or more elongated medical devices (EMDs) during robotic interventional medical procedures.

BACKGROUND

[0003] Catheters and other EMDs may be used during medical procedures for the diagnosis and/or treatment of diseases of various vascular systems, including neurovascular intervention (NVI), percutaneous coronary intervention (PCI) and peripheral vascular intervention (PVI). These procedures typically involve navigating a guidewire through patient vasculature and advancing a catheter, valve, stent, etc. via the guidewire to deliver therapy.

[0004] A physician may use an imaging system to obtain a contrast-enhanced image for use in diagnosis, identification of lesion location(s) and determination of a path through which the guidewire or catheter may advance to the location of a target (e.g., a lesion). Contrast-enhanced images are also obtained while the physician manipulates the proximal end of the guidewire or catheter to direct the distal tip thereof into vessels which lie on the path to the target location and avoid advancing into side branches of the vasculature, while monitoring for complications such as perforation and dissection.

[0005] Flexibility of the catheter or other medical device is desired to facilitate negotiation of the vasculature. It is also desirable for the distal tip to be more bendable than the rest of the device, while still allowing the device to apply torque to the tip. Some conventional “steerable” catheters include multiple cables (sometimes referred to as push/pull wires) integrated into the wall of the catheter. By applying tension to the cables at the proximal end of such a catheter, the distal tip of the catheter can be bent in various directions to assist in navigating the vasculature when the catheter is advanced.

[0006] Some EMDs include an external member and an internal member coupled to a distal portion of the external member. The distal end is bent or otherwise deformed by causing relative motion between the external member and internal member. These EMDs advantageously present a smaller cross-section than the cable-based steerable EMDs described above.

[0007] Control of the distal tip requires manipulation of handheld features to manually rotate the external member with respect to the internal member and/or manually retract and insert the internal member with respect to the external member. Improved systems for control of such EMDs are desired, which may provide improved precision and/or accuracy of the relative movement between the external member and the internal member and, as a result, improved control over the distal tip or other actuatable device coupled thereto. Such improvements may result in increased procedure speed and improved safety.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] Embodiments will become more fully understood from the following detailed description, taken in conjunction with the accompanying drawings, wherein the reference numerals refer to like

parts in which:

[0009] FIG. **1** is a perspective view of an exemplary catheter-based procedure system in accordance with some embodiments;

[0010] FIG. **2** is a schematic block diagram of an exemplary catheter-based procedure system in accordance with some embodiments;

[0011] FIG. **3** is a perspective view of a robotic drive for a catheter-based procedure system in accordance with some embodiments;

[0012] FIGS. **4A** and **4B** are perspective views of an EMD;

[0013] FIG. **5** is a perspective view of an EMD configured for robotic activation in accordance with some embodiments;

[0014] FIG. **6** is a schematic view of robotic actuation of an EMD in accordance with some embodiments;

[0015] FIG. **7** is a schematic view of robotic actuation of an EMD in accordance with some embodiments;

[0016] FIG. **8** is a schematic view of robotic actuation of an EMD in accordance with some embodiments;

[0017] FIG. **9** is a schematic view of robotic actuation of an EMD in accordance with some embodiments;

[0018] FIG. **10** is a schematic view of robotic actuation of an EMD in accordance with some embodiments;

[0019] FIG. **11** is a schematic view of a fully inserted position of an EMD during robotic actuation thereof in accordance with some embodiments;

[0020] FIG. **12** is a schematic view of an EMD with actuatable elements mounted thereto in a first alternative arrangement in accordance with some embodiments;

[0021] FIG. **13** is a schematic view of an EMD with actuatable elements mounted thereto in a second alternative arrangement in accordance with some embodiments;

[0022] FIG. **14** is an isometric view of an actuatable element coupled to a drive member and rotatably coupling a hemostasis valve to a luer connector coupled to an internal member; and

[0023] FIG. **15** is an exploded view of the internal member, luer connector, actuatable element and hemostasis valve of FIG. **14**.

DETAILED DESCRIPTION

[0024] The following description is provided to enable any person in the art to make and use the described embodiments. Various modifications, however, will be readily-apparent to those in the art.

[0025] As used herein, EMD refers to, but is not limited to, catheters (e.g., guide catheters, microcatheters, balloon/stent catheters), wire-based devices (e.g., guidewires, microwires, proximal pushers for embolization coils, stent retrievers, self-expanding stents, flow divertors, etc.), and medical devices comprising any combination of these.

[0026] Some embodiments facilitate, in a robotic system, operation of an EMD including an inner member disposed within an external member lumen defined by an external member, and in which relative motion between the internal member and external member results in action at the distal portion of the EMD. The external member lumen need not extend the full length of the external member in some embodiments. The external member may comprise a tube but embodiments are not limited thereto. Either or both of the inner member and the external member may comprise multiple components.

[0027] Examples of the resulting action at the distal end include but are not limited to bending the distal portion in a case the EMD is a guidewire or catheter (e.g., Columbus by Rapid Medical, Bendit by Bendit), expanding or compressing the diameter of a distal portion as in an adjustable stent retriever (e.g., Tigertriever by Rapid Medical,) controlling distal and proximal elements of a stent retriever (e.g., ThrombX retriever by ThrombX Medical) or an adjustable remodeling device

(e.g., Comaneci by Rapid Medical, Cascade by Perflow Medical). The internal member and the external member may comprise separate respective EMDs. Such respective separate EMDs may be selectively operationally coupled at the distal portions thereof.

[0028] Some embodiments facilitate, in a robotic system, the application of such relative motion between an external member and an internal member disposed within the external member. The internal member may be partially disposed in the external member such that a portion of the internal member extends from one or both ends of the external member. The relative motion may be linear, rotational, or both. Relative rotational motion is achieved in some embodiments by rotating the proximal end of the external member and/or the proximal portion of the internal member in different directions and/or at different speeds. Relative linear motion is achieved by advancing or retracting the proximal portion of the external member and/or the internal member in different directions and/or at different speeds. Rotation of the whole EMD without causing relative rotational motion is achieved by rotating both proximal ends of the external member and internal member in the same direction (i.e., clockwise or counter-clockwise) at the same angular rate. Advancement or retraction of the whole EMD without causing relative linear motion is achieved by moving both proximal ends of the external member and internal member in the same direction at the same speed.

[0029] According to some embodiments, relative rotational movement is facilitated by attaching a rotationally-actuatable element, such as but not limited to a gear, on the outer surface of one or both of the external member and the internal member. The rotationally-actuatable element may be attached to the outer surface at a location which results in engagement with a drive mechanism of a cassette into which the external member or internal member is loaded.

[0030] Relative linear movement may be facilitated by attaching a locating feature with bearing surfaces fore and aft to one or both of the external member and the internal member. The locating feature may be attached to a location which results in engagement with a feature of a cassette into which the external member or internal member is loaded such that the feature engages with the bearing surfaces to move the external member or internal member fore and aft as a result of linear movement of the cassette. In some embodiments, the bearing surfaces are integral or otherwise coupled to the rotationally-actuatable element.

[0031] According to some embodiments, the length of the internal member which protrudes from the external member when the internal member is not in tension to result in action at the distal portion of the EMD may be different from the length used for handheld operation. In particular, and according to some embodiments, length of the internal member may be determined so that the distance between its proximal end and the proximal end of the external member is at least as long as the minimum operational distance between respective mounting features of adjacent cassettes in which the external member and internal member are loaded.

[0032] Via manipulation of the external member and internal member of such an EMD simultaneously at the same or different rates, the action at the distal portion (e.g., bending, expansion, contraction) may occur faster than it would as a result of moving either the external member while the internal member is fixed or the internal member while the external member is fixed.

[0033] A robotic system can be calibrated to an input device to control the tip of the EMD accurately. For example, rotation of a knob on an input device by 60 degrees may cause a 60-degree bend or an input device is moved to correspond accurately to the desired radius of curvature of the EMD's distal tip. A specific radius of curvature may be utilized to match the vessel radius of curvature to maintain the device in a particular location (e.g., when deploying therapy which may move the other devices).

[0034] Tracking of the distal portion of the EMD by an imaging system (e.g., a fluoroscopy system) may allow automatic control to advance the EMD and bend the distal portion so as to navigate the EMD to a target without human intervention. If the three-dimensional centerline of the

desired vessel pathway to a target is known, then the robotic system could programmatically bend the EMDs distal tip while the EMD is advanced to follow the vessel pathway to the target.

[0035] Robotic actuation of an EMD may generally allow coordination of multiple successive and/or simultaneous inserting, bending and/or rotating motions to navigate the EMD to select a vessel, advance through a tortuous or a narrowed vessel, or stay on a desired path (i.e., avoid moving into an undesired side branch). Robotic actuation according to some embodiments may cause the EMDs distal tip to undulate (with or without rotation, reciprocating rotation or reciprocating advancement) to reduce friction on the vessel walls so as to facilitate advancement or retraction of the EMD and/or of another adjacent or coaxial EMD through a tortuous or a narrowed vessel section.

[0036] According to some embodiments, robotically-actuated motions of the distal tip of an EMD as described herein can be coordinated with other EMDs. For example, an EMD may be disposed with the lumen of an aspiration catheter and controlled as described herein to assist advancement of the aspiration catheter to a clot without requiring the aspiration catheter to cross the clot and risk fragmentation of the clot.

[0037] Bending a distal tip of an EMD as described here may be used to avoid vessel damage as when a guidewire distal tip is bent into a J-configuration so that, when advanced, the tip is prevented from entering a side branch and perforating arteries which may not be angiographically visualized in an NVI. The J-configuration can also be used as knuckle to perform a sub-intimal dissection in order to move past a CTO (chronic total occlusion) in a coronary procedure.

[0038] The relative motion facilitated by some embodiments may be limited, mechanically and/or via software, to either prevent vessel injury or damage the EMD itself. In some embodiments, a sensor installed on the EMD or in the rotational and/or linear motion actuator to measure force and the measurement is used to limit the amount of force imposed on the vessel or the device. The sensor could measure strain as with a strain gauge or fiber Bragg grating integrated into the EMD or the actuator.

[0039] FIG. 1 is a perspective view of an exemplary catheter-based procedure system **10** in accordance with some embodiments. Catheter-based procedure system **10** may be used to perform catheter-based medical procedures, e.g., percutaneous intervention procedures such as a PCI (e.g., to treat STEMI), an NVI (e.g., to treat an emergent large vessel occlusion (ELVO)), PVI (e.g., for critical limb ischemia (CLI), etc.). Catheter-based medical procedures may include diagnostic catheterization procedures during which one or more catheters or other EMDs are used to aid in the diagnosis of a patient's disease. For example, during one embodiment of a catheter-based diagnostic procedure, a contrast media is injected into one or more arteries through a catheter and an image of the patient's vasculature is acquired while the contrast media resides therein.

[0040] Catheter-based medical procedures may also include catheter-based therapeutic procedures (e.g., angioplasty, stent placement, treatment of peripheral vascular disease, clot removal, arterial venous malformation therapy, treatment of aneurysm, etc.) during which a catheter (or other EMD) is used to treat a disease. Therapeutic procedures may be enhanced by the inclusion of adjunct devices **54** (shown in FIG. 2) such as, for example, intravascular ultrasound (IVUS), optical coherence tomography (OCT), fractional flow reserve (FFR), etc. It should be noted, however, that one in the art would recognize that certain specific percutaneous intervention devices or components (e.g., type of guidewire, type of catheter, etc.) may be selected based on the type of procedure that is to be performed. Catheter-based procedure system **10** can perform any number of catheter-based medical procedures with minor adjustments to accommodate the specific percutaneous intervention devices to be used in the procedures.

[0041] Catheter-based procedure system **10** includes, among other elements, a bedside unit **20** and a control station **26**. Bedside unit **20** includes a robotic drive **24** and a positioning system **22** that are located adjacent to a patient **12**. Patient **12** is supported on a patient table **18**. The positioning system **22** is used to position and support the robotic drive **24**. The positioning system **22** may be,

for example, a robotic arm, an articulated arm, a holder, etc. The positioning system **22** may be attached at one end to, for example, a rail on the patient table **18**, a base, or a cart. The other end of the positioning system **22** is attached to the robotic drive **24**. The positioning system **22** may be moved out of the way (along with the robotic drive **24**) to allow for the patient **12** to be placed on the patient table **18**. Once the patient **12** is positioned on the patient table **18**, the positioning system **22** may be used to situate or position the robotic drive **24** relative to the patient **12** for the procedure. In some embodiments, patient table **18** is operably supported by a pedestal **17**, which is secured to the floor and/or earth. Patient table **18** is able to move with multiple degrees of freedom, for example, roll, pitch, and yaw, relative to the pedestal **17**. Bedside unit **20** may also include controls and displays **46** (shown in FIG. 2). For example, controls and displays may be located on a housing of the robotic drive **24**.

[0042] The term front will refer to the side of the robotic drive **24** that faces the patient **12** and away from the positioning system **22**, while the term rear refers to the side of the robotic drive **24** that is closest to the positioning system **22**. The terms top, up, and upper refer to the general direction away from the direction of gravity and the terms bottom, down, and lower refer to the general direction in the direction of gravity.

[0043] Generally, the robotic drive **24** may be equipped with the appropriate percutaneous interventional devices and accessories **48** (shown in FIG. 2) (e.g., EMDs including an internal member and an external member as described herein, guidewires, various types of catheters including balloon catheters, stent delivery systems, stent retrievers, embolization coils, liquid embolics, aspiration pumps, device to deliver contrast media, medicine, hemostasis valve adapters, syringes, stopcocks, inflation device, etc.) to allow the user or operator **11** to perform a catheter-based medical procedure via a robotic system by operating various controls of a control system as described herein such as the controls and input module located at the control station **26**. Bedside unit **20**, and in particular the robotic drive **24**, may include any number and/or combination of components to provide bedside unit **20** with the functionality described herein. A user or operator **11** at control station **26** is referred to herein as the control station user, control station operator, user or operator. A user or operator at bedside unit **20** is referred to as bedside unit user or bedside unit operator.

[0044] The robotic drive **24** includes a plurality of device modules **32a-d** mounted to a rail or linear member **60** (shown in FIG. 3). The rail or linear member **60** guides and supports the device modules. Each of the device modules **32a-d** may be used to drive an EMD such as a catheter or guidewire. For example, the robotic drive **24** may be used to automatically feed a guidewire into a diagnostic catheter and into a guide catheter in an artery of the patient **12**. One or more devices, such as an EMD, enter the body (e.g., a vessel) of the patient **12** at an insertion point **16** via, for example, an introducer sheath.

[0045] Bedside unit **20** is in communication with control station **26**, allowing signals generated by the controls of control station **26** to be transmitted wirelessly or via hardwire to bedside unit **20** to control various functions of bedside unit **20**, including functions of the robotic drive **24**. As discussed below, control station **26** may include a control computing system **34** (shown in FIG. 2) or be coupled to the bedside unit **20** through a control computing system **34**. Bedside unit **20** may also provide feedback signals (e.g., loads, speeds, operating conditions, warning signals, error codes, etc.) to control station **26**, control computing system **34** (shown in FIG. 2), or both. Communication between the control computing system **34** and various components of the catheter-based procedure system **10** may be provided via a communication link that may be a wireless connection, cable connections, or any other means capable of allowing communication to occur between components.

[0046] The term local is used to refer to the location of the patient **12** and bedside unit **20**. Catheter procedure system **10** may be operated by a control station **26** at the local site, a control station **26** at a remote site, or both a local control station **26** and a remote control station **26** at the same time. At

a local site, user or operator **11** and control station **26** are located in the same room or an adjacent room to the patient **12** and bedside unit **20**. As used herein, a local site is the location of the bedside unit **20** and a patient **12** or subject (e.g., animal or cadaver) and the remote site is the location of a user or operator **11** and a control station **26** used to control the bedside unit **20** remotely. The term remote is used to refer to locations that do not have physical access to the bedside unit **20** and/or patient **12** at a local site.

[0047] In some embodiments, the remote site and the local (patient) site are away from one another, for example, in different rooms in the same building, different buildings in the same city, different cities, or other different locations where the remote site does not have physical access to the bedside unit **20** and/or patient **12** at the local site.

[0048] Control station **26** includes input module **28** including controls configured according to some embodiments to receive user manipulations for controlling robotic drive **24** and/or various other components or systems of catheter-based procedure system **10**. In the embodiment shown, control station **26** allows the user or operator **11** to control bedside unit **20** to perform a catheter-based medical procedure. For example, input module **28** may be configured to cause bedside unit **20** to perform various tasks using percutaneous intervention devices (e.g., EMDs) interfaced with the robotic drive **24** (e.g., to advance, retract, or rotate a guidewire, advance, retract or rotate a catheter, inflate or deflate a balloon located on a catheter, position and/or deploy a stent, position and/or deploy a stent retriever, position and/or deploy a coil, inject contrast media into a catheter, inject liquid embolics into a catheter, inject medicine or saline into a catheter, aspirate on a catheter, or to perform any other function that may be performed as part of a catheter-based medical procedure). Robotic drive **24** includes various drive mechanisms to cause movement (e.g., linear and rotational movement) of the components of the bedside unit **20** including the percutaneous intervention devices in response to user manipulation of the controls of input module **28**.

[0049] An input module **28** may include device selection buttons as described below to allow the operator **11** to select which of the percutaneous intervention devices loaded into the robotic drive **24** are controlled via user manipulation of input controls. Automated move buttons may be used to enable algorithmic movements that the catheter-based procedure system **10** may perform on a percutaneous intervention device without direct command from the user or operator **11**.

[0050] An input module **28** may also include a balloon or stent control that is configured to instruct inflation or deflation of a balloon and/or deployment of a stent. An input module **28** may include one or more buttons, scroll wheels, joysticks, touch screen, etc. that is dedicated to instruct control of a particular component or components. In addition, one or more touch screens may display one or more icons (not shown) presenting relative positions of input modules **28** or various components of catheter-based procedure system **10**. Such one or more touch screens may present a user interface for specifying and/or presenting a configuration of the controls of input module **28** and one or more functions, including but not limited to linear and/or rotational locking functions.

[0051] Control station **26** may include a display **30**. In some embodiments, the control station **26** may include two or more displays **30**. Display **30** may be configured to display information or patient specific data to the user or operator **11** located at control station **26**. For example, display **30** may be configured to display image data (e.g., X-ray images, MRI images, CT images, ultrasound images, etc.), hemodynamic data (e.g., blood pressure, heart rate, etc.), patient record information (e.g., medical history, age, weight, etc.), lesion or treatment assessment data (e.g., IVUS, OCT, FFR, etc.). In addition, display **30** may be configured to display procedure specific information (e.g., procedural checklist, recommendations, duration of procedure, catheter or guidewire position, volume of medicine or contrast agent delivered, etc.). Further, display **30** may be configured to display information to provide the functionalities associated with control computing system **34** (shown in FIG. 2). Display **30** may include touch screen capabilities to provide some of the user input capabilities of the system.

[0052] Catheter-based procedure system **10** also includes an imaging system **14**. Imaging system

14 may be any medical imaging system that may be used in conjunction with a catheter based medical procedure (e.g., non-digital X-ray, digital X-ray, CT, MRI, ultrasound, etc.). In an exemplary embodiment, imaging system **14** is a digital X-ray imaging device that is in communication with control station **26**. In one embodiment, imaging system **14** may include a C-arm (shown in FIG. **1**) that allows imaging system **14** to partially or completely rotate around patient **12** in order to obtain images at different angular positions relative to patient **12** (e.g., sagittal views, caudal views, anterior-posterior views, etc.). In one embodiment, imaging system **14** is a fluoroscopy system including a C-arm having an X-ray source **13** and a detector **15**, also known as an image intensifier.

[0053] Imaging system **14** may be configured to acquire X-ray images of the appropriate area of patient **12** during a procedure. For example, imaging system **14** may be configured to acquire one or more X-ray images of the head to diagnose a neurovascular condition. Imaging system **14** may also be configured to take one or more X-ray images (e.g., real time images) during a catheter-based medical procedure to assist the operator **11** of control station **26** to properly position a guidewire, guide catheter, microcatheter, stent retriever, coil, stent, balloon, etc. during the procedure. The image or images may be displayed on display **30**. For example, images may be displayed on display **30** to allow the user or operator **11** to accurately move a guide catheter or guidewire into the proper position.

[0054] In order to clarify directions, a rectangular coordinate system is introduced with X, Y, and Z axes. The positive X axis is oriented in a longitudinal (axial) distal direction, that is, in the direction from the proximal end to the distal end, stated another way from the proximal to distal direction. The Y and Z axes are in a transverse plane to the X axis, with the positive Z axis oriented up, that is, in the direction opposite of gravity, and the Y axis is automatically determined by right-hand rule.

[0055] FIG. **2** is a block diagram of catheter-based procedure system **10** in accordance with an exemplary embodiment. Catheter-procedure system **10** may include a control computing system **34**. Control computing system **34** may physically be, for example, part of control station **26** (shown in FIG. **1**). Control computing system **34** may generally comprise a computer processing unit suitable to provide catheter-based procedure system **10** with the various functionalities described herein. For example, control computing system **34** may be an embedded system, a dedicated circuit, a general-purpose system programmed with the functionality described herein, etc. Control computing system **34** is in communication with bedside unit **20**, control station **38**, additional communications systems **40** (e.g., a telepresence system, and patient sensors **56** (e.g., electrocardiogram (ECG) devices, electroencephalogram (EEG) devices, blood pressure monitors, temperature monitors, heart rate monitors, respiratory monitors, etc.).

[0056] Control computing system **34** is also in communication with imaging system **14**, patient table **18**, additional medical systems **50**, contrast injection systems **52** and adjunct devices **54** (e.g., IVUS, OCT, FFR, etc.). The bedside unit **20** includes a robotic drive **24**, a positioning system **22** and may include additional controls and displays **46**. As mentioned above, the additional controls and displays may be located on a housing of the robotic drive **24**. Interventional devices and accessories **48** (e.g., guidewires, catheters, etc.) interface to the bedside system **20**. In some embodiments, interventional devices and accessories **48** may include specialized devices (e.g., EMDs including an internal member and an external member as described herein, IVUS catheter, OCT catheter, FFR wire, diagnostic catheter for contrast, etc.) which interface to their respective adjunct devices **54**, namely, an IVUS system, an OCT system, and FFR system, etc.

[0057] In various embodiments, control computing system **34** is configured to receive and generate control signals based on user manipulation of the controls of input module **28** of control station **26**, and/or based on information accessible to control computing system **34**, such that a medical procedure may be performed using catheter-based procedure system **10**.

[0058] Catheter-based procedure system **10** may be connected or configured to include any other

systems and/or devices not explicitly shown. For example, catheter-based procedure system **10** may include image processing engines, data storage and archive systems, automatic balloon and/or stent inflation systems, medicine injection systems, medicine tracking and/or logging systems, user logs, encryption systems, systems to restrict access or use of catheter-based procedure system **10**, etc.

[0059] FIG. **3** is a perspective view of a robotic drive **24** for a catheter-based procedure system **10** in accordance with some embodiments. Embodiments are not limited to the robotic drive **24** of FIG. **3**. The robotic drive **24** of FIG. **3** includes multiple device modules **32a-d** coupled to a linear member **60**. Each device module **32a-d** is coupled to the linear member **60** via a stage **62a-d** moveably mounted to the linear member **60**. A device module **32a-d** may be connected to a stage **62a-d** using a connector such as an offset bracket **78a-d**. In another embodiment, the device module **32a-d** is directly mounted to the stage **62a-d**.

[0060] Each stage **62a-d** may be independently actuated to move linearly along the linear member **60**. Accordingly, each stage **62a-d** (and the corresponding device module **32a-d** coupled to the stage **62a-d**) may independently move relative to each other and the linear member **60**. A drive mechanism is used to actuate each stage **62a-d**. In the embodiment shown in FIG. **3**, the drive mechanism includes independent stage translation motors **64a-d** coupled to each stage **62a-d** and a stage drive mechanism **76**, for example, a lead screw via a rotating nut, a rack via a pinion, a belt via a pinion or pulley, a chain via a sprocket, or the stage translation motors **64a-d** may be linear motors themselves. In some embodiments, the stage drive mechanism **76** may be a combination of these mechanisms, for example, each stage **62a-d** could employ a different type of stage drive mechanism. In some embodiments where the stage drive mechanism is a lead screw and rotating nut, the lead screw may be rotated and each stage **62a-d** may engage and disengage from the lead screw to move, e.g., to advance or retract. In the embodiment shown in FIG. **3**, the stages **62a-d** and device modules **32a-d** are in a serial drive configuration.

[0061] Each device module **32a-d** includes a device module **68a-d** and a cassette **66a-d** mounted on and coupled to the device module **68a-d**. In the embodiment shown in FIG. **3**, each cassette **66a-d** is mounted to the device module **68a-d** in a vertical orientation. In other embodiments, each cassette **66a-d** may be mounted to the device module **68a-d** in other mounting orientations. Each cassette **66a-d** is configured to interface with and support a proximal portion of an EMD (not shown). In addition, each cassette **66a-d** may include elements to provide one or more degrees of freedom in addition to the linear motion provided by the actuation of the corresponding stage **62a-d** to move linearly along the linear member **60**. For example, the cassette **66a-d** may include elements that may be used to rotate the EMD when the cassette is coupled to the device module **68a-d**.

[0062] Each device module **68a-d** includes at least one coupler to provide a drive interface to the mechanisms in each cassette **66a-d** to provide the additional degree of freedom. Each cassette **66a-d** also includes a channel in which a device support **79a-d** is positioned, and each device support **79a-d** is used to prevent an EMD from buckling. A support arm **77a**, **77b**, and **77c** is attached to each device module **32a**, **32b**, and **32c**, respectively, to provide a fixed point for support of a proximal end of the device supports **79b**, **79c**, and **79d**, respectively. The robotic drive **24** may also include a device support connection **72** connected to a device support **79**, a distal support arm **70** and a support arm **770**. Support arm **770** is used to provide a fixed point for support of the proximal end of the distal-most support arm **79a** housed in the distal most device module **32a**. In addition, an introducer interface support (redirector) **74** may be connected to the device support connection **72** and an EMD (e.g., an introducer sheath). The configuration of robotic drive **24** has the benefit of reducing volume and weight of the drive robotic drive **24** by using actuators on a single linear member.

[0063] To prevent contaminating the patient with pathogens, healthcare staff use aseptic technique in a room housing the bedside unit **20** and the patient **12** or subject (shown in FIG. **1**). A room housing the bedside unit **20** and patient **12** may be, for example, a cath lab or an angio suite.

Aseptic technique consists of using sterile barriers, sterile equipment, proper patient preparation, environmental controls and contact guidelines. Accordingly, all EMDs and interventional accessories are sterilized and can only be in contact with either sterile barriers or sterile equipment. In some embodiments, a sterile drape (not shown) is placed over the non-sterile robotic drive **24**. Each cassette **66a-d** is sterilized and acts as a sterile interface between the draped robotic drive **24** and at least one EMD. Each cassette **66a-d** can be designed to be sterile for single use or to be re-sterilized in whole or part so that the cassette **66a-d** or its components can be used in multiple procedures.

[0064] As used herein, the term cassette generally refers to a component of a robotic drive system including components to support and move (e.g., rotate and/or translate) at least one EMD. A device module generally refers to a component of a robotic drive system that includes one or more motors with drive couplers which interface with the EMD-moving elements of the cassette. A cassette may provide a sterile interface between at least one EMD and a device module directly or through a device adapter. The term drive module refers to the combination of a device module and a cassette.

[0065] In some embodiments, an EMD is a catheter having a hub at a proximal end of the catheter and a flexible shaft extending from the hub toward the distal end of the catheter, wherein the shaft is more flexible than the hub. In one embodiment the catheter includes an intermediary portion that transitions between the hub and the shaft that has an intermediate flexibility that is less rigid than the hub and more rigid than the shaft. In some embodiments the intermediary portion is a strain relief.

[0066] The longitudinal axis of a member (for example, an EMD or other element in the catheter-based procedure system) is the line or axis along the length of the member that passes through the center of the transverse cross section of the member in the direction from a proximal portion of the member to a distal portion of the member. For example, the longitudinal axis of a guidewire is the central axis in the direction from a proximal portion of the guidewire toward a distal portion of the guidewire even though the guidewire may be non-linear in the relevant portion.

[0067] Linear movement of a member refers to translation of the member along the longitudinal axis of the member. For example, when the distal end of an EMD is linearly moved in a distal direction along its longitudinal axis into or further into the patient, the EMD is being advanced. When the distal end of an EMD is linearly moved in a proximal direction along its longitudinal axis out of or further out of the patient, the EMD is being withdrawn.

[0068] In this regard, linear insertion refers to inserting a first member into a second member along the longitudinal axis of the second member. For example, an EMD that is linear loaded in a collet is linear inserted in the collet. An example of linear insertion could be referred to as back loading a catheter on the proximal end of a guidewire. Lateral insertion refers to inserting a first member into a second member along a direction in a plane perpendicular to the longitudinal axis of the second member. Lateral insertion can also be referred to as radial loading or side loading.

[0069] Rotational movement of a member refers to the change in angular orientation of the member about the local longitudinal axis of the member. For example, rotational movement of an EMD corresponds to clockwise or counterclockwise rotation of the EMD about its longitudinal axis due to an applied torque. Continuous motion refers to motion that does not require a reset and is uninterrupted, while discrete motion refers to motion that requires a reset and is interrupted.

[0070] The terms distal and proximal define relative locations of two different features. With respect to a robotic drive, the terms distal and proximal are defined by the position of the robotic drive in its intended use relative to a patient.

[0071] When used to define a relative position, the distal feature is the feature of the robotic drive that is closer to the patient than a proximal feature when the robotic drive is in its intended in-use position. Within a patient, any vasculature landmark further away along the path from the access point is considered more distal than a landmark closer to the access point, where the access point is

the point at which the EMD enters the patient. Similarly, the proximal feature is the feature that is farther from the patient than the distal feature when the robotic drive is in its intended in-use position. [0072] When used to define direction, the distal direction refers to a path on which something is moving or is aimed to move or along which something is pointing or facing from a proximal feature toward a distal feature and/or patient when the robotic drive is in its intended in-use position. The proximal direction is the opposite direction of the distal direction. For example, referring to FIG. 1, a robotic device is shown from the viewpoint of an operator facing a patient. In this arrangement, the distal direction is along the positive X coordinate axis and the proximal direction is along the negative X coordinate axis.

[0073] With respect to movement of modules, and referring to FIG. 3, an EMD is moved in a distal direction on a path toward a patient through the introducer interface support 74 which defines the distal end of the robotic drive 24. The proximal end of the robotic drive 24 is the point furthest from the distal end along the negative X axis.

[0074] With respect to positions of the individual modules, and also referring to FIG. 3, the most distal device module is the device module 32a closest to the distal end of the robotic drive 24. The most proximal device module is the device module 32d positioned furthest from the distal end of the robotic drive 24 along the negative X axis. The relative position of device modules is determined by their relative location to the distal end of the robotic drive. For example, device module 32b is distal to device module 32c.

[0075] With respect to distal/proximal portions, sections or ends of an EMD or the robotic drive, the portions of cassette 66a and device module 68a are defined by their relative location to the distal end of the robotic drive. For example, the distal end of cassette 66a is the portion of the cassette that is closest to the distal end of the robotic drive and the proximal end of cassette 66a is the portion of the cassette that is furthest from the distal end of the robotic drive along the negative X axis when the cassette is in-use position on device module 68a. Stated in another way, the distal end of cassette 66a is the portion of the cassette through which an EMD is closest to the path leading to a patient in the in-use position.

[0076] As previously discussed, embodiments of a control station 26 can include a variety of different input modules for controlling the bedside unit 20. Input modules can include a variety of different input controls (for example, buttons, scroll wheels, joysticks, etc.) that can be manipulated by a user to control (or, instruct) operation of the robotic drive 24. These input controls can be arranged in different layouts or patterns on the input module to facilitate desired functions and cooperative sequencing thereof to perform a desired task requiring independent (and sometimes simultaneous) movement of multiple EMDs and/or independent (and possibly simultaneous) movement of different portions of a same EMD as described herein.

[0077] FIG. 4A and 4B are perspective views of EMD 400 which may be used in conjunction with some embodiments. Embodiments are not limited to EMD 400. EMD 400 includes internal member 410 disposed inside external member 420. A distal portion 412 of internal member 410 is coupled to distal portion 422 of external member 420. The term “coupled” encompasses any attachment method, including but not limited to, welding, ultrasonic welding, thermal bonding, adhesive bonding, molding, and others. The coupling may occur at any surface disposed toward the distal ends of internal member 410 and external member 420. Although distal portion 412 of internal member is shown substantially flush with a distal end of external member 420, a distal portion of internal member 410 may extend past the distal end of external member 420 in some embodiments. A proximal portion of internal member 410 may extend past the proximal end of external member 420 in some embodiments. The portion of the internal member 410 may be operatively coupled to an actuatable element extending past the proximal end of external member 420.

[0078] Each of internal member 410 and external member 420 may be moved linearly in a proximal direction and a distal direction, and rotated clockwise and counterclockwise. The linear

movement allows relative motion therebetween in a longitudinal direction. This relative motion and the coupling of the distal portions thereof causes bending of the distal ends as is known in the art. According to some embodiments, internal member **410** and external member **420** are also or alternatively configured for relative rotational movement. Such rotational movement may result in bending or other deformation of the distal ends thereof.

[0079] As is known in the art, at least one of internal member **410** and external member **420** may be slotted with slots to increase flexibility toward the distal ends thereof so as to improve steerability. The degree of flexibility may be determined by the number of slots, the spacing therebetween, the shape of the slots, the angle subtended by the slots, the thickness of and material, and other factors. Some embodiments achieve desired flexibility using a flexible material to serve in place of the above-described slotted portions and a rigid stiffener in place of the non-slotted portions.

[0080] In some embodiments, internal member **410** and external member **420** are composed of a suitably flexible, appropriate biocompatible material, including but not limited to, stainless steel (e.g., AISI **316**), nitinol, cobalt-chromium alloy, nickel-titanium alloy, and others, plastics (e.g., nylon, polypropylene, and many others) or combinations thereof. The composition of internal member **410** may differ from the composition of external member **420**. Either or both of internal member **410** and external member **420** may comprise machined features and/or component assemblies.

[0081] In some embodiments, internal member **410** defines a lumen throughout its length, which may define a lumen over the entire length of the EMD. During a procedure, fluid may be injected into the lumen from a proximal end of internal member **410**. Fluid and material may also be extracted from vasculature (e.g., aspiration) via the lumen. A connector such as a luer connector may be coupled to a proximal end of internal member **410**. Such a connector may facilitate a suitable fluid-tight connection between the lumen and an injection/suction/other system such as but not limited to a syringe, a hemostasis valve, a tube or other device.

[0082] FIG. **5** is a perspective view of EMD **500** configured for robotic activation in accordance with some embodiments. As described with respect to EMD **400**, EMD **500** includes internal member **510** disposed inside external member **520** and distal portions thereof are coupled to facilitate bending in response to relative movement. Internal member **510** and external member **520** of EMD **500** may exhibit any of the characteristics described above with respect to EMD **400** of FIGS. **4A** and **4B**.

[0083] Internal member **510** and external member **520** are movable relative to one another in a longitudinal direction. According to some embodiments, internal member **510** and external member **520** are also or alternatively configured for relative rotational movement. The relative movement and the coupling of the distal portions thereof causes bending and/or other deformation of the distal ends.

[0084] Actuable elements **515** and **525** are coupled, respectively, to internal member **510** and to external member **520**. Each of actuable elements **515** and **525** may be independently driven in some embodiments to rotate the respective member/tube to which it is coupled. Such rotation may result in relative rotational movement between internal member **510** and external member **520**.

[0085] Advantageously, rotation of internal member **510** and external member **520** in opposite directions can cause a particular magnitude of relative rotation faster than rotation of only one of internal member **510** and external member **520**, assuming identical rotation speeds. Nevertheless, as will be described below, some embodiments may comprise rotation of one of internal member **510** and external member **520** while the other is fixed to prevent rotation thereof. Such embodiments may omit an element to actuate rotational movement from the internal member/external member which is held relatively fixed rotationally.

[0086] Although the rotationally-actuable features of actuable elements **515** and **525** are depicted as gear teeth, embodiments are not limited thereto. In one non-exhaustive embodiment, one or both of actuable elements **515** and **525** comprise a pulley or an O-ring including surfaces

to be frictionally engaged by a drive such as a belt, for example. In some embodiments, no rotational actuatable elements are coupled to internal member **510** and external member **520** but drive elements are used to impart rotation to internal member **510** and/or external member **520** via contact with a surface of internal member **510** and/or external member **520**. Embodiments are not limited to one rotational actuatable element per member/tube.

[0087] Each of actuatable elements **515** and **525** comprise linearly-actuatable features **516**, **517** and **526**, **527** to facilitate linear movement of the respective internal member **510** and external member **520**. For example, features of a cassette in which internal member **510** is mounted may engage against feature **516** when the cassette moves in a proximal direction, resulting in retraction of internal member **510** from external member **520**, assuming the longitudinal position of external member **520** remains fixed. Conversely, features of the cassette in which internal member **510** is mounted may engage against feature **517** when the cassette moves in a distal direction, resulting in advancement of internal member **510** into external member **520**, again assuming the longitudinal position of external member **520** remains fixed.

[0088] A feature of a cassette in which external member **520** is mounted may engage against feature **526** when the cassette moves in a proximal direction, resulting in movement of internal member **510** in the proximal direction, while a feature of the cassette may engage against feature **527** when the cassette moves in a distal direction, resulting in movement of external member **520** in a distal direction. Any of the above linear movements may be used to change a relative longitudinal relationship between internal member **510** and external member **520**.

[0089] In some embodiments, a guidewire torquer (pin vise) or collet affixed to internal member **510** is used as a linearly- and/or rotationally-actuatable element to facilitate linear and/or rotational motion of internal member **510**. In some embodiments, such a linearly- and/or rotationally-actuatable element is coupled to such a guidewire torquer (pin vise) or collet affixed to internal member **510**.

[0090] Embodiments are not limited to a single actuatable element including features to provide rotational and linear motion. Embodiments are also not limited to rotational and linear motion of both internal member **510** and external member **520**. For example, each of internal member **510** and external member **520** may be coupled to a respective zero or more actuatable elements which are robotically-drivable to cause rotation thereof, and to a respective zero or more actuatable elements which are robotically-drivable to cause linear movement thereof. As will be illustrated below, a rotationally- and/or linearly-actuatable element may be coupled to any suitable location of internal member **510** and/or external member **520**.

[0091] FIG. **6** is a schematic view of robotic actuation of an EMD in accordance with some embodiments. External member **520** is loaded into cassette **620** of a robotic catheter system as described above with respect to cassettes **66a-66d** of robotic drive **24**. As described, mechanisms in cassette **620** are driven by a drive module. Driving of such mechanisms may drive actuatable element **525** to rotate external member **520** relative to internal member **510**. In the FIG. **6** embodiment, cassette **620** may move linearly to move external member **520** linearly relative to internal member **510**.

[0092] FIG. **7** is a schematic view of robotic actuation of an EMD in accordance with some embodiments. Internal member **510** is loaded into cassette **710** of a robotic catheter system such that such mechanisms of cassette **710** may drive actuatable element **515** to rotate internal member **510** relative to external member **525**. Cassette **710** may move linearly to move internal member **510** linearly relative to external member **520**.

[0093] FIG. **8** is a schematic view of robotic actuation of an EMD in accordance with some embodiments. External member **520** is loaded into cassette **820** of a robotic catheter system and mechanisms in cassette **820** may be driven to drive actuatable element **525** to rotate external member **520** relative to internal member **510**. In the FIG. **8** embodiment, cassette **810** may move linearly to move internal member **510** linearly relative to external member **520**.

[0094] As shown in FIG. 9, internal member **510** may be loaded into cassette **910** of a robotic catheter system such that such mechanisms of cassette **910** may drive actuatable element **515** to rotate internal member **510** relative to external member **520**. Cassette **920** may move linearly to move external member **520** linearly relative to internal member **510**.

[0095] FIG. 10 illustrates internal member **510** loaded into cassette **1010** and external member **520** loaded into cassette **1020**. Each of cassettes **1010** and **1020** include mechanisms to drive respective actuatable elements **515** and **525** as described above with respect to FIG. 5. Each of cassettes **1010** and **1020** may move linearly in proximal and distal directions to move internal member **510** and external member **520** relative to one another. Such linear movement as described herein may be facilitated by features of a cassette which engage corresponding features of a linearly-actuatable element coupled to respective internal member **510** or external member **520** as described above with respect to FIG. 5. In some embodiments, the cassette features may comprise features which hold internal member **510** or external member **520** fixed with respect to the cassette while the cassette moves linearly.

[0096] As described above, relative linear and/or rotational motion of an internal member and an external member of an EMD may cause a desired action at the distal portion thereof. Some embodiments operate to receive a single operator command to perform the desired action (e.g., bend tip by a certain amount, expand clot retriever) and in response, control motors associated with each of the respective two cassettes which support the internal member and the external member to linearly and/or rotationally move the internal member and the external member to cause the required relative motion between the internal member and the external member which results in the desired action.

[0097] FIG. 11 illustrates cassettes **1110** and **1120** of a robotic drive positioned as close to one another as allowed by the robotic drive. Such a position determines a minimum length of a proximal portion of internal member **510** which extends from external member **520**. The length should be sufficient for allowing loading of internal member within cassette **1110**. Such a requirement may require increasing a length of internal member **510** with respect to conventionally-available steerable catheters including an internal member and an external member.

[0098] FIGS. 12 and 13 illustrate different positions at which rotational actuatable elements **515** and **525** may be coupled to internal member **510** and external member **520** according to some embodiments. As mentioned above, zero or more actuatable elements may be coupled to any location of internal member **510** and/or external member **520**. The actuatable elements are coupled to facilitate engagement with corresponding drive elements of cassettes **1210**, **1220**, **1310** and **1320**.

[0099] FIG. 14 is an isometric view and FIG. 15 is an exploded view of actuatable element assembly **158** coupled to internal member **122** including a lumen according to some embodiments. Gear teeth **160** of actuatable element assembly **158** engages drive member **58** of a cassette and rotatably couples assembly **158** to internal member **122**. Such an arrangement forms a fluid tight rotational seal with male luer **41** of rotating element **40** and creates a continuous fluid path from hemostasis valve **176** to a lumen of internal member **122**. In a case that internal member **122** does not include a lumen, hemostasis valve **176** and the luer connectors may be omitted.

[0100] Gear teeth **160** of actuatable element assembly **150** is driven by drive gear **58** to impart rotation to internal member **122** while isolating a body of hemostasis valve **176** from rotational motion such that the position of second leg **178** of valve **176** does not rotate when internal member **122** is rotated. Bracket **190** interacts with groove **182** to support assembly **158** as it rotates and is itself secured to either base **32** or wall **74**. Hemostasis valve **176** is supported by bracket **192** that is itself secured to either base **32** or wall **74**. Brackets **190** and **192** provide stability to longitudinal axis **50** of valve **176** and also serve as features to cause linear movement of internal member **122** when a cassette in which brackets **190** and **192** are disposed is moved linearly.

[0101] Computer-executable program code for controlling a catheter-based procedure system or

presenting a user interface as described herein may be stored on non-transitory computer readable media. Computer readable media includes volatile and nonvolatile, removable, and non-removable media implemented in any method or technology for storage of information such as computer readable instructions, data structures, program modules or other data. Computer readable media includes, but is not limited to, random access memory (RAM), read-only memory (ROM), electrically erasable programmable ROM (EEPROM), flash memory or other memory technology, compact disk ROM (CD-ROM), digital versatile disks (DVD) or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium which can be used to store the desired instructions and which may be accessed by system 10 (shown in FIG. 1), including by internet or other computer network form of access.

Claims

1. An elongated medical device (EMD) comprising: an external member defining a lumen; an internal member disposed in the lumen and coupled to a distal portion of the external member; and a linearly-actuatable element coupled to the internal member, wherein linear actuation of the linearly-actuatable element causes relative linear movement between the external member and the internal member and deformation of the distal portion of the external member.
2. The device of claim 1, further comprising: a second linearly-actuatable element coupled to the external member, wherein linear actuation of the second linearly-actuatable element causes second relative linear movement between the external member and the internal member and second deformation of the distal portion of the external member.
3. The device of claim 2, further comprising: a rotationally-actuatable element coupled to the external member, wherein actuating the rotationally-actuatable element causes relative rotational movement between the external member and the internal member and third deformation of the distal portion of the external member.
4. The device of claim 3, wherein the rotationally-actuatable element comprises gear teeth.
5. The device of claim 3, further comprising: a second rotationally-actuatable element coupled to the internal member, wherein actuating the second rotationally-actuatable element causes second relative rotational movement between the external member and the internal member and fourth deformation of the distal portion of the external member.
6. The device of claim 1, further comprising: a rotationally-actuatable element coupled to the internal member, wherein actuating the rotationally-actuatable element causes relative rotational movement between the external member and the internal member and second deformation of the distal portion of the external member.
7. The device of claim 6, wherein the linearly-actuatable element and the rotationally-actuatable element comprise a same single element comprising linearly-actuatable features and rotationally-actuatable features.
8. The device of claim 6, wherein the rotationally-actuatable element comprises gear teeth.
9. The device of claim 6, further comprising: a second rotationally-actuatable element coupled to the external member, wherein actuating the second rotationally-actuatable element causes second relative rotational movement between the external member and the internal member and third deformation of the distal portion of the external member.
10. The device of claim 8, wherein the linearly-actuatable element and the rotationally-actuatable element comprise a same single element comprising linearly-actuatable features and rotationally-actuatable features, and wherein the second linearly-actuatable element and the second rotationally-actuatable element comprise a second same single element comprising second linearly-actuatable features and second rotationally-actuatable features.
11. A elongated medical device (EMD) comprising: an external member defining a lumen; an internal member disposed in the lumen and coupled to a distal portion of the external member; and

a linearly-actuatable element coupled to the external member, wherein linear actuation of the linearly-actuatable element causes relative linear movement between the external member and the internal member and deformation of the distal portion of the external member.

12. The device of claim 11, further comprising: a rotationally-actuatable element coupled to the external member, wherein actuating the rotationally-actuatable element causes relative rotational movement between the external member and the internal member and third deformation of the distal portion of the external member.

13. The device of claim 12, wherein the linearly-actuatable element and the rotationally-actuatable element comprise a same single element comprising linearly-actuatable features and rotationally-actuatable features.

14. The device of claim 13, wherein the rotationally-actuatable features comprise gear teeth.

15. The device of claim 11, further comprising: a rotationally-actuatable element coupled to the internal member, wherein actuating the rotationally-actuatable element causes relative rotational movement between the external member and the internal member and second deformation of the distal portion of the external member.

16. The device of claim 15, wherein the rotationally-actuatable element comprises gear teeth.

17. A method comprising: loading an external member of an elongated medical device (EMD) into a robotic drive, the external member defining a lumen; loading an internal member of the device into the robotic drive, the internal member disposed in the lumen and coupled to a distal portion of the external member; and controlling the robotic drive to actuate a linearly-actuatable element coupled to the external member, wherein actuation of the linearly-actuatable element causes relative linear movement between the external member and the internal member and deformation of the distal portion of the external member.

18. The method of claim 17, further comprising: controlling the robotic drive to actuate a second linearly-actuatable element coupled to the internal member, wherein linear actuation of the second linearly-actuatable element causes second relative linear movement between the external member and the internal member and second deformation of the distal portion of the external member.

19. The method of claim 18, further comprising: controlling the robotic drive to actuate a rotationally-actuatable element coupled to the external member, wherein actuating the rotationally-actuatable element causes relative rotational movement between the external member and the internal member and third deformation of the distal portion of the external member.

20. The method of claim 18, further comprising: controlling the robotic drive to actuate a rotationally-actuatable element coupled to the internal member, wherein actuating the rotationally-actuatable element causes relative rotational movement between the external member and the internal member and second deformation of the distal portion of the external member.
