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Thrombi removal system having a thrombi removal catheter

Abstract

A thrombi removal catheter includes a sheath having a distal axial opening at a distal end in fluid communication with a lumen, and a lateral opening that extends through a side wall to the lumen. The lateral opening is proximally spaced from the distal end. An elongate member is disposed in the lumen of the sheath and is configured for longitudinal movement relative to the sheath. The elongate member has a proximal position and a distal position relative to the sheath. When the elongate member is in the proximal position, the distal axial opening of the sheath is closed by a distal blocker element of the elongate member and the lateral opening of the sheath is open, and when the elongate member is in the distal position, the lateral opening of the sheath is closed by the proximal blocker element and the distal axial opening of the sheath is open.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS

(1) This application is a U.S. National Phase of International Application No. PCT/US2020/067241, entitled “Thrombi Removal System Having a Thrombi Removal Catheter” and filed Dec. 29, 2020, which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

(2) The present invention relates to thrombus removal, and, more particularly, to a thrombi removal system having a thrombi removal catheter.

BACKGROUND ART

(3) Thrombosis is a condition wherein a blood clot, known as a thrombus, is formed within a blood vessel, thus obstructing the normal blood flow through the blood vessel. Interventional medical devices, such as catheters, may be used to help breakup and/or remove the thrombus from the blood vessel using static continuous vacuum pressure. However, it has been observed that when static continuous vacuum is applied to a more robust blood clot, the blood clot tends to attach to the tip of the catheter without breaking, hence interrupting the aspiration through the catheter.

(4) What is needed in the art is a thrombi removal system having a thrombi removal catheter which can break up robust blood clots more effectively.

SUMMARY OF INVENTION

(5) The present invention provides a thrombi removal system having a thrombi removal catheter configured to facilitate intermittent and redirected application of vacuum, e.g., to a blood clot in a blood vessel, and which may provide a mechanical component to aid in clot fragmentation.

(6) The invention, in one form, is directed to a thrombi removal catheter for use in a thrombi removal system. The thrombi removal catheter includes an elongate sheath having a proximal end, a distal end, a side wall that defines a lumen that extends from the proximal end to the distal end, a distal axial opening at the distal end in fluid communication with the lumen, and at least one lateral opening that extends through the side wall to the lumen. The at least one lateral opening is proximally spaced from the distal end. An elongate member is disposed in the lumen of the elongate sheath. The elongate member is configured for longitudinal movement relative to the elongate sheath. The elongate member has a proximal position and a distal position relative to a position of the elongate sheath. The elongate member has a proximal blocker element and a distal blocker element that is longitudinally spaced from the proximal blocker element. The proximal blocker element has a longitudinal passage. The thrombi removal catheter is configured such that: when the elongate member is in the proximal position, the distal axial opening of the elongate sheath is closed by the distal blocker element of the elongate member and the at least one lateral opening of the elongate sheath is open, and when the elongate member is in the distal position, the at least one lateral opening of the elongate sheath is closed by the proximal blocker element and the distal axial opening of the elongate sheath is open.

(7) The invention, in another form, is directed to a thrombi removal system. The thrombi removal system includes the thrombi removal catheter as described herein, a vacuum source, and a driver mechanism. The vacuum source is coupled in fluid communication with the lumen of the elongate sheath. The driver mechanism is coupled to at least one of the elongate member and the elongate sheath. The driver mechanism is configured to longitudinally move the elongate member relative to the elongate sheath by longitudinally moving at least one of the elongate member and the elongate sheath.

(8) An advantage of the present invention is that the device of the present invention provides for

more effective removal of thrombi and/or allows a greater portion of the thrombus material to be removed.
(9) Another advantage of the present invention is that the thrombi removal system and thrombi removal catheter facilitate and interrupt vacuum application to the area of the thrombus so as to fatigue the clot material.
(10) Another advantage of the present invention is that, in combination with the intermittent application of vacuum to the thrombus, the thrombi removal catheter may be longitudinally reciprocated to slice and/or fragment the blood clot mechanically as the thrombi removal catheter comes in contact with the blood clot.
(11) Another advantage of the present invention is that the thrombi removal catheter is configured to engage the blood clot at both of the tip portion of the catheter and at a side location (or side locations) of the catheter, so that any remaining thrombus material is less likely to be left behind.
(12) Yet another advantage of the present invention is that the operator is less likely to have to stop the procedure to manually clear the catheter tip to open a clogged aspiration passage.

Description

BRIEF DESCRIPTION OF DRAWINGS
(1) The above-mentioned and other features and advantages of this invention, and the manner of attaining them, will become more apparent and the invention will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:
(2) FIG. **1** is a block diagram depicting a thrombi removal system that includes a vacuum source, a driver mechanism, a controller circuit, and a thrombi removal catheter having an inner elongate member disposed in an outer elongate sheath;
(3) FIG. **2** is an exploded side view of the thrombi removal catheter of FIG. **1**, with the elongate member separated from the elongate sheath;
(4) FIG. **3** is an enlarged side view of a distal portion of the thrombi removal catheter of FIGS. **1** and **2**, wherein the elongate member is positioned in a proximal position relative to the elongate sheath;
(5) FIG. **4** is an enlarged side view of a distal portion of the thrombi removal catheter of FIGS. **1** and **2**, wherein the elongate member is positioned in a distal position relative to the elongate sheath;
(6) FIG. **5** is an enlargement of a distal portion of the exploded side view of the thrombi removal catheter as depicted in FIG. **2**, wherein the elongate member includes an elongate element, a proximal blocker element, and a distal blocker element;
(7) FIG. **6** is an end view of the elongate sheath of FIGS. **1**-**5**;
(8) FIG. **7** is an enlarged view of the proximal blocker element taken along line **7**-**7** of FIG. **5**;
(9) FIG. **8** is an enlarged section view of the distal blocker element taken along line **8**-**8** of FIG. **5**;
(10) FIG. **9**A is a section view of an optional embodiment, associated with line **9**A-**9**A of FIG. **3**, wherein an annular seal may be radially interposed between a side wall of the elongate sheath and the distal blocker element of the elongate member;
(11) FIG. **9**B is a section view of an optional embodiment, associated with line **9**B-**9**B of FIG. **4**, wherein an annular seal may be radially interposed between the side wall of the elongate sheath and the proximal blocker element of the elongate member;
(12) FIG. **10** is a modification of the embodiment of FIG. **1**, wherein the controller circuit of FIG. **1** is omitted and the driver mechanism is in the form of a manual handle;
(13) FIG. **11** is another embodiment of a thrombi removal catheter in accordance with an aspect of the present invention, wherein the elongate member of the thrombi removal catheter of FIGS. **1**-**10**

is replaced with an alternative configuration of an elongate member configured from an elongate cannula;
(14) FIG. **12** is a section view of the proximal blocker element taken along line **12-12** of FIG. **11**; and
(15) FIG. **13** is a section view of the distal blocker element taken along line **13-13** of FIG. **11**.
(16) Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate embodiments of the invention, and such exemplifications are not to be construed as limiting the scope of the invention in any manner.
DESCRIPTION OF EMBODIMENTS
(17) Referring now to the drawings, and more particularly to FIG. **1**, there is shown a thrombi removal system **10** that includes a thrombi removal catheter **12**, a vacuum source **14**, a driver mechanism **16**, and a controller circuit **18**.
(18) Referring also to FIGS. **2-6**, thrombi removal catheter **12** includes an elongate sheath **20** and an elongate member **22** that is coaxial with elongate sheath **20** along a longitudinal axis **24**. In the present embodiment, elongate sheath **20** has a lumen **26** and elongate member **22** is slidably disposed in lumen **26** of elongate sheath **20**. Elongate member **22** is configured for longitudinal movement relative to elongate sheath **20**. Each of elongate sheath **20** and elongate member **22** is made of flexible material so as to be adaptable to a vasculature along its respective longitudinal length. The flexible material may be plastic or metal. Some examples of suitable plastics include Pebax, polyimide, etc. Some examples of suitable metals include stainless steel, nitinol, etc.
(19) Elongate sheath **20** includes a distal axial opening **28** and at least one lateral opening **30**. In the present embodiment, the at least one lateral opening **30** is represented as a plurality of lateral openings in elongate sheath **20**, wherein the plurality of lateral openings include two diametrically opposed lateral openings, individually identified as lateral opening **30-1** and lateral opening **30-2**. Collectively, lateral opening **30-1** and lateral opening **30-2** may be referenced as lateral openings **30-1**, **30-2**. However, for convenience, the term "lateral opening **30**" will be used to reference structure that includes at least one of lateral opening **30-1** and/or lateral opening **30-2**, and does not preclude the inclusion of additional lateral openings, e.g., circumferentially spaced between lateral opening **30-1** and lateral opening **30-2**. In the present embodiment, lateral opening **30** may be located in a distal section of elongate sheath **20**, e.g., near a distal end of elongate sheath **20**.
(20) During a thrombectomy, distal axial opening **28** and lateral opening **30** are alternatingly opened and closed by a reciprocating longitudinal movement of elongate member **22** relative to elongate sheath **20** in a distal direction **34** and a proximal direction **36** along longitudinal axis **24**. In one embodiment, the cumulative size, i.e., area of the opening, of lateral opening **30** may be selected, for example, to be equal to the size, i.e., area of the opening, of distal axial opening **28**. However, alternatively, the cumulative size, i.e., area of the opening, of lateral opening **30** may be selected, for example, to be different from the size, i.e., area of the opening, of distal axial opening **28**, so that the flow velocities through lateral opening **30** and through distal axial opening **28** are different. The structure and operation of thrombi removal catheter **12** will be discussed in further detail below.
(21) Vacuum source **14**, e.g., a local vacuum pump, is coupled in fluid communication with lumen **26** of elongate sheath **20** of thrombi removal catheter **12** via a connection manifold **38**. Connection manifold **38** is configured with openings, passages, and seals to facilitate the interface of vacuum source **14**, and driver mechanism **16**, with thrombi removal catheter **12**. Vacuum source **14** may be controlled by control instructions executed by controller circuit **18**, or alternatively, may be a simple ON/OFF switch to operate a vacuum pump, e.g., to selectively supply electrical power to an electrical vacuum pump.
(22) Driver mechanism **16** is drivably coupled to thrombi removal catheter **12** to facilitate the longitudinal movement of elongate member **22** relative to elongate sheath **20** by a longitudinal movement of at least one of elongate member **22** and elongate sheath **20**. For example, driver

mechanism **16** may be coupled to at least one of elongate member **22** and elongate sheath **20**, wherein driver mechanism **16** is configured to longitudinally move elongate member **22** relative to elongate sheath **20** by longitudinally moving at least one of elongate member **22** and elongate sheath **20**. In the present, driver mechanism **16** is drivably connected to elongate member **22** so as to longitudinally move elongate member **22** while elongate sheath **20** is not longitudinally driven. Alternatively, for example, driver mechanism **16** may be drivably connected to elongate sheath **20** so as to longitudinally move elongate sheath **20** while elongate member **22** is not longitudinally driven.

(23) In accordance with an aspect of the present invention, driver mechanism **16** is configured to longitudinally move elongate member **22** relative to elongate sheath **20** in a longitudinal reciprocation manner. Driver mechanism **16** may be, for example, a motive power source **16-1** drivably coupled to a linear drive member **16-2**, wherein the linear drive member **16-2** is mechanically coupled to one of elongate member **22** and elongate sheath **20**. In one example, the motive power source **16-1** is a rotary motor and the linear drive member **16-2** is a rotational-to-linear translation (e.g., pinion/rack) gear assembly. In another example, the motive power source **16-1** is a linear motor and the linear drive member **16-2** is a magnetic linear translator core member. In another example, the motive power source **16-1** is a solenoid and the linear drive member **16-2** is a ferrous linear translator core member. In the case that the driver mechanism **16** is an electrical power source, the motive power source **16-1** supplies electrical energy. In the case that the driver mechanism **16** is a pneumatic power source, the motive power source **16-1** supplies fluid energy (e.g., air pressure, positive and/or negative).

(24) Controller circuit **18** is communicatively coupled to driver mechanism **16**. Controller circuit **18** may include a user interface, e.g., in the form of operator buttons and/or a touch screen display. Controller circuit **18** is configured to operate driver mechanism **16** to alternatingly position elongate member **22** in a proximal position **40** (see FIG. **3**; i.e., a retracted position) and a distal position **42** (see FIG. **4**; i.e., an extended position) relative to elongate sheath **20**. Controller circuit **18** may be a commercially available microcontroller, or alternatively, may be formed as one or more Application Specific Integrated Circuits (ASIC). In the present embodiment, controller circuit **18** includes one or more programmable microprocessors and associated circuitry, such as an input/output interface, clock, buffers, non-transitory electronic memory, etc. Such non-transitory electronic memory may include volatile memory circuits, such as random access memory (RAM), and non-volatile memory circuits, such as read only memory (ROM), electronically erasable programmable ROM (EEPROM), NOR flash memory, NAND flash memory, etc.

(25) Controller circuit **18** is configured via software and/or firmware to execute program instructions to perform functions, such as effecting a longitudinal reciprocation of elongate member **22** relative to elongate sheath **20** of thrombi removal catheter **12**. For example, controller circuit **18** may be configured, e.g., via execution of program instructions, to operate driver mechanism **16** to alternate the positioning of elongate member **22** relative to elongate sheath **20** during reciprocation at a predetermined time interval. The predetermined time interval may be, for example, in a range of 0.05 and 2.5 seconds. Also, a full cycle of reciprocating movement of elongate member **22** relative to elongate sheath **20** may be, for example, a time period in a range of 0.1 seconds to 5 seconds.

(26) Referring to FIGS. **1-8**, elongate sheath **20** has a proximal end **20-1**, a distal end **20-2**, and a side wall **20-3** that defines lumen **26**. In the present embodiment, each of lumen **26** and side wall **20-3** extends from proximal end **20-1** to distal end **20-2**. In the present embodiment, proximal end **20-1** is connected to connection manifold **38** (see also FIG. **1**). Distal axial opening **28** is located at distal end **20-2** and is in fluid communication with lumen **26**.

(27) In the present embodiment, with reference to FIGS. **2-5**, each of the lateral openings **30-1**, **30-2** radially extends through side wall **20-3** to lumen **26**. Each of the lateral openings **30-1**, **30-2** is proximally spaced from distal end **20-2** of elongate sheath **20**. By way of example, and not by

limitation, the spacing between distal end **20-2** of elongate sheath **20** and lateral opening **30** may be in a range of 0.5 to 1.5 centimeters.
(28) In the present embodiment, elongate member **22** is disposed in lumen **26** of elongate sheath **20**. Elongate member **22** is configured, e.g., in size and in shape, for longitudinal movement relative to elongate sheath **20**. Referring to FIGS. **3** and **4**, elongate member **22** has a proximal position **40** and a distal position **42** relative to a position of elongate sheath **20**.
(29) Referring to FIGS. **3-5**, elongate member **22** has a proximal end **22-1** and a distal end **22-2**. In the present embodiment, proximal end **22-1** of elongate member **22** is mechanically coupled, e.g., via a threaded coupling, snap coupling, crimping, or weld, to linear drive member **16-2** of driver mechanism **16** (see also FIG. **1**). Elongate member **22** further includes an elongate element **44**, a proximal blocker element **46**, and a distal blocker element **48** that are arranged between proximal end **22-1** and distal end **22-2** of elongate member **22**. In the present embodiment, elongate element **44** extends from proximal end **22-1** and distal end **22-2** of elongate member **22**. In the present embodiment, proximal blocker element **46** may be located in a distal section of elongate member **22**, e.g., near distal end **22-2** of elongate member **22** proximal to distal blocker element **48**.
(30) In the present embodiment, elongate element **44** may be configured as an elongate cannula, i.e., a tube, having a guidewire lumen **44-1**. Guidewire lumen **44-1** is configured, e.g., in size and shape, to receive a guidewire during a thrombectomy so as to guide thrombi removal catheter **12** to the blood clot.
(31) Distal blocker element **48** is located proximate distal end **22-2** of elongate member **22**. In the present embodiment, distal blocker element **48** extends proximally from distal end **22-2** of elongate member **22**. Distal blocker element **48** is longitudinally spaced from proximal blocker element **46**. Distal blocker element **48** is connected to elongate element **44**, such as for example, by weld, solder, or an adhesive, or may be formed integral with elongate element **44** via molding.
(32) Proximal blocker element **46** is located proximal to distal blocker element **48**. Proximal blocker element **46** is connected to elongate element **44**, such as for example, by weld, solder, or an adhesive, or may be formed integral with elongate element **44** via molding. By way of example, and not by limitation, the spacing between proximal blocker element **46** and distal blocker element **48** may be in a range of 0.5 to 1.5 centimeters.
(33) Referring also to FIG. **7**, proximal blocker element **46** has a longitudinal passage **46-1**. With elongate member **22** disposed in lumen **26** of elongate sheath **20**, longitudinal passage **46-1** of proximal blocker element **46** is in fluid communication with lumen **26**. Proximal blocker element **46** may be configured, for example, as a cylinder having longitudinal passage **46-1**. Referring to FIGS. **3-5**, proximal blocker element **46** has a beveled distal end **46-2**. Optionally, proximal blocker element **46** may include a beveled proximal end **46-3**. In the present embodiment, beveled distal end **46-2** is configured, e.g., in size and in shape, to longitudinally pass across lateral opening **30** (e.g., each lateral opening **30-1**, **30-2**) of side wall **20-3** of elongate sheath **20** to effect a scissoring cutting action as elongate member **22** longitudinally moves from proximal position **40** to distal position **42**.
(34) Referring also to FIG. **8** in conjunction with FIGS. **3-5**, in the present embodiment, distal blocker element **48** may be a solid structure, or at least a radially closed structure, that has a closed distal end **48-1** that defines a tapered tip **48-2**, and may have a closed proximal end **48-3** that defines a proximal beveled surface **48-4**. Tapered tip **48-2** may be, for example, beveled or pointed. Referring to FIGS. **3-5**, proximal beveled surface **48-4** is configured, e.g., in size and in shape, to longitudinally pass into distal axial opening **28** of elongate sheath **20** and across distal end **20-2** of side wall **20-3** of elongate sheath **20** to effect a scissoring cutting action as elongate member **22** longitudinally moves from distal position **42** to proximal position **40**.
(35) Referring to FIG. **9**A, optionally, a first annular seal **50** may be radially interposed between side wall **20-3** of elongate sheath **20** and distal blocker element **48** of elongate member **22**. First annular seal **50** may be in the form of an O-ring, a rubber sleeve, or a rubberized coating. Referring

to FIG. **9**A in conjunction with FIG. **3**, first annular seal **50** is configured, e.g., in thickness and position, to seal an annular region **52** between side wall **20-3** of elongate sheath **20** and distal blocker element **48** when distal blocker element **48** is in proximal position **40**.

(36) Similarly, referring to FIG. **9**B, optionally, a second annular seal **54** may be radially interposed between side wall **20-3** of elongate sheath **20** and proximal blocker element **46** of elongate member **22**. Second annular seal **54** may be in the form of an O-ring, a rubber sleeve, or a rubberized coating. Referring to FIG. **9**B in conjunction with FIG. **4**, second annular seal **54** is configured, e.g., in thickness and position, to seal an annular region **56** between side wall **20-3** of elongate sheath **20** and proximal blocker element **46** when proximal blocker element **46** is in distal position **42**.

(37) In operation, with reference to FIGS. **3** and **4**, when elongate member **22** is in proximal position **40**, distal axial opening **28** of elongate sheath **20** is closed by distal blocker element **48** of elongate member **22** and lateral opening **30** (e.g., each lateral opening **30-1**, **30-2**) of elongate sheath **20** is open. As such, when elongate member **22** is in proximal position **40**, a first fluid path **58** is defined through lateral opening **30** (e.g., each of lateral opening **30-1**, **30-2**) to lumen **26** of elongate sheath **20** to the exclusion of distal axial opening **28**. First fluid path **58** also extends through longitudinal passage **46-1** of proximal blocker element **46** to facilitate fluid communication of lateral opening **30** (e.g., each lateral opening **30-1**, **30-2**) of elongate sheath **20** with vacuum source **14**. As such, when elongate member **22** is in proximal position **40**, aspiration is effected by vacuum source **14** at lateral opening **30** to the exclusion of distal axial opening **28**.

(38) Conversely, when elongate member **22** is in distal position **42**, lateral opening **30** (e.g., each lateral opening **30-1**, **30-2**) of elongate sheath **20** is closed by proximal blocker element **46** and distal axial opening **28** of elongate sheath **20** is open. As such, when elongate member **22** is in distal position **42**, a second fluid path **60** (different from first fluid path **58**) is defined through distal axial opening **28** to lumen **26** of elongate sheath **20** to the exclusion of lateral opening **30** (e.g., to the exclusion of each lateral opening **30-1**, **30-2**). Second fluid path **60** extends through longitudinal passage **46-1** of proximal blocker element **46** to facilitate fluid communication of distal axial opening **28** of elongate sheath **20** with vacuum source **14**. As such, when elongate member **22** is in distal position **42**, aspiration is effected by vacuum source **14** at distal axial opening **28** to the exclusion of lateral opening **30**.

(39) Thus, in accordance with the present embodiment, each of first fluid path **58** and second fluid path **60** extends through longitudinal passage **46-1** of proximal blocker element **46**, but the selection as between first fluid path **58** through lateral opening **30** or second fluid path **60** through distal axial opening **28** depends upon the position of elongate member **22** at proximal position **40** or at distal position **42**.

(40) In one implementation of the present invention, controller circuit **18** executes program instructions to operate driver mechanism **16** so as to alternatingly position elongate member **22** in proximal position **40** (see FIG. **3**) and distal position **42** (see FIG. **4**) relative to elongate sheath **20**. For example, controller circuit **18** may execute program instructions to alternate the positioning of elongate member **22** relative to elongate sheath **20** in proximal position **40** and distal position **42** at a predetermined time interval. As such, vacuum applied to the thrombus alternates between first fluid path **58** through lateral opening **30** (e.g., each lateral opening **30-1**, **30-2**) of elongate sheath **20**, and second fluid path **60** through distal axial opening **28** of elongate sheath **20**.

(41) In the present embodiment, for example, the predetermined time interval is in a range of 0.05 and 2.5 seconds. Stated differently, a full cycle of movement of elongate sheath **20** from proximal position **40** to distal position **42**, and back to proximal position **40**, has a time period in a range of 0.1 seconds to 5 seconds. The number of full cycles may be determined by the user, such as for example, by user observation, or in some implementations, may be a predetermined value stored in controller circuit **18**.

(42) FIG. **10** shows another embodiment of the present invention, wherein driver mechanism **16** is

a manual handle **62** that is connected to one of elongate member **22** and elongate sheath **20**, so as to alternatingly position elongate member **22** in proximal position **40** (see FIG. **3**) and distal position **42** (see FIG. **4**) relative to elongate sheath **20**. Controller circuit **18** of FIG. **1** may also be removed in the embodiment of FIG. **10**, wherein vacuum source **14** is then manually activated, e.g., by an ON/OFF switch.

(43) Referring to FIGS. **11-13**, there is shown another embodiment for a thrombi removal catheter **70** in accordance with an aspect of the present invention that may replace thrombi removal catheter **12** of FIG. **1**. Thrombi removal catheter **70** includes elongate sheath **20** and an elongate member **72** that is coaxial with elongate sheath **20** along longitudinal axis **24**. Thrombi removal catheter **70** differs from thrombi removal catheter **12** in that elongate member **22** is replaced with elongate member **72**. As such, the function and operation of thrombi removal catheter **70** is identical to that of thrombi removal catheter **12**, discussed above with respect to FIGS. **1-10**.

(44) Referring to FIG. **11**, elongate member **72** is slidably disposed in lumen **26** of elongate sheath **20**. Elongate member **72** is configured for longitudinal movement relative to elongate sheath **20**. Each of elongate sheath **20** and elongate member **72** is made of flexible material so as to be adaptable to a vasculature along its respective longitudinal length. The flexible material may be plastic or metal. Some examples of suitable plastics include Pebax, polyimide, etc. Some examples of suitable metals include stainless steel, nitinol, etc.

(45) During a thrombectomy, distal axial opening **28** and the lateral opening **30** (e.g., each lateral opening **30-1**, **30-2**) are alternatingly opened and closed by a reciprocating longitudinal movement of elongate member **72** relative to elongate sheath **20** in distal direction **34** and proximal direction **36** along longitudinal axis **24**.

(46) Referring again to FIGS. **11-13**, elongate member **72** is formed as a cannula **74** having a side-section removed to form a notch **76** so as to define a proximal blocker element **78** and a distal blocker element **80**, which correspond generally to proximal blocker element **46** and distal blocker element **48** of the embodiment of FIGS. **1-10**. Cannula **74** has a lumen **74-1**. In the present embodiment, lumen **74-1** of cannula **74** may be coupled in direct fluid communication with vacuum source **14**, or may be coupled in indirect fluid communication with vacuum source **14** via lumen **26** of elongate sheath **20**.

(47) In the present embodiment, elongate member **72** includes a guidewire lumen **82**, e.g., as a separate tube or as a lumen in the side wall of elongate member **72**. Guidewire lumen **82** is configured, e.g., in size and shape, to receive a guidewire during a thrombectomy.

(48) Referring to FIGS. **11** and **12**, proximal blocker element **78** has a longitudinal passage **78-1** in fluid communication with lumen **74-1** of cannula **74**. In the present embodiment, proximal blocker element **78** is configured, for example, as a cylinder having longitudinal passage **78-1**. Proximal blocker element **78** has a beveled distal end **78-2**. In the present embodiment, beveled distal end **78-2** is configured, e.g., in size and in shape, to longitudinally pass across lateral opening **30** (e.g., each lateral opening **30-1**, **30-2**) of side wall **20-3** of elongate sheath **20** to effect a scissoring cutting action as elongate member **72** longitudinally moves from proximal position **40** to distal position **42** (see, e.g., FIGS. **3** and **4**).

(49) Referring to FIGS. **11** and **13**, distal blocker element **80** is longitudinally spaced from proximal blocker element **78**, and distal blocker element **80** is located proximate distal end **72-1** of elongate member **72**. In the present embodiment, distal blocker element **80** extends proximally from distal end **72-1** of elongate member **72**. Distal blocker element **80** includes a closed distal end **80-1** that defines a tapered tip **80-2** and may have a closed proximal end **80-3** that defines a proximal beveled surface **80-4**. Distal blocker element **80** may be closed by plugging, e.g., filling, cannula **74** at distal blocker element **80**. Proximal beveled surface **80-4** is configured, e.g., in size and in shape, to longitudinally pass into distal axial opening **28** of elongate sheath **20** and across distal end **20-2** of side wall **20-3** of elongate sheath **20** to effect a scissoring cutting action as elongate member **72** longitudinally moves from distal position **42** to proximal position **40** (see, e.g.,

FIGS. **3** and **4**).
(50) The following items also relate to the invention:
(51) In one embodiment, the invention relates to a thrombi removal catheter for use in a thrombi removal system. The thrombi removal catheter may include an elongate sheath having a proximal end, a distal end, a side wall that defines a lumen that extends from the proximal end to the distal end, a distal axial opening at the distal end in fluid communication with the lumen, and at least one lateral opening that extends through the side wall to the lumen. The at least one lateral opening is proximally spaced from the distal end. An elongate member is disposed in the lumen of the elongate sheath. The elongate member is configured for longitudinal movement relative to the elongate sheath. The elongate member has a proximal position and a distal position relative to a position of the elongate sheath. The elongate member has a proximal blocker element and a distal blocker element that is longitudinally spaced from the proximal blocker element. The proximal blocker element has a longitudinal passage. The thrombi removal catheter is configured such that: when the elongate member is in the proximal position, the distal axial opening of the elongate sheath is closed by the distal blocker element of the elongate member and the at least one lateral opening of the elongate sheath is open; and when the elongate member is in the distal position, the at least one lateral opening of the elongate sheath is closed by the proximal blocker element and the distal axial opening of the elongate sheath is open.
(52) In any of the embodiments, the thrombi removal catheter may be configurable such that when the elongate member is in the proximal position, a first fluid path may be defined through the at least one lateral opening to the lumen of the elongate sheath to the exclusion of the distal axial opening, and when the elongate member is in the distal position, a second fluid path may be defined through the distal axial opening to the lumen of the elongate sheath to the exclusion of the at least one lateral opening.
(53) In the embodiment of the preceding paragraph, each of the first fluid path and the second fluid path may extend through the longitudinal passage of the proximal blocker element.
(54) In any of the embodiments, the at least one lateral opening may be one of a plurality of side openings in the elongate sheath.
(55) In the embodiment of the preceding paragraph, the plurality of side openings may include two diametrically opposed lateral openings.
(56) In any of the embodiments, the proximal blocker element may be a cylinder.
(57) In any of the embodiments, the proximal blocker element may have a beveled distal end configured to longitudinally pass across each of the at least one lateral opening of the side wall of the elongate sheath to effect a scissoring cutting action as the elongate member longitudinally moves from the proximal position to the distal position.
(58) In any of the embodiments, the distal blocker element may have a closed distal end that defines a pointed tip and a closed proximal end that defines a proximal beveled surface, wherein the proximal beveled surface may be configured to longitudinally pass across the distal end of the side wall of the elongate sheath to effect a scissoring cutting action as the elongate member longitudinally moves from the distal position to the proximal position.
(59) In any of the embodiments, optionally, the elongate member may include an elongate cannula that may have a guidewire lumen. The elongate cannula may have a first end and a second end. The distal blocker element may be located proximate the second end of the elongate cannula and the distal blocker element may be connected to the elongate cannula. The proximal blocker element may be located proximal to the distal blocker element and the proximal blocker element may be connected to the elongate cannula.
(60) In any of the embodiments, optionally, a first annular seal may be radially interposed between the side wall of the elongate sheath and the distal blocker element. The first annular seal may be configured to seal an annular region between the side wall of the elongate sheath and the distal blocker element when the distal blocker element is in the proximal position. A second annular seal

may be radially interposed between the side wall of the elongate sheath and the proximal blocker element. The second annular seal may be configured to seal an annular region between the side wall of the elongate sheath and the proximal blocker element when the proximal blocker element is in the distal position.

(61) In any of the embodiments, each of the elongate sheath and the elongate member may be made of flexible material so as to be adaptable to a vasculature along its respective longitudinal length.

(62) In another embodiment, the invention relates to a thrombi removal system that may include the thrombi removal catheter according to any of previous embodiments. The thrombi removal system may also include a vacuum source coupled in fluid communication with the lumen of the elongate sheath. A driver mechanism may be coupled to at least one of the elongate member and the elongate sheath. The driver mechanism may be configured to longitudinally move the elongate member relative to the elongate sheath by longitudinally moving at least one of the elongate member and the elongate sheath.

(63) In any embodiment of the thrombi removal system, the driver mechanism may be configured to longitudinally move the elongate member relative to the elongate sheath in a longitudinal reciprocation manner.

(64) In the embodiment of the preceding paragraph, the driver mechanism may be a motive power source drivably coupled to a linear drive member. The linear drive member may be mechanically coupled to one of the elongate member and the elongate sheath.

(65) In the embodiment of the preceding paragraph, the motive power source may be one of a rotary motor, a linear motor, and solenoid. The motive power source may be configured to be powered by one of electrical energy and fluid energy.

(66) In any embodiment having a linear drive member, the linear drive member may be one of a rotational-to-linear gear assembly and a linear translator core member.

(67) In any embodiment of the thrombi removal system, a controller circuit may be communicatively coupled to the driver mechanism. The controller circuit may be configured to operate the driver mechanism to alternatingly position the elongate member in the proximal position and the distal position relative to the elongate sheath.

(68) In any embodiment having a controller circuit, the controller circuit may be configured to operate the driver mechanism to alternate the positioning of the elongate member relative to the elongate sheath in the proximal position and the distal position at a predetermined time interval.

(69) In the embodiment of the preceding paragraph, the predetermined time interval may be in a range of 0.05 and 2.5 seconds.

(70) In any embodiment of the thrombi removal system, the thrombi removal system may be configured (configurable) such that a full cycle of movement of the elongate member relative to the elongate sheath from the proximal position to the distal position, and back to the proximal position, may have a time period in a range of 0.1 seconds to 5 seconds.

(71) In another embodiment of the thrombi removal system, the driver mechanism may be a manual handle connected to one of the elongate member and the elongate sheath.

(72) As used herein, the term “near” and other words of degree are relative modifiers intended to indicate permissible variation from the characteristic so modified. It is not intended to be limited to the absolute value or characteristic which it modifies but rather possessing more of the physical or functional characteristic than its opposite, and approaching or approximating such a physical or functional characteristic.

(73) Also, as used herein, the term “coupled”, and its derivatives, is intended to embrace any operationally functional connection, i.e., a direct connection or an indirect connection.

(74) While this invention has been described with respect to at least one embodiment, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure

as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

Claims

1. A thrombi removal catheter for use in a thrombi removal system, comprising: an elongate sheath having a proximal end, a distal end, a side wall that defines a lumen that extends from the proximal end to the distal end, a distal axial opening at the distal end in fluid communication with the lumen, and at least one lateral opening that extends through the side wall to the lumen, the at least one lateral opening being proximally spaced from the distal end; an elongate member disposed in the lumen of the elongate sheath, the elongate member configured for longitudinal movement relative to the elongate sheath, the elongate member having a proximal position and a distal position relative to a position of the elongate sheath, the elongate member having a proximal blocker element and a distal blocker element that is longitudinally spaced from the proximal blocker element, the proximal blocker element having a longitudinal passage; the thrombi removal catheter configured such that: when the elongate member is in the proximal position, the distal axial opening of the elongate sheath is closed by the distal blocker element of the elongate member and the at least one lateral opening of the elongate sheath is open; and when the elongate member is in the distal position, the at least one lateral opening of the elongate sheath is closed by the proximal blocker element and the distal axial opening of the elongate sheath is open.
2. The thrombi removal catheter according to claim 1, wherein when the elongate member is in the proximal position, a first fluid path is defined through the at least one lateral opening to the lumen of the elongate sheath to the exclusion of the distal axial opening, and when the elongate member is in the distal position, a second fluid path is defined through the distal axial opening to the lumen of the elongate sheath to the exclusion of the at least one lateral opening.
3. The thrombi removal catheter according to claim 2, wherein each of the first fluid path and the second fluid path extends through the longitudinal passage of the proximal blocker element.
4. The thrombi removal catheter according to claim 1, wherein the at least one lateral opening is one of a plurality of side openings in the elongate sheath.
5. The thrombi removal catheter according to claim 4, wherein the plurality of side openings includes two diametrically opposed lateral openings.
6. The thrombi removal catheter according to claim 1, wherein the proximal blocker element is a cylinder.
7. The thrombi removal catheter according to claim 1, wherein the proximal blocker element has a beveled distal end configured to longitudinally pass across each of the at least one lateral opening of the side wall of the elongate sheath to effect a scissoring cutting action as the elongate member longitudinally moves from the proximal position to the distal position.
8. The thrombi removal catheter according to claim 1, wherein the distal blocker element has a closed distal end that defines a pointed tip and a closed proximal end that defines a proximal beveled surface, wherein the proximal beveled surface is configured to longitudinally pass across the distal end of the side wall of the elongate sheath to effect a scissoring cutting action as the elongate member longitudinally moves from the distal position to the proximal position.
9. The thrombi removal catheter according to claim 1, wherein the elongate member includes an elongate cannula having a guidewire lumen, the elongate cannula having a first end and a second end, the distal blocker element being located proximate the second end of the elongate cannula and the distal blocker element being connected to the elongate cannula, the proximal blocker element being located proximal to the distal blocker element and the proximal blocker element being connected to the elongate cannula.
10. The thrombi removal catheter according to claim 1, comprising: a first annular seal radially interposed between the side wall of the elongate sheath and the distal blocker element, the first

annular seal configured to seal an annular region between the side wall of the elongate sheath and the distal blocker element when the distal blocker element is in the proximal position; and a second annular seal radially interposed between the side wall of the elongate sheath and the proximal blocker element, the second annular seal configured to seal an annular region between the side wall of the elongate sheath and the proximal blocker element when the proximal blocker element is in the distal position.

11. The thrombi removal catheter according to claim 1, wherein each of the elongate sheath and the elongate member is made of flexible material so as to be adaptable to a vasculature along its respective longitudinal length.

12. A thrombi removal system, comprising: a thrombi removal catheter according to claim 1; a vacuum source coupled in fluid communication with the lumen of the elongate sheath; and a driver mechanism coupled to at least one of the elongate member and the elongate sheath, the driver mechanism configured to longitudinally move the elongate member relative to the elongate sheath by longitudinally moving at least one of the elongate member and the elongate sheath.

13. The thrombi removal system according to claim 12, wherein the driver mechanism is configured to longitudinally move the elongate member relative to the elongate sheath in a longitudinal reciprocation manner.

14. The thrombi removal system according to claim 13, wherein the driver mechanism is a motive power source drivably coupled to a linear drive member, the linear drive member being mechanically coupled to one of the elongate member and the elongate sheath.

15. The thrombi removal system according to claim 14, wherein the motive power source is one of a rotary motor, a linear motor, and solenoid, the motive power source being configured to be powered by one of electrical energy and fluid energy.

16. The thrombi removal system according to claim 14, wherein the linear drive member is one of a rotational-to-linear gear assembly and a linear translator core member.

17. The thrombi removal system according to claim 12, comprising a controller circuit communicatively coupled to the driver mechanism, the controller circuit configured to operate the driver mechanism to alternatingly position the elongate member in the proximal position and the distal position relative to the elongate sheath.

18. The thrombi removal system according to claim 17, wherein the controller circuit is configured to operate the driver mechanism to alternate the positioning of the elongate member relative to the elongate sheath in the proximal position and the distal position at a predetermined time interval.

19. The thrombi removal system according to claim 18, wherein the predetermined time interval is in a range of 0.05 and 2.5 seconds.

20. The thrombi removal system according to claim 12, wherein a full cycle of movement of the elongate member relative to the elongate sheath from the proximal position to the distal position, and back to the proximal position, has a time period in a range of 0.1 seconds to 5 seconds.

21. The thrombi removal system according to claim 12, wherein the driver mechanism is a manual handle connected to one of the elongate member and the elongate sheath.