



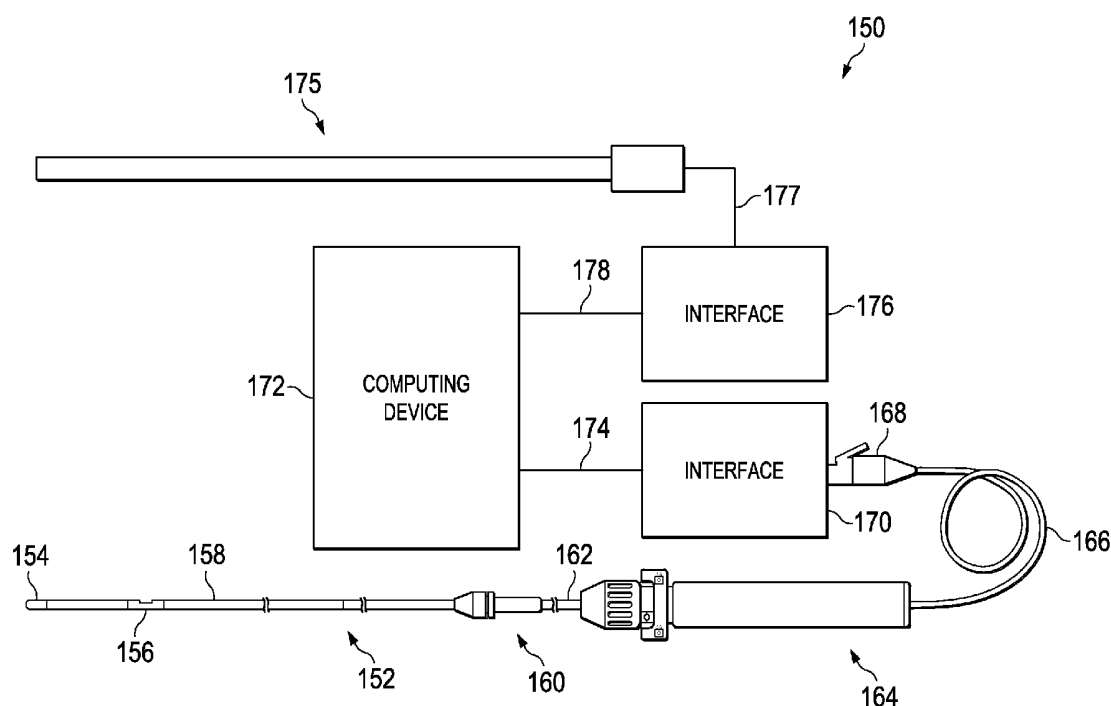
US 20160007866A1

(19) **United States**(12) **Patent Application Publication**
Tochterman et al.(10) **Pub. No.: US 2016/0007866 A1**(43) **Pub. Date: Jan. 14, 2016**(54) **DEVICES, SYSTEMS, AND METHODS FOR
ASSESSMENT OF VESSELS****Publication Classification**(71) Applicant: **Volcano Corporation**, San Diego, CA
(US)(72) Inventors: **Andrew Tochterman**, Carlsbad, CA
(US); **Fergus Merritt**, Escondido, CA
(US)(51) **Int. Cl.****A61B 5/0215** (2006.01)**A61B 5/00** (2006.01)(52) **U.S. Cl.**CPC **A61B 5/02158** (2013.01); **A61B 5/7246**
(2013.01)(21) Appl. No.: **14/798,178**(22) Filed: **Jul. 13, 2015****Related U.S. Application Data**(60) Provisional application No. 62/024,005, filed on Jul.
14, 2014.

(57)

ABSTRACT

Devices, systems, and methods for visually depicting a vessel and evaluating treatment options are disclosed. The methods can include introducing instruments into the vessel of a patient and obtaining proximal and distal pressure measurements of a stenosis of the vessel, calculating a pressure ratio based on the obtained proximal and distal pressure measurements, applying a correlation factor to the calculated pressure ratio to produce a predicted diagnostic pressure ratio, and displaying the predicted diagnostic pressure ratio to a user.



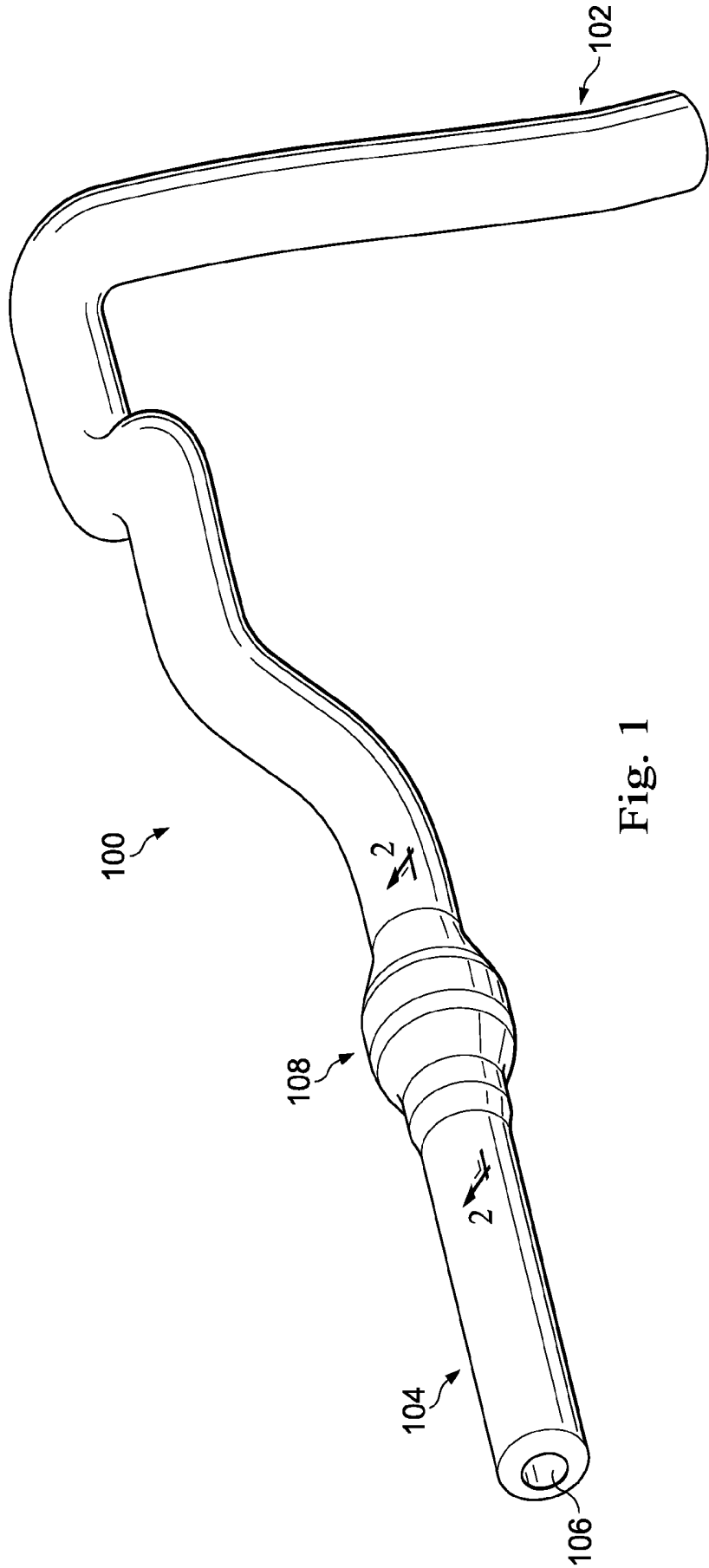


Fig. 1

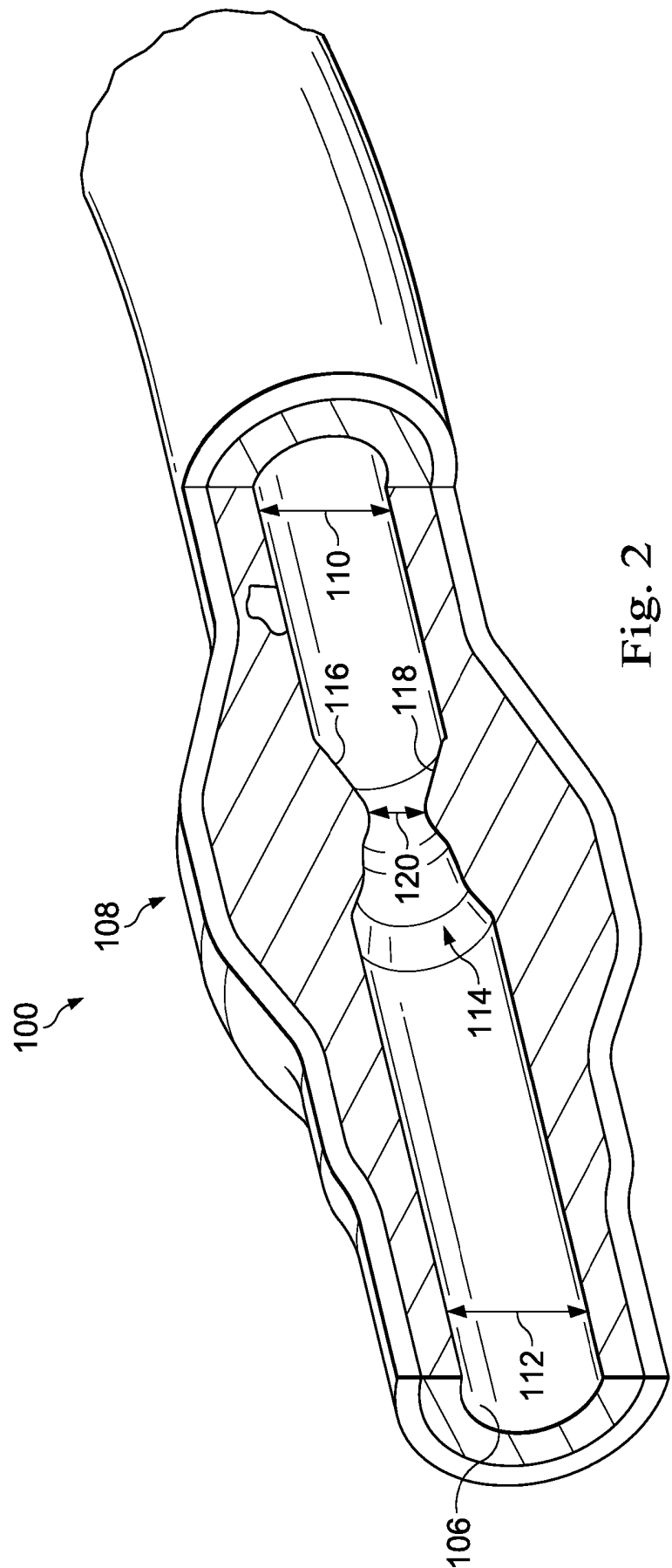


Fig. 2

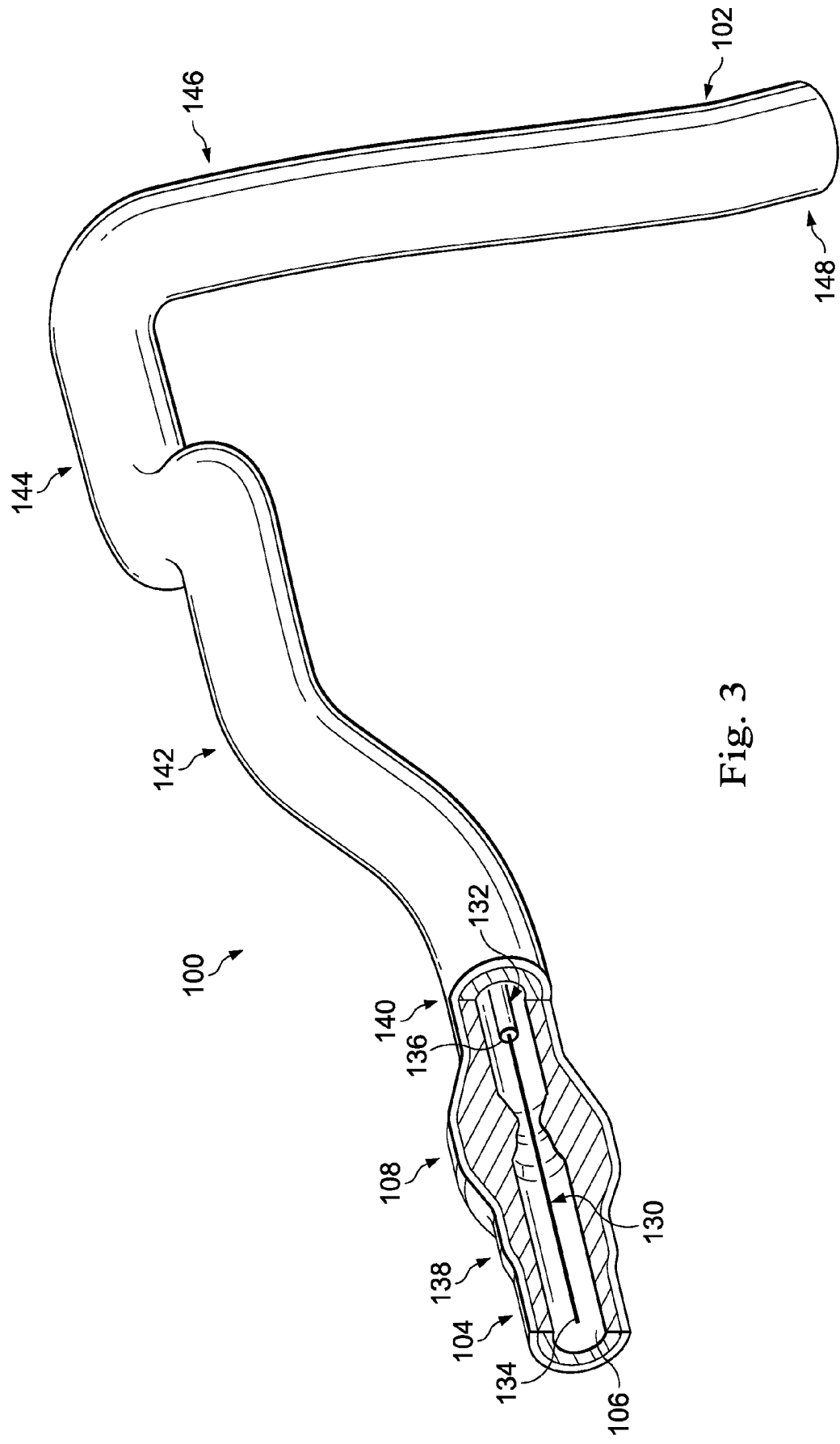


Fig. 3

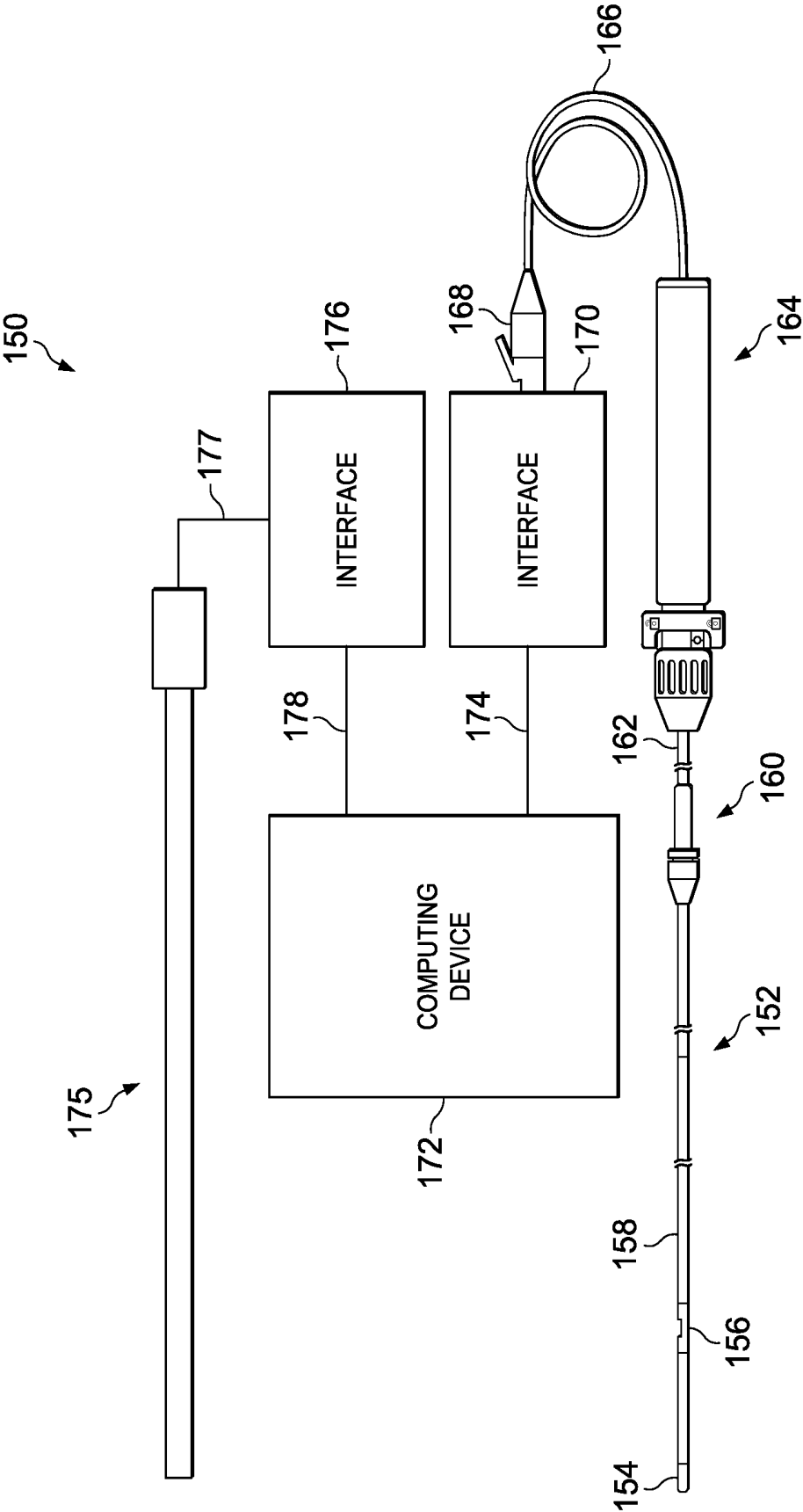
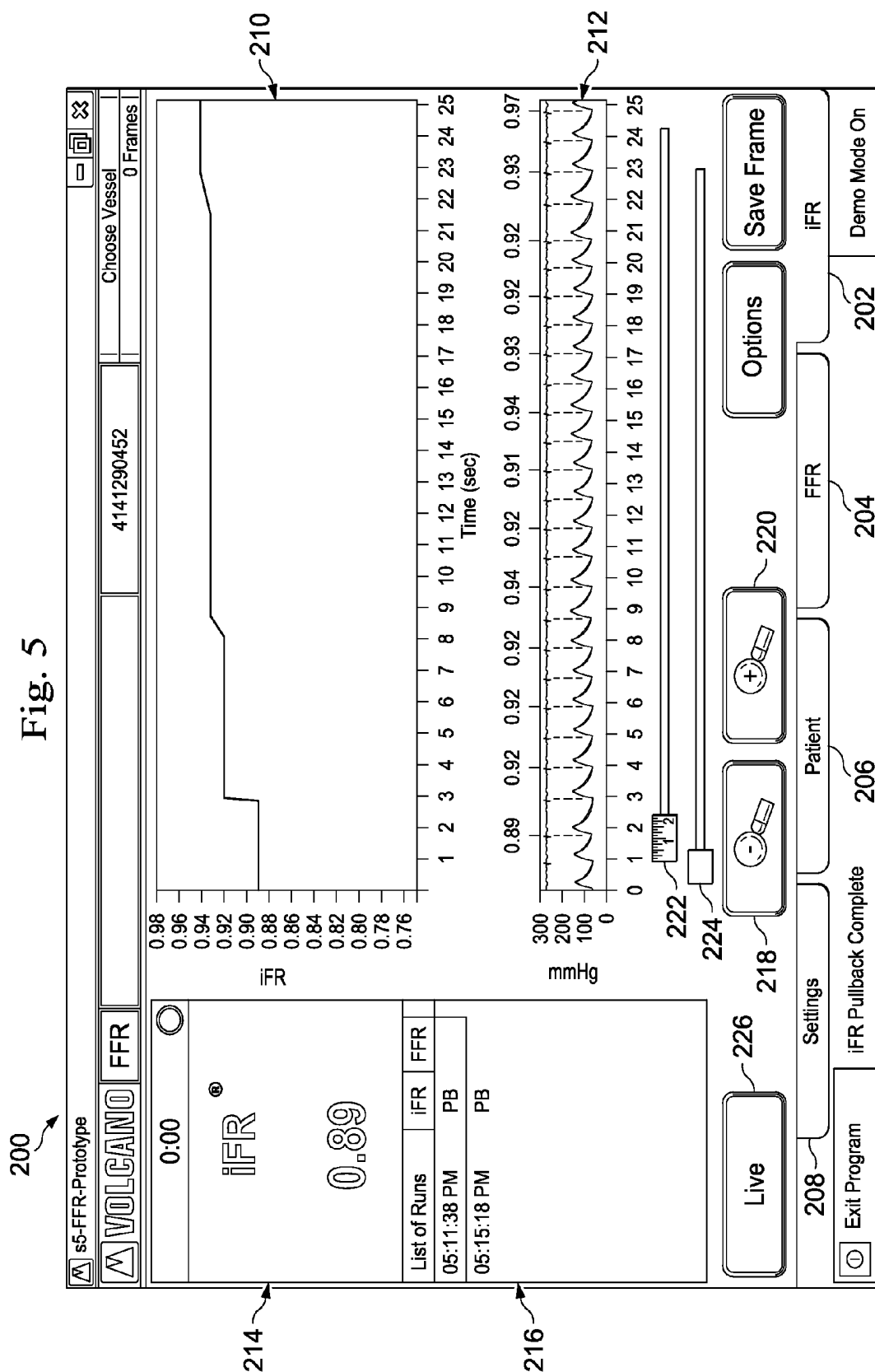


Fig. 4



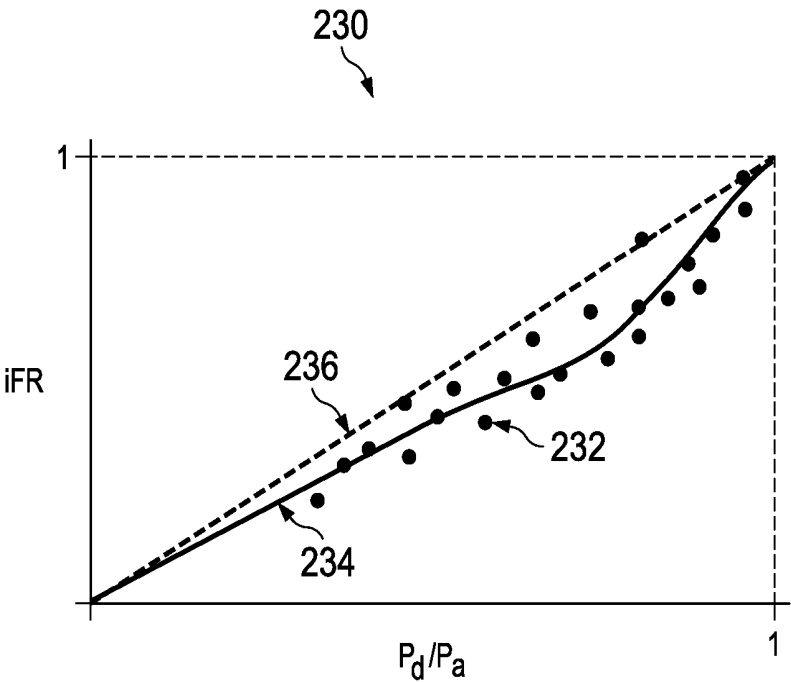


Fig. 6

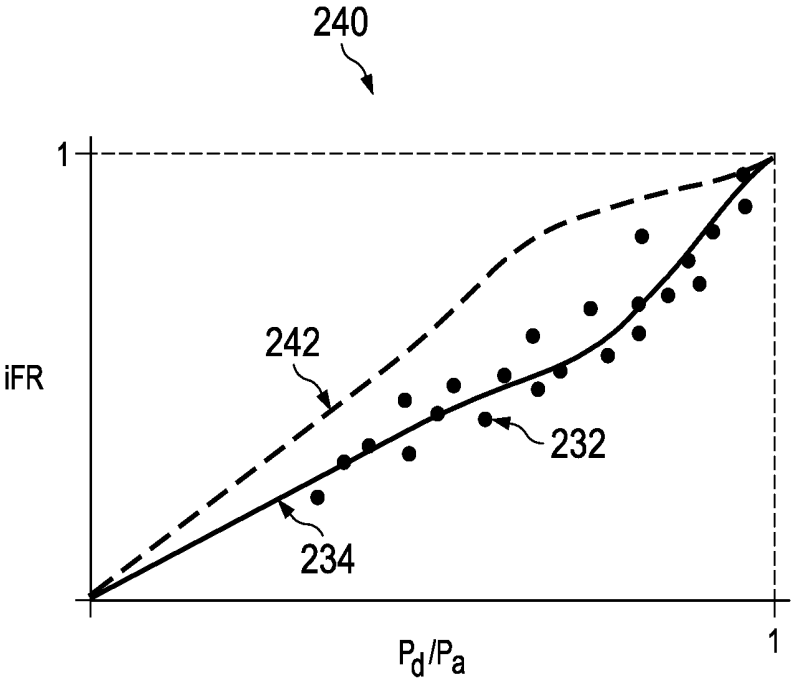


Fig. 7

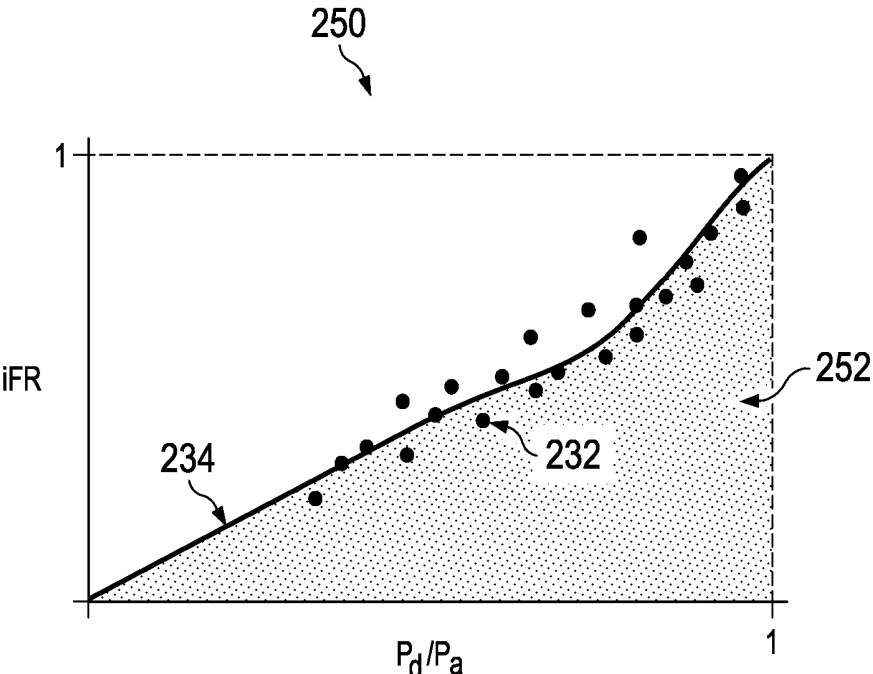


Fig. 8

DEVICES, SYSTEMS, AND METHODS FOR ASSESSMENT OF VESSELS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority to and the benefit of the U.S. Provisional Patent Application No. 62/024, 005, filed Jul. 24, 2014, which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The present disclosure relates generally to the assessment of vessels and, in particular, the assessment of the severity of a blockage or other restriction to the flow of fluid through a vessel. Aspects of the present disclosure are particularly suited for evaluation of biological vessels in some instances. For example, some particular embodiments of the present disclosure are specifically configured for the evaluation of a stenosis of a human blood vessel.

BACKGROUND

[0003] A currently accepted technique for assessing the severity of a stenosis in a blood vessel, including ischemia causing lesions, is fractional flow reserve (FFR). FFR is a calculation of the ratio of a distal pressure measurement (taken on the distal side of the stenosis) relative to a proximal pressure measurement (taken on the proximal side of the stenosis). FFR provides an index of stenosis severity that allows determination as to whether the blockage limits blood flow within the vessel to an extent that treatment is required. The normal value of FFR in a healthy vessel is 1.00, while values less than about 0.80 are generally deemed significant and require treatment. Common treatment options include angioplasty and stenting.

[0004] Coronary blood flow is unique in that it is affected not only by fluctuations in the pressure arising proximally (as in the aorta) but is also simultaneously affected by fluctuations arising distally in the microcirculation. Accordingly, it is not possible to accurately assess the severity of a coronary stenosis by simply measuring the fall in mean or peak pressure across the stenosis because the distal coronary pressure is not purely a residual of the pressure transmitted from the aortic end of the vessel. As a result, for an effective calculation of FFR within the coronary arteries, it is necessary to reduce the vascular resistance within the vessel. Currently, pharmacological hyperemic agents, such as adenosine, are administered to reduce and stabilize the resistance within the coronary arteries. These potent vasodilator agents reduce the dramatic fluctuation in resistance predominantly by reducing the microcirculation resistance associated with the systolic portion of the heart cycle to obtain a relatively stable and minimal resistance value.

[0005] However, the administration of hyperemic agents is not always possible or advisable. First, the clinical effort of administering hyperemic agents can be significant. In some countries (particularly the United States), hyperemic agents such as adenosine are expensive, and time consuming to obtain when delivered intravenously (IV). In that regard, IV-delivered adenosine is generally mixed on a case-by-case basis in the hospital pharmacy. It can take a significant amount of time and effort to get the adenosine prepared and delivered to the operating area. These logistic hurdles can impact a physician's decision to use FFR. Second, some

patients have contraindications to the use of hyperemic agents such as asthma, severe COPD, hypotension, bradycardia, low cardiac ejection fraction, recent myocardial infarction, and/or other factors that prevent the administration of hyperemic agents. Third, many patients find the administration of hyperemic agents to be uncomfortable, which is only compounded by the fact that the hyperemic agent may need to be applied multiple times during the course of a procedure to obtain FFR measurements. Fourth, the administration of a hyperemic agent may also require central venous access (e.g., a central venous sheath) that might otherwise be avoided. Finally, not all patients respond as expected to hyperemic agents and, in some instances, it is difficult to identify these patients before administration of the hyperemic agent.

[0006] In addition to the difficulties presented by the administration of hyperemic agents, health care providers may also be challenged in making timely assessments for treatments. Medical procedures for cardiovascular issues are generally time-sensitive, and doctors may not have sufficient lead time to perform traditional tests used to gather and calculate accurate pressure measurements and other treatment information.

[0007] Accordingly, there remains a need for improved devices, systems, and methods for assessing the severity of a blockage in a vessel and, in particular, a stenosis in a blood vessel. In that regard, there remains a need for improved devices, systems, and methods for assessing the severity of a stenosis in the coronary arteries that do not require the administration of hyperemic agents. Further, there remains a need to quickly estimate pressure measurements and ratios in a vessel. Finally, there remains a need for improved devices, systems, and methods for providing visual depictions of vessel that allow assessment of the vessel and, in particular, any stenosis or lesion of the vessel.

SUMMARY

[0008] Embodiments of the present disclosure are configured to assess the severity of a blockage in a vessel and, in particular, a stenosis in a blood vessel. In some particular embodiments, the devices, systems, and methods of the present disclosure are configured to correlate standard pressure measurements obtained without the use of a hyperemic agent (e.g., Pa and Pd) to one or more accepted diagnostic pressure calculations (e.g., FFR, iFR, etc.) that allow assessment of the vessel and, in particular, any stenosis or lesion of the vessel.

[0009] In some embodiments, methods of evaluating a vessel of a patient are provided. The method includes introducing at least one instrument into the vessel of the patient, obtaining from the instrument proximal pressure measurements within the vessel at a position proximal of a stenosis of the vessel, obtaining from the instrument distal pressure measurements within the vessel at a position distal of the stenosis of the vessel, calculating a pressure ratio for each cardiac cycle based on the average distal pressure measurement and the average proximal pressure measurement in the vessel of the patient during each cardiac cycle of the patient, applying a correlation factor to the calculated pressure ratio to produce a predicted diagnostic pressure ratio, and displaying the predicted diagnostic pressure ratio to a user.

[0010] In some instances, the correlation factor is selected for a particular patient and/or a calculated pressure ratio of the patient based on empirical data defining a relationship between calculated pressure ratios based on standard pressure

measurements obtained without the use of a hyperemic agent (e.g., Pa and Pd) and accepted diagnostic pressure calculations (FFR, iFR, etc.). Accordingly, the selected correlation factor can take into account patient characteristics, pressure measurement characteristics, and/or combinations thereof. In some instances, the correlation factor has a fixed value. Alternatively, the correlation factor has a variable value. For example, in some instances a first correlation value is assigned to calculated pressure ratios below 0.5, a second correlation value is assigned to a calculated pressure ratios between 0.5 and 0.7, and a third correlation value is assigned to a calculated pressure ratios above 0.7. Any number of correlation values can be utilized for any number of ranges of calculated pressure ratios. In some instances, the correlation factor is defined based on a relationship of a slope of a plot of calculated pressure ratios relative to accepted diagnostic pressure ratios. In some instances, the correlation factor is defined based on a relationship of a measure of curvature of a plot of calculated pressure ratios relative to accepted diagnostic pressure ratios. In some instances, the correlation factor is defined based on a relationship of an approximated polynomial function of a plot of the calculated pressure ratio relative to accepted diagnostic pressure ratios. In some instances, the correlation factor is defined based on a relationship of an area below the curve of a plot of the calculated pressure ratio relative to accepted diagnostic pressure ratios.

[0011] A system for evaluating a vessel of a patient is also provided that comprises one or more instruments sized and shaped for introduction into the vessel of the patient and a processing system in communication with the one or more instruments. The processing unit is configured to obtain proximal pressure measurements measured within the vessel at a position proximal of a stenosis of the vessel, obtain distal pressure measurements measured within the vessel at a position distal of the stenosis of the vessel, calculate a pressure ratio based on the obtained proximal and distal pressure measurements, apply a correlation factor to the calculated pressure ratio to produce a predicted diagnostic pressure ratio, and display the predicted diagnostic pressure ratio to a user.

[0012] Additional aspects, features, and advantages of the present disclosure will become apparent from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Illustrative embodiments of the present disclosure will be described with reference to the accompanying drawings, of which:

[0014] FIG. 1 shows a diagrammatic perspective view of a vessel having a stenosis according to an embodiment of the present disclosure.

[0015] FIG. 2 shows a diagrammatic, partial cross-sectional perspective view of a portion of the vessel of FIG. 1 taken along section line 2-2 of FIG. 1.

[0016] FIG. 3 shows a diagrammatic, partial cross-sectional perspective view of the vessel of FIGS. 1 and 2 with instruments positioned therein according to an embodiment of the present disclosure.

[0017] FIG. 4 shows a diagrammatic, schematic view of a system according to an embodiment of the present disclosure.

[0018] FIG. 5 shows a portion of a screen display according to an embodiment of the present disclosure.

[0019] FIG. 6 shows a relationship between a calculated pressure ratio based on basic pressure data and an accepted diagnostic pressure ratio according to an embodiment of the present disclosure.

[0020] FIG. 7 shows a relationship between a calculated pressure ratio based on basic pressure data and an accepted diagnostic pressure ratio according to another embodiment of the present disclosure.

[0021] FIG. 8 shows a relationship between a calculated pressure ratio based on basic pressure data and an accepted diagnostic pressure ratio according to another embodiment of the present disclosure.

DETAILED DESCRIPTION

[0022] For the purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It is nevertheless understood that no limitation to the scope of the disclosure is intended. Any alterations and further modifications to the described devices, systems, and methods, and any further application of the principles of the present disclosure are fully contemplated and included within the present disclosure as would normally occur to one skilled in the art to which the disclosure relates. In particular, it is fully contemplated that the features, components, and/or steps described with respect to one embodiment may be combined with the features, components, and/or steps described with respect to other embodiments of the present disclosure. For the sake of brevity, however, the numerous iterations of these combinations will not be described separately.

[0023] Referring to FIGS. 1 and 2, shown therein is a vessel **100** having a stenosis according to an embodiment of the present disclosure. In that regard, FIG. 1 is a diagrammatic perspective view of the vessel **100**, while FIG. 2 is a partial cross-sectional perspective view of a portion of the vessel **100** taken along section line 2-2 of FIG. 1. Referring more specifically to FIG. 1, the vessel **100** includes a proximal portion **102** and a distal portion **104**. A lumen **106** extends along the length of the vessel **100** between the proximal portion **102** and the distal portion **104**. In that regard, the lumen **106** is configured to allow the flow of fluid through the vessel. In some instances, the vessel **100** is a blood vessel. In some particular instances, the vessel **100** is a coronary artery. In such instances, the lumen **106** is configured to facilitate the flow of blood through the vessel **100**.

[0024] As shown, the vessel **100** includes a stenosis **108** between the proximal portion **102** and the distal portion **104**. Stenosis **108** is generally representative of any blockage or other structural arrangement that results in a restriction to the flow of fluid through the lumen **106** of the vessel **100**. Embodiments of the present disclosure are suitable for use in a wide variety of vascular applications, including without limitation coronary, peripheral (including but not limited to lower limb, carotid, and neurovascular), renal, and/or venous. Where the vessel **100** is a blood vessel, the stenosis **108** may be a result of plaque buildup, including without limitation plaque components such as fibrous, fibro-lipidic (fibro fatty), necrotic core, calcified (dense calcium), blood, fresh thrombus, and mature thrombus. Generally, the composition of the stenosis will depend on the type of vessel being evaluated. In that regard, it is understood that the concepts of the present disclosure are applicable to virtually any type of blockage or other narrowing of a vessel that results in decreased fluid flow.

[0025] Referring more particularly to FIG. 2, the lumen 106 of the vessel 100 has a diameter 110 proximal of the stenosis 108 and a diameter 112 distal of the stenosis. In some instances, the diameters 110 and 112 are substantially equal to one another. In that regard, the diameters 110 and 112 are intended to represent healthy portions, or at least healthier portions, of the lumen 106 in comparison to stenosis 108. Accordingly, these healthier portions of the lumen 106 are illustrated as having a substantially constant cylindrical profile and, as a result, the height or width of the lumen has been referred to as a diameter. However, it is understood that in many instances these portions of the lumen 106 will also have plaque buildup, a non-symmetric profile, and/or other irregularities, but to a lesser extent than stenosis 108 and, therefore, will not have a cylindrical profile. In such instances, the diameters 110 and 112 are understood to be representative of a relative size or cross-sectional area of the lumen and do not imply a circular cross-sectional profile.

[0026] As shown in FIG. 2, stenosis 108 includes plaque buildup 114 that narrows the lumen 106 of the vessel 100. In some instances, the plaque buildup 114 does not have a uniform or symmetrical profile, making angiographic evaluation of such a stenosis unreliable. In the illustrated embodiment, the plaque buildup 114 includes an upper portion 116 and an opposing lower portion 118. In that regard, the lower portion 118 has an increased thickness relative to the upper portion 116 that results in a non-symmetrical and non-uniform profile relative to the portions of the lumen proximal and distal of the stenosis 108. As shown, the plaque buildup 114 decreases the available space for fluid to flow through the lumen 106. In particular, the cross-sectional area of the lumen 106 is decreased by the plaque buildup 114. At the narrowest point between the upper and lower portions 116, 118 the lumen 106 has a height 120, which is representative of a reduced size or cross-sectional area relative to the diameters 110 and 112 proximal and distal of the stenosis 108. Note that the stenosis 108, including plaque buildup 114 is exemplary in nature and should be considered limiting in any way. In that regard, it is understood that the stenosis 108 has other shapes and/or compositions that limit the flow of fluid through the lumen 106 in other instances. While the vessel 100 is illustrated in FIGS. 1 and 2 as having a single stenosis 108 and the description of the embodiments below is primarily made in the context of a single stenosis, it is nevertheless understood that the devices, systems, and methods described herein have similar application for a vessel having multiple stenosis regions.

[0027] Referring now to FIG. 3, the vessel 100 is shown with instruments 130 and 132 positioned therein according to an embodiment of the present disclosure. In general, instruments 130 and 132 may be any form of device, instrument, or probe sized and shaped to be positioned within a vessel. In the illustrated embodiment, instrument 130 is generally representative of a guide wire, while instrument 132 is generally representative of a catheter. In that regard, instrument 130 extends through a central lumen of instrument 132. However, in other embodiments, the instruments 130 and 132 take other forms. In that regard, the instruments 130 and 132 are of similar form in some embodiments. For example, in some instances, both instruments 130 and 132 are guide wires. In other instances, both instruments 130 and 132 are catheters. On the other hand, the instruments 130 and 132 are of different form in some embodiments, such as the illustrated embodiment, where one of the instruments is a catheter and

the other is a guide wire. Further, in some instances, the instruments 130 and 132 are disposed coaxial with one another, as shown in the illustrated embodiment of FIG. 3. In other instances, one of the instruments extends through an off-center lumen of the other instrument. In yet other instances, the instruments 130 and 132 extend side-by-side. In some particular embodiments, at least one of the instruments is as a rapid-exchange device, such as a rapid-exchange catheter. In such embodiments, the other instrument is a buddy wire or other device configured to facilitate the introduction and removal of the rapid-exchange device. Further still, in other instances, instead of two separate instruments 130 and 132 a single instrument is utilized. In some embodiments, the single instrument incorporates aspects of the functionalities (e.g., data acquisition) of both instruments 130 and 132.

[0028] Instrument 130 is configured to obtain diagnostic information about the vessel 100. In that regard, the instrument 130 includes one or more sensors, transducers, and/or other monitoring elements configured to obtain the diagnostic information about the vessel. The diagnostic information includes one or more of pressure, flow (velocity), images (including images obtained using ultrasound (e.g., IVUS), OCT, thermal, and/or other imaging techniques), temperature, and/or combinations thereof. The one or more sensors, transducers, and/or other monitoring elements are positioned adjacent a distal portion of the instrument 130 in some instances. In that regard, the one or more sensors, transducers, and/or other monitoring elements are positioned less than 30 cm, less than 10 cm, less than 5 cm, less than 3 cm, less than 2 cm, and/or less than 1 cm from a distal tip 134 of the instrument 130 in some instances. In some instances, at least one of the one or more sensors, transducers, and/or other monitoring elements is positioned at the distal tip of the instrument 130.

[0029] The instrument 130 includes at least one element configured to monitor pressure within the vessel 100. The pressure monitoring element can take the form a piezo-resistive pressure sensor, a piezo-electric pressure sensor, a capacitive pressure sensor, an electromagnetic pressure sensor, a fluid column (the fluid column being in communication with a fluid column sensor that is separate from the instrument and/or positioned at a portion of the instrument proximal of the fluid column), an optical pressure sensor, and/or combinations thereof. In some instances, one or more features of the pressure monitoring element are implemented as a solid-state component manufactured using semiconductor and/or other suitable manufacturing techniques. Examples of commercially available guide wire products that include suitable pressure monitoring elements include, without limitation, the PrimeWire PRESTIGE® pressure guide wire, the PrimeWire® pressure guide wire, and the ComboWire® XT pressure and flow guide wire, each available from Volcano Corporation, as well as the PressureWire™ Certus guide wire and the PressureWire™ Aeris guide wire, each available from St. Jude Medical, Inc. Generally, the instrument 130 is sized such that it can be positioned through the stenosis 108 without significantly impacting fluid flow across the stenosis, which would impact the distal pressure reading. Accordingly, in some instances the instrument 130 has an outer diameter of 0.018" or less. In some embodiments, the instrument 130 has an outer diameter of 0.014" or less.

[0030] Instrument 132 is also configured to obtain diagnostic information about the vessel 100. In some instances,

instrument **132** is configured to obtain the same diagnostic information as instrument **130**. In other instances, instrument **132** is configured to obtain different diagnostic information than instrument **130**, which may include additional diagnostic information, less diagnostic information, and/or alternative diagnostic information. The diagnostic information obtained by instrument **132** includes one or more of pressure, flow (velocity), images (including images obtained using ultrasound (e.g., IVUS), OCT, thermal, and/or other imaging techniques), temperature, and/or combinations thereof. Instrument **132** includes one or more sensors, transducers, and/or other monitoring elements configured to obtain this diagnostic information. In that regard, the one or more sensors, transducers, and/or other monitoring elements are positioned adjacent a distal portion of the instrument **132** in some instances. In that regard, the one or more sensors, transducers, and/or other monitoring elements are positioned less than 30 cm, less than 10 cm, less than 5 cm, less than 3 cm, less than 2 cm, and/or less than 1 cm from a distal tip **136** of the instrument **132** in some instances. In some instances, at least one of the one or more sensors, transducers, and/or other monitoring elements is positioned at the distal tip of the instrument **132**.

[0031] Similar to instrument **130**, instrument **132** also includes at least one element configured to monitor pressure within the vessel **100**. The pressure monitoring element can take the form a piezo-resistive pressure sensor, a piezo-electric pressure sensor, a capacitive pressure sensor, an electromagnetic pressure sensor, a fluid column (the fluid column being in communication with a fluid column sensor that is separate from the instrument and/or positioned at a portion of the instrument proximal of the fluid column), an optical pressure sensor, and/or combinations thereof. In some instances, one or more features of the pressure monitoring element are implemented as a solid-state component manufactured using semiconductor and/or other suitable manufacturing techniques. Currently available catheter products suitable for use with one or more of Siemens AXIOM Sensis, Mennen Horizon XVu, and Philips Xper IM Physiomonitring 5 and include pressure monitoring elements can be utilized for instrument **132** in some instances.

[0032] In accordance with aspects of the present disclosure, at least one of the instruments **130** and **132** is configured to monitor a pressure within the vessel **100** distal of the stenosis **108** and at least one of the instruments **130** and **132** is configured to monitor a pressure within the vessel proximal of the stenosis. In that regard, the instruments **130**, **132** are sized and shaped to allow positioning of the at least one element configured to monitor pressure within the vessel **100** to be positioned proximal and/or distal of the stenosis **108** as necessary based on the configuration of the devices. In that regard, FIG. 3 illustrates a position **138** suitable for measuring pressure distal of the stenosis **108**. In that regard, the position **138** is less than 5 cm, less than 3 cm, less than 2 cm, less than 1 cm, less than 5 mm, and/or less than 2.5 mm from the distal end of the stenosis **108** (as shown in FIG. 2) in some instances. FIG. 3 also illustrates a plurality of suitable positions for measuring pressure proximal of the stenosis **108**. In that regard, positions **140**, **142**, **144**, **146**, and **148** each represent a position that is suitable for monitoring the pressure proximal of the stenosis in some instances. In that regard, the positions **140**, **142**, **144**, **146**, and **148** are positioned at varying distances from the proximal end of the stenosis **108** ranging from more than 20 cm down to about 5 mm or less. Generally, the

proximal pressure measurement will be spaced from the proximal end of the stenosis. Accordingly, in some instances, the proximal pressure measurement is taken at a distance equal to or greater than an inner diameter of the lumen of the vessel from the proximal end of the stenosis. In the context of coronary artery pressure measurements, the proximal pressure measurement is generally taken at a position proximal of the stenosis and distal of the aorta, within a proximal portion of the vessel. However, in some particular instances of coronary artery pressure measurements, the proximal pressure measurement is taken from a location inside the aorta. In other instances, the proximal pressure measurement is taken at the root or ostium of the coronary artery.

[0033] In some embodiments, at least one of the instruments **130** and **132** is configured to monitor pressure within the vessel **100** while being moved through the lumen **106**. In some instances, instrument **130** is configured to be moved through the lumen **106** and across the stenosis **108**. In that regard, the instrument **130** is positioned distal of the stenosis **108** and moved proximally (i.e., pulled back) across the stenosis to a position proximal of the stenosis in some instances. In other instances, the instrument **130** is positioned proximal of the stenosis **108** and moved distally across the stenosis to a position distal of the stenosis. Movement of the instrument **130**, either proximally or distally, is controlled manually by medical personnel (e.g., hand of a surgeon) in some embodiments. In other embodiments, movement of the instrument **130**, either proximally or distally, is controlled automatically by a movement control device (e.g., a pullback device, such as the Trak Back® II Device available from Volcano Corporation). In that regard, the movement control device controls the movement of the instrument **130** at a selectable and known speed (e.g., 2.0 mm/s, 1.0 mm/s, 0.5 mm/s, 0.2 mm/s, etc.) in some instances. Movement of the instrument **130** through the vessel is continuous for each pullback or push through, in some instances. In other instances, the instrument **130** is moved step-wise through the vessel (i.e., repeatedly moved a fixed amount of distance and/or a fixed amount of time). Some aspects of the visual depictions discussed below are particularly suited for embodiments where at least one of the instruments **130** and **132** is moved through the lumen **106**. Further, in some particular instances, aspects of the visual depictions discussed below are particularly suited for embodiments where a single instrument is moved through the lumen **106**, with or without the presence of a second instrument.

[0034] In some instances, use of a single instrument has a benefit in that it avoids issues associated with variations in pressure measurements of one instrument relative to another over time, which is commonly referred to as drift. In that regard, a major source of drift in traditional Fractional Flow Reserve (FFR) measurements is divergence in the pressure reading of a guide wire relative to the pressure reading of a guide catheter. In that regard, because FFR is calculated as the ratio of the pressure measurement obtained by the guide wire to the pressure measurement obtained by the catheter, this divergence has an impact on the resulting FFR value. In contrast, where a single instrument is utilized to obtain pressure measurements as it is moved through the vessel, drift is negligible or non-existent. For example, in some instances, the single instrument is utilized to obtain relative changes in pressures as it is moved through the vessel such that the time period between pressure measurements is short enough to prevent any impact from any changes in pressure sensitivity

of the instrument (e.g., less than 500 ms, less than 100 ms, less than 50 ms, less than 10 ms, less than 5 ms, less than 1 ms, or otherwise).

[0035] Referring now to FIG. 4, shown therein is a system 150 according to an embodiment of the present disclosure. In that regard, FIG. 4 is a diagrammatic, schematic view of the system 150. As shown, the system 150 includes an instrument 152. In that regard, in some instances instrument 152 is suitable for use as at least one of instruments 130 and 132 discussed above. Accordingly, in some instances the instrument 152 includes features similar to those discussed above with respect to instruments 130 and 132 in some instances. In the illustrated embodiment, the instrument 152 is a guide wire having a distal portion 154 and a housing 156 positioned adjacent the distal portion. In that regard, the housing 156 is spaced approximately 3 cm from a distal tip of the instrument 152. The housing 156 is configured to house one or more sensors, transducers, and/or other monitoring elements configured to obtain the diagnostic information about the vessel. In the illustrated embodiment, the housing 156 contains at least a pressure sensor configured to monitor a pressure within a lumen in which the instrument 152 is positioned. A shaft 158 extends proximally from the housing 156. A torque device 160 is positioned over and coupled to a proximal portion of the shaft 158. A proximal end portion 162 of the instrument 152 is coupled to a connector 164. A cable 166 extends from connector 164 to a connector 168. In some instances, connector 168 is configured to be plugged into an interface 170. In that regard, interface 170 is a patient interface module (PIM) in some instances. In some instances, the cable 166 is replaced with a wireless connection. In that regard, it is understood that various communication pathways between the instrument 152 and the interface 170 may be utilized, including physical connections (including electrical, optical, and/or fluid connections), wireless connections, and/or combinations thereof.

[0036] The interface 170 is communicatively coupled to a computing device 172 via a connection 174. Computing device 172 is generally representative of any device suitable for performing the processing and analysis techniques discussed within the present disclosure. In some embodiments, the computing device 172 includes a processor, random access memory, and a storage medium. In that regard, in some particular instances the computing device 172 is programmed to execute steps associated with the data acquisition and analysis described herein. Accordingly, it is understood that any steps related to data acquisition, data processing, instrument control, and/or other processing or control aspects of the present disclosure may be implemented by the computing device using corresponding instructions stored on or in a non-transitory computer readable medium accessible by the computing device. In some instances, the computing device 172 is a console device. In some particular instances, the computing device 172 is similar to the s5™ Imaging System or the s5i™ Imaging System, each available from Volcano Corporation. In some instances, the computing device 172 is portable (e.g., handheld, on a rolling cart, etc.). Further, it is understood that in some instances the computing device 172 comprises a plurality of computing devices. In that regard, it is particularly understood that the different processing and/or control aspects of the present disclosure may be implemented separately or within predefined groupings using a plurality of computing devices. Any divisions and/or combinations of the

processing and/or control aspects described below across multiple computing devices are within the scope of the present disclosure.

[0037] Together, connector 164, cable 166, connector 168, interface 170, and connection 174 facilitate communication between the one or more sensors, transducers, and/or other monitoring elements of the instrument 152 and the computing device 172. However, this communication pathway is exemplary in nature and should not be considered limiting in any way. In that regard, it is understood that any communication pathway between the instrument 152 and the computing device 172 may be utilized, including physical connections (including electrical, optical, and/or fluid connections), wireless connections, and/or combinations thereof. In that regard, it is understood that the connection 174 is wireless in some instances. In some instances, the connection 174 includes a communication link over a network (e.g., intranet, internet, telecommunications network, and/or other network). In that regard, it is understood that the computing device 172 is positioned remote from an operating area where the instrument 152 is being used in some instances. Having the connection 174 include a connection over a network can facilitate communication between the instrument 152 and the remote computing device 172 regardless of whether the computing device is in an adjacent room, an adjacent building, or in a different state/country. Further, it is understood that the communication pathway between the instrument 152 and the computing device 172 is a secure connection in some instances. Further still, it is understood that, in some instances, the data communicated over one or more portions of the communication pathway between the instrument 152 and the computing device 172 is encrypted.

[0038] The system 150 also includes an instrument 175. In that regard, in some instances instrument 175 is suitable for use as at least one of instruments 130 and 132 discussed above. Accordingly, in some instances the instrument 175 includes features similar to those discussed above with respect to instruments 130 and 132 in some instances. In the illustrated embodiment, the instrument 175 is a catheter-type device. In that regard, the instrument 175 includes one or more sensors, transducers, and/or other monitoring elements adjacent a distal portion of the instrument configured to obtain the diagnostic information about the vessel. In the illustrated embodiment, the instrument 175 includes a pressure sensor configured to monitor a pressure within a lumen in which the instrument 175 is positioned. The instrument 175 is in communication with an interface 176 via connection 177. In some instances, interface 176 is a hemodynamic monitoring system or other control device, such as Siemens AXIOM Sensis, Mennen Horizon XVu, and Philips Xper IM Physio-monitoring 5. In one particular embodiment, instrument 175 is a pressure-sensing catheter that includes fluid column extending along its length. In such an embodiment, interface 176 includes a hemostasis valve fluidly coupled to the fluid column of the catheter, a manifold fluidly coupled to the hemostasis valve, and tubing extending between the components as necessary to fluidly couple the components. In that regard, the fluid column of the catheter is in fluid communication with a pressure sensor via the valve, manifold, and tubing. In some instances, the pressure sensor is part of interface 176. In other instances, the pressure sensor is a separate component positioned between the instrument 175 and the interface 176. The interface 176 is communicatively coupled to the computing device 172 via a connection 178.

[0039] Similar to the connections between instrument 152 and the computing device 172, interface 176 and connections 177 and 178 facilitate communication between the one or more sensors, transducers, and/or other monitoring elements of the instrument 175 and the computing device 172. However, this communication pathway is exemplary in nature and should not be considered limiting in any way. In that regard, it is understood that any communication pathway between the instrument 175 and the computing device 172 may be utilized, including physical connections (including electrical, optical, and/or fluid connections), wireless connections, and/or combinations thereof. In that regard, it is understood that the connection 178 is wireless in some instances. In some instances, the connection 178 includes a communication link over a network (e.g., intranet, internet, telecommunications network, and/or other network). In that regard, it is understood that the computing device 172 is positioned remote from an operating area where the instrument 175 is being used in some instances. Having the connection 178 include a connection over a network can facilitate communication between the instrument 175 and the remote computing device 172 regardless of whether the computing device is in an adjacent room, an adjacent building, or in a different state/country. Further, it is understood that the communication pathway between the instrument 175 and the computing device 172 is a secure connection in some instances. Further still, it is understood that, in some instances, the data communicated over one or more portions of the communication pathway between the instrument 175 and the computing device 172 is encrypted.

[0040] It is understood that one or more components of the system 150 are not included, are implemented in a different arrangement/order, and/or are replaced with an alternative device/mechanism in other embodiments of the present disclosure. For example, in some instances, the system 150 does not include interface 170 and/or interface 176. In such instances, the connector 168 (or other similar connector in communication with instrument 152 or instrument 175) may plug into a port associated with computing device 172. Alternatively, the instruments 152, 175 may communicate wirelessly with the computing device 172. Generally speaking, the communication pathway between either or both of the instruments 152, 175 and the computing device 172 may have no intermediate nodes (i.e., a direct connection), one intermediate node between the instrument and the computing device, or a plurality of intermediate nodes between the instrument and the computing device.

[0041] Referring now to FIG. 5, shown therein is a screen display 200 according to an embodiment of the present disclosure. The screen display 200 includes multiple tabs, including an iFR tab 202, an FFR tab 204, a patient tab 206, and a settings tab 208. In FIG. 5, the iFR tab 202 has been selected and displayed to a user. As shown, the iFR tab 202 includes a graph 210 and a corresponding pressure waveform plot 212. The screen display 200 also includes a window 214 that shows an estimated diagnostic pressure ratio. In that regard, in some instances the estimated diagnostic pressure ratio is determined by applying a correlation factor to basic or raw pressure measurements (e.g., Pd and Pa) obtained without the use of a hyperemic agent. In that regard, the correlation factor is utilized to correlate the basic or raw pressure measurements to an accepted diagnostic pressure ratio, such as FFR or iFR. Additional aspects of this correlation are discussed below. The screen display 200 also includes a win-

dow 216 showing the runs or pullbacks available for display to the user. In the illustrated embodiment, two different runs are available and identified by a corresponding time stamp. In that regard, a user can select the desired run from the window 216 and the data shown in the graph 210 and pressure waveform plot 212 will update accordingly.

[0042] The screen display 200 also includes zoom buttons 218, 220 that allow a user to zoom out or in, respectively, on the graph 210 and the pressure waveform plot 212. To this end, the screen display 200 includes a ruler 222 showing the relative scale of the graph 210 and the pressure waveform plot 212. In some instances, the ruler 222 provides a dimensional scale of the graphical display of the graph 210 and/or the pressure waveform plot 212 relative to the vessel length and/or the pullback length. The scale of the ruler 222 automatically updates in response to selective actuation of the zoom buttons 218, 220 in some implementations.

[0043] The screen display 200 also includes a slider 224. The slider 224 allows the user to move along the length of the vessel and/or the corresponding pullback data. For example, in some instances the left end of the slider 224 corresponds to the beginning of the pullback and the right end of the slider corresponds to the end of the pullback. By moving the slider 224 between the first and second ends, a user can see corresponding portions of the pressure data in the graph 210 and the pressure waveform plot 212. Accordingly, a user can focus on certain portions of the vessel and pullback data using the zoom buttons 218, 220 in combination with the slider 224. In some instances, the numerical value of the pressure ratio displayed in window 214 is updated based on the position of the slider and/or. In that regard, in some instances the numerical value of the pressure ratio displayed in window 214 is based solely on the pressure data being displayed in the graph 210 and the pressure waveform plot 212. However, in other instances the numerical value of the pressure ratio displayed in window 214 is based one of or a combination of the pressure data being displayed in the graph 210 and the pressure waveform plot 212 and pressure data not displayed in the graph 210 and the pressure waveform plot 212.

[0044] In that regard, the graph 210 and pressure waveform plot 212 of screen display 200 illustrate aspects of pressure measurements obtained as one instrument is moved through the vessel and another instrument is maintained at a fixed location. In that regard, in some instances the pressure measurements are representative of a pressure ratio between a fixed location within the vessel and the moving position of the instrument as the instrument is moved through the vessel. For example, in some instances a proximal pressure measurement is obtained at a fixed location within the vessel while the instrument is pulled back through the vessel from a first position distal of the position where the proximal pressure measurement is obtained to a second position more proximal than the first position (i.e., closer to the fixed position of the proximal pressure measurement). For clarity in understanding the concepts of the present disclosure, this arrangement will be utilized to describe many of the embodiments of the present disclosure. However, it is understood that the concepts are equally applicable to other arrangements. For example, in some instances, the instrument is pushed through the vessel from a first position distal of the proximal pressure measurement location to a second position further distal (i.e., further away from the fixed position of the proximal pressure measurement). In other instances, a distal pressure measurement is obtained at a fixed location within the vessel and the

instrument is pulled back through the vessel from a first position proximal of the fixed location of the distal pressure measurement to a second position more proximal than the first position (i.e., further away from the fixed position of the distal pressure measurement). In still other instances, a distal pressure measurement is obtained at a fixed location within the vessel and the instrument is pushed through the vessel from a first position proximal of the fixed location of the distal pressure measurement to a second position less proximal than the first position (i.e., closer the fixed position of the distal pressure measurement).

[0045] The pressure differential or gradient between the two pressure measurements within the vessel (e.g., a fixed location pressure measurement and a moving pressure measurement) is calculated as a ratio of the two pressure measurements (e.g., the moving pressure measurement divided by the fixed location pressure measurement), in some instances. In some instances, the pressure differential or gradient is calculated for each heartbeat cycle of the patient. In that regard, the calculated pressure ratio is calculated by dividing the average distal pressure over the heartbeat cycle by the average proximal pressure over the heartbeat cycle in some embodiments. In other embodiments, only a portion of the heartbeat cycle is utilized to calculate the pressure ratio. Again, the proximal and distal pressure measurements used for calculating the pressure ratio can be averaged over the portion of the heartbeat cycle in some instances.

[0046] The calculated pressure ratios can be modified using one or more correlation factor(s) to estimate a clinically accepted diagnostic pressure ratio, including fractional flow reserve (FFR) as well as an instantaneous wave free ratio (iFR). In that regard, iFR pressure ratios may be calculated as described in one or more of PCT Patent Application Publication No. WO 2012/093260, filed Jan. 6, 2012 and titled "APPARATUS AND METHOD OF CHARACTERISING A NARROWING IN A FLUID FILLED TUBE," PCT Patent Application Publication No. WO 2012/093266, filed Jan. 6, 2012 and titled "APPARATUS AND METHOD OF ASSESSING A NARROWING IN A FLUID FILLED TUBE," U.S. patent application Ser. No. 13/460,296, filed Apr. 30, 2012 published as U.S. Patent Application Publication No. 2013/0046190 on Feb. 21, 2013 and titled "DEVICES, SYSTEMS, AND METHODS FOR ASSESSING A VESSEL," PCT Patent Application Publication No. WO 2013/028612, filed Aug. 20, 2012 and titled "DEVICES, SYSTEMS, AND METHODS FOR VISUALLY DEPICTING A VESSEL AND EVALUATING TREATMENT OPTIONS," U.S. Provisional Patent Application No. 61/856,509 filed Jul. 19, 2013, now U.S. patent application Ser. No. 14/335,605, filed on Jul. 18, 2014 and published as U.S. Patent Application Publication No. 2015/0025330 on Jan. 22, 2015, and titled "DEVICES, SYSTEMS, AND METHODS FOR ASSESSMENT OF VESSELS," and U.S. Provisional Patent Application No. 61/856,518, filed Jul. 19, 2013 now U.S. patent application Ser. No. 14/335,680, filed on Jul. 18, 2014 and published as U.S. Patent Application Publication No. 2015/0025398 on Jan. 22, 2015, and titled "DEVICES, SYSTEMS, AND METHODS FOR ASSESSING A VESSEL WITH AUTOMATED DRIFT CORRECTION," each of which is hereby incorporated by reference in its entirety. In that regard, the predicted diagnostic pressure ratios of the present disclosure may be a predicted diastolic pressure ratio that estimates a resting pressure ratio during a diastolic portion of a heartbeat cycle of the patient. Further, the predicted

diastolic pressure ratio may estimate the resting pressure ratio during part of the diastolic portion of a heartbeat cycle of the patient. In that regard, the part of the diastolic portion of the heartbeat cycle may be a diagnostic window as described in "DEVICES, SYSTEMS, AND METHODS FOR ASSESSING A VESSEL," PCT Patent Application Publication No. WO 2013/028612, filed Aug. 20, 2012, which is hereby incorporated by reference in its entirety.

[0047] The correlation factor(s) may have a fixed value. Alternatively, the correlation factor(s) may be variable. For example, different correlation scale factors may be utilized for different ranges or values of calculated pressure ratios. As a particular example, a first correlation value is assigned to calculated pressure ratios below 0.5, a second correlation value is assigned to a calculated pressure ratios between 0.5 and 0.7, and a third correlation value is assigned to a calculated pressure ratios above 0.7. Any number of correlation values can be utilized for any number of ranges of calculated pressure ratios.

[0048] Correlation factors may be selected in view of previously collected data. In that regard, empirical correlation data can be utilized to select the best correlation factor(s) for a particular patient. For instance, basic pressure ratio measurements can be collected along with FFR, iFR, and/or other accepted diagnostic pressure ratios from a large number of patients/vessels and utilized to define correlation factors between the basic pressure ratio measurements and the accepted diagnostic pressure ratios. Thus, an accurate relationship between the basic pressure ratio measurements and the accepted diagnostic pressure ratios can be determined for similar patients. In that regard, various patient factors (e.g., vessel of interest, age, gender, overall health, previous medical procedures, body mass index, etc.) can be taken into account when selecting the correlation factor(s) to be used. A database or library of correlation factors can be built and maintained based on the previously performed procedures to allow selection of the most appropriate correlation factors for a particular patient. The accuracy of the estimated diagnostic pressure ratio can be continually improved over time as increased data points and corresponding correlation factors are populated for various patient types, vessel types, and/or other characteristics.

[0049] The correlation factors can be determined based on the relationship between accepted diagnostic pressure ratios (FFR, iFR, etc.) and corresponding basic pressure data for the same vessel. In that regard, it is understood that both natural vessels of actual patients as well as artificial/simulated vessels may be used to define the relationship between the basic pressure data and the accepted diagnostic pressure ratios that is utilized to identify suitable correlation factors.

[0050] Referring now to FIGS. 6-8, shown therein are various ways of evaluating the relationship between calculated pressure ratios (based on the basic pressure data) and an accepted diagnostic pressure ratio that can be utilized to define correlation factor(s) in accordance with the present disclosure. For example, FIG. 6 shows a graph 230 in which a number of data points 232 are plotted. Each data point 232 is plotted to represent how the pressure ratio calculated using basic pressure data (e.g., Pd/Pa) relates to an accepted diagnostic pressure ratio, in this case iFR. Plot 234 smooths out the relationship between the calculated pressure ratio and the accepted diagnostic pressure ratio. In that regard, plot 234 can smooth out or map the data provided by points 232 in any suitable way, including averaging, best fit, etc. Graph 230 also

shows plot 236 that would correspond to a one-to-one relationship between the calculated pressure ratio (based on basic pressure data) and the accepted diagnostic pressure ratio. In the exemplary data set shown in graph 230, the calculated pressure ratio tends to be under plot 236. In some instances, a polynomial equation defining the difference between plot 234 and plot 236 is used to define the correlation factor utilized to provide an estimated diagnostic pressure ratio based on the calculated pressure ratio. For example, FIG. 7 shows a graph 240 having a plot 242 that accounts for the differences between plot 234 and 236 that can be utilized to define a correlation factor to provide the estimated diagnostic pressure ratio.

[0051] The correlation factor can be defined based on various relationships between the calculated pressure ratio (based on the basic pressure data, such as Pd/Pa) and the accepted diagnostic pressure ratio (such as FFR, iFR, etc.), including relationships based on the slope of the data points 232 or plot 234 of the calculated pressure ratio to the accepted diagnostic pressure ratio, based on a measure of curvature of the data points 232 or plot 234 of the calculated pressure ratio to the accepted diagnostic pressure ratio, based on an approximated polynomial function of the plot 234 of the calculated pressure ratio to the accepted diagnostic pressure ratio, based on an area below the curve of the plot 234 of the calculated pressure ratio to the accepted diagnostic pressure ratio, and/or other mathematical characteristics of the relationship between the calculated pressure ratio and the accepted diagnostic pressure ratio. For example, FIG. 8 shows a graph 250 where the area 252 under the plot 234 has been shaded to show the relationship between the calculated pressure ratio and the accepted diagnostic pressure ratio.

[0052] Persons skilled in the art will also recognize that the apparatus, systems, and methods described above can be modified in various ways. Accordingly, persons of ordinary skill in the art will appreciate that the embodiments encompassed by the present disclosure are not limited to the particular exemplary embodiments described above. In that regard, although illustrative embodiments have been shown and described, a wide range of modification, change, and substitution is contemplated in the foregoing disclosure. It is understood that such variations may be made to the foregoing without departing from the scope of the present disclosure. Accordingly, it is appropriate that the appended claims be construed broadly and in a manner consistent with the present disclosure.

What is claimed is:

1. A method of evaluating a vessel of a patient, comprising:
 - introducing at least one instrument into the vessel of the patient;
 - obtaining from the at least one instrument proximal pressure measurements from within the vessel at a position proximal of a stenosis of the vessel;
 - obtaining from the at least one instrument distal pressure measurements within the vessel at a position distal of the stenosis of the vessel;
 - calculating a pressure ratio for each cardiac cycle based on the average distal pressure measurement and the average proximal pressure measurement in the vessel of the patient during each cardiac cycle of the patient;
 - applying a correlation factor to the calculated pressure ratio to produce a predicted diagnostic pressure ratio, and
 - displaying the predicted diagnostic pressure ratio to a user.

2. The method of claim 1, wherein the predicted diagnostic pressure ratio correlates to an accepted diagnostic pressure ratio.

3. The method of claim 2, wherein the accepted diagnostic pressure ratio is at least one of fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR).

4. The method of claim 3, wherein the correlation factor has a fixed value.

5. The method of claim 3, wherein the correlation factor is variable.

6. The method of claim 5, wherein the correlation factor has a first correlation value for calculated pressure ratios below a first threshold, a second correlation value for calculated pressure ratios between the first threshold and a second threshold, and a third correlation value for calculated pressure ratios above the second threshold.

7. The method of claim 3, wherein the correlation factor is defined based on a relationship of a slope of a plot of calculated pressure ratios relative to accepted diagnostic pressure ratios.

8. The method of claim 3, wherein the correlation factor is defined based on a relationship of a measure of curvature of a plot of calculated pressure ratios relative to accepted diagnostic pressure ratios.

9. The method of claim 3, wherein the correlation factor is defined based on a relationship of an approximated polynomial function of a plot of calculated pressure ratios relative to accepted diagnostic pressure ratios.

10. The method of claim 3, wherein the correlation factor is defined based on a relationship of an area below the curve of a plot of calculated pressure ratios to accepted diagnostic pressure ratios.

11. A system for evaluating a vessel of a patient, comprising:

- one or more instruments sized and shaped for introduction into the vessel of the patient;

- a processing system in communication with the one or more instruments, the processing unit configured to:

- obtain, from the one or more instruments, proximal pressure measurements measured within the vessel at a position proximal of a stenosis of the vessel;

- obtain, from the one or more instruments, distal pressure measurements measured within the vessel at a position distal of the stenosis of the vessel;

- calculate a pressure ratio based on the obtained proximal and distal pressure measurements;

- apply a correlation factor to the calculated pressure ratio to produce a predicted diagnostic pressure ratio; and
 - output the predicted diagnostic pressure ratio to a display.

12. The system of claim 11, wherein the predicted diagnostic pressure ratio correlates to an accepted diagnostic pressure ratio.

13. The system of claim 12, wherein the accepted diagnostic pressure ratio is at least one of fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR).

14. The system of claim 13, wherein the correlation factor has a fixed value.

15. The system of claim 13, wherein the correlation factor is variable.

16. The system of claim 15, wherein the correlation factor has a first correlation value for calculated pressure ratios below a first threshold, a second correlation value for calculated pressure ratios between the first threshold and a second

threshold, and a third correlation value for calculated pressure ratios above the second threshold.

17. The system of claim **13**, wherein the correlation factor is defined based on a relationship of a slope of a plot of calculated pressure ratios relative to accepted diagnostic pressure ratios.

18. The system of claim **13**, wherein the correlation factor is defined based on a relationship of a measure of curvature of a plot of calculated pressure ratios relative to accepted diagnostic pressure ratios.

19. The system of claim **13**, wherein the correlation factor is defined based on a relationship of an approximated polynomial function of a plot of calculated pressure ratios relative to accepted diagnostic pressure ratios.

20. The system of claim **13**, wherein the correlation factor is defined based on a relationship of an area below the curve of a plot of calculated pressure ratios to accepted diagnostic pressure ratios.

* * * * *

公开了用于在视觉上描绘血管和评估治疗选择的装置，系统和方法。该方法可包括将器械引入患者的血管中并获得血管狭窄的近端和远端压力测量值，基于所获得的近端和远端压力测量值计算压力比，将相关因子应用于计算的压力比率至产生预测的诊断压力比，并向用户显示预测的诊断压力比。

