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(54) METHODS AND APPARATUS FOR THE IDENTIFICATION AND STABILIZATION OF VULNERABLE PLAQUE

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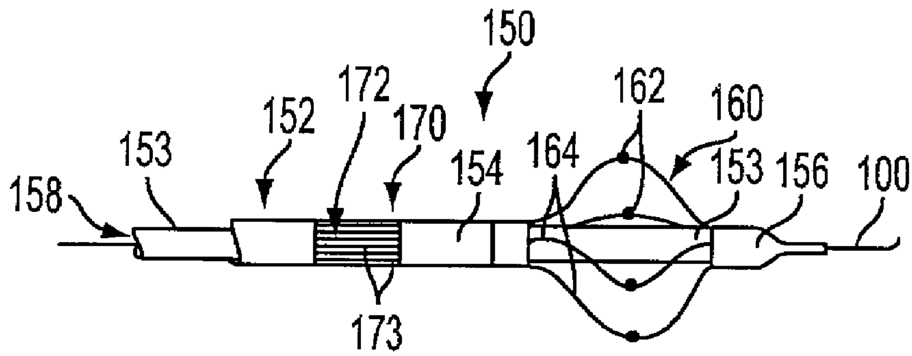
(57) **ABSTRACT**

The present invention provides methods and apparatus for identifying and stabilizing vulnerable plaque via multi-functional catheters having both thermography and imaging capabilities. It is expected that correlating imaging and thermography data will facilitate improved identification of vulnerable plaque. Apparatus of the present invention may also be provided with optional stabilization elements for stabilizing vulnerable plaque. Methods of using apparatus of the present invention are provided.



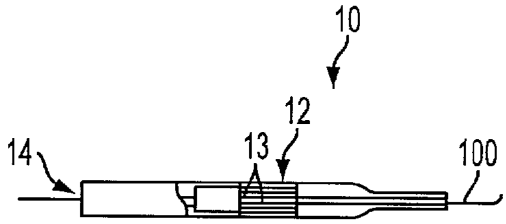


FIG. 1
(PRIOR ART)

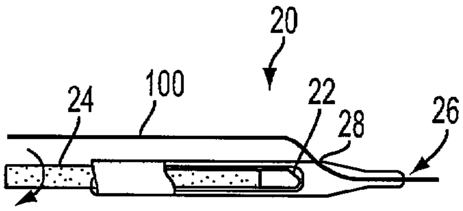


FIG. 2
(PRIOR ART)

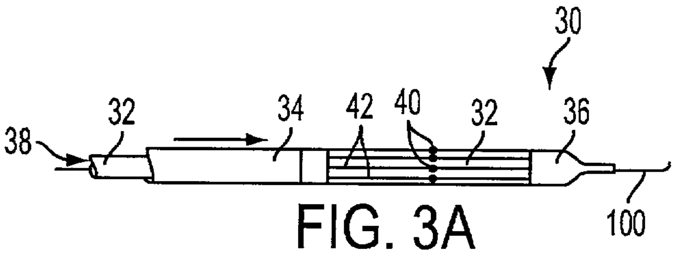


FIG. 3A
(PRIOR ART)

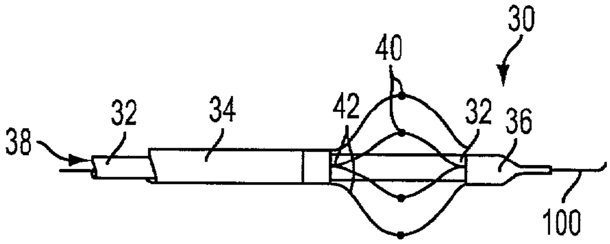


FIG. 3B
(PRIOR ART)

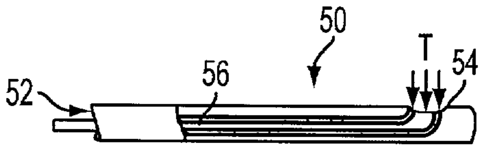


FIG. 4
(PRIOR ART)

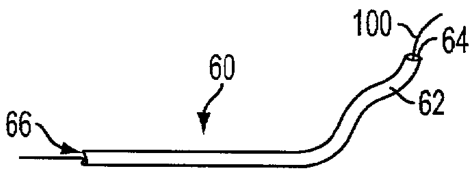


FIG. 5
(PRIOR ART)

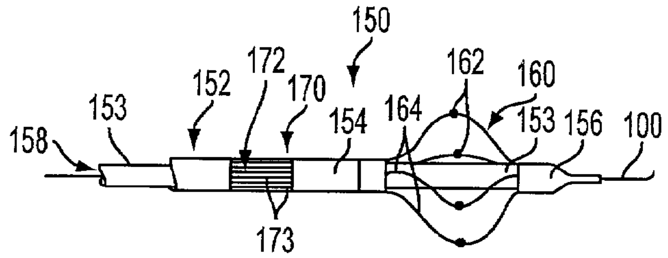


FIG. 6

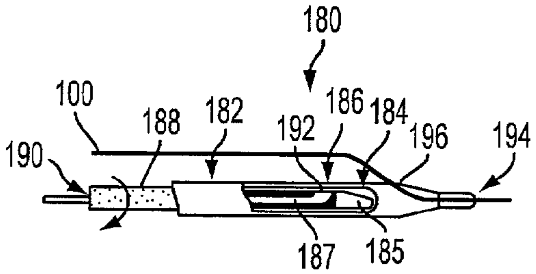


FIG. 7

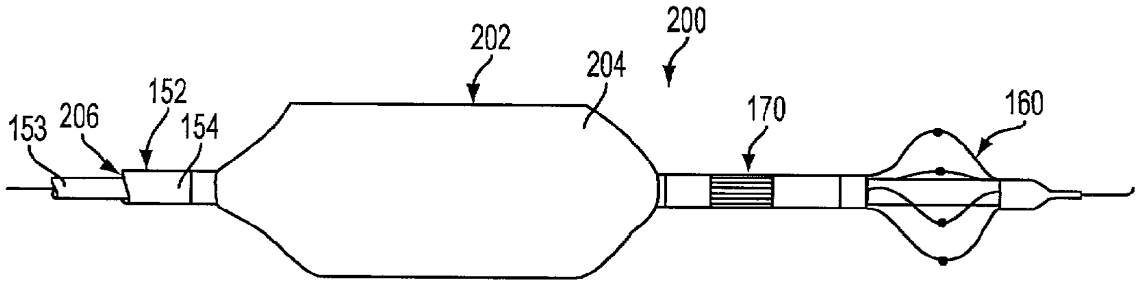


FIG. 8

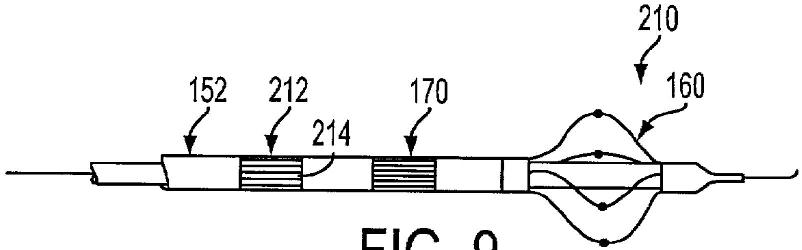


FIG. 9

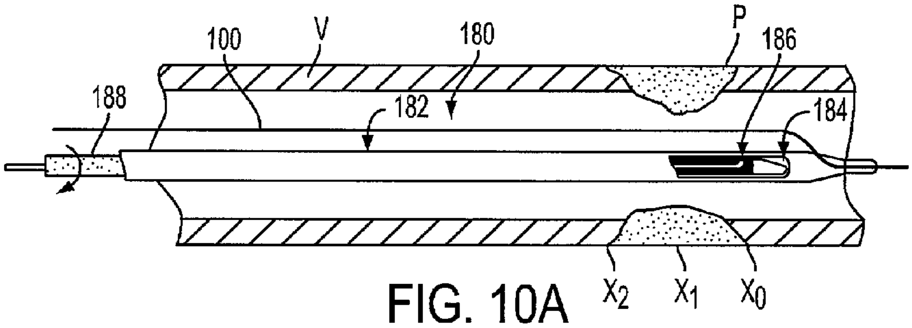


FIG. 10A

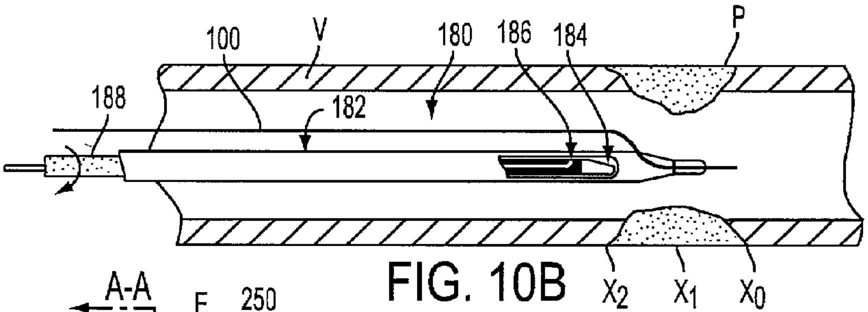


FIG. 10B

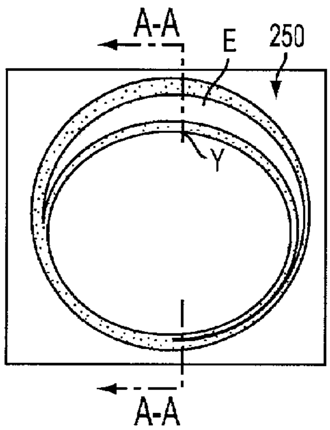


FIG. 11A

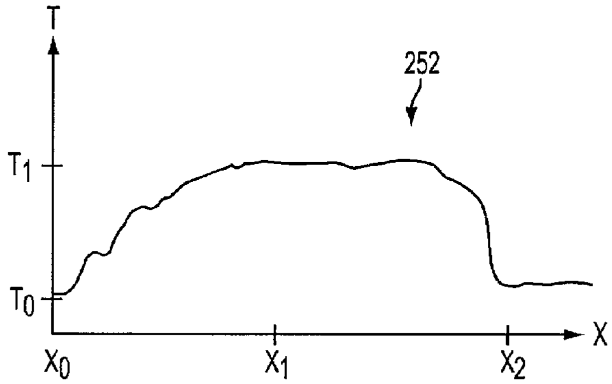


FIG. 11B

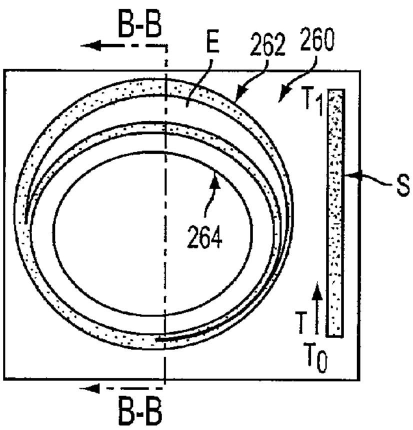


FIG. 12

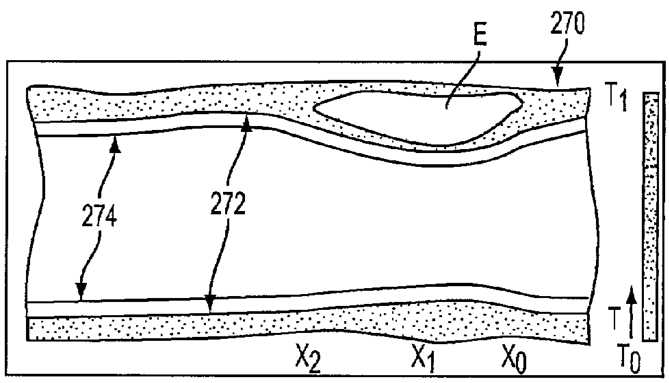


FIG. 13

METHODS AND APPARATUS FOR THE IDENTIFICATION AND STABILIZATION OF VULNERABLE PLAQUE

FIELD OF THE INVENTION

[0001] The present invention relates to methods and apparatus for identifying and stabilizing vulnerable plaque. More particularly, the present invention relates to specialized catheters having both an imaging element and a thermographer for improved identification of vulnerable plaque. Apparatus of the present invention may in addition include an optional stabilization element for stabilizing the plaque.

BACKGROUND OF THE INVENTION

[0002] Vulnerable plaque is commonly defined as plaque having a lipid pool with a thin fibrous cap, which is often infiltrated by macrophages. Vulnerable plaque lesions generally manifest only mild to moderate stenoses, as compared to the large stenoses associated with fibrous and calcified lesions. While the more severe stenoses of fibrous and calcified lesions may limit flow and result in ischemia, these larger plaques often remain stable for extended periods of time. In fact, rupture of vulnerable plaque is believed to be responsible for a majority of acute ischemic and occlusive events, including unstable angina, myocardial infarction, and sudden cardiac death.

[0003] The mechanism behind such events is believed to be thrombus formation upon rupture and release of the lipid pool contained within vulnerable plaque. Thrombus formation leads to plaque growth and triggers acute events. Plaque rupture may be the result of inflammation, or of lipid accumulation that increases fibrous cap stress. Clearly, prospective identification and stabilization of vulnerable plaque is key to effectively controlling and reducing acute ischemic and occlusive events.

[0004] A significant difficulty encountered while attempting to identify and stabilize vulnerable plaque is that standard angiography provides no indication of whether or not a given plaque is susceptible to rupture. Furthermore, since the degree of stenosis associated with vulnerable plaque is often low, in many cases vulnerable plague may not even be visible using angiography.

[0005] A variety of techniques for identifying vulnerable plaque are being pursued. These include imaging techniques, for example, Intravascular Ultrasound ("IVUS"), Optical Coherence Tomography ("OCT"), and Magnetic Resonance Imaging ("MRI"). Two primary IVUS techniques have been developed. The first is commonly referred to as rotational IVUS, which uses an ultrasound transducer that is rotated to provide a circumferential image of a patient's vessel. The second technique is commonly referred to as phased-array IVUS, which uses an array of discrete ultrasound elements that each provide image data. The image data from each element is combined to form a circumferential image of the patient's vessel.

[0006] Rotational IVUS systems are marketed by the Boston Scientific Corporation of Natick, Mass., and are described, for example, in U.S. Pat. No. 6,221,015 to Yock, which is incorporated herein by reference. Phased-array IVUS systems are marketed by JOMED Inc., of Rancho Cordova, Calif., and are described, for example, in U.S. Pat. No. 6,283,920 to Eberle et al., as well as U.S. Pat. No. 6,283,921 to Nix et al., both of which are incorporated herein by reference. Optical Coherence Tomography systems are developed by Lightlab Imaging, LLC., of Westford, Mass., and are described, for example, in U.S. Pat. No. 6,134,003 to Tearney et al., which is incorporated herein by reference. U.S. Pat. No. 5,699,801 to Atalar et al., which also is incorporated herein by reference, describes methods and apparatus for Magnetic Resonance Imaging inside a patient's vessel.

[0007] A primary goal while characterizing plaque-type via an imaging modality is identification of sub-intimal lipid pools at the site of vulnerable plaque. In an IVUS study entitled, "Morphology of Vulnerable Coronary Plaque: Insights from Follow-Up of Patients Examined by Intravascular Ultrasound Before an Acute Coronary Syndrome" (Journal of the American College of Cardiology, 2000; 35:106-11), M. Yamagishi et al., concluded that, "the risk of rupture is high among eccentric lesions with a relatively large plaque burden and a shallow echolucent zone." IVUS allows characterization of the concentricity or eccentricity of lesions, as well as identification of echolucent zones, which are indicative of lipid-rich cores. However, while IVUS and other advanced imaging modalities may provide a means for identifying vulnerable plaque and selecting patients likely to benefit from aggressive risk factor interventions, such imaging modalities typically require a significant degree of skill, training and intuition on the part of a medical practitioner in order to achieve a proper diagnosis.

[0008] In addition to imaging techniques, biological S techniques have also been proposed for identifying vulnerable plaque. Biological techniques typically rely on characterization of material properties of the plaque. Biological techniques include thermography, biological markers, magnetic resonance, elastography and palpography. Biological markers typically attempt to 'tag' specific tissue types, for example, via chemical receptors, with markers that allow easy identification of tissue type. Magnetic resonance operates on the principal that different tissue types may resonate at different, identifiable frequencies. Techniques combining Magnetic Resonance Imaging and biological markers have also been proposed in which superparamagnetic iron oxide nanoparticles are used as MRI contrast media. It is expected that vulnerable plaque will preferentially take up the nanoparticles by virtue of macrophage infiltration, leaking vasa vasorum, and permeable thin cap (M. AbouQamar et al., Poster Abstract, Transcatheter Cardiovascular Therapeutics, 2001, Washington, D.C.).

[0009] Elastography and palpography seek to characterize the strain modulus, or other mechanical properties, of target tissue. Studies have shown that different plaque types exhibit different, identifiable strain moduli, which may be used to characterize plaque type. Elastography is described, for example, in U.S. Pat. No. 5,178,147 to Ophir et al., which is incorporated herein by reference. Palpography is described, for example, in U.S. Pat. No. 6,165,128 to Cespedes et al., which also is incorporated herein by reference.

[0010] Thermography seeks to characterize tissue type via tissue temperature. Tissue temperature may be characterized, for example, via thermographers, thermistors, thermosensors, thermocouples, thermometers, spectrography, spectroscopy, and infrared. Tissue characterization via thermographers has been known for some time; for example, U.S. Pat. No. 4,960,109 to Lele et al., which is incorporated herein by reference, describes a multi-function probe for use in hyperthermia therapy that employs at least one pair of temperature sensors.

[0011] It has been observed that vulnerable plaque results in a temperature increase at a vessel wall of as much as about 0.1-1.5° C. A review of thermographic apparatus and techniques for plaque characterization is provided by C. Stefanadis in "Plaque Thermal Heterogeneity—Diagnostic Tools and Management Implications" (Expert Presentation, Transcatheter Cardiovascular Therapeutics, Washington, D.C.). Thermography apparatus and methods are also provided in Greek Patent No. 1003158B to Diamantopoulos et al., Greek Patent No. 1003178B to Toutouzas et al., and Greek Utility Model No. 98200093U to Diamantopoulos et al., all of which are incorporated herein by reference. U.S. Pat. No. 5,445,157 to Adachi et al., which is incorporated herein by reference, describes a thermographic endoscope including an infrared image forming device. U.S. Pat. No. 5,871,449 to Brown and U.S. Pat. No. 5,935,075 to Casscells et al., both incorporated herein by reference, describe catheters capable of detecting infrared radiation.

[0012] Although passing reference is made in the Abstract of the Casscells patent to using the infrared detection system with or without ultrasound, no ultrasound apparatus is described. If ultrasound were to be used, it would presumably be applied using known techniques, i.e. extravascularly or via a secondary, stand-alone IVUS catheter. Using extravascular ultrasound or a secondary, stand-alone IVUS catheter, in conjunction with an infrared catheter is expected to increase the complexity, time, and cost associated with identifying vulnerable plaque.

[0013] For the purposes of the present invention, in addition to temperature characterization, thermography includes characterization of tissue pH, for example, via Near-Infrared ("NIR") Spectroscopy. T. Khan et al., have shown that inflamed regions of plaque exhibit lower pH, and that NIR Spectroscopy may be used to measure such pH ("Progress with the Calibration of A 3-French Near Infrared Spectroscopy Fiberoptic Catheter for Monitoring the pH Of Atherosclerotic Plaque: Introducing a Novel Approach For Detection of Vulnerable Plaque," Poster Abstract, Transcatheter Cardiovascular Therapeutics, 2001, Washington, D.C.).

[0014] Although thermography is a promising new technique for identifying vulnerable plaque, it has several drawbacks. First, since thermography doesn't provide image data, it is expected that medical practitioners will have difficulty determining proper locations at which to use a thermographer in order to characterize plaque type. Thus, secondary, stand-alone imaging apparatus may be required in order to adequately identify and characterize plaque. Requiring separate imaging and thermography apparatus is expected to increase complexity, time and cost associated with identifying vulnerable plaque. Additionally, thermography provides no indication of the eccentricity of a plaque or of the presence or magnitude of lipid pools disposed in the plaque, both of which have been shown to indicate the presence of vulnerable plaque.

[0015] A drawback common to prior art techniques for identifying and stabilizing vulnerable plaque is that identification and stabilization are typically achieved using separate apparatus. Stabilization techniques include both local and systemic therapy. Localized techniques include angioplasty, stenting, mild heating, photonic ablation, radiation, local drug injection, gene therapy, covered stents and coated stents, for example, drug-eluting stents. Systemic therapies include extreme lipid lowering; inhibition of cholesterol acyltransferase (Acyl-CoA, "ACAT"); matrix metalloproteinase ("MMP") inhibition; and administration of anti-inflammatory agents, anti-oxidants and/or Angiotensin-Converting Enzyme ("ACE") inhibitors.

[0016] Multi-functional devices have been proposed in other areas of vascular intervention. For example, U.S. Pat. No. 5,906,580 to Kline-Schoder et al., which is incorporated herein by reference, describes an ultrasound transducer array that may transmit signals at multiple frequencies and may be used for both ultrasound imaging and ultrasound therapy. PharmaSonics, Inc., of Sunnyvale, Calif., markets therapeutic ultrasound catheters, which are described, for example, in U.S. Pat. No. 5,725,494 to Brisken et al., incorporated herein by reference. U.S. Pat. No. 5,581,144 to Corl et al., incorporated herein by reference, describes another ultrasound transducer array that is capable of operating at multiple frequencies.

[0017] In addition to multi-functional ultrasound devices, other multi-functional interventional devices are described in U.S. Pat. Nos. 5,571,086 and 5,855,563 to Kaplan et al., both of which are assigned to Localmed, Inc., of Palo Alto, Calif., and both of which are incorporated herein by reference. However, none of these devices, nor the multi-functional ultrasound devices discussed previously, are suited for rapid identification and stabilization of vulnerable plaque in accordance with the principles of the present invention.

[0018] In view of the drawbacks associated with previously known methods and apparatus for identifying and stabilizing vulnerable plaque, it would be desirable to provide methods and apparatus that overcome those drawbacks.

[0019] It would be desirable to provide methods and apparatus that reduce the skill and training required on the part of medical practitioners in order to identify and stabilize vulnerable plaque.

[0020] It would be desirable to provide methods and apparatus for identifying and stabilizing vulnerable plaque that reduce the cost, complexity and time associated with such procedures.

[0021] It would be desirable to provide methods and apparatus that are multi-functional.

[0022] It would be desirable to provide methods and apparatus that facilitate characterization of lesion eccentricity, echogenicity, and temperature or pH.

[0023] It would be desirable to provide methods and apparatus that combine imaging, thermography and, optionally, vulnerable plaque stabilization elements in a single device.

SUMMARY OF THE INVENTION

[0024] In view of the foregoing, it is an object of the present invention to provide apparatus and methods for identifying and stabilizing vulnerable plaque that overcome drawbacks associated with previously known apparatus and methods.

[0025] It is an object to provide methods and apparatus that reduce the skill and training required on the part of medical practitioners in order to identify and stabilize vulnerable plaque.

[0026] It also is an object to provide methods and apparatus for identifying and stabilizing vulnerable plaque that reduce the cost, complexity and time associated with such procedures.

[0027] It is another object to provide methods and apparatus that are multi-functional.

[0028] It is yet another object to provide methods and apparatus that facilitate characterization of lesion eccentricity, echogenicity, and temperature or pH.

[0029] It is an object to provide methods and apparatus that combine imaging, thermography and, optionally, vulnerable plaque stabilization elements in a single device.

[0030] These and other objects of the present invention are accomplished by providing apparatus for identifying vulnerable plaque comprising a catheter having both an imaging element and a thermographer. Providing both thermography and imaging in a single, multi-functional catheter is expected to decrease the cost and increase the accuracy of vulnerable plaque identification, as well as simplify and expedite identification, as compared to providing separate, standalone thermography and imaging. Apparatus of the present invention also may be provided with optional stabilization elements for stabilizing vulnerable plaque, thereby providing vulnerable plaque identification and stablization in a single device.

[0031] In a first embodiment of the present invention, a catheter is provided having a phased-array IVUS imaging system and a plurality of thermocouples. The plurality of thermocouples may be deployed into contact with an interior wall of a patient's body lumen, thereby providing temperature measurements along the interior wall that may be compared to IVUS images obtained with the imaging system to facilitate identification of vulnerable plaque. In a second embodiment, a catheter is provided with a rotational IVUS imaging system and a fiber optic infrared thermography system. The infrared system's fiber optic is preferably coupled to the rotating drive cable of the rotational IVUS imaging system, thereby providing a full circumferential temperature profile along the interior wall of the patient's body lumen.

[0032] In a third embodiment, apparatus of the present invention is provided with, in addition to an imaging element and a thermographer, an optional stabilization element. The stabilization element comprises an inflatable balloon. In a fourth embodiment, the stabilization element comprises a second ultrasound transducer that resonates at therapeutic ultrasound frequencies, as opposed to ultrasonic imaging frequencies. As yet another embodiment, the imaging element of the present invention comprises an ultrasound transducer that is capable of transmitting multiple frequencies that are suited to both ultrasonic imaging and ultrasonic therapy, thereby providing both vulnerable plaque imaging and stabilization in a single element. These embodiments are provided only for the purpose of illustration. Additional embodiments will be apparent to those skilled in the art and are included in the scope of the present invention.

[0033] Imaging and thermographic data are preferably coupled in order to facilitate identification of vulnerable plaque. Coupling may be achieved using position indication techniques, for example, using an IVUS pullback system that is modified to simultaneously monitor the position of both the imaging element and the thermographer. IVUS pullback systems are described, for example, in U.S. Pat. No. 6,290,675 to Vujanic et al., U.S. Pat. No. 6,275,724 to Dickinson et al., U.S. Pat. No. 6,193,736 to Webler et al., and PCT Publication WO 99/12474, all of which are incorporated herein by reference.

[0034] Imaging data and thermographic data, coupled using position indication techniques, are preferably simultaneously graphically displayed, for example, on a standard computer monitor. The coupled data is preferably displayed in an overlayed fashion so that a medical practitioner may rapidly correlate temperature measurements obtained at a given position within the patient's body lumen to images obtained at that position. Rapid correlation is expected to simplify, expedite and increase the accuracy of vulnerable plaque identification, as well as facilitate plaque stabilization. It is expected that additional data also may be obtained, coupled and provided in the graphical display, for example, palpography data. Blood flow imaging, as described, for example, in U.S. Pat. Nos. 5,453,575 and 5,921,931 to O'Donnell et al., both of which are incorporated herein by reference, may also be provided.

[0035] Methods of using the apparatus of the present invention are also provided.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] Further features of the invention, its nature and various advantages, will be more apparent from the following detailed description of the preferred embodiments, taken in conjunction with the accompanying drawings, in which like reference numerals apply to like parts throughout, and in which:

[0037] **FIG. 1** is a schematic cut-away view of a prior art phased-array IVUS catheter;

[0038] **FIG. 2** is a schematic cut-away view of a prior art rotational IVUS catheter;

[0039] **FIGS. 3A and 3B** are schematic side views of a prior art thermography catheter having a plurality of thermocouples, and shown in a collapsed delivery configuration and an expanded deployed configuration, respectively;

[0040] **FIG. 4** is a schematic cut-away view of a prior art thermography catheter having a side-viewing infrared thermographer;

[0041] **FIG. 5** is a schematic side view of a prior art thermography catheter having a steerable distal region with a thermocouple;

[0042] **FIG. 6** is a schematic side view of a first embodiment of a catheter in accordance with the principles of the present invention having an imaging element and a thermographer;

[0043] **FIG. 7** is a schematic cut-away view of a second embodiment of apparatus of the present invention having an imaging element and a thermographer;

[0044] **FIG. 8** is a schematic side view of a third embodiment of apparatus in accordance with the present invention having an optional stabilization element;

[0045] **FIG. 9** is a schematic side view of a fourth embodiment of the present invention having an alternative stabilization element;

[0046] **FIGS. 10A and 10B** are schematic side views, partially in section, of the apparatus of **FIG. 7** disposed at a target site within a patient's vessel, illustrating a method of using the apparatus of the present invention;

[0047] **FIGS. 11A and 11B** are schematic views of graphical user interfaces that display imaging and thermographic data, respectively, obtained, for example, via the method of FIGS. **10**, with the thermographic data of **FIG. 11B** obtained along side-sectional view line A--A of **FIG. 11A**;

[0048] **FIG. 12** is a schematic view of a graphical user interface that couples and simultaneously displays imaging and thermographic data obtained along a cross-section of the patient's vessel; and

[0049] **FIG. 13** is a schematic view of an alternative graphical user interface that simultaneously displays coupled imaging and thermographic data along side-sectional view line B--B of **FIG. 12**.

DETAILED DESCRIPTION OF THE INVENTION

[0050] The present invention relates to methods and apparatus for identifying and stabilizing vulnerable plaque. More particularly, the present invention relates to specialized catheters having both an imaging element and a thermographer for improved identification of vulnerable plaque. Apparatus of the present invention may in addition include an optional stabilization element for stabilizing the plaque.

[0051] With reference to **FIG. 1, a** prior art phased-array Intravascular Ultrasound ("IVUS") catheter is described. Catheter **10** comprises phased-array ultrasound transducer **12** having a plurality of discrete ultrasound elements **13**. Catheter **10** further comprises guide wire lumen **14**, illustratively shown with guide wire **100** disposed therein. Catheter **10** also may comprise multiplexing circuitry, amplifiers, etc., per se known, which may be disposed on and/or electrically coupled to catheter **10**. Transducer array **12** of catheter **10** is electrically coupled to an imaging system (not shown), per se known, that provides excitation waveforms to the transducer array, and interprets and displays data received from the array.

[0052] **FIG. 2** depicts a prior art rotational IVUS catheter. Catheter **20** comprises ultrasound transducer **22** disposed on a distal region of rotatable drive cable **24**. Drive cable **24** is proximally coupled to a driver (not shown), e.g. an electric motor, for rotating the drive cable and ultrasound transducer **22**, thereby providing transducer **22** with a 360° view. Catheter **20** further comprises guide wire lumen **26** that opens in side port **28** distally of transducer **22**. Guide wire **100** is illustratively disposed within lumen **26**. As with transducer array **12** of catheter **10**, transducer **22** of catheter **20** is electrically coupled to an imaging system (not shown), per se known, that provides excitation waveforms to the transducer, and interprets and displays data received from the transducer.

[0053] As discussed hereinabove, it has been shown that sub-intimal lipid pools at the site of plaque, as well as the eccentricity of the plaque, are key indicators of vulnerable plaque susceptible to rupture. It has also been shown that IVUS may be used to determine the eccentricity of plaque, as well as to identify echolucent zones, which are indicative of lipid-rich cores. However, achieving proper identification of vulnerable plaque via IVUS or any of a host of other advanced imaging modalities (e.g. Magnetic Resonance Imaging or Optical Coherence Tomography) may require a significant degree of skill, training and intuition on the part of a medical practitioner.

[0054] With reference now to **FIGS. 3, a** prior art thermography catheter is described. Catheter **30** comprises outer tube **34** coaxially disposed about inner tube **32**. Inner tube **32** comprises distal tip **36** and guide wire lumen **38**, in which guide wire **100** is illustratively disposed. Catheter **30** further comprises a plurality of thermocouples **40** disposed near its distal end. Each thermocouple comprises a wire **42** coupled proximally to the distal end of outer tube **34** and distally to distal tip **36** of inner tube **32**. The proximal and distal ends of each wire **42** are further electrically coupled to a processor (not shown) that captures and translates voltages generated by thermocouples **40** into temperature values, for example, via known calibration values for each thermocouple.

[0055] As seen in **FIG. 3**, catheter **30** is expandable from the collapsed delivery configuration of **FIG. 3A** to the expanded deployed configuration of **FIG. 3**B, by advancing outer tube **34** with respect to inner tube **32**. Such advancement causes thermocouples **40** to protrude from catheter **30** so that the thermocouples may contact the interior wall of a patient's body lumen. Catheter **30** is adapted for intravascular delivery in the collapsed configuration of **FIG. 3**A, and is adapted for taking temperature measurements at a vessel wall in the expanded configuration of **FIG. 3B**.

[0056] Referring to **FIG. 4**, another prior art thermography catheter is described. Catheter **50** comprises lumen **52**, which extends from a proximal end of catheter **50** to distal side port **54**. Fiber optic **56** is disposed within lumen **52** and is proximally coupled to an infrared thermography system (not shown). Catheter **50** thereby comprises a side-viewing fiber optic thermography catheter capable of measuring ambient temperature T near distal side port **54**.

[0057] By disposing side port **54** of catheter **50** within a patient's body lumen, the temperature of the patient's body lumen may be measured to facilitate identification of vulnerable plaque. However, a significant drawback of catheter **50** for identification of vulnerable plaque is that fiber optic **56** has only a limited field of view, and vulnerable plaque is typically eccentric, i.e. occurs predominantly on one side of a vessel. Thus, if side port **54** of catheter **50** were not rotated to the side of the vessel afflicted with vulnerable plaque build-up, it is expected that the ambient temperature T measured with catheter **50** would not reflect the presence of vulnerable plaque.

[0058] With reference to **FIG. 5**, yet another prior art thermography catheter is described. Catheter **60** comprises steerable distal end **62** having thermistor **64** coupled thereto. Thermistor **64** is proximally attached to a processor (not shown) that converts measurements taken with thermistor **64** into temperature measurements. Catheter **60** further comprises guide wire lumen **66** having guide wire **100** illustratively disposed therein.

[0059] Distal end **62** of catheter **60** may be positioned against a patient's body lumen to provide temperature measurements where thermistor **64** contacts the body lumen. However, a significant drawback of catheter **60** is that thermistor **64** only provides temperature measurements at a single point at any given time. It is therefore expected that eccentric vulnerable plaque will be difficult to identify with catheter **60**, especially when distal end **62** of catheter **60** is disposed against the unaffected, or mildly affected, side of a patient's vessel suffering from eccentric vulnerable plaque.

[0060] As discussed previously, although thermography is a promising new technique for identifying vulnerable plaque, all the thermography devices described hereinabove have several drawbacks. First, since thermography doesn't provide image data, it is expected that medical practitioners will have difficulty determining proper locations at which to use a thermographer in order to characterize plaque type. Thus, secondary, stand-alone imaging apparatus may be required in order to adequately identify and characterize plaque. Requiring separate imaging and thermography apparatus is expected to increase complexity, time and cost associated with identifying vulnerable plaque. Additionally, thermography provides no indication of the eccentricity of a plaque or of the presence or magnitude of lipid pools disposed in the plaque, both of which have been shown to indicate the presence of vulnerable plaque.

[0061] With reference now to **FIG. 6, a** first embodiment of apparatus in accordance with the present invention is described that provides both an imaging element and a thermographer in a single device. By providing both imaging and thermography in a single device, the present invention combines positive attributes of stand-alone imaging systems and stand-alone thermographers described hereinabove, while reducing previously-described drawbacks associated with such stand-alone systems. Apparatus **150** of **FIG. 6** comprises catheter body **152**, thermographer **160** and imaging element **170**.

[0062] Catheter body **152** comprises outer tube **154** coaxially disposed about inner tube **153**. Inner tube **153** comprises distal tip **156** and guide wire lumen **158**, in which guide wire **100** is illustratively disposed. Thermographer **160** comprises a plurality of thermocouples **162**. Any number of thermocouples **162** may be provided. Each thermocouple comprises a wire **164** coupled proximally to the distal end of outer tube **154** and distally to distal tip **156** of inner tube **153**. The proximal and distal ends of each wire **164** are further electrically coupled to a processor (not shown) that captures and translates voltages generated by thermocouples **162** into temperature values, for example, via known calibration values for each thermocouple.

[0063] Imaging element **170** comprises phased-array ultrasound transducer **172** having a plurality of discrete ultrasound elements **173**. Imaging element **170** optionally may comprise multiplexing circuitry, flexible circuitry or substrates, amplifiers, etc., per se known, which may be disposed on and/or electrically coupled to apparatus **150**. Transducer array **172** of imaging element **170** is electrically coupled to an imaging system (not shown), per se known, that provides excitation waveforms to the transducer array, and interprets and displays data received from the array. The imaging system coupled to imaging element **170** and the processor coupled to thermographer **160** are preferably combined into a single data acquisition and analysis system (not shown) for capturing and interpreting data received from apparatus **150**.

[0064] As with catheter **30** of FIGS. **3**, apparatus **150** is expandable from a collapsed delivery configuration to the expanded deployed configuration of **FIG. 6**, by advancing outer tube **154** of catheter body **152** with respect to inner tube **153**. Such advancement causes thermocouples **162** of thermographer **160** to protrude from catheter body **152** so that the thermocouples may contact the interior wall of a patient's body lumen. Apparatus **150** is adapted for intravascular delivery in the collapsed configuration, and is adapted for taking temperature measurements at a vessel wall in the expanded configuration. Imaging via imaging element **170** may be achieved in either the collapsed delivery configuration or the expanded deployed configuration, thereby facilitating positioning of apparatus **150** at a stenosed region within a patient's vessel.

[0065] Thermographer **160** comprises multiple thermography sensors, illustratively in the form of thermocouples **162**, disposed radially about catheter body **152**. Temperature measurements obtained from these sensors may be displayed graphically as a 2-dimensional map or image, for example, as a cross-sectional temperature profile within a patient's vessel. Such a cross-sectional temperature profile may be compared with a cross-sectional image of the vessel obtained at the same location, for example, via imaging element **170**. By advancing or retracting catheter body **152**, this 2-dimensional map, as well as the cross-sectional image, may be extended to 3-dimensions. Translation of catheter body **152** may be achieved, for example, using position indication techniques and/or a pullback system, per se known. Illustrative methods and apparatus for displaying thermographic and imaging data are provided hereinbelow with respect to FIGS. **11-13**.

[0066] Apparatus **150** is expected to provide significant advantages over prior art, stand-alone imaging and thermography catheters, such as catheters **10** and **30**, used either alone or in combination. Specifically, apparatus **150** is expected to decrease the complexity of obtaining both temperature and imaging data at a target site, as well as to facilitate correlation of such data. Additionally, apparatus **150** is expected to reduce the cost of obtaining both temperature and imaging data, as compared to providing both a stand-alone imaging system and a stand-alone thermography system.

[0067] Since vascular lumens commonly afflicted with vulnerable plaque, such as the coronary arteries, are often very small, it is expected that difficulty may be encountered while trying to simultaneously position separate imaging and thermography catheters at the site of vulnerable plaque; furthermore, a stand-alone thermography catheter may block imaging of portions of the vessel wall. Apparatus **150** overcomes these drawbacks. Additionally, apparatus **150** is expected to reduce the skill required on the part of a medical practitioner to identify vulnerable plaque via IVUS, by providing a secondary indication of vulnerable plaque in the form of temperature measurements. Likewise, apparatus **150** is expected to increase the likelihood of proper vulnerable plaque identification via thermography, by providing a secondary indication of vulnerable plaque in the form of IVUS imaging that allows examination of plaque eccentricity and echogenicity. Additional advantages of the present invention will be apparent to those of skill in the art.

[0068] Referring now to **FIG. 7, a** second embodiment of apparatus in accordance with the present invention in described. Apparatus **180** comprises catheter **182** having imaging element **184** and thermographer **186**. Imaging element **184** comprises a rotational IVUS imaging element, and thermographer **186** comprises a rotational infrared thermographer.

[0069] Catheter **182** further comprises rotatable drive cable **188** having lumen **190** that distally terminates at side port **192**. Catheter **182** still further comprises guide wire lumen **194** that opens in side port **196** distally of drive cable **188**. Guide wire **100** is illustratively shown disposed in lumen **194**.

[0070] Thermographer **186** of catheter **182** comprises fiber optic **187** disposed within lumen **190** of drive cable **188**. Imaging element **184** of catheter **182** comprises ultrasound transducer **185** disposed on rotatable drive cable **188**. Drive cable **188** is proximally coupled to a driver (not shown), e.g. an electric motor, for rotating the drive cable, as well as ultrasound transducer **185** of imaging element **184** and fiber optic **187** of thermographer **186**, thereby providing imaging element **184** and thermographer **186** with a 360° view.

[0071] As with transducer **22** of catheter **20**, transducer **185** is electrically coupled to an imaging system (not shown), per se known, that provides excitation waveforms to the transducer, and interprets and displays data received from the transducer. Likewise, as with fiber optic **56** of catheter **50**, fiber optic **187** is proximally coupled to an infrared thermography system (not shown). Preferably, the imaging system of imaging element **184**, the infrared thermography system of thermographer **186**, and the driver coupled to drive cable **188**, are combined into a single data acquisition and analysis system (not shown) for capturing and interpreting data received from apparatus **180**. Alternatively, a subset of these elements may be combined.

[0072] Apparatus **180** provides many of the advantages described hereinabove with respect to apparatus **150**. Additionally, as compared to infrared thermography catheter **50**, described hereinabove with respect to **FIG. 4**, thermographer **186** of apparatus **180** provides significantly enhanced thermographic capabilities. Specifically, by coupling thermographer **186** to rotatable drive cable **188**, thermographer **186** is capable of providing a full circumferential temperature profile along the interior wall of a patient's body lumen, without necessitating potentially inaccurate manual rotation of the infrared thermographer by a medical practitioner. A stand-alone, rotatable infrared thermography catheter (not shown), similar to apparatus **180** but without imaging capabilities, is contemplated and is included in the scope of the present invention.

[0073] With reference to **FIG. 8, a** third embodiment of apparatus in accordance with the present invention is described that includes an optional stabilization element, in addition to an imaging element and a thermographer. The stabilization element is adapted to stabilize vulnerable plaque, thereby providing vulnerable plaque identification and stablization in a single device. Apparatus **200** comprises all of the elements of apparatus **150**, including catheter body **152**, thermographer **160** and imaging element **170**, and further comprises stabilization element **202**.

[0074] Stabilization element **202** comprises inflatable balloon **204**. Balloon **204** is inflatable from a collapsed delivery configuration to the deployed configuration of **FIG. 8** by suitable means, for example, via an inflation medium injected into the balloon through annulus **206** formed between the inner wall of outer tube **154** and the outer wall of inner tube **153** of catheter body **152**. Additional inflation techniques will be apparent to those skilled in the art.

[0075] It is expected that, once vulnerable plaque has been identified in a patient's vessel via thermographer **160** and/or imaging element **170**, stabilization element **202** may be positioned at the location of the identified vulnerable plaque. Stabilization element **202** may then be deployed, i.e. balloon **204** may be inflated, at the site of vulnerable plaque to stabilize the plaque, for example, by compressing, rupturing, scaffolding and/or sealing the plaque in the controlled environment of a catheterization laboratory. In addition to balloon **204**, stabilization element **202** may be provided with additional stabilization elements (not shown), for example, a stent, a covered stent, a stent graft, a coated stent, or a drug-eluting stent, to further enhance stabilization of vulnerable plaque. Additional stabilization elements will be apparent to those of skill in the art.

[0076] In order to facilitate identification and stabilization of vulnerable plaque, the distances between stabilization element **202**, thermographer **160** and imaging element **170** are preferably provided or measured. Furthermore, the distances between the imaging, thermography and optional stabilization elements of all embodiments of the present invention are preferably provided or measured. This facilitates coupling of thermographic and imaging data, as well as proper positioning of optional stabilization elements.

[0077] Providing vulnerable plaque identification and stabilization elements in a single device, in accordance with the principles of the present invention, provides all of the benefits of apparatus **150** described hereinabove, as well as the additional advantage of not having to provide stand-alone apparatus for plaque stabilization. This, in turn, is expected to decrease the cost, time and complexity associated with identifying and stabilizing vulnerable plaque, as well as to decrease the crossing profile of such apparatus, as compared to stand-alone apparatus used concurrently. Further still, providing identification and stabilization in a single device is expected to simplify accurate placement of stabilization elements at the site of identified vulnerable plaque.

[0078] Referring now to **FIG. 9, a** fourth embodiment of the present invention having an alternative vulnerable plaque stabilization element, is described. Apparatus **210** comprises all of the elements of apparatus **150**, including catheter body **152**, thermographer **160** and imaging element **170**, and further comprises stabilization element **212**. Stabilization element **212** comprises therapeutic ultrasound transducer **214**, which is capable of resonating at, and transmitting, therapeutic ultrasound frequencies. Transducer **214** may comprise a single element or an array of elements. Transducer **214** is attached to an excitation unit (not shown) capable of causing resonance within the transducer. The excitation unit is preferably combined with the imaging system (not shown) of imaging element **170**.

[0079] Therapeutic ultrasound frequencies, at which therapeutic transducer **214** preferably is capable of resonating and transmitting, are typically described as low frequencies, for example, frequencies below 10,000,000 Hertz, or 10 Megahertz ("MHz"), and even more preferably frequencies below about 500,000 Hertz, or 500 Kilohertz ("kHz"). Conversely, transducer array **172** of imaging element **170** preferably is capable of resonating at, and transmitting, imaging ultrasound frequencies. Imaging ultrasound frequencies are typically described as high frequencies, for example, frequencies above about 10 Megahertz ("MHz"). These frequencies are provided only for the sake of illustration and should in no way be construed as limiting.

[0080] It is expected that, once vulnerable plaque has been identified in a patient's vessel via thermographer **160** and/or imaging element **170**, stabilization element **212** may be positioned at the location of the identified plaque and activated, i.e. ultrasound transducer **214** may provide therapeutic ultrasound waves, to stabilize the plaque, for example, by compressing, rupturing, and/or sealing the plaque in the controlled environment of a catheterization laboratory. As with apparatus **200**, the distances between stabilization element **212**, thermographer **160** and imaging element **170** are preferably provided or measured in order to facilitate vulnerable plaque identification, as well as positioning of stabilization element **212** prior to activation.

[0081] In addition to therapeutic ultrasound transducer **214**, stabilization element **212** may be provided with additional stabilization elements (not shown), for example, contrast, tissue-tag, or therapeutic agents, such as drug capsules, that rupture and are released upon exposure to ultrasound waves generated by therapeutic ultrasound transducer **214**. Additional stabilization elements will be apparent to those of skill in the art. Apparatus **210** is expected to provide many of the benefits described hereinabove with respect to apparatus **150** and apparatus **200**.

[0082] As yet another embodiment of the present invention, apparatus may be provided in which imaging element **170** and stabilization element **212** of apparatus **210** are replaced with a single ultrasonic transducer array that is capable of transmitting multiple frequencies suited to both ultrasonic imaging and ultrasonic therapy, thereby providing both vulnerable plaque imaging and stabilization in a single element. Techniques for providing an ultrasound transducer capable of resonating at multiple frequencies are provided, for example, in U.S. Pat. No. 5,906,580 to Kline-Schoder et al., as well as U.S. Pat. No. 5,581,144 to Corl et al., both of which are incorporated herein by reference.

[0083] With reference to **FIG. 10, a** method of using apparatus of the present invention is provided, illustratively using apparatus **180** described hereinabove. In **FIG. 10**, vessel V is afflicted with eccentric vulnerable plaque P that manifests only mild stenosis within vessel V. Catheter **182** of apparatus **180** is percutaneously advanced into vessel V, for example, over guide wire **100**, such that imaging element **184** and thermographer **186** are disposed distally of distal edge x_0 of vulnerable plaque P, as seen in **FIG. 10A**. Drive cable **188** is rotated via its driver (not shown) such that imaging element **184** and thermographer **186** are provided with a full 360° view.

[0084] Catheter **182** is then withdrawn proximally across the stenosis until imaging element **184** and thermographer **186** are disposed proximally of proximal edge x_2 of vulnerable plaque P, as seen in **FIG. 10B**. Imaging and thermography data are collected via imaging element **184** and thermographer **186**, respectively, during proximal retraction of catheter body **182** across the stenosis. Proximal retraction may be achieved manually or using a pullback system. Pullback systems are described, for example, in U.S. Pat. No. 6,290,675 to Vujanic et al., U.S. Pat. No. 6,275,724 to Dickinson et al., U.S. Pat. No. 6,193,736 to Webler et al., and PCT Publication WO 99/12474, all of which are incorporated herein by reference.

[0085] As will be apparent to those of skill in the art, catheter **182** alternatively may be advanced distally across vulnerable plaque P during data acquisition, or catheter **182** may be held stationary at a location of interest, for example, location x_1 in the middle of vulnerable plaque P. Additionally, when vulnerable plaque P has been identified, apparatus **180** optionally may be provided with stabilization elements capable of compressing, rupturing, sealing, scaffolding and/or otherwise treating the plaque in the controlled environment of a catheterization laboratory. Exemplary stabilization elements include balloon **204** of apparatus **200**, and therapeutic ultrasound transducer **214** of apparatus **210**. Additional stabilization elements will be apparent to those of skill in the art.

[0086] With reference now to **FIG. 11**, in conjunction with **FIG. 10**, graphical user interfaces for displaying and interpreting imaging and thermography data, collected, for example, using the methods of **FIG. 10**, are described. **FIG. 11A** provides cross-sectional IVUS image **250** formed from imaging data obtained at location x_1 within the patient's vessel V. Image **250** is eccentric and comprises echolucent zone E, which is indicative of a shallow lipid pool. Both the eccentricity and echogenicity of image **250** are indicative of vulnerable plaque P, with increased risk of rupture, at location x_1 within vessel V.

[0087] **FIG. 11B** displays temperature measurements T as a function of position x. Graphing temperature as a function of position requires that the position of the thermographer be recorded. Such position indication may be achieved, for example, using a pullback system, such as those described hereinabove.

[0088] In **FIG.** 11B, temperature measurements are obtained and graphed along point Y of section line A--A in **FIG. 11A** during proximal retraction of catheter **182** within vessel V from distal edge x_0 to location x_1 to proximal edge x_2 of vulnerable plaque P. The reference temperature within vessel V at locations proximal and distal of vulnerable plaque P is approximately T_0. All temperatures may be provided as a relative change in temperature with respect to reference temperature T_0, or temperatures may be provided on an absolute scale, as in **FIG. 11B**.

[0089] As seen in graph **252**, as catheter **182** is proximally retracted across vulnerable plaque P, the temperature at the interior wall of vessel V along point Y rises from reference temperature T_0 to local maximum temperature T_1. Temperature T_1 is obtained at location x_1 within vessel V. The temperature within the vessel recedes back to reference temperature T_0 while catheter body **182** is further retracted from location x_1 to proximal edge x_2 of vulnerable plaque P.

The increase in temperature from reference temperature T_0 to temperature T_1 in the region surrounding location x_1 within the vessel may be as much as 0.1-1.5° C. This range is provided only for the purpose of illustration and should in no way be construed as limiting.

[0090] The increase in temperature from T_0 to T_1 is indicative of vulnerable plaque susceptible to rupture. By comparing and correlating the thermographic data of graph **252** of **FIG. 11B** to IVUS image **250** of **FIG. 11**A, identification of vulnerable plaque P is corroborated and confirmed. Thus, providing both imaging and thermography simplifies vulnerable plaque identification while reducing a level of skill required on the part of a medical practitioner in order to properly diagnose such plaque.

[0091] In addition to graphing temperature measurements as a function of position, temperature measurements may alternatively be displayed as dynamic, individual measurements (not shown) obtained at the current position of the thermographer. As yet another alternative, temperature measurements may be displayed for an entire vessel cross-section (see **FIG. 12**), such as a cross-section of temperature measurements obtained at location x_1. Cross-sections of thermography and imaging data at a given position may be compared to provide rapid and proper identification of vulnerable plaque.

[0092] Referring now to **FIG. 12, a** graphical user interface for concurrently displaying both imaging and thermography data is described. In **FIG. 12**, imaging and thermography data are correlated and coupled prior to display, for example, using position indication techniques and/or a pullback system, such as an IVUS pullback system that is modified to simultaneously monitor the position of both the imaging element and the thermographer. Optional stablization elements may also be monitored via position indication techniques and/or a pullback system. IVUS pullback systems are described hereinabove.

[0093] In **FIG. 12**, imaging and thermography data, coupled using position indication techniques, are simultaneously displayed in a graphical, overlayed fashion, for example, on a standard computer monitor. Graphical user interface **260** comprises imaging cross-section **262** and thermography cross-section **264**. Both imaging cross-section **262** and thermography cross-section **264** were obtained at location x_1 within vessel V. Imaging cross-section **262** is eccentric and contains echolucent zone E, which is indicative of a shallow lipid pool.

[0094] Thermography cross-section **264** is displayed with reference to temperature intensity scale S that ranges between T_0 and T_1. Scale S may be provided as a color shift, an intensity shift, or a combination thereof. Furthermore the line width along thermography cross-section **264** may be altered to indicate changes in temperature. Additionally, the range of scale S may be extended beyond T_0 and T_1, or may be displayed as a change in temperature ΔT from a reference background temperature, such as T_0. Additional scales S will be apparent to those of skill in the art and are included in the present invention. As can be seen in **FIG. 12**, the intensity of thermography cross-section **264**, and thus the temperature within vessel V, increases along eccentric echolucent zone E of imaging cross-section **262**, which is indicative of vulnerable plaque.

[0095] Overlaying imaging and thermography data facilitates rapid correlation of the temperature at a given position within vessel V to the image obtained at that position. Rapid correlation is expected to simplify, expedite and increase the accuracy of vulnerable plaque identification. Additional data may also be obtained, coupled and provided in the graphical display, for example, palpography data (not shown). Palpographic techniques are described, for example, in U.S. Pat. No. 6,165,128 to Cespedes et al., which is incorporated herein by reference. Blood flow imaging may also be provided (not shown). Blood flow imaging is described, for example, in U.S. Pat. Nos. 5,453,575 and 5,921,931 to O'Donnell et al., both of which are incorporated herein by reference.

[0096] Referring now to **FIG. 13**, an alternative graphical user interface that simultaneously displays coupled imaging and thermography data is described. Graphical user interface **270** overlays imaging and thermography data in a manner similar to interface **260** of **FIG. 12**. However, interface **270** displays data obtained along side-sectional view line B--B of **FIG. 12** during retraction or advancement of apparatus of the present invention across vulnerable plaque P. Retraction or advancement across plaque P is preferably achieved using a modified IVUS pullback system, as described hereinabove.

[0097] Graphical user interface **270** comprises imaging side-section **272** and thermography side-section **274**. Imaging side-section **272** is eccentric and comprises echolucent zone E, which is most pronounced in the region around location x_1 within vessel V. Likewise, thermography side-section **274** is of greatest intensity in the region around echolucent zone E of imaging side-section **272**. Concurrent analysis of imaging side-section **272** and correlated thermography side-section **274** is expected to facilitate improved identification of vulnerable plaque. As with the cross-sectional view of graphical user interface **260** of **FIG. 12**, additional information, for example, palpography information or blood flow information, may be provided within the side-sectional view of graphical user interface **270**, in order to further facilitate plaque identification. The additional data, e.g. the palpography data or the blood flow data, is preferably obtained concurrently with imaging data, for example, via the imaging element.

[0098] While preferred illustrative embodiments of the present invention are described hereinabove, it will be apparent to those of skill in the art that various changes and modifications may be made therein without departing from the invention. For example, the specific structure of the imaging elements, thermographers, and stabilization elements of the embodiments of FIGS. **6-10**, are provided only for the sake of illustration. Contemplated imaging elements include, but are not limited to, ultrasound transducers, linear-array ultrasound transducers, phased-array ultrasound transducers, rotational ultrasound transducers, forward-looking ultrasound transducers, radially-looking ultrasound transducers, magnetic resonance imaging apparatus, angiography apparatus, optical coherence tomography apparatus, and combinations thereof. Contemplated thermographers include, but are not limited to, thermocouples, thermosensors, thermistors, thermometers, spectrography devices, infrared thermographers, fiber optic infrared thermographers, ultrasound-based thermographers, spectroscopy devices, near infrared spectroscopy devices, and combinations thereof.

[0099] Contemplated stabilization elements include, but are not limited to, balloons, stents, coated stents, covered stents, stent grafts, eluting stents, drug-eluting stents, magnetic resonance stents, anastamosis devices, ablation devices, photonic ablation devices, laser ablation devices, RF ablation devices, ultrasound ablation devices, therapeutic ultrasound transducers, sonotherapy elements, coronary bypass devices, myocardial regeneration devices, sonotherapy devices, drug delivery devices, gene therapy devices, atherectomy devices, heating devices, plaque rupture devices, secondary-substance modifiers, therapeutic agents, contrast agents, drug capsules, tissue-type tags, extreme lipid lowering agents, cholesterol acyltransferase inhibitors, matrix metalloproteinase inhibitors, anti-inflammatory agents, anti-oxidants, angiotensin-converting enzyme inhibitors, radiation elements, brachytherapy elements, local drug injection elements, gene therapy elements, photodynamic therapy elements, photoangioplasty elements, cryotherapy elements, and combinations thereof. Additional imaging elements, thermographers, and optional stabilization elements will be apparent to those of skill in the art. The appended claims are intended to cover all combinations of imaging elements, thermographers, and, optionally, stabilization elements that fall within the true spirit and scope of the present invention.

[0100] Furthermore, apparatus of the present invention may optionally be provided with a distal protection device (not shown), in order to capture emboli and/or other material released, for example, during stabilization of vulnerable plaque. Distal protection devices are provided, for example, in U.S. Pat. No. 6,348,062 to Hopkins et al., and U.S. Pat. No. 6,295,989 to Connors, III, both of which are incorporated herein by reference. Additional distal protection devices, per se known, will be apparent to those of skill in the art. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

What is claimed is:

1. Apparatus for identification of vulnerable plaque, the apparatus comprising:

a catheter having a distal region;

an imaging element disposed on the catheter in the distal region; and

a thermographer disposed on the catheter adjacent the imaging element.

2. The apparatus of claim 1, wherein the imaging element is chosen from the group consisting of ultrasound transducers, linear-array ultrasound transducers, phased-array ultrasound transducers, rotational ultrasound transducers, forward-looking ultrasound transducers, radially-looking ultrasound transducers, magnetic resonance imaging apparatus, angiography apparatus, optical coherence tomography apparatus, and combinations thereof.

3. The apparatus of claim 1, wherein the thermographer is chosen from the group consisting of thermocouples, thermosensors, thermistors, thermometers, spectrography devices, infrared thermographers, fiber optic infrared thermographers, ultrasound-based thermographers, spectroscopy devices, near infrared spectroscopy devices, and combinations thereof.

4. The apparatus of claim 1 further comprising a stabilization element.

5. The apparatus of claim 4, wherein the stabilization element is chosen from the group consisting of balloons, stents, coated stents, covered stents, stent grafts, eluting stents, drug-eluting stents, magnetic resonance stents, anastamosis devices, ablation devices, photonic ablation devices, laser ablation devices, RF ablation devices, ultrasound ablation devices, therapeutic ultrasound transducers, sonotheraphy elements, coronary bypass devices, myocardial regeneration devices, sonotherapy devices, drug delivery devices, gene therapy devices, atherectomy devices, heating devices, plaque rupture devices, secondary-substance modifiers, therapeutic agents, contrast agents, drug capsules, tissue-type tags, extreme lipid lowering agents, cholesterol acyltransferase inhibitors, matrix metalloproteinase inhibitors, anti-inflammatory agents, anti-oxidants, angiotensin-converting enzyme inhibitors, radiation elements, brachytherapy elements, local drug injection elements, gene therapy elements, photodynamic therapy elements, photoangioplasty elements, cryotherapy elements, and combinations thereof.

6. The apparatus of claim 4 further comprising a distal protection device.

7. The apparatus of claim 1, wherein the apparatus is adapted to perform a function chosen from the group consisting of elastography, palpography, and blood flow imaging.

8. The apparatus of claim 1 further comprising a graphical user interface for displaying imaging and thermography data obtained with the imaging element and thermographer, respectively.

9. The apparatus of claim 8, wherein the imaging and thermography data are coupled and displayed simultaneously.

10. The apparatus of claim 9, wherein the graphical user interface is adapted to display imaging and thermography data obtained along a cross-section of a patient's vessel.

11. The apparatus of claim 9, wherein the graphical user interface is adapted to display imaging and thermography data obtained along a side-section of a patient's vessel.

12. The apparatus of claim 1 further comprising position indication elements for determining the position of the imaging element and the thermographer.

13. The apparatus of claim 1 further comprising a pull-back system coupled to the catheter.

14. The apparatus of claim 8, wherein the graphical user interface is further adapted to display data chosen from the group consisting of palpography data and blood flow data.

15. A method for identifying vulnerable plaque within a body lumen of a patient, the method comprising:

providing apparatus comprising a catheter having both an imaging element and a thermographer;

percutaneously advancing the catheter to a target region within the patient's body lumen;

obtaining an image of the target region with the imaging element;

obtaining temperature data at the target region with the thermographer; and

comparing the image and the temperature data obtained at the target region to determine if vulnerable plaque is present at the target region

16. The method of claim 15, wherein an increase in temperature at the target region is indicative of vulnerable plaque.

17. The method of claim 15, wherein eccentric stenosis observed in the image is indicative of vulnerable plaque.

18. The method of claim 15, wherein echolucent zones observed in the image are indicative of vulnerable plaque.

19. The method of claim 15, wherein comparing the image and the temperature data further comprises coupling and simultaneously displaying the image and the temperature data.

20. The method of claim 15 further comprising obtaining additional data at the target region with the imaging element,

wherein comparing the image and the temperature data further comprises comparing the image, temperature and additional data obtained at the target region to determine if vulnerable plaque is present at the target region.

21. The method of claim 20, wherein obtaining additional data comprises obtaining additional data chosen from the group consisting of palpography data and blood flow data.

22. The method of claim 15 further comprising stabilizing the target region at locations where vulnerable plaque has been identified.

23. The method of claim 22 further comprising providing distal protection while stabilizing the target region at locations where vulnerable plaque has been identified.

24. Apparatus for identification of vulnerable plaque, the apparatus comprising:

a catheter having proximal and distal ends, and a bore extending from the proximal end towards the distal end;

a rotatable drive cable having a distal region; and

a side-viewing fiber optic coupled to the distal region of the drive cable,

wherein the rotatable drive cable is disposed within the bore, and

wherein the side-viewing fiber optic is proximally coupled to an infrared thermography system.

25. The apparatus of claim 23, wherein the rotatable drive cable is coupled to a driver adapted to rotate the drive cable and side-viewing fiber optic, thereby providing the side-viewing fiber optic with a 360° field of view.

26. The apparatus of claim 23 further comprising an imaging element.

27. The apparatus of claim 25, wherein the imaging element comprises an ultrasound imaging transducer coupled to the distal region rotatable drive cable.

28. The apparatus of claim 26, wherein the ultrasound imaging transducer is proximally coupled to an ultrasound imaging system.

29. The apparatus of claim 23 further comprising a stabilization element.

* * * * *

专利名称(译)	用于识别和稳定易损斑块的方法和设备		
公开(公告)号	US20030199747A1	公开(公告)日	2003-10-23
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[标]申请(专利权)人(译)	MICHLITSCH KENNETHĴ CESPEDES EDUARDO IGNACIO		
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IPC分类号	A61B1/24 A61B5/00 A61B8/06 A61B8/12 A61B6/00 A61B8/00		
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外部链接	Espacenet USPTO		

摘要(译)

本发明提供了用于通过具有热成像和成像能力的多功能导管识别和稳定易损斑块的方法和装置。预计关联成像和热成像数据将有助于改善易损斑块的识别。本发明的装置还可以设置有可选的稳定元件，用于稳定易损斑块。提供了使用本发明的装置的方法。