A guidance and viewing system (40, 49, 50) based on multiplexed optical coherence domain reflectometry is incorporated into a catheter, endoscope, or other medical device (110, 190) to measure the location, thickness, and structure of the arterial walls or other intra-cavity regions at discrete points on the medical device during minimally invasive medical procedures. The information will be used both to guide the device through the body and to evaluate the tissue through which the device is being passed. Multiple optical fibers (20, 82) are situated along the circumference of the device. Light from the distal end of each fiber is directed onto the interior cavity walls via small diameter optics. Both forward viewing and side viewing fibers can be included. The light reflected or scattered from the cavity walls is then collected by the fibers and multiplexed at the proximal end to the sample arm (42) of an optical low coherence reflectometer.
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CATHETER GUIDED BY OPTICAL COHERENCE DOMAIN REFLECTOMETRY

The United States Government has rights in this invention pursuant to Contract No. W-7405-ENG-48 between the United States Department of Energy and the University of California for the operation of Lawrence Livermore National Laboratory.

BACKGROUND OF THE INVENTION

The invention relates generally to catheters and endoscopes and other inspection instruments, and more particularly to guidance and viewing systems for catheters and endoscopes and other inspection instruments.

Optical coherence domain reflectometry (OCDR) is a technique developed by Youngquist et al. in 1987 (Youngquist, R. C. et al., "Optical Coherence-Domain Reflectometry: A New Optical Evaluation Technique," 1987, Optics Letters 12(3):158-160). Danielson et al. (Danielson, B. L. et al., "Guided-Wave Reflectometry with Micrometer Resolution," 1987, Applied Physics 26(14): 2836-2842) also describe an optical reflectometer which uses a scanning Michelson interferometer in conjunction with a broadband illuminating source and cross-correlation detection. OCDR was first applied to the diagnosis of biological tissue by Clivaz et al. in January 1992 (Clivaz, X. et al., "High-Resolution Reflectometry in Biological Tissues," 1992, Optics Letters 17(1):4-6). A similar technique, optical coherence tomography (OCT), has been developed and used for imaging with catheters by Swanson et al. in 1994 (Swanson, E. A. et al., U.S. Patents 5,321,501 and 5,459,570). Tearney et al. (Tearney, G. J. et al., "Scanning Single-Mode Fiber Optic Catheter-Endoscope for Optical Coherence Tomograph," 1996, Optics Letters 21(7):543-545) also describe an OCT system in which a beam is scanned in a circumferential pattern to produce an image of internal organs. U.S. Patent 5,570,182 to Nathel et al. describes method and apparatus for detection of dental caries and periodontal disease using OCT. However,
as OCT systems rely on mechanical scanning arms, miniaturizing them enough to leave room for other devices in the catheter is a serious problem.


In a prior art OCDR scanning system 10, shown in Figure 1, light from a low coherence source 12 is input into a 2x2 fiber optic coupler 14, where the light is split and directed into sample arm 16 and reference arm 18. An optical fiber 20 is connected to the sample arm 16 and extends into a device 22, which scans an object 24. Reference arm 18 provides a variable optical delay. Light input into reference arm 18 is reflected back by reference mirror 26. A piezoelectric modulator 28 may be included in reference arm 18 with a fixed mirror 26, or modulator 28 may be eliminated by scanning mirror 26 in the Z-direction. The reflected reference beam from reference arm 18 and a reflected sample beam from sample arm 16 pass back through coupler 14 to detector 30 (including processing electronics), which processes the signals by techniques that are well known in the art to produce a backscatter profile (or "image") on display 32.

**SUMMARY OF THE INVENTION**

This invention is a device which is incorporated into a catheter, endoscope, or other medical device to measure the location, thickness, and structure of the arterial walls or other intra-cavity regions at discrete points on the medical device during minimally invasive medical procedures. The information will be used both to guide the device through the body and to evaluate the tissue through which the device is being passed. Multiple optical fibers are situated along the circumference of the device. Light from the distal end of each fiber is directed onto the interior cavity walls via small diameter optics (such as gradient index lenses and mirrored corner cubes). The light reflected or
scattered from the cavity walls is then collected by the fibers which are multiplexed at the proximal end to the sample arm of an optical low coherence reflectometer. The resulting data, collected sequentially from the multiple fibers, can be used to locate small structural abnormalities in the arterial or cavity wall (such as aneurysms or arteriovenous malformations) that are currently not resolvable by existing techniques. It also provides information about branching of arteries necessary for guiding of the device through the arterial system. Since only the periphery of the catheter device is used for sensing, the central region maintains usefulness for other diagnostic or surgical instruments. This device can be incorporated into standard medical catheters, endoscopes, or other medical devices, such as surgical laser fibers, angioplasty balloons, intravascular ultra-sound probes, colonoscopes, and any other device which is traversing the body. Similarly, the invention may be implemented in non-medical inspection devices.

This invention is an optical guidance and sensing system for catheters, endoscopes and other devices based on a multiplexed optical coherence domain reflectometer (OCDR). By multiplexing between a number of sensor fibers with an optical switch, the OCDR system of the invention has multiple sequentially accessed sensor points consisting of the tip of each multiplexed fiber. These sensor points measure the scattering of light as a function of distance from the fiber tip, thus determining both the distance between the fiber tip and the nearest tissue and any structure in that tissue.

These fibers can be placed anywhere in the catheter with their tips ending at the locations where sensing is to occur. For guiding purposes, a number of fibers could be placed in a ring around the catheter wall (or embedded in it) with their tips at the distal end of the catheter. Miniature collimating and reflection optics can be used to deflect the light from the fiber tips toward the vascular walls, thus sensing any branching of the vasculature or abnormalities in the walls.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1 is a prior art OCDR scanning system.

Figure 2A is a schematic diagram of an OCDR system for catheter guidance and optical sensing with multiplexed sample arm.
Figure 2B is a schematic diagram of an OCDR system for catheter guidance and optical sensing with multiplexed sample arm and optical circulator.

Figure 2C is a schematic diagram of an OCDR system for catheter guidance and optical sensing with multiplexed sample arm using polarized light.

Figures 3A, B are side and top views of a rotating helix reference mirror.

Figures 4A, B are sectional and side views of an OCDR optical sensing catheter.

Figure 5 is a display generated by the catheter guidance and sensing system.

Figure 6 shows a balloon catheter with OCDR scanning fibers.

Figure 7 shows a catheter with OCDR scanning fibers at various positions along its length.

DETAILED DESCRIPTION OF THE INVENTION

The invention uses a multiplexed optical coherence domain reflectometer in a catheter or endoscope or other tubular inspection device for guidance and for optical sensing of in vivo cavity structures during minimally invasive medical procedures or for similar exploration of nonmedical systems.

The catheter/device guidance and optical sensing system 40 is illustrated in Figure 2A. The device is based on an optical coherence domain reflectometer (OCDR) which has been multiplexed. Except for the multiplexed feature, the system is similar to the prior art system 10 of Figure 1. Output from a low coherence light source 12 is split at the 2 x 2 fiber optic coupler 14 and directed through a multiplexed sample arm 42 toward the sample 24 and through a reference arm 18 to reference mirror 26. Reflections from the mirror 26 and backscattered light from the sample 24 are recombined at the coupler 14 and propagated to the detector 30 (and light source 12). Constructive interference creates a signal at the detector 30 when the sample and reference reflections have traveled approximately the same optical group delay. The shorter the coherence length of the source, the more closely the sample and reference arm group delays must be matched for constructive
interference to occur. By imposing a changing optical delay in the reference arm 18 with a known velocity, either by scanning mirror 26 in the Z-direction or with a piezomodulator 28 (with fixed mirror 26), the amplitudes and longitudinal positions of reflections from the sample 24 can be measured with high precision. The sample arm 42 contains a multiplexer 44 for switching between several (e.g., 8) optical fibers 20-1 ... 20-8, allowing sequential spatially distinct regions to be diagnosed consecutively using the same basic OCDR system. The fibers can be placed anywhere in the device 22.

An alternate embodiment, catheter optical sensing system 50, is shown in Figure 2B. Catheter sensing system 50 is similar to catheter sensing system 40 of Figure 2A, except that an optical circulator 52 is added to the system and detector 30 is replaced by balanced detector unit 54. Balanced detector unit 54 includes a pair of detectors 56, 58 with associated processing electronics and produces a backscatter profile on display 32.

OCDR/OCT systems are based on white light Michelson interferometers in which light from a source is split via a beamsplitter into two arms, a reference arm and a sample arm. Light is then reflected back to the beamsplitter in both arms. The light returning to the beamsplitter is then split, half returning to the source and the rest going to a detector. The light returning to the source is wasted and can cause the source to lase, reducing the bandwidth of the source.

The optical circulator 52 has three ports, as shown in Figure 2B. The first port is connected to the output of source 12 and the second port is connected to coupler 14. Thus light from source 12 passes through optical circulator 52 to coupler 14 and into reference arm 18 and multiplexed sample arm 42, as before. In system 40 of Figure 2A, the light returning to coupler 14 from reference and sample arms 18, 42 would be split, with some going to detector 30, where useful information is obtained, and some going back to source 12. In system 50 of Figure 2B, some of the light passing back through coupler 14 goes to detector unit 54 and some goes back to the second port of optical circulator 52. But light returning to the second port of optical circulator 52 cannot pass back through the first port to source 12. Instead, the light passes through the third port to detector unit 54.
Thus putting an optical circulator 52 in the source arm between source 12 and coupler 14 allows the light that would have returned to the source 12 to be sent to another detector. Detector unit 54 contains a pair of balanced detectors 56, 58. Detector 58 receives the light which passes directly from coupler 14 while detector 56 receives the light which passes back through optical circulator 52. Thus detector unit 54 can utilize all the reflected light. In the balanced detection scheme, the signal on the second detector is subtracted from the first. The signal caused by heterodyning between light in the reference and sample arms is 180 degrees out of phase on the two detectors.

The use of optical circulator 52 provides three benefits: (1) it protects source 12 from optical back reflections which can cause it to lase; (2) it allows detector unit 54 to collect twice as much light, enhancing system sensitivity; (3) balanced detection is achieved by subtracting the signal on one detector from the other which eliminates source or ring noise as fluctuations in source intensity appear equally on both detectors and thus cancel when the two signals are subtracted.

Another embodiment, catheter optical sensing system 49, is shown in Figure 2C. Catheter sensing system 49 is similar to catheter sensing system 40 of Figure 2A, except that the polarization of the light through the system is controlled by polarization maintaining (PM) fibers and optics. Mismatches between the polarization states of the light returning from the reference and sample arms 42, 18 in system 40 causes reduction in the coherent interference between light from the two arms and thus losses of signal. Control of the polarization state of the light in the system can both eliminate losses in signal due to depolarization of the light and provide the additional capability of measurement of the birefringence of the sample 24. In this embodiment, linearly polarized light is introduced into the system either through use of a linearly polarized broadband light source 12 or by placing linear polarizer 51 directly after an unpolarized source 12. The linear polarization of the light is then maintained through the use of PM fibers and a PM fiber optic coupler 14 where the linear polarization is one of the two modes of the PM fiber and PM coupler 14. The polarization state of the light returning from the reference arm 18 is modified by either a waveplate or faraday rotator 53 so as to be equally split between the two modes (orthogonal polarizations) of the PM fiber. A polarization beam splitter
55 in the detector arm splits the two polarizations and directs them to
two separate detectors 57, 59 of detector unit 54. In one embodiment, the
optical fibers 20-1 ... 20-8 in the sample arm 42 are not polarization
maintaining. In this case, the polarization beam splitter 55 ensures that
the polarization state of the light from the reference and sample arms 42,
18 is matched on each detector 57, 59, thus eliminating the losses due to
depolarization of the light. The light returning from the sample arm 42
is then measured by summing the signals from the two detectors 57, 59.
In another embodiment, the optical fibers 20-1 ... 20-8 in the sample arm
42 are polarization maintaining. The fibers 20-1 ... 20-8 can be oriented
such that the light leaving the fibers is linearly polarized at an angle
approximately 45° relative to the fast axis of birefringence of the sample
24. Alternatively a quarter waveplate 85 (shown in Fig. 4B) can be placed
at the distal end of each fiber 20-1 ... 20-8 to cause the light entering the
sample to be circularly polarized. In either case, the total light in all
polarization states returning from the sample 24 is once again
determined by summing the signal from the two detectors 57, 59. In
addition, detector unit 54 includes means for ratioing the output signals
from detectors 57, 59; the birefringence of the sample 24 is determined
based on the arc tangent of the ratio of the signals from the two detectors
57, 59.

As previously described, a variable optical delay can be
produced in reference arm 18 by scanning reference mirror 26 back and
forth in the Z-direction (see Figures 1, 2A-B). However, there are two
key issues in varying the axial length of the reference arm: linearity of
the axial scan and duty cycle.

A rotating helix reference mirror 60, shown in Figures 3A,
B, can be used to smoothly vary the path length in the reference arm of
the OPCR system. Mirror 60 is formed of a disk 62 with a radius R
which varies from R1 to R2 over its entire circumference. Lateral edge
surface 64 of disk 62 is a highly reflective mirror so that a collimated
light beam 66 incident thereon at normal incidence will be reflected back.
Collimated light beam 66 is formed by collimating the diverging light
from optical fiber 70, which forms the reference arm of the OPCR
system. Lens 68 is used to collimate the output of fiber 70. When the
beam is reflected back by surface 64, lens 68 focuses the light back into
fiber 70.
When mirror 60 is positioned so that beam 66 is incident on point 72, at which the radius R=R2, the longest radius, the path length ΔZ between lens 68 and surface 64 is the shortest. As mirror 60 is rotated about shaft 74, which fits into central opening 76 and is turned by motor 78, the path length ΔZ increases as R decreases. As mirror 60 completes an entire 360 degree revolution, R=R1, the shortest radius, is reached and ΔZ has increased by ΔR=R2-R1. Beam 66 then returns to point 72 and starts a new cycle. In each cycle, the path length ΔZ changes by ΔR, or the optical path length change in the reference arm ΔL changes by ΔZ=2ΔR=2(R2-R1). Disk 62 can typically be about 2 inches in diameter and 0.2 inches thick, with a ΔR of about 0.2 inches. Thus the optical path length will be varied by about half an inch on each cycle.

As shown in Figures 4A, B, the fibers 82 are embedded in plastic cover or catheter wall 84 around the circumference of the catheter or device 80 to maximize available space for other devices. The number of fibers 82 surrounding the core 86 is dependent on the limit of the device size, the fiber optic diameter, the desired speed of acquisition, and the necessary radial resolution. Either single or multiple mode optical fibers can be used. Single mode fibers are preferable for maximizing the longitudinal resolution. However, multimode fibers can be made smaller, thus maximizing radial resolution and catheter flexibility. Average sizes for single mode fibers are on the order of 100 μm diameter, while an average catheter is 1 to 3 mm in diameter. Thus, although eight fibers are shown in Figure 4A, a maximum of about 30 to 100 single mode fibers could be used. Miniature optics 88, e.g. GRIN lenses 90 and mirrored corner cubes 92, as shown at the top of Fig. 4B, can be used for collimating and directing the light emerging from the fiber tips onto the arterial or cavity wall. The optical elements 88 extend through cover 84, or cover 84 is optically transparent to allow light to be transmitted to and received from the surrounding area. Miniature optics 88 can be eliminated and just the bare fiber tip can be used, as shown at the bottom of Fig. 4B; also different combinations of optical elements, e.g. GRIN lens 90 without corner cube 92 or corner cube 92 without GRIN lens 90, can also be used. Thus with different optical arrangements, foreward and/or side viewing can be obtained.

The scan data can be displayed, as shown in Figure 5, as a radial pie slice 96 for each fiber containing either a single line of data, or
multiple adjoining lines portraying a history of the data collected by the fiber. Each segment 96 is the scan obtained by one of the side viewing fibers, which have been multiplexed to produce a 360 degree view. The boundaries 98 represent the artery walls. Since there are only a discrete number of fibers and sectors 96, there are some discontinuities in the boundaries 98. However, boundary 100 is clearly much farther away and represents a junction with a secondary artery.

An inflatable balloon catheter device 110 comprising a catheter tube 112 having an inflatable balloon 114 attached thereto is shown in Fig. 6. Optical fibers 116 are mounted on (as shown at top of Fig. 6) or embedded in (as shown at bottom of Fig. 6) the balloon 114. Additional fibers 118 may be mounted on (as shown at top of Fig. 6) or embedded in (as shown at bottom of Fig. 6) the catheter tube 112 inside balloon 114. By including miniature optics 120, e.g. GRIN lens 122 and corner cube 124, at the ends of fibers 116, 118, the fibers can be side viewing. Thus fibers 116 can be used to detect the arterial wall 126 while the internal fibers 118 can be used to detect the balloon 114.

A catheter device 130 as shown in Fig. 7 may have a plurality of fibers 132-1 ... 132-6 mounted on (or embedded in) catheter tube 134 with individual fibers extending to different lengths along the tube 134. Each fiber may terminate in optical elements 136, e.g. GRIN lens 138 and corner cube 140, for side viewing, or some of the fibers can be forward viewing. Thus features found a different locations along the length of the catheter can be viewed without moving the catheter.

Applications for the invention include any method or procedure where accurate catheter or device positioning is beneficial, including angioplasty, stroke treatment, aneurysm, arteriovenous malformations, ophthalmic surgery, laparoscopic surgery, arthroscopic surgery, treatment of colorectal disorders, sinus disorders, ear surgery, pneumothoracic surgery, spinal surgery, bladder surgery, esophageal surgery, uterine disorders, essentially any treatment that requires accurate information about tissue structures while using a catheter or other tool inside a body cavity. In addition to medical applications, the invention can be used for non-medical instruments which can be used to inspect and probe in situ locations.

Changes and modifications in the specifically described embodiments can be carried out without departing from the scope of the
invention, which is intended to be limited only by the scope of the appended claims.
CLAIMS

1. Apparatus comprising:
   an inspection device;
   a plurality of optical fibers arranged around the periphery of
   the inspection device, each fiber having a distal and proximal end, the
   fibers directing light transmitted through the fiber to a surrounding area
   and collecting light reflected back from the surrounding area;
   an optical coherence domain reflectometer (OCDR);
   a multiplexer connecting the OCDR to the proximal ends of
   the fibers to sequentially switch to each of the fibers.

2. The apparatus of Claim 1 wherein the inspection device
   is a tubular medical device.

3. The apparatus of Claim 2 wherein the tubular medical
   device is a catheter or endoscope.

4. The apparatus of Claim 1 wherein the fibers are
   embedded in or mounted on a surface of a wall of the inspection device.

5. The apparatus of Claim 1 wherein the inspection device
   is a balloon catheter comprising a catheter tube and an inflatable balloon
   mounted on the tube, and at least some of the fibers are mounted on the
   inflatable balloon.

6. The apparatus of Claim 1 further comprising optical
   elements connected to the distal ends of at least some of the fibers.

7. The apparatus of Claim 6 wherein the optical elements
   comprise a graded index lens and a corner cube at the distal ends of the
   fibers.

8. The apparatus of Claim 1 wherein some fibers are
   forward viewing and some fibers are side viewing.

9. The apparatus of Claim 1 wherein the distal ends of at
   least some of the fibers are positioned at different lengths along the
   inspection device.
10. The apparatus of Claim 1 wherein the OCDR comprises:
a 2 x 2 fiber optic coupler having first, second, third, and
fourth ports;
    a low coherence source connected to the first port;
    the multiplexer being connected to the second port;
    a reference arm connected to the third port;
    a detector unit connected to the fourth port.
11. The apparatus of Claim 10 further comprising a display
device connected to the detector unit.
12. The apparatus of Claim 10 further comprising an optical
circulator connected between the source and the first port of the coupler
and also connected to the detector unit.
13. The apparatus of Claim 12 wherein the detector unit
comprises a pair of balanced detectors, one detector being connected to
the optical circulator and the other detector being connected to the
fourth port of the coupler.
14. The apparatus of Claim 10 wherein the reference arm
comprises a scanning reference mirror.
15. The apparatus of Claim 14 wherein the scanning
reference mirror comprises a rotating helix reference mirror.
16. The apparatus of Claim 15 wherein the rotating helix
reference mirror comprises a disk with a radius which varies from a first
radius to a second radius over its entire circumference, and having a
mirror surface around its circumference.
17. The apparatus of Claim 10 wherein the reference arm
comprises a piezomodulator and a stationary reference mirror.
18. The apparatus of Claim 10 wherein the optical fibers are
polarization maintaining (PM) fibers and the coupler is a PM coupler.
19. The apparatus of Claim 18 wherein the source is a
linearly polarized light source or an unpolarized light source and a
linear polarizer following the source.
20. The apparatus of Claim 19 further comprising a
waveplate or Faraday rotator in the reference arm.
21. The apparatus of Claim 20 wherein the detector unit
comprises a pair of detectors, and further comprising a polarization
beamsplitter positioned before the detectors to split returning light into
two orthogonal polarizations, each polarization being input into a corresponding detector.

22. The apparatus of Claim 21 wherein the detector unit includes means for determining birefringence versus depth of a sample by ratioing output signals from the pair of detectors.

23. The apparatus of Claim 22 wherein linearly polarized light in the sample arm is directed into a birefringent sample with its axis of polarization at about 45° relative to the fast axis of the sample.

24. The apparatus of Claim 22 further comprising a quarter wave plate placed at the distal end of each of the fibers to cause light incident onto the sample to be circularly polarized.
FIG. 4A

FIG. 4B

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FIG. 5
FIG. 6

FIG. 7

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**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 6 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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**D. DOCUMENTS CONSIDERED TO BE RELEVANT**

15 July 1999

**Date of the actual completion of the international search**

27/07/1999

**Date of mailing of the international search report**

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