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Bergman et al.

(54) 3-D MAPPING FOR GUIDANCE OF DEVICE ADVANCEMENT OUT OF A GUIDE CATHETER

(71) Applicant: **Corindus, Inc.**, Waltham, MA (US)

(72) Inventors: **Per Bergman**, West Roxbury, MA (US); **Steven Blacker**, Framingham, MA (US); **Jerry Jennings**, Chelsea, MA (US); **Nicholas Kottenstette**, Worcester, MA (US); **Jean-Pierre Schott**, Weston, MA (US)

(73) Assignee: **CORINDUS, INC.**, Waltham, MA (US)

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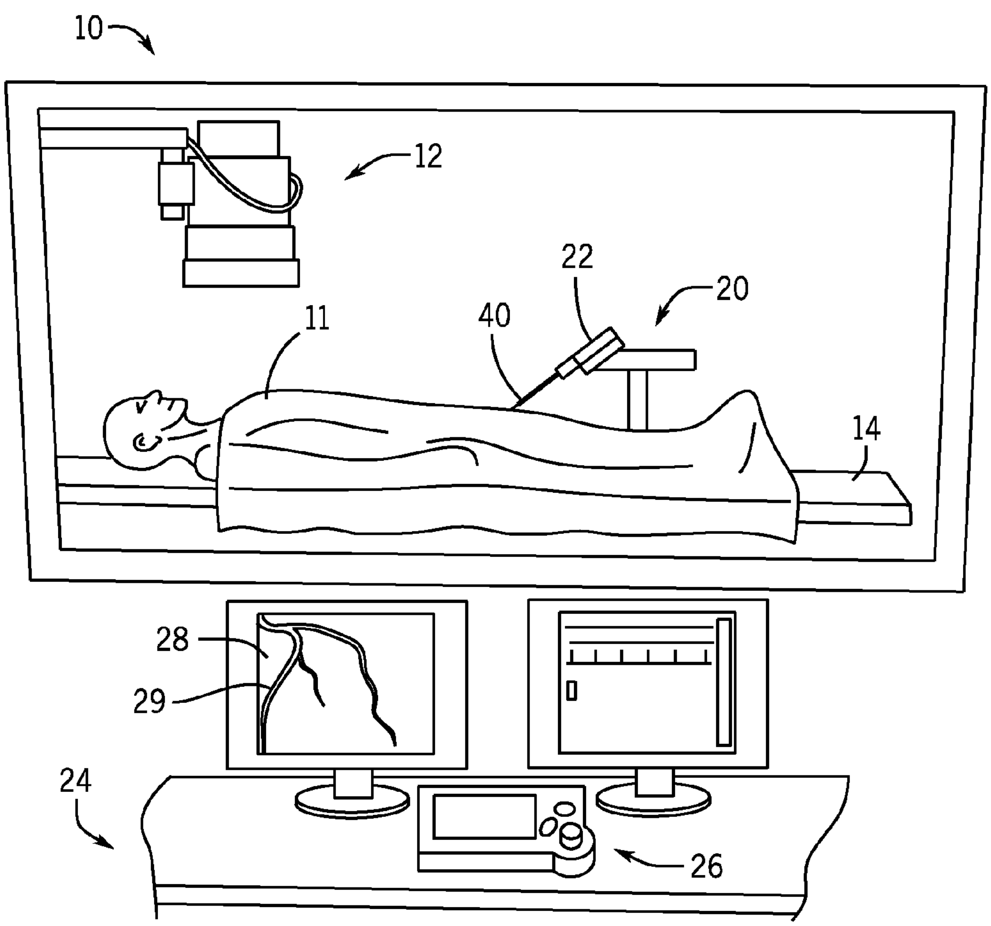
(57) **ABSTRACT**

The present disclosure involves a process for guiding the distal end of a guide wire or working catheter as it emerges from the distal end of a guide catheter into a blood vessel. The distal end of the guide wire or working catheter is provided with an X-ray marker, a determination is made that this distal end has emerged from the distal end of the guide catheter and a fluoroscopic image of the distal end of a guide wire or working catheter is taken. This image is correlated with the length of guide wire or working catheter inserted into the guide catheter. After further advancement of the guide wire or working catheter, another fluoroscopic image of the distal end of a guide wire or working catheter is taken and this image is correlated with the length of guide wire or working catheter which has been inserted into the guide catheter.



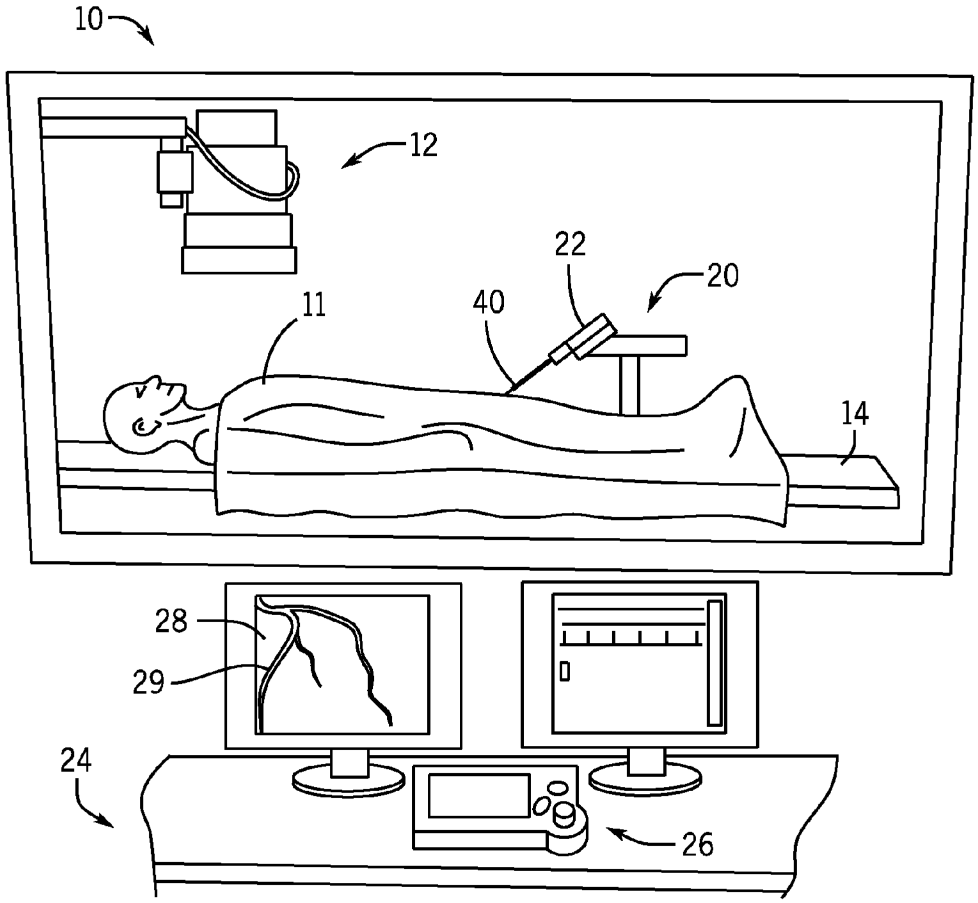


FIG. 1

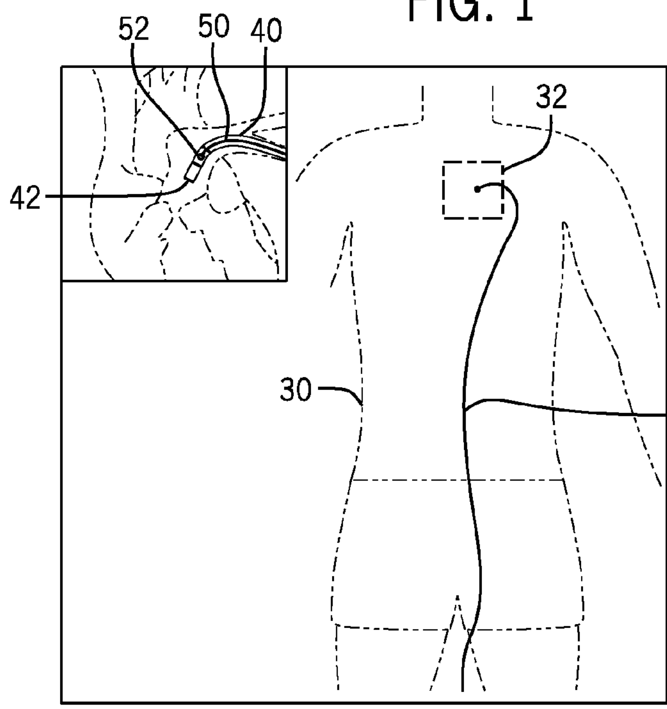


FIG. 2

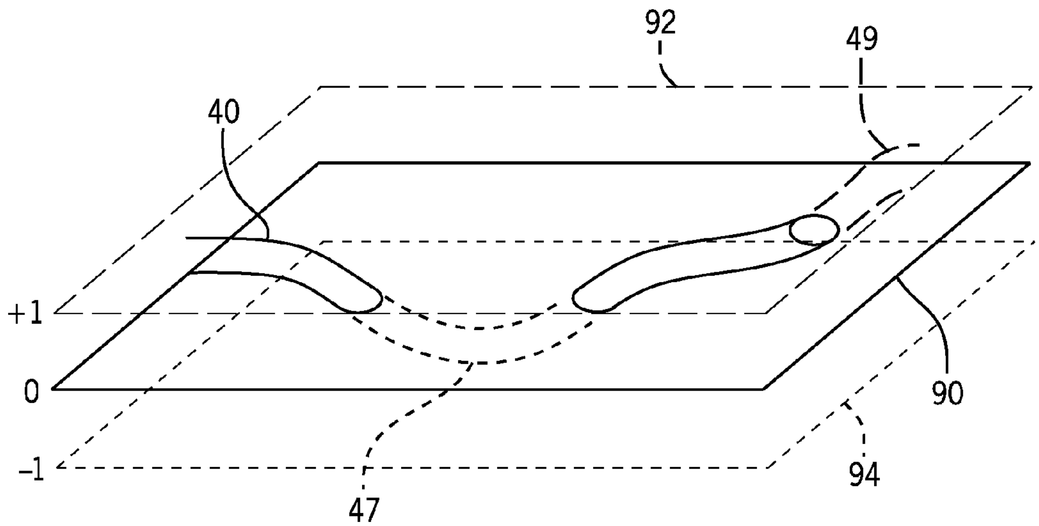

92
49
40
+1
0
–1
90
94
47

FIG. 3

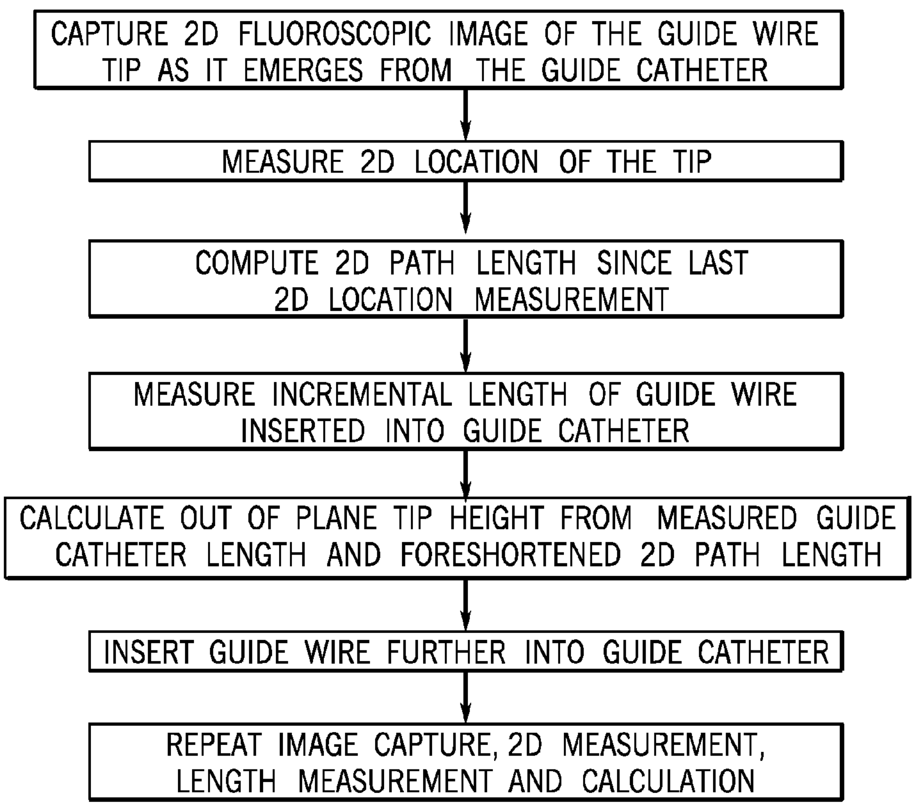

CAPTURE 2D FLUOROSCOPIC IMAGE OF THE GUIDE WIRE TIP AS IT EMERGES FROM THE GUIDE CATHETER
MEASURE 2D LOCATION OF THE TIP
COMPUTE 2D PATH LENGTH SINCE LAST 2D LOCATION MEASUREMENT
MEASURE INCREMENTAL LENGTH OF GUIDE WIRE INSERTED INTO GUIDE CATHETER
CALCULATE OUT OF PLANE TIP HEIGHT FROM MEASURED GUIDE CATHETER LENGTH AND FORESHORTENED 2D PATH LENGTH
INSERT GUIDE WIRE FURTHER INTO GUIDE CATHETER
REPEAT IMAGE CAPTURE, 2D MEASUREMENT, LENGTH MEASUREMENT AND CALCULATION

FIG. 4

3-D MAPPING FOR GUIDANCE OF DEVICE ADVANCEMENT OUT OF A GUIDE CATHETER

CROSS-REFERENCE TO RELATED PATENT APPLICATIONS

[0001] This application is a Non-Provisional of U.S. Provisional Application No. 61/839,459, filed Jun. 26, 2013, entitled "ROBOTIC IMAGE CONTROL SYSTEM", of which is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] Systems exist for the robotic feeding of percutaneous interventional devices such as guide wires and working catheters into guide catheters. The guide catheters are typically placed by manual manipulation of medical personnel such that their distal ends are adjacent to the site of action for the intervention, typically a valve or chamber of the heart or a lesion in a blood vessel such as an artery. In the case of coronary arteries the guide catheter may be placed adjacent to the entrance of the artery into the aorta. The interventional devices such as guide wires and working catheters may be fed by the operation of robotic controls by medical personnel such as shown in U.S. Pat. No. 7,887,549. The working catheters may be equipped with balloons, stents or stents enclosing balloons. The path of a guide wire or working catheter as it emerges from the distal end of a guide catheter should follow the lumen of the blood vessel into which it is being inserted and this path may not lie in a single 2-D plane. Guiding the advancement of such a device with a fluoroscopic image that typically lies in a plane thus presents some challenges.

SUMMARY OF THE INVENTION

[0003] The present invention involves a process for guiding the distal end of a guide wire or working catheter as it emerges from the distal end of a guide catheter into a blood vessel. The distal end of the guide wire or working catheter is provided with an X-ray marker, a determination is made that this distal end has emerged from the distal end of the guide catheter and a fluoroscopic image of the distal end of a guide wire or working catheter is taken. This image is then correlated with the length of guide wire or working catheter that has been inserted into the guide catheter. After further advancement of the guide wire or working catheter, another fluoroscopic image of the distal end of a guide wire or working catheter is taken and this image is correlated with the length of guide wire or working catheter which has been inserted into the guide catheter. This information is used to guide the further advancement of guide wire or working catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] This application will become more fully understood from the following detailed description, taken in conjunction with the accompanying figures, wherein like reference numerals refer to like elements in which:

[0005] FIG. **1** is a schematic of the environment in which percutaneous interventional procedures are robotically performed.

[0006] FIG. **2** is a schematic of the placement of a guide catheter and a guide wire in a human body.

[0007] FIG. **3** is a schematic of a guide catheter in relationship to the plane of a 2-D fluoroscopic image.

[0008] FIG. **4** is a flow diagram of creating a 3-D map of the path of a guide wire emerging from a guide catheter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0009] Referring to FIG. **1**, the environment in which the various embodiments of the present invention find particular utility involves a catheter laboratory **10** for robotically performing percutaneous interventional procedures. A patient **11** is supported on a table **14** and the procedure is observed with fluoroscopic X-ray equipment **12**. A cassette **22** supported by a robotic arm **20** which is used to automatically feed a guide wire **50** (shown in FIG. **2**) into a guide catheter **40** seated in an artery of the patient **11**. The cassette **22** is controlled from a remote station **24** in order to isolate the medical personnel conducting the procedure from exposure to the X-ray radiation used to monitor the procedure by use of fluoroscopic equipment. The station includes remote controls **26** for controlling the cassette **22** and a screen **28** with which to monitor the progress of the procedure. It displays the arterial system **29** being addressed by the procedure. U.S. Pat. No. 7,887,549, incorporated herein by reference, has a detailed disclosure of this environment.

[0010] Referring to FIG. **2**, a guide catheter **40** that has been fed into the torso **30** of a patient **11** to reach the cardiac region **32**. Within the guide catheter **40** is a guide wire **50** whose tip **52** has not yet passed out of the distal end **42** of the guide catheter **40**. The X-ray equipment which is used to monitor the progress of the guide wire **50** as it passes through the guide catheter **40** and approaches its distal terminus **42** may be controlled such that it images the entire path until the guide wire tip enters the cardiac region **32** and then just images the cardiac region **32**. It may also be controlled to take images at a more frequent rate once the tip **52** enters the region **32**.

[0011] Referring to FIG. **3**, a guide catheter **40** follows the path of an artery that is not illustrated. It has a portion **47** that has passed below the plane **90** of the fluoroscopic image into a lower plane **94** and it has a portion **49** that has passed above the plane **90** into a higher plane **92**. Iterative fluoroscopic images in plane **90** can be combined with measurements of the length of guide wire being fed into the guide catheter to yield an indication of the **3**-D path of the guide catheter and therefore the artery itself.

[0012] Referring to FIG. **4**, a step-by-step procedure may be followed to develop the indication of the 3-D path of a guide wire or working catheter as it emerges from the distal end of a guide catheter from iterative fluoroscopic images.

[0013] One embodiment involves using the Pythagorean Theorem to estimate the location of the tip of a guide wire in three dimensional space. The apparent length of the guide wire distal portion in a fluoroscopic image is taken as one leg, the length of guide wire involved in the image is taken as the hypotenuse and the height out of the plane is taken as the other leg of a right triangle. Basic trigonometry allows a calculation of the angle of the hypotenuse out of the plane of the image.

[0014] One embodiment involves taking fluoroscopic images repeatedly and performing correlations repeatedly during the further advancement of the guide wire or working catheter. Each correlation may be used to guide the advancement of the guide wire or working catheter from the point of that correlation.

[0015] One embodiment involves determining the emergence of the distal end of the guide wire or working catheter using an X-ray marker on the guide catheter and a fluoroscopic image that includes this marker and the distal end of the guide catheter. This X-ray marker may be located close enough to the distal end of the guide catheter that any movement of the guide wire or working catheter the out of plane of this fluoroscopic image can be ignored in making the determination without creating a significant error. One embodiment involves measuring the length of guide wire or working catheter fed to the guide catheter after the distal end of the guide wire or working catheter is detected at this X-ray marker and this measurement is used to determine the emergence.

[0016] One embodiment involves using the foreshortening in the fluoroscopic images to estimate the path of the blood vessel extending from the distal end of the guide catheter to the ultimate destination of the distal end of the guide wire or working catheter.

[0017] One embodiment involves using image-processing software to determine when the distal end of the guide wire or working catheter has emerged from the guide catheter. This software may also be involved in controlling the taking of fluoroscopic images and the correlations of these images with the length of guide wire or working catheter fed to the guide catheter.

[0018] One embodiment involves using the information obtained from determining the position in three dimensional space of the distal end of a guide wire or working catheter to align the plane of a 2-D fluoroscopic image approximately tangent to the path of its further advancement. Multiple 2-D fluoroscopic images may be used to determine a series of tangents to the blood vessel along the path of further advancement and the X-ray equipment is adjusted to provide a 2-D fluoroscopic image whose plane is approximately tangent to a portion of the path of further advancement yet to be traversed. One embodiment involves taking the 2-D fluoroscopic images with X-ray equipment mounted on a C-arm and rotating the C-arm is to align the plane.

[0019] One embodiment involves taking fluoroscopic images at frequent enough intervals after the distal end of a guide wire or working catheter has emerged from the distal end of the guide catheter that any change from moving away from to moving toward the plane of the 2-D fluoroscopic images may be readily detected.

[0020] One embodiment involves fitting the discrepancies between the actual length fed of a guide wire or working catheter and the apparent travel after emergence from the distal end of the guide catheter in the fluoroscopic images to an anatomical model. The precise three-dimensional path of any given blood vessel may be unique to that blood vessel and to the person in whom that blood vessel resides but blood vessels of a certain type generally follow a certain generalized path. For instance the right coronary artery (RCA) follows the same generalized path away from the ascending aorta despite differences from individual to individual.

[0021] One embodiment involves taking multiple fluoroscopic images at a given point in the progression of the guide wire or working catheter out of the distal end of the guide catheter. The images at a given point lie in different planes. This facilitates determining the position of the distal end of the guide wire or working catheter in three-dimensional space at that point in its progression.

[0022] One embodiment involves using standard comparison techniques on successive fluoroscopic images. Successive images may be aligned using a feature or "reference point" expected to be invariant between the images being compared. Alternatively a shift or a shift and rotation within the fluoroscopic plane may be calculated to cause the second image to correspond to the first with a high degree of correlation. One image may be selected as a reference or "gold standard" image and all other images compared to it or two successive images may just be compared to each other. If the two images as a whole cannot be matched with a high degree of correlation, the effective area of interest can be minimized to contain just the information needed to follow the distal end of the guide wire or working catheter. Successive images may be timed so that they both occur at the same point in the patient's cardiac or breathing cycle or both. The aim is to minimize any difference between the images that is not related to the progression or travel of the guide wire or working catheter.

[0023] While the foregoing written description of the invention enables one of ordinary skill to make and use what is considered presently to be the best mode thereof, those of ordinary skill will understand and appreciate the existence of variations, combinations, and equivalents of the specific embodiment, method, and examples herein. The invention should therefore not be limited by the above described embodiment, method, and examples, but by all embodiments and methods within the scope and spirit of the invention as claimed.

What is claimed is:

1. A process for guiding the distal end of a guide wire or working catheter as it emerges from the distal end of a guide catheter residing in a blood vessel comprising;

providing the distal end of the guide wire or working catheter with an X-ray marker;

determining that this distal end has emerged from the distal end of the guide catheter;

taking a fluoroscopic image of the distal end of a guide wire or working catheter;

correlating this image with the length of guide wire or working catheter which has been inserted into the guide catheter;

after further advancement of the guide wire or working catheter, taking another fluoroscopic image of the distal end of a guide wire or working catheter and correlating this image with the length of guide wire or working catheter which has been inserted into the guide catheter;

using this information to guide the further advancement of guide wire or working catheter.

2. The process of claim **1** wherein fluoroscopic images are taken repeatedly and correlations are performed repeatedly during the further advancement of the guide wire or working catheter.

3. The process of claim **2** wherein each correlation is used to guide the advancement of the guide wire or working catheter from the point of that correlation.

4. The process of claim **1** wherein the emergence of the distal end of the guide wire or working catheter is determined using an X-ray marker on the guide catheter and a fluoroscopic image that includes this marker and the distal end of the guide catheter.

5. The process of claim **4** wherein this X-ray marker is located close enough to the distal end of the guide catheter that any movement of the guide wire or working catheter the out of plane of this fluoroscopic image can be ignored in making the determination.

6. The process of claim **1** wherein the emergence of the distal end of the guide wire or working catheter is determined using an X-ray marker on the guide catheter.

7. The process of claim **6** wherein the length of guide wire or working catheter fed to the guide catheter after the distal end of the guide wire or working catheter is detected at this X-ray marker is measured and this measurement is used to determine the emergence.

8. The process of claim **1** wherein the foreshortening in the fluoroscopic images is used to estimate the path of the blood vessel extending from the distal end of the guide catheter to the ultimate destination of the distal end of the guide wire or working catheter.

9. The process of claim **1** wherein the ultimate destination is a valve or chamber of a human heart or a lesion in a human blood vessel.

10. The process of claim **1** wherein the emergence is determined with image processing software.

11. The process of claim **1** wherein the information is used to align the plane of a 2-D fluoroscopic image approximately tangent to the path of further advancement.

12. The process of claim **11** wherein multiple 2-D fluoroscopic images are used to determine a series of tangents to the blood vessel along the path of further advancement and the X-ray equipment is adjusted to provide a 2-D fluoroscopic image whose plane is approximately tangent to a portion of the path of further advancement yet to be traversed.

13. The process of claim **12** wherein the X-ray equipment generating the 2-D fluoroscopic images is mounted on a C-arm and the C-arm is rotated to align the plane.

14. The process of claim **11** wherein the images are taken as the guide wire or the working catheter is advanced and the time interval between successive images is short enough that any change from moving away from to moving toward the plane of the 2-D fluoroscopic images may be readily detected.

15. The process of claim **2** wherein the discrepancies between the actual length fed and the apparent travel in the fluoroscopic images are fitted to an anatomical model.

16. The process of claim **1** wherein fluoroscopic images in more than one plane are used.

17. The process of claim **1** wherein successive images are compared using a common reference point appearing in all the images.

18. The process of claim **1** wherein successive images are compared using a common subregion of the image appearing in all the images.

19. The process of claim **2** wherein the timing of the successive images is such that cardiac motion is normalized.

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