(54) Title: **A STEERABLE COLONOSCOPE PROBE WITH VARIABLE STIFFNESS**

(57) Abstract: An assembly for advancing a colonoscope through the colon comprises a colonoscope (2), a tube (4) and means for steering the tube (4). The steering means comprises a series of wires (20) extending along the tube (4) to the tube distal end (5) to which the wires (20) are attached. By pulling on one or more wires (20) from a proximal end of the tube (4), the tube distal end (4) may be steered by an operator as desired. The stiffness of the colonoscope (2) may be increased or decreased in use.
A STEerable COLONOSCOPE PRobe WITH VARIABLE STIFFNESS

Introduction

This invention relates to an assembly and a method for advancing a probe through a lumen. In particular it relates to an assembly and a method for advancing a colonoscope through a colon.

During conventional colonoscopy procedures a colonoscope is advanced through the tortuous sigmoid colon until the colonoscope reaches the descending colon. The colonoscope is then manipulated to reduce the redundancy in the sigmoid colon. When the sigmoid colon has been straightened, the colonoscope is typically further advanced through the colon.

However, this type of procedure is generally difficult to perform, and/or painful for the patient due to stretching of the colon which occurs upon impact between the colonoscope and the wall of the colon as the colonoscope is advanced, especially during advancement of the colonoscope around the bends of the tortuous sigmoid colon.

This invention is aimed at overcoming this problem.

Statements of Invention

According to the invention, there is provided a method of advancing a colonoscope through a colon, the method comprising the steps of:-

a) providing a colonoscope;

b) providing a tube;
c) inserting the colonoscope into a colon;

d) advancing the colonoscope until the colonoscope encounters a bend in the colon;

e) advancing the tube over the colonoscope;

f) steering the tube around the bend in the colon; and

g) advancing the colonoscope out of the tube beyond the bend.

Because the tube can be steered around a bend in a colon, the method and assembly of the invention enables a colonoscope to be advanced through a colon while minimising or avoiding contact between the colonoscope and the wall of the colon, even in the case of a tortuous colon.

In one embodiment of the invention the steps d) to g) are repeated at least once to advance the colonoscope through the colon in an incremental manner.

In another case the tube is advanced over the colonoscope until the tube distal end is substantially aligned with the colonoscope distal end.

The tube may be steered around the bend by manipulating the tube. Alternately the tube is steered around the bend by manipulating the colonoscope.

In a preferred embodiment of the invention the method comprises the step of altering in situ the stiffness of the colonoscope and/or the tube so that the colonoscope is stiff relative to the tube before advancing the tube over the colonoscope. By altering the stiffness in situ so that the colonoscope is stiff relative to the tube during
advancement of the tube over the colonoscope, the colonoscope acts as a stiff guide to guide advancement of the tube and minimise contact between the tube and the colon wall.

The method may comprise the step of altering in situ the stiffness of the colonoscope and/or the tube so that the colonoscope is flexible relative to the tube before advancing the colonoscope out of the tube. By altering the stiffness in situ so that the colonoscope is flexible relative to the tube during advancement of the colonoscope out of the tube, the tube acts as a stiff guide to guide advancement of the colonoscope and minimise contact between the colonoscope and the colon wall.

The tube may be steered around the bend after altering the stiffness so that the colonoscope is flexible relative to the tube.

The stiffness of the colonoscope may be altered. In another embodiment the stiffness of the tube is altered.

The invention minimises impact between the colonoscope and the colon wall, thus minimising stretching of the colon and the resultant discomfort or pain experienced by the patient during such a colonoscopy procedure, and also making the colonoscopy procedure easier to perform.

In one application, the invention enables a colonoscopist to advance a colonoscope through a sigmoid colon without stretching of the sigmoid colon being caused.

It will be appreciated that it is not essential that the steps of the method be performed in a certain order. For example, the tube may be steered around a bend in a colon before or after altering the stiffness so that the colonoscope is flexible relative to the tube.
In another aspect of the invention, there is provided an assembly for advancing a colonoscope through a lumen, the assembly comprising:

a colonoscope;

a tube having a colonoscope lumen extending therethrough for passing the tube over the colonoscope; and

means for steering the tube.

In one embodiment the tube comprises the means for steering.

In another embodiment the colonoscope comprises the means for steering, the colonoscope being engagable with the tube to steer the tube.

The assembly may comprise means for altering the stiffness of the colonoscope and/or the tube between a first mode in which the colonoscope is stiff relative to the tube, and a second mode in which the colonoscope is flexible relative to the tube.

The colonoscope may comprise the means for altering the stiffness of the colonoscope. Preferably the tube is of constant stiffness. The tube may be pliable.

In another case the tube may comprise the means for altering the stiffness of the tube.

In one embodiment the colonoscope comprises means to view a lumen distally of the colonoscope.

The viewing means further assist in avoiding contact between the assembly and a colon wall.
The invention also provides in another aspect a probe for advancing through a lumen, the probe comprising:-

5 means for steering the probe; and

means for altering the stiffness of the probe between a first mode in which the probe is relatively stiff, and a second mode in which the probe is relatively flexible.

10 According to a further aspect of the invention, there is provided a tube having a probe lumen extending therethrough for passing the tube over a probe, the tube comprising:-

15 means for steering the tube; and

means for altering the stiffness of the tube between a first mode in which the tube is relatively flexible, and a second mode in which the tube is relatively stiff.

20 In this specification the term bend will be understood to mean any geometrical configuration of the lumen, and/or any matter present in the lumen whether attached to the lumen wall or otherwise, which acts to hinder passage of the probe and/or the tube through the lumen.
Brief Description of the Drawings

The invention will be more clearly understood from the following description of an embodiment thereof, given by way of example only, with reference to the accompanying drawings in which:

Fig. 1 is a schematic view illustrating advancing a colonoscope through a colon;

Fig. 2 is a schematic view illustrating advancing a tube over the colonoscope;

Fig. 3 is a schematic view illustrating steering the tube around a bend in the lumen;

Fig. 4 is a schematic view illustrating advancing the colonoscope out of the tube;

Fig. 5 is a schematic view illustrating advancing the tube over the colonoscope;

Fig. 6 is a schematic view illustrating steering the tube around a bend in the colon;

Fig. 7 is a schematic view illustrating advancing the colonoscope out of the tube;
Figs. 8(a) to 8(e) are schematic views illustrating advancing a colonoscope through a colon;

Fig. 9 is perspective view of a steerable tube used in the invention, in one configuration of use; and

Fig. 10 is a perspective view of the tube of Fig. 9 in another configuration of use.

**Detailed Description**

Referring to the drawings, there is illustrated an assembly according to the invention for advancing a colonoscope probe through a colon.

The assembly comprises a colonoscope probe 2, having a distal end 3, a tube 4 having a distal end 5 and a proximal end 19, means for steering the tube 4, and means for altering the stiffness of the colonoscope 2 and/or the tube 4.

The tube 4 has a probe lumen 6 extending through the tube 4 to facilitate passing the tube 4 over the colonoscope 2.

In this case, the tube 4 comprises the means for steering the tube 4. As illustrated in Figs. 9 and 10 the steering means may be provided by one or more wires 20 extending along the tube 4 to the tube distal end 5 to which the wires 20 are attached. By pulling on a handle 21 on one or more wires 20 from a proximal end of the tube 4, the tube distal end 5 may be steered by an operator as desired. The wires 20 are shown exposed on the outside of the tube for illustrative purposes. They may be in a sheath and/or may be located in the wall of or on the inside or outside of the tube 4.
In the tube 4 of Figs. 9 and 10 a single wire 20 is provided extending through eyelets 22. This simple version facilitates steering in one direction which is the plane of the eyelets. Adding another linear series of eyelets and associated steering wire will allow further steering flexibility in another plane.

The colonoscope probe 2 may be of an energy actuated polymer material, such that upon application of energy, in this case a particular voltage difference across the colonoscope 2, the stiffness of at least portion of the colonoscope 2 may be increased or decreased. The stiffness of the tube 4, in this case, remains constant, the tube 4 being pliable.

In a first mode the colonoscope 2 is stiff relative to the tube 4 to facilitate advancement of the tube 4 over the colonoscope 2 (Fig. 2), and in a second mode the colonoscope 2 is flexible relative to the tube 4 to facilitate advancement of the colonoscope 2 out of the probe lumen 6 (Fig. 4).

The colonoscope 2 has means to view a lumen, such as a colon 7, distally of the colonoscope distal end 3. The viewing means is provided by a fibre optic cable extending through the colonoscope 2.

In use, the colonoscope 2 is inserted into the colon 7, and advanced through the colon 7 until the colonoscope distal end 3 encounters a bend 8 in the colon 7, (Fig. 1) or a large polyp on the colon wall, or some other obstruction to further advancement of the colonoscope 2.

The stiffness of the colonoscope 2 is then altered in situ by applying a voltage difference across the colonoscope 2 so that the assembly is in the first mode and the colonoscope 2 is stiff relative to the tube 4. The tube 4 is advanced over the stiff colonoscope 2 until the tube distal end 5 is substantially aligned with the
colonoscope distal end 3 (Fig. 2). Because the colonoscope 2 is stiff relative to the tube 4 during advancement of the tube 4 over the colonoscope 2, the colonoscope 2 acts as a stiff guide to guide advancement of the tube 4. In this way impact between the tube 4 and the colon 7 is minimised, and stretching of the bend 8 of the colon 7 into a loop is avoided.

By applying a voltage difference across the colonoscope 2, the stiffness of the colonoscope 2 is altered again in situ this time to the second mode so that the colonoscope 2 is flexible relative to the tube 4, and the tube 4 is manipulated to steer the tube distal end 5 around the bend 8 in the colon 7 (Fig. 3). By advancing the flexible colonoscope 2 out of the probe lumen 6, the colonoscope 2 passes around the bend 8 and further through the colon 7 (Fig. 4). Because the colonoscope 2 is flexible relative to the tube 4 during advancement of the colonoscope 2 out of the tube 4, the tube 4 acts as a stiff guide to guide advancement of the colonoscope 2. In this way impact between the colonoscope 2 and the colon 7 is minimised, and stretching of the bend 8 of the colon 7 into a loop is avoided.

The colonoscope 2 is advanced until the colonoscope distal end 3 encounters a second bend 9 in the colon 7. To pass the colonoscope 2 around the second bend 9, the procedure described previously with reference to Figs. 1 to 4 is repeated. In particular, the colonoscope 2 is stiffened, and the tube 4 is advanced over the stiff colonoscope 2 (Fig. 5). The colonoscope 2 is then made flexible, the tube distal end 5 is steered around the second bend 9 (Fig. 6), and the flexible colonoscope 2 is advanced out of the probe lumen 6 (Fig. 7).

Referring to Figs. 8(a) to 8(e) there is illustrated another assembly for advancing a colonoscope through a colon in which parts similar to those of Figs. 1 to 7 are assigned the same reference numerals. In this case a bending section 30 is configured to bend in one direction. Activating a steering mechanism will generally cause the overtube tip 30 to embed in the colon wall. The body of the overtube 31 is
then rotated until the bend is correctly aligned in the lumen of the colon. The probe may then be advanced and the method repeated at the next bend encountered.

It will be appreciated that this procedure for advancing a colonoscope beyond bends and/or other obstructions in a colon may be repeated as many times as necessary to advance the colonoscope through the colon in an incremental manner.

It will further be appreciated that the colonoscope probe may comprise means for steering in addition to or as an alternative to the steering means on the tube. In such a case, the probe may be manipulated to engage the probe distal end with the tube, and thereby steer the tube around a bend in a lumen, before altering the stiffness so that the probe is flexible relative to the tube.

The steering means may be provided in any suitable form. Energy actuated polymers could be used to steer the colonoscope and/or the tube.

The stiffness of the tube may be altered in situ in addition to or as an alternative to altering the stiffness of the colonoscope in situ, provided that in the first mode the colonoscope is stiff relative to the tube and in the second mode the colonoscope is flexible relative to the tube.

Any suitable means for altering the stiffness of the colonoscope probe and/or the tube may be employed. For example, a series of wires may be provided extending along the colonoscope to the distal end to which the wires are attached. By manipulation of one or more of the wires, the colonoscope probe stiffness may be altered. A similar arrangement could be used for altering the stiffness of the tube.

Although the assembly and method of use thereof have been described in detail in relation to advancement of a colonoscope through a colon, it will be appreciated that
the invention may be used for advancement of a probe through any lumen, such as a
vasculature, or a tortuous pipe network, or a small-scale cable duct.

The invention is not limited to the embodiments hereinbefore described, with
reference to the accompanying drawings, which may be varied in construction and
detail.
Claims

1. An assembly for advancing a colonoscope through a lumen, the assembly comprising:-

   a colonoscope;

   a tube having a colonoscope lumen extending therethrough for passing the tube over the colonoscope; and

   means for steering the tube.

2. An assembly as claimed in claim 1 wherein the tube comprises the means for steering.

3. An assembly as claimed in claim 1 or 2 wherein the probe comprises the means for steering, the probe being engagable with the tube to steer the tube.

4. An assembly as claimed in any of claims 1 to 3 wherein the assembly comprises means for altering the stiffness of the colonoscope and/or the tube between a first mode in which the colonoscope is stiff relative to the tube, and a second mode in which the colonoscope is flexible relative to the tube.

5. An assembly as claimed in claim 4 wherein the colonoscope comprises the means for altering the stiffness of the colonoscope.

6. An assembly as claimed in claim 5 wherein the tube is of constant stiffness.

7. An assembly as claimed in claim 6 wherein the tube is pliable.
8. An assembly as claimed in claim 4 wherein the tube comprises the means for altering the stiffness of the tube.

9. An assembly as claimed in any of claims 1 to 8 wherein the colonoscope comprises means to view a lumen distally of the colonoscope.

10. An assembly substantially as hereinbefore described with reference to the accompanying drawings.

11. A probe for advancing through a lumen, the probe comprising:-
    
    means for steering the probe; and
    
    means for altering the stiffness of the probe between a first mode in which the probe is relatively stiff, and a second mode in which the probe is relatively flexible.

12. A tube having a probe lumen extending therethrough for passing the tube over a probe, the tube comprising:-
    
    means for steering the tube; and
    
    means for altering the stiffness of the tube between a first mode in which the tube is relatively flexible, and a second mode in which the tube is relatively stiff.
13. A method of advancing a colonoscope through a colon, the method comprising the steps of:-

a) providing a colonoscope;

b) providing a tube;

c) inserting the colonoscope into a colon;

d) advancing the colonoscope until the colonoscope encounters a bend in the colon;

e) advancing the tube over the colonoscope;

f) steering the tube around the bend in the colon; and

g) advancing the colonoscope out of the tube beyond the bend.

14. A method as claimed in claim 13 wherein the steps d) to g) are repeated at least once to advance the colonoscope through the colon in an incremental manner.

15. A method as claimed in claim 13 or 14 wherein the tube is advanced over the colonoscope until the tube distal end is substantially aligned with the colonoscope distal end.

16. A method as claimed in any of claims 13 to 15 wherein the tube is steered around the bend by manipulating the tube.
17. A method as claimed in any of claims 13 to 15 wherein the tube is steered around the bend by manipulating the colonoscope.

18. A method as claimed in any of claims 13 to 17 wherein the method comprises the step of altering in situ the stiffness of the colonoscope and/or the tube so that the colonoscope is stiff relative to the tube before advancing the tube over the colonoscope.

19. A method as claimed in any of claims 13 to 18 wherein the method comprises the step of altering in situ the stiffness of the colonoscope and/or the tube so that the colonoscope is flexible relative to the tube before advancing the colonoscope out of the tube.

20. A method as claimed in claim 19 wherein the tube is steered around the bend after altering the stiffness so that the colonoscope is flexible relative to the tube.

21. A method as claimed in any of claims 18 to 20 wherein the stiffness of the colonoscope is altered.

22. A method as claimed in any of claims 18 to 20 wherein the stiffness of the tube is altered.

23. A method substantially as hereinbefore described with reference to the accompanying drawings.
INTRODUCTION SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61BI/005 A61B1/31 A61M25/01

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 7 A61B A61M

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)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Relevant to claim No.</th>
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<tr>
<td>X</td>
<td>US 5 337 733 A (BAUERFEIND HERBERT ET AL) 16 August 1994 (1994-08-16) column 5, line 5 - column 7, line 32; figures</td>
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<td>US 6 203 494 B1 (MORIYAMA HIROKI) 20 March 2001 (2001-03-20) column 8, line 36 - column 9, line 36; figures</td>
<td>1,2,4,8, 9</td>
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Further documents are listed in the continuation of box C.

* Special categories of cited documents:
*A* document defining the general state of the art which is not considered to be of particular relevance
*E* earlier document but published on or after the international filing date
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
*C* document referring to an oral disclosure, use, exhibition or other means
**P** document published prior to the international filing date but later than the priority date claimed

*"* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Date of the actual completion of the international search
24 June 2003

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 51 651 apo nl, Fax: (+31-70) 340-2016

Date of mailing of the international search report
04/07/2003

Authorized officer
Ruff, C

Form PCT/ISA/10 (second sheet) (July 1997)
<table>
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| X        | US 4 601 283 A (CHIKAMA TOSHIRO)  
22 July 1986 (1986-07-22)  
column 2, line 45 - column 5, line 36; figures | 1,3,4,12 |
| X        | US 4 543 090 A (MCCOY WILLIAM C)  
24 September 1985 (1985-09-24)  
column 2, line 27 - column 5, line 39; figures | 11 |
| A        |                                                                                  | 1,3-7               |
Continuation of Box I.2

Claims Nos.: 10,23

Claims 10 and 23 solely rely on references to the drawings (Rule 6.2(a) PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.
### Box I  Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **X** Claims Nos.: 13–23 because they relate to subject matter not required to be searched by this Authority, namely:

2. **X** Claims Nos.: 10,23 because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
   - see FURTHER INFORMATION sheet PCT/ISA/210

3. **☐** Claims Nos. because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II  Observations where unity of Invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. **☐** As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. **☐** As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. **☐** As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. **☐** No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- **☐** The additional search fees were accompanied by the applicant’s protest.
- **☐** No protest accompanied the payment of additional search fees.
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