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(54) Title: APPARATUS AND METHOD FOR ENDOSCOPIC COLECTOMY

(57) Abstract: Apparatus and methods for endoscopic colectomy are described herein. A colectomy device having a first and a second tissue approximation device is mounted on a colonoscope separated from one another. During deployment of the colectomy device, a diseased portion of the colon is positioned inbetween the tissue approximation devices. The tissue approximation devices are radially expanded such that they contact and grasp the colon wall at two sites adjacent to the diseased portion of the colon. The diseased portion is separated from the omentum and is transected using a laparoscope or is drawn into the colonoscope for later removal. The tissue approximation devices are then urged towards one another over the colonoscope to approximate the two free edges of the colon into contact together where they are fastened to one another using the tissue approximation device as a surgical stapler to create an end-to-end anastomosis.



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APPARATUS AND METHOD FOR ENDOSCOPIC COLECTOMY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefits of priority to U.S. Provisional Patent Application Serial No. 60/347,674 filed January 9, 2002, the entirety of which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to surgical methods and apparatus. More particularly, it relates to methods and apparatus for performing endoscopic colectomy.

BACKGROUND OF THE INVENTION

[0003] Endoscopy studies the intraluminal aspects of hollow organs of the upper and lower intestine including the esophagus, stomach and the colon through cannulation of the lumen via the mouth or anus. Endoscopic polypectomy is presently limited to a submucosal resection. The endoscopist is often unable to completely resect a sessile polyp or lesion and therefore the patient is subjected to subsequent definitive surgery, i.e. resection of the base of the tumor. Endoscopic polypectomy can be used to debulk sessile masses but it is unable to resect mural disease. Incomplete resection of a sessile polyp may destroy the biopsy specimen and alter the relationship of the gross specimen given to the pathologist thereby resulting in the pathologist possibly providing incorrect or incomplete study results. The endoscopist is also unable to correct uncommon, but life threatening, procedural complications such as perforations. Other cases where resection is required are invasive tumors, perforation from different causes, inflammatory bowel disease, diverticulosis and others.

[0004] Surgical approaches for resecting diseased tissue are largely practiced by making large laparotomy incisions or using minimally invasive techniques such as laparoscopic surgery in which tissues are resected and repaired through small incisions.

[0005] There are numerous surgical devices enabling surgeons to resect diseased tissue and subsequently anastomose remaining tissue either through a conventional incision

or using a laparoscope and making one or more relatively small incisions. Additionally, endoscopically assisted stapling devices are known which enable surgeons to remotely anastomose luminal structures such as the bowel. Endoscopically assisted bowel anastomosis nevertheless typically requires extraluminal assistance via a traditional laparotomy incision or use of a laparoscope.

[0006] Trends in surgery are towards minimally invasive procedures as evidenced by developments including laparoscopic cholecystectomy, laparoscopic appendectomy and laparoscopically assisted partial colectomies and hernia repairs. All of these minimally invasive procedures involve introducing a laparoscope through the abdominal wall and creating other associated openings to gain access to the peritoneal cavity in order to perform the necessary surgical procedure. Typically, general anesthesia is required. Endoscopically possible procedures include polypectomy, mucosectomy, and cauterization. During "laparoscopic colectomy" today the colon is separated from its omentum laparoscopically and then the colon is exteriorized out of the abdominal cavity, through a laparotomy incision where the resection and anastomosis are performed extracorporeally.

[0007] Disadvantages of the laparoscopic method include the need to traverse the abdominal wall, increased operating time secondary to the lack of exposure for the procedure and possibly the need to convert to an "open" laparotomy in the course of performing the procedure.

[0008] Present stapling techniques in surgery are for the most part functionally adequate but limited. Devices exist including the GIA and EEA staplers which can be used to transect tissue in a linear or circular fashion, respectively, with subsequent anastomosis with staples. The linear GIA is relatively versatile. The EEA is primarily suited for lower colonic circular anastomosis after a lesion has been surgically removed (via laparotomy or laparoscopically) or during a colostomy takedown procedure.

[0009] The rigid post of the EEA stapler severely limits its use, as well as requiring that an open procedure be utilized. The steerable endoscopic stapler is useful in allowing for more bowel accessibility; however, it remains dependent upon transabdominal surgical exposure prior to utilization. While laparoscopic surgical instruments have been used for bowel anastomosis, in such procedures the bowel is exteriorized through the laparoscopic incision and anastomosed extracorporeally or in an augmented stapled side-to-side fashion.

[0010] U.S. Patents 5,868,760 and 6,264,086 describe a method and apparatus for performing endolumenal resection of tissue, in particular for removal of diseased portions

of a patient's colon. This purely endolumenal approach to colostomy does not fully address the surgical anatomy of the colon. As is well known, the colon and other viscera are connected and supported within the abdomen by the omentum, a membranous extension of the peritoneum that carries the blood supply to the colon. Resection of more than a small portion of the colon requires mobilization of the colon from the omentum and ligation or cauterization of the blood vessels supplying that portion of the colon. This aspect is not addressed by the endolumenal approach described; therefore it would be suitable for resecting only small portions of the colon.

[0011] Commonly owned and copending U.S. Patent Application Serial Nos. 09/790,204 filed February 20, 2001 (now U.S. Patent No. 6,468,203); 09/969,927 filed October 2, 2001; and 10/229,577 filed August 27, 2002, describe steerable colonoscopes that uses serpentine motion to facilitate rapid and safe insertion of the colonoscope into a patient's colon. The technology described therein can also be used in conjunction with the methods and apparatus of the present invention to facilitate endoscopic colectomy or resection of any other part of the gastrointestinal system including, but not limited to, the esophagus, duodenum, jejunum and ileum or any other tubular organ like the bronchus. These patents and patent applications, and all other patents and patent applications referred to herein, are hereby incorporated by reference in their entirety.

SUMMARY OF THE INVENTION

[0012] In keeping with the foregoing discussion, the present invention takes the form of methods and apparatus for performing endoscopic colectomy that combine the advantages of the laparoscopic and endolumenal approaches. The diseased portion of the colon to be resected is identified using either laparoscopic and/or colonoscopic techniques or using another imaging modality. A colectomy device mounted on a colonoscope grasps the colon wall at two sites adjacent to a diseased portion of the colon. Using laparoscopic techniques, the diseased portion of the colon is separated from the omentum and the blood vessels supplying it are ligated or cauterized. The colon wall is transected to remove the diseased portion and the excised tissue is removed using the laparoscope or drawn into the colectomy device for later removal upon withdrawal of the colonoscope. The colectomy device approximates the two ends of the colon and performs an end-to-end anastomosis. If the part to be resected is a tumor, prior to the resection, the edges of the segment to be

resected will be stapled to seal it and prevent spillage of malignant cells to the healthy tissue.

[0013] The methods and apparatus of the present invention provide a number of benefits not realized by the prior art approaches to colectomy. As stated above, the purely endolumenal approach does not provide for separation of the colon from the omentum, which is necessary when resecting more than just a small portion of the colon wall. By combining laparoscopic techniques with a colonoscope-mounted colectomy device, the present invention overcomes this deficiency in the prior art allowing a more comprehensive approach to colectomy. Unlike prior art laparoscopic techniques, however, the colon does not need to be exteriorized for excision of the diseased portion or anastomosis of the remaining colon. The colonoscope-mounted colectomy device approximates the ends of the colon and performs an anastomosis from the interior of the lumen of the colon. The excised tissue can be drawn into the colectomy device for removal through the lumen of the colon along with the colonoscope or can be taken out by the laparoscope, which can be done through a very small incision in the patient's skin. The prior art approach also does not protect from leaking of malignant cells to the periphery. This idea will enable sealing of the tissue with staples at its ends to prevent such leakage. Optionally, it will be done with the help of a laparoscopic device that will serve as an anvil. Unlike the prior art procedure, the present invention will optionally use a balloon inflated in the lumen of the colon or any other resected organ before stapling, and by this assure the anastomosis will be ideal with the best possible approximation of the edges.

[0014] The use of colonoscopic techniques in the present invention provides another benefit not realized by a purely laparoscopic approach. Since colonoscopic examination is at present the most definitive diagnostic method for identifying diseases of the colon, locating the lesions through the exterior of the colon by laparoscopy or even by direct visualization can be somewhat problematic. Using the colonoscope to identify and isolate the diseased portion of the colon from within the lumen helps assure that the correct portions of the colon wall are excised and makes clean surgical margins without residual disease more assured as well.

[0015] In a preferred embodiment, the present invention utilizes a steerable colonoscope as described in U.S. Patent Application Serial Nos. 09/790,204 (now U.S. Patent No. 6,468,203); 09/969,927; and 10/229,577, which have been incorporated by reference. The steerable colonoscope described therein provides a number of additional

benefits for performing endoscopic colectomy according to the present invention. The steerable colonoscope uses serpentine motion to facilitate rapid and safe insertion of the colonoscope into the patient's colon, which allows the endoscopic colectomy method to be performed more quickly and more safely. Beyond this however, the steerable colonoscope has the capability to create a three-dimensional mathematical model or map of the patient's colon and the location of any lesions identified during the initial examination. Lesions found during a previous examination by CT, MRI or any other imaging technology can also be mapped onto the three-dimensional mathematical model of the colon. By generating a three-dimensional map of the colon, the system knows where each part of the endoscope is in the colon and will be able to localize the two parts of the dissecting and stapling system exactly in the desired location. During surgery, this information can be used to quickly and accurately return the colonoscope to the location of the identified lesions where the colonoscope-mounted colectomy device will be used to complete the endoscopic colectomy procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG 1 is a phantom drawing illustrating a diseased portion of the colon being separated from the omentum using laparoscopic techniques through a small incision in a patient's abdomen.

[0017] FIG 2 is a cutaway drawing illustrating a steerable colonoscope with a colectomy device mounted thereon being inserted through the lumen of a patient's colon.

[0018] FIG 3 is a cutaway drawing showing the gripping mechanism of the colonoscope-mounted colectomy device expanded within the lumen of the colon.

[0019] FIG 4 illustrates the colon after the diseased portion has been excised and removed with the colonoscope-mounted colectomy device in position to approximate the transected ends of the colon.

[0020] FIG 5 illustrates the colonoscope-mounted colectomy device performing an end-to-end anastomosis to complete the endoscopic colectomy procedure.

DETAILED DESCRIPTION OF THE INVENTION

[0021] FIG 2 is a cutaway drawing illustrating a steerable colonoscope **100** with a colectomy device **102** mounted thereon being inserted through the lumen of a patient's colon. As mentioned before, the same technique may apply for every other tubular shaped organ. Preferably, the steerable colonoscope **100** is constructed as described in U.S. Patent Application Serial Nos. 09/790,204 (now U.S. Patent No. 6,468,203); 09/969,927; and 10/229,577, with multiple articulating segments that are controlled to move with a serpentine motion that facilitates insertion and withdrawal of the colonoscope with a minimum of contact and stress applied to the colon walls. In addition, the control system of the steerable colonoscope **100** has the capability to construct a three-dimensional mathematical model or map of the colon as it advances through lumen under control of the operator. The three-dimensional mathematical model of the colon and the location and nature of any lesions identified in the course of an initial colonoscopic examination can be stored and used in performance of the endoscopic colectomy procedure. In alternate embodiments, the colectomy device **102** of the present invention may be mounted on a colonoscope of a different design and construction.

[0022] The colectomy device **102** can be permanently or removably mounted on the steerable colonoscope **100**. The colectomy device **102** has a distal component **104** and a proximal component **106**. The distal component **104** and the proximal component **106** each have an expandable member **108** and a gripping mechanism **110** for gripping the wall of the colon. The expandable member **108** may be an inflatable balloon or a mechanically expandable mechanism. The gripping mechanism **110** may comprise a plurality of circumferentially located ports within which attachment points **112**, e.g., needles, hooks, barbs, etc., may be retractably positioned about an exterior surface of the expandable member **108**. Alternatively, the gripping mechanism **110** may utilize a vacuum gripper through a plurality of circumferentially located ports around the distal component **104** and/or the proximal component **106** or other known gripping mechanisms. In the case of the vacuum gripper, gripping mechanism **110** is in fluid communication through the ports and through the colonoscope **100** to the proximal end of the colonoscope **100** to a vacuum pump (not shown). At least one, and optionally both, of the distal component **104** and the proximal component **106** are movable longitudinally with respect to the body of the steerable colonoscope **100**. Rails, grooves or the like **114** may be provided on the body of

the steerable colonoscope **100** for guiding the longitudinal movement of the distal component **104** and the proximal component **106**.

[0023] In addition, the colectomy device **102** includes a surgical stapler **116** or other anastomosis mechanism. The surgical stapler **116** is carried on either the distal component **104** or the proximal component **106** and a stapler anvil **118** is carried on the other of these components. The surgical stapler **116** may be configured similarly to any number of conventional stapling devices which are adapted to actuate staples into tissue. Another option is that there is a stapler and an anvil on both components for stapling and sealing the edges. Optionally, the colectomy device **102** may include a cutting device and/or electrocautery and/or a laser device for transecting the colon wall. Optionally, the colectomy device **102** may also include a vacuum mechanism or the like for drawing the excised tissue into the colectomy device **102** for later removal along with the steerable colonoscope **100**.

[0024] FIG 2 shows the steerable colonoscope **100** with the expandable members **108** of the distal component **104** and the proximal component **106** in a contracted or deflated condition for easy passage through the lumen of the patient's colon. The control system of the steerable colonoscope **100** monitors the position of each segment of the colonoscope **100** as it is advanced within the colon and can signal to the operator when the segments carrying the distal component **104** and the proximal component **106** of the colectomy device **102** are correctly positioned with respect to a previously detected lesion in the colon. Alternatively, the control system of the steerable colonoscope **100** can be programmed to advance the colonoscope **100** automatically through the lumen of the colon and to stop it when the distal component **104** and the proximal component **106** of the colectomy device **102** are correctly positioned with respect to the lesion in the colon. Alternatively, the control system will be able to automatically guide and deliver the two components to the desired location after the colonoscope has been inserted to the colon.

[0025] FIG 3 is a cutaway drawing showing the expandable members **108** of the distal component **104** and the proximal component **106** of the colonoscope-mounted colectomy device **102** expanded within the lumen of the colon so that the gripping mechanism **110** grips the wall of the colon. The distal component **104** and the proximal component **106** may be expanded through any number of expansion devices. For instance, they may be radially expanded upon spoke-like support structures or they may be configured to radially expand in a rotational motion until the desired expansion diameter is

attained. At this point, with the diseased portion of the colon identified and isolated by the colonoscope-mounted colectomy device **102**, the diseased portion is separated from the omentum and the blood vessels supplying it are ligated and/or cauterized using laparoscopic techniques. FIG 1 is a phantom drawing illustrating a diseased portion of the colon being separated from the omentum using laparoscopic techniques through a small incision in a patient's abdomen.

[0026] Next, the diseased portion of the colon is excised by transecting the colon at the proximal and distal end of the diseased portion. The colon may be transected using laparoscopic techniques or using a cutting mechanism and/or electrocautery device mounted on the colectomy device **102**. The excised tissue is removed using the laparoscope or drawn into the colectomy device **102** for later removal upon withdrawal of the steerable colonoscope **100**. FIG 4 illustrates the colon after the diseased portion has been excised and removed with the colonoscope-mounted colectomy device **102** in position to approximate the transected ends of the colon.

[0027] The remaining ends of the colon are approximated one to the other by moving the distal component **104** and/or the proximal component **106** longitudinally with respect to the body of the steerable colonoscope **100**, as shown by the arrows. Optionally, the proximal component **106** may be longitudinally translated towards the distal component **104** or both components **104**, **106** may be approximated simultaneously towards one another. The ends of the colon are stapled to one another to create an end-to-end anastomosis **120** using the surgical stapler **116** and stapler anvil **118** on the colectomy device **102**. Once the ends of the tissue have been approximated, staples or other fastening devices, e.g., clips, screws, adhesives, sutures, and combinations thereof, etc., may be actuated through the surgical stapler **116** such that they pierce both ends of the tissue against the stapler anvil **118**. FIG 5 illustrates the colonoscope-mounted colectomy device performing an end-to-end anastomosis **120** to complete the endoscopic colectomy procedure. Once the anastomosis **120** is complete, the expandable members **108** of the distal component **104** and the proximal component **106** are deflated or contracted and the steerable colonoscope **100** and the colectomy device **102** are withdrawn from the patient's body. The expanded members will assure a very accurate end-to-end anastomosis and prevent stenosis that can happen as a result of inaccurate approximation of the two ends.

[0028] In an alternative method using the colonoscope-mounted colectomy device **102**, the diseased portion of the colon may be excised using a cutting device within the

colectomy device **102** after the ends of the diseased portion have been approximated and anastomosed. The excised tissue is drawn into the colectomy device **102** and removed when the steerable colonoscope **100** is withdrawn from the patient.

[0029] In another alternative method, the colectomy procedure may be performed entirely from the endolumenal approach using the colonoscope-mounted colectomy device **102** without laparoscopic assistance. This method would be particularly advantageous for resection of small portions of the colon where it may not be necessary to mobilize an extended portion of the colon from the omentum to achieve successful approximation and anastomosis. The three-dimensional mapping capability of the steerable colonoscope **102** would be used to locate previously identified lesions without laparoscopic assistance.

[0030] While the present invention has been described herein with respect to the exemplary embodiments and the best mode for practicing the invention, it will be apparent to one of ordinary skill in the art that many modifications, improvements and subcombinations of the various embodiments, adaptations and variations can be made to the invention without departing from the spirit and scope thereof.

CLAIMS

I claim:

1. An endoscopic device for approximating tissue within a hollow body organ, comprising:

an elongated body having a plurality of articulatable segments and a steerable distal portion, wherein each of the segments are configurable to assume a selected shape along an arbitrary path when the elongated body is advanced distally or proximally;

a first tissue approximation component positioned about the elongated body, wherein the first component is adapted to radially expand and adhere a first region of tissue to a plurality of tissue gripping regions circumferentially located about the first component; and

a second tissue approximation component positioned about the elongated body proximally of the first component, wherein the second component is adapted to radially expand and adhere a second region of tissue to a plurality of tissue gripping regions circumferentially located about the second component,

wherein the first component and the second component are adapted to approximate and securely fasten the first region to the second region of tissue.

2. The endoscopic device of claim 1 wherein the first and the second tissue approximation components each comprise a radially expandable ring.

3. The endoscopic device of claim 1 wherein the first and the second tissue approximation components each comprise a radially expandable balloon.

4. The endoscopic device of claim 1 wherein the plurality of tissue gripping regions on each of the first and the second tissue approximation components comprise vacuum ports.

5. The endoscopic device of claim 1 wherein the plurality of tissue gripping regions on each of the first and the second tissue approximation components comprise retractable fasteners.

6. The endoscopic device of claim 5 wherein the retractable fasteners are selected from the group consisting of needles, hooks, and barbs.

7. The endoscopic device of claim 1 wherein the first tissue approximation component is adapted to slide longitudinally towards the second tissue approximation component along at least a portion of the elongated body within rails or grooves defined along the elongated body such that the first region is adjacent to the second region of tissue.

8. The endoscopic device of claim 1 wherein the second tissue approximation component is adapted to slide longitudinally towards the first tissue approximation component along at least a portion of the elongated body within rails or grooves defined along the elongated body such that the first region is adjacent to the second region of tissue.

9. The endoscopic device of claim 1 wherein the first and the second tissue approximation components are each adapted to slide longitudinally towards one another along at least a portion of the elongated body within rails or grooves defined along the elongated body such that the first region is adjacent to the second region of tissue.

10. The endoscopic device of claim 1 wherein the first or the second tissue approximation component contains a plurality of fasteners adapted to fasten the first region to the second region of tissue.

11. The endoscopic device of claim 10 wherein the fasteners are selected from the group consisting of staples, clips, screws, adhesives, sutures, and combinations thereof.

12. A method of endoscopically approximating tissue within a hollow body organ, comprising:

positioning an elongated body adjacent to a portion of tissue to be excised from the hollow body organ;

releasably fastening a first region of tissue circumferentially about a first tissue approximation component and a second region of tissue circumferentially about a second tissue approximation component such that the tissue to be excised is positioned between the first and the second tissue approximation components;

removing the tissue to be excised from between the first and the second tissue approximation components;

approximating the first and the second tissue approximation components such that the first and the second regions of tissue are adjacent to one another; and

fastening the first region of tissue to the second region of tissue.

13. The method of claim 12 wherein the first and the second regions of tissue are releasably fastened to the first and the second tissue approximation components, respectively, via a vacuum force.

14. The method of claim 12 wherein the first and the second regions of tissue are releasably fastened to the first and the second tissue approximation components, respectively, via a plurality of fasteners.

15. The method of claim 14 wherein the fasteners are retractable.

16. The method of claim 12 wherein releasably fastening comprises radially expanding the first and the second tissue approximation components into contact with the first and the second regions of tissue, respectively.

17. The method of claim 12 wherein removing the tissue to be excised comprises laparoscopically excising the tissue from between the first and the second tissue approximation components.

18. The method of claim 12 wherein approximating the first and the second tissue approximation components comprises longitudinally translating the first and the second tissue approximation components towards one another along the elongated body.

19. The method of claim 12 wherein fastening the first region of tissue to the second region of tissue comprises stapling or suturing the first region to the second region via the first or the second tissue approximation component.

20. The method of claim 12 further comprising radially reducing a diameter of the first and the second tissue approximation components.

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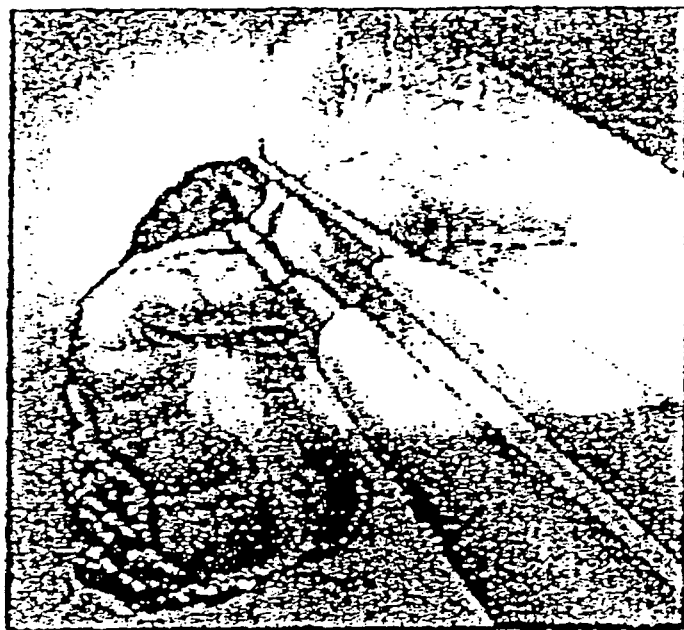


FIG 1

2/3

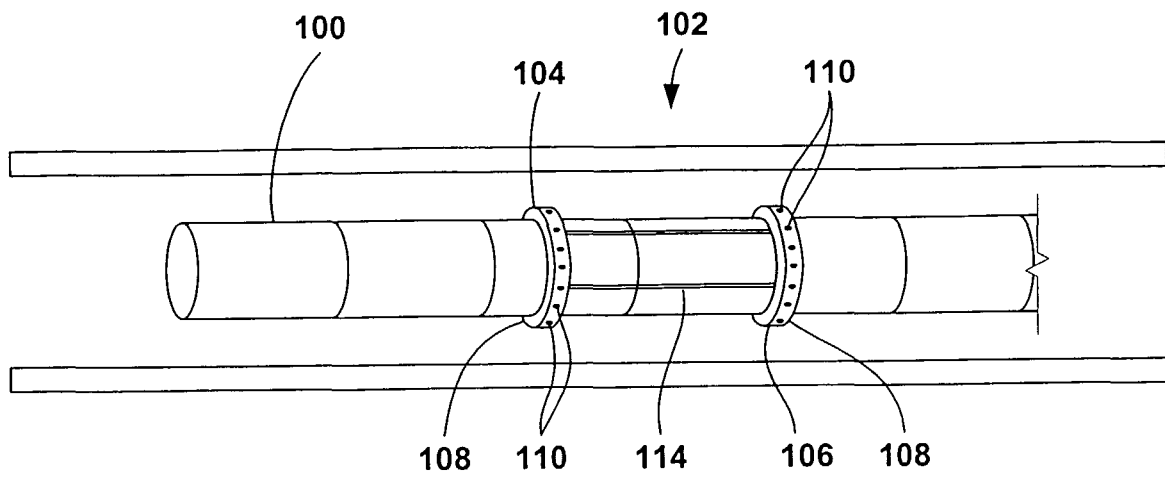


FIG 2

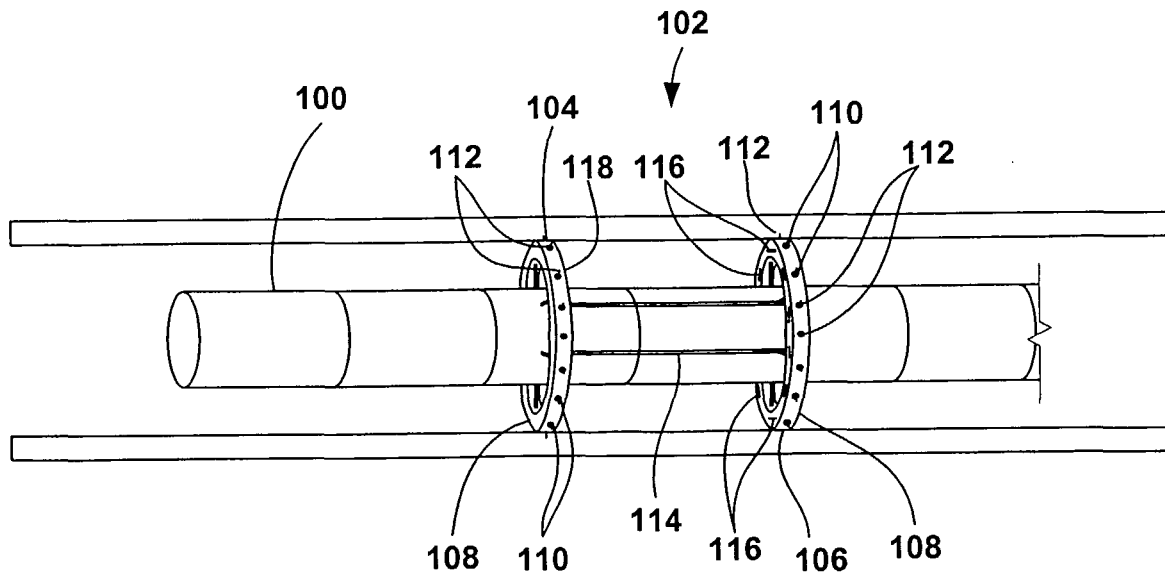


FIG 3

3/3

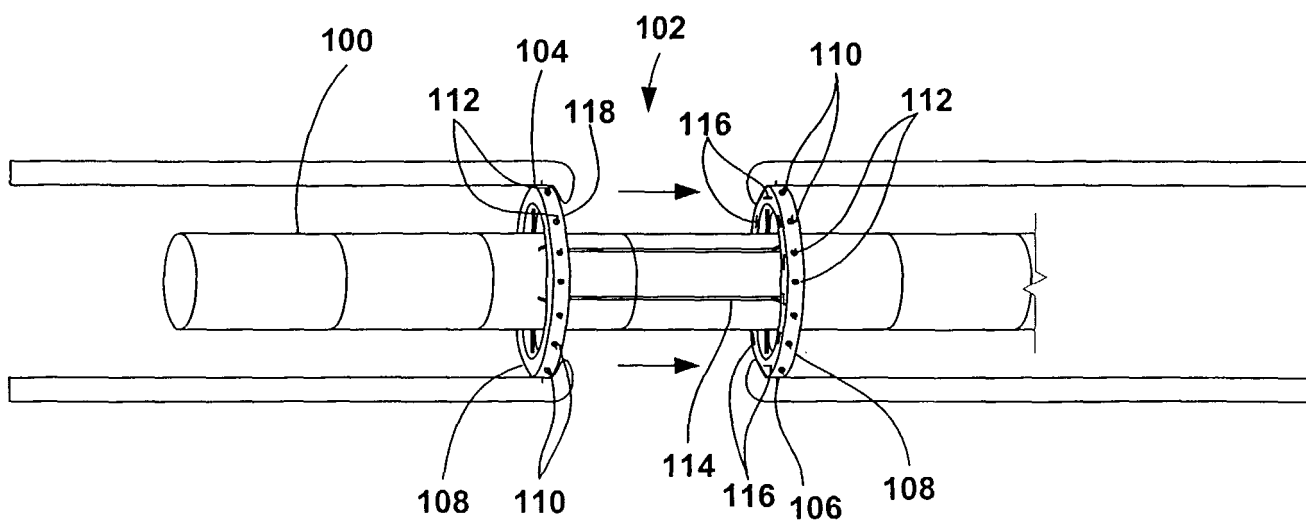


FIG 4

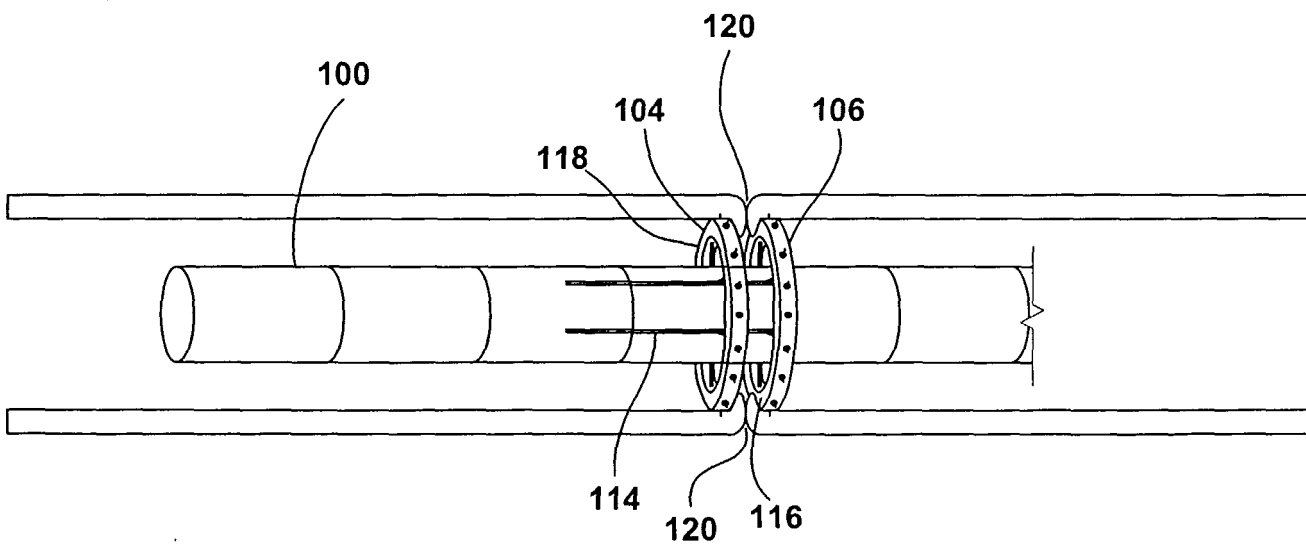


FIG 5

专利名称(译)	用于内窥镜结肠切除术的装置和方法		
公开(公告)号	EP1469781A2	公开(公告)日	2004-10-27
申请号	EP2002794411	申请日	2002-12-20
[标]申请(专利权)人(译)	新引导系统公司		
申请(专利权)人(译)	NEOGUIDE系统公司.		
当前申请(专利权)人(译)	NEOGUIDE系统公司.		
[标]发明人	BELSON AMIR		
发明人	BELSON, AMIR		
IPC分类号	A61B17/32 A61B A61B1/00 A61B1/31 A61B17/00 A61B17/08 A61B17/11 A61B17/115 A61B17/22		
CPC分类号	A61B1/00147 A61B1/0055 A61B1/0058 A61B1/31 A61B17/1114 A61B2017/003 A61B2017/00557 A61B2017/1103 A61B2017/22034 A61B2017/22054 A61B2034/2059 A61B17/00234 A61B17/1155 A61B2017/00296 A61B2017/00314 A61B2017/00349 A61B2017/00353 A61B2017/1132		
优先权	60/347674 2002-01-09 US		
其他公开文献	EP1469781A4 EP1469781B1		
外部链接	Espacenet		

摘要(译)

本文描述了用于内窥镜结肠切除术的装置和方法。具有第一和第二组织接近装置的结肠切除装置安装在彼此分离的结肠镜上。在结肠切除术装置的展开期间，结肠的患病部分位于组织接近装置之间。组织接近装置径向扩张，使得它们在与结肠的疾病部分相邻的两个部位处接触并抓握结肠壁。将病变部分与网膜分离，并使用腹腔镜进行横切，或将其拉入结肠镜中以便以后取出。然后在结肠镜上朝向彼此推动组织接近装置，以使结肠的两个自由边缘接近在一起，在那里它们使用组织接近装置作为外科吻合器固定到彼此，以产生端对端吻合。