Design and instrumentation of new devices for performing appendectomy at colonoscopy (with video)

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Background: There is increasing interest in natural orifice surgery (NOS). Because the lumen of the appendix is connected to the cecum, a minimally invasive method for removing the appendix by colonoscopy may be feasible.

Objectives: Our purpose was to design, develop, and test new devices for inverting and removing the appendix by colonoscopy.

Design: Prospective prototype development program.

Setting: University-based study in 25 colons from adult human cadavers.

Interventions and Methods: Various prototypes were evaluated by inserting them into the appendiceal orifice to its luminal tip, with the intent to invert the appendix in a controlled fashion into the lumen of the cecum. The advantage of using a tubular structure as a counterforce to aid inversion of the appendix was evaluated. When inversion was incomplete, the growing tissue strain was relieved by endoluminal incision of the mesenteric side of the appendix. Closure methods with endoloops or ligating loops were studied. Appendiceal resection was completed by snare diathermy, leaving an inverted intraluminal stump.

Main Outcome Measurement: Ability to invert the appendix into the cecum.

Results: The mean appendix length and luminal diameter were 84 ± 23 mm and 4.9 ± 1.2 mm, respectively. It was possible to advance various types of inversion devices to the tip of the appendiceal lumen. Partial inversion of the appendix was successful in 22 of 25 tests. Mesenteric tissue tension, tissue volume, and device slippage were the main reasons for incomplete inversion. The complete inversion was achieved with a combination of vacuum, tip grip, counterforce at the appendix base, and eventually endoluminal incision.

Conclusions: The inversion of the human appendix by colonoscopy seems feasible and may be an alternative approach to conventional appendectomy.

Acute appendicitis is the most common abdominal emergency,[1] accounting for a million hospital days per year in the United States.[2] Between 7% and 12% of humans have this condition at some point in life.[3] The incidence peaks in the second and third decades and decreases thereafter, but appendicitis may affect all ages.[4] Classically, appendicitis is believed to develop from primary obstruction of the appendiceal lumen and secondary bacterial infection.[2,5] At least one third of inflamed appendices occur without obstruction, and the pathogenesis of appendicitis in these patients is controversial.[2] Primary infection by viruses (eg, cytomegalovirus), bacteria (eg, *Yersinia*), or parasites (eg, *Amoebae*) may initiate this process as well as antigen stimulation of the mucosal immune system. Colonoscopic trauma may precipitate appendicitis.[6]

Abbreviation: AID, appendix-inverting device.

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Appendectomy is the treatment of choice. Techniques range from open or laparoscopic appendectomy to the surgical inversion of the appendix into the cecum (specifically in incidental cases).[1,2] For years, appendectomies have been performed by a right lower quadrant oblique or transverse incision. In 1983, Semm[7] introduced the laparoscopic surgery that proved to be useful for both diagnosis and treatment of a variety of intra-abdominal conditions. Laparoscopic appendectomy is associated with reduced complications, discomfort, and hospitalization time, but it is still controversial in complicated cases.[1,8-11]

The removal of the appendix has no known consequence on bowel function. Although the risk for development of appendicitis during one's lifetime is about 1 in 8, prophylactic appendectomy is not justified. However, incidental appendectomy is a common practice in young patients during abdominal surgery for reasons other than appendicitis.[12] The benefit of incidental appendectomy in patients aged 30 to 50 years is considered small, and there is little justification for incidental appendectomy in elderly patients. Interestingly, appendectomy protects from the development of ulcerative colitis, the mechanism of which is not understood.[13,14] This protective effect is most prominent in individuals who had their surgical treatment before the age of 20 years.[14] A prospective study to test the effect of appendectomy in patients with chronic active ulcerative colitis is currently in progress (Dr Graham L. Radford-Smith, personal communication).

Natural orifice transluminal endoscopic surgery is intended to perform abdominal operations such as appendectomy through the mouth, anus, or vagina.[15,16] Because the appendiceal lumen connects to the cecum, appendectomy through a colonoscopic approach seems to be a reasonable candidate procedure. We envisioned that the inversion of the vermiform appendix into the cecum and its removal are feasible by means of colonoscopy. In fact, the endoscopic removal of surgically or spontaneously intussuscepted (inverted) appendices has been described in several cases.[17-21] Most of these procedures had been performed without actually knowing that the appendix was snared because the inverted appendix had been misinterpreted as a cecal polyp.[19,22] Here we describe the design and development of devices that enable the inversion of the appendix through colonoscopy.

Capsule Summary

What is already known on this topic

- Spontaneous inversion of the appendix into the colon has been described, providing a minimally invasive method for removing the appendix by colonoscopy.

What this study adds to our knowledge

- In a prospective study using cadaveric colons and several prototype inversion devices, partial inversion of the appendix was successful in 22 of 25 tests, but complete inversion was achieved with a combination of vacuum, tip grip, counterforce at the appendix base, and eventually endoluminal incision.

MATERIAL AND METHODS

Cadaver model

The human appendix has a unique anatomy, and no animal model is available with a similar appendix.[23] The closest structural similarity is the pig uterine horn, which, however, does not connect to the colon and thus cannot be used for our intraluminal approach.[24] Therefore, we decided to test our devices in human cadavers. The protocol was approved by the hospital's institutional review board. Cadavers with a history of abdominal surgery or infectious disease were excluded. After pathologic inspection the ileocecal specimen was removed and cleaned with tap water. The position of the cecum was classified as *symmetric* (combining the conic and quadrate type with symmetry and similar size of the saccule on each side of the anterior tenia), *asymmetric* (the normal type with asymmetric and unequal-sized saccules), or *superasymmetric* (appendix orifice in close proximity to the ileocecal junction).[25] Similarly the position of the appendix was judged as *retrocecal*, *pelvic*, *subcecal*, *preileal,* or *postileal*. The inner appendix length was measured from tip to base (in millimeters), and the luminal diameter was tested by insertion of standardized probes (in 0.5-mm diameter increments).

Tip versus base inversion

In the first set of experiments, we compared 2 types of appendix inversions on the bench: one that started at the appendix tip with the tip being grasped and inverted into the lumen of the appendix and a second that started at the appendix base with the proximal parts of the appendix being inverted into the cecum. For modeling of tip inversion, a string was knotted into the appendix tip and pulled into the cecum. Tip inversion was limited because pulling at the tip caused the appendix to fold, thereby reducing the space within its lumen and resulting in an early halt. For base inversion, a stent with several flaps on the sides was inserted and pulled into the cecum. Base inversion was generally feasible; however, mesenteric tissue of the mesoappendix accumulated in the space between the inverted appendix layers and caused a halt of the inversion process. To overcome this limitation, the space between these layers was enlarged by a surgical (nonperforating) incision. This incision was directed from the lumen of the cecum into the mesenteric side of the inverted part of the appendix. Any inversion that would allow removal of the entire appendix without opening the peritoneal cavity (by snaring the inverted stump at its base) was considered successful.

Prototype testing

In the next set of experiments, different prototypes for base inversion were tested to evaluate their grip forces and handling characteristics. A balloon-inverting device displayed easy insertion because of a slim design but low traction force. In addition, the relatively large intraluminal diameter of the balloon added to the inverted volume of the mesenteric tissue and was obstructive to the completion of the inversion. Inverters with a tissue grab design (such as flaps on stents similar to a Tannenbaum design) offered a good grip but were not further considered because of the potential tissue injury and the inability to revert the procedure. The third group of devices was based on vacuum. For such devices a flexible tube with a series of holes connected to a high-performance vacuum pump was used (10 mPa, 8 m^3/h, Trivac D8B, Leybold Heraeus, Pfäffikon, Switzerland). An outer cover sleeve was designed to slide over these holes to control the number of holes that are exposed (Fig. 1A). Such a device was

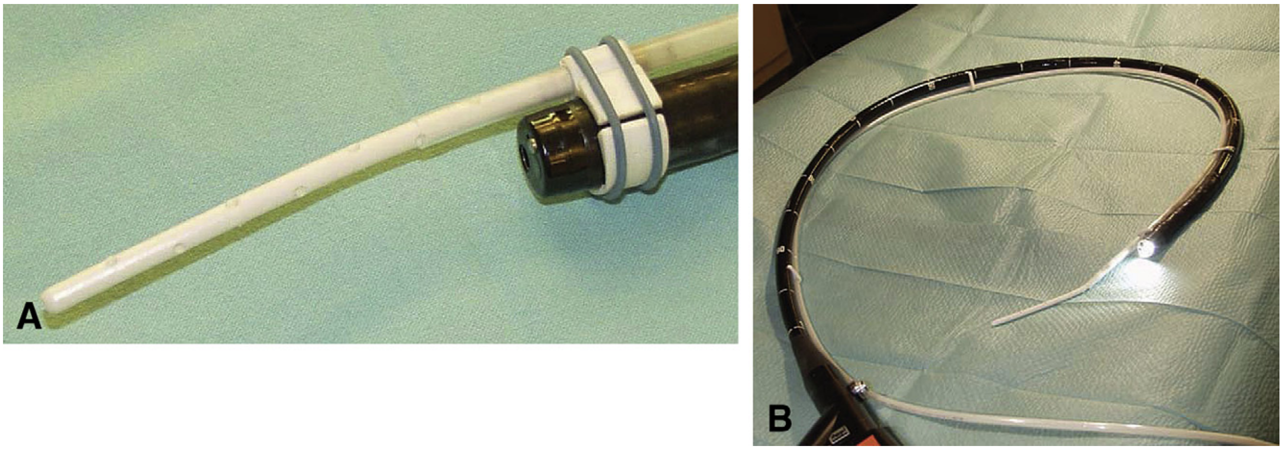

Figure 1. Tubular sucking device. A flexible tube with several holes was produced from mesh-enforced silicon (**A**). It was highly flexible but did not lose its shape through application of vacuum or tear apart when providing forces to invert the appendix. The device was attached to a Teflon tube that runs in a Teflon coversheet and was attached to the colonoscope (**B**). The device was controlled from the back by an assistant and attached to a vacuum pump. It could be extended out and pulled in.

produced from reinforced *silicone* in a mold, connected to the vacuum pump, and clipped to the outside of a colonoscope (Fig. 1B). Inversion tests were performed with various ileocecal specimens. An acrylic cube with a round opening was built (Fig. 2A). The opening was sealed by a rubber membrane that was sewn around the colon opening of the cadaver specimen. Vacuum was applied and adjusted for proper expansion of the ileocecal specimen (with the ileum ligated to prevent leakage). The cube allowed us to test devices together with an endoscope and gave us a similar view as during colonoscopy (Fig. 2B).

Tip grip vacuum prototype

To improve the final grip during the inversion of the appendix, a device that combined suction holes and grabbing of the appendix tip was created. The tip grip mechanism was realized by a metal brush that extended out of the vacuum tube and engaged with the distal appendix wall (Fig. 3A). Vacuum would allow the wall to collapse onto this metal brush, which was then pulled in, thereby trapping appendix wall tissue between the brush and the distal tube (Fig. 3B).

RESULTS

Detailed description of the procedure

Because the lumen of the appendix is connected to the cecum, we envision an endoscopic procedure for removing the appendix that involves 5 steps.

1. Placement of colonoscope and overtube. The procedure starts with advancing a colonoscope into the cecum (Fig. 4A). Before colonoscopy, a colon overtube will be placed over the colonoscope. The length of this overtube is about 100 cm (to ensure placement of its tip in the cecum), and its diameter is about 22 mm (to allow inversion of the appendix into the overtube). The overtube is advanced together with the colonoscope, the colonoscope guiding around bends, the overtube following the direction of the scope after straightening it. The distal end of the overtube is kept behind the tip of the colonoscope to allow full maneuverability of the scope. The overtube has a seal that prevents insufflated air to leak. The proximal end of the overtube has a handle to ensure good maneuverability and to prevent the overtube from complete insertion into the colon. The inner surface of the overtube comprises a coating of a lubricating material to ensure smooth advancement of the overtube over the colonoscope and vice versa.

The overtube may hold various channels with a sealed proximal end at the handle and a distal opening at the tip of the overtube. One channel will be used to control the detachable ligating loop, which is loaded into the overtube tip before the procedure. Another channel may hold the appendix-inverting device (AID) if it is too big to fit through the endoscope working channel.

2. Appendix imaging. When the colonoscope has reached the cecum, a guidewire is advanced into the orifice of the vermiform appendix through the working channel of the colonoscope (Fig. 4B). The position of this guidewire can be monitored by fluoroscopy. Next, an irrigating catheter is placed over the guidewire and advanced to the tip of the appendix, the guidewire is removed, and the appendix lumen is cleaned by flushing the catheter with saline solution. Appendicitis can be diagnosed by the appearance of purulent material. The appendix is filled with contrast media and radiographs are taken. Appendix characteristics (diameter, length, and location) and conditions (eg, obstruction or perforation) can be diagnosed. To reduce slippage of the forthcoming inverting device, the mucous layer can be flushed with N-

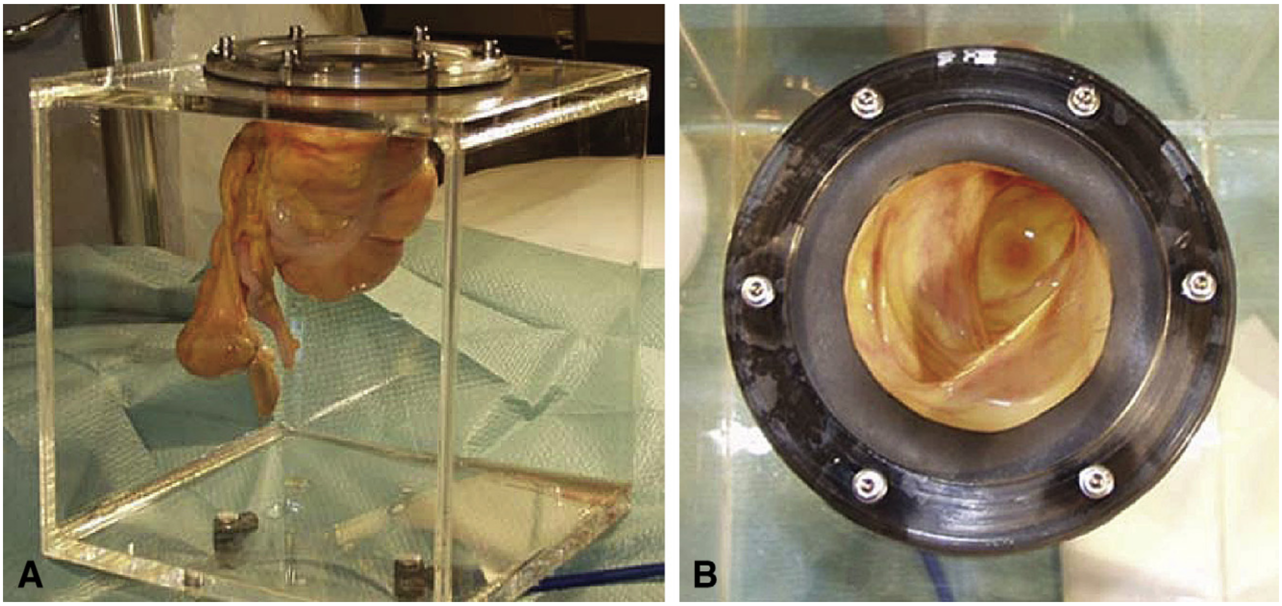

Figure 2. Human cadaver model. The ileocecal region was removed from the rest of the intestine and cleaned. The terminal ileum was ligated with a string and the ascending colon was sewn into a rubber membrane, which was fixed into an acrylic cube (**A**). Vacuum was applied to the cube, allowing the ileocecum to expand, thereby opening up the lumen of the cecum and providing a simulation of the expanded cecum during endoscopy (**B**).

Figure 3. Tip grip vacuum prototype. This device was similar to the tubular sucking device with an additional brush at its tip (**A**). When the brush was extended out of the tube and vacuum was applied, the inner tip of the appendix was grabbed. Pulling of the brush caused the appendix wall to snag between the tube and the brush and provided excellent tip grip (**B**).

acetylcysteine or a similar solution. If the orifice or the lumen is obstructed, balloon dilation may be performed with standard dilation balloons.

3. Inversion of the appendix. The guidewire is exchanged with the catheter (Fig. 4C). The lumen of the appendix and its orifice are dilated with a colon dilation balloon to increase the ability for device insertion and appendix inversion. Then the AID is advanced into the appendiceal lumen, either through the working channel of the colonoscope or (if too large) through an extra channel of the overtube. The distal end of the overtube is positioned around the orifice of the appendix. To invert the appendix, the handle of the AID is pulled, and the overtube is used to produce counterforce around the orifice of the appendix. This causes the vermiform appendix to partially or completely invert into the cecum. For partial inversion, the inverted proximal portion of the appendix is cut longitudinally with a needle-knife. If the cut is directed to the lower posterior lip of the ileocecal valve, it should prevent opening of the peritoneal cavity. The needle-knife may be inserted through the overtube or the colonoscope. The clockwise position of the needle-knife to the appendix can be adjusted through rotation of the overtube over the colonoscope. During the cutting, a continuous pull has to be provided by the inversion device to ensure further inversion. Any inversion that positions the tip of the appendix inside the orifice of the appendix (monitored by fluoroscopy) is sufficient to advance in the procedure.

4. Ligation. Before the procedure, a detachable ligating loop (formed from standard suture and a Roeder knot) is loaded to the tip of the overtube (Fig. 4D). The function of this device is to place a tight suture over the appendiceal orifice to prevent peritoneal leakage and bleeding from the appendix artery. The loop is controlled by a wire (which runs in one of the overtube channels) and is deployed when the tip of the inverting device (and appendix) has reached a position inside and proximal to the tip of the overtube. After the loop is deployed,

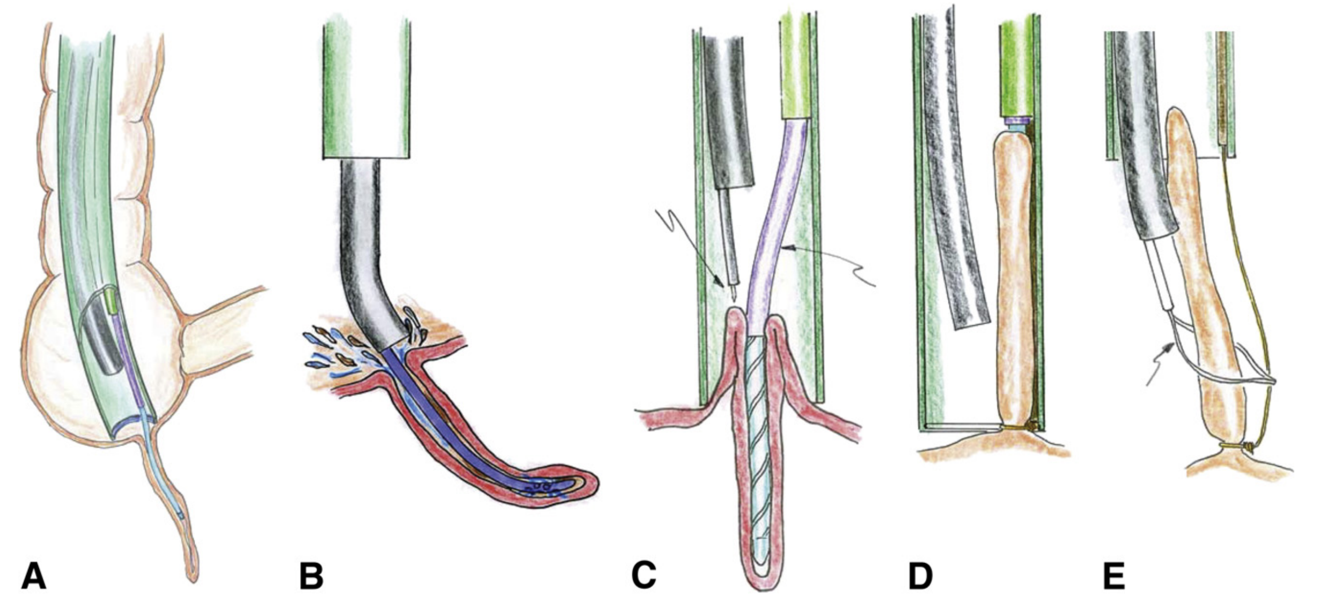

Figure 4. Instrumentation. **A,** A colonoscope and an overtube are placed in the cecum. **B,** A catheter is inserted into the appendiceal orifice, the appendix is flushed and filled with contrast media to diagnose the size and position (by fluoroscopy) and to test for possible luminal obstruction or perforation. **C,** An AID *(right arrow)* is introduced and the appendix is inverted by pulling it into the cecum and providing counterforce with an overtube against the wall of the cecum. To complete inversion, an incision of the inverted part of the appendiceal wall may be performed (*left arrow* indicating needle-knife). **D,** The inverted appendix is ligated and thereby fixed in its position with a detachable loop that is preloaded onto the tip of the overtube. **E,** The AID is released, and the appendix is transected with a polypectomy snare *(arrow)* and removed through the overtube for pathologic examination.

the AID is released from the inverted tissue and the suture is trimmed.

5. Removal of the appendix. A standard snare wire loop is placed over the inverted vermiform appendix to cut it and retrieve it through the overtube (Fig. 4E). The overtube is kept in place and used for fast reinsertion of the colonoscope for a second look at the colonoscopic appendectomy site. Hemostasis clips can be used to fix the ligating loop in position or to control bleeding. Finally, both the colonoscope and the overtube are removed.

Inversion bench testing

This procedure is based on the assumption that the appendix can be inverted by endoscopic means and requires a set of novel devices; the most important is the AID. Twenty-five human ileocecal specimens were received from the department of pathology, and the lumen was manually cleaned from feces with tap water. The position of the appendix was retrocecal in 14 cases, pelvic in 7, prececal in 2, and preileal or postileal in 1 each. The mean luminal length and diameter were 84 ± 23 mm (52-125 mm) and 4.9 ± 1.2 mm (3-7 mm), respectively. Partial obstruction of the lumen was present in 7 of 25 cases.

In the first set of specimens (n = 11), tests were performed with simplified inverting devices that use the various inverting mechanisms. It was possible to introduce at least 1 of the AIDs in all specimens. When inversion started at the appendix base, partial inversion was successful in 10 of 11 tests. The median length of the partially inverted stump was 13 mm (3-18 mm). The tension and volume of the mesoappendix (from fat deposit) were the main reasons for incomplete inversion. Complete inversion was achieved after endolumenal incision in 10 of 11 tests. The mean volume of the resected tissue (inverted appendix including its mesoappendix) was 6.8 ± 1.9 cm^3.

From the devices tested, the vacuum-assisted tubes showed the best results. This approach was further developed to a flexible, mesh-reinforced tubular sucking device (Fig. 1 Video 1, available online at www.giejournal.org) that was connected to a vacuum pump and attached to the outside of a colonoscope. Further tests were performed in the acrylic cube (Fig. 2). In this set of experiments, partial inversion of the appendix was achieved in 4 of 4 cases. Only one complete inversion was achieved. Slippage of the device was the main reason for partial inversion, caused by the loss of grip during the advancement of the inversion process. In fact, the further the inversion proceeded, the fewer holes of the tubular sucking device were actually engaged to the appendix wall. On the other hand, pulling forces increase with the advancement of the inversion process. Structural improvements of the device surface were insufficient to overcome this weakness in 3 additional cases.

To improve the device grip during advanced appendix inversion, the tip-grip-vacuum prototype was developed. This device was based on the structure-improved vacuum tube and was combined with a wire brush that can be exposed at the tip of the device. With this combination of vacuum

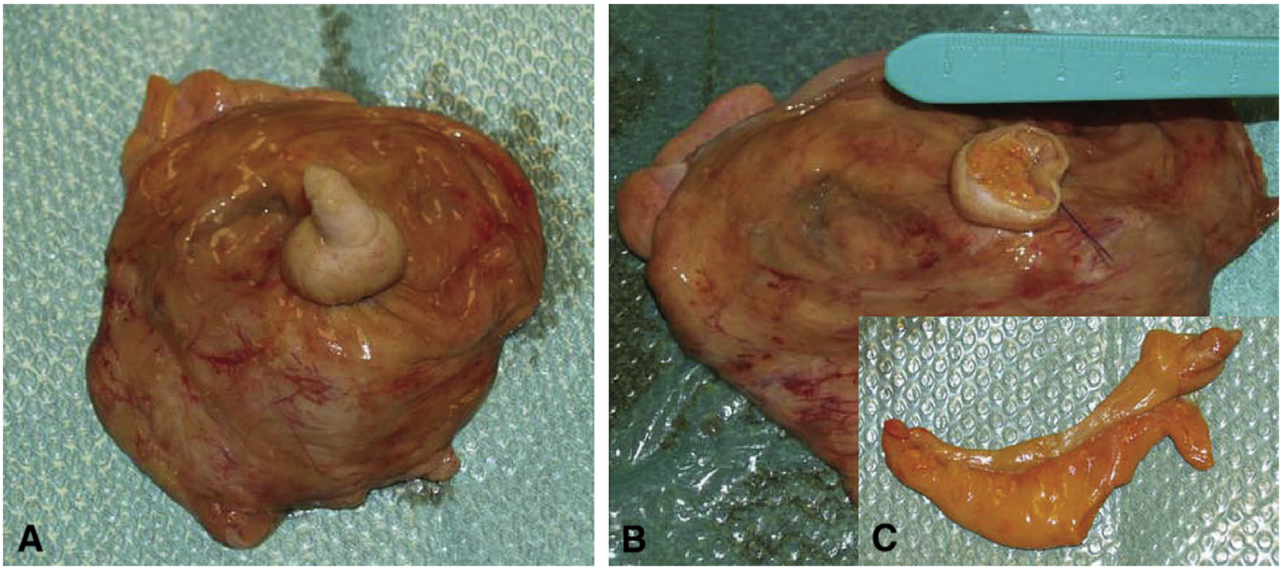

Figure 5. Completed inversion and removal of the appendix. View into the open cecum showing the ligated inverted appendiceal stump before (**A**) and after (**B**) resection of the appendix (**C**).

and tip grip, pulling forces up to 20 N were achieved. This device was tested in 7 experiments without any slippage. Partial inversion was achieved in all cases. When combined with balloon dilation and the use of a tubular structure for applying appropriate counterforce, complete inversion was achieved in 5 of 5 cases without endoluminal cutting (Fig. 5). In 3 cases, the inversion procedure was performed in situ after median laparotomy. The in situ inversion process was similarly successful as with the resected specimen. The mean volume of the resected tissue was 7.4 ± 2.0 cm^3.

DISCUSSION

This study was performed to develop and test new devices for performing appendectomy during colonoscopy. This open orifice access involves a series of new devices such as an AID, a tubular structure for providing counterforce at the appendix base and a closure device. In several sets of human cadaver experiments we demonstrated the feasibility of inserting an AID into the appendiceal lumen and of inverting the appendix beginning the inversion at its base. The inversion was commonly associated with impaction of mesenteric tissue in the inverted stump, resulting in incomplete inversion. Dilation of the appendiceal orifice with a balloon, the addition of a tip-grabbing function to the AID, and proper counterforce at the appendix base by using a tubular structure improved the ability to fully invert the appendix (including its mesoappendix) into the cecal lumen. If inversion was incomplete, an endoluminal longitudinal incision at the mesenteric side of the partially inverted appendix was performed, which enabled a completed inversion.

With use of the tip-grip-vacuum device, inversion of the appendix into the cecal lumen proved feasible. Other devices such as the tubular structure and the suture ligation mechanism need to be further developed before colonoscopic appendectomy becomes a reality. Once this is accomplished, it may be applied as a minimally invasive method in patients without acute appendicitis because tissue swelling is likely to obstruct the appendix lumen and interfere with the ability to introduce the AID. Because the diameter of the AID does not fit through a colonoscope working channel, the AID was first attached with clips to the outer side of a colonoscope and later guided in a separate channel within a simplified overtube. This overtube seems essential to the completion of the procedure. The overtube will also hold a channel for the ligation material, which is needed to fix the inverted stump in inverted position and to close the appendix base before appendix removal. If the appendix tissue is considered normal, it might not be necessary to remove the appendix after ligation because we may expect tissue necrosis though ischemia within days, similar to what has been observed with surgical inversions.[26] During the preparation of this article such an overtube (Megachannel; Minos Medical Inc, Irvine, Calif) was constructed. Cadaver and human tests will be initialized in the coming months.

The advantages of this intraluminal technique over the current methods are quite obvious. No incisions of the skin or the abdominal wall are necessary, resulting in less postinterventional pain and a better cosmetic outcome. During colonoscopic appendectomy only the visceral, but not parietal, peritoneum is injured. Because the visceral peritoneum and the appendix itself do not have sensible nerve supply, the pain level of colonoscopic appendectomy is expected to be comparable with endoscopic polypectomy and thus will not require general anesthesia. This is considered the greatest advantage because it reduces costs and risk. Eventually, colonoscopic appendectomy can be performed within endoscopy suites in an outpatient setting, further saving costs for operating room and hospital stay.[27] We expect fewer long-term complications such as bowel adhesions or incisional hernia.

Even if we cannot envision this procedure to fully replace open or laparoscopic appendectomy (specifically in children with acute symptoms), it is a first step to explore the possibility of natural orifice surgery from inside the colon. One application may become steroid-resistant ulcerative colitis; other applications may include recurrent right lower quadrant pain of unknown origin or interval appendectomy after acute appendicitis treated with antibiotics. As improvement in diagnostic imaging reduced the number of appendectomies among the youthful population, there is a growing proportion of adults who still have their appendices in place. This population will be at risk for appendicitis later in life. If the side effects and costs of colonoscopic appendectomy are low, and techniques are refined for early diagnosis, it may even become an incidental procedure during screening colonoscopy.

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DISCLOSURE

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