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A self-locking loop as an alternative to purse-string suture in colon anastomosis

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A self-locking loop as an alternative to purse-string suture in colon anastomosis

En självlåsande loop som alternativ till tobakspungssutur vid colonanastomos

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SUMMARY

Colorectal cancer is among the most common and most deadly cancer types in man. Surgical removal of the tumour is the treatment of choice. Anastomotic leakage is a common and feared complication to this procedure associated with further complications and increased mortality. The exact mechanisms and risk factors of anastomotic leakage have yet to be completely understood. Alternative techniques to anastomose colon are currently investigated, aimed to develop safer and easier methods with reduced risk of complications.

Intraluminal stapling or manual suturing are the conventionally used methods of anastomosis. Adaptive Anaerobic Anastomosis is a new method for anastomosis of the colon that is currently under development. The methodology is in principal based on two ring-shaped implants that lock the two intestinal ends together while the lumen remains open and allows passage of intestinal content. As the colon heals the locking rings will eventually detach and pass through the rectum.

In Adaptive Anaerobic Anastomosis and intraluminal stapling, the colon lumen is temporarily sealed around the anvil shaft of the device using a purse-string suture. The aim of this study was to evaluate the feasibility of replacing the purse-string suture for closure of the colon, using a short-time implant in the form of a flexible self-locking loop, mainly in conjunction with the Adaptive Anaerobic Anastomosis method.

The self-locking loop was tested *in vitro* on pig intestines (n=10) and *in vivo* in ten pigs anastomosed using either Adaptive Anaerobic Anastomosis or intraluminal stapling.

The self-locking device could close the lumen around the Adaptive Anaerobic Anastomosis and stapler instruments. Subjectively, the device achieved a good tissue grip and a tight closure of the colon. The technology was perceived as easy to use and potentially time saving. This study suggested that the self-locking device may be an alternative to stapler or purse-string suture for the temporary closure of the colon in colon anastomosis. Additionally, possible improvements of the design of the self-locking loop were suggested.

SAMMANFATTNING

Colorektalcancer är bland de vanligaste och mest dödliga cancertyperna hos människa. Behandling är i första hand kirurgiskt avlägsnande av tumören. Anastomosläckage är en vanligt förekommande och fruktad komplikation associerad med ytterligare komplikationer och ökad mortalitet. Mekanismer och riskfaktorer för anastomosläckage är inte helt kända. Alternativa metoder för anastomos av colon är under utveckling.

Konventionellt används intraluminär stapling eller manuell suturering för att skapa anastomos av colon. Adaptiv Anaerob Anastomos är en ny metod under utveckling. Metodiken baseras i princip på två ringformade implantat som låser ihop tarmändarna medan tarmlumens kontinuitet kvarstår för passage av tarminnehåll. Efter läkning lossnar låsringarna och passerar ut med avföringen.

Vid både Adaptiv Anaerob Anastomos och intraluminär stapling försluts tarmlumen tillfälligt runt verktygets städ med en tobakspungssutur. Målet med denna studie var att utvärdera möjligheten att ersätta denna tobakspungssutur med ett korttidsimplantat i form av en självlåsande loop, huvudsakligen vid användning av Adaptiv Anaerob Anastomos.

Den självlåsande loopen testades *in vitro* på färsk gristarm (n=10) samt *in vivo* på tio grisar vid anastomos med antingen Adaptiv Anaerob Anastomos eller intraluminär stapling.

Den självlåsande loopen kunde användas för att försluta lumen runt städet vid Adaptiv Anaerob Anastomos samt runt troakar och städ vid intraluminär stapling. Subjektivt åstadkoms ett bra vävnadsgrepp och en god förslutning. Teknologin upplevdes som enkel att använda och potentiellt tidsbesparande. Resultatet av studien antyder att en självlåsande loop kan användas för att ersätta tobakspungssutur eller stapler för tillfällig förslutning av colon vid colonanastomos. I arbetet identifieras även potentiella förbättringar av den självlåsande loopens design.

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INTRODUCTION

Colorectal cancer is among the most common cancer types in humans and among those associated with the highest mortality in both men and women. The incidence varies between countries but is reported to be 46.3 per 100 000 people-years in Europe (Ferlay *et al.*, 2013). Surgical removal is the basis of treatment for colorectal cancer (Mitry *et al.*, 2002; Weitz *et al.*, 2005; Rahbari *et al.*, 2009). Other indications for colorectal resection include trauma and inflammatory disease of the intestines (Masoomi *et al.*, 2015).

Following resection of the colon, clinically evident anastomotic leakage is a frequently reported complication which is often associated with further complications and increased mortality (Schrock *et al.*, 1973; Fielding *et al.*, 1980; Alves *et al.*, 2002).

The conventional method for achieving anastomosis of the colon consists of either suturing or stapling the resected intestinal ends together, with stapling currently being the most common (Corman *et al.*, 2012). Adaptive Anaerobic Anastomosis is a new suture-free method for anastomosis of the colon, currently under development (CarpoNovum AB, 2015).

In the Adaptive Anaerobic Anastomosis method, as well as in traditional stapled anastomoses, the colon lumen is sealed using a stapler or a purse-string suture. With the aim to provide an easy to use and less time consuming alternative for the temporary sealing of the colon, a new method was developed, based on the principle of a flexible, self-locking loop. The aim of this study was to evaluate the feasibility of using this self-locking loop for sealing of the colon in conjunction with the Adaptive Anaerobic Anastomosis method for colon anastomosis.

LITERATURE REVIEW

Surgical procedure of resection and anastomosis

The colon in the human is roughly 1.5 meters long. Starting in the lower right quadrant, the ascending colon runs along the right side of the abdomen to about the height of the right kidney, where it turns medially in the hepatic flexure. The transverse colon crosses the abdominal cavity from the hepatic flexure to the splenic flexure located just beneath the spleen. From the splenic flexure the descending colon runs along the left side of the abdomen down to the pelvis, where it turns into the sigmoid colon, a bend connecting it to the rectum (Corman *et al.*, 2012).

Elective resection of the colon is precluded by cleansing and preparation of the bowel. When conducting open surgery, most surgeons prefer to access the abdomen through a midline incision, but some variation in the approach exists (Corman *et al.*, 2012).

Resections are generally divided into either right or left (hemi-)colectomy, transverse colectomy, sigmoid colectomy, subtotal or total colectomy, or low or high anterior (rectal) resection, depending on what part of the bowel is affected (Corman *et al.*, 2012).

The abdomen is accessed and explored. The segment of colon which is to be removed is mobilised by dissection and the blood vessels supplying the segment are ligated. The bowel is clamped and cut at each side of the growth. It is then anastomosed either end-to-end, end-to-side, side-to-side or side-to-end at the surgeon's discretion, the objective being to establish an anastomosis without tension (Corman *et al.*, 2012).

It was suggested as early as 1826 that best healing would be attained by apposition of the bowel ends serosa to serosa, attained by applying inverting sutures (Lembert, 1826; Corman, 1988). Both single layer and two layer suturing technique has since been in use. It has been shown that anastomotic leakage rates are similar between the two (Fielding *et al.*, 1980; Burch *et al.*, 2000), while single layer sutures take less time to complete and are less costly in terms of materials (Burch *et al.*, 2000). Manual suturing and stapling techniques did not differ in terms of anastomotic leakage, overall morbidity and mortality according to a study by Docherty *et al.* (1995).

The circular stapler, while there are slight variations between brands and models, consists of a hand-held end with a firing trigger, and a cylindrical stapler housing, connected to each other by a tube. The stapler housing contains the stapler cartridge, a circular knife and a trocar which can be protracted by the turning of a knob on the handle. In addition, the stapler device consists of a separate anvil against which the stapling is made, in the form of a cone or disk with a short shaft protruding perpendicular to its base (Covidien, 2013; Ethicon endo-surgery, 2013).

After transection of the colon, the anvil is inserted into the open end of the bowel and the colon lumen is closed around the anvil shaft using a purse-string suture (Ravitch *et al.*, 1979; Zachariah, 2010).

The stapler device can be used transanally or abdominally. At a transanal approach the device is introduced through the anus and negotiated to the height of the distal end of the transected colon. At an abdominal approach the device is introduced into the bowel through a colostomy made about 10 cm from the transected bowel end (Zachariah, 2010; Corman *et al.*, 2012). If the latter approach is used the colostomy is closed by sutures or a linear stapler after finishing of the stapling, but will then represent an additional risk of leakage (Zachariah, 2010). The bowel end can be sealed by a staple row, in which case the trocar is extended from the device to pierce the tissue (Covidien 2013; Ethicon endo-surgery 2013). Alternatively, the trocar is extended through the open end of the colon, after which the lumen is closed around the trocar using a purse-string suture (Ravitch *et al.*, 1979; Zachariah, 2010).

The purse-string sutures as part of the surgical procedure can be made either manually or by the use of a purse-string clamp (Ravitch *et al.*, 1979; Vignali *et al.*, 1997).

The anvil shaft is slid over the trocar, attaching the anvil to the stapler device (Covidien 2013; Ethicon endo-surgery 2013). By retracting the trocar into the stapler housing the bowel ends are pulled tightly together. By squeezing the trigger the staplers are fired and the circular knife cuts through the double diaphragm consisting of the bowel closed around trocar and anvil (Ravitch et al., 1979; Zachariah 2010).

After removal of the device the stapled anastomosis is inspected. If it is found unsatisfactory it may be reinforced by manual sutures (Docherty *et al.*, 1995).

Anastomotic leakage and other complications

Anastomotic leakage (AL) is one of the most feared complications of colorectal resection (Rullier *et al.*, 1998; Shogan *et al.*, 2013). It is a frequently reported complication often associated with further complications and increased mortality (Schrock *et al.*, 1973; Fielding *et al.*, 1980; Docherty *et al.*, 1995; Alves *et al.*, 2002).

Alves *et al.* (2002) found that 67% of patients diagnosed with AL were also diagnosed with one or more other complications, compared to those without AL where only 24% experienced other complications. Mortality is significantly higher in patients who develop AL than in those who don't. Several studies report that 29-37% of all postoperative deaths are related to anastomotic leakage (Schrock *et al.*, 1973; Docherty *et al.*, 1995; Alves *et al.*, 2002).

There is little consensus between studies as to the definition of anastomotic leakage and many different terms are used to describe the occurrence, making comparison between studies difficult. Additionally, the inclusion criteria and limitations vary between studies, contributing to the range of reported leakage rates (Rahbari *et al.*, 2009).

Available studies report overall anastomotic leakage rates of between 2,8% and 12,8% (Schrock *et al.*, 1973; Fielding *et al.*, 1980; Docherty *et al.*, 1995; Rullier *et al.*, 1998; Alves *et al.*, 2002; Yeh *et al.*, 2005). Many studies have investigated risk factors for AL, but it is suggested that surgeons have little success in predicting the occurrence of AL (Karlizcek *et al.*, 2009).

There appears to be a consensus between authors that the greatest risk of AL is found in low rectal anastomosis. It is hypothesised that this is due to the greater technical difficulty of conducting surgery in a deep and narrow pelvis (Shogan *et al.*, 2013). At what height above the anal verge the distinction between a low and high anastomosis is made varies from <5 cm (Rullier *et al.*, 1998; Yeh *et al.*, 2005) to <7 cm (Vignali *et al.*, 1997) and in some cases the distinction is simply made between extraperitoneal and intraperitoneal anastomoses (Schrock *et al.*, 1973; Fielding *et al.*, 1980), but most studies find increased risk of AL in low compared to high anastomoses (Schrock *et al.*, 1973; Fielding *et al.*, 1980; Vignali *et al.*, 1997; Rullier *et al.*, 1998; Matthiessen *et al.*, 2004; Yeh *et al.*, 2005). In a multivariate analysis, Matthiessen *et al.* (2004) found a significant difference in AL between anastomoses made at or below 6

cm (24%), from 6,5-10 cm (13%) and 10,5-15 cm (4%) above the anal verge, showing low anastomosis to be a risk factor for leakage.

Many studies have attempted to identify other risk factors of AL, but these results are less conclusive. As Shrock *et al.* (1973) points out, most studies on this subject are retrospective, with a risk that relevant factors are missed and hence not investigated.

Alves *et al.* (2002) found that difficulties encountered during surgery, preoperative leukocytosis, septic conditions during surgery and amount of transfused blood received to be risk factors of AL in a multivariate analysis. In another multivariate analysis, Matthiessen *et al.* (2004) found that difficulties encountered during surgery, preoperative radiation treatment and male gender to be risk factors. Other studies also find male gender (Rullier *et al.*, 1998; Yeh *et al.*, 2005) and amount of transfused blood received (Schrock *et al.*, 1973; Yeh *et al.*, 2005) to be risk factors of AL. Some studies suggest preoperative radiation treatment is a risk factor (Schrock *et al.*, 1973; Alves *et al.*, 2002) while others show conflicting results (Enker *et al.*, 1999; Peeters *et al.*, 2005).

Emergency surgery is a risk factor according to one study (Schrock *et al.*, 1973) which was not in agreement with other studies (Fielding *et al.*, 1980; Docherty *et al.*, 1995). Shrock *et al.* (1973) discusses in their study that the negative effect of glucocorticoid treatment on wound healing should be inferred to colonic wound healing, although they could find no significant correlation in their own study. However, later studies have associated steroid treatment with increased AL risk (Alves *et al.*, 2002). Studies have also suggested that perioperative hypotension, duration of surgery (Schrock *et al.*, 1973), NSAID treatment (Gorissen *et al.*, 2012) and obesity (Rullier *et al.*, 1998) may be associated with greater AL risk.

Three studies report 33%, 22% and 12% mortality rates in patients with AL compared to 2,6%, 7,1% and 1,6%, respectively, in patients without AL (Schrock *et al.*, 1973; Fielding *et al.*, 1980; Alves *et al.*, 2002). In contrast, one study reports no difference in mortality between patients with and without AL (Alves *et al.*, 2005).

A temporary diverting stoma is used to unburden the anastomosis in some cases, at the discretion of the surgeon. There are conflicting results regarding whether diverting stomas contribute to lower AL rates (Peeters *et al.*, 2005; Matthiessen *et al.*, 2007) or not (Rullier *et al.*, 1998; Matthiessen *et al.*, 2004). However, stomas are recommended for high risk patients, as a measure to decrease the negative consequences of a potential leakage (Alves *et al.*, 2002; Peeters *et al.*, 2005; Hanna *et al.*, 2015). While there are benefits to the creation of a stoma, they may also impact the quality of life of the patient (Hanna *et al.*, 2015). The intention may be to construct a temporary stoma, but several studies involving long time follow up have shown that the stoma often becomes permanent (Matthiessen *et al.*, 2004; Matthiessen *et al.*, 2007; Blumetti *et al.*, 2014).

Alternatives and variations in surgical methods

Laparoscopic surgery is an alternative to laparotomy (Lourenco *et al.*, 2008). The abdomen is entered using 3-5 ports around 10 mm in size (Senagore *et al.*, 2004). The tumour is located and ligation of vessels and mobilisation of the bowel segment to be removed is conducted (Senagore *et al.*, 2003; 2004). The bowel segment is then extracted through a 4-6 cm long incision (Senagore *et al.*, 2004) or extension of the umbilical port (Makino *et al.*, 2014). Extracorporeal resection is then commenced (Senagore *et al.*, 2003; 2004). Alternatively, anastomosis of the rectum can be commenced by use of an intraluminal circular stapler, assisted by laparoscopy (Senagore *et al.*, 2006). Variations to the laparoscopic surgery such as robot-assisted and single-port laparoscopic surgery exist and are being evaluated (Levic *et al.*, 2015).

Laparoscopic surgery is more time consuming than open surgery (Veldkamp, 2005; Lourenco *et al.*, 2008) but offer the benefits of less pain (Veldkamp, 2005), earlier restored bowel function (Veldkamp, 2005; Mistrangelo *et al.*, 2015) and shorter hospital stay (Lourenco *et al.*, 2008; Mistrangelo *et al.*, 2015; Masoomi *et al.*, 2015). Most studies find laparoscopic surgery to have similar (Köckerling *et al.*, 1999; Veldkamp, 2005; Lourenco *et al.*, 2008) or lower (Moghadamyeghaneh *et al.*, 2014; Masoomi *et al.*, 2015) general complication rates to open surgery and it is considered to be a safe alternative (Köckerling *et al.*, 1999; Lourenco *et al.*, 2008).

A procedure that cannot be completed laparoscopically is converted to open surgery (Senagore *et al.*, 2004). This is required in 5,6%-17% of patients undergoing laparoscopic surgery, according to different studies (Köckerling *et al.*, 1999; Senagore *et al.*, 2003; 2004; Veldkamp, 2005; Senagore *et al.*, 2006; Mistrangelo *et al.*, 2015; Moghadamyeghaneh *et al.*, 2014; Masoomi *et al.*, 2015). Conversion is associated with increased complication rates (Lourenco *et al.*, 2008; Moghadamyeghaneh *et al.*, 2014; Masoomi *et al.*, 2015). However, some argue that complication rates in converted surgery are still lower than in all-open surgery (Moghadamyeghaneh *et al.*, 2014; Masoomi *et al.*, 2015).

As complication rates for routine surgical procedures for anastomosis of the colon have been and still remain high, new methods and variations to the surgical procedure are continuously being developed and evaluated. *Ex vivo* attempts have been made to anastomose colon using a coagulation tissue fusion technique (Santini *et al.*, 2013; 2015). Paral *et al.* (2014) attempted to construct colon anastomoses *in vivo* in pigs using a cyanoacrylate tissue glue.

The concept of a compression anastomosis was introduced by Denan in 1826. Several different devices have since been used to conduct compression anastomoses, before subsequently falling out of favour for one reason or another (Kaidar-Person *et al.*, 2008; Zbar *et al.*, 2012). Murphy's button introduced in 1892 and used for a few decennia thereafter consisted of two metallic rings held in place inside the bowel by a purse-string suture on each side of the anastomotic line (Zbar *et al.*, 2012). The principle of the biofragmentable

anastomotic ring (BAR) introduced by Hardy *et al.* (1987) is similar, but with the rings constructed from polyglycolic acid, making them biodegradable. These rings will partially dissolve and fragment before passing with the stool (Hardy *et al.*, 1987; Kaidar-Person *et al.*, 2008; Zbar *et al.*, 2012). Recently, a new compression device using a shape-memory nickel-titanium alloy have been developed and used (Kaidar-Person *et al.*, 2008; Masoomi *et al.*, 2013). The material of the NiTi ColonRings make them more pliable at low temperatures at which they are inserted in the bowel. When the rings are subsequently warmed to body temperature, they return to their original form, achieving a compression anastomosis (Stewart *et al.*, 2007).

Adaptive Anaerobic Anastomosis – a new methodology to anastomose colon to colon or colon to rectum

Adaptive Anaerobic Anastomosis is a new method of anastomosis of the colon that is currently being developed. The methodology is in principal based on a ring-locking device that is inserted into each open bowel end and locked to the intestinal end by an elastic O-ring. A dual-male part is connected to one ring and then the other, thus locking the resected colon ends together. The ring shape of the device allows passage of intestinal content (CarpoNovum AB, 2015).

The tissue of the intestinal ends is adapted serosa-to-serosa between the O-rings of each end. As the anastomosis heals, the entire device will eventually detach and is expelled with the faeces in 7-14 days (Vilhjalmsson *et al.*, 2015a).

LapAid is one of the applicators used to place the rings into the intestine, intended for use in the upper rectum. The LapAid consist of a hand-held end with a firing trigger connected by a tube to a cylindrical device housing, as well as a separate anvil. The device housing holds a circular knife and a protractible trocar and is loaded with one anastomotic ring. The anvil is shaped like a cone with the tip cut off, and with a short shaft protruding from its base. The anvil holds the O-ring and provides a surface for the circular knife to cut against (CaproNovum AB, 2015).

The anvil with the O-ring is inserted into the proximal open end of the colon and the lumen is closed around the anvil shaft by use of a purse-string suture. The extended LapAid trocar is connected to the anvil shaft. The trocar is then retracted into the device housing by turning of a knob on the LapAid handle. By retraction of the trocar the end of the device housing is approximated to the intestinal end with anvil inside. By squeezing the firing trigger the anastomotic ring locks onto the O-ring inside the lumen and the circular knife cuts away the colon tissue closed around the anvil shaft by the purse-string suture. This procedure is repeated for the distal end of the bowel and they are then connected by a dual-male piece (CarpoNovum AB, 2015).

After the creation of the anastomosis it is visually inspected. The level of anastomotic adaption may also be measured through a catheter system connected to one of the anastomotic rings (Vilhjalmsson *et al.*, 2015a; 2015b).

MATERIAL AND METHODS

The self-locking device

A flexible band with a case at one end containing a locking mechanism was constructed using computer aided design (Solidworks, Dassault Systèmes SolidWorks Corporation, Concord, USA). The other end of the band could be fed through the locking case where the locking mechanism ensured it could be moved in one way only by locking into perforations of the band. The flexible band formed a self-locking loop, similar in construction to that of a cable tie. Studs were added to the side of the flexible band that was constructed to form the inside of the loop in order to enhance the tissue grip at closure of the loop around tissue. A steel mould was made for injection moulding of the flexible band. The material used for injection moulding was polyamide 6 (Prototal PDS AB, Tistelvägen 1, 531 71 Vinninga).

Ethical approval

The Uppsala Animal Ethics Committee, Sweden and Swedish Board of Agriculture approved the study (C402/2012 and 38-9492/12).

Test in tissue – *in vitro*

Fresh, lukewarm pig intestines were collected from the local abattoir for use in a cadaver test. The fatty tissue was dissected to expose the colon. The colon was transected approximately 15 cm from the anus. The LapAid anvil was inserted into the lumen. The self-locking loop was placed around the transected colon and the loop was tightened around the anvil inside the lumen. The closure was visually inspected and the locked loop was cut off and removed for inspection of the compressed colonic tissue. This *in vitro* test was repeated ten times.

Test in tissue – *in vivo*

The self-locking loop was tested *in vivo* in ten (10) pigs of approximately 50 kg anaesthetised primarily for testing of the Adaptive anaerobic anastomosis methodology (CarpoNovum AB, Halmstad, Sweden). In five pigs, the colon was anastomosed using the size 29 anastomotic ring and in five using a size 29 Touchstone circular stapler with a transanal approach. The pigs were placed in dorsal recumbency and the abdomen was accessed through a midline incision. The descending colon was localised and clamped with two large forceps. The colon was then transected between the two forceps. Surrounding tissue was dissected to expose the serosal surface of the colon and allow for serosa-serosa apposition of the anastomosis.

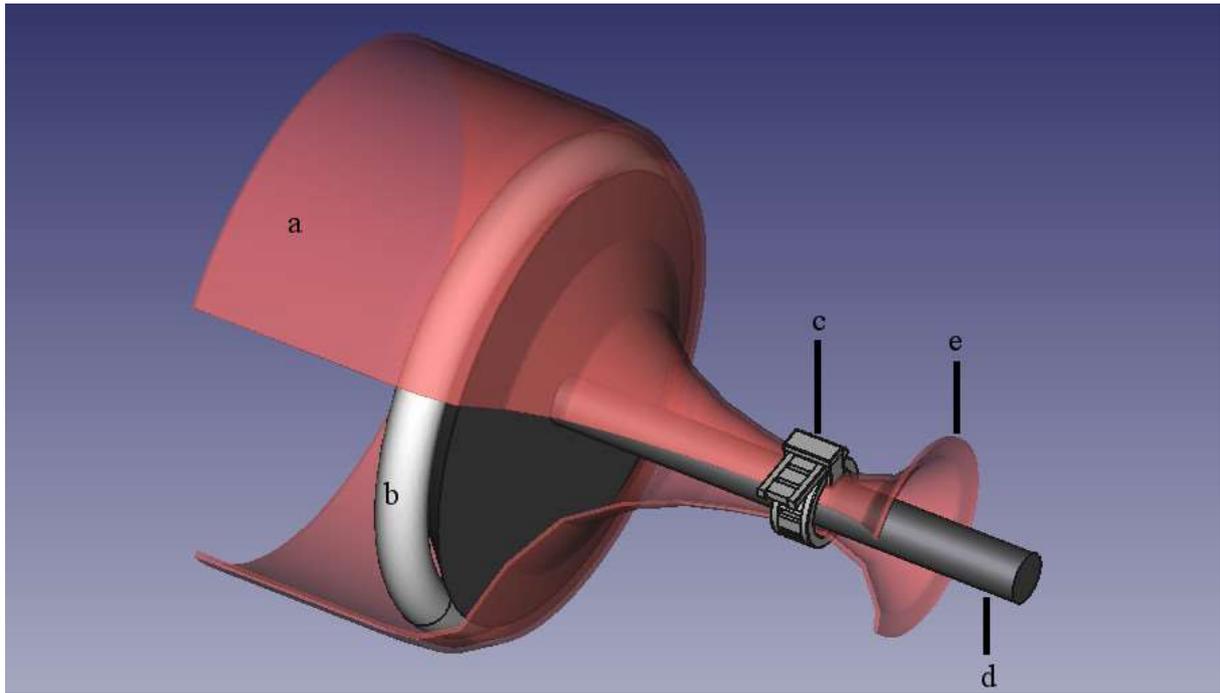


Figure 1 Sketch of the self-locking loop closing the colon lumen around the anvil shaft. Bowel shown opened for demonstrative purposes. a: Bowel. b: Elastic ring of the Adaptive Anaerobic Anastomosis, on anvil. c: The self-locking loop. d: Tip of anvil shaft, to be connected to LapAid trocar. e: Transected end of colon.

When Adaptive Anaerobic Anastomosis was used (n=5), two self-locking loops were used, one on each side of the anastomosis. The self-locking loop was placed around the transected colon and the loop was tightened around the anvil shaft inside the lumen (Fig 1). Following tightening of the loop, colon tissue protruding beyond the closed loop was resected. Excess band protruding from the locking case was cut off. The anastomosis procedure was then completed according to the Adaptive Anaerobic Anastomosis methodology.

In the conventional circular stapler pigs (n=5), following perioperative enema, the stapler anvil was inserted into the lumen of the proximal end of the transected colon. The self-locking loop was placed around the transected colon and the loop was tightened around the anvil shaft inside the lumen. Colon tissue protruding beyond the closed loop was resected and excess band protruding from the locking case was cut off. The circular stapler was inserted rectally and the trocar was aligned with the transected end of the colon.

A second self-locking loop was placed around the distal end of the colon and the loop was tightened around the tying area of the trocar inside the lumen. Colon tissue protruding beyond the closed loop was resected and excess band protruding from the locking case was cut off. The anastomosis was then completed with circular stapling according to established procedure.

RESULTS

The implant was constructed and the product was injection moulded. The implant formed a self-locking loop (Fig 2).

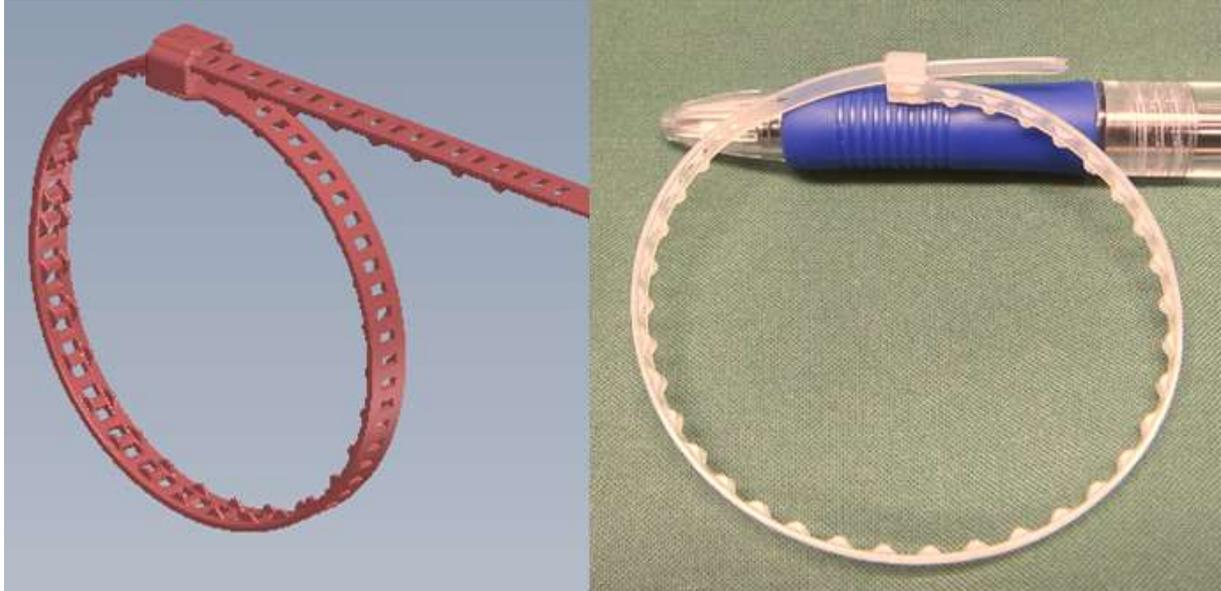


Figure 2 *The constructed implant formed a self-locking loop. Implant shown with ballpoint pen for size reference.*

In the *in vitro* test the self-locking loop could close the colonic lumen around the LapAid anvil in all attempts (n=10) (Fig 3).

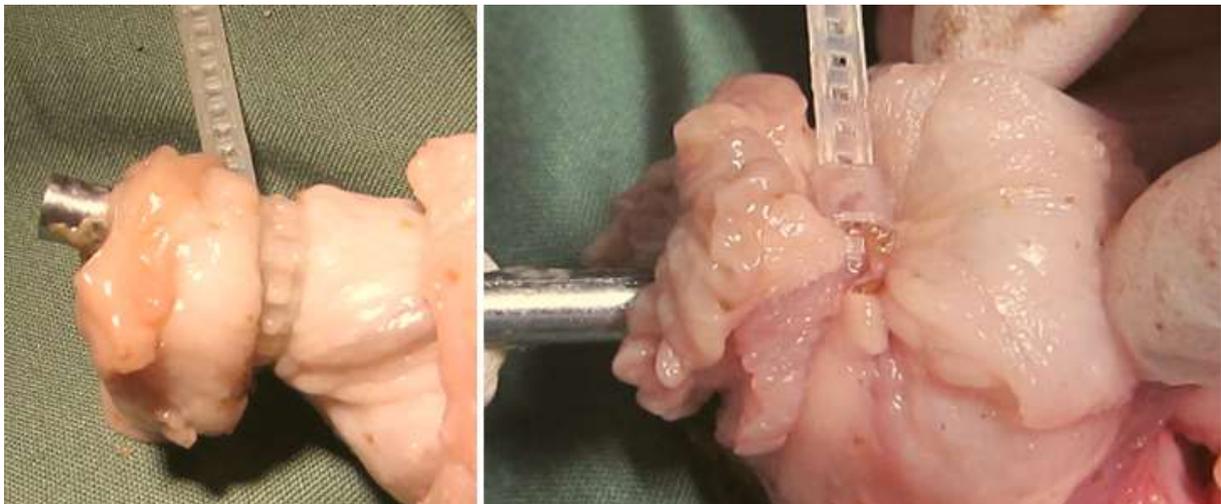


Figure 3 *In the in vitro test the implant could close the lumen around the anvil shaft.*

Subjectively, the device achieved a tight closure of the colon lumen and a satisfying tissue grip. No damage to the colon tissue adjacent to the implant was seen on visual inspection at removal of the self-locking loop. There were visual marks from compression of the colon tissue inside the tightened loop but no perforations were observed.

At removal of the loop it was noted that a small amount of tissue had been pulled into the locking case along with the flexible band as the loop was tightened.

In the *in vivo* test the self-locking loop could close the colonic lumen around the adaptive anaerobic anastomosis anvil (n=10), the circular stapler anvil (n=5) and the circular stapler trocar (n=5) (Fig. 4). The implant achieved a subjectively good tissue grip in all attempts. After resection of the tissue protruding beyond the closed loop, the compressed colonic tissue was firmly held in place by the closed loop in all attempts. Following cutting off the excess band protruding from the locking case, the anastomosis procedure could be continued without interference of the tightened implant in place in both Adaptive anaerobic anastomosis rings and circular stapler anastomosis.

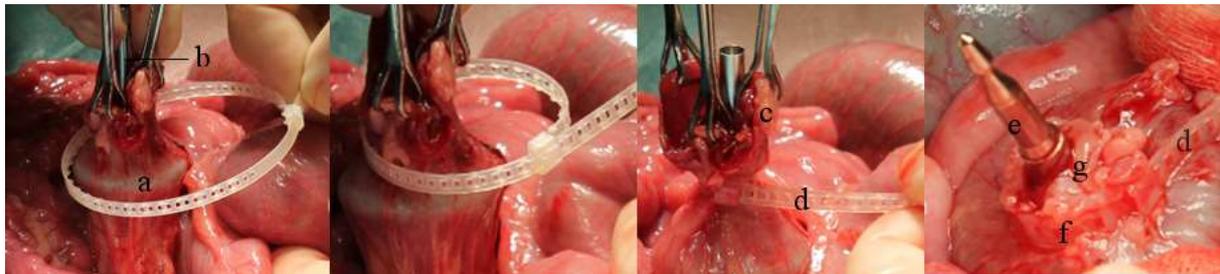


Figure 4 In the *in vivo* test the self-locking loop could close the colonic lumen around the anvil of both Adaptive Anaerobic Anastomosis rings and circular stapler as well as around the trocar of the circular stapler. a: The Adaptive Anaerobic Anastomosis O-ring on anvil inside bowel. b: The Adaptive Anaerobic Anastomosis anvil shaft. c: Excess tissue protruding beyond tightened loop, to be cut off. d: Excess band protruding from the locking case of the tightened loop, to be cut off. e: Trocar of circular stapler. f: Loop tightened around the trocar. g: Colon margin after excess tissue protruding beyond tightened loop is cut off.

DISCUSSION

This study demonstrated feasibility of using the self-locking short-term implant to close the lumen around the trocar and anvil used for colon anastomosis.

Adaptive anaerobic anastomosis is a new method under development for anastomosis of the colon. In Adaptive anaerobic anastomosis as well as in the traditionally used anastomosis method of circular stapling, the colon is sealed using a stapler or a purse-string suture. The self-locking loop was tested as an alternative technique for closure of the colon lumen around the Adaptive anaerobic anastomosis anvil both *in vitro* and *in vivo* and additionally around the anvil and trocar of the circular stapler *in vivo*.

In the *in vitro* tests, the colon tissue was visually inspected after removal of the tightened loop. There were visual marks of compression of the colon tissue inside the tightened loop, but no perforation or other damage was observed. Even if perforating damage to the colon tissue inside the tightened loop could potentially occur, it may be considered clinically irrelevant as this compression is temporary and the loop along with this tissue is subsequently removed.

It was noted in the *in vitro* testing that a small amount of tissue could be pulled into the locking case along with the flexible band as the loop was tightened. This did not appear to cause any complications in this pilot study, but the possible hazard of tissue interfering with the locking mechanism was recognised and should be considered in future testing.

This study mostly tested the use of a self-locking loop in the conjuncture with the Adaptive anaerobic anastomosis device, as well as a few tests with the circular stapler device. However, owing to the similarities in the tying areas of the respective anvils and trocars of the devices, we suggest the possibility to extrapolate the results from one to the other.

Subjectively, the self-locking loop achieved a tight closure of the colon lumen and a satisfying tissue grip. In this feasibility study time and duration of surgery was not studied in detail but it was the notion of the experienced surgeon conducting the *in vivo* tests that the self-locking loop had the potential to be time saving.

In all tests, the self-locking loop was subjectively easy to use. However, in the testing of the self-locking loop, some issues for design development were identified. A reduction of thickness of the tip of the flexible band may facilitate an easier introduction into the locking case. This measure could possibly be combined with enlarged tracks inside the locking case. A more rounded off design of the ventral aspects of the locking case may reduce the risk imposed by sharp edges. Additionally, it was suggested to add ridges to the outside of the locking case to enable a secure grip with forceps.

In the testing described here, the loop was mostly tightened by hand. Depending on circumstances such as hard-to-reach anastomosis, laparoscopic surgery or the risk of hands slipping if the implant gets wet, a suggested improvement was that the band could be held and tightened by the use of forceps or other instruments. For this purpose, a gripping handle of sorts could be added to the locking case, enabling a secure fixation of the locking case inside the jaws of a pair of forceps.

The self-locking loop is in principle similar to a cable tie. For conventional cable ties, combined tools for tightening and cutting of the tie are available. The construction and use of a similar device for tightening and cutting of this implant could be considered.

It was noted that for the self-locking loop to be usable with the smaller sizes of the surgical devices, such as the size 26 Adaptive anaerobic anastomosis LapAid, it is important that the circumference of the loop, fully tightened around tissue, remain sufficiently small to fit in the device housing. The size of the band is also of importance when it comes to potential laparoscopic use, where it should be able to be passed through a 10 mm port.

The number of performed tests in this feasibility study was low (10+20), which is a study limitation. However, no complication or negative interference with the used technologies for anastomosis was observed.

This study suggests improvements of minor details of the implant. Future study proposals include objectively scoring its ease of use and studying if the implant enables a shorter duration of surgery. Additionally, with low rectal anastomosis already being the technically most challenging (Shogan *et al.*, 2013), the possibility of using the band in a narrow space should also be tested. The use of the self-locking loop in the increasingly popular laparoscopic procedures also remains to be evaluated.

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