Buttressing of the Staple Line in Gastrointestinal Anastomoses: Overview of New Technology Designed to Reduce Perioperative Complications

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Key Words

Anastomosis • Staple line reinforcement • Bovine pericardium • Laparoscopy

Abstract

Background: Mechanical stapling devices are widely used in all fields of surgery as they can cut and sew tissue in a quick and easy manner. However, complications like bleeding or leakage at the staple line are frequently encountered and can have devastating consequences. Recent developments have led to the introduction of staple line reinforcement to reduce these complications. **Methods:** The literature has been reviewed to find and describe different methods to improve stapled resections and to give an extensive overview of the different staple line reinforcement materials, their properties and indications. **Results:** Several types of staple line reinforcement are available. Reinforcement of the staple line with membranes of either non-, semi- or absorbable material seems to be effective in minimizing the risk of leakage and bleeding by providing strength to the cut tissue. **Conclusion:** Application of staple line reinforcement material seems a promising technique in preventing leakage and bleeding at the stapled suture line, thus potentially reducing complications of gastrointestinal surgery. More studies are needed to investigate the exact properties, behavior and effects of the staple line reinforcement material.

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Introduction

In abdominal surgery, linear and circular cutting/stapling devices have been commonly used for many years. They allow for quick division and closure of tissue which shortens the operating time and are used for handling virtually all kinds of tissues [1]. For minimally invasive surgery, devices adapted to pass through the trocars are available. A wide array of staple devices from different companies are on the market. They vary in staple size, gap width and staple shape, each having its inherent drawbacks. Stapled resection and anastomosis have not shown fewer complications than hand-sewn procedures [2]. However, their use has become standard in many operations, because of the shortened operating time and reduced tissue manipulation.

Adjustments to the dimensions and mechanics of the devices have improved their functioning since the earliest types. However, complications still arise at the staple line when performing gastrointestinal resections. The type and frequency of complications depend on the performed resection and localization in the gastrointestinal tract. Additionally, a small part of the complications may be attributed to device failure [3].

A new approach to diminish complications is to use staple line reinforcement to buttress the staple line. In this paper, we attempt to illustrate this relatively new concept with its possible advantages and drawbacks.

Complications of the staple line, such as anastomotic leakage and hemorrhage, are frequently encountered. Specific complications are related to different sites in the gastrointestinal tract (table 1).

Resection and anastomosis of the stomach have been in use for treatment of malignancy or ulcerative disease. While nowadays hardly employed for ulcerative disease, partial stomach resections are increasingly performed as a part of bariatric surgery. Complications related to the stapled resection or anastomosis usually consist of bleeding and, to a lesser extent, of leakage. Perioperative bleeding rates may vary from 6 to 15% [4, 5]. Anastomotic leaks are encountered in 1–5.5% of the cases [6], with accompanying complications such as severe sepsis.

Stapled colorectal anastomosis compared with hand-sewn anastomoses have not shown to have a better outcome [2]. Leak rates in colorectal anastomosis may vary from 7 to 13% and mortality following leak can range from 6 to 40% [2, 7]. Formation of abscess and fistula due to dehiscence are a dreaded complication after colorectal anastomosis and are hard to treat. Obstruction or stenosis is encountered in 6–10%, but can usually be dilated with few clinical consequences [8].

Especially for colonic anastomosis, where leakage has the most devastating consequences, many attempts have been made to decrease the problem of anastomotic dehiscence by reinforcing the anastomosis and to facilitate construction.

Efforts to Reduce Anastomotic Complications

Technical aids for construction of anastomoses (table 2), such as the SBS tube and Coloshield, have not proven to be very successful. The SBS tube is a resorbable tube developed to give tissue support during construction for more adequate apposition and reduction of tension [9, 10]. The Coloshield is a latex or silicone tube designed for physically barring the anastomosis from bacterial load, reduction of tension and protection against intraluminal content [11–13]. Decrease in leakage and dehiscence were reported; however, complications such as erosion of the tube through the bowel wall and obstruction were seen [14].

The application of fibrin glue to seal off the colonic anastomosis has been tested in an effort to reduce leakage of intraluminal content and strengthen the anastomosis. In rat models, it appeared not to be a feasible technique [15–17]. In gastric resection, the application of fibrin glue to support and seal off the staple line seemed more suc-

Table 1. List of complications at staple line

Gastrointestinal site	Complications	Percentage	References
Colorectum	anastomotic dehiscence	7–13	2, 7
Stomach	bleeding	6–15	4, 5
	anastomotic leakage	1–4	4, 6

Table 2. Aids for colorectal anastomosis construction

Device	Mechanism	Objective
SBS tube	nonattached intraluminal degradable tube	facilitating suturing, temporary support
Coloshield	nondegradable intraluminal tube sewn to bowel	shielding from intestinal contents
Fibrin glue	glue application on the outer side	seal of seamline, supporting anastomosis

cessful, which was shown both in a swine model and a clinical series [18].

The design of the stapler device itself has varied regarding staple shape, width and height. Also, the number of staple rows, two or three, may vary. Which one of these variations is employed is the choice of the manufacturer. To our knowledge, no comparative studies addressing these issues exist. However, all types of surgical stapler devices suffer from a certain amount of malfunctions contributing to postoperative complications. Brown and Woo [19] reported fatalities associated with surgical staplers based on Food and Drug Administration malfunction and injury reports. Failure of the staples to form was reported most frequently, but also device failures and misfirings were regularly observed. In 40.2%, the device problems were followed by anastomotic failure. Nevertheless, it was noted that probably not all problems were reported. No relation with a specific brand of stapler device was determined.

Staple Line Reinforcement

Although considerably reducing operating time, stapled anastomosis has not been proven to be superior to hand-sewn anastomosis in terms of dehiscence, leakage and abscess formation [2, 20].

Fig. 1. Endoscopic stapler with staple line reinforcement material in laparoscopic Roux-en-Y gastric bypass before (a) and after stapling (b).

After resection and stapling, the integrity of the tissue will normally serve to prevent the staples from tearing through the tissue. When healing is completed, the staples either remain at the site of stapling or can be passed with the stools [21]. The staples do not elicit much cellular response. However, diseased tissue is often more fragile. Especially inflammatory processes reduce tissue strength due to decreased amounts of collagen [22–24]. Additionally, edema may form due to manipulation or disease. Decreased tissue strength combined with more manipulations will result in the staples tearing through the tissues, resulting in anastomotic leak or bleeding [25, 26].

During the operating procedure, bleeding at the staple line may hamper the visibility on the field of operation and prolong the operating time if extensive hemostasis is necessary. Especially in laparoscopic procedures, this can be an aggravating situation. As surgical staplers are used more frequently, it has become increasingly important to implement a reliable means to support fragile tissue to uphold the stapled line during the healing process and to provide a seal against bleeding and leakage.

A recent strategy employed to reduce and perhaps eliminate leaks and hemorrhage after gastrointestinal surgery is reinforcement of staples with various materials. A thin strip of buttressing material is incorporated between the staples and the tissue to ensure staple line security (fig. 1).

Application of reinforcement material in the staple line is thought to moderate tension of the staple line because it acts as a neutralization plate. Further, the but-

tressing material seals off the staple holes and narrows the spaces in between each staple. Thus, leakage, bleeding and tearing at the staple line can be reduced, especially in diseased and fragile tissue.

Juettner et al. [27] described the addition of polydioxane ribbon to the staple line in severe emphysematous lungs, and Itoh et al. [28] did a similar study with absorbable poly (L-lactic acid-co-epsilon-caprolactone) film. The use of a bovine pericardial strip to reinforce the staple line in lung surgery was later reported in the mid nineties by Cooper [29]. Persistent air leaks and bleeding after pulmonary resection were controlled by using a strip of bovine pericardium to seal off the staple holes and the pulmonary margin. In several studies, staple line reinforcement was reported to have positive effects on air leak and bleeding [30–32]. Use of the bovine pericardium staple line reinforcement technique has since become frequent in pulmonary surgery [31, 33].

Following the beneficial results in lung resections, bovine pericardium staple line reinforcement was also used in gastric resections in an attempt to reduce complications. The two studies investigating this technique showed positive results regarding leakage and bleeding [34, 35] which were markedly reduced.

The success of the use of bovine pericardium staple line reinforcement has led to the development of different variants of the reinforcement concept. The goal of reinforcement of the staple line is different for the various organs.

Table 3. List of different staple line reinforcement materials

	Material	Stapler type	Company
Nonabsorbable material	ePTFE (Seamguard)	linear	W.L. Gore & Associates, Inc.
Semiabsorbable material	bovine pericardium (Peristrips Dry)	circular linear	Synovis Life Technologies, Inc.
	porcine small bowel (Surgisis)	linear	Cook Biotech Inc.
Absorbable material	polyglycolic acid:trimethylene carbonate (Seamguard bioabsorbable)	linear	W.L. Gore & Associates, Inc.
	cellulose (Xcell)	linear	Xylos Corp.

Types of Reinforcement Materials

Several types of staple line reinforcement materials are available. They can be categorized as nonabsorbable, semiabsorbable or bioabsorbable. Semiabsorbable materials of bovine origin and nonabsorbable expanded polytetrafluoroethylene (ePTFE) have been the earliest available materials. However, the use of bioabsorbable staple line reinforcement materials has also gained ground.

The bovine pericardium and ePTFE types were first indicated for lung resections, for which they are still predominantly used, and later for gastric resections. Currently, the range of indications is being expanded to resection of solid organs such as the pancreas, liver and spleen, and in the future, indication for colorectal resections is expected as well.

Here, we describe the different types of staple line reinforcement materials available (table 3).

Nonabsorbable Material

ePTFE, Seamguard Staple Line Reinforcement Material[®]. This staple line reinforcement product is made of ePTFE (W.L. Gore & Associates, Flagstaff, Ariz., USA). The material is constructed like a sleeve that can be slid over both arms of the stapling device, without need for additional fixing to the stapler before firing. After firing, the material is released from the arms by pulling a ripcord. If necessary, the excess material can be trimmed. This product is available for both open and endoscopic procedures [36, 37].

Semiabsorbable Material

Bovine Pericardium, Peristrips[®] Dry. The bovine pericardium strip, Peristrips Dry (Synovis Life Technologies, Inc., St. Paul, Minn., USA), is temporarily attached to

the stapler with a gel. The gel is applied to the inner surface of both stapler arms after which the stapler is positioned over the bovine pericardium strips and locked. It takes approximately 2 min for the strips to adhere to the stapling device after which it is ready to be positioned and fired. With the bovine pericardium facing the tissue, the stapler device is fired and the tissue is cut after which the stapler can be removed. The remaining material will be incorporated by host tissue after healing.

The product has been indicated for resections of the stomach, the small bowel and the mesentery. Bovine pericardium staple line reinforcement material will be available for circular staplers in the near future.

Porcine Small Intestinal Submucosa, Surgisis[®] Staple Line Reinforcement. Staple line reinforcement manufactured of porcine small intestinal submucosa, Surgisis (Cook Biotech Inc., West Lafayette, Ind., USA), is another animal tissue buttress material suitable for anastomotic and nonanastomotic staplers. The material provides a bioscaffold for tissue growth. It is indicated for lung and gastric resections, but also for muscle flap reinforcement, repair of hernias and pelvic floor reconstructions [38, 39].

Absorbable Material

Polyglycolic Acid:Trimethylene Carbonate, Seamguard[®] Bioabsorbable Material. The Seamguard bioabsorbable staple line reinforcement (W.L. Gore & Associates) (fig. 2) is made of a synthetic fiber web that is composed of polyglycolic acid:trimethylene carbonate Maxon polymer. This copolymer is found in many applications of which resorbable Maxon sutures are the most well known [40–42].

Fig. 2. Absorbable polymer membrane Seamguard (W.L. Gore & Associates, Inc.) [46].

Like the ePTFE material, the Seamguard is formed like a sleeve to be fitted over the stapler arms and is released by pulling the suture that holds the sleeve in place.

Hydrolytic and enzymatic reactions lead to the breakdown of the material [43, 44] but invoke no antigenic response, which makes it strongly biocompatible. It maintains its strength for approximately 4–6 weeks, and after 6 months, the material is fully resorbed.

It has originally been indicated for soft tissue resections such as lung and gastric procedures, but recently, it has been approved for use in solid organs as well, such as the pancreas.

Cellulose, Xylos™ Surgical Reinforcing Material. Xcell SDMC surgical film (Xylos Corporation, Trenton, N.J., USA) is originally developed as a wound dressing. However, various medical applications are being developed from this biomaterial. This dry sterile material composed of microbially derived cellulose matrix has a multilayered, 3-dimensional structure [45]. The cellulose is produced by the *Acetobacter xylinum* bacteria. This biosynthesized cellulose has been processed into a resorbable form. Research is in progress to evaluate and construct it as a possible staple line reinforcing material used for gastrointestinal surgery.

Properties of Ideal Reinforcing Material

The outlined staple line reinforcement products are made of widely varying materials with different properties. To decide which would be the most ideal, it has been

Table 4. Important characteristics for staple line reinforcement material

Ease of use
Biocompatibility
Low infection potential
Flexibility and strength
Impermeability to fluids preventing leaks
Hemostatic properties
Low adhesion score

proposed that their properties should meet several demands as listed in table 4 [46].

A considerable difference exists between the various materials as far as these properties are concerned. For example, the ePTFE and Seamguard staple line reinforcement materials are very easily and quickly employed. Virtually no extra time is needed for the preparation and use of the material for both scrub nurse and surgeon. In contrast, bovine pericardium strips demand more handling time due to the required adherence to the stapler with a gel.

The presence of foreign material in the abdominal cavity should not lead to an increase in adhesions. No specific data are available for the different materials regarding this issue. However, Maxon polymer does not elicit an increase in adhesion formation when used for hand-sewn procedures in the abdominal cavity [41, 47]. Therefore, in the form of staple line reinforcement material, it is expected not to increase adhesions either, although no mention has been made of it in the existing studies.

The absorbable materials have the advantage that they do not form a permanent foreign body. This may avoid dangers such as infection of the material. Xenomaterials such as the bovine pericardium strips additionally carry the risk of animal source contamination. More importantly, as it is integrated but not absorbed by the host tissue, there is a reasonable chance of migration of the material. Problems encountered with the use of nonabsorbable materials are described later.

Experiences with Staple Line Reinforcement

Bleeding at the staple line in partial stomach resections is rarely life-threatening, but it can be very aggravating especially during laparoscopic procedures. Impairment of visualization and excessive bleeding can be

Table 5. List of studies supporting the efficacy of staple line reinforcement

Authors	Patients	GI site	Material	Benefit	Level of evidence
Angrisani et al. [34]	98	stomach	bovine pericardium	yes	level I
Shikora et al. [35]	250	stomach	bovine pericardium	yes	level II
Consten et al. [4]	20	stomach	PGA:TMC	yes	level II
Nguyen et al. [50]	34	stomach	PGA:TMC	yes	level I
Franklin et al. [51]	30	colon	PGA:TMC	yes	level I

GI = Gastrointestinal; PGA = polyglycolic acid; TMC = trimethylene carbonate.

prevented with the use of staple line reinforcement, thus avoiding long and complicated procedures [48]. Additionally, tearing of tissue can be avoided by supporting the staple line with reinforcement material. This was shown in animal studies where burst pressure was significantly increased in reinforced staple lines [49].

In colorectal anastomosis, the postoperative dehiscence of the staple line is a prominent and life-threatening issue. The role of staple line reinforcement is to reduce tension by spreading forces evenly, to reduce the space in between staples and to prevent tearing of the staples through the tissue. In pulmonary resections, air leakage through the staple line was proven to be reduced. Thus, closure of the spaces between the staples in gastrointestinal resections may also be a means to reduce leakage of minute amounts of intraluminal content and bacteria to the abdominal cavity as well as malignant cells in case of tumor resection.

In addition to pulmonary resections, bovine pericardium staple line reinforcement has proven to be successful in bariatric procedures in several studies [34, 35]. During laparoscopic Roux-en-Y gastric bypasses, blood loss was significantly decreased or even absent, thereby improving the visibility with fewer conversions and reduced operating time. Postoperative leakage or staple line failure was diminished. These studies showed the effectiveness of the concept in the short term.

Though not much experience has been gained with absorbable material, evidence of its benefit is accumulating.

In two separate prospective studies, application of absorbable staple line reinforcement material (Seamguard) in gastric resections as part of bariatric surgery showed a significant reduction in blood loss [4, 50] and no leakage at intra- and postoperative testing.

The effects in colorectal anastomosis have been investigated in a pilot study of 30 patients in which all anasto-

moses were performed with a linear stapler [51]. Although mainly safety and ease of use were demonstrated in this study, no bleeding and clinically apparent leakage could be seen at the staple line.

There is yet a limited number of level I studies to support the efficacy of staple line reinforcement (table 5). Currently, several trials are conducted for further investigation.

Complications Related to Nonabsorbable Material

Despite the positive results with staple line reinforcement, reports on complications also accumulated. Several cases have been published in which erosion and migration of the bovine pericardium into the lung was described after pulmonary resection causing pneumonia [52–56]. This complication was seen several weeks to months after resection. The same phenomenon of erosion and migration was seen in a patient after gastric resection. This patient was reported to expectorate fragments of the strip after 4 weeks [57] indicating that the material had migrated intraluminally. The intraluminal migration of the bovine pericardium may be due to an inflammatory reaction to the xenomaterial. No such cases have been described for ePTFE, which is observed to give less tissue response [37].

These problems with the bovine pericardium strip remaining in the operated area have led to the development of absorbable staple line reinforcement, which maintains the benefits, but avoids the complications due to the permanent and allogenic nature of the bovine pericardium [58, 59]. No such undesirable side effects have been described for absorbable reinforcement material.

Discussion

Resection and anastomosis of abdominal organs with stapler devices have become commonplace in surgical practice. Not only in open procedures are these devices frequently used, but with the rapid development of laparoscopic procedures, the use of endoscopic staplers has increased dramatically. Introduction of the endostapler has greatly facilitated laparoscopic procedures. Although the stapler devices in general shorten operating times, the number of complications has not been reduced. The introduction of staple line reinforcement may prove a solution to the problem of leakage, bleeding and dehiscence as the results so far have shown. However, choice of material is to be considered carefully. Although all types of staple line reinforcement seem equally adequate in reducing complications at the staple line, the material itself can cause problems. As described, bovine pericardium material is prone to erosion and migration due to inflammatory response and carries the risk of animal source contamination. Further, the demanding handling characteristics make it difficult to employ them quickly at the operating table. Erosion of the nonabsorbable ePTFE graft has never been reported. This may be due to the low host response to the material [37] as it is biocompatible, unlike bovine pericardium. Nevertheless, ePTFE will remain at the site of implantation even after its function is lost. The Seamguard offers a possible solution to this, being manufactured of biodegradable material: while the wound is healing it maintains its strength, but when the healing is complete, the material gradually dissolves. The polyglycolic acid:trimethylene carbonate (Maxon) polymer has a long history as absorbable suture. It is resorbed quickly and has no tendency to induce adhesions or other adverse events [41, 47]. Additionally, no risk of animal contamination exists and it is highly biocompatible.

Moreover, simple loading on the stapler ensures that it hardly takes any additional time to employ this type of staple line reinforcement.

The various studies suggest that there is a reduction in perioperative complications with the use of absorbable staple line reinforcement material. This may lead to a lower need for blood transfusion with a decrease in its associated risk. Fewer reoperations for postoperative bleeding or leakage may be expected as well, thus reducing the hospital stay. Increased recurrence of malignancy is seen after leakage of colorectal anastomosis, which has been attributed to spill of tumor cells through the anastomotic site [60–63]. If the incidence of leakage can be reduced as a result of staple line reinforcement, it seems likely that there would be a positive effect on tumor recurrence as well. All these aspects might lead to lower costs additional to the benefits for the patient.

Although the studies on the use of the various staple line reinforcement materials show a decrease in complications, it is not clear if any of them are superior, as no extensive comparative studies exist.

Conclusion

Staple line reinforcement technique is an effective technique in reducing perioperative complications in stapled resection and anastomosis. Different staple line reinforcement materials are available. In early experimental and clinical studies, absorbable staple line reinforcement material seems to have considerable advantages over non- or semiabsorbable staple line reinforcement. Not much experience has been gained with absorbable staple line reinforcement until now. However, as available results are very promising, this new technique needs further investigation.

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