Optimizing stapled gastro-intestinal anastomosis: TOP stapler concept explained

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Introduction

In intestinal surgery, surgical staplers are often used to construct an anastomosis, i.e. to make a connection between two ends of intestine. In circular stapling, a circular ring of staples is released in one action, holding both intestinal ends together and restoring continuity of the digestive tract.

Although the design of staplers and (peri-) operative conditions have been optimized in the last decades, still 3-19% of operations with stapled anastomoses lead to postoperative anastomotic leakage, leading to re-operation, morbidity, mortality, and high costs[1]. Postoperative stricture formation at the anastomotic site and adhesions pose additional challenges and threats to the patients.

By improving design of the stapler apparatus, complication rates can be reduced, hereby reducing morbidity, mortality and health care expenses.

Ischemia at the anastomotic site leads to impaired anastomotic healing leading to leakage, stricture formation, and adhesions

Healing of a digestive tract anastomosis outside the peritoneal or pleural cavity (for example a cervical esophago-gastrostomy, or a low colorectal anastomosis) is more frequently impaired than healing of an intra-peritoneal or intra-pleural anastomosis. Impaired healing may lead to leakage and stenosis[1-8].

Observations in experimental anastomoses

In an experimental study in rats, jejunal inverted anastomoses either inside the peritoneal cavity or outside the peritoneal cavity (i.e. pre-fascial, subcutaneous, see Figures 1, 2) were compared. Different anastomotic extra-mucosal suturing techniques using 8-0 Vicryl led to different results.

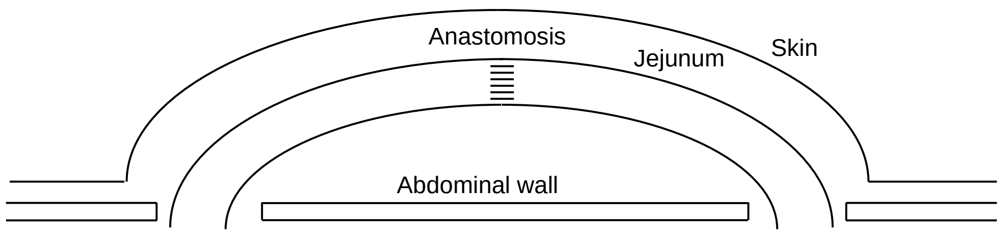

Figure 1 *Schematic drawing of the experimental jejuno-jejunostomy in an extra-anatomic position, outside the abdominal cavity.*

Figure 2 Experimental pre-fascial jejuno-jejunostomy in rat before skin closure

Blood supply of the jejunal cut ends before constructing the anastomosis was uncompromised.

When anastomoses were performed with a standard running suture technique, about 30-40% of anastomoses in the subcutaneous environment developed anastomotic leakage, whereas in anastomoses intra-peritoneally no postoperative leakage occurred. On planned reoperation after 3 or 7 days, dense and extensive fibrous adhesions completely covered the anastomotic line in the anastomoses of the subcutaneous environment, in the intra-peritoneal group the anastomoses were covered by adhesions of intestines, mesentery, omentum, or peritoneum. In occasional early reoperation, within a few hours after initial operation, edema and ischemia (white/pale appearance) of the anastomotic area was noticed, deeply indented by the running suture[9,10].

When suturing technique was changed and a limited number of transverse interrupted sutures were used for the anastomosis, with mild tension, no leakage occurred in both groups. At reoperation after 3 or 7 days, the number and extent of adhesions was obviously reduced, both in the subcutaneous environment and intraperitoneally: only some thin, flimsy adhesions were present and most parts of the anastomotic lines were not covered.

There were no differences in bursting pressure, tensile strength and hydroxyproline content and concentrations in non-leaking anastomotic segments inside and outside the peritoneal cavity[10,11].

Changing anastomotic technique in cervical esophago-gastrostomy and colo-rectal anastomosis might reduce leakage, stricture formation and adhesions

Impaired anastomotic healing of the cervical esophago-gastrostomy and the low colo-rectal anastomosis can be caused by local ischemia[6,11-16,39,40]. A second factor contributing to impaired anastomotic healing of these anastomoses is hypothesized to be the absence of reactive, vascular tissues (this paper).

As seen in our experimental study, anastomotic technique may induce ischemia, leading to poor healing and extensive fibrosis/ scarring. In another experimental studies on suturing techniques, equivocal results were observed[17,21].

Ischemia of an anastomotic line can lead to focal necrosis and leakage; leakage predisposes for stenosis[7,18-24]. However, ischemia is also a potent adhesiogenic factor[25,26]. When ischemia at an intestinal anastomotic line occurs, adhesions develop and cover the ischemic area. These adhesions of reactive, vascular tissues (intestines, mesenterium, omentum, and mesothelium) provide valuable additional vascular supply and thereby aid in anastomotic healing[19,25,27-30]. When preventing these protective adhesions by coverage of digestive tract anastomoses by avascular omentum, peritoneum, rubber or polyethylene wraps, very high leakage rates result, due to partial necrosis and/ or infection of the anastomosis[27,28,30-32]. A free peritoneal patch around an anastomosis increased stricture formation of a cervical esphagogastrostomy[33].

In the running suture technique, the intestinal cut ends are spirally encircled by the suture filament. Postoperative edema of the anastomotic area, traction on the anastomosis or application of too much tension while suturing, leads to constriction and ischemia of the entwined intestinal wall[6,17,21,34] . Also, the circular continuity of the suture filament precludes expansion in radial direction at the anastomotic site, thereby interfering in normal peristalsis and possibly adding to stricture formation.

In the interrupted suture technique, the intestinal tissue surrounding the sutures is appositioned without constriction, even when the sutures are tight.
Also, blood vessels in the intestinal wall are mainly oriented in the longitudinal direction (figure 3). The transverse interrupted sutures impose the least possible interruption of the vascularisation of the anastomotic area. Moderate suture tension provides the best histologic and microangiographic results[35]. Furthermore, the anastomotic area still has the opportunity to expand in a radial direction.

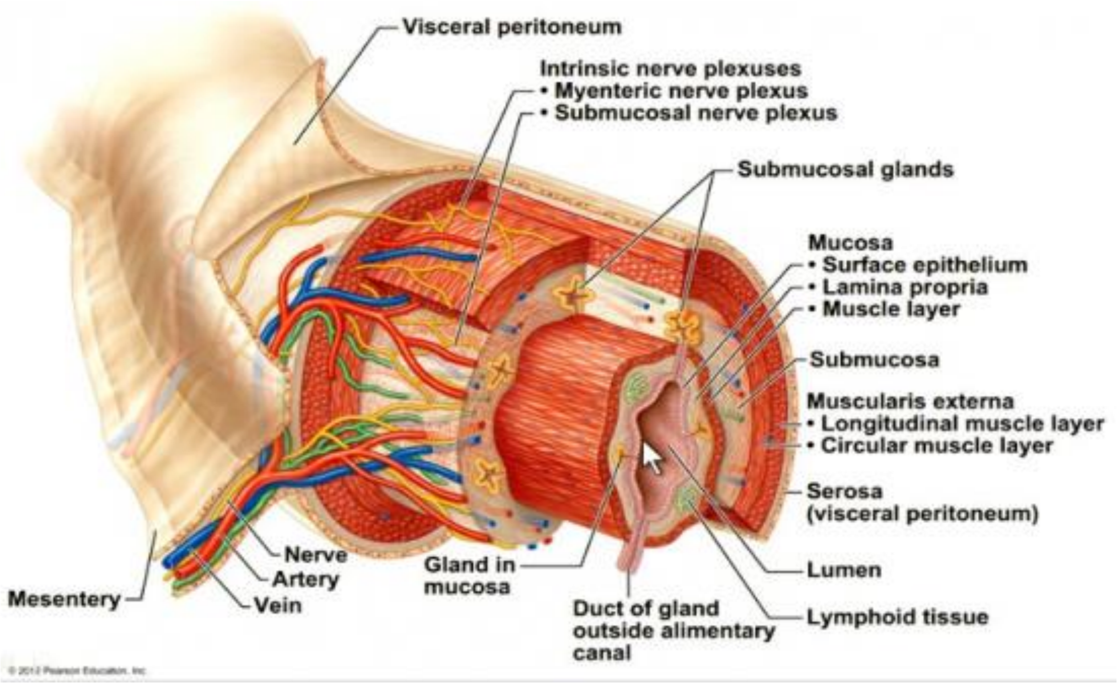

Figure 3 Schematic picure showing the longitudinal orientation of the intestinal bloodvessels (drawing: Pearson Education Inc).

In our experimental series, the protective effect of environmental factors was clearly demonstrated. In the subcutaneous environment of the experimental study, reactive vascular tissues are not present. Ischemia occuring at the anastomotic line cannot succesfully be covered by vascular adhesions, leading to high leakage rates when using the running suture technique. Intraperitoneally, anastomoses were completely covered by vascular adhesions of intestines, omentum, and mesenterium.

When anastomotic technique was changed, transverse interrupted sutures with a mild to moderate tension technique were used, aimed at reducing ischemia of the anastomotic line, no leakage developed both intra-peritoneally and subcutaneously. Lacking the adhesiogenic stimulus, the amount and extent of adhesions was vastly reduced.

Since in the cervical oeophago-gastrostomy or the low colo-rectal anastomosis reactive, vascular tissues are not available (comparable to the subcutaneous experimental position) for protection of the anastomosis, extra care should be taken to prevent ischemia of the anastomotic line.

If anastomotic technique can be adjusted so that ischemia at the anastomotic suture line can be reduced as much as possible, healing of the cervical esophago-gastostomy and low colo-rectal anastomoses might be less frequently impaired[36].

Conventional (ETE) stapling design

Stapling lines in standardly used anastomotic (e.g. ETE) stapling devices contain two or three rows of interdigitating and overlapping staples, parallel to the cut end (see *Figure 4*), leading to a watertight closure. In development of gastro-intestinal staplers, watertight closure was deemed necessary since the first stapling devices were tested in everting gastric anastomoses[37]. Staples are used to join the intestinal tissues.

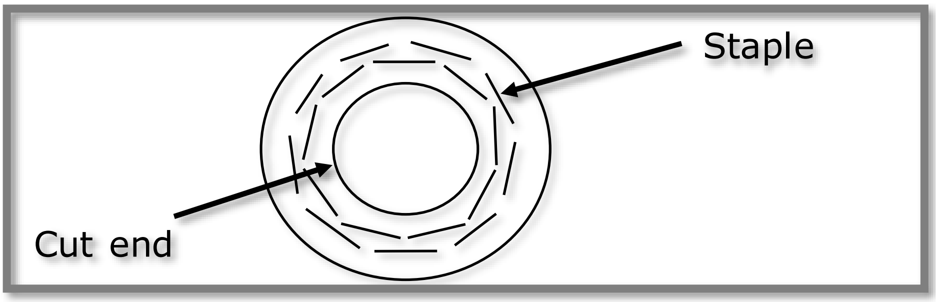

Figure 4 Schematic trans-sectional drawing of a commonly used EEA stapling line: two rows of interdigitating and overlapping staples.

In these first stapled everting anastomoses, highly acidic gastric mucosa was apposed. Opposing mucosa layers do not blend or adhere due to its regenerative nature. High compression staples induced necrosis, followed by fibrosis forming a connection between anastomosed mucosal layers.

The current staplelines obstruct bloodflow to the anastomotic area and intestinal cut ends due to design:

- The anastomotic area is completely occupied by double rows of tight, overlapping staples, leaving no room for expansion of tissue locally or radially.
- Staple compression force exceeds local tissue perfusion pressure[38], exacerbated by postoperative edema of the anastomotic area.
- The orientation of the staples is perpendicular to the main intestinal vessels.

This design therefore leads to ischemia, possibly leading to necrosis, fibrosis, and stricture of the anastomotic area. Clinically adhesions, leakage, and stricture might ensue.

Adjusting stapling design for optimal healing

In the inverting intestinal anastomosis usually performed nowadays, easily confluent serosal layers are apposed, as opposed to the highly acidic gastric mucosa apposition in the first stapled everting anastomoses.

The cut end in our experimental study provided enough inflammatory reaction to heal the anastomosis. Since necrosis (inducing fibrosis) is not necessary in the inverting anastomosis, it is possible to focus on optimizing (wound-) conditions at the anastomotic site, in order to prevent aforementioned complications.

A new stapler is proposed with two rows of staples of different orientation:

A first, inner, staple line is proposed directly adjacent to the cut end of the intestine, with staple orientation parallel to this cut end (*Figure 5*). Purpose of this staple line is to prevent hemorrhagic complications of the cut end of the transected intestines. Pressure of compressing the staples is adjusted to the local needs: at the cut end, the compressing force is above tissue perfusion pressure. In anastomotic healing this line will become necrotic. This staple line is hemostatic and called the anastomotic <u>sealing line</u>.

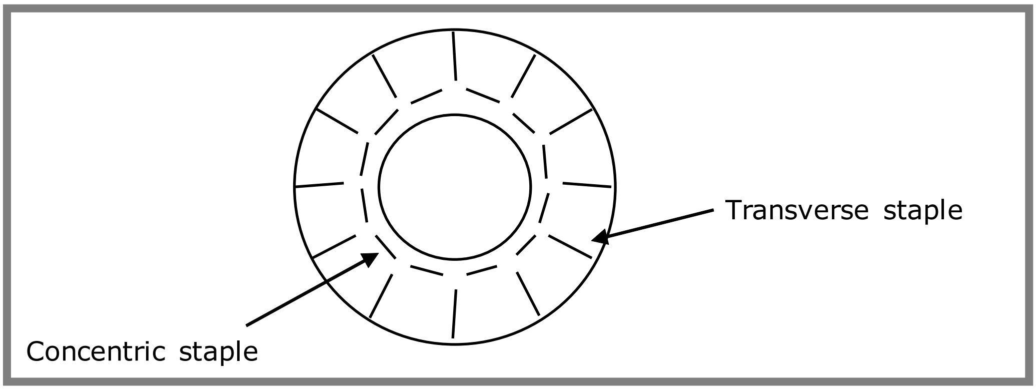

Figure 5 Schematic trans sectional drawing of proposed new 'TOP' staple line alternative configuration:
Inner line of conventional staples ensures hemostasis (sealing line).
Outer staple line orientation and lower staple compression pressure ensure maximal perfusion at the anastomotic site (healing line).

Directly adjacent to this sealing line, an outer staple line of transverse staples, transverse to the cut end and oriented along the long axis of the gut, optimizes blood flow to the anastomotic area (Figure 5). Pressure of compression is adjusted, i.e. diminished as compared to conventional stapling, in anticipation of post-surgery edema. Only apposition of intestinal tissue is aimed for with this staple line. This staple line is called the anastomotic <u>healing line</u>.
Following necrosis of the inner staple line, the radially oriented staples have a second advantage of enabling radial distension of the bowel wall when passing sizeable bowel contents.

The configuration with concentric inner staple line and a radial outer staple line is called the Tensile & Optimal Perfusion (TOP) stapler.

See also the following documents:

- *Development of the experimental TOP stapler prototype*
- *Experimental testing of the TOP stapler prototype*

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