

Early protective ileostomy closure following stoma formation with a dual-sided absorbable adhesive barrier

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Summary

Background Usually, a temporary and diverting ileostomy is reversed not earlier than 8 weeks because of adhesions and edema along with vulnerability of the intestinal wall. We aimed to evaluate whether early closure of loop ileostomy during index admission using an antiadhesive bioabsorbable membrane is feasible and safe.

Methods We included all patients undergoing ileostomy formation due to conventional or laparoscopy-assisted colorectal resections and stoma closure within 2 weeks using a dual-sided film between January 2011 and June 2012. Evaluation comprised patients' demographic and disease characteristics, with objective to assess the rate and time interval of planned early stoma closure and length of hospital stay. Complications were divided related to stoma formation and closure. Follow-up data were collected by defined oncological aftercare.

Results A total of 14 patients with a median age of 66 years were included. Median length of hospital stay was 27 days (range, 19–34 days), time between stoma formation and closure was 10 days (range, 8–14 days), and time of discharge was 8 days (range, 6–10 days) after stoma closure. Two complications related to stoma formation occurred in the form of one parastomal hernia and one wound infection. Complications related to stoma closure occurred in five patients—one small bowel anastomotic

leak in one patient and incisional hernias at stoma site in four patients.

Conclusion Early ileostomy closure at index admission using an adhesive barrier appears to be a safe alternative to traditional closure.

Keywords Early stoma closure · Loop ileostomy closure · Closing of small bowel stoma

Introduction

Anastomotic leakage is a life-threatening complication in colorectal surgery. Current prospective randomized studies strongly recommend defunctioning loop ostomy as a routine procedure in patients undergoing low rectal cancer surgery [1]. Diverting stoma formation is also commonly performed as a part of the operations for inflammatory bowel disease to minimize the impact of sepsis from an anastomotic leakage [2, 3]. However, it is remarkable that various studies have reported an overall stoma-related complication rate of 21–70% [4]. There is no clear evidence on whether ileostomy or colostomy is the better technique to adopt [5]. The reported outcomes were not statistically or clinically significant different except for higher rate of stoma prolapse and parastomal hernia in patients with colostomy [6]. The frequency of parastomal herniation before, and incisional herniation after, the closure of a transverse colostomy in a randomized study supports the choice of loop ileostomy [7].

The ideal time for ileostomy closure remains controversial. Reversal is usually performed not earlier than 8–12 weeks after the primary operation because of adhesions, vulnerability, and edema of the intestinal wall. The time between ostomy construction and closure is often longer than initially planned, and approximately 20% of temporary planned ostomies have never been closed [8]. Stoma-related complications can occur (retraction,

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necrosis, prolapse, infection, stenosis, peristomal skin irritation, high output with dehydration, and so on) impairing patients quality of life [8]. We aimed to make this time shorter, ideally less than 2 weeks, to reduce the frequently occurring stoma-related morbidity in these patients and thus improve quality of life and reduce length of inpatient stay. Two weeks are long enough for assurance of anastomotic healing [9]. Another point is that morbidity of patients following closure of a temporary ileostomy during or after the beginning of adjuvant chemotherapy or radiochemotherapy is much higher than in patients receiving no additional therapy [10]. Morbidity might possibly be lowered to the level of patients receiving no additional therapy if ileostomy closure was performed before the beginning of an adjuvant therapy [10]. In practice, stoma closure is often delayed after finishing adjuvant therapy, and this can last 6 months [8]. The only available randomized prospective trial comparing early with late ileostomy closure reported an increased rate of wound infections due to early ileostomy closure compared with traditional time of reversal [11]. The results of a retrospective study underlined these findings [12].

We aimed to investigate the impact of using a dual-sided, absorbable, and antiadhesive film (Prevadh[®], Covidien™ Brunn am Gebirge, Austria) around the stoma to form an adhesion barrier and make early stoma closure possibly easier, feasible, and safer. Prevadh[®] is an absorbable barrier to prevent formation of adhesions in abdominal surgery, and the material gets completely absorbed within 2 weeks. The antiadhesive-prepared ostomy should therefore be taken down within 14 days. Thereafter, dense adhesions emerge, and it is better to wait at least 8 weeks if the time frame of 2 weeks cannot be observed.

Methods

Between January 2011 and June 2012, all consecutive patients undergoing a loop ileostomy to relieve a colorectal or coloanal anastomosis were considered for inclusion in our study. We conducted a retrospective evaluation of prospectively collected data in a single-center observational study design. Only if early reversal of ileostomy within 2 weeks after construction could be performed, patients were included in the study. Dropout patients were also recorded for reasons of exclusion. Evaluation comprised demographic and disease characteristics. Patients with both benign and malignant diseases were included regardless whether the latter ones received neoadjuvant radiochemotherapy. The level of colorectal or coloanal anastomosis also had no influence in recruitment. All patients consented in written form for the study after receiving comprehensive information including the option of delayed ostomy closure. Two suitable patients decided in favor of delayed closure because of the risk for potential delayed anastomotic leaks after early closure and could not be included in our study. Data were collected from patients' medical records and medical files.

All initial operations were performed by one experienced colorectal surgeon (more than 1000 open and 300 laparoscopic procedures) in the same technique of anastomosis creation using a circular stapler. A transverse colectomy was performed if a low colorectal or coloanal anastomosis was required. The exact localization for the scheduled ileostomy before the patients underwent colorectal resection was always preoperatively marked by stoma nurses at the right side of the abdomen considering the patients supine, sitting, and standing positions and the level of the belt. A preferably terminal ileum loop was tunneled at the mesenteric side (Fig. 1), and a 12 × 12-cm Prevadh[®] dual-sided film was placed around the stoma loop (Fig. 2) through the abdominal wall and through the right rectus muscle. Prevadh[®] film has two sides with different structures and is completely absorbed within 15 days. The smooth nonporous side is composed of atelocollagen type 1, polyethylene glycol, and glycerol and forms the adhesion barrier, which is why this side must be oriented to the abdominal wall. The porous side consists only of atelocollagen type 1 and is directed to the small bowel. The antiadhesive barrier can be adhered with the supplied maltodextrin solution. In laparoscopy-assisted resections, the Prevadh film was brought in from outside the abdominal cavity and wrapped around the

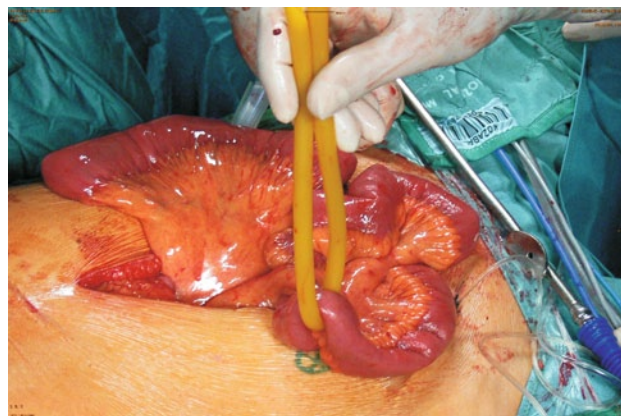


Fig. 1 Underpinning of stoma loop on mesenteric side

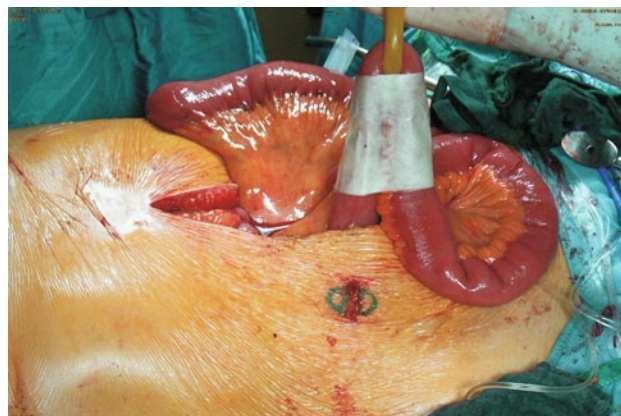


Fig. 2 Prevadh[®] wrapped around the stoma loop

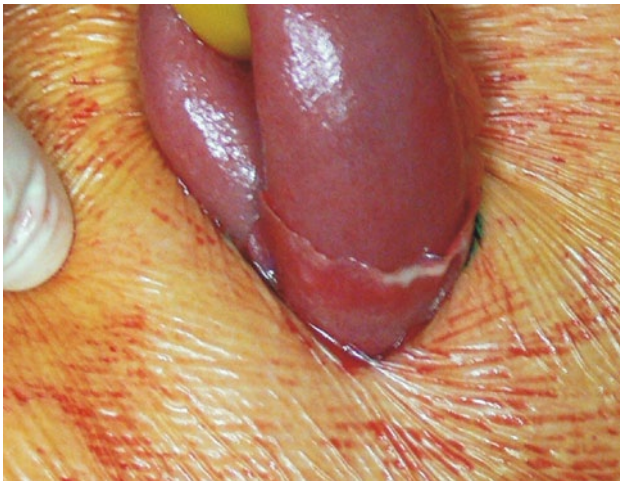


Fig. 3 Small bowel loop with laparoscopic Prevaadh® application

small bowel (Fig. 3). The last surgical step included fixing the ileostomy by mucocutaneous everting sutures. Colorectal anastomotic healing was examined by clysterizing water-soluble radiographic agent and direct anastomotic visualization by endoscopy.

Early stoma closure was always performed in the same standardised way: an antibiotic prophylaxis was routinely given 30 min before operation (sultamicillin, Unasyn® 3 g). After peristomal skin incision, the ostomy was mobilized and preliminary closed by sutures. The mobilization of the loop at takedown of the ileostomy was easy and fast, and the initially Prevaadh®-covered part of the small intestine did not require resection because the adhesive barrier was completely absorbed at this time. Then, the bowel was cautiously prepared, and the ostomy was consequently sparingly resected to avoid stenosis after simple closure of the anterior wall. Afterward, a handmade, two-rowed, end-to-end anastomosis was performed. The fascia closure (anterior rectus sheath) was performed in transverse direction with absorbable sutures.

The evaluation aimed to assess the frequency of ostomy-associated complications and we differentiated between ostomy construction and closure-related complications, which were also grouped according to Clavien Dindo's classification [13]. We made a distinction between early (< 30 days) and late-term complications (> 30 days).

Furthermore, we documented the time between ostomy construction and closure, the time between closure and discharge, and the overall length of hospital stay.

Oncological patients were staged preoperatively in accordance with oncological guidelines, and all patients with benign indications suffered from complicated diverticulitis and underwent a computed tomography scan of the abdomen and colonoscopy to rule out further pathologies.

Table 1 Complications due to ileostomy formation

Complications due to ileostomy formation	Clavien Dindo's classification
<i>Study patients: n = 14</i>	
Peristomal wound infection: 1	IIIa
Stoma prolapse: 0	
Stoma retraction: 0	
Stoma necrosis: 0	
Stoma stenosis: 0	
Parastomal fistula: 0	
Parastomal hernia: 1	I
Stoma bleeding: 0	
<i>Out of study: n = 2</i>	
One patient with fistula from transverse coloplasty not suited for early stoma closure	
One patient incurred a pulmonary embolism and died 3 days after colorectal resection	

Follow-up data were collected on all oncological patients in accordance with the S3 guidelines [14]. Defined oncological aftercare was provided quarterly during the first 2 years and semiannually thereafter for up to 5 years. In patients with benign diseases (diverticulitis), a routine control colonoscopy was performed 1 year after resection. Descriptive and basic statistical evaluation was performed.

Results

During the observation period of 18 months, 16 patients underwent a loop ileostomy for fecal diversion after creation of colorectal or coloanal anastomosis. Two patients could not be included in the study. One patient died of a pulmonary embolism 3 days after bowel resection. The other patient incurred a colonic fistula of the transverse coloplasty, which was detected in the rectal enema of radiographic agent and required postponing the stoma closure. This patient underwent ostomy reversal after 180 days and endoscopically successful treatment of the fistula. Two more patients refused the participation and decided upon delayed ostomy closure.

Fourteen patients fulfilled the inclusion criteria (eight male and six female). The median age was 66 years (range, 43–86 years), and the median body mass index was 26.7 kg/m² (range, 20.4–31.8 kg/m²). Patients' disease characteristics are shown in Fig. 4. Adjuvant chemotherapy was indicated in nine patients and was initiated in eight patients after a median of 4 weeks after primary operation and 2 weeks after ostomy closure. One patient incurred a leakage of the reversed ileostomy 5 days after stoma closure and required a further operation that delayed adjuvant chemotherapy for 6 weeks after colorectal resection.

Complications related to ostomy construction are shown in Table 1, and complications related to ostomy

Fig. 4 Patients' disease characteristics

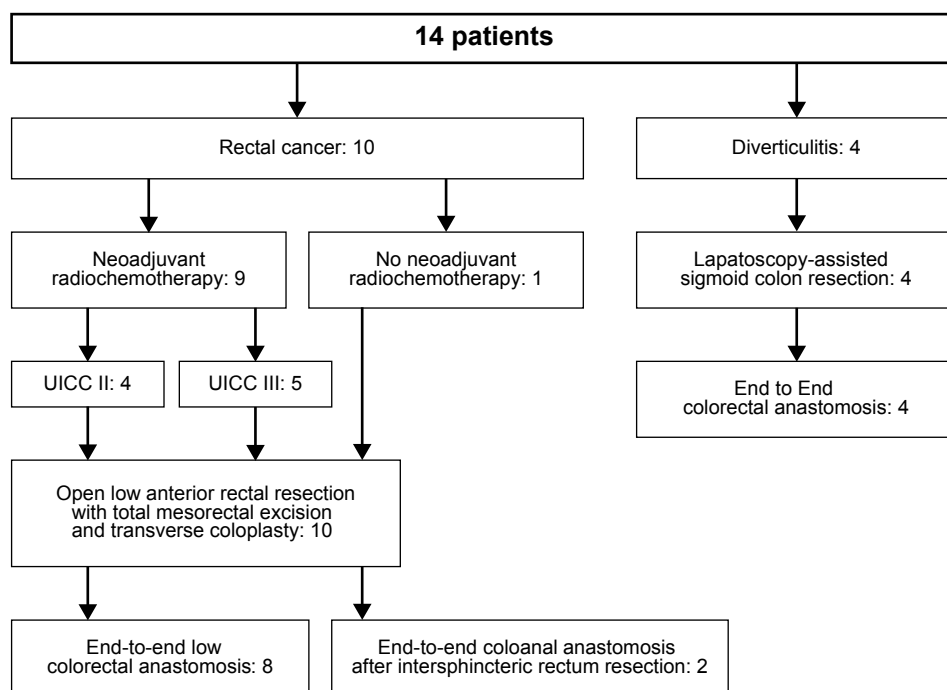


Table 2 Complications due to ileostomy closure

Complications due to ileostomy closure	Clavien Dindo's classification
Wound infection: 0	
Bleeding/hematoma: 0	
Small bowel obstruction: 0	
Anastomotic leak: 1	IVa
Stoma site hernia ^a : 4 ^b	IIIb

^aMedian time of occurrence: 10 months (range, 4–21 months)
^bThree after open and one after laparoscopic surgery

Table 3 Morbidity and mortality

	Included patients (n=14)	Excluded patients (n=2)
<30-Day morbidity	n=3 (21.4%) One parastomal wound infection One parastomal hernia One small bowel anastomotic leak after stoma closure	n=1 Colonic fistula from transverse colectomy
>30-Day morbidity	n=4 (28.6%) Four incisional hernias on stoma site	0
<30-Day mortality	0	n=1 Pulmonary embolism
>30-Day mortality	0	0

closure, in Table 2. Morbidity and Mortality are depicted in Table 3.

Reversal of ileostomy was performed after a median of 10.4 days after primary operation (range, 8–14 days). Patients' dismissal was at a median of 8.1 days after stoma reversal (range, 6–10 days), and the median length of hospital stay was 26.9 days (range, 19–34 days). The

time exposure for the placement of the adhesive barrier was on an average of 8 minutes.

The median follow-up duration was 26 months (range, 18–36 months). Overall follow-up data were made available for all 14 patients.

Discussion

A loop ileostomy is a common adjunct to formation of a low colorectal anastomosis, but it is not without significant physical and psychological morbidity and financial cost [8]. Feasibility and safety of early ileostomy closure during the index admission has been previously reported [11, 15–18]; however, some authors documented increased rate of wound infections [11, 12]. Regarding these results, we went without a control arm and aimed to investigate whether the usage of an absorbable adhesive barrier can make an early ostomy closure more safe and potentially reduce wound morbidity. We did not record a wound infection after stoma reversal. Timing of ostomy reversal within two weeks after stoma creation is essential because of the subsequent absorption of the film with following formation of adhesions to the bowel.

Mabrut et al. [19] confirmed in their prospective multicenter study the safety of Prevadh® adhesion barrier in different kinds of abdominal surgery and suggested that it might prevent adhesion formation on peritoneal injured surfaces. This was the reason for our decision to prove this material for early stoma closure. However, large randomized controlled trials are necessary to prove real effectiveness on clinical long-term outcomes.

Two previous studies have evaluated the usage of a defined bioabsorbable adhesion barrier for stoma closure. In these studies, early stoma closure was performed

at a median of 37 days [20] and 21 days [9], respectively, and the results suggest reduced peristomal adhesions and facilitated early stoma closure without increased morbidity. Neither the complications due to ostomy formation nor those of ostomy reversal in our patients seemed to be associated with the tested adhesive barrier. The one peristomal wound infection after ostomy formation occurred in a contaminated field and could be managed conservatively by using antiseptic dressings after initial wound debridement without anesthesia. The anastomotic leak was conditioned by an impaired blood supply of the mesenteric-sided anastomotic area owing to the mesenterial sutures for covering the staple line.

The dual film can easily be used in open and laparoscopic procedures. Whether the adhesion barrier should better be rolled up and slid through a trocar for laparoscopic placement or whether the film should better be put in place from outside the abdominal cavity, as we have done, has not been examined yet.

Another advantage of early ostomy closure is the potential reduction of the length of hospital stay and ostomy reversal during index admission [18]. This is desirable because in our experience, education for ostomy treatment at home might be protracted and difficult. However, length of hospital stay in our cohort of patients was long because of various duration of preoperative inpatient staging and tumor board discussion and relatively late dismissal after stoma closure (mean of 8 days). Our patients were closely monitored after stoma closure to perceive late-term complications due to colorectal or coloanal anastomosis and complications of small bowel anastomosis. It is worth noting that the one small bowel anastomotic leakage in our series occurred 5 days after stoma closure. However, earlier discharge after a median of two days after ileostomy reversal is considered to be safe and achievable [21]. No late-term leaks or other complications due to colorectal and coloanal anastomosis after stoma closure occurred in our series. We concluded that early stoma closure does not pose a risk for safe and durable healing of colorectal and coloanal anastomosis. The patients leave the hospital without ostomy, and they need only one admission. We have not proved cost-effectiveness, but we expect potential savings.

In nonrandomized studies, patients were selected for early stoma closure if they were in a good condition and did not take steroids [16]. Exclusion criteria in a single prospective randomized trial were signs of active infection and organ failure in the postoperative period or radiological signs of anastomotic leakage [11]. Within our recruitment time, two patients could not be included (pulmonary embolism and colonic fistula). All other patients providing a written consent were consecutively included regardless of their underlying disease, general condition, and drug treatment.

How to prove anastomotic healing and rule out postoperative leakage before stoma closure is discussed controversially. Alves et al. [11] performed a water-soluble contrast examination through the ileostomy 7 days after

surgery to avoid a transanal approach with any potential anastomotic injury. Our ways of examining the anastomotic integrity were transanal radiographic and endoscopic investigation [22] without any documented complications or anastomotic injuries. Radiographic filling using a balloon for sealing might be tricky in cases of coloanal or low colorectal anastomosis. We prefer to check the anastomosis with rectoscopy in these cases. We routinely perform intraoperative rectoscopy due to colorectal resections for monitoring the anastomosis, and we are not afraid that anastomotic injuries can occur if early postoperative gastrointestinal endoscopy seems to be required for detection and treatment of anastomotic bleeding. In cases of delayed stoma closure (>6 weeks), the continence was checked by stoma nurses using an enema of semolina pudding. We spared this procedure because of the scheduled early ostomy reversal. We did not want to jeopardize the anastomotic healing. No late anastomotic leak occurred either in coloanal or in colorectal anastomosis.

In our institution, transverse loop colostomy is generally the traditional standard for fecal diversion to protect colorectal anastomosis. The concept of early stoma closure may not be suitable for colostomy because of the edematous peristomal tissue and vulnerable intestinal wall and is marginally practiced. However, Lewis and Weeden [23] reported already in 1982 its feasibility, with encouraging results of early colostomy closure after 4 weeks. Because of the encouraging results of our study, we consider making ileostomy and early closure the standard practice after evaluation of the outcome of our colostomy patients.

Edwards et al. [7] reported in their randomized study that the frequency of herniation before or after colostomy closure is high and therefore supports ileostomy as a better method for defunctioning an anastomosis. Naturally, parastomal hernia does not play a substantial role in cases of planned (early) stoma closure, but incisional hernia after stoma closure still remains a problem with significant clinical impact. In our series, the relatively high rate of incisional hernia at stoma site was unexpected and has nothing to do with the absorbable adhesive barrier. We can exclude that the antiadhesive material in the abdominal wall can enhance the hernia rate because of the complete absorption of the film within 14 days. The material is liquefying and seems to be jellylike prior to absorption. We observed this fact in cases of early stoma closure already after 8 days. If we took down the ileostomy after 14 days, we did not observe any residues of the antiadhesive material. The extent of the required abdominal wall defect for ileostomy formation seems to be equal in laparoscopic and open procedures and smaller compared with colostomy creation. Apart from careful and tight fascia closure, we do not know how to prevent stoma site hernias without prosthetics, which are so far not used in our daily practice. The safety and efficacy of stoma-site reinforcement after stoma reversal using synthetic or biological meshes has to be evaluated in prospective randomized trials to establish whether there are any realizable benefits of this trials [24].

A limitation of our study is the single-arm retrospective observational design, and our small series does not provide sufficient detail to impact the care of others regarding time-point and adjuncts for stoma closure. However, our analysis extends to areas of interest, for which until now only rare data were available. The overall complication rate of nearly 50% (stoma formation and reversal, Table 3) has to be seen critically because the most frequent complications were independent of the adhesive barrier, such as hernias at the stoma site for example. Essentially, no wound complications due to ileostomy closure occurred, wherefore we called the method safe.

In *conclusion*, the results of our study suggest that the use of a dual-sided, absorbable, and antiadhesive film is feasible and enhances the mobilization of the defunctioning bowel loops from the abdominal wall without a negative impact in wound healing disorders and parastomal hernia rate. Generally, early stoma closure offers advantages to our patients such as decreased stoma-associated morbidity, lower psychological burden, and stoma reversal during index admission. The overall length of hospital stay may be shortened, and no further readmission due to potential stoma complications or for scheduled stoma reversal is required. The use of an antiadhesive film should be compared with other method(s) and observed on a larger cohort to come to a reliable conclusion regarding feasibility and safety. Further prospective studies are warranted to demonstrate these points clearer and should also investigate the outcome regarding continence in patients after early stoma closure. Less sphincter atrophy and less fibrotic transformation of muscles may lead to better continence after early stoma reversal.

Conflict of interest

Gernot Koehler, Georg Spaun, Ruzica-Rosalía Lukećina, Stavros A. Antoniou, Oliver Owen Koch, and Klaus Emmanuel have no conflicts of interest or financial ties to disclose.

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