CASE REPORT

Padlock Clip® defect closure system - Endoscopic closure of an accidental esophageal perforation during an EMR procedure

Dr. David L. Diehl | Geisinger Medical Center | Danville, PA

Procedure:

Endoscopic closure (with the Padlock Clip defect closure system) of an esophageal perforation that occurred during an endoscopic mucosal resection (EMR) procedure.

Patient History:

76-year-old male with chronic gastroesophageal reflux disease (GERD) was found to have nodular Barrett's mucosa with high grade dysplasia and was referred for endoscopic treatment. Careful endoscopic evaluation was done, aided by a clear distal cap fitted to the standard gastroscope, and a 3cm segment of Barrett's mucosa with prominent nodularity was identified near the GE junction (see Fig. 1). The decision was made to manage this with band-assisted EMR. One nodular area was removed without any problems, but after resection of an adjacent nodular area, a small perforation was evident (see Fig. 2).

Fig. 1

Padlock Clip System Use:

The endoscope was removed and a Padlock Clip defect closure system immediately fitted to the endoscope. There were no problems advancing the scope into position on the defect. The perforation was centered in the middle of the cap of the Padlock Clip system and suction applied. Since the perforation was fresh, the tissue was mobile and suction worked well to recruit the tissue into the cap – a grasper was not needed. Some fat was suctioned into the tissue, which helped "plug" the perforation and was not of concern. The Padlock Clip system clip was then deployed with complete closure of the perforation (see Fig. 3).

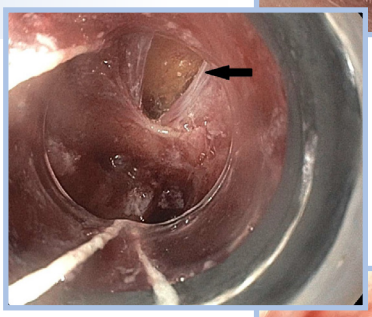

Fig. 2

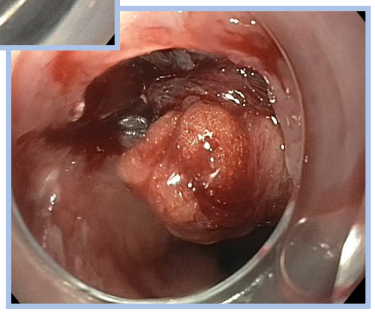

Fig. 3

Results:

A gastrograffin contrast study was immediately done to confirm closure of the defect. This contrast study demonstrated no extravasation of contrast, confirming closure. If there was failure of closure, an esophageal stent would have been placed. The patient was in good condition following the procedure.

Conclusion:

"The Padlock Clip® [defect closure system] can be set up in seconds and allowed instant management of an esophageal perforation. Complete closure of the defect was achieved and confirmed by contrast study."

-DR. DAVID L. DIEHL

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STERIS | US endoscopy

CASE REPORT

Iatrogenic colon perforation closure with the Padlock Clip® defect closure system

Dr. David L. Diehl | Geisinger Medical Center | Danville, PA

Procedure:

Endoscopic closure of colonoscopic perforation with Padlock Clip system.

Patient History:

An 87 year-old woman underwent a surveillance colonoscopy at an outside endoscopy center. The sigmoid colon was narrowed and tortuous, and despite careful endoscope advancement by the endoscopist, a perforation occurred. This was recognized promptly and an attempt at closure with through the scope clips was made. However, due to the angulated and narrow lumen, closure was not effective.

The patient was transferred the same day to the advanced endoscopy unit at our hospital. A repeat sigmoidoscopy was done about 3 hours later. A gastroscope was utilized for better maneuverability in the sigmoid colon. Water filling of lumen was done to avoid air insufflation into the peritoneum. Two through-the-scope clips could be seen near a small defect, but the defect clearly was not closed. One of the clips could be seen partially entering the defect **(See fig. 1)** and was removed with a grasper prior to closure with the Padlock Clip defect closure system. **(See fig. 2)**

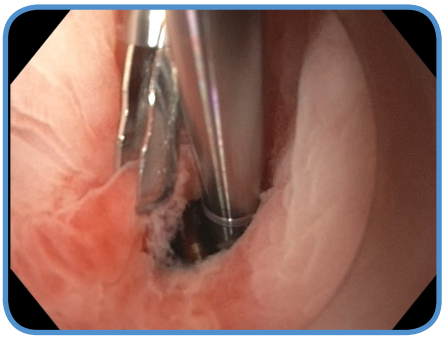

Fig. 1

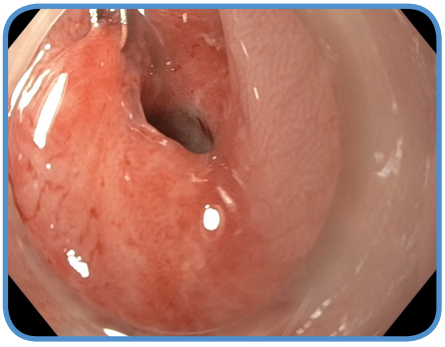

Fig. 2

Padlock Clip defect closure system use:

A Padlock Clip device was loaded onto the gastroscope. The endoscope could be advanced to the area of perforation, and the single attached through-the-scope clip was centered within the Padlock Clip system tissue chamber. Full suction was applied for a few seconds, and then the Padlock Clip device deployed. Position of the Padlock Clip device looked good, and the previous hemostatic clip was within the area of closure **(See fig. 3 & 4).** The site was tattooed after applying the Padlock Clip device, in order to assist the surgeon in localizing the site just in case surgery became necessary.

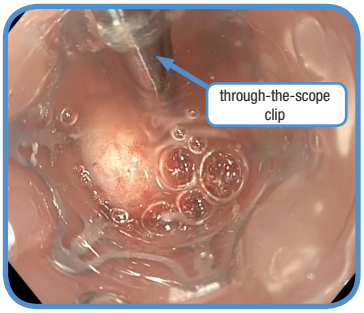

Fig. 3

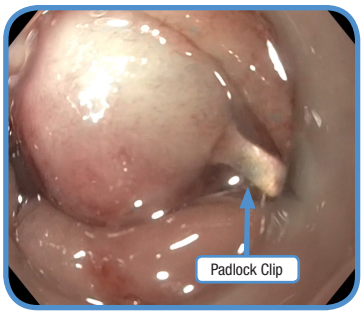

Fig. 4
(post-clip deployment)

continue to results & conclusion →

Results:

Discussion with the colorectal surgeon followed, and he recommended conservative management with hospital admission and IV antibiotics only. A CT scan was not recommended. The patient did very well and did not develop abdominal pain or signs of peritonitis. She was discharged after a 2-day hospitalization and did not require surgery.

Immediate identification and closure of iatrogenic colonic perforations that might occur during colonoscopy can allow avoidance of surgery. In this case, through-the-scope clips were inadequate to provide closure. The Padlock Clip system allowed for complete closure, and emergency surgery with possible colostomy could be avoided in this elderly patient.

Conclusion:

"The Padlock Clip [defect closure system] quickly closed a colonoscopic perforation in a tortuous and narrow area of the sigmoid colon, and surgical repair could be avoided"

-DR. DAVID L. DIEHL

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Endoscopy

CASE REPORT

Padlock Clip® defect closure system - Endoscopic closure of a bleeding polypectomy site

Dr. David L. Diehl | Geisinger Medical Center | Danville, PA

Procedure:

Endoscopic closure of a bleeding polypectomy site.

Patient History:

A 75-year-old man was referred for a repeat colonoscopy to address a large semi-pedunculated sigmoid colon polyp (**See Fig. 1**). The area near the polyp had been previously marked with tattoo.

Good lifting was noted after injection of saline and dilute indigo carmine, and the polyp could be removed en bloc with a large snare. Immediately after polypectomy, bleeding was noted from the polypectomy site (**See Fig. 2**). The endoscope had been fitted with a clear distal attachment cap (Reveal® cap, STERIS Endoscopy) which allowed localized water flooding. This assisted in identifying a bleeding point in the base of the resected polyp. Hemostatic forceps were used to cauterize a bleeding point within the polypectomy base. After cautery of a single site, bleeding ceased (**See Fig. 3**).

Next, a Padlock Clip device was used to secure the polypectomy site. The Padlock Clip device was quickly attached to the endoscope and advanced to the polypectomy site. The site was centered within the cap, full suction applied, and the clip was deployed (**See Fig. 4**). After clip deployment, the small arteriole that was the likely source of bleeding was noted in the center of the resection base. This was eradicated with soft cautery with hemostatic forceps.

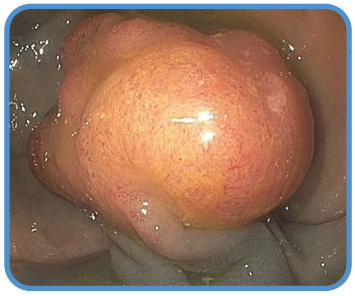

Fig. 1: Large semi-pedunculated sigmoid colon polyp

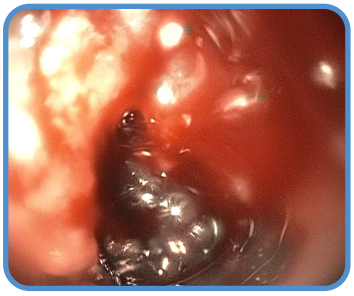

Fig. 2: Bleeding visible after polyp resection

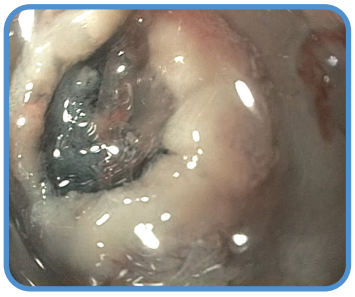

Fig. 3: Polypectomy site after treatment with hemostatic forceps

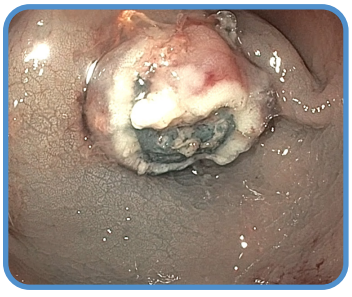

Fig. 4: Padlock Clip device deployed over the polypectomy site

Results:

The patient did well after the procedure, and no delayed bleeding was noted. The Padlock Clip defect closure system led to prompt closure of a bleeding polypectomy site and prevented delayed bleeding from this site. A single clip could be used quickly and provided a more secure closure than the use of multiple small hemostatic clips.

Conclusion:

"The Padlock Clip defect closure system allowed rapid and secure closure of a bleeding polypectomy site, ensuring that delayed bleeding would not occur. Use of this larger single clip was quicker and easier to use than multiple smaller hemostatic clips. Visualization of the post-polypectomy target during the procedure was excellent."

-DR. DAVID L. DIEHL

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STERIS
Endoscopy

CASE REPORT

Padlock Clip® defect closure system - Endoscopic management of post-band ulceration

Dr. Demetrios Tzimas | Trinity Health of New England Medical Group

Procedure:

Endoscopic management of post-band ulcerations in an exsanguinating patient using the Padock Clip System system

Patient History:

A 56-year-old woman with decompensated cirrhosis was recently admitted with variceal bleeding and treated with four bands using a standard band ligation system. She was re-admitted to our hospital two weeks later with syncope and hematemesis secondary to massive upper GI bleeding. The patient was taken for urgent endoscopy.

Treatment

Endoscopy demonstrated massive bleeding from two post-band ulcerations. There was spurting blood from the vessel with red-out of the esophagus due to bleeding. Re-banding was not possible, and standard therapies for hemostasis such as injection, bipolar cautery, and hemostatic clips all failed to control the bleeding. The tissue chamber of the Padlock Clip system was used during the procedure to easily localize the vessels despite the red-out caused by the massive bleeding. To prevent further exsanguination, two over-the-scope Padlock Clip devices were deployed over each ulcer with excellent results and achieved complete hemostasis. The patient was then brought to interventional radiology in stable condition for transjugular intrahepatic portosystemic shunt. She was extubated and doing well the next day.

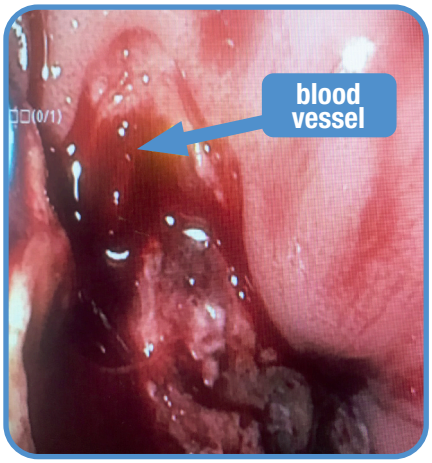

Fig. 1: Bleeding from post-band ulcerations

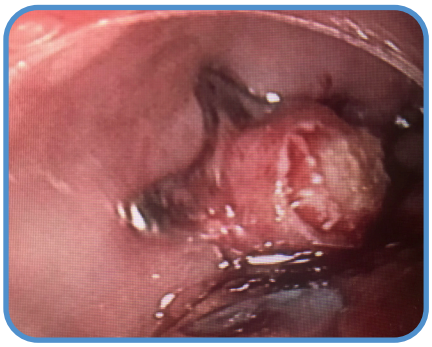

Fig. 2: Padlock Clip Device placed over bleeding ulcer, achieving hemostasis

Conclusion:

"The Padlock Clip [defect closure system] was able to save this patient's life. Without the aid of the Padlock Clip system to help localize the vessel and the ease of use of the system, this patient would have died. It provided us with the ability to achieve complete hemostasis and send the patient to interventional radiology in stable condition"

-DR. DEMETRIOS TZIMAS

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CASE REPORT

Closure of Anastomotic Leaks and Fistulas with the Padlock Clip® defect closure system: A Case Series

Authors: Hoke, Julia W.; Mulloy, Clairissa D., MS; Hodgdon, Ian A., MD, FACS General Surgery Division - Louisiana State University Health Sciences Center, New Orleans, LA

Abstract

Background:
Historically the treatment of fistulas was either non-operative: controlling the leakage with ostomy bags, diet restriction and parenteral nutrition, or open surgical treatments. Leakage from bowel perforation was treated with drainage or surgery also. In recent years, endoscopy has gained favor in a multitude of domains due to the reduced morbidity and mortality associated with endoscopic versus open technique, and the high failure rate of fistulas healing spontaneously. To a limited extent, over-the-scope (OTS) clips have been employed to close fistulas and leaks for some years; though the role of the Padlock Clip system had not been widely discussed. Porcine models demonstrate the Padlock Clip system is a safe and effective way to address fistulas and perforations but had up until this point not been used in human patients for these indications.

Summary:
We report on a series of 4 consecutive cases by a single surgeon between May and June 2019. In these cases we utilized the Padlock Clip system to repair 2 colonic leaks and 2 gastrocutaneous fistulas.

Conclusion:
We report success with the Padlock Clip system in gastrointestinal leak and fistula repair of all 4 patients with no significant untoward events. We recommend the use of the Padlock Clip system as a safe and effective alternative to an open approach to address such anatomical defects due to the improved known healing time and infection rates associated with endoscopic approaches and in the setting of successful repair.

Introduction

Due to the relatively low morbidity and mortality associated with endoscopic techniques, an increasing number of gastrointestinal disorders are treated using this method. The risk of perforation in diagnostic esophagogastroduodenoscopy (EGD) is about 0.033%, and the risk of perforation in an interventional EGD is between 1.2% and 5.2%[1,2]. These data show that endoscopy is a safe procedure and can be considered an alternative to open surgical repair.

A large multicenter, retrospective study tested an over-the-scope (OTS) clip system (OTSC, Ovesco Endoscopy AG, Tubingen, Germany) for closing certain GI defects. Specifically, the study looked at closure of perforations, leaks, and fistulas for primary and rescue repair. Long-term success was achieved in 60.2% of the patients at median follow-up of 146 days with success rate higher for perforations (90%) and leaks (73.3%) compared to fistulas (42.9%)[3]. Long-term success was higher when the OTSC was the primary therapy (69.1%) compared to rescue therapy (46.9%)[3]. This study helps establish endoscopic clipping as a safe and effective intervention for multiple GI defects.

Introduction (continued)

The Padlock Clip system (STERIS | US Endoscopy, Mentor, OH, U.S.) is a relatively new OTS clip that has been successfully tested in porcine models in gastrotomy and colonic closures[4,5]. There are few descriptions of the Padlock Clip system in clinical settings, but it has been described in a case series for treatment of recurrent bleeding esophageal fistulas. The series showed the Padlock Clip system to be relatively simple and effective in difficult cases[6].

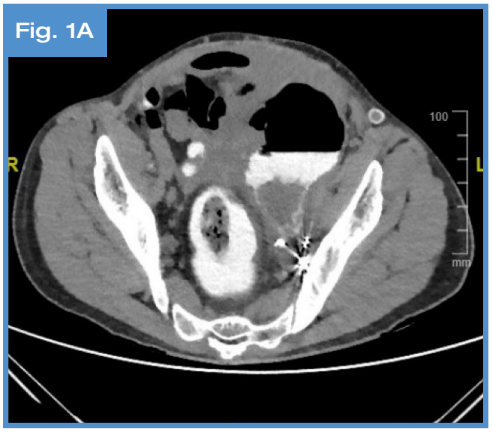
The Padlock Clip system is an OTS clip made of nitinol with 6 inner needles on the applicator cap which is deployed via thumb press. The Padlock Clip device design has suction that allows adhesion to the cap without requiring additional instruments. Once the clip is deployed, it will spring back to its hexagonal ring form to gather and compress the tissue thereby closing the defect. This design allows it to maintain its hold on tissue against GI pressures, while still allowing blood flow to the area. Herein, we share our experience with the OTS Padlock Clip system for closure of leaks and fistulas in a series of consecutive cases by a single surgeon from May to June 2019.

A description of patient demographic data, etiology, clinical condition, and previous treatment are listed in **Table 1.**

Case 1: Colon leak

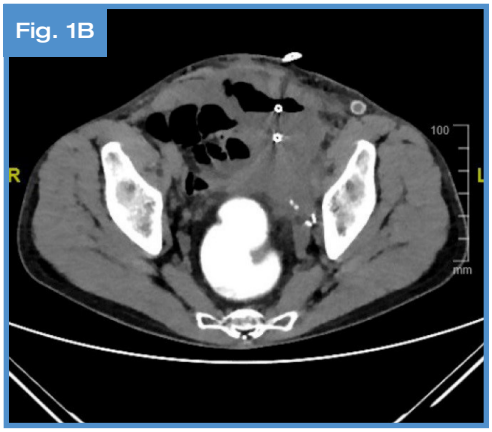
A 27-year-old male with a history of pelvic teratoma status-post (S/P) resection complicated by bowel perforation requiring an osotomy, now s/p ostomy reversal and hernia repair, presented to the emergency department (ED) with 1 week of abdominal pain, fever, and dysuria. Computerized Tomography (CT) scan without contrast showed a left lower quadrant 9.5cm air-fluid collection with likely fistulous connection to postsurgical colon 6 months post op. He was admitted for IV antibiotics and interventional radiology (IR) drainage of the fluid collection. Four days later he was evaluated via colonoscopy and found to have a 2mm, fistulized perforation at the lateral staple line of the proximal anastomosis. The leak was closed during colonoscopy with the Padlock Clip system. He was discharged home 5 days later in good condition. He returned to the ED 41 days later with abdominal pain. CT scan showed possible left lower quadrant fluid collection. IR placed percutaneous drainage. There was concern for possible recurrent fistulous leak. CT pelvis with rectal contrast showed no evidence of colorectal leak (see **Fig. 1A & 1B**). He was discharged in stable condition with a scheduled appointment for a colonoscopy 1 week from discharge. The repeat scope showed the Padlock Clip device to be in place and no leakage. Patient later returned to clinic and had his drain removed with no recurrent fistula 12 weeks post clip.

Fig. 1A



A: Fistulous colon leak. Site of leak prior to repair

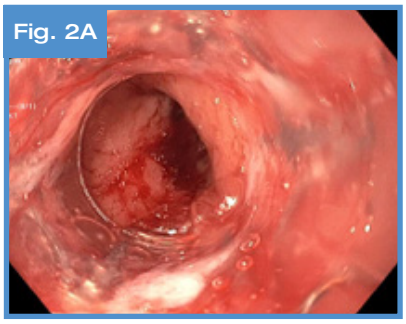
Fig. 1B



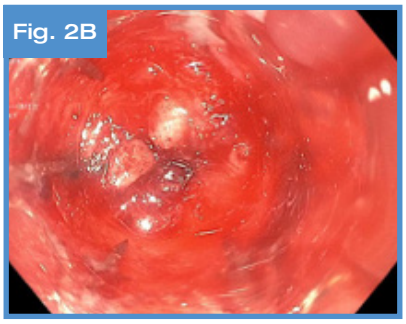
B: No evidence of recurrent colorectal leak

Case 2: Gastric sleeve leak with gastrocutaneous fistula

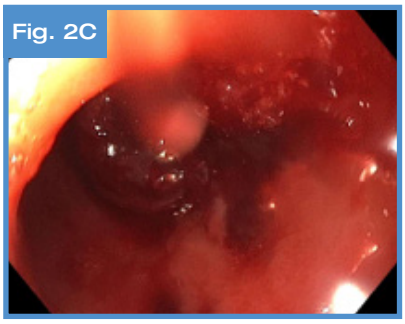
A 71-year-old female with a complicated surgical history s/p gastric sleeve leak presented with a gastrocutaenous fistula for over 1 year. A percutaneous endoscopic gastrostomy (PEG) tube was placed through the fistula with gastrojejunal extension to feed distally and block leakage. She presented to the ED 14 days later with loss of PEG tube. On hospital day 1, she was taken for EGD and a Padlock Clip device was placed to repair the gastrocutaneous fistula (See **Fig. 2A, 2B, & 2C**). The procedure was successful, with no bleeding, air, or fluid leakage noted at the end of the procedure. The patient followed up in clinic 2 weeks later and was noted to have continued drainage of about 150-175mL from the gastrocutaneous fistula with thin liquids. At 11 weeks follow up, she had no fistula output and was no longer requiring an ostomy bag. She was also asble to tolerate regular diet and stop TPN (total parenteral nutrition).



A: Gastric sleeve leak with enterocutaneous fistula. Site of fistula



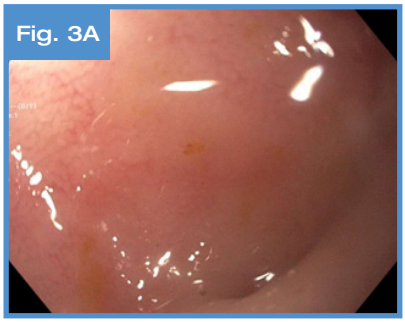
B: Fistula suctioned into cap



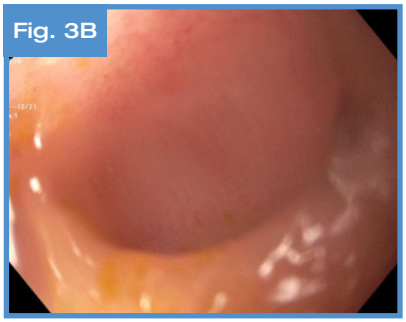
C: Bulging tissue after closure of enterocutaneous fistula

Case 3: Colon leak with abscess and fistula

A 56-year-old female with history of ileocolonic Crohn's disease with colonic strictures s/p colectomy with ileosigmoid anastomosis in 2018, complicated by enterocutaneous fistula in the region of the anastomosis now presented with several days of pain deep to the superior aspect of her midline laparotomy incision. CT showed intraabdominal fluid collection for which IR placed a drain. The drain output gradually decreased, but the fistula continued to drain. A flexible sigmoidoscopy showed the enterocutaneous fistula at the ileal blind limb near anastomosis. The patient was taken to endoscopy and Padlock Clip device was placed for closure of the enterocutaneous fistula (see **Fig. 3A & 3B**). She tolerated the procedure well. CT scan with rectal contrast s/p placement of the Padlock Clip showed no further communication or evidence of the fistula. Drain output continued to decrease and was removed on day 9. Patient was discharged in stable condition. Patient had recurrence of fluid collection and repeat CT with rectal contrast was performed and no leakage seen, underwent open incision and drainage of collection.



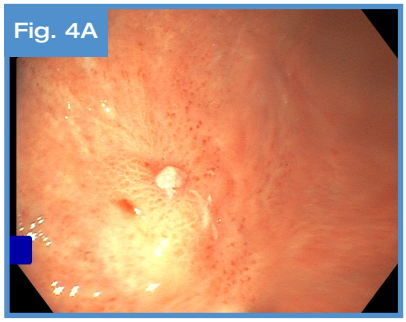
A: Enterocutaneous fistula with colon leak



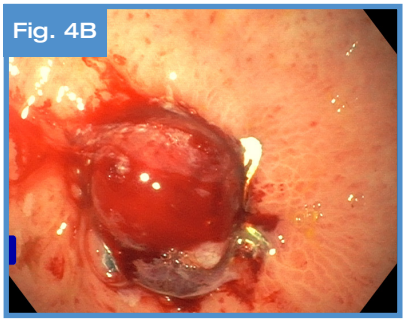
B: Sigmoid colon after clipping of enterocutaneous fistula

Case 4: Gastrocutaneous fistula leak

A chronic gastrocutaneous fistula was diagnosed in a 64-year-old male s/p PEG tube placement and subsequent removal for HPV+ squamous cell carcinoma at the base of the tongue. Patient was still having leakage 6 months post PEG tube removal by radiology. On the day of surgery, the patient was taken to the operating room and the gastroscope was inserted into the oropharynx. The stomach was examined, and the prior site of the gastrostomy tube was visualized. At the site, a small punctate area of granulation tissue was present, and it was deemed that it would be amendable to endoscopic clipping. The scope was removed and reinserted with the Padlock Clip system, which was placed directly over the fistula tract. The site was suctioned into the scope and the Padlock Clip device was placed in adequate position (see **Fig. 4A & 4B**.). The granulation tissue of the skin was then dissected and excised. The patient was in stable condition after the procedure and discharged home. Patient was seen in clinic 3 weeks later and no leakage.



A: Small punctuate area of granulation tissue



B: Padlock Clip device placed in adequate position over fistula tract

Discussion

2 patients were female and 2 were male with a mean age of 55 years. 1 patient had undergone multiple previous colonic resections for colonic leaks, but for all patients in this series the Padlock Clip system was the initial treatment for the presenting GI defect. Each case had immediate success visualized in the endoscopy suite, and the 2 colon abscesses that recurred there was no leakage with rectal contrast. There was no bleeding and no evidence of fluid or air leakage. 2 colon patients experienced recurrent fluid collections, but CT scan showed no evidence of colorectal leak, so this is not assumed to be a failure or adverse effect of the clip. One patient became positive for C.Difficile during their hospitalization, but this is not directly associated with the use of the Padlock Clip system. No other major adverse events were observed on follow up (see **Table 2**).

Cases utilizing endoscopic techniques for repair of GI defects are increasing in popularity due to the low morbidity and mortality associated with such procedures. The risk of perforation is very low making endoscopy a reasonable alternative to open surgery for closure of GI defects, specifically for leaks and fistulae. The OTSC has been the most commonly used system until now and long-term success was achieved in the majority of patients with few adverse events[3]. Before this series, the Padlock Clip system was successfully tested in gastrostomy and colonic closures in porcine models and described in case series for treatment of recurrent bleeding and esophageal fistulae with successful closure and without major adverse effects[4,5,6]. These cases take these findings a step further and illustrate that the Padlock Clip system can be safely and effectively used for treatment of fistulae and GI perforations.

Conclusion

In our series, the Padlock Clip system was used in 4 patients for treatment of colon leaks and closure of gastrocutaneous fistulas. Endoscopic therapy was successful in all 4 cases without adverse events associated with the intervention. We recommend incorporation of the Padlock Clip system into all general surgery practices as first-line intervention for similar problems. It is a relatively safe and easy procedure and is a promising alternative for treatment of a variety of GI defects.

Lessons learned

The Padlock Clip system was successfully used in the repair of gastrointestinal leak and fistula repair in 4 patients between May and June 2019. We recommend the Padlock Clip system as a safe and effective alternative to open approaches to repair such defects.

Table 1. Patient Demographic and Clinical Information

Number	Age (year)	Etiology	Clinical Condition	Comorbidities	Previous Treatment
1	27	Pelvic teratoma s/p ex-lap resection w/ end ostomy; s/p ostomy reversal & hernia repair, now leak from proximal anastomosis	Colonic Leak	Testicular cancer	None
2	71	Gastric sleeve	Gastrocutaneous fistula with gastric leak	HTN, morbid obesity, asthma, malnutrition, perforated PUD, DM, gout	Multiple colonic resections
3	56	Crohns disease	Gastrocutaneous fistula with colon leak	Cervical cancer, Crohns disease	None
4	64	Gastrotomy tube	Gastrocutaneo us fistula	HCV, asthma, HPV+ small cell carcinoma of base of the tongue	Enterocutaneous fistula excision at same encounter

Table 2. Results of the Padlock Clip system application

Number	Technical success	Treatment outcome	Salvage procedure (surgery, interventional radiology)	Adverse events/ morbidity	Follow up (weeks)
1	Yes	Closure of colon fistula on CT with rectal contrast	Yes	Recurrent left lower quadrant fluid collection resolved with IR drain	12
2	Yes	Closure of gastrocutaneous fistula	No	None	11
3	Yes	Closure of colonic fistula on CT with rectal contrast	Yes	Recurrent fluid collection after IR drain removal treated with I and D	7
4	Yes	Closure of chronic gastrocutaneous fistula	No	None	3

References

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