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## Abstract

Natural orifice transluminal endoscopic surgery (NOTES) is becoming more accepted by patients and clinicians alike as new data are published and new clinical trials surface. As these studies emerge we find that there are certain features of NOTES that are common to all types of natural orifice procedures. Among these are that they must include a method of exit from the lumen, procedures for carrying out the intended operation, including methods of obtaining access, retraction, and triangulation, and finally closure of the exit site once the surgery is done. This chapter reviews these fundamentals of NOTES, with emphasis on luminal exit and closure techniques, as these are the foundation of NOTES.

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## Keywords

Natural orifice • Gastrotomy closure • Surgery • Myotomy • Endoscopy • Fundamentals

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## Abbreviations

EFTR	Endoscopic full-thickness resection
ESD	Endoscopic submucosal dissection
EUS	Endoscopic ultrasound
FNA	Fine-needle aspiration
GI	Gastrointestinal
NOTES	Natural orifice transluminal endoscopic surgery
OTSC	Over-the-scope clip
PEG	Percutaneous endoscopic gastrostomy
POEM	Per-oral endoscopic myotomy

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## Introduction

Natural orifice transluminal endoscopic surgery (NOTES) is a surgical technique using a naturally occurring orifice (mouth, anus, urethra, vagina, or naris) to gain access to a body cavity or potential space beyond that orifice. When the mouth or anus is the site of entry, surgery can be carried out in the wall of the gut (e.g., per-oral endoscopic myotomy), or completely outside the gut in the mediastinum, elsewhere in the chest, in the abdomen, lesser sac, or pelvis. The surgery can take place in a true body cavity, or in a potential space such as the retroperitoneum. In all cases, one would expect to adhere to standard surgical principles that govern open or laparoscopic surgery. When first proposed, a flexible endoscope was anticipated to be the operating platform [1]. We now know that rigid surgical instruments can be used in natural orifice surgery and that this type of operation is still considered NOTES.

A natural orifice method is attractive for many theoretical reasons. It should leave no visible scars, and there is likely faster return of bowel function, shorter hospital stay (therefore, there may be a value benefit), less postoperative pain, and performance in an outpatient or ambulatory setting [2]. It has also been suggested that wound infection is potentially less of a problem (although this has not been proven in randomized trials), and that some vexing long-term postoperative problems such as incisional hernias and port site hernias would be greatly diminished. Finally, although not confirmed in randomized, prospective clinical trials, there may be a safety benefit with this most minimally invasive of surgical methods.

In this chapter, we review the fundamentals of NOTES such as getting started, devices utilized, gaining access to the surgical site through a natural orifice, and closure after the operation is completed. These are fundamental issues common to any NOTES procedure. Other topics such as individual types of surgical procedures and how to perform them (POEM, transvaginal

cholecystectomy, etc.) will be dealt with elsewhere in this text.

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## Training, Credentialing, and Getting Started

At the time of this writing, we do not know of any formalized training programs in NOTES, and certainly none that are accredited. So if one is to begin doing NOTES, one must seek an avenue of training. This could be an apprenticeship with others actively engaged in human NOTES cases, animal laboratory training, cadaver laboratory training, or a combination of these. We recommend as much practice as possible in the animal laboratory, on both explants/models and on live animal subjects, prior to booking a first human case. Indeed, each individual hospital or institution will have local regulations regarding procedural competency and accreditation. Know the rules of your own institution and follow them to get permission to start performing NOTES. We recommend a proctor to guide you on your first few cases so that lessons learned the hard way by experts can be passed on to you before you experience the same pitfalls. More details on how to get started in NOTES have been reported by us previously [3, 4]. Also, one must consider, given the relatively experimental nature of NOTES cases at the current time, whether local Institutional Research Board approval is necessary prior to undertaking the first case.

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## Equipment

A multidisciplinary team is the usual approach to NOTES. In some circumstances, an individual surgeon might have training and skills in therapeutic endoscopy and could potentially do NOTES alone. However, in most cases, a surgeon well versed in laparoscopic equipment and procedures partners with an interventional endoscopist familiar with advanced therapeutic endoscopic equipment and procedures. Often,

**Table 2.1** Equipment commonly used in NOTES

Flexible endoscope and light source
Therapeutic gastroscope (2 channel)
Standard gastroscope
Transnasal thin gastroscope
Colonoscope, pediatric or adult
Linear-array echoendoscope
Laparoscopic tower and light source
Oblique and straight-viewing laparoscopes
CO <sub>2</sub> insufflator, laparoscopic, and endoscopic
Electrocautery
Standard laparoscopic accessories
Ports, graspers, dissectors, sump suction, hook cautery, clipping devices, stapling devices, suturing materials, etc.
Standard endoscopic accessories
Guidewires, cannulas, cold biopsy and grasping forceps, hot biopsy forceps or coagulation forceps, triangle-tip knife, hook knife, Hybrid Knife, needle knives, dilating balloons (biliary and enteric), stone-extraction balloons, rigid and screw-type dilators, endoscopic suturing devices, hemostatic clips, over-the-scope clips, Dormia baskets, snares, endoscopic overtubes, sclerotherapy needles, and FNA needles

this “cross-pollination” allows for improvisation and off-label use of devices or equipment that might not otherwise be enjoined. See Table 2.1 for a list of devices commonly used in NOTES.

### Luminal Exit Techniques

Exiting the lumen of the gut can be rather a frightening experience, at least for endoscopists who have been conditioned throughout conventional GI training to stay within the lumen, and that to do otherwise constitutes a perforation and therefore a complication. When exiting the lumen, one runs the risk of injuring a nearby organ or causing bleeding from vessels on the serosal side of a hollow organ that cannot be seen when the site of exit is selected. Every effort should be made to exit in a location and a manner that minimizes these risks. Therefore, certain landmarks should be sought and rules followed when exiting a natural orifice. For example, the

“triangle of safety” can be used for transvaginal access [5]. We always attempt to exit the stomach or bowel on the antimesenteric border, where blood vessels are the fewest and smallest. Some exiting techniques were specifically designed with safety in mind.

#### (1) Direct Incision

This is the simplest but also the least safe of exiting techniques. A needle knife or other cutting device is used to incise the hollow organ in layers to provide a full-thickness defect through which the endoscope can be passed. The risk of injury to nearby loops of bowel and/or solid organs is not negligible. But this method is simple and quick. It is often used in nonsurvival animal experiments where perforation of a nearby loop of bowel is of little consequence. This type of exit is also the most difficult to close, essentially requiring endoscopic suturing or, if the defect is not too big, over-the-scope clips (OTSCs). This is yet another reason why this method is used in nonsurvival experiments, where closure is not attempted or at least is not critical because the animal is to be sacrificed immediately afterward. Some workers initially advocated the use of endoscopic ultrasound (EUS) to provide additional safety, but they now feel that this has little added value, and most do not use EUS in an attempt to make gastric puncture/incision safer [6].

#### (2) Puncture and Dilate

This method comprises a blind puncture with a 19-ga EUS needle placed through the working channel of a straight endoscope followed by the passage of a guidewire into the abdominal or other cavity. Risk of puncturing another organ is low if the puncture is done smoothly and slowly. Other hollow viscera tend to float away from the needle. If solid organ anatomy is kept in mind, this can be done safely. Once a guidewire is advanced into the peritoneal cavity, the needle is removed leaving the wire in place. A standard 15- to 18-mm esophageal dilation balloon can then be advanced over the wire and used to dilate

the tract. One then pushes the balloon through with the endoscope, whose tip follows it out into the abdominal cavity. An additional way of increasing the safety of this technique is to insufflate the abdomen with CO<sub>2</sub> prior to anterior wall gastric puncture. This helps to prevent injury to other viscera nearby at the time of the gastric puncture or incision [7].

An advantage to this method is that there is no cutting, so bleeding risk is minimized. Another advantage is that without cutting, the muscle layers stretched during the dilation tend to return to their original configuration once the endoscope is removed, and closure may be simplified. Indeed, as will be shown in the next section, Jagannath et al. did not even close the gastrotomy site (a needle knife rather than a needle was used to make the initial small puncture) in a porcine survival model after ligation and transection of the uterine horn to simulate appendectomy [8].

### (3) PEG technique

This is likely the safest but also the most complicated method of entry into the abdomen. Because the method utilizes techniques normally used in PEG placement, it can only be used for gastric exit into the peritoneal cavity. The method has been described in detail by Kantsevov et al. [9]. In brief, the method comprises endoscopic insufflation of the stomach, transcutaneous needle puncture, and guidewire insertion under endoscopic viewing and then removal of the wire out through the mouth as would normally be done for PEG placement. The wire is then back loaded into the working channel and is captured and pulled out through the biopsy port. The scope is then reinserted and used to anchor the wire in the stomach. Next, capnoperitoneum is achieved with a transabdominal Veress needle and CO<sub>2</sub>. Finally, the wire is pushed into the abdomen from the skin side, after fixing it in place on the stomach side with the tip of the endoscope. By pushing firmly on the skin side of the wire, it has no place else to go except to “knuckle” or flex into the inflated abdomen. A through-the-scope (TTS) balloon can then be

advanced along the wire and pushed along the wire across the wall, much like a push PEG technique, and then used to dilate the puncture site to allow the scope to exit into the abdominal cavity.

The advantages to this method are that it is very safe, there is no cutting, thus minimizing bleeding risk, and closure is made easier. Disadvantages are that it is a bit time-consuming and complicated compared to just cutting one’s way out of the stomach, and also that only the anterior of the stomach can be exited (which may not be appropriate for some NOTES procedures). Because of its safety profile, we use the PEG technique exclusively in survival animal studies and would recommend it in human procedures as well.

### (4) Tunneling Methods

Several groups have now reported on the creation of a submucosal tunnel proximal to the seromuscular incision used to exit the stomach or esophagus [10–12]. These are all variations on a theme. Briefly, saline is injected submucosally, lifting the mucosa from the muscle layers and expanding the submucosal potential space. A mucosal incision is made at one end of the saline lift. By blunt dissection with forceps or balloons, or by using electrocautery, a long submucosal tunnel is formed that allows passage of a cap-fitted endoscope. Further injections of saline and continued dissection are used to lengthen the tunnel. Then, the muscle and serosa are incised to allow the endoscope to pass into the mediastinum or peritoneal cavity. Once the extraluminal procedure is completed, the endoscope is withdrawn. The mucosotomy and myotomy are at distant sites; they do not overlap. The mucosal tunnel acts as a flap valve preventing luminal contents from exiting through the tunnel. Most investigators [10–15] will close the mucosotomy with endoscopic hemostatic clips as insurance against leakage.

An advantage to this technique is that it provides for a very easy and safe closure. In addition, the exit site can be targeted at a place on the stomach (for gastric exit) that might not be

achievable with the PEG method. However, it is time-consuming, adding to the time of the procedure and therefore to its cost. It requires considerable endoscopic skill as well, and experience in endoscopic submucosal dissection (ESD) or POEM is a prerequisite.

## Closure Methods

Gastrotomy or other enterotomy closure has been an area of active research since the inception of NOTES. Various devices have been designed specifically for this purpose, and others such as hemostatic clips are adapted for closure and are essentially used off-label. The actual devices (rather than the techniques of closure) have been reviewed elsewhere [16]. Many surgeons and endoscopists emphasize the importance of adherence to proper surgical principles to prevent leaks. Leakage of luminal contents into the abdomen or mediastinum would be a potential postoperative disaster, so as much research attention has been paid to closure methods as to the surgical procedures being developed.

It is beyond the scope of this chapter to review the physiology of intraluminal gut pressures and what factors may contribute to the failure of an enterotomy closure, but a few salient points should be made. Surgical dogma has long held that enterotomy closures must be able to withstand “cough pressure” or the intra-abdominal pressure changes that occur when coughing. The mean intra-abdominal pressure can be as much as 165 cm H<sub>2</sub>O (121 mm Hg) during cough [17]. However, our group has observed that extraluminal and intraluminal pressures are nearly identical during simulated cough and that pressure changes as a cause of leak are greatly overstated [18]. Shear forces, failure to appose the edges of a defect, and breakdown of the closure (dehiscence, device failure) are all more important than simple pressure changes in the abdomen because these pressure changes are the same both inside and outside the lumen, and the pressure differential or pressure gradient across the gut wall is near zero even during cough. Clearly, something else must influence leakage rather than pressure alone.

Indeed, some surgeons do not even close the gastrotomy after uterine horn resection as will be shown in the next section.

We will now briefly review the types of closures most commonly encountered (no closure, hemostatic clips, OTSC, and T-tags). An exhaustive treatment of closure methods is beyond the scope of this chapter, and the interested reader is referred to several reviews on this subject [16, 19].

### (1) No Closure

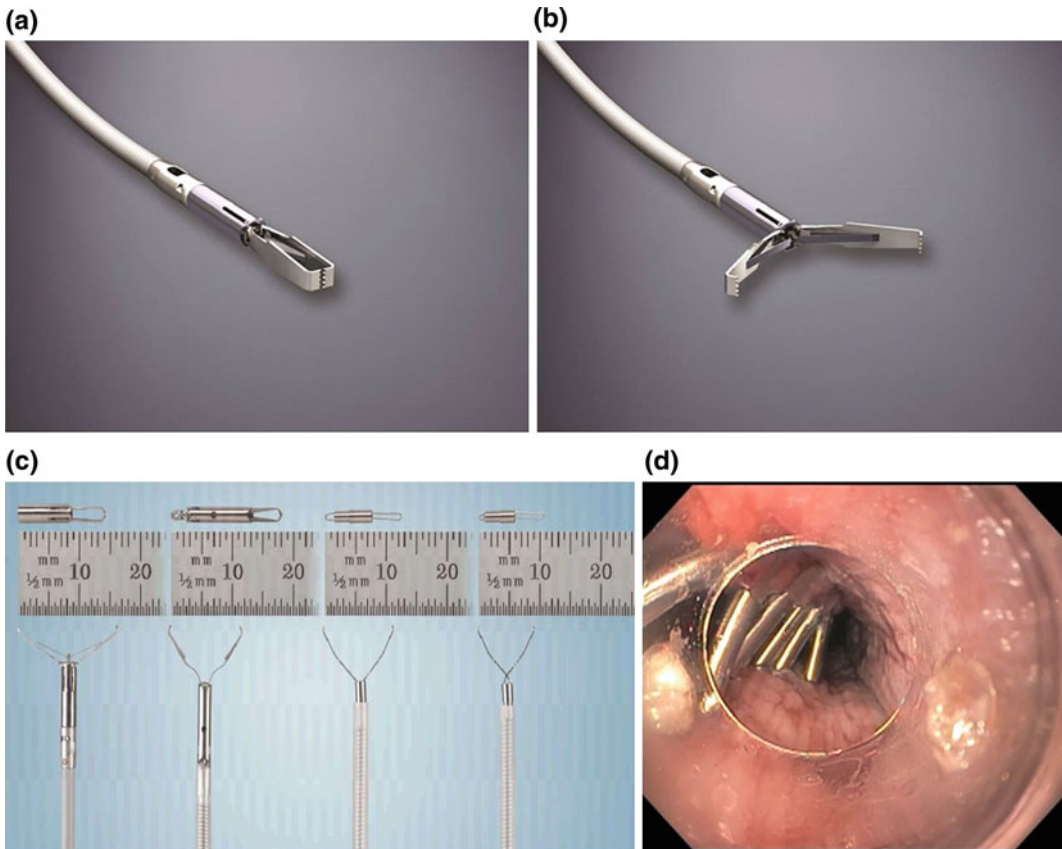
Jagannath et al. did not close the gastrotomy exit site in their survival porcine model of appendectomy (transgastric uterine horn resection) [8]. Exit was made by needle-knife puncture, but the tract was dilated with a balloon prior to pushing the endoscope across the gastric wall and into the abdominal cavity. The endoscope was simply withdrawn at the end of the procedure. The animals were fasted overnight and then given standard laboratory chow the next day. There were no leaks or infections. It is theorized that a small defect is easily tolerated (we know this from EUS/FNA) and that balloon dilation of the defect serves to spread the muscle fibers but not cut them. They spring back tonically, and the gastrotomy closes rapidly after endoscope removal. To our knowledge, no one has tried this yet in humans.

### (2) Clips

Clip closure was one of the first methods used in NOTES enterotomy closure. Many case reports had already been published describing effective closure of iatrogenic perforations with endoscopic hemostatic clips after EMR, polypectomy, or other endoscopic procedures. Much work was subsequently done in the animal laboratory with the closure of intentional perforations, and clips were shown to be effective. Work initially began with hemostatic clips [20–23], and later, work was done with OTSC clips [24–33].

#### a. Hemostatic Clips

Endoscopic hemostatic clips are titanium devices that are intended for endoscopic hemostasis of



**Fig. 2.1** **a** Endoscopic hemostatic clip closed. **b** Endoscopic hemostatic clip open. **c** Various types of endoscopic hemostatic clips. **d** Clip closure of the esophagus

after POEM (Permission for use granted by Cook Medical Incorporated, Bloomington, Indiana)

arterial hemorrhage (Fig. 2.1). Most have two arms; some can be rotated, some can be opened and closed repeatedly, and some can do both. They are useful for peptic ulcer bleeding, Dieulafoy's lesions, postpolypectomy or postsphincterotomy bleeding, or for bleeding colonic diverticula and other lesions. However, they can also be used off-label to close a mural defect.

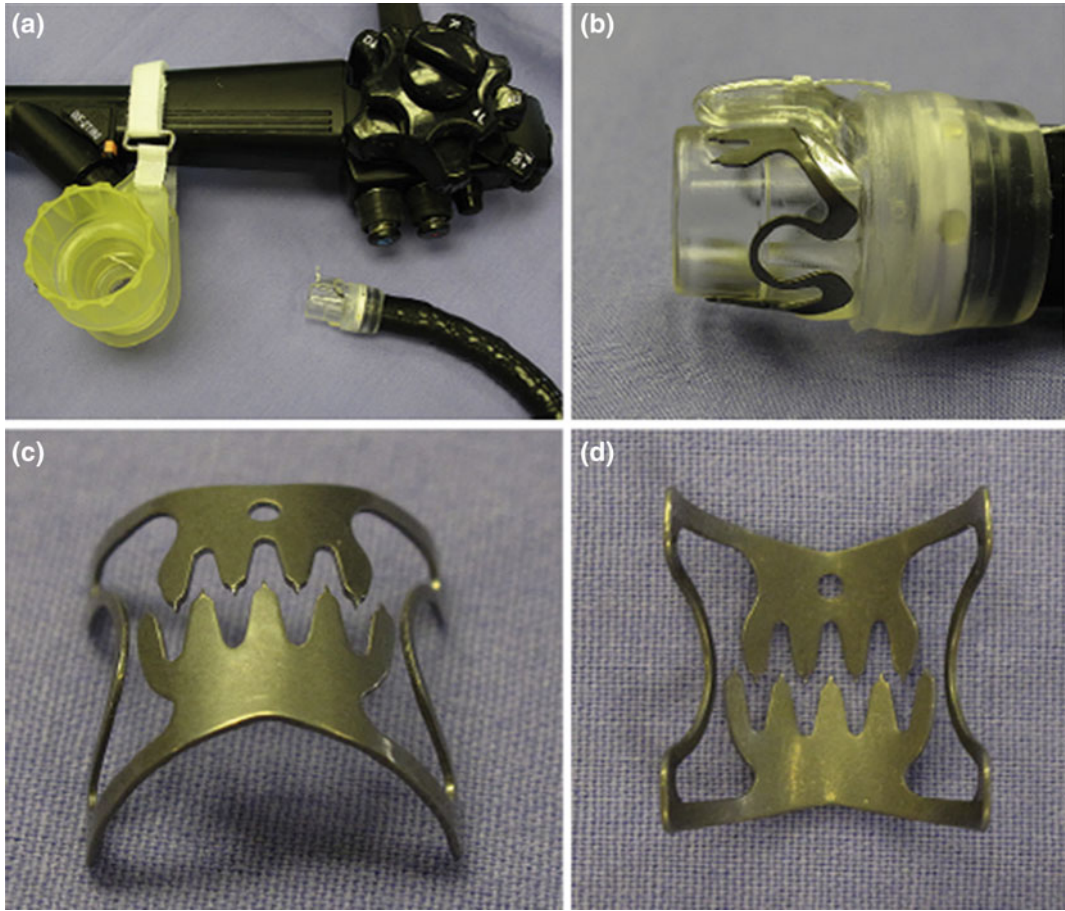
Raju et al. demonstrated that endoscopic hemostatic clips could be used to close small, full-thickness colon defects in a porcine model [20]. Merrifield et al. used hemostatic clips to close the gastrotomy after transgastric uterine horn resection in a survival porcine study [21]. However, 3 of the 5 experimental animals developed significant complications due to incomplete or failed gastric closure. Given this, it

seems that clip closure can be risky, and strict attention must be paid to the integrity and strength of the closure. Fritscher-Ravens et al. have demonstrated effective closure of esophageal perforations in a swine NOTES model using hemostatic clips [22]. Tsunada et al. demonstrated that clip closure could be effective in human patients. Seven patients who suffered full-thickness gastric perforations after EMR had their defects closed successfully using endoscopic hemostatic clips [23]. No patient required laparotomy.

#### b. OTSC

The most commonly used OTSC for both NOTES and closure of defects after ESD or





**Fig. 2.2** The Ovesco over-the-scope clip. **a** Delivery system mounted on the endoscope. **b** Close-up view of open clip in transparent cap. **c** Clip in closed position, convex

(serosal) side. **d** Clip in closed position, concave (mucosal) side. (Used with the permission from Ovesco Endoscopy)

EFTR (endoscopic full-thickness resection) is the OTSC<sup>®</sup> Closure system (Ovesco Endoscopy, Tübingen, Germany). These clips are made of nitinol and are in the shape of overlapping jaws or “bear claws” (Fig. 2.2). The jaws are in the closed position when manufactured, but are flexed into the open position when mounted on the tip of an endoscope. When deployed by pulling back the inner collar of the deployment pod, the device will snap shut into the closed position due to the memory properties of nitinol. This entraps the gastrotomy between the jaws of the clip, thus sealing the defect.

The feasibility of OTSC closure of defects was noted as far back as 2008 [24]. This study

used the Ovesco OTSC<sup>®</sup> to close gastric defects made after needle-knife exit in a nonsurvival porcine model. Defects were primarily closed in 8 of 9 experimental subjects, but the ninth could not be closed effectively due to a 20-mm rent accidentally made in the gastric wall. In 3 of the remaining 8 animals, the closure did not withstand “burst pressures,” a fact that may not be clinically significant as noted earlier [18]. Nevertheless, the feasibility of using OTSC for closure had been established.

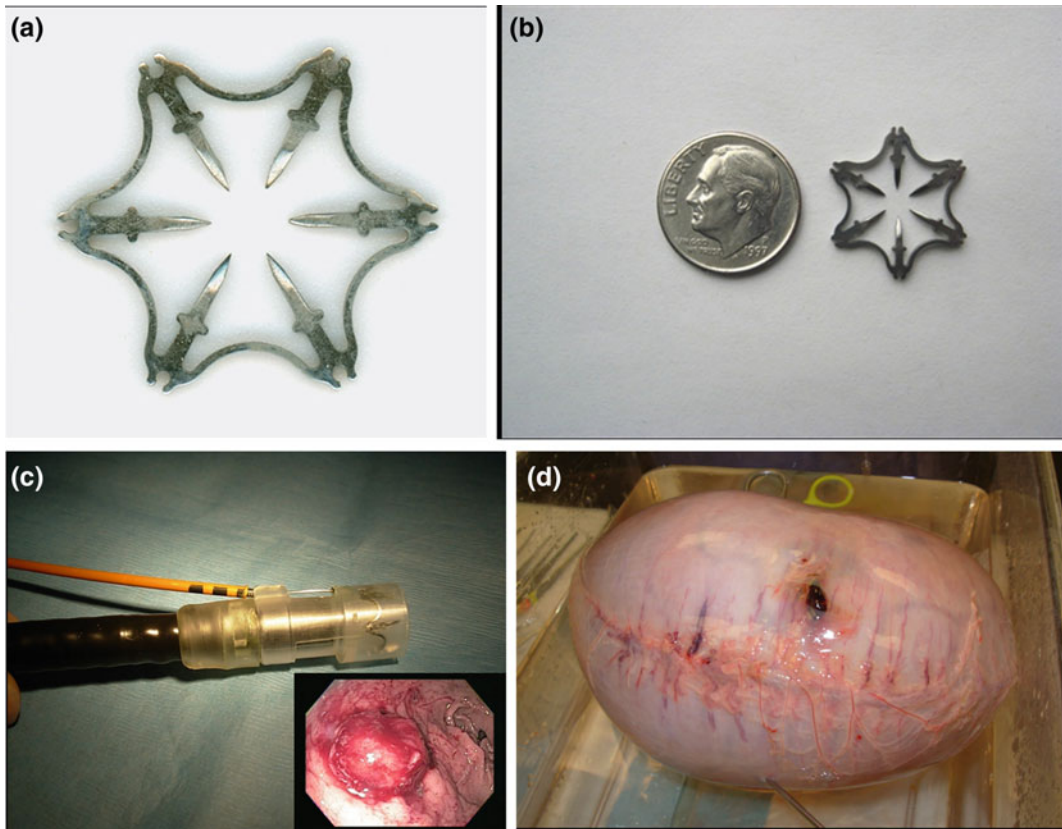
Matthes et al. used the Ovesco OTSC to close standardized defects in explanted porcine stomachs and then burst tested them with compressed air under water to assess for strength of the

closure [25]. Many similar ex vivo studies, in vivo survival and nonsurvival animal studies, and human studies have shown them to be effective as closure devices for NOTES and other iatrogenic perforations in the stomach, duodenum, colon, and esophagus [26–29].

Although used less commonly, the Padlock Clip™ OTSC (Aponos Medical, Kingston, NH) has also been used for closure of persistent fistulas, as well as transgastric and transcolonic NOTES. Originally approved for endoscopic hemostasis, this device consists of a hexagonal nitinol clip mounted in a translucent cap that fits over the endoscope. It has 6 prongs which, when deployed, gather tissue into the center of the hexagon, thus tamponading a bleeding site or, in the case of NOTES, sealing the defect (Fig. 2.3).

Our group published some of the first animal work with this device. We demonstrated in 2009, in an explant study with burst pressures, that the Padlock Clip™ could provide a secure gastric closure for NOTES [30]. Later, we reported the use of the Padlock Clip™ for gastrotomy closure in a survival study [31]. Two pigs were survived for 2 weeks, and 2 were survived for 6 weeks. All animals did well, the device appeared to be easy to use, and it provided a secure closure. So and Adler published a case report of closure of a persistent tracheoesophageal fistula in a human patient using the Padlock Clip™ [32], and Guarner-Argente et al. reported successful colonic closure with this device [33].

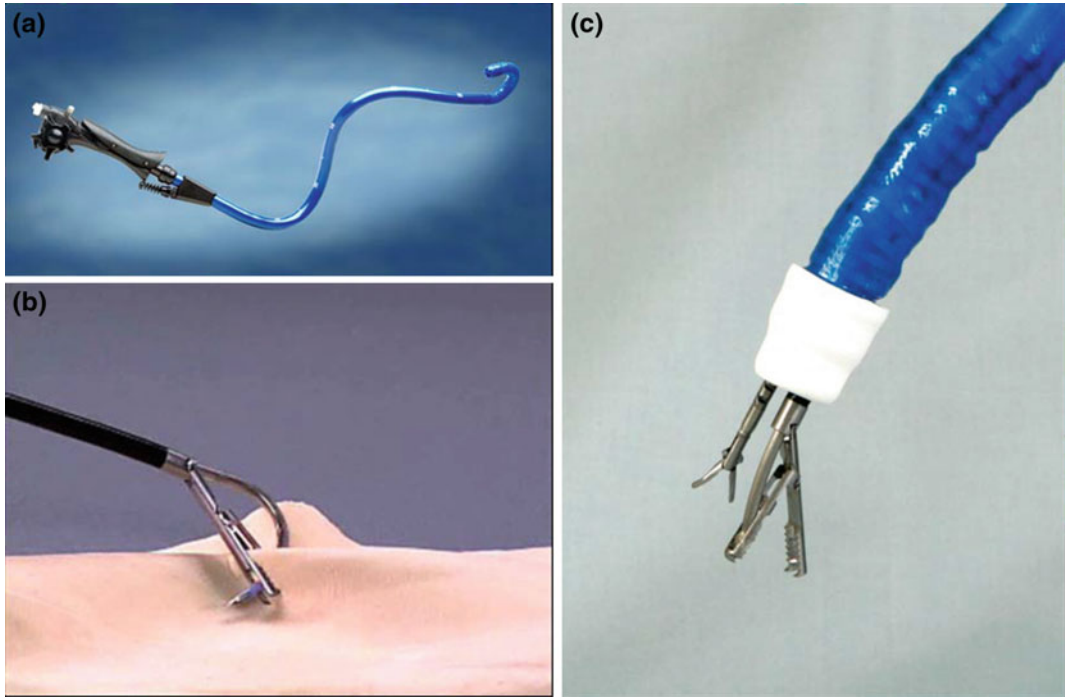
We have used the device a twice for closure of persistent gastrocutaneous fistulas in humans



**Fig. 2.3** **a** Padlock-G over-the-scope clip. **b** Actual size. **c** Padlock-G mounted on an endoscope in its delivery system. *Inset* Appearance of the Padlock-G after

intra gastric placement to seal a gastrocutaneous fistula post-PEG removal. **d** Burst pressure testing showing effective closure at high pressure





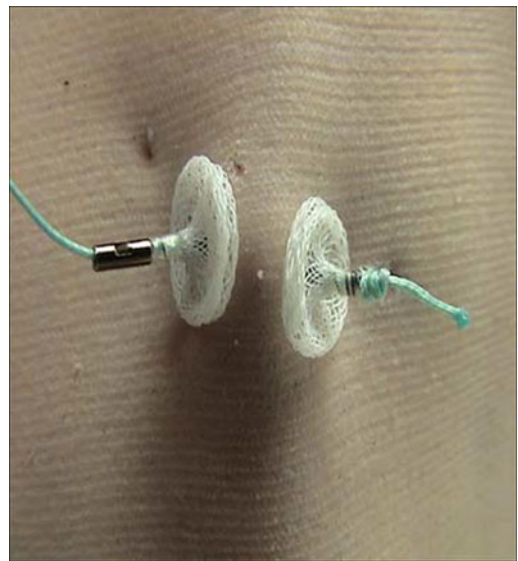
**Fig. 2.4** **a** The ShapeLock™ overtube. **b** The g-Prox® device. **c** The ShapeLock™ overtube with devices inserted

after PEG removal, but we feel it suffers from design flaws in the deployment system (a trip-wire that pushes rather than pulls to deploy the device, and so this wire is prone to kinking or bending, with failed deployment). A newer deployment system is being developed.

### (3) Endoscopic Suturing

Endoscopic suturing methods have been employed for gastrotomy closure since the inception of NOTES. Swanstrom and coworkers described the transport system (Transport, USGI Medical, San Capistrano, CA), which is a flexible but locking overtube that has 4 ports for insertion of graspers and other instruments for NOTES (Fig. 2.4) [34]. This group uses the g-Prox needle (USGI Medical, San Capistrano, CA) to deliver expandable tissue anchors (so-called snowshoe tissue anchors) to approximate tissue for gastrotomy closure (Fig. 2.5).

Kanstevoy et al. have used the Over-Stitch suturing device (Apollo Endosurgery Inc, Austin,



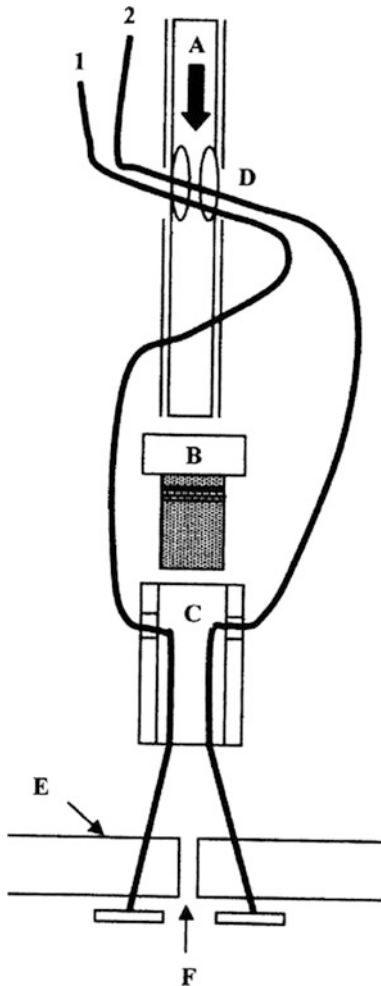
**Fig. 2.5** Tissue anchor placed with g-Prox® device

TX) to close a persistent gastrocutaneous fistula after PEG removal [35]. This device is the newest generation of the venerable “Eagle Claw”

endoscopic suturing device [36]. Since that time, many authors have reported the use of the Overstitch device for closure of gastrotomies, colotomies, and esophagotomies after POEM and other NOTES procedures [37].

#### (4) T-Tags

T-tags are short ( $\sim 1$  cm) metal rods with a suture attached at its midpoint. These can be loaded into an 18-ga or 19-ga needle and placed transmurally, either endoscopically or percutaneously (Fig. 2.6) [38]. When traction is placed on the suture, the metal bar swings perpendicular to the axis of traction and acts as a tissue anchor.



**Fig. 2.6** Schematic of T-tag closure of a tissue defect

Several groups have published their results using T-tags for gastrotomy closure [21, 38, 39]. Our own group has done work along these lines and has determined that trailing sutures can become tangled, extracorporeal knots are difficult to tie, tight tissue apposition can be a challenge, and in general, T-tag closure can be problematic. We circumvented some of these problems by using multiple T-tags mounted on a single suture [40, 41]. This is accomplished by utilizing tags with a metal loop through which a suture can be threaded. The endoscopic needle must be modified to have a longitudinal slot cut into it in order to allow the looped T-tag to be loaded. When multiple such tags are placed on a single suture, and the suture is cinched tightly, the effect is similar to a purse-string suture (Figs. 2.7 and 2.8).

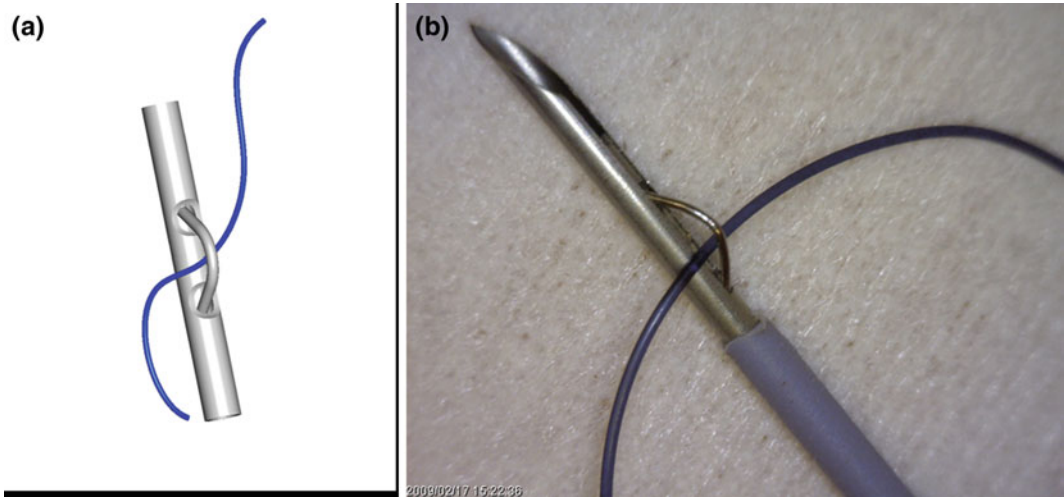
#### (5) Miscellaneous (Endoloops with Clips, Flaps, PEG, etc.)

Many other closure methods have been reported, to include endoscopic loops (detachable snares) in combination with clips [42], tunnels and mucosal flaps [10–15], PEG closure (placement of a PEG through the gastrotomy after NOTES) [43], “8-ring” device with clips [44], percutaneous suture closure of a gastrotomy [45], etc. As noted earlier, it is beyond the scope of this chapter on fundamentals to review exhaustively all closure methods. Interested readers are encouraged to start with the references listed here and to refer to technical reviews [16, 19].

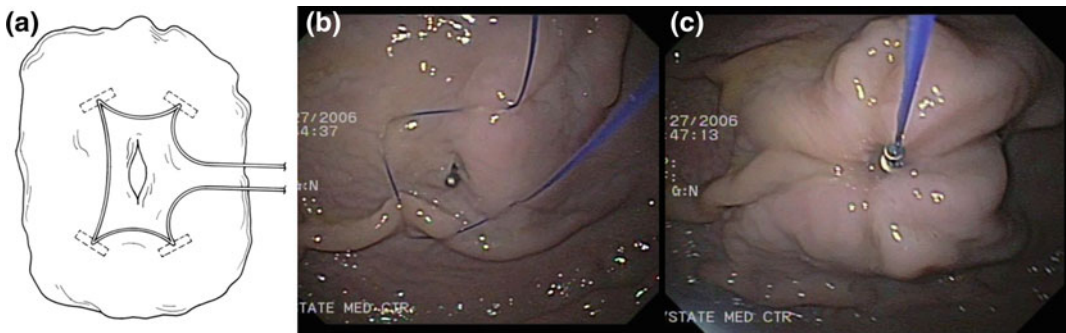
### Tips and Tricks, or Lessons Learned

#### (1) Maintaining Access

We learned early in our animal work that once capnoperitoneum has been achieved, repeat luminal exit from the stomach or colon can be a challenge. Insufflation of the abdominal cavity tends to compress the stomach or colon, and repeat location of the original exit site can be very difficult. Repeat luminal exit is even more demanding if the gastric exit was balloon-dilated



**Fig. 2.7** **a** Schematic of looped T-tag. **b** Looping T-tag loaded in slotted 19-ga needle and mounted on nylon suture. (Permission for use granted by Cook Medical Incorporated, Bloomington, Indiana)



**Fig. 2.8** **a** Schematic of looped T-tag closure. **b** Four looped T-tags placed in a square around gastric defect. **c** Prolene suture cinched tightly with friction-fit collar and

closing gastric defect. (Permission for use granted by Cook Medical Incorporated, Bloomington, Indiana)

rather than cut. Tonic retraction of the gastric musculature tends to close the gastrotomy site very quickly, and it can be a frustrating and fruitless endeavor to find and exit the gastrotomy. Therefore, we have learned to leave a guidewire in the abdominal cavity, which can be followed endoscopically, like a trail of breadcrumbs [46] to locate the exit site. Indeed, the scope can be back loaded over the wire so that locating the exit site is assured. This can be very useful in transvaginal cholecystectomy if the endoscope must be removed for any reason. Finding one's way through the mesentery into the abdomen

from the pelvis can be challenging, and leaving a wire to guide the way can be quite helpful.

We have subsequently improved on just leaving a loose wire in the abdomen. With the endoscope already in the abdomen, a needle puncture through the lower abdominal wall into the insufflated abdomen is performed under endoscopic viewing. A guidewire can then be passed to the endoscope, captured with a snare, and pulled out through the subject's mouth. The percutaneous end can be fixed with a hemostat at the skin level, and traction can be applied at the mouth. This so-called "monorail" method allows

for repeated endoscope or device passage over the guidewire easily, quickly, and safely despite capnoperitoneum, and with no chance of dislodging the guidewire.

## (2) Spatial Orientation

In general, spatial orientation seems to be less of a problem for endoscopists than surgeons. Endoscopists are comfortable working in retroflexion. In addition, they are utterly unable to determine true anterior, posterior, cephalad, caudad, left, or right during intraluminal endoscopy, and so they tend not to concern themselves with these parameters.

On the other hand, surgeons rely on spatial orientation much more and can easily become confused when the anatomic landmarks are not in proper orientation. We have learned to take advantage of these differences in training and experience. There are times, during transvaginal cholecystectomy for example, when paying attention to the true horizon, keeps one out of trouble. By the same token, there are times when an endoscopist's ability to work retroflexed and upside down brings a considerable advantage. Once again, we have found that having both surgeons and endoscopists on the team is of considerable value.

## (3) Tissue Retraction and Triangulation

As anyone who attempts NOTES using a flexible endoscope will quickly learn, inability to perform tissue retraction is a serious constraint. Given that the accessory channel(s) of flexible endoscopes are in line with the shaft, ability to retract or triangulate is quite restricted. Blunt dissection and spreading of tissue are limited by the size of the devices that can be inserted through the working channel as well. One way to overcome such limitations is to use a laparoscopic port (so-called hybrid NOTES) for retraction or dissection. An additional endoscope can be inserted, either through the same natural orifice or from another orifice. In transvaginal cholecystectomy, multiple rigid laparoscopic instruments may be inserted alongside each other and left parallel or

crossed to effect tissue retraction. These considerations may have given birth to techniques ultimately used in single-incision laparoscopic surgery (SILS). Extracorporeal magnets have also been used effectively for organ retraction, although not yet in human cases [47, 48]. Let us not forget gravity. Placing a patient in deep Trendelenburg or reverse Trendelenburg position, rotating the patient into the left or right lateral decubitus position, or even placing the patient prone may all yield effective organ or tissue "retraction" by the use of gravity.

## (4) Improvising and Off-Label Use of Devices

When performing NOTES, it becomes readily apparent that the development of devices by industry has not kept pace with innovation by clinician researchers. We are left with common devices used in endoscopy and laparoscopic surgery that may need to be adapted to different uses. Endoscopic caps, guidewires (as noted above), hot and cold forceps, snares, grasping forceps, PEGs, needle knives, stents, and other devices may be used off-label to achieve desired outcomes. For example, we have modified an esophageal stent deployment system to deliver hernia mesh aseptically through the mouth to the abdomen [49]. Esophageal dilation balloons can be used to dilate gastrotomies. Closure is effected with hemostatic clips. We have also used a flexible laparoscopic stapler transorally to create a stapled cystogastrostomy to drain pancreatic pseudocysts [50, 51]. Truly, "necessity is the mother of invention" when it comes to innovation in NOTES.

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## Complications

As with any other surgical or endoscopic procedure, despite our best efforts, immediate or delayed adverse events will sometimes occur. These include infection, bleeding, perforated viscus, anesthesia or metabolic complications, pulmonary or cardiac complications, damage to bystander organs, bile duct or other ductal or vascular injuries, and conversion to laparoscopic

or open procedure. It is beyond the scope of this chapter to address adverse events in detail, but suffice it to say that as in open or laparoscopic surgery, standard surgical attention to infection control, hemostasis, and proper technique are of critical importance in NOTES. Also, the NOTES surgeon must be prepared to recognize and react to adverse events quickly and decisively using the endoscopic or laparoscopic tools at hand. If trouble looms large, one should reach out to surgical or endoscopic colleagues for additional help when dealing with immediate or delayed complications.

## Conclusion

NOTES procedures require extensive knowledge of the tools available to the advanced therapeutic endoscopist. For this reason, we still espouse the formation of a multidisciplinary team. Gastric closure remains an area of investigation for transgastric NOTES procedures, and in part due to this reason, transvaginal procedures (which are closed with simple external sutures) have become more widely adopted. An operating suite with both laparoscopic and advanced therapeutic endoscopic equipment is a must in order to perform these procedures.

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