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NOTES and Endoluminal Surgery

Humana Press

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Foreword

In 2004, Dr. Anthony Kalloo and his colleagues introduced a disruptive concept involving passing an endoscope through the wall of the stomach and into the peritoneal cavity in order to perform a gastrojejunostomy. Shortly following this, Drs. Rao and Reddy demonstrated a transgastric appendectomy performed via an endoscope through a patient's mouth. These creative innovations ignited a firestorm of discussion and research in endoscopic surgery.

A group of surgeons and gastroenterologists came together to form the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR). This group intended that this new concept be introduced with attention to patient safety and careful outcomes assessment.

Industry responded admirably to the needs of the researchers and developed a host of new technologies to facilitate these endeavors. In the research laboratory, new procedures were developed by essentially every surgical specialty and through every natural orifice.

Practical application of the methods was begun under careful institutional review board supervision. Initially, however, results demonstrated the procedures to be somewhat difficult to perform, labor-intensive, and costly. Many were ready to abandon the concept.

Yet, throughout the world, others continued to study and perfect the procedures, gaining great success and acceptance. Additionally, concepts gained from the study of NOTES were adapted to new areas, and single-port surgery and intramural procedures such as per-oral endoscopic myotomy (POEM) emerged.

Today, it seems clear that NOTES is quite alive. New and improved concepts and technology continue to enhance the procedures and expand the applications.

This monograph will serve as an important milestone in documenting the progress and growth of natural orifice surgery and crediting those who have made great contributions to the field.

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Acknowledgements

I would like to thank my wife Kirsten and my children Julia, Justin, and Daniel, for affording me the time to complete this project.

I would like to thank my early surgical mentors, Dr. John K. Edoga and Dr. Demetrius E. M. Litwin, both of whom taught me the value of innovation in the search for better and less invasive therapies to treat disease.

I would like to thank my surgical leaders, Dr. Richard B. Wait and Dr. Neal E. Seymour, for supporting our NOTES research and encouraging us to keep forging ahead.

I would like to thank my co-editors and research partners, Dr. David J. Desilets and Dr. David B. Earle, for their spirit of adventure and for teaching and reinforcing the concept of teamwork.

Lastly, I would like to thank all the authors of this book, without whom there is no project. Good will can only be thanked with true gratitude.

John R. Romanelli

I would like to thank my wife Carla, for putting up with my frequent absences from the family during this project. Without your support, I can do none of the things that I do.

I would like to thank interventional endoscopy mentor, Doug Howell, who taught me the value of persistence, risk-taking, and ignoring naysayers who tell us "it will never work."

I would like to thank my co-editors and research partners, Dr. John Romanelli and Dr. David Earle, for their faith in me and my skills, for their can-do attitude, and for pushing me in directions I did not know I would love.

I would also like to thank the authors of this book, who gave freely of their precious time and effort, and without whom the textbook would not exist. Thank you colleagues. You are the best!

David J. Desilets

I would like to thank my wife Noreen and three daughters, Emily, Lindsey, and Allison, for supporting me to read and write about my life's passion—surgery. I would also like to acknowledge my mentor, Felicien Steichen, M.D., a true surgical innovator, and whose surgical stapling techniques are used worldwide on a daily basis. Dr. Steichen started the Institute of Minimally Invasive Surgery in the mid-1990s, to foster an innovative spirit that thrives today. During the final year of his life, he expressed interest and concern about going through a normal organ to get to a diseased one, yet never tried to stifle the innovation. I would also like to acknowledge John Bookwalter, M.D., another surgeon innovator who also has a daily impact on the global practice of surgery. John has given me much encouragement to help complete this book. And without Richard Wait, M.D., Ph.D., believing in me during and after my training, I would never have had the opportunity to start and run a minimally invasive surgery fellowship and thus the opportunity to co-edit this book. Finally, I would like to thank all the authors and my co-editors, whose collaborative effort will help advance the field of surgery for years to come.

David B. Earle

Note From the Editors

There are two words that factor prominently in this textbook, both of which have multiple spelling options. We chose to simplify with one spelling for each word for the purposes of this text.

NOTES is an acronym trademarked with the US Patent and Trademark Office in January 2007 for the purpose of "promoting training, development and fundraising services for surgical techniques utilizing natural orifices…" The word was spelled as such reflecting the concept of crossing the lumen of a hollow viscus. The "T" in NOTES stands for translumenal, spelled with an "e" in the original white paper published in 2006 and in the trademark application in 2007. This did not follow the form of the word "intraluminal," however, and many authors have reverted to spelling the word "transluminal." We have chosen to largely sidestep this issue by utilizing the acronym NOTES wherever possible. This acronym is widely accepted and understood—a testament to the early thought leaders who chose to codify this new concept with uniformity.

Also, the word "per-oral" is often spelled with and without the hyphen and as one word or two separate ones. We are choosing to use the hyphenated form because, although it was initially spelled without the hyphen by Dr. Inoue, who first published the seminal work on POEM, most publications now routinely use the hyphenated form.

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The History of NOTES

1

John R. Romanelli and David B. Earle

Abstract

Natural orifice translumenal endoscopic surgery (NOTES™) was officially born in 2005 when a forward thinking group of gastroenterologists and surgeons convened to discuss, organize, codify, and elucidate concerns about this potential new disruptive surgical idea. This meeting came on the heels of a report of "flexible transgastric peritoneoscopy" from Johns Hopkins University [1] and several subsequent experiments in animal models expanding upon the possibilities this technique represented [2]. The NOTES moniker was adopted at this meeting, as was the formation of the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR®) [2]. But a peek into the history of surgery via the natural orifice reveals that the idea was an old one, dating back into the 1800s in some cases. Many animal experiments were performed, demonstrating many new and novel techniques to commonly performed operations, and scientific investigation was undertaken to determine the safety and feasibility of these approaches. Human work began to emerge in 2005 and continues to develop; in some cases, becoming widely adopted.

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A Disruptive Approach to a Disruptive Approach

While physicians have peered into the depths of the human body through its natural openings for more than 100 years, natural orifice translumenal endoscopic surgery, or NOTES™, dates back to 2005. This occurred when a group of gastroenterologists and surgeons convened in an attempt to propagate this disruptive concept of minimally invasive surgery in a thoughtful, scientific, and safe manner. The meeting was catalyzed by a report of "flexible transgastric peritoneoscopy" published by Kalloo et al. in 2004. The procedure was performed in a swine model, and subsequent animal work by the same group at Johns Hopkins University demonstrated the feasibility of procedures such as transgastric ligation of fallopian tubes, cholecystectomy, gastrojejunostomy, and splenectomy [1]. The novel innovation was the use of the flexible endoscope as the operating platform.

The slow progress of utilizing a natural orifice has gone from simply looking to performing procedures adjacent to the opening, and finally to performing procedures far from the natural orifice. While all procedures were both enhanced and limited by one technological device or another, the technologic restrictions did not limit the imagination and foresight of the surgical and gastroenterological pioneers that laid the foundation for NOTES™ as we know it today.

In 2005, fourteen thought leaders, representing the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) and the American Society of Gastrointestinal Endoscopy (ASGE), assembled in Phoenix, Arizona, to form a working group on this nascent field. The result of this meeting was an important white paper written by the working group published in 2006 [2]. There were three critical accomplishments from this meeting.

The first accomplishment was an agreement on nomenclature. Although the focus at the time of the meeting was on transgastric surgery, the leaders recognized that other routes of access to the abdomen, namely transvaginal or transcolonic, could also develop. The term "natural orifice translumenal endoscopic surgery" was adopted to describe this, and the acronym NOTES™ was born. It was also uniformly agreed upon that these were to be considered surgical procedures because "tissue resection and repair is the ultimate goal of accessing intraperitoneal organs." The working group named itself the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR), a clever acronym for the development of incisionless surgery. While it may seem trivial to have spent so much effort on nomenclature and taxonomy, one only needs to consider the bewildering sea of names and acronyms created to describe techniques and devices used in single-port laparoscopic surgery to realize that agreement on nomenclature is important [3].

The second accomplishment was to define criteria by which one could participate in NOSCAR, with an eye on avoiding the large increase in complications caused by the last revolution in gastrointestinal surgery: the introduction of laparoscopy. In the name of patient safety, NOSCAR outlined the following criteria for participation:

1. A multidisciplinary team, consisting of advanced laparoscopists and advanced therapeutic endoscopists
2. Membership in SAGES and/or ASGE
3. An on-site animal laboratory for both research and training

4. Must be willing to share laboratory data at NOSCAR semiannual meetings
5. Must be willing to perform all human cases under the auspices of Institutional Research Board (IRB) approval
6. Must be willing to submit cases to a society-sponsored registry.

The third accomplishment was to define the current limitations in the ability to perform NOTES™ procedures. They outlined the following eleven potential barriers to the safe introduction of NOTES™ in human patients:

1. Access to peritoneal cavity
2. Gastric (intestinal) closure
3. Prevention of infection
4. Development of a suturing device
5. Development of anastomotic (non-suturing) device
6. Spatial orientation
7. Development of a multitasking platform to accomplish procedures
8. Control of intraperitoneal hemorrhage
9. Management of iatrogenic intraperitoneal complications
10. Physiologic untoward events
11. Training other providers.

This paper immediately set into motion those interested in NOTES™ research and development, as well as the clinical introduction of these techniques.

Transvaginal Approach

Transvaginal surgery dates back to ancient times. Some claim that the first surgical procedure described in history was a vaginal hysterectomy by Themison of Athens in 50 BC. Others claim the first vaginal hysterectomy was performed by Soranus of Ephesus in 120 AD, whose treatise, gynecology, has survived into modern times (translated into English in 1956) [4, 5]. This was considered a seminal work at the time and provided a look at ancient obstetric and gynecological techniques. Soranus described a transvaginal hysterectomy for severe uterine prolapse associated with ischemia and gangrene. Morbidity and mortality, however, were almost universal. In the eleventh century, an Arabian physician, Alsaharavius, wrote of vaginal hysterectomy, and there are some who believe that these patients survived. Clearer reports of survival date back about 500 years; Berengarius da Carpi of Bologna in 1507 performed a partial vaginal hysterectomy on a patient who survived. More incredible is the case of Faith Howard, a 46-year-old peasant, who performed a vaginal hysterectomy on herself in 1670. She was said to be carrying a heavy load when her uterus prolapsed completely. Frustrated by this frequent occurrence, she grabbed her uterus, pulled as hard as possible, and cut the whole lot of it with a short knife. The bleeding soon stopped and she lived on for many years, with a persistent vesico-vaginal fistula [5, 6]. The first elective cases began to appear in the literature from France and Germany shortly after 1800—and many years before Charles Clay reported the abdominal hysterectomy in 1843, which unfortunately was unsuccessful due to an incorrect diagnosis and early postoperative mortality [5, 7]. Vaginal hysterectomy for cancer was reported in 1892 by Terrier and Hartman [8].

In the late 1800s Durhssen, Mackerodt, and Martin of Berlin, Germany, utilized anterior colpotomy to perform transvaginal operations of the tubes, ovaries, and uterus for a variety of conditions, including ectopic pregnancy, and the use of “morcellement” for the removal of very large uterine myomas. At the annual meeting of the British Medical Association in London in 1895, Martin touted the decreased morbidity compared to laparotomy as justification for the approach. He closed the colpotomy initially with silk and silver wire, but abandoned these for juniper catgut. Postoperatively, the vaginal wound was said to take only 8–10 days to heal, “so that about the twelfth day the patient may be allowed to leave bed.” No local treatment was necessary, and all of his 152 cases recovered without “feverish reaction.” [9].

In 1901, Russian gynecologist Dmitry Von Ott presented his work in St. Petersburg using a posterior colpotomy for a variety of gynecological operations. Unique to his approach, which he dubbed “ventroscopy,” was the use of “a peanut-sized lamp and a spoon-shaped shield to protect the patient from burn," and reflected light into the cavity using metallic mirrors and a headlamp. He also utilized the Trendelenburg position and placed a cotton swab in the vagina, allowing filtered air to be vacuumed into the peritoneal cavity, creating a "natural form of insufflation." His technique was used by the Europeans into the 1920s to 1930s, and by the Americans from the 1940s to 1960s [10].

Transvaginal tubal ligation was further advanced by the Japanese in 1970 [11], and there were additional scattered case reports throughout the 1970s. Transvaginal oophorectomy (at the same time as a hysterectomy) was revisited by Nichols in 1978 [12]. He noted that access to the ovaries could be very challenging due to the constraints of the size of the colpotomy and the bony anatomy.

Transvaginal specimen extraction was first described in the early 1990s. Delvaux et al. from Brussels [13] described a case report of a laparoscopic cholecystectomy in a woman with large gallstones, where they opted for specimen removal via a posterior colpotomy rather than removal from a larger abdominal wall incision. Also in 1993, Breda et al. in Italy used a posterior colpotomy for extraction of a tuberculous left kidney after laparoscopic nephrectomy [14]. Although these reports were overlooked at the time, they were proof of concept that organs not immediately adjacent to the vagina can be safely removed via this natural orifice.

In the mid-1990s, there were two reports of transvaginal oophorectomy using an endoscope. In London Magos published a technique using a standard laparoscopic instrumentation without pneumoperitoneum, and Yuen in Hong Kong, in his published experience, commented on the difficulty of manipulating three instruments in such a small working space—a prescient statement given the subsequent development of single-site surgery and the challenges that the concept introduced [15, 16].

It was not until the turn of the twenty-first century, about 100 years since the first surgeon peered through the vaginal vault into the peritoneal cavity using a small lamp with metal mirrors that our current concept of transvaginal NOTES™ came into being.

In 2007, Scott et al. used a swine model to perform transvaginal cholecystectomy utilizing a proprietary magnetic instrument system [17]. The first report of a transvaginal cholecystectomy in the USA was presented as a video at the April 2007 annual meeting of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). This seminal video was the first time a human NOTES™ cholecystectomy had been presented, and it utilized a hybrid approach with a transvaginal flexible endoscope and umbilical laparoscopic port and took approximately 3 h. This report was immediately criticized, with one surgeon interviewed for a New York Times article calling the procedure "repulsive," stating that "the idea of puncturing internal organs and then sewing them up was cause for concern". She further stated that "As a woman I find it very invasive, physically and emotionally. To me it's quite distasteful." [18]. The report of the video was published in December of the same year [19].

The first South American report of transvaginal cholecystectomy also appeared in the literature in 2007. Zorron et al. performed a case the same week as Bessler's group in New York, and the case was successfully completed with endoscopic instruments placed alongside the vaginal endoscope. Amazingly, the procedure lasted only 66 min, and this technique quickly gained popularity in Brazil [20].

Also in 2007, Marescaux and colleagues at IRCAD (Institut de Recherche contre les Cancers de l'Appareil Digestif; French: Institute for Research into Cancer of the Digestive System) in Strasbourg reported a hybrid transvaginal cholecystectomy using a flexible endoscope aided by a single, 2-mm, laparoscopic port in a human. The authors were careful to report that "all of the principles of cholecystectomy were strictly adhered to," and that the patient had an uneventful recovery [21]. A second human case, this one from Hamburg, was published a month later, where Zornig and colleagues performed a cholecystectomy with standard laparoscopic instrumentation (i.e., a rigid endoscope) via the vagina and one umbilical port. The authors emphasized that the vaginal access was better for closure and infection, and rigid instrumentation was easier to use than a flexible endoscope [22]. This approach became common in Europe for those who adopted the procedure.

The first case report of human transvaginal appendectomy came in 2008 from India. The report details six attempted cases: the first three failed, the next two were completed with a 3-mm laparoscope in the umbilicus, and the final case succeeded as a purely transvaginal case. In the final case, pneumoperitoneum was initiated via a transumbilical Veress needle. Hot biopsy forceps were used to divide the mesoappendix, and endoloops were used to secure the appendix. All patients in the series recovered uneventfully [23].

After these early reports there have been hundreds of articles published about transvaginal operations. While the vast majority of these focused on cholecystectomy, removal of all of the GU organs, liver, spleen, and stomach have also been reported. Exploration and specimen removal have also been reported, along with hernia repair.

Importantly, genuine concerns about the safety and appropriateness of a transvaginal approach gave rise to a host of published surveys given to patients, spouses, and healthcare workers. These surveys suggest there is no specific patient type that prefers a transvaginal approach over standard laparoscopy. Results are highly variable when examined by age, reason for operation, and BMI. Concerns regarding scarring and cosmesis were generally less important compared to issues related to safety and recovery time. In general, patients were more likely to accept a transvaginal approach compared to healthcare workers [24–33].

Transgastric Approach

The first published cases of transgastric surgery appeared in 1950, when Scovel and Holliger reported a case of transgastric pancreatocystogastrostomy [34]. In 1959, Brewer and Shumway reported transgastric catheter drainage of a pancreatic pseudocyst [35]. Although both of these cases were performed via laparotomy, they were the first cases that described crossing the lumen of a hollow organ to gain access to the operative field, an important precursor to NOTES™. Another interesting concept using a transgastric approach was published by Petropoulos in 1979, where he described a transgastric route for highly selective vagotomy to control peptic ulcer symptoms [36].

In 1980, Ponsky et al. in Cleveland described the percutaneous placement of a gastrostomy tube, rather than placement via a laparotomy incision [37]. A monumental achievement at the time, this drastically reduced the invasiveness of gastrostomy tube placement. The procedure was accomplished via a natural orifice, traversed the lumen of a hollow viscus, and utilized a flexible endoscope. One could easily argue that Ponsky's PEG tube is the very first NOTES™ procedure by today's standards.

Another use of transgastric surgery was for specimen extraction. In 1998, Gagner published a series of needlescopic cholecystectomies where a gastrotomy was performed, and the gallbladder was placed into the stomach. After laparoscopic suturing of the stomach, the gallbladder was extracted orally with an endoscope [38]. Although the work was published and successful, local criticism prompted abandonment of the idea.

Kalloo et al. published their landmark paper on transgastric peritoneoscopy in 2004, and this immediately opened the eyes of many to the potential toward intra-abdominal surgical procedures via the natural orifice, in this case, the mouth. Using a swine model, the authors created a gastrotomy using a needle knife and passed a guidewire across the opening. The gastric wall was dilated with a balloon or enlarged with a pull-type sphincterotome. The endoscope was passed into the abdominal cavity, and a liver biopsy was performed. The gastrotomy was closed using endoscopic clips. They performed 12 nonsurvival cases and later 5 survival cases [1]. This series demonstrated that deliberate perforation and subsequent closure of the gastrointestinal tract, with a minor procedure performed through the opening, was safe and repeatable. This study began to fuel the imaginations of both gastroenterologists and gastrointestinal and endoscopic surgeons about the possibilities of incisionless surgery in the abdominal cavity.

Also in 2004, a surgeon and a gastroenterologist team in Hyderabad, India, performed a human NOTES™ case. Rao and Reddy had a patient with severe burn scars on the abdominal wall who presented with acute appendicitis, so they chose a transgastric route to the abdomen [39]. Although this work has never been formally published, they presented a video of this case at both the Society of American Gastrointestinal and Endoscopic Surgeons and Digestive Disease Week annual meetings in 2005. In the operation, they used an endoscope to transit the stomach and used bipolar cautery via the endoscope to divide the mesoappendix. An endoscopic loop was utilized to ligate the appendiceal stump, and a hot snare was used to divide the appendix. Using an overtube, they withdrew the specimen through the mouth. They later reported seven successful cases using this approach in 2010 [40].

In 2005, Kalloo's group followed their initial work with a report detailing the transgastric ligation of the fallopian tubes in a swine survival study [41]. Six pigs underwent unilateral tubal ligation using endoloops, with the opposite side left intact as a control. Necropsy at two weeks revealed all ligations to be successful both radiographically (hysterosalpingogram) and histologically. There was no evidence of infection or other complications. Also in 2005, Kantsevoy and colleagues performed endoscopic gastrojejunostomy in two pigs. They utilized a prototype suturing device dubbed the "Eagle Claw" to secure a loop of jejunum to the gastrotomy site. Midway through the two-week survival period, both contrast and endoscopic examination revealed patent anastomoses with no evidence of leakage. At the two-week necropsy, there were no signs of infection, abscess, leakage, or adhesions [42]. Park and colleagues in Sweden published their swine series of nonsurvival and survival transgastric cholecystectomies in 2005 [43]. They utilized two side-by-side endoscopes, and all survival cases were successful. The gastrotomy site was closed with an endoscopic suturing technique, which they also used to successfully perform three cholecystogastrostomies. Importantly, they described the concept of utilizing a laparoscopic instrument to facilitate the procedure, which they would later refer to as "hybrid NOTES™"—a hybrid of laparoscopic and NOTES™ techniques. In 2005–2006, Thompson et al. in Boston published two reports using a survival swine model that included transgastric peritoneal explorations, oophorectomy and partial hysterectomy [44, 45]. Endoscopic clips were used for gastric closure. All cases in both studies were successful and without complications. In 2006, Gostout et al. at the Mayo clinic developed a model for appendicitis, creating inflammation of the uterine horn with an injection, followed by endoscopic transgastric resection two days later with a second procedure. This report is also important because it described gastric closure using T-tags rather than endoscopic clips [46]. In 2006, the "Apollo Group" performed transgastric splenectomy in a nonsurvival swine model. The splenic vessels were ligated with endoscopic loops and a single endoscopic clip; the vessels were divided with an endoscopic polypectomy snare. The gastrotomy was enlarged for specimen removal with a sphincterotome and closed with endoscopic clips [47].

Transgastric work on the biliary tree, mostly looking at cholecystectomy, began in the laboratory setting in 2007. These early experiments focused on feasibility and device development, recognizing the need for a flexible instrument platform that could be "rigidized." [48–54]. The first human cases of transgastric cholecystectomy were reported by Auyang et al. in 2009 [55]. Four transgastric cholecystectomies were completed via a hybrid approach—the cystic duct and artery were ligated with a laparoscopic clip applier. They noted the difficulty of performing the entire case in a retroflexed position, as has been noted by others.

Our group reported initial experience with transoral, transgastric pancreatic pseudocystgastrostomy in 2008 [56]. Our initial patient was a critically ill man with a large infected pancreatic pseudocyst, who was hemodynamically unstable. Two double-pigtail stents had previously been placed endoscopically into the infected cyst, but due to hemorrhage and the presence of debris, endoscopic drainage had failed. We removed the stents, dilated the tract with an endoscopic balloon dilator, and passed a flexible, transoral linear stapler through the opening into the cyst. Firing the stapler created a stapled pseudocyst-gastrostomy. Further details on this technique are discussed elsewhere in this text.

Transgastric peritoneoscopy was reported by Hazey et al. in 2008 in ten patients [57]. In this pilot series, patients that had a pancreatic mass and were to undergo diagnostic staging laparoscopy prior to potential pancreaticoduodenectomy underwent both laparoscopy and transgastric endoscopic peritoneoscopy. For patients who went on to undergo pancreaticoduodenectomy, the gastrotomy site was resected. For those were not resectable, the gastrotomy site was used for the palliative gastrojejunostomy. The findings at laparoscopy and endoscopic peritoneoscopy were in agreement in 9 of 10 patients, leading the authors to conclude that the approach was safe.

Transanal Approach

While Ponsky was working on endoscopic surgery of the upper GI tract in the early 1980s, Buess in Germany began work on the lower GI tract with a technique he coined transanal endoscopic microsurgery (TEM) [58]. In 1985, he reported twelve rectal operations with surgical suturing utilizing an operating endoscope [59]. He continued developing the technique, and over the next decade more reports by him and by others emerged. While there were scattered case reports of colectomy via a transanal approach dating back to the 1950s, its use aside from abdominoperineal resection was not popularized until after the development of the laparoscopic approach to colon surgery in the 1990s. In the early 1990s, Franklin in San Antonio began using a transanal approach for specimen extraction after laparoscopic colectomy [60].

A review from 2011 found only 19 reports from a search spanning five-and-a-half decades (1955–2011). They concluded that natural orifice specimen extraction (NOSE) was safe and feasible, but lack of a uniform technique made widespread adoption limited [61].

The evolution of TEM has utilized the same concept with newer instrumentation and a further reach. This concept has adapted the single-port devices for use in transanal operations and rebranded the technique transanal minimally invasive surgery, or TAMIS. First reported in about 2010 by Atallah and colleagues in Orlando, this technique is rapidly gaining enthusiasm among colorectal surgeons as the equipment is much easier to use compared to that used for TEM [62].

Transesophageal Approach

An interesting offshoot of the NOTES™ transgastric work was the idea of mediastinal work being done outside the lumen of the esophagus. Fritscher-Ravens et al. published nonsurvival and survival porcine studies looking at mediastinal exploration across the esophageal lumen in 2007. The esophagotomy site was chosen with endoscopic ultrasound to avoid vascular injury and was closed with both endoscopic clips or suturing. All of the pigs who were survived six weeks were found that have healed the esophagotomy sites, and none suffered from mediastinitis or leak [63].

Another important early work in the esophagus was published in 2007 by Pasricha and colleagues in Texas [64]. They used a swine model for performing a transesophageal myotomy of the lower esophageal sphincter (LES). In four animals, they made an incision in the mucosa of the esophagus 5 cm above the LES. A balloon was then used to open the submucosal plane, and a monopolar needle knife was used to divide the circular muscle fibers of the LES. The mucosa was then clipped closed. All animals survived for one week, and at necropsy, all of the closure sites had healed without evidence of infection. This seminal work led to the clinical application of a similar technique in humans, first performed in Japan by Inoue and colleagues. In their 2010 publication, they described the technique and results in their first 17 patients and coined the term per-oral endoscopic myotomy (POEM). Their extensive experience in endoscopic submucosal dissection was a significant factor in moving forward with this approach in humans [65]. A noteworthy difference in their technique was the use of dyed saline to distend the submucosal space, along with division of the connective tissue under direct vision using a monopolar triangular-shaped knife rather than a balloon. This procedure has since been performed on thousands of patients across the globe, sparking research, development, and continuing education opportunities, along with almost 200 peer-reviewed publications on the technique.

Transurethral Approach

The urethra has typically been disregarded as a viable natural orifice for utilizing NOTES™ techniques, primarily due to its diminutive diameter. Transurethral surgery has been the domain of urologists since the late 1890s. The first report of rigid cystoscopy in a male patient appeared in 1898 by Howard Kelly and remains a seminal work to this day [66]. Interestingly, illumination of the bladder came via reflection from a head mirror. By 1908, bladder tumors were routinely being removed endoscopically by urologists, albeit not without significant morbidity and mortality [67]. Transurethral resection of the prostate (TURP) began in 1926, when Stern in New York City used a novel "resectoscope." [68]. Stern later moved to Florida and was subsequently expelled from the American Urological Association (AUA) for attempting to charge urologists a $5 fee for every TURP. Stern died in 1946, never having been readmitted to the AUA [69]. Scattered case reports began to appear in the 1940s concerning ureteral instrumentation and stone extraction, which were widely reported by the late 1950s and 1960s. Wagenknecht published the first account of cystoscopy with flexible endoscopic technology in Germany in 1982 [70]. It was not until 2006 that the transurethral approach began looking and operating on organs distant from the genitourinary tract. Lima and colleagues published a series of nonsurvival and survival cases in a swine model, initially performing trans-vesical peritoneoscopy. They did not close the bladder, rather decompressed it for four days, allowing all cases to heal successfully. They subsequently published work on cholecystectomy and nephrectomy in a nonsurvival swine model using the transurethral approach in combination with a transgastric approach [71–73]. In 2009, more reports emerged utilizing a transurethral approach in an animal model to access organs outside of the urethra and bladder [74–76].

The limited size of the urethra, however, obviously restricts specimen extraction size, and this led Lima and colleagues in Portugal to experiment with endoscopic morcellation in a nonsurvival swine model for nephrectomy in 2011 [77].

Limitations of instrumentation and clinical scenarios, along with the availability of other natural orifices, make the urethra less practical for most NOTES™ applications. Continued research in this area remains important, as it may spawn the development of better techniques and instrumentation that could be applied in a wide array of applications.

Transsphenoidal Approach

Transsphenoidal pituitary gland surgery is another procedure performed via a natural orifice. The earliest known case report of a transsphenoidal approach to pituitary tumors was published by Hirsch in 1949 [78], another early account of this technique more than twenty years later from France in 1972 [79]. The first reported use of an endoscope for this technique arrived 6 years later from Germany [80]. In the latter report, high-pressure lumbar air insufflation was used in combination with an angled rigid endoscope to provide a quality view and the ability to distinguish tumor from normal pituitary tissue. The use of flexible endoscopic technology for hypophysectomy has emerged over the last decade with scattered case reports.

NOTES™ Hernia Repair

Given its purely reconstructive nature and frequent use of an implantable prosthetic, we have included hernia repair as a separate section, encompassing a variety of natural orifice approaches. Initial reports of NOTES™ hernia repair appeared in 2007. Hu and colleagues used a transgastric approach in a nonsurvival swine model to create a small (3 × 2 cm) laparotomy incision from the inside, not opening the skin. This was repaired with a prototype endoscopic suturing device, and the gastrostomy was closed with endoscopic clips [81]. Also in 2007, Thompson et al. used a transanal approach in a survival porcine model [82]. They introduced an approximately 2 × 3 cm piece of composite hernia mesh (polytetrafluoroethylene—PTFE/polypropylene—PP) into the peritoneal cavity through a small colotomy with a mesh delivery device over a guidewire. The mesh had preplaced ferro-magnetic endoscopic clips on the corners and was held on the abdominal wall with a magnet placed on the exterior surface of the abdominal wall. The mesh was then fixed with T-tags and a suture crimping device. The colotomy was initially closed with an endoscopic loop and subsequently with the same T-tag sutures used to fix the mesh. The 3 animals in the survival portion of the study all thrived for 14 days and showed no evidence of any complications.

In 2008, Bingener and colleagues simulated a ventral hernia repair using a transgastric approach in a survival swine model [83]. They placed a 2 cm^2 PP mesh using a delivery device and clipped it to the peritoneum of the abdominal wall with an endoscopic clip. The gastrotomy was successfully closed in all cases with endoscopic clips. At the two-week necropsy, there was a 36% gross infection rate of the mesh.

In 2009, Kantsevoy's group used a nonsurvival and survival swine model to use PTFE mesh to repair an iatrogenically created abdominal wall defect. After a mesh infection of the first survival animal, the subsequent four animals had the mesh placed with a sterile cover, and no infections were observed. All gastrotomy sites were successfully closed with T-bars [84].

Sherwinter in Brooklyn published his work on transgastric inguinal hernia repair in 2009–2010. In the survival study, a biological mesh was delivered through an overtube and fixed on the peritoneum at the myopectineal orifice with glue. The gastrotomy was closed with an endoscopic suturing device, and all 5 animals survived the 14-day period. Necropsy revealed no complications and all mesh to be in proper position [85, 86].

Our group also reported a similar technique with polypropylene and used a sterile mesh delivery device. The mesh was fixed to the abdominal wall with transfascial sutures and endoscopically delivered nitinol tacks [87]. Our subsequent survival model confirmed the ability to place a 10 × 15 cm PP mesh without clinical infection [88].

In 2010, reports began emerging detailing case reports of human repair of small primary and incisional ventral hernias. All have used a transvaginal approach with both biological and synthetic meshes. Long-term follow-up is still in progress, but the procedure seems to be feasible [89–92].

Conclusion

Natural orifice translumenal endoscopic surgery, no longer in its infancy, has evolved with the combination of disruptive innovative research, meticulous attention to technique development in animal models, and a collaborative environment between surgeons and gastroenterologists. New reports of human NOTES™ procedures surface frequently, and acceptance of this disruptive technology seems assured. Lessons learned from the laparoscopic revolution were applied to prevent poor outcomes. While the relative lack of development of special instrumentation for NOTES™ has hindered the widespread growth and adoption of these procedures, some of what has been learned is increasingly being applied to modern surgical patient care. Spin offs from NOTES™, including single-port laparoscopic surgery and endoluminal surgery, continue to evolve and mature as well. The future of NOTES™ seems bright, as long as pioneers in the field continue to innovate, collaborate, and push the envelope of "minimally invasive surgery" in an effort to improve the lives of our patients.

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Fundamentals of NOTES

2

David J. Desilets

Abstract

Natural orifice translumenal 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.

Keywords

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

Abbreviations

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

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Introduction

Natural orifice translumenal 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.

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.

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_2 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