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Advancing the Future of Minimally Invasive Surgery

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Introduction

Advances in minimally invasive surgery in the past 20 years—and particularly in the past five—have been nothing short of astonishing. Surgery once meant large, painful incisions requiring substantial recovery time, monitoring, and scarring. But as laparoscopy and endoscopy have evolved both philosophically and technologically, the possibility for a wide variety of surgeries to be performed in a way that leaves no visible scarring looms large on the horizon.

CO₂ Insufflation for Intraoperative Endoscopy

Because of advances in technology, many surgeries—ranging from highly complex to very simple—can be performed via minimally invasive procedures. The use of carbon dioxide (CO₂) instead of air to expand the bowel during endoscopy falls into the latter category. “This is not a big advance in technology, but it is an important development. CO₂ insufflation is ideal when a surgeon needs to do an upper endoscopy or

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colonoscopy in the midst of a laparoscopic procedure,” said Richard L. Whelan, MD.

Room air, when insufflated into the intestines, sits inside the lumen for hours, causing pain and bloating. CO₂, on the other hand, is absorbed within minutes.^{1,2} In fact, CO₂ is 25 times more soluble than room air in blood and tissue and can be absorbed up to 150 times faster than nitrogen, which is a major component of room air.³⁻⁵ Once absorbed, CO₂ is quickly cleared by the lungs.² Some early adopters of endoscopy recognized that for patient comfort in the elective setting, CO₂ insufflation was superior to air. “It is logical to use CO₂ for all endoscopies, because even when performing colonoscopy outside the operating room, you don’t want the bowel to be distended at the end of the procedure,” said Dr. Whelan. All endoscopies require the bowel to be dilated in order to perform the examination. Most patients will pass the air within the bowel fairly quickly after colonoscopy, however, some patients retain the air, which causes distension and possible discomfort. “That patient then sits in the endoscopy suite for hours, or, rarely, has to be admitted and is miserable,” said Dr. Whelan. “So the idea of using CO₂ for endoscopic insufflation in the outpatient setting made sense, too. There were some people who did this in the 1970s. They attached a CO₂ tank to the insufflator and found a way to pump the CO₂ in without having an official, FDA-approved device.” One study, published in 1992, noted that the provision of such a device by industry was long overdue.⁶

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—Jeffrey W. Milsom, MD

Physicians realized that with these “jury-rigged” devices, when CO₂ is used to dilate the bowel for endoscopy, the bowel rapidly absorbs the gas and the bowel diameter quickly returns to normal. This is not the case with room air. Many studies have found CO₂ insufflation during endoscopy to be safe and superior to room air in terms of patient comfort, and some recommend that the use of CO₂ become standard procedure for screening exams.^{1,2,6-13} “At the end of the procedure, you’ve pumped quarts of air into the bowel. When you pull out the scope, if you’ve used room air, the gas will just sit there because the bowel cannot absorb most of the components of air,” Dr. Whelan said. “But if you fill the entire colon with CO₂ and withdraw the scope, the bowel will be back to normal size within 10 or 15 minutes because this soluble gas is absorbed across the bowel wall into the bloodstream, and then is excreted by the lungs.”

With or without access to a device approved specifically for CO₂ insufflation during colonoscopy—such as the Olympus UCR intraluminal insufflation unit—gastroenterologists and endoscopists are aware of the superiority of CO₂ to room air in terms of patient safety.¹²⁻¹⁵ The ability of CO₂ to be rapidly absorbed makes it quite useful for minimally invasive procedures in the operating room, where laparoscopy and colonoscopy are being used together to treat benign colonic tumors without surgeons having to resort to bowel resection. “There are certain situations when you need to use an endoscope during an operation—when we don’t know exactly where the polyp or lesion is located, for example,” Dr. Whelan said. Although gastroenterologists will usually tattoo the area by injecting India ink along the intestinal wall adjacent to the polyp to make it visible to the surgeon, sometimes the tattoos aren’t visible. In other instances, tattoos may not have been placed at all.

Combining Laparoscopy and Colonoscopy

“We are now doing operations combining laparoscopic and colonoscopic methods to remove benign lesions,” said Jeffrey W. Milsom, MD. For instance, if a patient has a large polyp that cannot be removed by a skilled gastroenterologist or surgeon during a routine colonoscopy, surgeons can perform a laparoscopy during a colonoscopy using CO₂. “It’s very feasible,” Dr. Milsom said. “The laparoscopic approach allows you to change the position of the intestine or invaginate the intestine, for example, if the polyp is around a bend or behind a fold. With laparoscopy, you can straighten out the wall of the intestine, which then allows the person doing the colonoscopy to see it well, and you can aggressively resect the polyp with colonoscopic methods.” This approach also allows for repairs to the intestinal wall that will be far less traumatic to the patient, with less pain and recovery time than if the repairs were made via bowel resection, “even a laparoscopic bowel resection,” said Dr. Milsom. “The use of CO₂ insufflation is actually the enabling technology.”

When surgeons use room air for insufflation during an intraoperative endoscopy, they may be tempted to put off colonoscopy until the end of the operation. “Prior to the CO₂ endoscopic insufflator, we would delay intraoperative endoscopy as long as possible during a laparoscopic operation in order to preserve the laparoscopic domain. There is limited working space in the abdominal cavity,” said Dr. Whelan. “If you distend the bowel with air, a lot of the working space is taken up by the distended intestine, which can make it more difficult to work laparoscopically. On occasion, it was necessary to convert to an open procedure via laparotomy because of the bowel distension caused by intraoperative endoscopy with air insufflation.” Dr. Whelan goes on to say, “CO₂ insufflation allows us to perform endoscopy without having to worry about bowel distension limiting our ability to complete the operation laparoscopically.” It is the impression of some surgeons that flexible

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—Paul G. Curcillo II, MD, FACS

endoscopy is being performed more often during abdominal operations than in the past. Dr. Whelan believes there are several reasons for this change. One is that there is a greater availability of flexible endoscopic equipment in operating rooms, in general, today. The second possible reason, according to Dr. Whelan, is the availability of CO₂ endoscopic insufflation devices. “Over the past five years in my practice there has been a notable increase in the percentage of operations during which a flexible endoscopic examination is carried out, from 15% to 20% to now 45% of operations.”

“The change for us is that, literally, we always have an endoscope available in the operating room to check the anastomosis, look for bleeding, or try to find any problem we can’t see by looking at the surface of the intestine,” said Dr. Milsom. Although this approach may sound like common sense, the surgeons and endoscopists who use CO₂ insufflation instead of regular air are still in the minority. “It’s a bit of a no-brainer,” Dr. Milsom said, “and I think it’s very simple.” One concern regarding the use of CO₂ for insufflation is that it may alter the pH of the patient’s bloodstream—that the rapid absorption of the CO₂ could result in acidification of the patients. However, this does not appear to be the case.¹⁶ For certain patients with advanced lung disease, CO₂ insufflation may not be indicated.¹⁷ “During laparoscopy, the lungs are already stressed from excreting the CO₂ absorbed through the abdominal cavity. If CO₂ endoscopy is performed simultaneously, the anesthesiologist has to increase either the rate of ventilation or the size of the breaths in order to ‘blow off’ the added CO₂,” explained Dr. Whelan. “In patients with severe lung disease, the lungs aren’t able to excrete the CO₂ gas efficiently, which results in a high concentration of CO₂ in the bloodstream.”

It is likely just a matter of time before CO₂ insufflation becomes standard, especially with the evolution of new surgical techniques. Natural Orifice Transluminal Endoscopic Surgery (NOTES) will be predicated on CO₂ endoscopy because, unlike with traditional laparoscopic surgery, there is no escape route for the insufflation gas. “CO₂ will be absorbed, whereas air will just sit there,” said Dr. Whelan. “For NOTES, this advance is absolutely critical.”

It is predicted that CO₂ insufflation will have many applications beyond NOTES. “For us, this simple but key technology is paving the way for a lot of new approaches to treating diseases,” Dr. Milsom said. “It’s going to be a major development that permits new types of therapies.”

Laparo-Endoscopic Single-Site Surgery

A relatively new, even less-invasive procedure is Laparo-Endoscopic Single-Site Surgery (LESS). LESS was recommended and adopted by a recent international multidisciplinary consortium convened at the Cleveland Clinic in June 2009. “LESS surgery involves a single umbilical or extra-umbilical skin incision through which surgical tools are inserted to create a stable platform for performing major surgery,” said Inderbir S. Gill, MD, MCh, who initiated the consortium. Arguably, the evolution of LESS was made possible by advances in surgical technique and innovation in surgical equipment—for example, improvements in imaging and the streamlining of tools that allow telescopes to share the same entry point as other instruments. “I would like to say that this kind of surgery presents the kindest cut to a procedure,” said Jihad Kaouk, MD.

Although the way LESS is performed today would not have been possible without current technology, the idea of conducting surgery through a single port is not entirely new. In 1997, in an early “LESS-like” procedure, an Italian surgeon performed a cholecystectomy through the umbilicus without placing the additional three ports typical to a traditional laparoscopic cholecystectomy (lap chole),¹⁸ “but he placed needles and sutures through the abdominal wall,” said Paul G. Curcillo II, MD, FACS, who, with his team, has been developing a single-port access (SPA) approach since April 2007. “It was a great idea—it introduced a new technique, but it involved stab wounds, putting needles through organs, and it never really took off.”

LESS, however, has shown great potential. “This has already caught a lot of attention in the urology community and has spread to involve gynecology,” said Dr. Kaouk, a member of the Cleveland Clinic team, which has completed more than 100 urology surgeries via LESS in the past year. General surgery practitioners have gotten involved, and experts predict other specialties will recognize the applications of LESS as well.¹⁹

Standard laparoscopy requires five or six 5-mm incisions in order for surgeons to achieve the triangulation necessary to perform a procedure. “Now, using these newer concepts, newer port devices—such as single ports with multiple channels—we can execute complex and delicate surgical maneuvers through one entry point,” said Dr. Gill. The entry point is a small incision (about 1.5- to 4-cm incision for LESS procedures) usually in the umbilicus—a good place to hide a scar.

“I think cosmetic consideration is a big thing. A scar is not only a cosmetic concern, it also reminds you of when you had surgery and pain—it’s a reminder of a tense time.”

—Paul G. Curcillo II, MD, FACS

“With LESS, we cause less trauma to the abdominal wall and thus less pain. So that’s the concept of this surgery.”

—Jihad Kaouk, MD

“Patients love it,” said Dr. Curcillo. “When someone comes into the office four or six months later and I have to stretch their belly button down to take a picture of the little scar they have, that means a lot.”

Some may feel, however, that if standard laparoscopy has proven to be safe and effective and far less invasive than open surgery, why make a change? “Why not?” Dr. Gill asked. “The smaller the cut, the less potential for patient morbidity.”

It is difficult to measure pain objectively; patients who undergo LESS Surgery cannot compare the amount of pain they experience with pain they would have experienced with standard laparoscopic surgery. With recovery time as a measure of pain, LESS would be hard-pressed to beat standard laparoscopy depending on the procedure performed; most patients are able to return to normal function within one or two days of a traditional lap chole.

Regardless, incisions hurt, and their number and placement make a difference. “We found that patients have less pain if we go through the umbilicus,” said Dr. Kaouk. The reason for this is that there is no muscle at the midline—the incision is made only through fascia, so muscle spasms

are avoided. “With LESS, we cause less trauma to the abdominal wall and thus less pain. So that’s the concept of this surgery.”

Superior Cosmetic Results

It is the virtual invisibility of the scar, however, that puts LESS head and shoulders cosmetically above standard laparoscopy in patients for whom this is a concern.²⁰⁻²³ “A 70-year-old steel worker from Chicago? Maybe not so much. But the people who do care, they are really impressed,” said Alexander S. Rosemurgy, MD. “When a young lady has no discernable scar from an operation, she is impressed.”

Parents are also concerned with scarring in their children. “Some are very determined to have LESS procedures—this is usually in the pediatric patients where parents want the smallest scar possible for their kids,” said Dr. Kaouk, who has performed and reported on pediatric varicocelectomy.²⁴ “It’s a simple procedure done outpatient with no visible scar.” Pediatric surgeons, in fact, have been interested in single-port,

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—Inderbir S. Gill, MD, MCh



Figure 1. Olympus deflectable-tip EndoEYE video laparoscope demonstrating 100 degrees of flexibility in four directions.



Figure 2. The TriPort Access System for LESS.

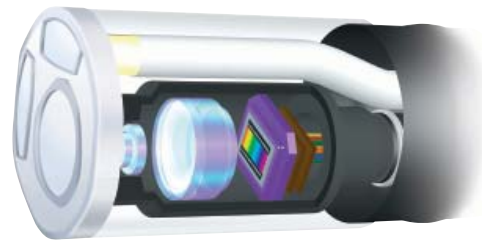


Figure 3. Olympus Charge-Coupled Device.



Figure 4. The Olympus deflectable-tip EndoEYE video laparoscope.

single-incision surgery for years. “The whole goal of the pediatric surgeon, aside from safe surgery, is to minimize scarring,” said Dr. Curcillo. “Because the truth is, if you minimize scarring, you minimize pain. And nobody wants to give a 6-year-old pain.”

Pain avoidance and visual satisfaction are a big part of the picture, but a virtually invisible scar can have an impact on a patient’s mental well-being as well. “I think cosmetic consideration is a big thing,” Dr. Curcillo said. “A scar is not only a cosmetic concern, it also reminds you of when you had surgery and pain—it’s a reminder of a tense time. So when people look and they can’t see the scar, it’s not like they didn’t have surgery, but there’s not as much of a reminder.”

The Role of Olympus

Early adopters of LESS Surgery credit significant advances in imaging in the last year alone, improvements in the technology of articulating instruments, and the availability of multichannel, single-port devices such as the TriPort from ASC (distributed by Olympus) for the procedure’s takeoff (Figure 2). “I think that LESS Surgery will continue to evolve so that anything that’s done laparoscopically will be considered for single-site surgery,” said Dr. Rosemurgy. “With advances in technology, the horizon is ours to take.”

One innovation has been the deflectable EndoEye imaging technology, which places the camera on the tip of the scope, eliminating the light post and second intrusive cable and allowing the instruments to share an entry point with other instruments. “The key thing for LESS is high-quality optics; can’t see, can’t do,” said Dr. Gill. “This new CCD (charge-coupled device) technology allows absolutely superb intraoperative visualization. Just the fact that the chip is at the distal end of the telescope—as opposed to a rod lens system—provides a far superior image.” Figure 3 demonstrates the CCD.

The Olympus HD EndoEYE laparoscope provides a digital image clearer than what was previously available, and its smaller size frees up room for other instruments (Figure 4). “The 5-mm deflectable EndoEYE has really allowed us to see well and be able to do things that would have been difficult without it,” Dr. Gill said.

Critical to success in laparoscopic surgery is achieving the proper triangulation to complete a procedure within the abdomen. The availability of multichannel single-port devices allows surgeons to introduce three or four instruments through the same site. “The instruments can be straight or bent; of variable length; and flexible, semiflexible, or articulating,” Dr. Gill said.

Although surgeons have had success performing single-site surgery with traditional rigid laparoscopic instruments, some find that recent advances in flexible instruments further enable them to perform procedures via LESS. “Now, with instruments that are flexible or are articulated, we can move the inner part of the instrument with minimal movement of the outer handle part,” explained Dr. Kaouk. “That way, you avoid clashing of the instruments.”

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—Lee L. Swanstrom, MD

Use of newer instruments—such as the Olympus Endo-Eye—instead of traditional laparoscopic tools requires surgeon facility with the new technology, which presents a learning curve for some. Nonetheless, the surgical platform is identical to that with which laparoscopic surgeons are already accustomed. “You’re going from the front and you’re looking down on an organ as if you were doing standard laparoscopy,” Dr. Gill said. “Only through one cut, not four.”

Applications for LESS

Since the first single-port laparoscopic surgeries were performed in spring 2007, the technique has been successfully applied to a wide variety of procedures: gastrotomy, appendectomy, cholecystectomy, adrenalectomy, varicocelelectomy, simple and radical nephrectomy and donor nephrectomy, renal cryoablation, splenectomy, pyeloplasty, ileal ureteral replacement, sacrocolpopexy, varicocelelectomy, Nissen fundoplication, ventral hernia repairs, bladder surgeries, oophorectomy, hysterectomy, and colorectal surgery.¹⁹⁻²⁶

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In many of these procedures, studies have been conducted showing that LESS and “LESS-like” techniques (many names and acronyms have been used to describe laparoscopic procedures performed through a single port) are safe and effective and sometimes preferable to traditional laparoscopic approaches. Until surgeons become comfortable with the approach and instrumentation, Dr. Kaouk suggests that a high degree of attention be paid to patient selection. “With any new technology, we should be very careful to assess the outcomes and to minimize complications and prove safety,” he said. “We started by being very selective—patients with early disease, and procedures that are not terribly complex.”

After they became comfortable with LESS, Dr. Kaouk, Dr. Gill, and the Cleveland Clinic team moved on to more challenging procedures, such as radical prostatectomy, cystectomy, and donor nephrectomy. They continue to avoid patients who are morbidly obese, however. “We think that may be challenging with the current instruments.”

With the currently available technology, LESS surgery is suited more ideally for patients on the smaller side—not too heavy and not too tall. “And it’s best if the operations are more straight-forward, not in patients who have had a lot of previous abdominal surgery,” Dr. Rosemurgy said. In the event that a LESS surgery becomes problematic, surgeons have

the option of converting, incision by incision, to traditional laparoscopy. Although this may seem to defeat the purpose and diminish the benefits of single-incision surgery, common sense would suggest, and some studies have shown, that reducing incisions by any number results in a reduction in pain and recovery time—that three ports are preferable to four, and two preferable to three.²⁷⁻³⁰

“Every time you reduce a port site, you reduce the potential complications of that port site, such as infection, hernia, and wound breakdown,” Dr. Curcillo said. “Also, every time I put a trocar in I could injure the bowel. And then there is the thought, could this be causing more pain as well.”

Dr. Curcillo offers all cholecystectomy patients the option, “but if I find it’s too difficult, I would add another port, so there would be two incisions instead of one,” he said. This is still an improvement over the traditional lap chole that starts with four 5-mm incisions. “If there is scar tissue or another problem, we’ll add another incision and then go to standard laparoscopy, and then open,” Dr. Curcillo said. Transition to either, however, has been rare in his experience. “In 35 cholecystectomies, we haven’t had a failure in single-port surgery. With oophorectomies, it depends on the amount of disease.”

There is a difference between failure of LESS and failure of laparoscopy. “If we have to put in another trocar, then we have two port sites, which is better than four,” Dr. Curcillo said. “There are some patients where you can put in four port sites and it doesn’t matter—you have to open that patient. That’s what we call a failure of laparoscopy.” The caveat is that all patients should be alert that their surgery may have to take the more traditional route once underway; but much as the conversion rate from laparoscopy to open surgery declined with experience, experts estimate that the conversion rate from LESS to traditional laparoscopy will decline too.

Natural Orifice Transluminal Endoscopic Surgery

As surgical techniques progressed from large, open incisions to less invasive laparoscopic procedures with multiple small incisions and now even less invasive, single-incision laparoscopy, endoscopy progressed as well in terms of diagnosis, intervention, and even surgery. From the convergence of laparoscopy and endoscopy has come NOTES and the development of a hybrid specialist with the combined skill-set of gastrointestinal therapeutic endoscopists and surgical endoscopists.

“That’s probably why you hear so much excitement about NOTES,” said Lee L. Swanstrom, MD. “It’s not so much the procedures, but the fact that gastroenterologists are getting access to technology—interventional flexible endoscopy—that lets them do surgery, and surgeons are extending laparoscopy even further to flexible endoscopy. That’s the next evolution of minimally invasive surgery.”

Flexible endoscopy started as a purely diagnostic

technology, used to check for bleeding or polyps that would be fixed or excised later by surgeons in the operating room. As the tools evolved, endoscopy became more interventional in nature—removing polyps and stopping bleeding—but always staying within the gastrointestinal tract.

At the same time, surgery was becoming progressively less invasive. “Right now, we’re at a point where those two lines cross: where flexible endoscopy has the tools to do surgery, and where surgery has gone from laparoscopy with rigid scopes to using flexible scopes,” Dr. Swanstrom said. “It’s an interesting meeting area.”

Currently, gastroenterologists comprise the majority of flexible endoscopy users, responsible for about 80% of its application, Dr. Swanstrom said. “Only about 50% of surgeons routinely do flexible endoscopy. But that’s changing now.” Although the evolution of both endoscopy and surgery has been gradual over the past 30 years, it’s really been only within the last four years that the notion of NOTES—surgery from within that leaves no external scar—has been feasible. Now it’s on the horizon as the next big paradigm shift.³¹⁻³³ “It evolved from the thoughts of gastroenterologists exploring new applications for interventional flexible endoscopy, who breached the gastrointestinal barrier and went into the peritoneal cavity,” Dr. Swanstrom said. “That awoke memories in a lot of surgeons about the start of laparoscopy when we started using rigid endoscopes to do surgery. That excitement has led to the last four years of enthusiasm and excited research and development.”

Physicians first began experimenting with the NOTES approach in animals in 2004 with tubal ligation, appendectomy, and cholecystectomy; they found it to be safe and effective; animal studies are still ongoing for other procedures.³⁴⁻³⁷ The first human case, an appendectomy in India, was performed in 2005 by a gastroenterologist and a laparoscopic surgeon. “Then, in 2007, there was a spate of human applications that’s rapidly growing,” Dr. Swanstrom said. “Some staging for cancer, appendectomy, but mostly cholecystectomy.”

The primary reason for the focus on the gallbladder is that there is a safe, minimally invasive fallback in case there are problems with a NOTES cholecystectomy. “If things aren’t going well, you just put in a couple more ports and you have your traditional lap chole,” Dr. Swanstrom said.

Currently, many laparoscopically assisted NOTES procedures are being performed in South America and Italy, as are a handful in North America, where forays into NOTES are hindered by the reluctance of third-party payers to reimburse for NOTES procedures. “That has slowed adoption here, but the early results have been fairly favorable,” Dr. Swanstrom said. “It certainly seems doable to perform cholecystectomy through the mouth, vagina, or anus, and the patients seem to benefit from that through less pain and possibly a quicker recovery time.”

Recently, transgastric, transvaginal, and transanal NOTES approaches have been used successfully for cholecystectomy, colon surgery, and cancer staging.^{38,39} The evolution of NOTES hinges partly on the ability of gastroenterologists

and surgeons to sidestep turf issues and work collaboratively, which many seem willing to do. What is really crucial, however, is the availability of technology that NOTES requires and the ability of the industry to provide that technology. Early NOTES pioneers called for advances in technology to support the new technique, and this continues to be an issue or, for industry, an opportunity.^{37,40-43}

“My feeling is that NOTES is going to change the way we look at laparoscopic surgery and flexible endoscopy—both camps are going to change,” Dr. Swanstrom said. “And that reflects on industry. Surgeons are going to look for companies that provide them with operating flexible endoscopes, and I think gastroenterologists will become interested in laparoscopy again.”

This hinges largely on improvements in optics, which have improved much in recent years, and in instruments tailored to different purposes. “For diagnostic physicians—gastroenterologists who do NOTES—there needs to be a flexible scope smaller than current scopes that allows them to get into the peritoneal or thorax cavities to do biopsies and ultrasounds,” Dr. Swanstrom said. Surgeons could benefit from a new generation of larger, more robust scopes, “maybe 15- to 18-mm in diameter with large channels that allow the equivalent of laparoscopic instruments through them to do true surgical procedures—excision of organs, reconstruction, or suturing.”

As a surgical device company that also focuses on flexible endoscopes, Olympus stands poised to do just that. “Olympus is involved in all of this—the future development of new clips, suturing machines and other devices that will help us do not just cholecystectomies, but suture bleeding, excise early cancers in the stomach, or take out bigger polyps,” Dr. Swanstrom said.

The Future of NOTES

Although NOTES presently is used mainly for cholecystectomy, Dr. Swanstrom envisions the approach being applied to other procedures and fields. “I think one of the biggest patient benefits is going to be in colorectal surgery,” he said. “In laparoscopic colorectal surgery, now they have to make a relatively huge incision to take the specimen out—they have to make a hole at some point—there’s little to be lost, little danger [in the shift to NOTES].” Other areas in which he sees NOTES being used include urology and gynecology. “There have been some versions of NOTES done with transvaginal hysterectomy and oophorectomy for some time,” Dr. Swanstrom said. “They may be able to use this new technology to the benefit of the patients.” NOTES may also prove useful in the surgical treatment of obese and morbidly obese patients.⁴⁴

Right now, it is hard to predict the future of NOTES. The day when all cholecystectomies are performed through the mouth is a long way off. “But much as they always say about sending man to the moon, it’s not so much what’s on the moon, but what you learn in getting there,” Dr. Swanstrom said.

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