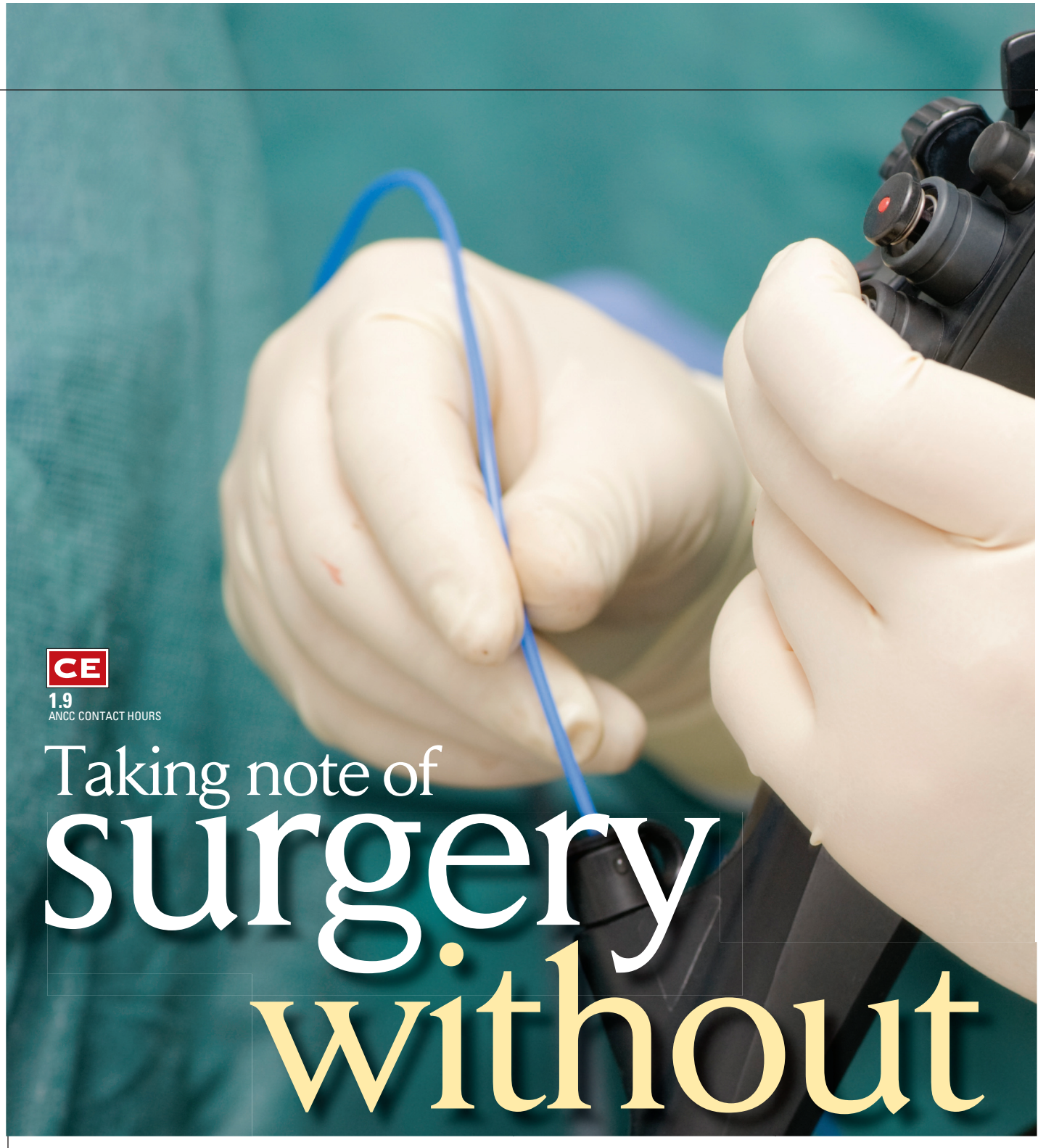

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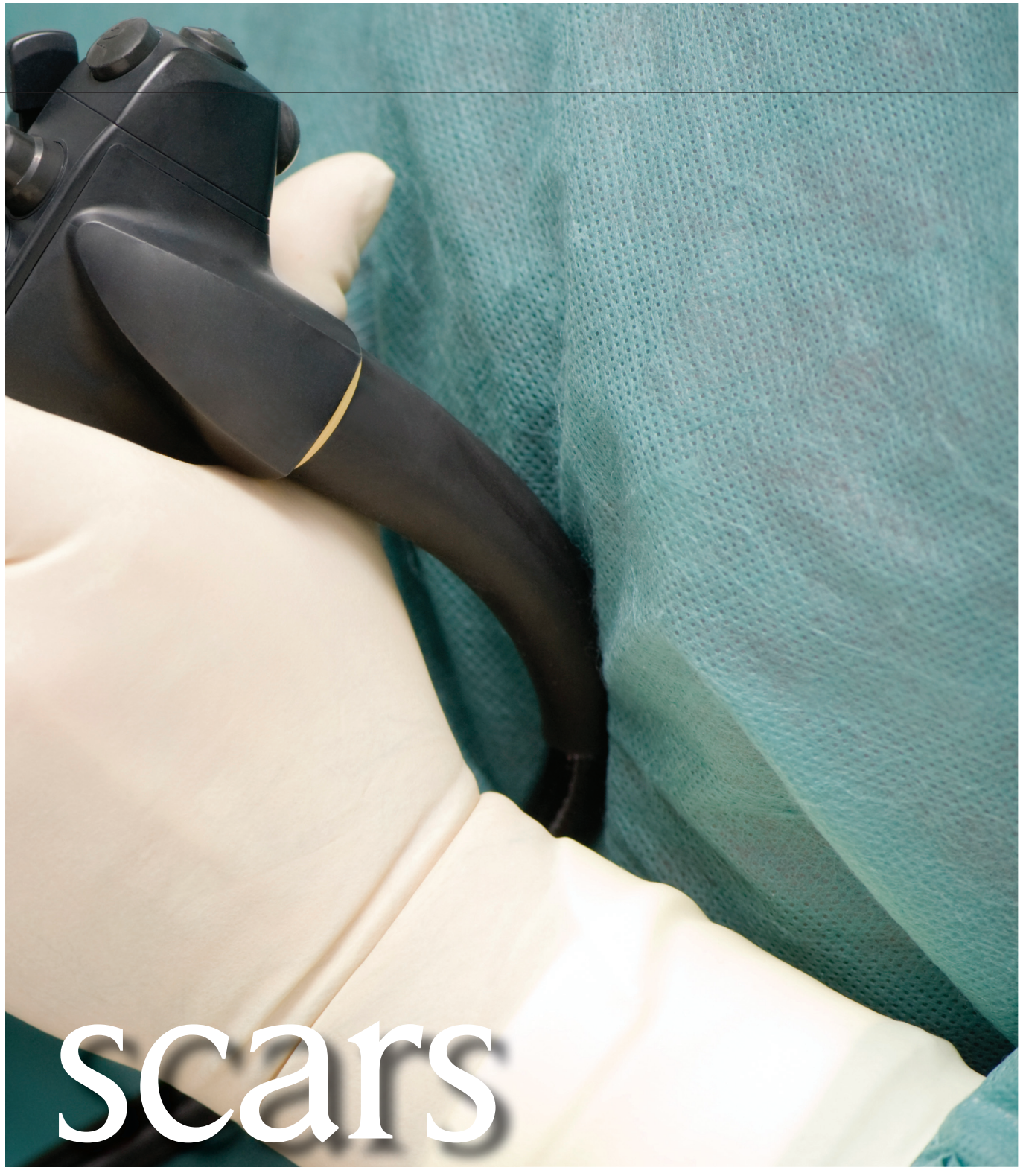
Taking note of surgery without

Learn about natural orifice translumenal endoscopic surgery (NOTES), an emerging technique that lets surgeons perform some procedures less invasively.

By Lynda Petty, BSN, RN

Just a couple of decades ago, a defined line separated open-heart surgeons and cardiologists, surgeons and radiologists, and gastrointestinal surgeons and gastroenterologists. That line was an incision—the culmination of years of training in the OR environment, tirelessly learning surgical techniques that required opening the patient's abdomen, pelvis, or chest in order to manipulate, resect, or repair the organs within those cavities.



Fast forward to 2011. Surgeons and gastroenterologists are collaboratively removing patients' gallbladders without making a skin incision, thanks to NOTES, an extension of interventional endoscopy.

In this investigational technique, a flexible endoscope is inserted via the mouth, anus, or vagina, and passed through the wall of the esophagus, stomach, colon, or vagina to enter the mediastinum, thoracic cavity, or peritoneal cavity. This technique eliminates the scars associated with laparoscopy or thoracoscopy. NOTES may also reduce postoperative pain, length of hospitalization, and costs.

Advancing surgical techniques

Surgeons have been performing transvaginal hysterectomies, for example, for many years, but the idea of removing the appendix or gallbladder through the vagina or mouth (transgastric route) is new. To date, the investigational NOTES procedures that have been performed on patients include transgastric appendectomy, transvaginal cholecystectomy, transgastric

cholecystectomy, percutaneous enteral gastrostomy salvage, and cancer staging.[1]

NOTES could prove to be most beneficial for morbidly obese patients, for whom open abdominal laparotomy and even laparoscopic access are surgically challenging and risky.[1]

The Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR), a working group of surgeons and gastroenterologists from the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), is developing standards for the emerging NOTES techniques.[2,3] In 2006, the group outlined major areas of research that needed to be addressed before NOTES could become a viable clinical application for humans. These areas of research included development of techniques for safe access into the peritoneal cavity, a reliable closure technique for the internal incision (to prevent leakage into the peritoneal cavity), infection prevention, and creation of advanced endoscopic surgical tools.[4] Researchers have used various techniques, including suturing, clips, T-fasteners, and novel closure devices, to obtain a secure closure of the enterotomy in animal trials. The closure device and technique must be easy to use and provide a nearly 100% secure closure of the enterotomy site.[1]

Surgical revolutions

NOTES may follow the course of acceptance that laparoscopic/videoscopic procedures followed in the 1990s. Today, videoscopic procedures commonly occur in the OR, endoscopy suite, pulmonary lab, and ambulatory surgery centers. Although gynecologists had been performing laparoscopic surgery and orthopedic surgeons had been performing arthroscopic surgery for many years, videoscopic procedures in general surgery began with the laparoscopic cholecystectomy in the late 1980s. A technique for removing the kidney laparoscopically was developed in the 1990s.[5]

During this evolution in surgery, going from open to minimally invasive procedures, the entire general surgical community had to be trained and monitored to use new video-assisted technology in such a way that assured safety and efficacy in the general population. Many minimally invasive techniques were developed and perfected, as were the instruments and technology that evolved to allow the surgeons better visualization while operating through smaller ports. Some mishaps also occurred that set the stage for how NOTES procedures and techniques are being developed, researched, and reported through the NOSCAR community.

Hybrid NOTES: A combo approach

Laparoscopic-assisted NOTES procedures are sometimes referred to as hybrid NOTES procedures. For instance, the surgeon may use the transvaginal route for cholecystectomy but also places up to 3 ports (5 mm or 3 mm) into the abdomen for tissue retraction and clip application. Visualization and tissue dissection is through the flexible endoscope and specimen removal is through the natural orifice. As technology evolves, the hybrid approach may not be necessary.

Minimally invasive surgical advancements

The NOTES concept was introduced to the U.S. gastroenterology and surgical community in 2004, when gastroenterologists from Johns Hopkins Medical Institute reported on their lab work to develop a NOTES approach to enter the peritoneal cavity using a flexible gastroscope with an incision through the wall of the stomach.[6] Since that report and the establishment of NOSCAR in 2005, much research has been done on NOTES.[3] NOSCAR recognizes that NOTES is neither purely surgical nor purely endoscopic, and collaboration between ASGE and SAGES is essential in promoting optimal patient care and safety.[3]

The first no-scar surgery performed on a human took place in 2007 at the University Hospital of Strasbourg in France. Using a transvaginal approach, surgeons removed a woman's gallbladder.[7] The flexible endoscope was inserted into the abdominal cavity through an incision in the vaginal wall; the gallbladder was removed using an endoscopic retrieval bag. A 2-mm needle was inserted into the umbilicus for gas insufflation of the peritoneal cavity and visualization via a videocamera system. Also in 2007, medical and surgical endoscopists at New York-Presbyterian Hospital/Columbia University Medical Center removed a woman's gallbladder transvaginally using a flexible endoscope with only minimal external incisions; the surgery is believed to have been the first of its kind in the United States.[8]

At the 2007 NOSCAR conference, workgroups presented criteria for the ideal anastomosis and measures to ensure anastomotic integrity, recommendations for suturing devices, considerations for access into the peritoneal cavity, proposed protocols for infection prevention. In 2008, building on the 2007 recommendations, workgroups progressed with topics such as developing a NOTES registry for all NOTES procedures, research design and getting human trials started, device development, training, simulation and credentialing, and future technique development.

Human multicenter trials of NOTES in the United States were announced in 2009, and in July 2010, NOSCAR announced the completion of the first transgastric and transvaginal cholecystectomies using NOTES. Surgeons at the University of California, San Diego School of Medicine, removed the gallbladder of a patient through the mouth; those at Baystate Medical Center in Springfield, Mass., removed the gallbladder of a patient through the vagina as part of the NOSCAR human trials. These human trials are the first in the world comparing oral and transvaginal NOTES to traditional laparoscopy procedures.[9]

The University of California surgeons made a tiny incision in the patient's stomach to pass a camera and to inflate the abdomen for optimal safety and visibility. (No sutures were needed for the incision.) The actual gallbladder removal was performed entirely through the mouth. Baystate Medical Center surgeons also made a small abdominal incision for similar reasons, but extracted the gallbladder through the vagina.[9] (See *Hybrid notes: A combo approach.*)

In 2006, Ohio State surgeons were among the first in the country to use the incisionless technology for diagnosing abdominal malignancies and staging cancer through the mouth. A flexible endoscopy tube encasing a fiber-optic camera and remote-controlled surgical cutting tool pierced the stomach wall for performing delicate surgical procedures. This particular procedure has been performed in more than 120 patients at Ohio State University Medical Center.[10]

Manufacturers, meanwhile, are working on advancements in the flexible endoscopes used in NOTES. One company has developed an endoscope that provides two channels to pass instruments and has extra flexion properties in comparison with the regular flexible scopes. Another manufacturer has developed a system that provides four large working channels that act as flexible trocars for introducing instruments that can be used in two-handed maneuvers.[1] Grasping and suturing instruments are being developed as well as tissue anchors and closure devices.

As the technology for NOTES advances, we may see small robotic devices that can travel down the operative port of a flexible endoscope and transform into a device with independent working appendices that retract, dissect, and grasp tissues.[11]

NOTES at limited centers

In the United State, NOTES procedures are being performed at the multicenter trial locations. Industry leaders in endoscopy and minimally invasive surgery are supporting NOTES research. A non-profit consortium of Boston teaching hospitals and engineering schools has awarded several million dollars for a 3-year grant to multidisciplinary, multi-institutional teams studying and advancing NOTES.[12] Training programs are being developed at leading academic centers by the pioneers in NOTES.

Perioperative nurses and NOTES

With NOTES, the perioperative nurse may encounter a new environment, which is familiar yet very different. Someday, NOTES procedures may be performed in the endoscopy suite.[1]

Questions that remain to be answered are whether the flexible endoscopes used in NOTES should be sterilized or processed by high level disinfection, how to position the patient, and "Do we perform a sponge, sharp, and instrument count?" The research studies being performed will help establish standards and practices for NOTES; until then, follow Association of periOperative Registered Nurse standards and recommended practices to maintain asepsis through sterilized instruments; maintaining a sterile field; separating sterile, clean, and contaminated items; and minimizing personnel movement while an invasive procedure is in progress. Follow safe patient positioning and perform surgical counts for all invasive procedures.[13]

The perioperative nurse will continue to be the patient's advocate, continue to be the person who develops the surgeon's preference card, who works with the surgeon and vendors to bring new technology into the OR, and the person to write the policies and procedures for ensuring that patients undergoing NOTES procedures receive the same standard

of safe, personalized care that all patients in the perioperative environment depend upon.

This will be an interesting era in the evolution of the surgical environment as patients learn more about incisionless surgery and begin to request it. **OR**

REFERENCES

1. Swanström LL, Khajanchee Y, Abbas M. Natural orifice translumenal endoscopic surgery: the future of gastrointestinal surgery. *Permanente J.* Spring 2008;12(2):42-47.

2. Society of American Gastrointestinal Endoscopic Surgeons. http://www.sages.org.

3. The Natural Orifice Surgery Consortium for Assessment and Research. http://www.noscar.org.

4. Rattner D, Kalloo A, et al. White Paper: ASGE/SAGES Working Group on Natural Orifice Transluminal Endoscopic Surgery. *Surg Endosc.* 2006;20:329-333.

5. Boston JMN. The kindest cuts of all. *Time.* 1992. http:/www.time.com/time/magazine/article/0,9171,975145,00.html.

6. Kalloo AN, Singh VK, Jagannath SB, et al. Flexible transgastric peritoneoscopy: A novel approach to diagnostic and therapeutic interventions in the peritoneal cavity. *Gastrointest Endosc.* 2004;60(1):114-117.

7. The Medical News. World's first no-scar surgery. 2007. http://www.news-medical.net/news/2007/04/27/24305.aspx.

8. New York-Presbyterian Hospital. Surgeons who helped pioneer revolutionary technique present international course on NOTES surgery. 2007. http://nyp.org/news/hospital/surgeons-notes-surgery.

9. American Society for Gastrointestinal Endoscopy. First transoral and transvaginal gallbladder removals performed as part of US multicenter human trial. *ScienceDaily.* 2010. http://www.sciencedaily.com/releases/2010/07/100707131405.

10. OSU Surgeon first to perform procedure. *Surgery Today, Quarterly Newsletter of The Ohio State University Department of Surgery.* 2010;19(4):2.

11. Tiwari MM, Reynoso JF, Lehman AC, Tsang AW, Farritor SM, Oleynikov D. In vivo miniature robots for natural orifice surgery: state of the art and future perspectives. *World J Gastrointestinal Surg.* 2010;2(6):217-223.

12. Center for Integration of Medicine and Innovative Technology. Minimally invasive surgery: natural orifice translumenal endoscopic surgery (NOTES). http://www.cimit.org/programs-notes.html.

13. Association of periOperative Registered Nurses Inc. *AORN Perioperative Standards and Recommended Practices 2010.* Denver, CO: AORN; 2010.

RESOURCES

Bessler M, Stevens PD, Milone L, Parikh M, Fowler D. Transvaginal laparoscopically assisted endoscopic cholecystectomy: a hybrid approach to natural orifice surgery. *Gastrointest Endosc.* 2007;66(6):1243-1245.

Hungess ES, Vaziri K. Hybrid natural orifice transluminal endoscopic surgery (NOTES) cholecystectomy. In: Soper NJ, Swanström LL, Eubanks S, eds. *Mastery of Endoscopic and Laparoscopic Surgery.* 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2009:634.

Marescaux J, Dallemagne B, Perretta S, Wattiez A, Mutter D, Coumaros D. Surgery without scars: report of transluminal cholecystectomy in a human being. *Arch Surg.* 2007;142(9):823-826.

Trunzo JA, Cavazzola LT, Elmunzer BJ, et al. Facilitating gastrotomy closure during natural-orifice transluminal endoscopic surgery using tissue anchors. *Endoscopy.* 2009;41(6):487-492.

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