

Clinical Gastroenterology
Series Editor: George Y. Wu

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David J. Desilets
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NOTES and Endoluminal Surgery

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Clinical Gastroenterology

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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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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 transluminal, 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 “transluminial.” 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 transluminal 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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Keywords

Natural orifice transluminal endoscopic surgery • NOTES • Transvaginal surgery • Transgastric surgery • Transanal surgery • Transurethral surgery • Transsphenoidal surgery • Transesophageal surgery

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 transluminal 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 transluminal 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