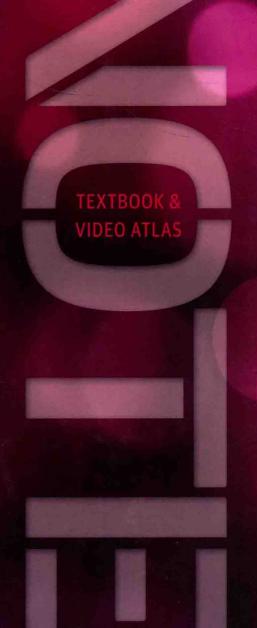
Edited by

Anthony N. Kalloo Jacques Marescaux Ricardo Zorron

Natural Orifice Translumenal Endoscopic Surgery





## Natural Orifice Translumenal Endoscopic Surgery (NOTES)

## **Textbook and Video Atlas**

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This edition first published 2012 @ 2012 by John Wiley & Sons, Ltd

Wiley-Blackwell is an imprint of John Wiley & Sons, formed by the merger of Wiley's global Scientific, Technical and Medical business with Blackwell Publishing.

Registered office: John Wiley & Sons, Ltd, The Atrium, Southern Gate, Chichester, West Sussex,

PO19 8SQ, UK

Editorial offices: 9600 Garsington Road, Oxford, OX4 2DQ, UK

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111 River Street, Hoboken, NJ 07030-5774, USA

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Library of Congress Cataloging-in-Publication Data

Natural orifice translumenal endoscopic surgery (NOTES): textbook and video atlas / edited by Anthony N. Kalloo, Jacques Marescaux, Ricardo Zorron.

p.; cm.

**NOTES** 

Includes bibliographical references and index.

ISBN 978-0-470-67103-0 (hardback : alk. paper)

I. Kalloo, Anthony, 1955- II. Marescaux, J. (Jacques) III. Zorron,

Ricardo. IV. Title: NOTES.

[DNLM: 1. Natural Orifice Endoscopic Surgery–methods. 2. Natural Orifice Endoscopic Surgery–education. WO 505]

617'.057-dc23

2011048892

A catalogue record for this book is available from the British Library.

Wiley also publishes its books in a variety of electronic formats. Some content that appears in print may not be available in electronic books.

Set in 9/12 pt Meridien by Toppan Best-set Premedia Limited Printed and bound in Malaysia by Vivar Printing Sdn Bhd

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## **Preface**

The use of natural body orifices as the primary portal of entry for peritoneal or thoracic interventions challenges conventional surgical and endoscopic principles. NOTES is the evolutionary merger of endoscopy and surgery, using their basic principles while challenging the dogma of both fields. NOTES evolved because of the quest to seek less invasive surgical interventions and will have the added benefit of improved cosmesis. Both of these benefits will be attractive to patients much like laparoscopic surgery was at its beginning.

NOTES has already impacted our current endoscopic and surgical practices. Procedures such as per-oral endoscopic myotomy (POEM), submucosal endoscopy and single port laparoscopy arose because of NOTES and are addressed in detail in this book. Improved instrumentation, robotization of flexible instruments and new endoscopic platforms are some of the downstream benefits of NOTES research, are also all delineated here.

Since the first human application in 2004, there has been tremendous progress in the understanding of the physiologic mechanisms created by NOTES. As a result of the work of many of our authors and others, we now have a large body of information that is the basis for this textbook. Furthermore, there is an ever-growing arena of clinical applications extending beyond digestive diseases.

This book is intended to be an in-depth resource of information on NOTES. The early chapters focus on basic princi-

ples and techniques such as access and closure techniques as well as infection control issues. Later chapters review current clinical applications such as appendectomy and cholecystectomy. The final chapters are dedicated to more up-and-coming and perhaps controversial topics such as veterinarian medicine and spinal interventions. We hope that these later chapters will lay a foundation and stimulate further research into these burgeoning areas. The video library should significantly enhance the knowledge base of this book by augmenting the detailed written descriptions of the various procedures. Our hope is that you will be both excited and inspired by the videos.

We thank our publisher, Wiley-Blackwell, for taking a chance on pioneering a textbook about this emerging field. We would especially like to thank Elisabeth Dodds at Wiley-Blackwell for her gentle persistence, eye for detail and great sense of humor in dealing with three editors from three different continents and authors from all over the world. Most of all, we are grateful to each of our authors who are esteemed experts in their fields and were able to dedicate significant time to this textbook, including the creation of videos, in a short period of time.

Anthony N. Kalloo Jacques Marescaux Ricardo Zorron January 2012

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# **Development of the NOTES Concept**

1

## **History of NOTES**

#### Xavier Dray<sup>1,2</sup> & Anthony N. Kalloo<sup>2</sup>

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Natural orifice translumenal endoscopic surgery (NOTES) is an endoscopic technique whereby surgical interventions can be performed with a flexible endoscope passed through a natural orifice (mouth, vulva, urethra, anus) then through a translumenal opening of the stomach, vagina, bladder, or colon [1]. NOTES has the potential to provide no scarring, reduced pain, and faster patient recovery compared to open and laparoscopic surgical procedures [1]. We present herein the landmarks in the history of NOTES, from the early stages of endoscopy and laparoscopy to its current development.

## Prehistory of NOTES (from ancient times to the late twentieth century)

It is difficult to date when people started to have a look into human bodies, and even harder to credit one individual with the invention of endoscopy. The earliest descriptions of endoscopy are by Hippocrates (460–375 BC), who described a rectal speculum. A three-bladed vaginal speculum was found in the ruins of Pompeii, demonstrating that Roman medicine also involved primitive endoscopic tools. At this time, nothing but ambient light was used, and only rigid instruments were available. Major technological developments leading to modern endoscopy and to modern laparoscopy were born in the nineteenth and twentieth centuries [2].

#### A brief history of endoscopy [3]

The first issue faced by the pioneers of endoscopy was the illumination problem. The first gastroscopy was reported by Kussmaul in 1868 [4]. Joseph Swan and Thomas Edison invented the incandescent electric light bulb in 1878, but this technology was incorporated into endoscopes only at the beginning of the twentieth century [3].

The second and more challenging problem was flexibility. Articulated lenses and prisms were proposed by Hoffmann in 1911 [5] and improved in 1932 by Wolf and Schindler, who developed a semi-flexible gastroscope [6]. However, the light source consisted of a distal light bulb that provided poor illumination and produced color distortion. In 1930, Lamm showed that bundles of glass fibers could be used as a conduit for a light source, and that this bundle could be bent with no effects on light transmission [7]. "Coherent" bundles, ordered in such a way that the position of a fiber at one end mirrors its position at the other end, provided a real image of internal organs [8]. An external light source transmitted through flexible and coherent fiber bundles could therefore illuminate internal organs.

Flexibility and illumination were combined by Harold Hopkins in 1954: the flexible fiber imaging device he invented was made of a tube of glass with thin lenses of air [9]. In 1958, Larry Curtiss and Basil Hirschowitz improved this system by using a highly transparent optical quality glass to give birth to a flexible fiberoptic endoscope [10].

In the late 1970s, the charge-coupled device (CCD) was incorporated into an endoscope [11]. This development heralded the modern era of endoscopy. The CCD allowed the display of endoscopic images on television screens and the connection of endoscopes and computers. From this major shift started a two-decade period described by Sivak as "the golden era of gastrointestinal endoscopy" [3]. Major achievements, which have since become routine procedures, were reported: endoscopic retrograde pancreatography (1968), colonoscopic polypectomy (1969), endoscopic retrograde cholangiography (1970), endoscopic sphincterotomy with bile duct stone removal (1974), percutaneous endoscopic gastrostomy (1980), endoscopic injection sclerotherapy (1980), endoscopic ultrasonography (1980), electronic CCD endoscope (1983), endoscopic control of upper

Natural Orifice Translumenal Endoscopic Surgery (NOTES): Textbook and Video Atlas, First Edition. Edited by Anthony N. Kalloo, Jacques Marescaux, Ricardo Zorron.

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gastrointestinal bleeding (1985), and endoscopic variceal ligation (1990) [3]. Modern endoscopy was born.

#### A brief history of minimally invasive surgery

Georg Kelling (Dresden, Saxony) reported on the first laparoscopic procedure in animals in 1902. Hans Christian Jacobaeus (Sweden) performed the first laparoscopic operation in humans in 1910. Many refinements were brought to the technique over decades. However, diagnosis and simple gynecologic procedures were the main applications [2]. A landmark in this early period of laparoscopy is the first diagnostic laparoscopy by Palmer in the 1950s [12]. In the 1960s gynecologists took up interventional laparoscopy. The first CO<sub>2</sub> hysteroscopy was reported by Frangenheim and Semm in the mid-1970s [2]. Tarasconi (Ob-Gyn, Passo Fundo, Brazil) reported on the first laparoscopic organ resection (salpingectomy) in 1976, since published in 1981 [13]. Kurt Semm (Kiel, Germany) performed the first laparoscopic appendectomy in 1981. Although he is now considered as one of the fathers of modern laparoscopy, he first met great skepticism and even scorn [14]. His suspension from medical practice was debated in the German Gynecological Society. The paper that he submitted on "endoscopic appendectomy" to the American Journal of Obstetrics and Gynecology was initially deemed unethical and was rejected. Semm persevered, introduced thermocoagulation, and developed many standard laparoscopic gynecologic procedures, including ovarian cyst enucleation, myomectomy, treatment of ectopic pregnancy, and laparoscopic-assisted vaginal hysterectomy. He published hundreds of papers on laparoscopy, established a company of laparoscopic instruments, and built the widely used pelvi-trainer [14]. By the end of the 1980s, laparoscopy was widely accepted in gynecology, but few general surgeons had included laparoscopy in their practice. The first lap-cholecystectomy was made by Erich Muhe (Erlangen, Germany) in 1986. Muhe met a lot of misunderstanding from his colleagues at this time, and even faced a lawsuit for "improper surgical action" [15]. The use of the computer chip TV camera in 1986 led to the era of modern laparoscopy: not only was a view of the operative field magnified onto a monitor, but also the surgeon could stand upright, and both his/her hands were free. Complex laparoscopic procedures were then developed. Philippe Mouret (Lyon, France) performed the first video-assisted laparoscopic cholecystectomy in 1987. Mouret mentored Dubois (Paris, France), Perissat (Bordeaux, France), and other collaborators. The so-called "French connection" made the laparoscopic technique more and more popular [16]. The first US laparoscopic cholecystectomy was performed in 1988. In the early 1990s, laparoscopic cholecystectomy was an accepted routine procedure. A dramatic explosion of laparoscopic applications occurred in the 1990s. Among others, landmarks in the history of laparoscopy are the first descriptions of truncal vagotomy

[17], nephrectomy [18], Billroth II gastrectomy [19], and splenectomy [20]. Similar developments have been achieved in thoracic surgery in the past 30 years. Minimally invasive surgery is now seen as one of the greatest achievements in the recent history of medicine.

#### On the verge of NOTES (1980-2000)

#### Translumenal endoscopic approaches

From the 1980s to the 2000s, numerous translumenal endoscopic procedures emerged. Some of them are now part of the routine practice of gastrointestinal endoscopy. Various endoscopic techniques consist of the creation of an artificial external opening into the digestive tract for nutritional support or gastrointestinal decompression. Percutaneous endoscopic gastrostomy (PEG) creation without laparoscopic assistance was first reported in 1980 by Gauderer et al. [21], then followed by variations such as percutaneous endoscopic jejunostomy and colostomy [22,23]. Endoscopic ultrasound (EUS) arose in 1980 [24]. Diagnostic EUS procedures were first based on imaging and Doppler only. Under EUS guidance, the fine needle aspiration (FNA) technique was developed to allow the sampling of lesions through the digestive wall [25]. EUS-FNA is now commonly used to target lesions in the mediastinum, in the biliary and pancreatic area, and in the mesorectum. Further refinement of the EUS technique has led to the ability to pass instruments (guidewires, fiducials, coils, radioactive seeds, pharmacological agents) using fine needles, leading to the concept of interventional EUS. Biliary, pancreatic, and vascular therapeutic EUS techniques are currently under evaluation [26].

Translumenal per-oral endoscopic access to the retroperitoneum is another gastrointestinal technique preceding the birth of NOTES. It was first described by Hans Seifert (Oldenburg, Germany) in 2000 [27]. After endoscopic transmural drainage of peripancreatic fluid collections is performed with EUS-FNA and wire-guided stent placement, the same transgastric access is expanded with balloon dilatation. The endoscope is advanced through the gastrointestinal wall into the retroperitoneum. Endoscopic removal of infected pancreatic necroses can be achieved under direct visual control. In a multicenter open study, initial clinical success was obtained in 80% of 93 patients, with a 26% complication and a 7.5% mortality rate at 30 days [28]. Similar results were found in a US multicenter study that included 104 patients [29]. Although not compared to surgery in randomized controlled studies, this endoscopic technique has become a valid therapeutic option. The concept of endoscopic debridement of necrosis was expanded to other conditions than pancreatitis and is now performed in expert centers to treat complications of postoperative leakage and fistula [30]. Although PEG, FNA-EUS, and endoscopic drainage of necrosis are definitely translumenal endoscopic procedures conducted through natural orifices they are not considered as true NOTES procedures as the endoscope is not advanced in the free peritoneal or thoracic cavity.

#### Transvaginal laparoscopy

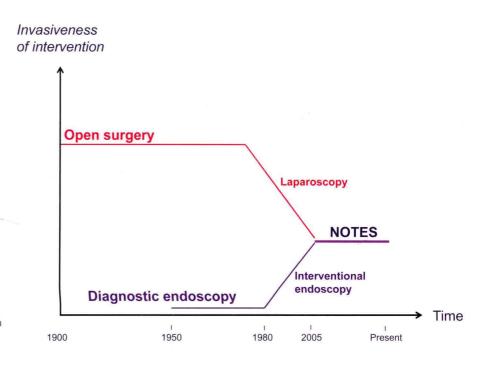
Transvaginal hydrolaparoscopy is a surgical technique that arose in the 1990s with the main purpose of diagnosing and treating infertility in women. The technique used a modified rigid and reusable laparoscope. The so-called "fertiloscopy" procedure combines a hydrolaparoscopy advanced through the vagina and the pouch of Douglas together with hysteroscopy and salpingoscopy with dye. A pioneer in this field is Antoine Watrelot (Lyon, France). After he developed the technique, he demonstrated that fertiloscopy is useful in the diagnosis of tubo-peritoneal abnormalities (a major causes of infertility), enables rational choices in the therapeutic strategy of infertility, improves pregnancy rates, and allows reductions in costs [31]. The technique does not involve a flexible instrument and is not dedicated to the exploration of the entire peritoneal cavity. However, it is seen as a close step on the way to NOTES.

#### The birth of NOTES (2000)

Flexible endoscopic procedures have become more and more invasive over recent decades. At the end of the twentieth century, frontiers in endoscopy were broken in a stepwise fashion. Diagnosis endoscopy is now possible all along the digestive tract (including the small bowel) and even in the duct of its main accessory glands (cm. pancreatoscopy) [32]. Imaging and sampling of oig. Deyond the digestive tract have been made possible by EUS-FNA. The most recent step was the possibility of voluntarily causing a breach in the integrity of the digestive wall to access and treat necrosis in the retroperitoneum [33].

Conversely, surgery is getting less and less invasive. Dr Hunter's quote in 1762 – "Surgery, gaining much from the general advance of knowledge, will be rendered both knifeless and bloodless" – was much ahead of his time. At the end of the twentieth century, laparoscopy has been demonstrated safe and cost-efficient, in a wide range of applications in abdominal, pelvic, and thoracic surgery. It has been fully accepted by medical and surgical communities. Minimally invasive surgery has therefore gained patients' satisfaction over the years and is now a standard of care for many indications. Some of its latest developments are the possibility to access and to treat through natural orifices (mostly through the vagina) and/or through a unique and small parietal incision (as proposed in single-incision laparoscopic surgery, SILS).

NOTES is born from the confluence of these two trends (Figure 1.1). Anthony Kalloo and the team (Figure 1.2) from the Johns Hopkins Hospital (Baltimore, USA) reported on the first NOTES procedure (transgastric peritoneoscopy) in a survival porcine model during the 2000 edition of the *Digestive Disease Week* (DDW) (see Video 1.1). In this initial approach (finally published in 2004) [34], access to the peritoneal cavity was gained with a flexible videogastroscope through the mouth and after needle-knife puncture



**Figure 1.1** Synoptic view of the confluence of interventional endoscopy and minimally invasive surgery over time, leading to the birth of NOTES.



**Figure 1.2** Sergey V. Kantsevoy, Sanjay B. Jagannath, Anthony N. Kalloo, and Hu Bing.

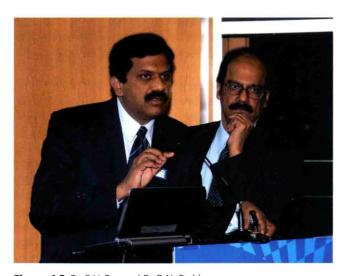


Figure 1.3 Dr G.V. Rao and Dr D.N. Reddy.

and balloon dilatation of the anterior wall of the stomach. Peritoneoscopy and liver biopsies were performed. Hemoclips were used to close the gastrotomy. Two years later, Rao and Reddy (Hyderabad, India) reported on the first human case (transgastric NOTES appendectomy) in a DDW video session (Figure 1.3) [35].

#### NOTES launching (2000–2004)

After its initial description, a few research groups showed interest in NOTES. At this early stage, much work was done out of the public view. Developmental studies aimed to make flexible endoscopes and ancillary instruments suitable and safe for translumenal access, and surgical procedures were being developed. Endoscope and overtube prototypes were conceived and designed with larger accessory chan-



Figure 1.4 NOSCAR group, July 2005.

nels, increased push force, wider freedom of movement, and variable rigidity [36]. Approximating and sewing instruments were developed. Among others, the group of Paul Swain (London, United Kingdom) was extremely active on this topic [37]. Along with these advances in the design of instruments, early procedures were refined, with animal experiments on organ removal and anastomosis, leading to the first descriptions of NOTES gastrojejunostomy, fallopian tube ligation, hysterectomy, and cholecystectomy [38–41].

#### **NOTES booming (2005–2008)**

#### **NOTES** societies

In July 2005, US leaders in the fields of both laparoscopy and gastrointestinal endoscopy came together for a summit meeting in New York City. These experts built up the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) group, a joint initiative supported by the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) (Figure 1.4). From this meeting, the NOSCAR group published a first White Paper in 2006 that aimed to guide research on NOTES [42]. The key message of the group was that developmental work and animal study were required before safe clinical evaluation could be attempted (Table 1.1). The group successfully called for the involvement of the industries of both endoscopy and surgery. Their first annual meeting under the name of NOSCAR was held in Boston in 2006. The first NOSCAR research grants were awarded in 2006, since then followed by yearly awards. Other international groups with similar goals and means followed this move throughout the world. In 2007, the first joint meeting of the European Association for Endoscopic Surgery (EAES) and the European Society of Gastrointesti-