Abhay Rane · Jeffrey A. Cadeddu
Mihir M. Desai · Inderbir S. Gill
Editors

Scar-Less Surgery

NOTES, Transumbilical, and Others

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This book is dedicated to those minimally invasive surgeons who have always strived to push the proverbial envelope to its limit in order to get the best for our patients. These dedicated kindred souls have often had to brave withering criticism from peer skeptics, but have nevertheless managed to prove their point by maximizing minimally invasive surgery.

Such an effort would not be complete without acknowledging our better halves: those who have always "stood and waited": Ruta, Marlo, Rimple, and Neeti.

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Preface

Natural orifice translumenal endoscopic surgery (NOTES) and laparoendoscopic single-site (LESS) surgery are based on the premise that patients would significantly benefit in terms of recovery time, physical discomfort, pain, and cosmesis by a surgery performed without visible scarring. Over the last five to seven years, there has been a rapid expansion of LESS and NOTES procedures across surgical specialites, with hundreds of procedures reported in the literature ranging from cholecystectomy to radical prostatectomy. To date, there has not been a comprehensive text providing detailed information on the techniques, their limitations, instrumentation requirements, and results. Such a source is necessary to catalog progress to date, provide concise state-of-the-art technical information, and serve as a resource text as clinicians embark on this exciting new frontier.

The initial chapters in this text provide state-of-the-art reviews of the advances in surgical instrumentation that have increased the feasibility of these procedures. Nevertheless, the challenge for LESS and NOTES techniques is whether they can be utilized to improve patient outcomes without significantly increasing surgical cost, operative time, or complications. The balance of the text expertly addresses this issue. One must keep in mind that the benefits of LESS and NOTES procedures are incremental compared to the transition from open surgery to laparoscopy, where it was fairly easy to demonstrate an advantage in morbidity. Convalescence, hospital stay, and pain were consistently better with minimally invasive surgery. Even though it is conceptually obvious, those in practice at the time laparoscopy was introduced will recall that the acceptance of laparoscopy's benefits was neither immediate nor universal. The transition from conventional laparoscopy to LESS is more subtle. Pure NOTES where the access is commonly transoral (transgastric) or transvaginal may have greater advantages in this regard. There is no doubt that LESS and NOTES provide clear advantages in cosmesis. LESS, with its single scar often undetectable in the umbilicus, and NOTES, with its absence of transabdominal incisions, are clearly most appealing to our increasingly sophisticated patients.

LESS and NOTES techniques are gaining momentum as the next frontier in minimally invasive surgery. It is critically important that surgeons maintain their pioneering spirit and evaluate these new approaches. This text serves as the first comprehensive reference for general and urologic surgeons while also highlighting future developments and research needs.

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Contents

Part IV Future Perspectives

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Part I
Overview

Chapter 1
Historical Perspectives of LESS and NOTES

Michael L. Blute Jr., Soroush Rais-Bahrami, and Lee Richstone

Keywords Laparoendoscopic single-site surgery • Natural orifice transluminal endoscopic surgery • Laparoscopy • Endoscopy

Introduction

The craft of surgery has undergone a remarkable transformation in a few short decades, evolving from traditional large incisions to smaller "keyhole" incisions characteristic of a minimally invasive approach. The drive toward minimally invasive techniques seeks to benefit patients by reducing pain and the physiologic responses to the stresses of open surgery. Smaller incisions limit disfigurement and improve upon cosmetic outcomes without compromising the exposure provided by open surgery with the advent of improved optical scopes and display mechanisms. Today, it is commonplace for patients to undergo major extirpative surgery through small incisions and enjoy a rapid recovery, with a brief hospitalization and quickened convalescence.

The introduction and diffusion of multiple-port, or "conventional," laparoscopy account for a large part of this revolution in the practice of surgery. This progress has been carried on by the development of robotic-assisted laparoscopy, which has allowed for the widespread diffusion of minimally invasive surgery, particularly for the lower urinary tract. More recently, the evolution of minimally invasive surgery has been characterized by the desire to perform completely scarless surgery. Two approaches to further improve the cosmetic outcomes of minimally invasive sugery,

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namely, natural orifice translumenal endoscopic surgery (NOTES) and laparoendoscopic single-site (LESS) surgery, have developed in tandem during recent years. Natural orifice surgery represents perhaps the Holy Grail of minimally invasive surgery: extirpative and/or reconstructive surgery with no violation of the externally visible body integument. Although proven feasible for some procedures, limitations in current technology and instrumentation have delayed and/or prevented the incorporation of NOTES into common, everyday surgical practice. In this context, interest was stirred in the concept of transumbilical "single-port" surgery, offering nearly scarless surgery.

As laparoscopic and now robotic LESS surgeries have been explored for a wide variety of procedures, it seems like something old has become new again, as single-port laparoscopy had, in fact, been first reported decades prior [1]. It is in this basic context that LESS and NOTES have emerged as the latest techniques in the continued evolution of modern surgery toward the least invasive approach to surgical intervention. The history of these techniques is brief but lends insight into the progression away from large, invasive surgery with open wounds and the morbidities experienced with these traditional approaches.

History of NOTES

Endoscopic procedures have been performed in the intralumenal gastrointestinal tract dating back to the early part of the twentieth century and perhaps represent the starting point for "natural orifice surgery." Rigid scopes were used to remove foreign bodies, dilate strictures, and excise accessible lesions. By 1960, flexible endoscopes were developed, allowing more extensive and invasive intubation of the gastrointestinal tract [2]. Endolumenal procedures performed today using flexible endoscopes range from biopsies to ablation to extirpative surgery replacing traditionally open or conventional laparoscopic surgery. The most commonly recognized application of flexible endoscopy is the use of a colonoscope for diagnostic and therapeutic management of the large bowel pathologies [3]. Additionally, the advances in fiber optic technology and flexible scopes now provide the maneuverability to perform complex endoscopy into the upper gastrointestinal tract and into the pancreaticobiliary duct system, which requires a very fine caliber endoscope with multiple levels of deflection and procedural dexterity.

Combining the emerging technologies of improved flexible optical scopes and the goals of providing more complex surgeries via endolumenal approaches, NOTES was developed. The successes of endoscopic procedures for intralumenal pathologies via biopsies, tumor excisions, and ablations have evolved into procedures initiated through the natural orifices to address pathologies outside the gastrointestinal lumen.

Also, the use of endoscopy in the genitourinary system via cystoscopy, vaginoscopy, and hysteroscopy has paralleled the advances of gastrointestinal endoscopy. Similarly, biopsies, mass excisions, and ablative procedures performed through a cystoscope or hysteroscope have now evolved into procedures whereby these instruments are used via the natural portal of entry to allow access to extralumenal pathologies or provide routes of specimen extraction previously not harnessed as a means of minimizing skin incisions [4–6].

Employing a puncture through the gastrointestinal tract with an endoscope to access extralumenal organs of interest was first used in animal models. NOTES surgery first began through a transgastric approach. A transgastric approach was proven safe for diagnostic imaging of the peritoneal cavity and the therapeutic purpose of removing tissue and organs [7, 8].

In early studies, cholecystectomy was performed via a transgastric and simultaneous transvesical approach in seven anesthetized pigs [9, 10]. Access was obtained through the stomach and urinary bladder, and the cholecystectomy was performed with a gastroscope transgastrically and a ureteroscope passed transvesically. The surgical dissection was performed gastroscopically. Five of the seven cases were performed successfully without complications, while two had evidence of bile leak and hemorrhage from the liver surface. These initial studies demonstrated the feasibility of performing a cholecystectomy exclusively through natural orifices.

This proof of concept quickly expanded from animal models to cases of successful transgastric NOTES in human patients. One of the earliest accounts of NOTES for gastrointestinal pathology in humans date back to 2004, when an appendectomy was first performed via a transgastric approach [11].

Now, increasing numbers of subsequent therapeutic procedures are being performed using these transgastric NOTES techniques, including cholecystectomy, gastrojejunostomy, splenectomy, hysterectomy, and oophorectomy [12–16]. In essence, this provides patients with an outwardly scarless approach, replacing traditional open surgical or conventional laparoscopic techniques that render patients with visible cutaneous scars at incision sites.

Considering all human natural orifices, any one could possibly be used for this form of surgery. More recently, other routes of entry into the body have been used to gain better access to various intraabdominal and retroperitoneal organs. These additional portals of access include the transvesical, transcolonic, and transvaginal approaches [17–19].

Another natural orifice that has recently been utilized not only as an access portal but also as an extraction site for NOTES is the vagina. Again, this is a "rediscovery" of sorts, as the vaginal canal has served as a well-established extraction site for over a century. Gynecologic surgeons have been performing vaginal hysterectomies since the late 1800s, using the vaginal canal as the extraction site for extirpative surgery for both benign and malignant uterine pathologies [20].

In 2002, urologists reported on their series of patients who underwent laparoscopic nephrectomies and extracted the specimen through the vagina, saving patients large abdominal wounds [21, 22]. More recently, in 2007 Lima and colleagues reported on a nephrectomy performed completely via natural orifices in a porcine model [23]. The authors were able to demonstrate the successful completion of a nephrectomy using transgastric and transvesical access in six porcine models. Interestingly, the authors realized that they were able to operate with a low CO_2

pressure of approximately 3 mmHg. This was accounted for by the entrance of the instruments into the abdomen being parallel to the abdominal wall, which was used as a fulcrum during mobilization. Secondly, they noted that the magnification properties of the endoscopic instruments required decreased levels of pneumoperitoneum pressure, potentially decreasing the stresses incurred by the use of routinely higher pneumoperitoneum pressures.

Kaouk and colleagues reported their experience with NOTES transvaginal nephrectomy with Veress needle access initially obtained via the umbilicus for establishing the pneumoperitoneum followed by a direct vision colpotomy through which a transvaginal access port was placed. The entire operation was then completed via the transvaginal route [24]. More recently, the same group reported a pure NOTES transvaginal nephrectomy with no cutaneous violations [25].

The ability to surgically excise an organ of greater mass than the gallbladder and harbored within the retroperitoneum can be done through natural orifices. The problem that arises, especially in male patients, is how to remove an organ of such a size while maintaining exclusively scarless surgery. This concept has yet to be addressed definitively with a uniformly consensual solution. However, ideas such as specimen morcellation, extension of the transgastric incision, or transcolonic extraction routes have been proposed and tested as alternatives to transabdominal removal, which would render the patient with a scar at the cutaneous extraction site.

The practice of NOTES to date is relatively novel, and experience with the technique is still rapidly evolving. Like conventional laparoscopy did decades earlier, the development of NOTES offered a revolutionarily new surgical approach with the intent of improving patient outcomes postoperatively, in terms of both cosmesis and convalescence.

Following the earliest reports of translumenal procedures, leaders in the fields of laparoscopy and endoscopy met to discuss the flourishing development of NOTES as a feasible surgical technique. In 2005, this meeting, or the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR), set goals to facilitate the advancement of research in this field. The group established basic foundations for NOTES research, encouraging a multidisciplinary team approach, the advancement of minimally invasive surgical skill sets, the sharing of data among NOSCAR members at annual meetings, and the use of institutional review board approval for all NOTES procedures performed on humans [26]. Since that initial meeting, many papers have been published on NOTES proving its feasibility and safety in both animal models and human patient series. General surgeons, urologists, gynecologists, and gastroenterologists have worked in concert to apply NOTES techniques to a wide variety of intraabdominal procedures.

As demonstrated, this surgical technique has been born within the past decade and taken a stronghold in an academic realm as an area of investigation to test its applicability and methods of improving it further. The future of NOTES in mainstream surgical practice is unclear to date. However, it has safely and successfully been applied for extirpative and minor reconstructive procedures in human subjects. It may establish a realm of surgery, a true paradigm shift masking any outward evidence of undergoing surgery [19].

History of LESS

Much like NOTES, laparoendoscopic single-site (LESS) surgery is often acclaimed as a novel technique in its infancy, while, in fact, it is a popularization and application of previously applied techniques. LESS is now taking a stronghold as an evolutionary step beyond conventional laparoscopy to minimize incisions as an effort to improve convalescence and postoperative cosmesis. Publications regarding the contemporary LESS experience demonstrate the breadth of experience for which LESS techniques have been employed successfully to accomplish a wealth of operative cases in general surgery, urology, gynecology, and other surgical specialties.

In 2008, innovative leaders in the field of minimally invasive surgery gathered to establish a universally applied terminology for single-site surgical techniques. The Laparoendoscopic Single-Site Surgery Consortium for Assessment and Research (LESSCAR) agreed upon LESS as the accepted nomenclature for this field of surgery. This consolidation brought together "keyhole" surgery, single-site access (SSA) surgery, single-port surgery (SPS), single-incision laparoscopic surgery (SILS), embryonic natural orifice translumenal endoscopic surgery (E-NOTES), natural orifice transumbilical surgery (NOTUS), one-port umbilical surgery (OPUS), transumbilical endoscopic surgery (TUES), transumbilical laparoscopic-assisted (TULA) surgery, and other terminology that was used previously [27]. This was done in efforts to unify rather than fragment this evolving field, consolidate research efforts, improve educational training programs, and universalize reporting in the literature. Now, LESS encompasses many forms of minimally invasive surgery, all with the concerted effort to minimize or eliminate the incisions needed for operative access [28].

The earliest cases of LESS date back several decades to the initial publications describing laparoscopy. Basic laparoscopic procedures marginally expanded upon the well-described diagnostic laparoscopy of the time. These operative maneuvers were performed via a single trocar accommodating a laparoscope and working instrument or incision immediately adjacent to the laparoscopic access trocar. The initial reports of operative laparoscopy centered on needle biopsies performed under laparoscopic visualization by general surgeons and female sterilization by gynecologists [29, 30]. These limited uses of single-site laparoscopy continued to the present day. However, over this time period, more complex operative cases were attempted and proven safe to be performed laparoscopically with the use of additional access trocars. Multiport laparoscopy was adopted as a minimally invasive approach allowing for more complex extirpative, reconstructive, or diagnostic operations for surgeons in many fields [31–33]. At many institutions, laparoscopy surmounted the classic open technique as the standard operative approach for certain procedures [34].

A second wave of interest in LESS arose in the past decade, recognizing LESS as the next natural iteration of minimally invasive laparoscopic surgery. Modifications were made to attempt cases via a single entry incision. Otherwise, LESS techniques largely mirrored those of conventional multiport laparoscopy for nearly all surgical operations that were proven feasible via laparoscopy.

Some of the earliest contemporary cases of LESS date back to 2005. Hirano and colleagues reported one of the first minimally invasive adrenalectomies performed in this manner [35]. In their study, 54 patients underwent a retroperitoneoscopic adrenalectomy via a 4.5-cm incision in the midaxillary line. They were able to perform the surgery through a 4-cm resectoscopic tube using endoscopes without carbon dioxide insufflation. Still, as LESS developed further, attempts at more complex surgery and extirpative surgery for larger organs were made. In 2007, Raman and colleagues performed nephrectomies on pigs using a single incision through which subcentimeter trocars were inserted; once the technique was perfected in the porcine model, nephrectomy was successfully performed in three human subjects [36]. The authors demonstrated the feasibility of using articulating laparoscopic instruments to improve triangulation for their approach to dissecting and removing the kidney. As demonstrated by these early studies and additional small series, great advances have been made in the field of LESS by urologic surgeons [37–39]. Much of the available literature describes urologic LESS, including LESS nephrectomy, partial nephrectomy, nephroureterectomy, pyeloplasty, prostatectomy, sacral colpopexy, and ureteral reimplant [40–42].

In parallel with urologists who have embraced LESS as an innovative advancement of minimally invasive surgery, general surgeons and other surgical specialists have adopted these techniques and principles for their respective fields of surgery.

Just as the laparoscopic cholecystectomy was initially embraced by general surgeons a few decades ago, so too has the application of LESS for gallbladder removal. One of the initial studies that began in 2007 involved 29 patients who were offered LESS and compared to those undergoing multiport laparoscopic removal. When the authors compared LESS to multiport laparoscopy, there were no significant differences in operative time, blood loss, length of hospital stay, conversion to open surgery, or postoperative pain [43]. A retrospective case-control study comparing keyhole nephrectomy to standard laparoscopy failed to demonstrate any difference in surgical parameters. They showed no difference in operative time, blood loss, narcotic use, complications, and hospital stay [44]. Similarly, Fader and colleagues assessed LESS with regards to its feasibility to treat gynecologic oncology disease processes [45]. The authors performed LESS with both standard laparoscopic instruments as well as robot assistance with the DaVinci robotic platform and reported the successful resection of various gynecologic malignancies, including uterine and ovarian. They commented in the discussion that their patients required little postoperative narcotics for adequate analgesia. Other areas where LESS has been successfully applied include gastric banding, appendectomy, and robotic radical prostatectomy, all revealing safety, feasibility, and perioperative outcomes comparable to the well-accepted conventional laparoscopic techniques for each operation [46–48].

As evidenced, the initial reports regarding the success and feasibility of LESS support its presence as the next generation of minimally invasive surgery. LESS holds all the benefits of standard laparoscopy and affords the patient the added advantage of being left with at most one abdominal scar, often hidden periumbilically or below the waistline as a mini-Pfannenstiel incision. Thus far, most investigations show an equivalence in perioperative and convalescence outcomes compared to conventional multiport laparoscopy. However, additional studies are required to prove whether LESS offers improved postoperative pain parameters and patient satisfaction outcomes in head-to-head comparisons by case type. LESS approaches are launching surgery—once a practice of large open incisions now reduced to multiple trocar incisions—to yet the next step of being minimally invasive.

Conclusions

The historical accounts of both contemporary NOTES and LESS applied toward complex surgeries are limited; they are less than a decade old in either case. Both have been conceived from the continuous drive to make surgery less invasive while achieving at least equivalent results produced by traditional open and conventional laparoscopic techniques. These surgical approaches have evolved, providing patients with complex surgical procedures with either a single superficial wound for LESS or no scars by utilizing the body's natural orifices for NOTES.

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Chapter 2
Overview: Rationale and Terminology

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Keywords LESS • Laparoendoscopic single-site surgery • Single site • Nomenclature • NOTES • Natural orifice translumenal endoscopic surgery

Introduction

In the last several decades, with the advent of the Internet and globalization, the world has seen unprecedented information dissemination and exchange. Accompanying this explosion of information has been an unquestionable and previously unparalleled increase in the development and propagation of technology and techniques in medicine and, in particular, in minimally invasive surgery.

Urology has long remained at the forefront of the development and implementation of such technologies. Its involvement in the improvement and distribution of these techniques worldwide is not surprising. Urology has long been a discipline with a dependence on innovative technology to minimize the invasive nature of our procedures. The nature of the urinary tract within the human body seems to spur innovation and has allowed urologists to keep at the leading edge of minimally invasive technological revolutions. In their simplest forms, single-site surgery and even NOTES procedures have been used by urologists for decades with the use of percutaneous nephrolithotomy via a single small incision and a multitude of transurethral endoscopic procedures. The application of similar principles to surgeries traditionally performed via open, or more recently laparoscopic and robotic-assisted, approaches is simply a natural extension of the urologist's current armamentarium to continue on his or her quest to minimize access-related trauma and improve outcomes.

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In the early 1990s, when conventional laparoscopy (CL) was in its infancy and Clayman performed the first laparoscopic nephrectomy [1], a revolution of surgical approach and thought occurred very rapidly. As it became clear that even the most complex of urologic reconstructive and oncologic procedures could be performed in ways that would allow for earlier recovery and minimization of morbidity, the scope of minimally invasive urology exploded. Today, the technology and techniques utilized during conventional laparoscopy have matured. These surgical approaches have evolved and, as a direct result, have given the minimally invasive community two progeny that are very much interrelated: natural orifice translumenal endoscopic surgery (NOTES) and laparoendoscopic single-site (LESS) surgery.

Prior to delving further into the world of urologic minimally invasive techniques and procedures, it is important to understand the history and rationale behind the development of these techniques, and the evolution of the standardization of their nomenclature. Current advances and issues that these approaches face, based on currently published white papers, clinical trials, and patient attitudes toward the new breed of minimally invasive surgical techniques, will also be reviewed.

Nomenclature

While the clinical applications of LESS have largely outshined those of NOTES mainly due to technical challenges related to access and instrumentation, the nomenclature and original studies of NOTES actually predate those of LESS. For this reason, most discussions of NOTES and LESS prefer to address them chronologically rather than the order in which they have been adopted into the clinical surgical repertoire.

NOTES

NOTES is the acronym used to describe procedures performed via natural orifice translumenal endoscopic surgery.

In its purest intended form, NOTES entails using one or more naturally occurring openings of the human body (i.e., mouth, nares, vagina, urethra, and anus) with the intention of puncturing through the wall of the accessed hollow organ (stomach, vagina, urinary bladder, and/or colon) to gain access to another body cavity/space (peritoneum, retroperitoneum, thorax, etc.). Following access, the surgeon then proceeds with the specific task of the intended operation using instruments introduced through the opening.

Other criteria related to the definition of NOTES have also been generally accepted and are as follows [2]:

- If instruments or ports are used transabdominally along with the natural orifice opening, but greater than 75 % of the dissection and operation is performed via the natural orifice, then the procedure is deemed a hybrid NOTES procedure.

- If the natural orifice is used only for additional port placement, but the majority of the operation is conducted via transabdominal ports, then the procedure takes on the designation of NOTES-assisted.
- If the natural orifice is used as an extraction point only, it is not considered NOTES.
- The umbilicus is not considered a natural orifice for purposes of NOTES designation.

LESS

LESS is also an acronym describing an endoscopic procedure. It stands for laparoendoscopic single-site surgery.

LESS procedures rely on a single access site, usually involving the transabdominal or retroperitoneal placement of ports. Because of the breadth of potential applications, the definition has become slightly more involved. It has been generally accepted that LESS also adheres to the following [2, 3]:

- A single, a multiple, or a single multi-port platform used through the single incision.
- If the umbilicus is used for access, the letter "U" shall be placed in front of the procedure, e.g., "U-LESS."
- Enlarging an incision for specimen retrieval does not exclude the procedure from being considered a LESS procedure.
- The adjunctive use of small needlescopic instruments/ports is encouraged if they enhance the surgeon's confidence and the patient's safety.
- A single incision with multiple fascial openings is not excluded from the LESS definition.

As seen, these are highly specific terminology and definitions that have been attached to a myriad of surgical procedures. The acronyms NOTES and LESS are the currently agreed-upon versions of a minimally invasive primordial alphabet soup that existed prior to 2006.

Nomenclature History

Prior to the consensus statement by the NOTES Working Group in 2008, the nomenclature used above for the procedures was referred to by several different combination and acronyms, a few of which can be seen in Table 2.1.

The lack of standardization of terminology led to confusion in the academic examinations of these techniques. It became difficult to perform meaningful literature searches and define inclusion criteria, making it impossible to report consistent results. Many centers were duplicating work due to the inability to accurately