

Consensus statement of the consortium for laparoendoscopic single-site surgery

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Natural orifice transluminal endoscopic surgery (NOTES) and single-port access surgery are significant new developments, surely not the last, in the continuing evolution of minimally invasive therapies. The potential these advances may hold for improved clinical outcomes is just beginning to be realized. Minimally invasive surgeons have already

begun to use single-incision access to perform a range of clinical procedures, with little to no formal guidance. Despite design shortcomings, currently available ports, instruments, optics, and supplemental technologies such as robotics have been used successfully to obtain initial experiences with these novel approaches.

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Historically, technological advances in instrument design have fueled newer clinical applications, the success of which in turn has necessitated the development of yet newer technology. This self-perpetuating cycle now stands at the threshold of a quantum leap forward due to the most recent developments in NOTES [1] and single-port surgery.

Informal discussions between thought leaders and interested specialists during the past year have indicated the need for an umbrella group that would lend direction to rational development of single-port surgery and serve as its driving force. To this end, the Laparoendoscopic Single-Site Surgery Consortium for Assessment and Research (LESSCAR)¹ was formed to serve as an international multidisciplinary ad hoc organization to advance the field of laparoendoscopic single-site (LESS) surgery. This white paper is the result of deliberations that took place during the inaugural meeting of LESSCAR in Cleveland, Ohio, on July 2008.

¹ Efforts are underway to secure trademark protection for the acronym LESSCAR. The aim of trademark protection is not to restrict its use but rather to ensure that it can be used freely by all individuals, organizations, and institutions that wish to conduct research and use single-port procedures. It is possible that the term's use might be restricted if a for-profit organization were to acquire trademark privileges.

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Aims and goals

The organization of LESSCAR was intended to coordinate and advance the emerging field of LESS surgery in a cohesive and responsible manner. The primary goal of LESSCAR is to develop the necessary techniques and technology to standardize the clinical outcomes of LESS surgery.

The basis for LESSCAR

The LESS approach is a new and rapidly expanding arena of clinical and basic research activity across many surgical disciplines. Early interest from the medical and corporate worlds has led to escalating clinical applications within a rather short time.

Despite this recent flurry of activity, or perhaps due to it, a plethora of terms and acronyms are used to describe the field single-port surgery, creating a lack of consensus with regard to basic terminology and structured protocols. Addressing these lacunae was an identified immediate need. Given the multidisciplinary scope of the single-port concept, considerable interest has been expressed by various parties for unifying and coordinating the field across disciplines. In response to this perceived need, LESSCAR was organized. It is intended to be a multidisciplinary group drawing on the experience of various specialties that possess the unique clinical expertise to advance the field safely. From the start, it was acknowledged that many thought leaders in the field were not present at the initial meeting of LESSCAR due to their nonavailability.

LESSCAR terminology

For any nascent field to develop and grow, defined terminology is a primary prerequisite for allowing a comprehensive flow of information among specialists and specialties. Yet in its infancy, and lacking formal structure, there was understandable confusion regarding terminology in the field of single-port surgery. To select the most appropriate name/designation for this field, LESSCAR thought the selected name should accurately encompass the following broad concepts: (1) a single entry port, (2) applicability to multiple locations (abdomen, pelvis, thorax), (3) laparoscopic, endoscopic, or robotic surgery, (4) umbilical or extraumbilical access, (5) intra- and transluminal (percutaneous single-port access) approach, and (6) and a broad reach so as to be inclusive, not exclusive. After extensive deliberations, LESSCAR unanimously concluded that the term laparoendoscopic single-site (LESS) surgery most accurately conveys the broad philosophical and practical aspects of the field.

To convey all procedural details clearly and fully, all scientific publications on LESS would require a “mandatory descriptive second line” that succinctly provides all relevant information at the very outset such as single incision length and location (abdominal [umbilical or extra-umbilical], thoracic, or pelvic); approach (transperitoneal, retroperitoneal, percutaneous intraluminal, or transluminal); number and type of ports used; type of surgery (laparoscopic, endoscopic, or robotic); type of laparoscope used (straight or flexible); type of instruments used (straight, curved, bent, articulating, or flexible); and whether any ancillary 2-mm needlescopic instrumentation is used.

For example, a manuscript reporting on a series of 12 patients undergoing single-access nephrectomy would read: “We present our single-center experience with 12 patients undergoing LESS radical nephrectomy for cancer. All procedures were performed transperitoneally with a single-port device (3-channel) via a 2.5-cm umbilical incision using a flexible 5-mm laparoscope and articulating instruments.”

In selecting the term LESS surgery for this class of minimally invasive procedures, LESSCAR reviewed an exhaustive list of more than 20 existing names for single-port surgery that had appeared in one form or another in the literature. None were considered to be as descriptive as LESS surgery. Notably, in its most recent white paper, the Urologic NOTES Group agreed with our terminology and also endorsed LESS surgery as the name for single-port surgery [2].

LESSCAR mandate and membership criteria

The mandate to advance the field of LESS surgery is assumed by LESSCAR (Table 1). The criteria for LESSCAR membership are deliberately broad (Table 2). Designed to be inclusive rather than exclusive, these criteria seek to draw on the energy and imagination of as many surgical disciplines as might benefit from the development of LESS procedures.

Technical clinical issues

The current status of the single-port surgery field requires that the technologies and instruments designed primarily for multiport standard laparoscopic procedures be used in LESS surgery. This poses severe technical challenges for surgeons and limits the types of procedures that can be undertaken safely. As the field of LESS surgery progresses, it is anticipated that instrumentation specific to single-port surgery will be developed rapidly. To make this possible, LESSCAR will seek to identify advantages, disadvantages, proposed modifications, and ideal designs of single-port instrumentation and platforms.

Single-port technology

Central to the performance of LESS surgery is the ability to achieve efficient and effective access to the surgical area of interest via a single port of entry. Recently developed multichannel single-port devices have already addressed this need admirably. However challenges remain. Important issues requiring additional development include an interchangeable diameter access channels within a single-port format and prevention of air leak with novel sealing mechanisms (gel, pneumatic). Anticipating ongoing refinements in single-port technology, LESSCAR recognizes that the use of three standard laparoscopic trocars through a single skin incision (with multiple fascial puncture sites) can provide the independence of movement necessary for LESS surgery.

Retraction and triangulation

The ability to triangulate and grasp tissues firmly enough to allow traction and countertraction for exposure and dissection is a basic requirement of surgery. One technical challenge of LESS surgery is limited triangulation and retraction of tissues due to confinement of optics and

Table 1 Mandate of the Laparoendoscopic Single-Site Surgery Consortium for Assessment and Research (LESSCAR)

- LESSCAR: Create an international multidisciplinary group of minimally invasive and endoscopic surgeons to bring focus, direction, and unifying coordination to the field of LESS
- Funding: Solicit, acquire, evaluate, and direct research grants
- Registry: Consider a Web-based, discipline-specific, international clinical registry database
- Research: Stimulate and coordinate LESS research efforts
- Industry: Establish close liaison with industry to develop purpose-built instruments and technology for LESS
- Annual meeting: Consider an annual meeting per LESSCAR consensus
- Newsletter: Update advances through a biannual LESS newsletter
- Symposia: Collaborate with major established professional organizations in various surgical disciplines to facilitate formal LESS presentations at their annual meetings

LESS laparoendoscopic single-site surgery

Table 2 Criteria for Laparoendoscopic Single-Site Surgery Consortium for Assessment and Research (LESSCAR) membership

- Have an expressed interest in or experience with LESS.
- Have access to clinical facilities capable of supporting LESS procedures.
- Conduct all LESS clinical research under institution review board (IRB) approval.
- Contribute to the LESSCAR outcomes registry database.
- Agree to present formal reports on clinical and research activity at LESSCAR symposia.

LESS laparoendoscopic single-site surgery

working instruments to a single axis. Industry is pursuing solutions to many of these problems through the development of next-generation flexible, articulating, or motorized instruments. In its role, LESSCAR will seek to provide an organized forum for assessing the efficacy of these new tools in specific clinical scenarios and to recommend refinements and improvements.

Endoscopes

High-fidelity vision is necessary for intraoperative visualization of anatomic regions and structures. The surgeon should be able to visualize structures from differing perspectives, preferably offline from the axis of instruments. Desirable design requirements include endoscopes and laparoscopes with minimal to no external profile and flexible or semirigid shafts. Ultimately, development of wireless, high-resolution charge-coupled devices and chip-on-the-stick technologies possessing maximal flexibility would represent a true advance.

Hemostasis

Reliable, secure, and rapid means of establishing hemostasis with thermal energy delivery systems, staples, clips, and sutures equivalent in efficiency to that of standard multiport laparoscopy is essential. Newer technologies should allow placement of staples, clips, and sutures with minimal repetitive instrument exchanges. Specifically in reference to LESS surgery, reducing the number of instrument exchanges is vitally important for reducing friction within the port and decreasing the likelihood of disturbing other instrumentation and therefore the surgical exposure. By thus minimizing surgeon distraction, this enhances operative efficiency and reduces operative times.

Ancillary use of 1.9-mm needle instruments

To enhance surgeon confidence, and thereby patient safety, LESSCAR endorses the discretionary adjunctive use of 1.9-mm needle instruments during LESS surgery. These

1.9-mm needle instruments are inserted through the 2-mm Veress needle port routinely used to achieve laparoscopic pneumoperitoneum. The 2-mm Veress needle ports have a 14-gauge outer diameter similar to certain intravenous needles [3]. As such, these needle ports require only a skin puncture for insertion rather than a formal skin incision, call for no suturing for skin closure, leave a minimal or no visible skin scar, and cause minimal to no morbidity.

By facilitating instrument triangulation, tissue retraction, and intracorporeal suturing/knot tying along the lines of standard multiport laparoscopy, these 1.9-mm needle instruments confer three important advantages: enhanced patient safety, increased intraoperative dexterity, and an expanded clinical repertoire of LESS surgery with immediate effect. However, the reliability, tensile strength, construction design, and variety of needle instruments need improvement. As mentioned earlier, any ancillary use of needle instruments should be stated clearly in the “mandatory descriptive second line.”

Percutaneous intra- and transluminal LESS surgery

The LESS surgery approach has the potential to develop the field of percutaneous intra- and transluminal surgery. By direct percutaneous entry to hollow organs such as the urinary bladder, stomach, and colon, newer intra- and transluminal procedures could be developed. Actually, initial reports of transvesical simple and radical prostatectomy have appeared already in the literature [4]. The potential advantages of this approach would include operating within a localized pneumoviscerum environment (e.g., pneumovesicum, pneumogastrum, or pneumocolum), in contrast to a generalized pneumoperitoneum (which compromises diaphragmatic/respiratory excursion), thereby potentially allowing certain major abdominal procedures to be performed under regional rather than general anesthesia.

In addition, the pneumo-inflated circumferential walls of a hollow organ act as a natural internal retractor, obviating the need for surgical retraction of adjacent structures and organs. In the future, intra- and transgastric or colonic procedures could be developed based on the LESS surgical platform.

Robotics

Robotically assisted procedures currently are an established component of many standard laparoscopic procedures. To develop the field of LESS surgery to the next level, computer-assisted robotic technologies represent a paradigm-changing advance that could potentially resolve the problems imposed by restricted range-of-motion and in-line work and vision. A stable multitasking robotic

platform dedicated to single port procedures could address these issues and enhance instrument manipulation and freedom.

In an effort to focus research and development, LESSCAR members were polled for their opinion as to which of the four general technology categories (ports, instruments, optics, robotics) required the most development to meet future needs of LESS surgery. The LESSCAR members thought the priorities were evenly divided across all four categories. They thought that each technology required refinement and design improvement and that industry should move forward on a broad front.

In addition, this informal poll found that the LESSCAR members thought the volume of procedures applicable to LESS may increase by approximately 50% during the next 5 years, with even higher projections of up to 80% in some specialties. Financial costs were recognized as an important consideration, with excessive costs potentially limiting applications in specific procedures despite the clinical benefits they might produce. This would hinder progress. In this regard, industry would be well advised to pursue the development of reusable instruments that are versatile and multifunctional to permit their use in the broadest possible range of clinical applications. Finally, it was recognized that although a close liaison with industry is essential for advancing LESS surgery, a clear declaration of any conflict of interest is mandatory.

Clinical research

Immediate clinical research challenges include establishing a comprehensive database, creating uniform data-reporting instruments for that database, and designing prospective randomized or case-controlled trials. Transumbilical LESS surgery, with its scar-of-entry concealed in the folds of the navel, raises the dream of near-complete cosmesis. However, any theoretical benefits beyond cosmesis, such as possible advantages in terms of postoperative morbidity and convalescence, will require prospective evaluation in carefully designed clinical trials.

In addition to evaluating any advantages of LESS surgery over standard laparoscopy, well-designed clinical trials also would be necessary to justify value-added payment from payors. Refining established validated tools or developing new quality-of-life (QoL) instruments specific to LESS surgery is anticipated to be somewhat of a challenge. Whereas clinical data are readily measurable, QoL outcomes are more subjective. As recognized by LESSCAR, the currently available validated Medical Outcomes Survey Short Form 12 (SF-12) and SF-36 questionnaires as well as the standard measures of postoperative morbidity such as analgesic requirements may be insufficiently sensitive to

detect differences in patient outcomes between LESS and standard laparoscopic surgery. These existing tools may need refinement, or newer tools might need to be developed.

It was noted that cosmesis, an important attribute of LESS surgery, is likely to fuel public demand for certain applications. However, it is emphasized that excellence in the major clinical outcomes of various substantial surgical procedures remains the fundamental goal of LESS surgery.

Registry database

As one of its goals, LESSCAR seeks to develop a collaborative, international, Web-based, registry database. The site would be secure, confidential, and designed with embedded checks and balances to ensure accuracy. This voluntary registry will facilitate prospective evaluation of outcomes for evolving LESS procedures, allow early identification of any deviation from safe practices, and permit comparison with standard laparoscopic surgery. Data reporting will be standardized, and reports will be required to contain all aspects of the “mandatory descriptive second line.”

The registry will be available to members and associated organizations that have contributed substantially to the database. Semiannual audits and an annual update at the annual LESSCAR meeting would be planned. Centrally maintained and coordinated by an oversight committee, each discipline-specific registry will be overseen by a designated LESSCAR member or members of that particular specialty. Discipline-specific registries may have differing life spans. For example, for high-volume procedures such as LESS cholecystectomy, the registry would have served its purpose after, say, 1,000 LESS cholecystectomies have been collected and published. Conversely, the registry of comparatively infrequently performed procedures such as LESS donor nephrectomy or LESS hemicolectomy may need to be maintained for a longer period until data and outcomes analyses reach levels sufficient to produce clinically significant findings and conclusions. A semiannual LESSCAR newsletter is being considered. The newsletter would keep members, related organizations, and interested parties informed about advances in the field.

Institutional review board approval

It is understood that institutional review board (IRB) approval will be required for those participating in, conducting, or reporting formal clinical studies. It is LESSCAR's intention to support these efforts by facilitating development and sharing relevant descriptions among its membership. This information is likely to be of substantial benefit in obtaining IRB approvals.

Animal research

A clear advantage of LESS surgery is that, similar to standard laparoscopic surgery, access is achieved via the anterior lateral abdominothoracic wall. This basic similarity in approach ensures that the surgeon seeking to use LESS surgery will benefit from his or her prior laparoscopic experience. This should shorten the learning curve and lead to more rapid clinical application of LESS procedures compared with NOTES. Indeed, for many applications, the introduction and refinement of specific LESS procedures already are well under way. Extensive animal studies to evaluate pathophysiologic and technical issues unique to NOTES, such as viscerotomy closure and sequelae of peritoneal contamination, will not be necessary for LESS procedures. However, animal studies are likely to be necessary for the development and evaluation of LESS surgery-specific technology and instrumentation.

Patient safety

The LESS approach to surgery seeks to improve surgical outcomes beyond those achieved by current standards of care for specific procedures. As with any new procedure, it is important that initial LESS surgical applications be duly conservative, with careful patient selection. Sensitivity to the potential for complications is critical, with these risks detailed during the informed consent process. The threshold for conversion to standard multiport laparoscopy, or even open surgery, must be appropriately low. Submission of detailed procedural records to the registry database will allow identification of favorable and unfavorable anatomic and disease characteristics, perioperative problems, areas of concern, and development of appropriate solutions. This will allow procedure-specific indications and contraindications to be described more accurately.

Skills training

At this writing, LESSCAR does not intend to become involved in certification, licensing, credentialing, or granting of formal approvals for surgeons to perform LESS procedures. This responsibility rightfully rests with individual surgeons, their organizations, and their institutions. It is recommended that before a LESS procedure is performed, the surgeon should possess adequate standard laparoscopic experience, and preferably should have undergone a certain amount of LESS surgical training. At a minimum, this should include 1–2 dedicated days of stepwise structured training incorporating inanimate

Table 3 Suggested stepwise format for laparoendoscopic single-site (LESS) surgery Training

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- Inanimate pelvi-trainer use with articulating, bent, flexible instruments and flexible endoscopes and laparoscopes
 - Hands-on training with the animal model (preferably)
 - Observation of live clinical LESS procedures
 - Mentoring and proctoring during initial LESS cases (preferably)
-

training models, “hands-on” animal training sessions, observation of clinical procedures, and performance of initial LESS surgeries in a mentored and proctored setting (Table 3). It is anticipated that training simulators similar to those developed for standard laparoscopy will appear in the future.

An additional observation is advanced. For patients undergoing cancer surgery, given the gravity of oncologic issues vis-à-vis procedural morbidity, the bar for considering LESS oncologic procedures should be higher than for noncancer applications.

Society partnerships

Partnership with NOSCART

Clearly, NOTES is a more futuristic and fundamentally paradigm-changing concept than LESS surgery. That said, it also should be recognized that both approaches inherently face similar technical and technological challenges imposed by in-line instrumentation and in-line visualization. Experiences, insights, and advances acquired by the one group likely will benefit the other. At their core, both the Natural Orifice Surgery Consortium for Assessment and Research (NOSCART) and LESSCAR share a common vision: to minimize and possibly eliminate the trauma of surgical access while creating a substantial novel platform for major surgery. The obvious benefits of collaboration with NOSCART include jointly engaging industry to influence prospectively the development of mutually beneficial instrumentation and technologies, to create mechanisms for database registries, to create a financial corpus and oversight for sponsoring basic and clinical research proposals, to facilitate rapid dissemination of ideas, and to eliminate duplication of efforts.

In 2006, Rattner and Hawes [5] of NOSCART recognized the need for such cooperative efforts in their editorial on NOTES, stating that “if NOTES is to reach a stage of widespread clinical applicability, there will be need for further innovation and collaboration on many fronts.” It is the general feeling of LESSCAR that the need for such collaboration is not approaching but has arrived.

Table 4 Identified current laparoendoscopic single-site (LESS) procedures in various surgical specialties tabulated according to anticipated surgical volumes

High-volume procedures	Intermediate-volume procedures	Low-volume procedures
Cholecystectomy	Adrenalectomy	Bariatric procedures
Appendectomy	Splenectomy	Myomectomy
Inguinal hernia repair	Hysterectomy	Prostate resection
Oophorectomy	Pelvic organ prolapse	Cystectomy
Salpingectomy	Donor nephrectomy	Partial nephrectomy
Endometriosis surgery	Ureteral re-implant	Retroperitoneal lymph node dissection
Tubal ligation	Ileal interposition	Esophageal myotomy
Pyeloplasty	Radical nephrectomy	Distal pancreatectomy
Simple nephrectomy	Small bowel resection	
Renal cyst decortication	Fundoplication	
Ablative renal surgery		
Pelvic lymphadenectomy		
Nephrectomy		
Gastric banding		
Colon resection		

Mechanisms of partnership with other surgical societies

With a view to advancing and disseminating LESS surgery, LESSCAR will seek to collaborate appropriately with various established professional surgical societies. Examples of such societies include the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), the American Society of Gastrointestinal Endoscopy, the American Society for Metabolic and Bariatric Surgery, the American College of Surgeons, the American Society of Colon and Rectal Surgeons, the American Pediatric Surgical Association, the Society of Thoracic Surgeons, the American Gynecological and Obstetrical Society, and the Endourology Society, among others. These societies will be invited to appoint one or more official members to LESSCAR and to consider hosting postgraduate and plenary sessions pertaining to LESS surgery at their annual meetings. As newer applications are identified, LESSCAR will seek to appraise the respective society.

Conclusion

As the latest advance in minimally invasive surgery, LESS has the potential to reduce the operative trauma of access to levels hitherto not realized. Given its considerable potential for multidisciplinary academic usage, during all scientific communications, the term “LESS surgery” should be followed by a “mandatory descriptive second line” to provide the reader with complete clarity regarding the procedure performed. The multidisciplinary LESSCAR has been formed with the mandate of coordinating and fostering advances in the field of single-port surgery. Given the high likelihood that patient and clinician demand will rapidly propel LESS surgery into wider clinical application

(Table 4), a proactively organized clinical and research infrastructure to ensure safety and enduring success is imperative. To bring this to fruition, LESSCAR will seek to collaborate with the respective professional societies.

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