Title: DEVICE FOR DISPLACEMENT OF ANTERIOR ABDOMINAL WALL.

Abstract: A laparoscopic procedure includes positioning a patient in a position for surgery. A tool is selected having a distal end and a proximal end separated by a tool body. An expandable member is provided at the distal end. The expandable member is expandable between an expanded state and a retracted state. The distal end is inserted through an anterior abdominal wall of a patient and into an abdominal space defined between the anterior abdominal wall and a posterior abdominal wall. The insertion is continued until the expandable member resides within said abdominal space and the proximal end resides external to the space. The expandable member is expanded within the abdominal space. The proximal end is drawn away from the patient by an amount for the expandable member to urge the anterior abdominal wall away from the posterior abdominal wall to expand the abdominal space. The expansion of the abdominal space may be enhanced by admission of a gas under pressure to the abdominal space.
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
DEVICE FOR DISPLACEMENT OF ANTerior
ABDOMINAL WALL

I.
CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. provisional patent application Serial Number 60/620,523 filed October 18, 2004.

II.
BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention pertains to laparoscopic surgical procedures. More particular, this invention pertains to a method and apparatus to expand an abdominal space.

2. Description of the Prior Art

Laparoscopic surgical procedures are well known. Abdominal laparoscopy procedures include techniques for expanding an abdominal space such as the peritoneal space defined between anterior and posterior peritoneal walls. Commonly, the peritoneal space is expanded by introduction of carbon dioxide gas into the peritoneal space to cause expansion of the space and lift an abdominal wall by as much as 3 to 4 centimeters or more. With the abdominal space expanded, laparoscopic procedures can be performed with enhanced visualization of the operative field.

Traditionally, laparoscopy is facilitated by the creation of a pneumoperitoneum using carbon dioxide (CO₂) gas. Hypercarbia due to transperitoneal absorption of the intraperitoneal CO₂ has been observed. A pCO₂ over 55 mmHg can cause an elevation of the heart rate, systolic blood pressure, central venous pressure, cardiac output, and left ventricular stroke volume as well as decrease the peripheral vascular resistance. ([Kraut EJ, Anderson JT, Safwat A, Barbosa R, Wolfe BM: Impairment of cardiac performance by laparoscopy in patients receiving positive pressure end-expiratory pressure. Arch Surg 1999;134:76-80.]) Hyperventilation is then needed to correct the hypercapnia.

The CO₂ insufflation of the peritoneal cavity also causes cephalad displacement of the diaphragm that causes increased peak inspiratory pressure, decreased functional residual and vital capacity, and increased intrathoracic pressure.
As a result of these pulmonary changes, these patients are at risk of atelectasis and a decreased paO₂. (Safran DB, Orlando R 3rd: Physiologic effects of pneumoperitoneum. Am J Surg 1994;167:281-286.) Ventilatory compensation is attempted by increasing the positive end expiratory pressure (PEEP), which has been found to both decrease atelectasis and preserve arterial oxygenation (Tokics L, Hedenstierna G, Strandberg A, Brismar B, Lundquist H: Lung collapse and gas exchange of spontaneous breathing, muscle paralysis, and positive end-expiratory pressure. Anesthesiology 1987;66:157-167.), but is associated with other problems as well. The combination of a CO₂ pneumoperitoneum and increased PEEP can have deleterious effects on different hemodynamic parameters. (Kraut EJ, Anderson JT, Safwat A, Barbosa R, Wolfe BM: Impairment of cardiac performance by laparoscopy in patients receiving positive pressure end-expiratory pressure. Arch Surg 1999;134:76-80.) Investigators have found a significant reduction in a patient's preload and cardiac output when the patient experienced both an intraperitoneal pressure of 15 mm Hg and PEEP of 10 cm H₂O, simultaneously. (Kraut EJ, Anderson JT, Safwat A, Barbosa R, Wolfe BM: Impairment of cardiac performance by laparoscopy in patients receiving positive pressure end-expiratory pressure. Arch Surg 1999;134:76-80.) The weight of the abdominal wall in obese patients often requires intraperitoneal pressures of 18 - 20 mmHg to achieve optimal exposure and adequate space for instruments during advanced laparoscopic procedures. (Eltabbakh GH, Piver S, Hempling RE, Recio FO: Laparoscopic surgery in obese women. Obstetrics and Gynecology 1999;94:704-708.)

Novel methods, such as gasless laparoscopy, have been advocated to avoid increased intraperitoneal pressure in these high-risk patients. During gasless laparoscopy, surgeons use a mechanical retractor fixed to the side of the O.R. table to
elevate the abdominal wall. Valveless cannulae are used to place instruments to allow air into and, thus, facilitate exposure of the intraperitoneal space during retraction of the anterior abdominal wall. Gasless laparoscopy produces a smaller detrimental change in hemodynamic and pulmonary parameters compared to traditional techniques. (Koivusalo AM, Kellokumpu I, Scheinin M, Tikkanen I, Makisalo H, Lindgren L: A comparison of gasless mechanical and conventional carbon dioxide pneumoperitoneum methods for laparoscopic cholecystectomy. Anesth Analg 1998;86:153-158.) However, optimal visualization is paramount to a successful laparoscopic procedure. Gasless techniques do not consistently provide optimal exposure (Paolucci V, Scheff B, Gutt CN, Encke A: The gasless laparoscopic cholecystectomy. Endose Surg Allied Technol 1995;3:76-80.) and have not been widely utilized.

III.
SUMMARY OF THE INVENTION

According to a preferred embodiment of the present invention, a method and apparatus are disclosed for performing a laparoscopic procedure. The method includes positioning a patient in a position for surgery. A tool is selected having a distal end and a proximal end separated by a tool body. An expandable member is provided at the distal end. The expandable member is expandable between an expanded state and a retracted state. The distal end is inserted through an anterior abdominal wall of a patient and into an abdominal space defined between the anterior abdominal wall and a posterior abdominal wall. The insertion is continued until the expanded member resides within said abdominal space and the proximal end resides external to the space. The expandable member is expanded within the abdominal space. The proximal end is drawn away from the patient by an amount for the
expandable member to lift the anterior abdominal wall away from the posterior abdominal wall to expand the abdominal space. The expansion of the abdominal space may be enhanced by admission of a gas under pressure to the abdominal space.

IV.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic presentation showing an abdominal space in transverse cross-section illustration expansion of the abdominal space by admission of pressurized carbon dioxide gas into the abdominal space;

FIG. 2 is a schematic presentation of expansion of an abdominal space with a mechanical displacement of an anterior abdominal wall according to a method and apparatus of the present invention;

FIG. 3 is the view of FIG. 2 showing the expansion of the abdominal space augmented by admission of a pressurized gas into the abdominal space;

FIG. 4 is a top plan view of a patient showing an anterior side of the patient with the apparatus of the present invention admitted into the abdominal space;

FIG. 5 is a longitudinal cross-sectional view of a first embodiment of a distal end of a tool according to the present invention just prior to insertion through an anterior abdominal wall;

FIG. 6 is the view of FIG. 5 following insertion of a distal tip through the abdominal wall and positioning of an expandable member within an abdominal space;

FIG. 7 is the view of FIG. 6 following retraction of an incision forming distal tip leaving an expandable member exposed within the abdominal space and in a deflated state;
FIG. 8 is the view of FIG. 7 following inflation of the expandable member to an expanded state;

FIG. 9 is a cross-sectional view of the apparatus of FIG. 5 showing a first embodiment where an outer sleeve has a C-shaped configuration to permit lateral removal relative to an internal component;

FIG. 10 is the view of FIG. 9 showing an alternative embodiment where the outer component encircles the inner component and is removed relative there to by axial sliding movement;

FIG. 11 is a view similar to that of FIG. 5 and showing an alternative embodiment where an incision-forming distal tip and an expandable member are provided on a common component;

FIG. 12 is a view similar to that of FIG. 8 with the expandable member of FIG. 11 shown in an expanded state; and

FIG. 13 is an alternative embodiment to that of FIG. 11 showing a protective sleeve surrounding the expandable member prior to insertion through an abdominal wall.

V.

DETAILED DESCRIPTION OF EMBODIMENTS

Referring now to the various drawing figures in which identical elements are numbered identically throughout, a description of a preferred embodiment of the present invention will now be provided.

With initial reference to FIG. 1, the technique of the laparoscopic procedure will first be described. FIG. 1 shows, in schematic form, an abdominal space AS defined between an anterior abdominal wall AAW and a posterior abdominal wall
PAW. The abdominal space may be a peritoneal space defined between anterior and posterior peritoneal surfaces or may be any other abdominal space defined between opposing walls. In this context an opposing wall may be any organ whose external surfaces define a space such as the patient's bowel. The anterior abdominal wall includes a left lateral side LLS and a right lateral side RLS with "left" and "right" being used with reference to the patient's perspective.

In order to enlarge the abdominal space AS, a gas is introduced under pressure into the abdominal space AS. The arrows A in FIG. 1 represent the acting pressure of the admitted pressurized gas. The gas is introduced from a source of pressurized gas such as a source 10 of carbon dioxide passed through a tube 12 into the abdominal space AS. The tube is placed through a lateral side (LLS or RLS) through an incision formed by a trocar or the like.

As previously noted, the resistance of the anterior abdominal wall AAW to displacement varies significantly from patient to patient. Particularly in obese patients, significantly higher carbon dioxide pressures are required to displace the anterior abdominal wall AAW. The wall AAW may include a large fat layer (or pannus) adding significant weight and resistance to displacement. The increased gas pressures result in increased morbidity and other adverse events already described.

FIG. 2 is the view of FIG. 1 showing enlargement of the abdominal space AS with a tool 20 according to the present invention. The tool 20 has a distal end 22 separated from a proximal end 24 by a tool body 26. As shown in FIG. 5, the distal end 22 has an incision forming distal tip 28 which is a knife edge for forming an incision and penetrating through the anterior abdominal wall AAW. The tool 20 further includes an expandable member 30 near the distal end 22. In a preferred embodiment, the expandable member 30 is an inflatable balloon 30. The tool body
includes a central lumen 32 passing through the length of the tool body and exposed at both the proximal end 24 and the distal end 22. Further, inflation lumen 34 (shown in FIG. 5) extends through a wall thickness of the tool body 26 from the proximal end 24 to the expandable member 30. Accordingly, admission of a pressurized gas to the inflation lumen 34 inflates the expandable member 30 from a deflated or retracted state shown in FIG. 5 to an expanded state shown in FIG. 8. At the proximal end 24, the inflation lumen 34 may be connected to a source of a fluid (gas or liquid) illustrated at source 36 in FIG. 2 and connected by a conduit 38 to the inflation lumen 34 at the proximal end 24.

The tool body 26 has sufficient rigidity to transmit a force from the proximal end 24 to the distal tip 28 in an amount sufficient to urge the distal tip to form an incision eye through the anterior abdominal wall AAW as illustrated in FIG. 6. In the embodiment of FIGS. 5-8, the tool 20 includes a first component 40 and a second component 42. The first component 40 is a flexible catheter, which contains the lumen 32 and inflation lumen 34 and carries the expandable member 30. The second component 42 is a rigid tube which will slide around the exterior of the first component 40. The second component 42 includes the distal tip 28. Combined, the first component 40 and second component 42 form the tool body 26 and tool 20. When assembled as illustrated in FIGS. 5 and 6, the first component 40 and second component 42 are aligned with the distal tip 28 projecting beyond the expandable member 30. The expandable member is positioned relative to the distal tip for the expandable member 30 to reside within the abdominal space AS after the distal tip 28 is advanced to the anterior abdominal wall AAW as illustrated in FIG. 6. After the positioning of FIG. 6, the first component 40 is retained in the position of FIG. 6 and the second component 42 is removed as illustrated in FIG. 7. Different alternative
constructions of the first and second components 40, 42 may be provided to accomplish such removal. For example, FIG. 9 illustrates the second component 42 having a C-shape in cross section to define a slot 44. After achieving the position of FIG. 6, the second component 42 is retracted and then may be moved laterally relative to the first component 40 to release the first component 40 from the second component 42. Alternatively, and as illustrated in FIG. 10, the second component 42 may completely surround the first component 44. In this case, the second component 42 is removed by sliding it axially off of the proximal end of the first component 40. With either configuration, the positioning of FIG. 7 is achieved with the expandable member 30 exposed without constraint within the abdominal space AS. Following this positioning, pressurized fluid is admitted to the inflation lumen 34 to expand the expandable member 30 to the expanded position shown in FIG. 8.

With the deployment of FIG. 8 attained, the proximal end of the first component 40 is drawn away from the patient. By reason of the balloon 30 opposing the anterior abdominal wall AAW, the anterior abdominal wall is urged away from the posterior abdominal wall PAW to enlarge the abdominal space AS. The proximal end of the first component 40 may be secured in a fixed position through any suitable means. For example, FIG. 2 shows a proximal end 24 attached by a clamp 46 to a rigid retractor arm 48 secured to any fixed platform 50 such as the operating table on which the patient lies.

The balloon 30, when expanded, has sufficient rigidity to resist collapse in response to the forces it experiences when lifting the anterior abdominal wall AAW upward to create the expanded abdominal space AS. This force is a function of the pressure of the balloon 30 against the anterior abdominal wall AAW and the surface area of opposition between the balloon and the anterior abdominal wall. Pressure
experienced to achieve a desired abdominal space enlargement will vary from patient to patient. Preferably, the balloon 30 will withstand pressures in excess of 15 millimeters per mercury equivalent in the abdominal space and more preferably in excess of 20 millimeters of mercury otherwise associated with a required carbon dioxide pressure to achieve optimal exposure and adequate space for obese patients.

While a clamp 46 is shown for attaching the proximal end 24 to the retractor arm 48, the event of a flexible first component 40 (illustrated in FIGS. 5-8), the proximal end of the first component may be secured to the retractor arm 48 by tying the proximal end to the retractor arm.

FIGS. 11-12 illustrates an alternative embodiment where the tool body 20 is not formed of two separable components 40, 42. In FIGS. 11-12, components in common were both previously described and numbered identically with the addition of the letter "a" to distinguish the embodiments. In FIG. 11, the tool 20a has a body 26a formed of rigid material 26a sufficient to absorb forces required to insert the trocar tip 28a through the anterior abdominal wall AAW. In the collapsed state, the expandable member 30a is fully received within an annular recess 31a formed in the tool body 26a near the distal end 22a. The central lumen 32a passes through the length of the body 26a and the inflation lumen 34a is received within the wall thickness of the tool body 26a in fluid flow communication with the balloon 30a. If desired, a protective sleeve 50a may surround the tool body 26a and the collapsed expandable member 30a throughout the insertion into the abdominal space AS. The sleeve 50a may be then retracted. Preferably the sleeve 50a is split along its length so that it can then be removed from the tool body 26a.

While the use of the tool 20 alone expands the abdominal space AS, (as illustrated in FIG. 2), such use may not optimize the formation of the enlarged
abdominal space AS. As illustrated in FIG. 4, the distal tip is preferably inserted into the abdominal wall AAW at a point located midway between the umbilicus U (commonly referred to as the navel) and the pubic symphysis PS (the pubic hair area of the patient). The incision point is located midway between the left L and right R sides of the patient. Use of the mechanical lifting tool 20 of the present invention alone does not alter the displacement of the posterior abdominal wall PAW and only lifts the central portion of the anterior abdominal wall AAW. FIG. 3 illustrates the use of the invention of FIG. 2 in combination with the prior art carbon dioxide inflation of FIG. 1. The admission of pressurized gas into the abdominal space AS results in gas pressure (illustrated by the phantom lines A in FIG. 3) acting against both the anterior abdominal wall AAW (including its lateral sides RLS, LLS) as well as the posterior abdominal wall PAW. This gas pressure augments the formation of the enlarged abdominal space resulting from the tool 20 acting alone. This augmentation is illustrated in FIG. 3 by the solid lines representing the positioning of the posterior abdominal wall PAW and lateral sides LLS, RLS in solid lines compared to phantom lines illustrating the positioning of the surfaces in FIG. 2. As an alternative to admitting the carbon dioxide through a lateral side, the carbon dioxide can be admitted through the lumen 32 illustrated by the phantom line 38' in FIG. 3 representing a conduit from the carbon dioxide source 10 to a proximal end of the lumen 32a in lieu of the conduit 38.

The invention of this patent application finds utility in virtually every kind of laparoscopic procedure involving entry into the abdominal cavity, or surgery at or on the anterior and posterior abdominal walls. This includes a wide variety of gynecologic laparoscopic procedures, from minor diagnostic procedures to surgery with minimal intra-abdominal surgery, such as a tubal ligation, through major surgical
procedures such as a hysterectomy. Diagnostic procedures include procedures to assess the pelvis for acute or chronic pain, ectopic pregnancy, endometriosis, adnexal torsion, etc. Dissection of adhesions arising from prior surgeries may be done laparoscopically. Ovarian cystectomy, oophorectomy and myomectomy are other laparoscopic procedures that may advantageously employ this invention. Fertility or sterilization reversal is effectively done laparoscopically, and takes advantage of the methods and device of this invention.

Laparoscopic procedures, and use of the invention of this application, are not limited to gynecologic procedures, however. Laparoscopy finds application generally in the biopsy, treatment and removal of tumors anywhere in the abdominal cavity. Other surgical procedures that are conveniently effected through laparoscopic techniques include gall bladder treatment and gall stone crushing or removal, liver biopsy, dissection and treatment and in general, surgery occurring anywhere in the abdominal cavity or on the walls thereof. This would include forget surgical procedures, assessment and surgery on the small bowel, colon and appendix, endocrine surgery and urologic procedures. A wide variety of procedures, many of which involve entry into the abdominal cavity, can make use of the apparatus and methods claimed herein, and are described in more detail in a wide variety of sources, including the website http://www.laparoscopy.com.

As noted, central lumen 32 of the device can be used for the admission of CO₂ from a source, or other fluid to help separate the anterior and posterior abdominal walls. Many laparoscopic surgical procedures require the admission of various other tools and devices into the abdominal cavity. Thus, frequently, a light source, and optical imaging devices such as an optical fiber-linked camera or similar device is used. Such devices are typically of small diameter, and can be passed through open
lumen 32 of catheter body 26. Such devices are connected to an illumination source, computer imaging processor, or other similar devices, which are readily substituted as elements passing through open lumen 32, as shown in Figure 8 as reference character 52.

Other devices can also be passed through lumen 32. Where the target of the procedure is readily accessible, biopsy tools, pinpoint cutting devices for the removal of tumors and other tissues, and similar devices can be passed through lumen 32. In some surgical procedures, at critical moments, or for purposes of clear viewing, it may be valuable to be able to clear away tissue that obstructs vision, fluid, etc. Under such circumstances, element 52 may be an inflatable bag at the distal terminus of the lumen 32. The bag may be deployed with a conduit as element 52, within the lumen, where the conduit can pass fluid to inflate the bag. In another embodiment, the inflatable bag, shown in partially inflated condition by phantom lines in Figure 8 as 54, the bag 54 can be sealed to, and stored within, central lumen 32, and inflated directly through the central lumen. When inflated, material at the end of the device 20 will be moved away until the pressure of inflation is released. Another device that may be inserted is a scintillation counter or similar device to detect local concentrations of radioactive tracer, such as when an attempt to localize tumors or lymph nodes for removal is required.

In other procedures, it is sometimes necessary to introduce dyes or liquid active agents of some type into the abdominal cavity. In others, lavage of the interior cavity is required. Some of these procedures require the fluid introduced be withdrawn from the abdominal cavity. In general, the device, generally 20, can be used to introduce fluids of this type (either gaseous or liquid). Many times, if the device of the invention is comprised of two parts, a stiff outer sheath and a relatively
flexible, thin walled catheter or similar collapsible tube, the tube will lack sufficient strength to support suction to withdraw the fluid. Accordingly, fluid may be introduced through central lumen 32, but to withdraw fluid through the same entry, the device must be adapted to provide a fairly stiff wall to resist collapse.

In the examples provided below, use of the well-known Foley brand catheter is described. There is no specific limitation on the type or brand of catheter or other tubular device to be used. Indeed, the tubular construction of the device illustrated in the drawings is just one alternative structure for the device. While an inflation lumen 34 of some type is required, to expand the inflatable article 30, where no additional device or agent is to be introduced through central lumen 30, the article need not be hollow. It should be noted, however, that the central force that needs to be taken into account when preparing the device is the resistance to lifting to be exerted by the anterior abdominal wall on the inflatable member, on application of a lifting force.

The present invention has been used in a prototype embodiment as described in Stany, et al, "Laparoscopic Exposure in Obese High-Risk Patients with Mechanical Displacement of the Abdominal Wall", Obstetrics and Gynecology, Vol. 103, No. 2 pages 383-386 (February 2004) incorporated herein by reference as those set forth in full.) That paper describes the use of a mechanical retractor combined with a 14 French (14F) Foley catheter to lift the anterior abdominal wall during advanced laparoscopy. The technique described in that paper and the clinical phase reports are as follows. The prototype was used to lift the anterior abdominal wall during advanced laparoscopy. This supplemental technique allowed standard laparoscopy equipment to be utilized in conjunction with a low-pressure pneumoperitoneum on patients at risk of pulmonary compromise, including those with morbid obesity.
The patients were placed in a low lithotomy position for the duration of the case. The foot of the operating table was dropped to a 45-degree angle. A standard reticulating Clark Socket (Birkova Products, Gothenburg NE) was used to secure a Martin's Arm Operative Retractor® (Marina Medical, Hollywood, FL) to the side rail of the angled foot of the table (Figure 1). The retractor was positioned between the patient's legs, and its joints/arms extended so that the end of the device was above the patient's pubic symphysis (Figure 2). Access to the intraperitoneal cavity was achieved and a pneumoperitoneum obtained in a standard fashion. A five-millimeter port was inserted in the midline approximately midway between the pubic symphysis and the umbilicus. A 14F latex Foley catheter with a 5-cc bulb was inserted through the port. A standard five-millimeter valved-port allowed passage the catheter without loss of the pneumoperitoneum. Approximately 7-10cc of normal saline was used to over-inflate the Foley bulb. The port was then retracted back along the catheter. The catheter was then secured into the Martin's arm. During laparoscopic visualization, the Martin's Arm Retractor was elevated so that the abdominal wall was lifted via the Foley catheter and exposure optimized. The catheter proved strong enough to support the abdominal wall without breaking. Enough mechanical lift was used to elevate the abdomen, but not so much that the catheter balloon pulled through the incision. The Martin's Arm Retractor was then secured in this position and maintained the lift on the anterior abdominal wall (Figure 3). The pneumoperitoneum was maintained with constant upward pressure of the Foley balloon acting as a seal over the incision created by the port. The laparoscopic surgery was performed in the usual manner and the Foley removed at the end of the case. The ports were closed in a standard fashion. The following section describes three separate cases in which this technique was employed.
Case 1

A 45 year-old multiparous female with a history of a previous abdominal hysterectomy for benign indications was referred for evaluation of symptomatic complex adnexal masses. Physical exam was significant for a BMI of 42 kg/m² (Holub Z, Jabor A, Kliment L, Fischlova D, Wagnerova M: Laparoscopic hysterectomy in obese women: a clinical prospective study. Eur J Obstet Gynecol Reprod Biol 2001;98:77-82.), left lower quadrant tenderness on bimanual examination, but an otherwise normal pelvic exam. Transvaginal ultrasonography identified bilateral complex 3 cm adnexal cysts.

A pneumoperitoneum was created with an open entry technique and insertion of a Hasson trocar. Using the aforementioned operative technique, the pneumoperitoneum required to maintain optimal operative visualization decreased to 10 - 11 mmHg after the mechanical lift was utilized. Before its use, intraperitoneal pressures of 15 - 17 mmHg yielded adequate visualization. Peak airway pressures remained stable throughout the entire case at 27 - 29 cm H₂O. Even in steep Trendelenberg, her end-tidal CO₂ measurements remained stable with no evidence of CO₂ retention. Intraoperative findings were significant for extensive pelvic adhesions and a 3 x 3 cm left hydrosalpinx. The right ovary was normal. The total operative time was two and one half hours.

Case 2

A 50 year-old multiparous female was referred for evaluation of a complex left ovarian cyst. She reported chronic pelvic pain. Her past medical history was significant for morbid obesity and spontaneous pneumothoraces that were treated with
thoracostomies and, eventually, a lobectomy. Physical exam was significant for a BMI of 45 kg/m (Holub Z, Jabor A, Kliment L, Fischlova D, Wagnerova M: Laparoscopic hysterectomy in obese women: a clinical prospective study. Eur J Obstet Gynecol Reprod Biol 2001;98:77-82.). The pelvic exam was limited by the patient's body habitus and no masses were palpated. Transvaginal ultrasonography showed a 3 cm complex left adnexal cyst with calcifications.

A pneumoperitoneum was created after direct insertion of a bladeless trocar under direct visualization with the laparoscope. Using the aforementioned operative technique, the intraperitoneal pressure that was required to maintain optimal operative visualization decreased to 8 - 10 mmHg with the mechanical lift. Before the lift, intraperitoneal pressures of 18 - 20 mmHg were required for adequate visualization. Peak airway pressures dropped from 27 to 23 mmHg after the application of the mechanical lift. With the lift, end-tidal CO\textsubscript{2} measurements remained stable with no evidence of retention, even in steep Trendelenberg. Intraoperative findings were remarkable for a 3 cm mature teratoma of the left ovary and a paratubal cyst. The total operative time was 45 minutes.

Case 3

The patient underwent a laparoscopic supravcervical hysterectomy, bilateral salpingo-oophorectomy, and lysis of adhesions. A pneumoperitoneum was created after direct insertion of a bladeless trocar under direct visualization with the laparoscope. Initially, incremental increases in intraperitoneal pressure to 20 mmHg were required to optimize pelvic exposure. This was associated with a peak airway pressure of 30 mmHg. With these parameters, though, the patient was only able to achieve an oxygen saturation of 89%. Once the Foley Lap-Lift was in place the intraperitoneal pressure dropped to 12 mmHg and the peak airway pressure went to the low 20's mmHg and the oxygen saturation improved to 99%. The case was completed laparoscopically. The total operative time was two and one half hours and included laparoscopic morcellation of the uterus.

These cases demonstrate the utilization of the Foley Lap-Lift, a simple technique of mechanical retraction of the anterior abdominal wall to augment the traditional pneumoperitoneum during laparoscopy. This technique decreased the intraperitoneal pressure required for the procedure while maintaining optimal visualization. The positive impact on these patients' ventilation was also evident in terms of decreased CO₂ retention and decreased or stable peak airway pressures that allowed these cases to be completed laparoscopically. Because of the concern for secondary pulmonary compromise associated with intraperitoneal pressures during her planned laparoscopic procedure, this novel technique was conceptualized for the first patient, but the true advantage was more evident in the second and third patients. The second patient was at significant risk for pulmonary compromise with her history. The third patient experienced a significant improvement in her respiratory parameters after the Foley Lap-Lift was placed. While traditionally a BMI near 35 kg/m² (Holub Z, Jabor A, Kliment L, Fischlova D, Wagnerova M: Laparoscopic hysterectomy in...
obese women: a clinical prospective study. Eur J Obstet Gynecol Reprod Biol 2001;98:77-82.) or greater has been used to define obesity, the surgeon's clinical judgment might identify overweight, but non-obese, patients who might benefit from this technique based on other comorbidities.

While the minimally invasive nature of operative laparoscopy makes it preferable over open procedures in general, patients with cardiopulmonary concerns or morbid obesity may still be at a high-risk for perioperative complications compounded by the pneumoperitoneum. Frequently, these cases need to be converted to a laparotomy because of CO2 retention or other pulmonary complications directly related to their pneumoperitoneum and Trendelenberg position. The mechanical displacement of the anterior abdominal wall using the Foley Lap-Lift technique can be utilized to decrease the intraperitoneal pressure needed during laparoscopy, while maintaining optimal visualization and potentially spare these patients a laparotomy.

For the foregoing detailed description of the present invention it has been shown how the objects of the present invention have been attained in the preferred embodiment. Among modifications that will occur to those of skill in the art is the substitution of alternate catheter or endoscopic devices, or alternative devices intended to 1) penetrate an abdominal wall and 2) of sufficient strength or rigidity to withstand the bending effect imposed by the forces acting on the expandable member when force is applied to draw the abdominal wall up away from the patient. Similarly, expandable elements other than balloons, per se, which may include spheroidal, elongated, or other shapes provided they are closed so as to expand in response to fluid passing through the inflation lumen and into the expandable member, may be envisioned. These modifications and equivalents of the disclosed concepts, such as
those which readily occur to one of ordinary skill in the art, are intended to be
included within the scope of the claims, which are appended hereto.
What is claimed is:

1. A tool for use in performing an abdominal laparoscopic procedure, said tool comprising:
   a distal end and a proximal end separated by a tool body;
   said distal end having an incision forming distal tip adapted for penetration of an anterior abdominal wall of a patient;
   an expandable member expandable between an expanded state and a retracted state and, in said retracted state, said expandable member sized to pass through an incision formed by said distal tip, and, in said expanded state, said expandable member sized to be blocked by said an anterior abdominal wall from passage through said incision;
   said expandable member disposed near said distal tip by a spacing selected for said expandable member to reside within a target abdominal space defined by said anterior abdominal wall and a posterior abdominal wall when said distal tip is within said space;
   said tool body having a length sufficient for said proximal end to reside external to said abdominal space when said expanded member resides within said abdominal space.

2. A tool according to claim 1 wherein said tool body has a rigidity sufficient to transmit a force from said proximal end to said distal tip in an amount sufficient to urge said distal tip to form said incision.
3. A tool according to claim 2 wherein said tool includes separable first and second components with said first component carrying said expandable member and said second member imparting said rigidity to said tool body.

4. A tool according to claim 1 wherein said tool includes separable first and second components with said first component carrying said expandable member and said second member carrying said distal tip.

5. A tool according to claim 1 wherein said expandable member is inflatable from retracted space to said expanded state upon admission of a fluid under pressure to said expandable member.

6. A tool according to claim 1 wherein said expandable member is structured when in said expanded state, to resist collapse in response to forces imparted by said anterior abdominal wall by an amount sufficient to expand said abdominal space.

7. A tool according to claim 6 wherein said force corresponds to a pressure within said abdominal space in excess of 15 mm Hg.

8. A tool according to claim 1 wherein said proximal end is adapted to be secured to a retainer fixed in position relative to said patient.
9. A tool according to claim 1 wherein said expandable member is adapted to seal against said anterior abdominal wall when pulled against said interior abdominal wall with a force sufficient to expand said abdominal space.

10. A tool according to claim 1 wherein said tool body includes a lumen accessible at said proximal end and extending through said tool body and out of said distal end.

11. A tool according to Claim 10, wherein said lumen is of sufficient size and character to pass a surgical instrument through said lumen from a position outside of said anterior abdominal wall of said patient to a position within an abdominal space of said patient.

12. A tool according to claim 11, wherein said surgical instrument is one of an optical fiber, a probe for recovering tissue, a blade for excising tissue, a radiation detector, an expandable object and a catheter for the admission of fluid.

13. A method for performing an abdominal laparoscopic procedure comprising:

   positioning a patient in a position for surgery;
   selecting a tool having:
   a distal end and a proximal end separated by a tool body;
   an expandable member at said distal end;
said expandable member expandable between an expanded state and a retracted state;
inserting said distal end through an anterior abdominal wall of said patient and into an abdominal space defined between said anterior abdominal wall and a posterior abdominal wall;
continuing said insertion until said expanded member resides within said abdominal space and said proximal end resides external to said space;
expanding said expandable member within said abdominal space;
drawing said proximal end away from said patient by an amount for said expandable member to urge said anterior abdominal wall away from said posterior abdominal wall to expand said abdominal space.

14. A method according to claim 13 wherein said distal end has an incision forming distal tip adapted for penetration of said anterior abdominal wall and form an incision therethrough.

15. A method according to claim 14 wherein said expandable member is sized, in said retracted state to pass through said incision and, in said expanded state, said expandable member is sized to be blocked by said an anterior abdominal wall from passage through said incision.

16. A method according to claim 13 wherein said expandable member is inflatable from retracted space to said expanded state upon admission of a fluid under pressure to said expandable member.
17. A method according to claim 13 further comprising admitting a gas under pressure to said abdominal space.

18. A method according to claim 13 further comprising fixing a position of said proximal end relative to said patient after said drawing step.

19. A method according to Claim 13, wherein said procedure is a laparoscopic surgery selected from the group consisting of gynecologic laparoscopic procedures, biopsy of a tumor, treatment of a tumor, removal of a tumor, gall bladder treatment, gall stone crushing, gall stone removal, liver biopsy, liver dissection, forgut surgical procedures, assessment of the small bowel, colon or appendix, surgery on the small bowel, colon or appendix, endocrine surgery and urologic procedures.

20. A method according to Claim 19, wherein said gynecologic laparoscopic procedure is selected from the group consisting of diagnostic procedures, tubal ligation, partial or full hysterectomy, dissection of adhesions arising from prior surgeries, ovarian cystectomy, oophorectomy, myomectomy, sterilization, and sterilization reversal.