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Original Article

Prospective Cohort Study Quantifying the Effect of the LevaLap 1.0 on the Distance between the Abdominal Wall and Intra-abdominal Viscera

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ABSTRACT **Study Objective:** More than 13 million laparoscopic procedures are performed globally every year. The LevaLap 1.0 device may facilitate safe abdominal access when using the Veress needle for initial abdominal insufflation during laparoscopic surgery. We undertook this study to test the hypothesis that use of the LevaLap 1.0 would increase the distance from the abdominal wall to underlying viscera and the retroperitoneum, including from major vessels.

Design: Prospective cohort study.

Setting: Referral center.

Patients: Eighteen patients scheduled to undergo an interventional radiology procedure under general anesthesia and muscle relaxation.

Interventions: Application of the LevaLap 1.0 device on the umbilicus and on Palmer's point, during computed tomography scanning.

Measurements: Distance from the abdominal wall to the underlying bowel and to retroperitoneal blood vessels and more distant intra-abdominal organs before and after vacuum was applied to the LevaLap 1.0.

Main Results: The device did not significantly increase the distance from the abdominal wall to the immediate underlying bowel. Alternatively, the LevaLap 1.0 created a significant increase in the distance between the abdominal wall at the access point and more distant intra-abdominal organs at the umbilicus and at Palmer's point (mean ± SD: +3.91 ± 2.32 cm, p = .001, and +3.41 ± 3.12 cm, p = .001, respectively). At the umbilicus, the device increased the distance between the abdominal wall and the anterior wall of the vena cava by +5.32 ± 1.22 cm (p = .004) or the anterior wall of the aorta by 5.49 ± 1.40 cm (p = .004). At Palmer's point, the device increased the distance between the anterior abdominal wall and the colon and/or small bowel by 2.13 ± 1.81 cm (p = .023). No adverse events were reported.

Conclusions: The LevaLap 1.0 increased the distance between abdominal wall and major retroperitoneal blood vessels by >5 cm, promoting safer access during Veress needle insufflation when performing laparoscopic surgery. Journal of Minimally Invasive Gynecology (2023) 00, 1−9. © 2023 AAGL. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/)

Keywords: Laparoscopy; Minimally invasive surgery; Veress needle; Abdominal access; Retroperitoneum; Laparoscopic safety; Device; Surgical complications

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More than 13 million laparoscopic procedures are performed globally every year, a volume that is expected to continue to increase as the benefits of minimally invasive surgery and robotic surgery over open procedures expand [1]. Although complication rates are overall low, up to 50% of all complications occur at the time of abdominal access or port placement [2]. During laparoscopic access, bowel injuries comprise almost 60% of all injuries and vascular injuries another 30% [3]. Access-related vascular and gastrointestinal injuries are the leading causes of fatalities after laparoscopic surgery [4]. Although some surgeons have advocated open access techniques as a way to reduce complications [5] and although these may be of value in patients known to have significant intraabdominal adhesions, in general, no significant differences in overall complication rates have been found for closed compared with open techniques for primary abdominal insufflation [6−8].

The rate of abdominal access-related complications is likely to continue to rise. This increase may, in part, be driven by an increase in the number of less experienced surgeons, despite the fact that the total volume of surgical procedures will actually increase [9,10]. For example, a national retrospective cohort study in The Netherlands observed that the broad implementation of advanced minimally invasive surgery procedures resulted in an increasing number of these procedures with increasing hospital volumes. However, a disproportionate rise in the number of gynecologists performing these procedures was observed, with per surgeon volumes remaining low and even decreasing for some procedures [9]. Other nations have also observed that although the number of laparoscopic surgeries has increased, the number of cases on a per surgeon basis decreased [10].

In addition, the number of female laparoscopic surgeons has increased commensurate with the number of women in the surgical fields [11]. However, although complications rates do not seem to vary significantly by surgeon gender when data are adjusted for volume and others [11,12], we should recognize that the growing number of female surgeons are generally at a disadvantage when it comes to abdominal access at laparoscopy. They are generally smaller and slighter in build [13], perform less surgeries on a per surgeon basis [10,11], and require greater activation of the upper body muscles [13] to gain laparoscopic access and have smaller hands, which leads many to experience more difficulties using laparoscopic instruments, including insertion trocars [14]. Consequently, there is a pressing need to develop approaches and technologies that will ease and facilitate abdominal access for laparoscopic surgery, potentially reducing the risk of laparoscopic access complications.

Core Access Surgical Technologies has developed a device, the LevaLap 1.0, that facilitates abdominal access when using the Veress needle for initial abdominal insufflation for laparoscopic surgery (Fig. 1). The device is a sterile clear plastic bell with a vacuum port that connects to a standard operating room (OR) vacuum system and an injection septum that, when placed over the surgical entry site, facilitates the placement of the Veress insufflation needle by raising the abdominal wall using standard OR wall suction. After placing the LevaLap 1.0 on the patient's abdomen, vacuum is applied through the vacuum port and the negative pressure lifts the patient's abdominal wall into the curve of the bell chamber. The Veress needle is then placed directly into the abdomen through the "injection septum." As the device brings the anterior abdominal wall closer to the cup of the device, a normal length Veress needle is used. The soft material of the "injection septum" absorbs and distributes needle pressure, allows needle puncture without leakage of the negative pressure, and permits 150-degree angulation of the needle during placement. After appropriate intraabdominal placement of the Veress needle is verified by the usual safety measures [15], the abdomen is insufflated using carbon dioxide. Once abdominal distention is complete, the Veress needle is retracted, LevaLap 1.0 suction is released, and the device is withdrawn from the operating field, leaving the abdominal region ready for surgery without significant marks on the abdominal skin.

Fig. 1

The LevaLap 1.0 (Core Access Surgical Technologies, Inc., Atlanta, GA, USA).

The LevaLap 1.0 provides a stable abdominal wall for insertion without the need to rely on variable surgeon upper body and hand strength and/or the use of potentially disfiguring towel clamps and other grasping instruments and without the need for a second operator during surgical access. Furthermore, the LevaLap 1.0 enables a safer and more successful abdominal entry by facilitating access at the first attempt, given that repeated attempts increase the risk of complications [15]. Finally, the device increases surgeon's control, precision, and speed during Veress needle placement by standardizing laparoscopic access so that the operator experiences the same feel case after case.

We hypothesized that the LevaLap 1.0 would increase the distance of the abdominal wall from the retroperitoneum, including from major vessels. To test this hypothesis, we studied the impact of using the LevaLap 1.0 to raise the abdominal wall by computed tomography (CT) scan in patients scheduled to undergo an interventional radiology procedure under general anesthesia. We also determined the impact of access point selection (umbilicus vs Palmer's point) on the result.

Materials and Methods

Subjects

Patients undergoing interventional radiology procedures at the European Institute of Oncology in Milan, Italy, that required at least 2 CT scans under general anesthesia, with muscle relaxation and intubation, were contacted. Subjects were then consented and assessed by medical history for concomitant medication and/or medical device use, as well as of weight, height, body mass index (BMI), blood pressure, and heart rate. The physical examination included the detection of previous abdominal surgery and of confirmed symptomatic abdominal hernia and the evaluation of subcutaneous fat layer.

Inclusion criteria included:

- Male and female patients ≥18 years
- Female patients of childbearing potential must have a negative pregnancy test.
- Patients that in spite of COVID pandemic must undergo a radiological procedure
- Patients with a subcutaneous fat layer ≤8 centimeters
- Ability of the patient to comprehend the full nature and purpose of the confidence interval
- Consent to the confidence interval and willing to comply with all its procedures

Exclusion criteria included:

- Initial evaluation is abnormal
- Pregnancy or breastfeeding
- Previous abdominal surgery
- Patients with confirmed symptomatic abdominal hernia
- Patients in emergency situations
- BMI >39 kg/m^2

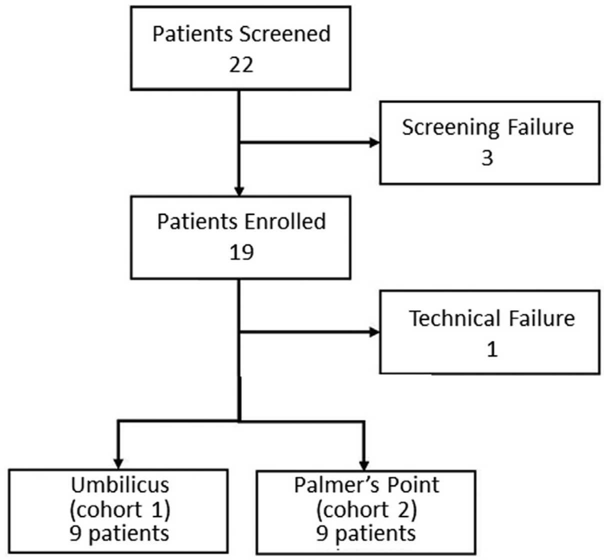
All subjects provided an informed consent and the study was approved by the review board for the Istituto Europeo di Oncologia (IEO).

Study Protocol

Patients recruited were undergoing an interventional radiology procedure under general anesthesia with a muscle relaxant, and intubation. Consequently, the planned intervention procedure mimics the standard preparation of patients who are candidates for the type of laparoscopic surgery in which the LevaLap would be used. The study was performed using the first and second planned CT scans (Aquilion ONE, Canon, Tustin, CA), before any contrast was injected. The basal scan served as the "baseline," whereas the second one CT image was performed immediately after positioning the LevaLap 1.0 over the access site being assessed (see below). We should note that the scans with the LevaLap 1.0 were performed as part of the planned scans and no extra CT scans were performed for this purpose.

Fig. 2

Study flowchart.



Patients were assigned in sequential order to cohort 1 (access position 1) or to cohort 2 (access position 2), as below:

- Access position 1 (cohort 1): The LevaLap 1.0 was positioned on the abdominal wall directly over the umbilicus.
- Access position 2 (cohort 2): The LevaLap 1.0 was positioned over the left upper quadrant of the abdominal wall, known as Palmer's point.

Once the interventional radiology procedure began and before the LevaLap 1.0 was deployed, a baseline CT scan, without contrast medium, was obtained with the patient in the normal supine position. After the initial images were completed and verified for quality, the LevaLap 1.0 was positioned over the assigned access site (see above). Wall suction was then connected to the LevaLap 1.0's suction port, and suction applied for a maximum of 3 minutes with a maximum negative pressure rated at 50 kPa (i.e., 400 mm

Table 1

Patient characteristics

Characteristic		All patients N = 18	Cohort 1 n = 9	Cohort 2 n = 9
Age, y/o	Mean (SD) min, max	65.2 (7.8) 52, 77	61.2 (6.2) 52, 71	69.2 (7.3) 57, 77
Gender	M/F	11/7	6/3	5/4
BMI	Mean (SD) min, max	27.7 (5.0) 20.0, 38.9	24.3 (2.8) 20.0, 27.8	31.0 (4.5) 26.1, 38.9
Fat layer during the first CT scan, cm	Mean (SD) min, max	2.45 (0.98) 1.0, 5.5	2.03 (0.53) 1.0, 2.9	2.87 (1.17) 1.6, 5.5

BMI = body mass index; CT = computed tomography; F= female; M = male; SD = standard deviation.

Fig. 3

Example CT scan denoting umbilicus before (left) and after (right) vacuum application with LevaLap 1.0. *Arrow* indicates ureteral stent positioned for renal thermal ablation. * = aorta/common iliac artery; + = small bowel; # = vena cava/common iliac vein. CT = computed tomography.

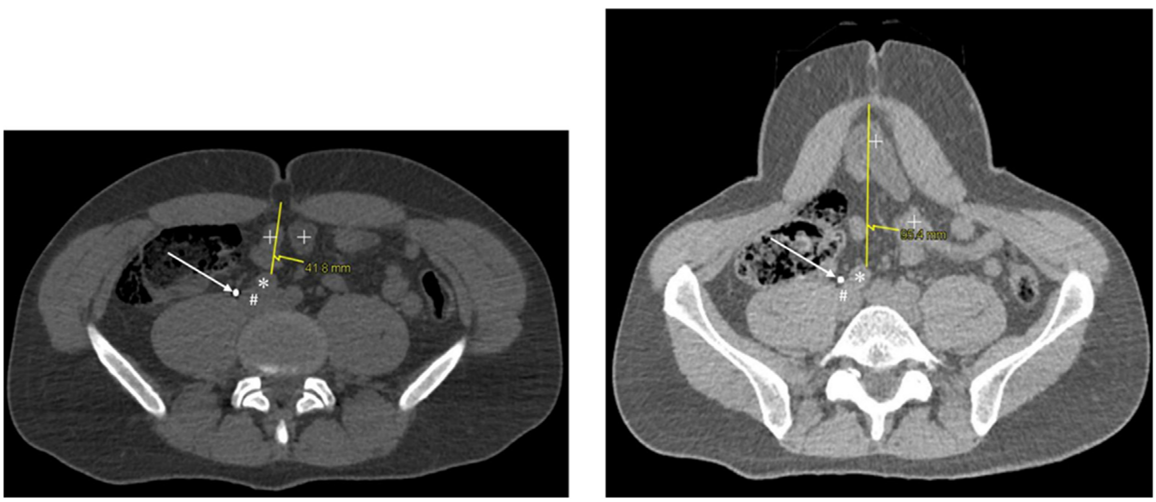


Fig. 4

Example CT scan denoting Palmer's point before (left) and after (right) vacuum application with LevaLap 1.0. *Arrow* indicates marker used to identify Palmer's point. *Arrow* heads indicate renal cysts. * = aorta/common iliac artery; + = small bowel; # = vena cava/common iliac vein; @ = kidney. CT = computed tomography.

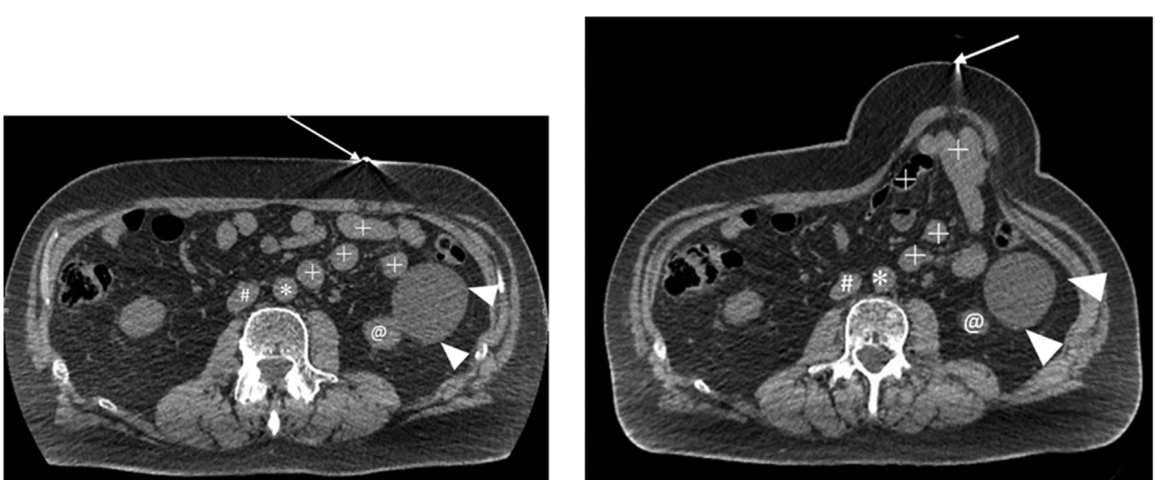


Table 2

Change in distance from the access point's anterior surface to the most proximate intra-abdominal viscera

Population	N	Axial plane (cm)				Sagittal plane (cm)			
		Before LevaLap 1.0 Mean (SD) min, max	After LevaLap 1.0 Mean (SD) min, max	Δ Mean (SD) min, max	p*	Before LevaLap 1.0 Mean (SD) min, max	After LevaLap 1.0 Mean (SD) min, max	Δ Mean (SD) min, max	p*
All patients	18	1.75 (1.52) 0.20, 6.10	1.93 (1.72) 0.20, 5.20	0.18 (1.09) −0.90, 3.1	0.97	1.99 (2.08) 0.20, 8.01	1.95 (1.70) 0.20, 5.20	−0.04 (1.28) −3.10, 3.10	.59
Cohort 1 (umbilicus)†	9	1.76 (1.12) 0.78, 4.11	2.08 (1.57) 0.20, 4.50	0.32 (1.30) −0.85, 3.10	0.93	1.75 (1.09) 0.80, 4.02	2.12 (1.56) 0.22, 4.50	0.37 (1.27) −0.78, 3.10	.91
Cohort 2 (Palmer's point)‡	9	1.75 (1.92) 0.20, 6.10	1.78 (1.94) 0.20, 5.20	0.03 (0.87) −0.90, 1.41	1.00	2.24 (2.81) 0.20, 8.01	1.79 (1.92) 0.20, 5.20	−0.45 (1.22) −3.10, 1.33	.38

SD = standard deviation.

* Two-sided, paired samples Wilcoxon signed-rank test, testing the null hypothesis of no difference between before and after LevaLap 1.0 application.

† Cohort 1 (umbilicus): main underlying viscerum considered was the anterior intestinal wall.

‡ Cohort 2 (Palmer's point): main underlying viscerum considered before LevaLap 1.0 placement: 5 colon and 4 small bowel; after LevaLap 1.0 placement: 5 colon, 3 small bowel, and 1 stomach.

Hg or 530 mbar). With the LevaLap 1.0 in place, the planned second CT scan was taken and, after image acquisition, the scans again verified for quality. Suction was then discontinued, and the device removed from the imaging field. Adverse event (AE), serious AEs, serious adverse device-related event (SADEs), and unexpected SADE were recorded.

Study End Points

The following measurements were obtained:

1) Change in distance from the access point's anterior surface to the most proximate at-risk intra-abdominal structures: the change in the distance (in cm) from the anterior surface of the linea alba to the anterior intestinal wall, for cohort 1, and from the anterior muscle surface below Palmer's point to the main proximate underlying viscera, for cohort 2, was measured both in the axial and sagittal planes with LevaLap 1.0 in place and compared with the baseline CT scan, as defined below:

$$\Delta \text{axial AS1} = \text{LevaLap axial AS1} - \text{baseline axial AS1}$$

$$\Delta \text{sagittal AS1} = \text{LevaLap sagittal AS1} - \text{baseline sagittal AS1}$$

where AS = anatomic structure and AS1 = anterior intestinal wall for cohort 1 and the main underlying viscera for cohort 2.

2) Change in axial distance from the access point's anterior surface to more distant at-risk intra-abdominal structures: The change in the axial distance (in cm) from the anterior surface of the linea alba to the anterior wall of the vena cava and aorta, for cohort 1, and from the anterior muscle surface below Palmer's point to a second and a third distant underlying viscera, for cohort 2, was measured with the LevaLap 1.0 in place and compared with the baseline CT scan, as defined below:

$$\Delta \text{AS2} = \text{LevaLap AS2} - \text{baseline AS2}$$

$$\Delta \text{AS3} = \text{LevaLap AS3} - \text{baseline AS3}$$

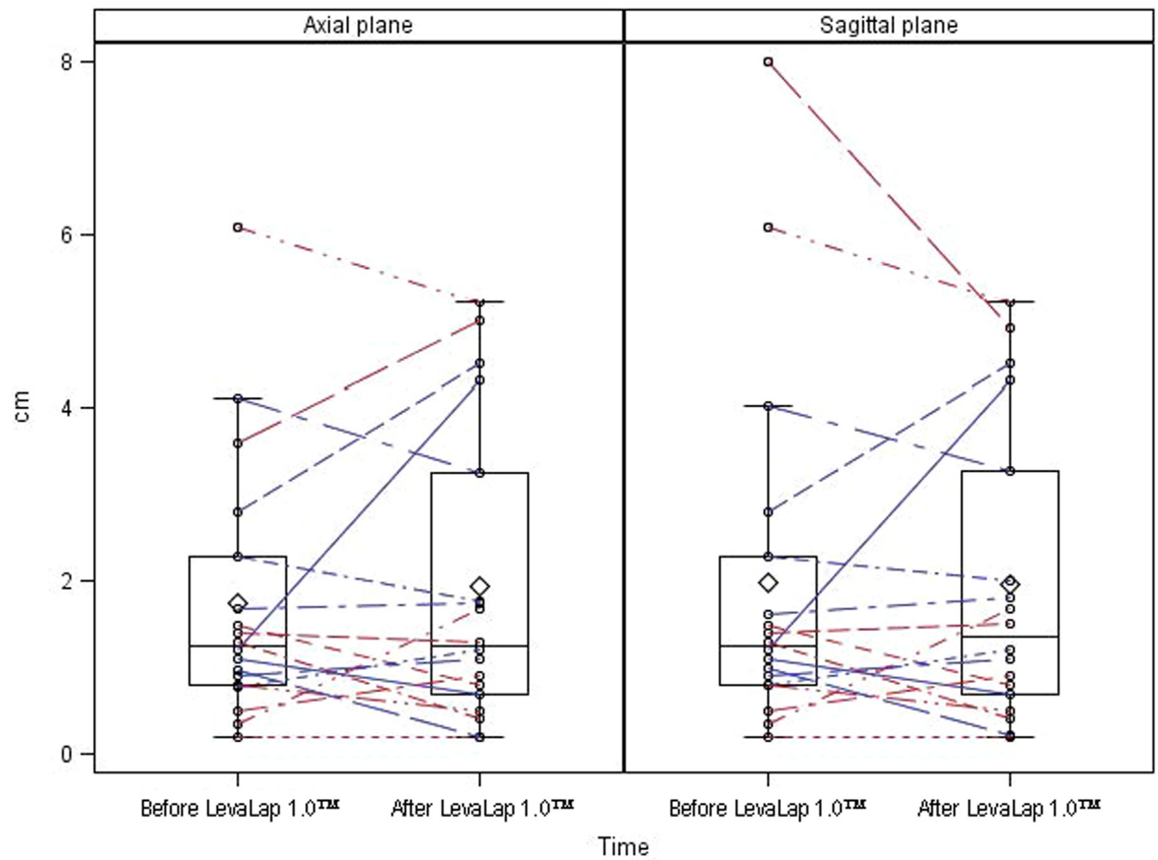
where AS2 = anterior wall of the vena cava for cohort 1 and a second distant underlying viscera for cohort 2 and AS3 = anterior wall of the aorta for cohort 1 and a third distant underlying viscera for cohort 2.

Statistical Analysis

The sample size was calculated based on an estimated effect size of one for both Δaxial AS1 and Δsagittal AS1. To detect such an effect with 95% power and a type I error of 2.5%, a sample size of 18 patients was deemed necessary. The paired samples Wilcoxon signed-rank test was used to test for changes in the measurements obtained with

Fig. 5

Change in distance from the access point's anterior surface to the most proximate intra-abdominal organs. Cohort 1 (umbilicus), blue lines; cohort 2 (Palmer's point), red lines.



LevaLap 1.0 in place and the measurements obtained from the baseline CT scan. For both the differences of primary interest (i.e., Δaxial AS1 and Δsagittal AS1) and of secondary interest (i.e., ΔAS2 and ΔAS3), to take into account the multiple comparisons being undertaken, a p-value of .025 was considered as statistically significant. These analyses were performed on both the whole patient population and stratified by cohort. We compared cohort 1 vs cohort 2 differences in Δaxial AS1, Δsagittal AS1, ΔAS2, and ΔAS3 using the 2 independent samples Wilcoxon rank-sum test.

Results

Subject Characteristics

The study flowchart is depicted in Fig. 2. Overall, 22 subjects were screened and 18 enrolled, 9 for cohort 1 and 9 for cohort 2. All enrolled subjects completed the study. Patients in cohort 2 were older (p = .034) and had higher BMI (p = .0047) but did not differ in the amount of subcutaneous fat layer measured during the first CT scan (Table 1).

Impact of LevaLap 1.0 on the Distance between the Abdominal Wall and Various Intra-abdominal Viscera

The mean negative pressure applied to lift the abdomen was 34.3 ± 5.61 kPa (range, 20−48 kPa). In one patient of cohort 1 (application at the umbilicus), the LevaLap 1.0 was not correctly applied because the umbilicus was not in axis plane of the LevaLap 1.0 apex. Nonetheless, the patient was included in the main analyses. Figs. 3 and 4 are example CT scans depicting the application of the LevaLap 1.0 at the umbilicus and at Palmer's point.

Considering more proximate viscera, at the umbilicus a slight, but not statistically significant, difference was observed from the access point's anterior surface to the most proximate anterior intestinal wall (mean difference in the axial plane, +0.32 ± 1.30 cm; in the sagittal plane, +0.37 ± 1.27 cm) (Table 2 and Fig. 5). At Palmer's point, no differences were also observed from the access point to the main proximate underlying viscera (+0.03 ± 0.87 cm in the axial plane and −0.45 ± 1.22 cm in the sagittal plane). For both the axial plane and sagittal planes, the effect of access point was negligible; that is, the mean difference between the 2 cohorts was 0.29 ± 0.52 cm (mean ± standard error) for the axial plane and 0.82 ± 0.59 cm for the sagittal plane.

Considering more distant viscera, at the umbilicus the LevaLap 1.0 increased the distance between the anterior abdominal wall to the anterior wall of the vena cava by +5.32 ± 1.22 cm (p = .004) and the anterior wall of the aorta by 5.49 ± 1.40 cm (p = .004) (Table 3 and Fig. 6). At Palmer's point, the device did not significantly increase the distance between the anterior muscle surface below Palmer's point to the first distant anatomic end point (colon or small bowel), although it significantly increased the distance between the anterior abdominal wall and second distant anatomic end point (colon or small bowel) by 2.13 ± 1.81 cm (p = .023). The mean difference between the 2 cohorts for the first distant end point was 3.83 ± 1.17 cm (mean ± standard error; p = .006), and for the second distant organ, it was 3.36 ± 0.78 cm (p = .002).

Safety Analysis

No AE, serious AE, SADE, and unexpected SADE events were reported during this study.

Discussion

Improving the ease of abdominal access during laparoscopy is an important step toward improving the safety of the procedure, given that >50% of all complications are associated with the initial abdominal entry. The Veress needle continues to be the most used method for initial insufflation today [16]. We have tested a novel device, the LevaLap 1.0, which facilitates safe and predictable abdominal access when using the Veress needle for initial abdominal insufflation during laparoscopic surgery by lifting the abdominal wall into a clear plastic bell using standard OR wall suction.

In this study, we tested the hypothesis that the use of the device would increase the distance of the abdominal wall from the retroperitoneum, including from major vessels. Not unexpectedly, considering that the intrabdominal pressure is normally negative with no true "free" or "empty" space [17], the device did not significantly increase the distance from the abdominal to the immediate underlying bowel. Alternatively, when considering more distant organs, the LevaLap 1.0 significantly increased the distance between the anterior abdominal wall and the anterior walls of the vena cava or the aorta by >5 cm. At Palmer's point, the device was able to increase the distance between the anterior abdominal wall at the left upper quadrant and the anterior wall of the colon and/or distant small bowel by >2 cm.

There have been other patented and patent-pending bell-shaped devices designed to assist in safer Veress needle entry for laparoscopic surgery. So far, only one device family has been commercialized for human use, the LapCap and LapCap2 (marketed by Aragon Surgical, Aesculap,

Table 3

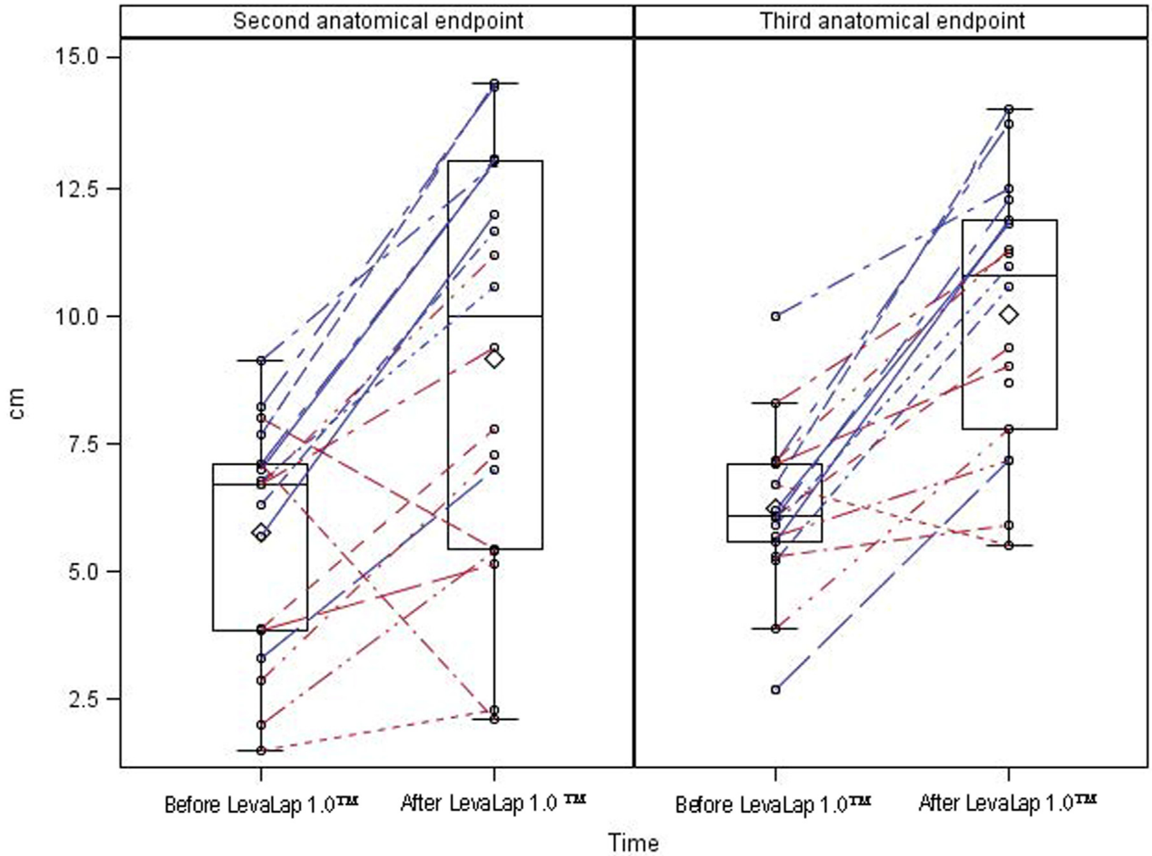
Change in axial distance from the access point's anterior surface to more distant intra-abdominal viscera

Population	N	Distance to first distant anatomic end point (cm)				Distance to second distant anatomic end point (cm)			
		Before LevaLap 1.0 Mean (SD) min, max	After LevaLap 1.0 Mean (SD) min, max	Δ Mean (SD) min, max	p*	Before LevaLap 1.0 Mean (SD) min, max	After LevaLap 1.0 Mean (SD) min, max	Δ Mean (SD) min, max	p*
All patients	18	5.77 (2.28) 1.50, 9.12	9.18 (4.00) 2.10, 14.50	3.41 (3.12) −5.00, 6.80	0.001	6.23 (1.62)† 2.70, 9.99	10.06 (2.58) 5.50, 14.00	3.91 (2.32) −1.20, 7.30	<.001
Cohort 1 (umbilicus)‡	9	6.81 (1.66) 3.30, 9.12	12.13 (2.29) 7.00, 14.50	5.32 (1.22) 3.70, 6.80	0.004	6.17 (1.91) 2.70, 9.99	11.66 (2.01) 7.20, 14.00	5.49 (1.40) 2.51, 7.30	.004
Cohort 2 (Palmer's point)§	9	4.74 (2.42) 1.50, 8.00	6.23 (3.03) 2.10, 11.20	1.49 (3.30) −5.00, 4.50	0.25	6.29 (1.35) 3.90, 8.30	8.45 (2.07) 5.50, 11.30	2.13 (1.81) −1.20, 4.10	.023

* Two-sided, paired samples Wilcoxon signed-rank test, testing the null hypothesis of no difference between before and after LevaLap 1.0 application.
† For one patient in cohort 2, the measurement to the second distant end point before LevaLap 1.0 was not evaluable.
‡ Cohort 1 (umbilicus): First distant anatomic end point: anterior wall of the vena cava; second distant anatomic end point: anterior wall of the aorta.
§ Cohort 2 (Palmer's point): First distant underlying viscerum considered before LevaLap 1.0 placement: 8 small bowel and 1 stomach; after LevaLap 1.0 placement: 2 colon and 7 small bowel. Second distant underlying viscerum considered before LevaLap 1.0 placement: 6 small bowel, 1 kidney, 1 pancreas, and 1 not evaluable; after LevaLap 1.0 placement: 2 colon and 7 small bowel.

Fig. 6

Change in axial distance from the access point's anterior surface to more distant intra-abdominal organs. Cohort 1 (umbilicus), blue lines; cohort 2 (Palmer's point), red lines.



Inc., and Life Care Medical Devices) and the Narvitas LapDome. Each company made slight improvements to the original LapCap design. There are limited published data regarding these devices [18−20]. These early devices successfully established an initial peritoneal additional safe space in only 89% to 92% of cases [18]. In addition, the insertion of the Veress needle was suboptimal in 2 ways: it was difficult for the surgeon to appropriately angle the needle, which caused the Veress needles to bend in some cases [19]. Additionally, the material at the injection port allowed the suction to leak through the injection site the injection site to pop through the dome for some patients [19]. Another disadvantage of the LapCap device was that the small area of tissue inside the cone could cause an artificially high pressure reading when the Veress needle was inserted, despite being in the correct placement [20]. Overall, clinicians found that these devices added little value to laparoscopic surgery [19]. Nonetheless, we should note that although the LapCap family is a predicate to the LevaLap 1.0 in terms of regulatory submission, the technical designs of both the LapCap and the LapDome differ from the device used in this study.

There is only one other study similar to the one presented. Daemen et al [21] assessed using CT scanning the effect of the LapDome (also known as the LapCap2) on the distance between the anterior abdominal wall at the umbilicus and the intrabdominal organs in 8 males and 4 females with a median age of 59.5 years. Consistent with our study, these investigators observed that the device tested minimally increased the median distance to the proximate intestines (by only 0.42 cm and 0.40 cm in the axial and sagittal plane, respectively). In turn, the median axial distances to the more distant vena cava and abdominal aorta increased to a much greater degree (by 3.23 cm and 3.16 cm, respectively, p = .002). Of note, the subjects in this study were not under anesthesia or muscle relaxants and likely the effect observed was less than it would be in the actual surgical environment.

This study has a number of strengths. The study allowed for paired analyses for device use at both the umbilicus and Palmer's point and used conditions similar to those encountered in the OR, including general anesthesia with intubation and muscle relaxation. The study also has limitations, including a small number of subjects and the fact that the study did not assess the placement of the Veress needle through the LevaLap 1.0. However, we should note that the introduction of the Veress needle into the abdomen would only result in the viscera proximate to the anterior abdominal wall to fall further way from the insertion site, further increasing the distances assessed.

In conclusion, our study results indicate that the LevaLap 1.0 device was successful in increasing the distance between the abdominal wall and the major retroperitoneal blood vessels by >5 cm. Through this mechanism, the LevaLap 1.0 device may promote a safer access to the abdomen during insufflation with Veress needle when performing laparoscopic surgery, although this remains to be demonstrated in subsequent studies.

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