

Experimental evaluation of an internal adjustable retractor in Laparo-Endoscopic Single Site surgery. (*White Paper*)

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Abstract

Introduction: As minimally invasive surgery migrates to a single port operative platform, the need for innovative retracting systems is becoming ever apparent. We evaluated an internal, adjustable retraction device for laparoendoscopic surgery, Versa lifter. *Methods:* Having received IRB approval we conducted a study using a porcine model. We performed 10 cholecystectomies and 10 gastric retraction procedures assessing multiple factors for the retraction device including ease of use, timing & damage to organs. *Results:* The VERSA LIFTER was very easy to deploy and retrieve with negligible peritoneal damage and overall a very intuitive system to use. Application and retrieval were completed in 3 minutes on average. *Conclusion:* The VERSA LIFTER is a very effective, efficient and intuitive system for adjustable internal organ retraction for Laparoendoscopic Single site surgery.

Keywords: Single-port, VERSA LIFTER®, Internal Retraction Device, Laparoendoscopic Single Site Surgery, dynamic suspension.

Introduction

In the past few years, minimally invasive surgery (MIS) has witnessed a new transition from laparoscopic surgery to Laparo-Endoscopic Single Site surgery (LESS) and Natural Orifice Transluminal Endoscopic Surgery (NOTES). These newer surgical methodologies were born out of the philosophy of reducing the size of abdominal incision's for patient's benefit. Although surgical access and instrumentation to perform the surgical process have undergone a sea of change, the caveats of surgery remain essentially the same. Surgeons can operate only if they can see what they are working on. Exposure is critical to both traditional and MIS, but it is even more crucial for MIS, since the surgeons forfeit their primary sense of touch and depend entirely on the visually based information of the surgical field to maintain the same degree of safety and surgical efficacy. In laparoscopic surgery, operator has to depend on the assistant's skills of exposure for getting optimal anatomical view and usually, one port is dedicated to introduce this retracting device. When new methods are being developed for reducing the number and size of abdominal incisions, it seems a step backwards to have one abdominal port only for the introduction of the laparoscopic retractors. The abdominal wall itself can be effectively utilized for organ retraction during laparoscopy and other methods of MIS. Few retracting systems for utilizing the abdominal wall for organ retraction have been published (1-5).

The present prospective trial evaluated the efficacy and safety of a novel totally internal retracting system that

provides adjustable retraction of intra-abdominal organs not only in LESS surgery in a swine model.

Material and methods

Study design

The study was designed as a prospective trial to evaluate the efficacy and safety of a new internal retracting device (VERSA LIFTER®, Surgical Perspective SAS, Strasbourg, FRANCE) in LESS surgery in a swine model. Two potential applications were studied. Cholecystectomy was chosen because it is one of the most commonly performed and studied LESS procedures. Stomach retraction and exposure were also evaluated to study the spectrum of applications of the VERSA LIFTER® for other more complex intra-abdominal surgeries, such as sleeve gastrectomy for morbid obesity

Experimental setup

A non-survival porcine model was utilized for this experiment. The animals were managed according to the Directive of the European Community Council. Ten medium sized pigs weighing 25 to 30 kg were utilized under general anesthesia. Anesthesia was induced with 1 mg/kg of propofol and 4 mg of pancuronium bromide. Endotracheal intubation was performed and anesthesia was maintained with isoflurane, 2%. At the end of the procedure, lethal doses of propofol and potassium chloride were successively administered.

Two laparoscopic surgeons, with different surgical experiences, performed LESS cholecystectomy in 5 animals each (total 10 procedures). Stomach retraction

and exposure were performed by both the surgeons in each animal (totaling 20 trials)..

Instrumentation

SILS port® (Covidien, Mansfield, MA, USA) with SILS® Hand instruments (“Clinch”, “Shears and Dissector” and “Hook”) were used for the procedures. Long (60 cm) 5 mm, 30° angulated laparoscope (KARL STORZ GmbH and Co. KG, Tuttlingen, Germany) was used for the surgical image. LigaSure™ 5 mm (Valleylab™ mode, Covidien, Norwalk, CT) was used for dissection of the omentum during stomach retroversion exercises.

The VERSA LIFTER® (Figure 1) is composed of 2 clips, linked by a thread. One clip is fixed on the targeted organ and the other one is fixed to the peritoneum. The thread linking the 2 clips can be shortened or lengthened, via a pulley system, to adjust organ retraction/suspension (length adjustable from 115 mm to 60mm tip to tip). The two clips are mounted on a laparoscopic applicator (figure 2), which fits into any laparoscopic trocar of diameter ≥ 8 mm. The clips are deployed from the delivery system into the abdominal cavity thanks to an ergonomic sliding trigger at the handle of the applicator. The applicator is used to add other VERSA LIFTER®, to change the retraction configuration, by adjusting the length of the connecting thread or changing the position of the clips, and to retrieve the clips.

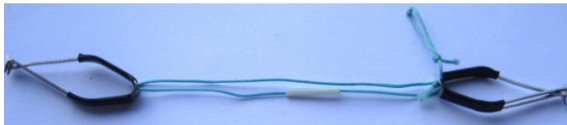


Figure 1: VERSA LIFTER in the deployed configuration



Figure 2: VERSA LIFTER delivery system

Procedures

Cholecystectomy

A SILS® port was introduced through a 2 cm infra-umbilical single incision and the gall bladder was localized. With the help of a Clinch SILS® Hand Instrument, the VERSA LIFTER® first clip was applied on the gall bladder fundus/body and then the second clip was applied on the left dome of the diaphragm. The thread was then adjusted to achieve adequate exposure of the Calot's Triangle (figure 3). Dissection was commenced with Hook SILS® Hand instrument to isolate the cystic duct and artery, which were then clipped with Endo Clip™ 5-mm clip Applier (Autosuture™, Covidien, USA). Position and length

of VERSA LIFTER® was modified during the procedure if needed. Gallbladder dissection was then completed with a hook and the device was removed.

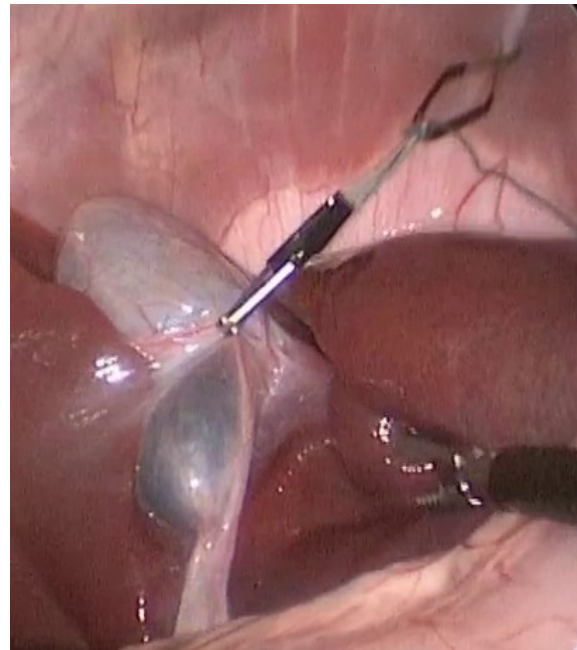


Figure 3 : Calot's triangle exposure

Retraction of the stomach

Through the SILS port, already in place for cholecystectomy, the stomach was localized and the omentum was dissected free from the greater curvature and gastro-epiploic arcade using a Ligasure™. Then, two VERSA LIFTERS® were attached between the greater curvature of stomach and the right dome of diaphragm. Both devices were then shortened one-by-one, to lift the stomach in order to expose the entire posterior surface of the stomach until the lesser curvature vessels were seen (figure 4). After 2 minutes of observation, the clips were retrieved.

Endpoints

Primary endpoint was to evaluate the efficacy and reliability of the VERSA LIFTER® in getting appropriate and stable exposure of the gallbladder and the stomach. Secondary endpoints were application and retrieval times, number of attempts to fix properly the clips, injuries to organs and to the peritoneum and overall ease of manipulation of the device.

An evaluation form was filled by the operators to assess efficacy, safety reliability, ergonomics and utility of the device, using a Likert scale type questionnaire (0: lower score – 5 highest score). Application time was defined as time from introduction of the applicator in the abdominal cavity to the time of adequate retraction was achieved.

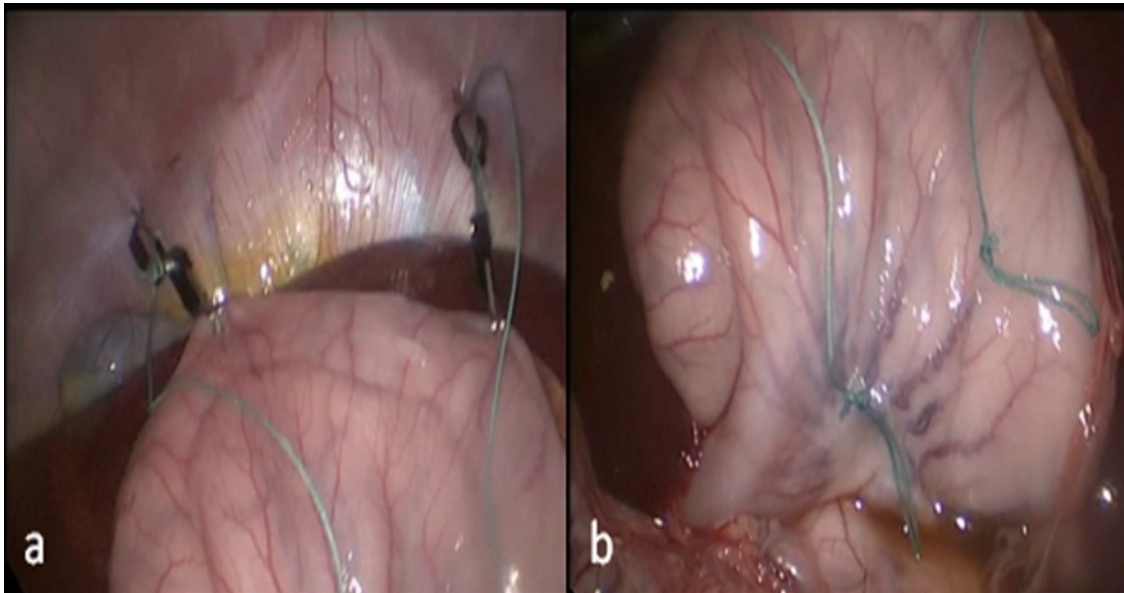


Figure 4 : A - VERSA LIFTER® lifting the stomach B - Exposure of the stomach

Retrieval time was defined as the time from introduction of applicator in the abdominal cavity to the time when both clips were retrieved and the applicator taken out from the surgical field. Times were plotted to obtain the learning curves for the two operators.

Results

In all the animals, the VERSA LIFTER® was smoothly introduced and manipulated through a 12 mm cannula inserted in the SILS® port system. During LESS cholecystectomy, the clips were successfully applied to the gallbladder wall and to the peritoneum following the shortening or the lengthening of the adjustable thread. Gallbladder-clipping was achieved in the first attempt while peritoneal clipping needed an average of 1.6 attempts. Efficient gallbladder retraction enabled surgeons to perform single port cholecystectomy in a mean time of 37 minutes (SD = ±16 minutes –table 1 and figure 5) in all the 10 swines without any complication or injury and without the need for any additional retracting device/system. Calot's triangle exposure achieved was adequate in all the cases and the cystic ducts were ligated always under good visual control. The average time needed for each step of application of the device is summarized in table 1. Application i.e. from introduction of the system in the abdominal cavity until clipping the peritoneum could be done in less than 2 minutes. Retrieval was also quick and easy requiring just over 2 minutes. The device provided retraction until the end of cholecystectomy procedure except in one procedure, in which the peritoneal clip slipped near the end of the procedure. Cholecystectomies were completed without

causing any puncture of the thin walled swine gallbladder by the clips and without causing peritoneal damage.

	Mean time [min:s]	Standard deviation [min:s]
Total cholecystectomy duration	37:20	15:35:00
VERSA LIFTER® application	01:47	01:32
VERSA LIFTER® retrieval	02:31	01:47

Table 1 :Timings for Cholecystectomy

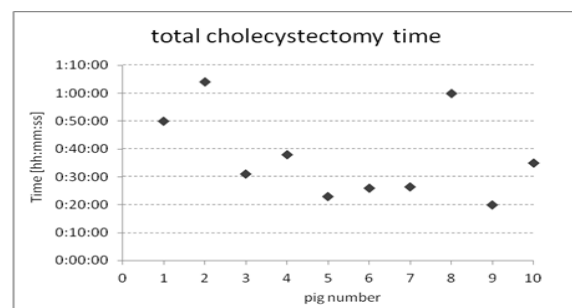


Figure 5: Total Cholecystectomy time details

Both operators rated their experience with VERSA LIFTER® as an 'easy-to-operate' device with good safety profile, giving excellent exposure of the Calot's triangle and without any interference with the operative process (Table 2). The device was rated high for its ergonomics and usefulness during a single port cholecystectomy procedure. The timings for application by each operator demonstrated a short learning curve with the plateau

achieved after three applications (Figure 6). In swine N°3, retrieval time has been exceptionally longer than others. This is explained by a minor malfunction in retrieval process with no incidence on safety and surgery duration.

Evaluation criteria	Score [Average (min-max)]
Ease of deployment (0=worst , 5= best)	4.9 (4-5)
Ease of retrieval (0=worst , 5= best)	4.3 (2-5)
Quality of Calot's triangle exposure (0=worst , 5= best)	4.6 (3-5)
Damage to gallbladder (0=none , 5= critical)	0.1 (0-1)
Damage to peritoneum (0=none , 5= critical)	0.4 (0-1)
Damage to surrounding organs (0=none , 5= critical)	0.1 (0-1)
Interference with operation process (0=none , 5= critical)	0 (0-0)
Ergonomics (overall) (0=worst , 5= best)	4.8 (4-5)
Usefulness (overall) (0=worst , 5= best)	4.6 (4-5)

Table 2 : Average scores given by the operators for various evaluation criteria of VERSA LIFTER®.

During stomach retraction, two VERSA LIFTERS® were successfully used in the setting of SILS® single port surgery for retracting the swine stomach by its greater curvature to the anterior abdominal wall for the access of posterior

stomach wall and lesser sac. Excellent exposure of the entire posterior stomach wall and stomach bed right next to the lesser curvature could be achieved in all the cases with the possibility and advantage of adjusting the length of thread to adjust exposure. The clip was atraumatic for the stomach wall (no serosal tear, no bleeding) and caused minimal damage to peritoneum attachment site. Stomach wall was clipped in almost always in the first attempt, while it took on an average of 1.35 - 1.5 attempts for each operator to clip the peritoneum. Deployment and retrieval of the device were quick each needing 1-2 minutes respectively (table 3), thus enabling usage of VERSA LIFTER® in approximately 3 minutes (figure 7) Figure 7 demonstrates the short learning curve and validates the time required for delivering the device.

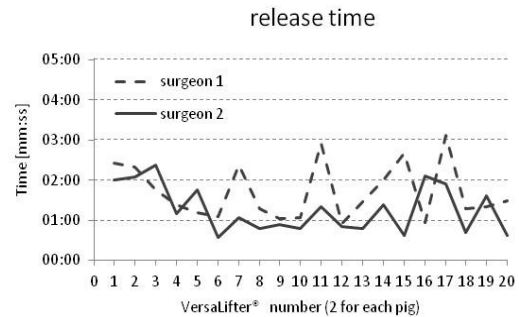


Figure 7: Timings for each clip application during stomach retroversion

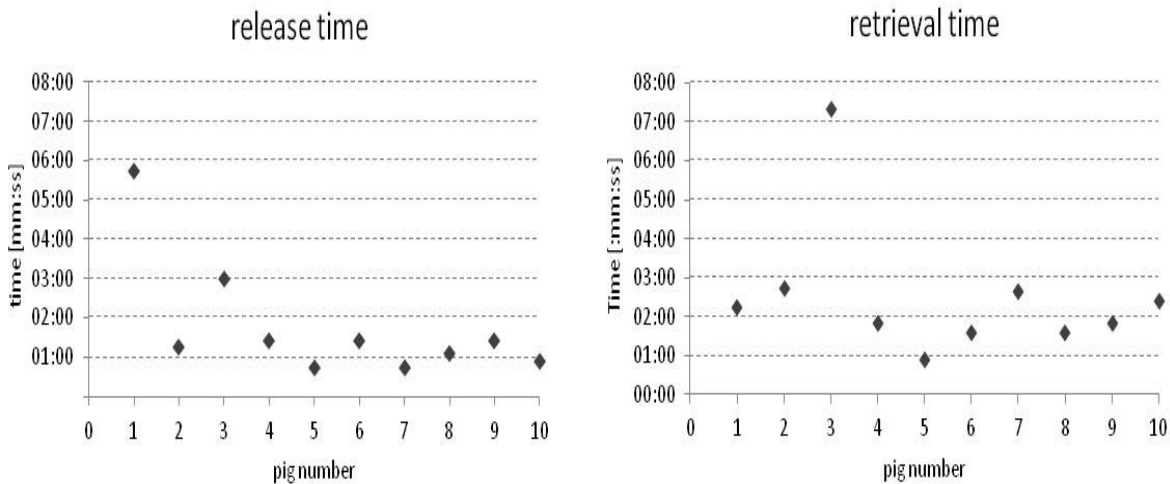


Figure 6: Learning curve plotted for VERSA LIFTER® use.

	Application of a [min]	VERSA LIFTER® surgeon 2	Retrieval of a VERSA LIFTER® [min]	surgeon 2
Mean time	01:36	01:17	01:48	01:57
standard deviation	00:38	00:37	00:26	00:34

Table 3: Timing for application and retrieval of VERSA LIFTER® during stomach retroversion.

Discussion

LESS surgery has greatly evolved in the last number of years. The proposed benefits of the technique are enhanced cosmetic result, less post-operative pain and reduced wound related morbidity. However, the technique is difficult to perform. Numbers of factors contribute to the steep learning curve. Collision of instruments inside the abdomen, collision of operating surgeon and assistant hands and instruments outside the abdomen, inadequate triangulation / exposure and retraction, reduced field of view (from obstructing instruments), in-line operating (as instruments inserted via a common channel) demand the need for specialized equipment. One of the greatest concerns of LESS is inadequate organ retraction. There have been numerous techniques and devices created to address this problem. The first of these methods described was the use of transabdominal stay sutures (1, 2). This is where a suture is passed through the anterior abdominal wall, then through an organ (e.g. gallbladder or appendix) to provide retraction. The drawback to this technique is the fixed retracting position and the risk of organ perforation with subsequent intraperitoneal biliary or faecal contamination.

A second method is the use of totally internal retractors delivered in the abdominal cavity through one of the LESS trocars. Endograb® (Virtual Ports, Misgav, Israel) (3) is an internally anchored retraction device with two grasping arms connected by a wire, where one grasping arm is attached to the viscus and the other to the anterior abdominal wall. The length of the connecting wire is fixed and adjustment of the exposure can only be achieved by repositioning the grasper. The same concept is proposed with the Cinch Organ Retractor System (Aesculap, Center Valley, USA). This device is composed of a bulldog clip, to grab the organ, and a hook to pinch the peritoneum. These two elements are linked with a non-adjustable silicone ring. To modify the retraction and organ exposure, the surgeon has to re-apply the anchoring position.

The practice of “conventional” laparoscopic cholecystectomy has shown that the position of the

grasper that retracts the gallbladder has frequently to be adjusted, to improve the exposure during the different steps of the procedure.

The particularity of the device (VERSA LIFTER®) tested in this study is the pulley system that allows for adjustable retraction. The length of the thread connecting the two clips facilitates a tension-free, secure, adequate and efficient placement of the clips, particularly on the parietal peritoneum. In the present study, the clip slipped from the peritoneum in only one cholecystectomy, at the end of the procedure. Retraction and suspension of the stomach was feasible in all attempts with 2 devices. Once the clips are applied, the length of the thread can easily be shortened or lengthened as required to get and adjust the retraction of the organ. Value of these features is promising but need to be confirmed in a clinical evaluation. Tests performed on human cadavers (not reported) showed that the strength of the clips was sufficient to retract efficiently the gallbladder. Translation to human use may require more devices, which can be delivered by the same applicator. In LESS sleeve gastrectomy, this type of gastric retraction/suspension could help in providing better exposure of the ideal line of division of the stomach.

Results of the study showed that the device was efficient, intuitive, ergonomic, easy to use, and that the spring-toothed design of the clips allows for a strong grip on the organs without any damage (to the stomach, gallbladder or peritoneum). No perforations of the gallbladder or injury to the stomach wall were observed. The concept of a laparoscopic internal retractor is not new but has been rejuvenated by the onset of LESS. Throughout the journey of minimization of minimal access surgery, these devices will certainly allow a reduction of the number of trocars used in more “conventional” laparoscopic procedures.

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Dhumane, Barry, Dallemagne, Perretta, Mutter, Marescaux

Experimental evaluation of an internal adjustable retractor in laparoendoscopic single site surgery

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Acknowledgement

This research program is supported by OSEO, Région Alsace, the European fund "FEDER" and the Communauté Urbaine de Strasbourg ("CUS"). This work was part funded by Royal College of Surgeons in Ireland Traveling Fellowship Grant SURGICAL PERSPECTIVE would like to thanks all IRCAD Team for their inputs and scientific feedbacks.