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Research Article

Use of a Novel Integrated Port Closure System - A Multi-Center Study

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Abstract

Background: The incidence of port site hernia (PSH) after laparoscopic surgery can reach up to 4%. The fascial closure at the port site can be challenging in some cases.

Methods: A multi-center, prospective, open label study to evaluate a new integrated port closure system (Gordian TroClose™ 1200 by Gordian Surgical™), is presented.

Results: Fifty patients were enrolled in the study. All enrolled patients underwent laparoscopic surgery, during which at least one TroClose1200 device was used per patient. Patients were followed for two and six weeks and for one year. No port PSH related to TroClose 1200 device was diagnosed at one year of follow-up. One PSH was diagnosed at a non-TroClose1200 trocar site. The surgeons were very satisfied with the new device's performance, with an average range of 4.8 - 5.0 out of 5.0 usability question being above 4.80 out of 5. No severe adverse events or device related adverse events were observed.

Conclusion: The TroClose 1200 is a simple, safe and friendly device that may reduce the incidence of port site hernia.

Keywords: *Port Site Hernia; Port Closure Device; Laparoscopic Surgery*

Abbreviations

PSH: Port Site Hernia; SAE: Severe Adverse Events; SD: Standard Deviation

Background

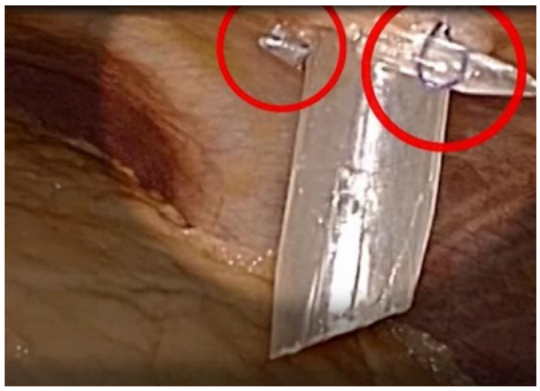
Fascial closure of port sites is a challenging and time-consuming part of laparoscopic surgery though it needs to be performed thoroughly in order to avoid PSH. PSH occurrence is related to patient characteristics such as obesity, type of surgery as well as port location and type of procedure. Factors relating to surgical technique include the port/trocar size, angle of insertion, widening of the port site defect due to retrieval of specimens and port site manipulation which is needed during long procedures. Traditional and hand suturing techniques both come with their own set of technical difficulties for surgeons and patient outcomes are not always consistent. In this article, we present the usage of the only integrated port closure system that incorporates a trocar and a closure device (Gordian TroClose™ 1200 by Gordian Surgical) which is a CE marked and FDA approved device. The system enables quick port site closure simply by tying two absorbable sutures connected to pre-deployed absorbable anchors.

Methods

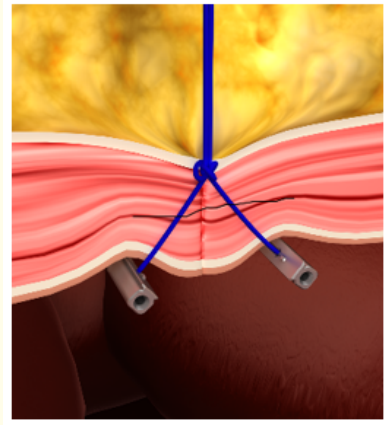
A prospective, single-arm, multi-center, international, open-label, non-randomized clinical study is presented in this article. The study was conducted with the approval of four ethics committees according to the regulations at each site (Helsinki Committee of the Baruch Padeh Medical Center, Poriya, Israel; Helsinki Committee of the Lady Davis Carmel Medical Center, Haifa, Israel; The Israeli Ministry of Health; and the Institutional Ethics Committee of the Kirloskar Hospital, Hyderabad, India). Patients aged 18 - 65 years who were scheduled for laparoscopic surgery with at least one 12 mm trocar and were willing to attend the follow up meetings were enrolled. Exclusion criteria were factors that affect wound healing including malnutrition (serum proteins < 5 g/dl or albumin below 3 g/dl), advanced cancer, and preoperative hemodynamic instability. Patients that were recruited to the study were operated using the TroClose1200 as well as other trocars which were routinely used in the hospital.

The TroClose1200 enables surgeons to use the device as a regular trocar as well as a closure system (Figure 1). After trocar insertion, the surgeon deploys two absorbable anchors that are attached to absorbable sutures (Figure 2). When the cannula is removed, the fascia was closed by simply tying the TroClose1200 sutures (Figure 2) which enables efficient closure of the port site.

Figure 1: *The TroClose1200 system (obturator assembled in the cannula). Left: the TroClose cannula's distal end with pre-loaded anchors and threads; Right: one anchor with its thread.*



A: TroClose1200 cannula and anchors in-situ in the abdominal wall, after deployment and removal of the obturator



B: TroClose1200 anchors in place just before port site closure, after cannula has been removed

C: Illustration of port site closure with anchors and tied sutures

Figure 2: *TroClose1200 application.*

Patients were followed-up two weeks, six weeks and one year after the procedure. In one medical center, the six weeks follow-up included ultrasound examination and at the other two medical centers ultrasound was performed at the one year follow-up meeting. The primary efficacy endpoint was defined as the ability of the TroClose1200 to serve as a working channel for laparoscopic surgical tools and to close the abdominal fascia at the end of the procedure which were assessed by a usability questionnaire. The secondary efficacy endpoint was defined as no signs of hernia observed during the physical examination at the two week and six week and one year follow-up. The primary safety endpoint was no serious adverse events of any kind and the secondary safety endpoint was no device related adverse events.

The data was analyzed using the SAS® 9.3 software package (SAS Institute, Cary, North Carolina). For descriptive statistics, sample size and absolute and relative frequencies are provided. For proportions of categorical variables and sample size, arithmetic mean, standard deviation, median, minimum and maximum for means of continuous variables were calculated.

For efficacy ease of use variables, the 95% lower and upper confidence intervals are presented along with the frequency of score = 5 out of 5. All analyses were performed on the PP analysis set.

Results

Fifty patients (14 males and 36 females) who underwent laparoscopic surgery were included in the study. The mean age was 40 years old (SD 15.73) and the mean body mass index (BMI) of all study patients was 39.21 (SD 9.20). Thirty-one patients were diagnosed with morbid obesity and were scheduled for bariatric laparoscopic surgery. The mean BMI of the morbidly obese patients was 42.74 (SD 6.86) and their mean weight was 118.71 kg (SD 24) (Table 1). Patients enrolled in the study were scheduled for laparoscopic procedures as detailed in table 2.

Criteria		
All patients (50)		
Gender	Male, N (%)	14 (28%)
	Female, N (%)	36 (72%)
Age (years)	Mean ± SD	40.00 ± 15.73
	median	38.0
	range	19 - 84
Height (cm)	Mean ± SD	165.33 ± 10.46
	median	164.0
	range	142 - 185
Weight (kg)	Mean ± SD	102.37 ± 30.60
	median	104.0
	range	52 - 192
BMI (kg/m^2)	Mean ± SD	39.21 ± 9.20
	median	41.40
	range	21.40 - 65.10
Bariatric patients data (31)		
Height (cm)	Mean ± SD	166.39 ± 9.29
	median	165.00
	range	150.00 - 185.00
Weight (kg)	Mean ± SD	118.71 ± 24.00
	median	118.00
	range	55.00 - 192.00
BMI (kg/m^2)	Mean ± SD	42.74 ± 6.86
	median	42.10
	range	21.40 - 65.10

Table 1: *Patient's data.*
**SD: Standard Deviation.*

Procedure	N
Sleeve gastrectomy	24
Cholecystectomy	9
Gastric bypass	7
Gynecological	4
Colorectal	3
Nissen fundoplication	2
Umbilical hernia	1

Table 2: *Types of procedures.*

**N: Number.*

All enrolled patients underwent laparoscopic surgery, during which at least one TroClose1200 device was used per patient. Thirty-two patients had three ports greater than or equal to 12 mm, four patients had two ports greater than or equal to 12 mm and only one patient had four ports greater than or equal to 12 mm. Twenty-three patients had one 12 mm port closed manually and four patients had two 12 mm ports closed manually. Five mm ports were not routinely sutured. Thirty-three patients had one port using the TroClose1200 device, 16 patients had two ports using the TroClose1200 device and one patient had three ports using the TroClose1200 device. Suturing was performed on ports of 12 mm and greater, ports that were widened due to tissue removal and ports located in the lower abdomen or in the midlines, all according to surgeon decision.

In 17 out of 19 cases in which tissue was extracted through a TroClose1200 port, the surgeons managed to close the port site with the previously deployed TroClose1200 closure system.

In three cases, the TroClose1200 was replaced successfully during the procedure with a 15 mm trocar. In these cases, the TroClose1200 cannula was removed patient and a 15 mm trocar was inserted into the existing port site without removing the anchors. At the end of the procedure, the 15 mm trocar was removed and the port site was closed using the TroClose1200 closure system.

Four cases of technical failure were reported: One minor gas leak, two incomplete closures following tissue extraction and one stop-cock failure.

No severe adverse event (SAE) of any kind were observed and no device related adverse events were reported. A list of procedure related and general adverse events is detailed in table 3.

	Type of Event	Number of Events	Patients (50)	Patients (%)
Procedure related adverse event	Incisional hernia	1	1	2
	Bleeding	1	1	2
	Other: epigastric pain, vomiting, abdominal pain, weakness, recurrent epigastric pain, dysphagia, abdominal wall pain (trocar site 5 mm) and suspected internal hernia	9	6	12
Blood and lymphatic system disorders	Iron deficiency anemia	1	1	2
Eye disorders	Blurred vision	1	1	2
Gastrointestinal disorders	Abdominal pain	7	5	10
	Abdominal pain upper	1	1	2
	Pancreatitis acute	1	1	2
General disorders and administration site conditions	Induration	1	1	2
	Pyrexia	1	1	2

Hepatobiliary disorders	Biliary colic	1	1	2
	Biliary cyst	1	1	2
Infections and infestations	Gastroenteritis	1	1	2
	Pneumonia	1	1	2
	Urinary tract infection	2	1	2
Injury, poisoning and procedural complications	Drain site complication	1	1	2
Medical device site induration	Medical device site induration	2	2	4
Musculoskeletal and connective tissue disorders	Back pain	2	2	4
	Flank pain	1	1	2
	Musculoskeletal pain	1	1	2
Nervous system disorders	Syncope	1	1	2
Surgical and medical procedures	Hysterectomy	1	1	2

Table 3: *Adverse events.*

**N: Number.*

The primary efficacy endpoint was defined as the ability of the TroClose1200 to serve as a working channel as well as the capability to close the abdominal fascia at the end of the procedure.

Surgeons were asked to evaluate the use of the trocar with a 1 to 5 score questionnaire. A score of 5 out of 5 was given in 46/50 patients for abdominal wall entry, 48/50 patients for deployment of the anchors, 41/50 patients for instrument use and replacement and in 47q50 patients for closure of the fascia (Table 4).

Ease of Use Question (Score 1 - 5)	No.	Mean	SD*	Median	Range	Percentage of 5/5 score [CI**]
Penetrating the abdominal wall	50	4.88	0.44	5.00	3.00 - 5.00	92.0% [80.8% - 97.8%]
Deployment of the anchors and sutures	50	4.96	0.20	5.00	4.00 - 5.00	96.0% [86.3% - 99.5%]
Instrument use and replacement	50	4.82	0.39	5.00	4.00 - 5.00	82.0% [68.6% - 91.4%]
Closure of the fascia	50	4.92	0.34	5.00	3.00 - 5.00	94.0% [83.5% - 98.7%]

Table 4: *Surgeon assessment of ease of use of the TroClose1200.*

**SD: Standard Deviation*

***: Confidence interval.*

Patients were examined for PSH during the follow up meeting at two and six weeks (attendance rate of 47/50 and 44/50 patients, respectively) as well as at the one-year follow-up (attendance rate of 40/50).

Thirty-four patients (68%) also had an ultrasound at the one year.

One PSH was diagnosed at a 12 mm regular trocar port site which according to the data was sutured manually during the procedure. No PSH was diagnosed in port sites created and closed with the TroClose1200 device.

Discussion

Port site closure is time consuming and sometimes challenging, but helpful in reducing PSH. PSH is underestimated outcome of laparoscopic surgery with greater importance in obese patients and can lead to troublesome complications.

The incidence of hernia after laparoscopic surgery ranges between 0.8 - 4.1% depending on follow-up period though it might be even lower for special procedures [3,5,6]. For example, an incidence of 0.17% of incisional hernias was reported for 3,560 gynecologic laparoscopies [4]. Analysis of 11,699 patients undergoing laparoscopic gastrointestinal procedures demonstrated a PSH incidence of 0.74% with a mean follow-up of 23.9 months [8]. The lowest incidence of PSH was for bariatric surgery with 0.57% in 2,644 patients with a mean follow-up of 67.4 months while the highest incidence was for laparoscopic colorectal surgery with an incidence of 1.47% in 477 patients with a mean follow-up of 71.5 months [8]. Another important factor is size of the port site with an incidence of 0.23% for 10-mm port site and 1.9% for 12-mm port site [10]. Our study demonstrated no hernia occurrence at TroClose1200 port site after one year follow-up. In in 17 out of 19 dilated port the TroClose1200 managed to close the port site successfully. Port dilatation was required for extraction of tissue, exchange of 15mm port or as for blind trocar insertion.

Among the factors relating to the patient characteristics, obesity is a risk factor for the development of PHS with an incidence of 6.3% for patients with a BMI greater than 30 [10]. In our study, 62% (31/50) of the recruited patients were morbidly obese with no PSH after one year follow-up, for TroClose1200 ports. A hernia was diagnosed in one case at the one year follow-up in a regular 12 mm port which was sutured manually (not a TroClose1200 port).

Our study has some limitations. First, the number of patients included in the study is small and 10 patients (20%) didn't complete the one year follow up. Also, the ultrasonic examination of the abdominal wall at one year was performed only in 68% of patients, so theoretically potentially PHS in this subgroup of patients could be missed [1,2,7,9,11].

Conclusion

The study results indicate that the TroClose1200 is a safe, simple, easy to use, and efficient closure system device that may reduce the incidence of PSH.

Declarations

The study was conducted with the approval of four ethics committees (IRB) according to the regulations at each site (Helsinki Committee of the Baruch Padeh Medical Center, Poriya, Israel; Helsinki Committee of the Lady Davis Carmel Medical Center, Haifa, Israel; The Israeli Ministry of Health; and the Institutional Ethics Committee of the Kirloskar Hospital, Hyderabad, India). Each patient signed the inform consent in order to participate in the study, as an essential requirement of the IRB.

The trial was registered on April 2016 at Clinical Trial.gov. Clinical trial identifier: NCT02746653.

All the data generated or analyzed during this study are included in this published article.

The study was funded by the company (Gordian surgical TM). The funding was used in order to pay the expenses of the Ultrasound examination and the clinical coordinator. None of the authors get paid or reimbursed by the company.

The study adheres to CONSORT guidelines and include a completed CONSORT checklist as an additional file.

All data generated or analyzed during this study are included in this published article [and its supplementary information files].

Drs. Qarawany Milad, Hagar Mizrahi, Surendra Ugale, Guy Pascal and David Hazzan have no conflicts of interest or financial ties to disclose.

Drs QM and HM wrote the manuscript, Dr GP organized, maintained the data and did the statistical analysis. Drs SU and DH elaborated the study design and reviewed the manuscript. All authors read and approved the final manuscript.

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