Madany closure: a novel technique for fascial closure in laparoscopic surgery

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Background
Laparoscopic surgery is now the accepted method of choice for practically all abdominal procedures. A number of trocar site closure techniques have been developed, but many of them are unaffordable and/or difficult to employ.
Patients and methods
The objective of this prospective interventional study is to assess the duration required to close the trocar site, the incidence of hemorrhage or other postoperative problems, and the safety and effectiveness of a novel fascial closure technique (the Madany closure). Patients who were eligible for laparoscopic cholecystectomy at the Aswan University Hospital's General Surgery Department were included.
Results
One hundred and thirty patients were included in our study. Most of the participants were females, representing 93.08% of patients. The mean age of participants was 40.07±10.02 years, and the median (interquartile range) total time for the complete closure of the port site was 83.5 s (44.75 s). After the follow-up period of 6 months, no patient developed a trocar-site hernia.
Conclusion
The Madany closure technique provides a safe, fast, and effective technique for the closure of laparoscopic port sites.

Keywords:
cholecystectomy, device, fascial closure, laparoscopy, port-site closure, port-site hernia, time for fascial closure, trocar site closure

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Introduction

Laparoscopic surgery has become the gold standard of care for surgical operations across various disciplines due to its ability to decrease perioperative complications, expedite recovery, and yield superior cosmetic outcomes [1].

It is now the accepted method of choice for practically all abdominal procedures. When American surgeon Ruddock initially proposed laparoscopic surgery in the early 1930s, he discussed how it was a better diagnostic technique than open surgery [2,3]. Professor MÏhe of Bħblingen performed the first laparoscopic procedure in 1985 [4].

Since that time, laparoscopic surgery's low rate of morbidity and death has led to its widespread acceptance. An increasing number of issues, including trocar-site hernias, have been linked to the growing use of laparoscopy in surgical procedures. Nevertheless, it requires tiny incisions to introduce trocars. At 1–3%, trocar-site hernias are rare but a cause of morbidity [5].

Since laparoscopic surgery was developed, additional technical challenges have emerged. One of them is the fascia closure at port sites, especially in cases where large trocars are used or if a port site has been dilated to extract an organ, such as the gallbladder. The current state of fascial closure is hindered by new technology, such as single-port laparoscopic surgery and the need for small cosmetic incisions. Since the first report of herniation at a trocar site following laparoscopy was reported, the risk of complications at the port site has been considerably decreased. Fascial closure at the port site is typically a tedious and challenging procedure that often involves larger skin incisions or blind suturing of the fascial defect (which carries the risk of an inadequate suture and intraperitoneal organ damage) [6].

The principle of laparoscopic surgery is to operate through ports, rendering a defect in the abdominal

wall. The operative procedure of this widely practiced laparoscopic surgery in modern medicine is not complete until the port sites 10 mm or more are closed with a fascial suture [7]. It is crucial to carefully close laparoscopic ports to reduce the risk of problems such as incisional hernias at the port site, bowel inclusion during port closures, and port-site infections [6,8–10]. An incisional hernia may result from inadequate suturing of the fascial defect, an infection, or a breakdown of the sutures [11]. The bowel's incorporation into the trocar-site closure was another observed problem [12].

As documented in the medical literature [6,13,14], many trocar-site closure techniques have been developed, but many need to be more affordable and/or easier to employ.

Various methods and tools have been created to offer quick and safe closure. Nevertheless, these instruments might only be available in some hospitals and surgical centers (e.g. third-world nations or distant places). Time and expense are also reduced when instrumentation is avoided. In addition to requiring extra equipment, many methods call for extra ports for intraabdominal visualization using a laparoscopic camera [15]. Hand-sutured closures do not require additional apparatus and are affordable and helpful [16].

This study was set to assess the safety, efficacy, and suitability of a newly developed technique of manual closure of trocar sites.

Patients and methods

Study design

The study complied with the most recent version of the Declaration of Helsinki and adopted the well-recognized GCP criteria. Furthermore, it was authorized by the Local Ethics Committee and complied with all applicable national rules and regulations. Under the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) Statement checklist, this study was planned as a single-group quasi-experimental investigation [17].

The study, approved by the institutional review board (IRB) (729/2/23), Faculty of Medicine, Aswan University, was conducted on patients who attended the general surgery outpatient clinic at Aswan University Hospital in February and April 2023. Before being included in the study, every participant who visited the center received a thorough explanation in Arabic regarding the procedure and its objective, and each participant signed an informed consent form.

The study covered all cases – male or female, 18 years of age or older – that come to the center and are qualified for cholecystectomy. However, every patient declined to participate, and individuals with mental impairments preventing them from undergoing the routine follow-up were excluded.

Every patient underwent a thorough history-taking process that covered their medical history, surgical history, and personal history (age, sex, and unique habits). After being admitted to the hospital, the patients were prepared to undergo the procedure.

Technique description

After finishing our laparoscopic maneuver inside the abdomen, we proceed with our technique for port-site fascial closure (the Madany closure).

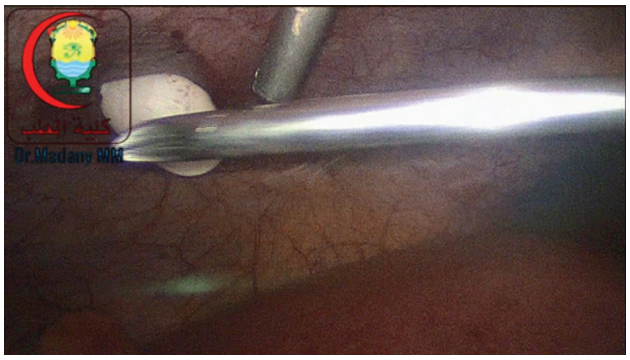
The Madany closure is performed in the following sequence:

(1) We get the laparoscopic needle holder (Fig. 1) from the inside of the abdomen to the outside through the port we intend to close (Fig. 2). Afterward, we get hold of the previously prepared 30 cm length Vicryl or PDS suture material 2 cm distal to the swaged end of the needle (Fig. 3). We used a 40 mm rounded needle.
(2) We pull it inside the abdominal cavity, keeping the free end of the thread outside clamped with forceps. The pneumoperitoneum is kept during this maneuver using the fingers of the surgeon or his assistant to seal the port. We grasp the needle at a suitable angle (Fig. 4) to close the port site (Figure 10Video 1).
(3) We perform single, or multiple intracorporeal continuous sutures (according to the size of the port) to the opposite edges of the port (Fig. 5) without performing a knot.

Figure 1

Only one instrument is used in Madany closure (laparoscopic needle holder).

Figure 2

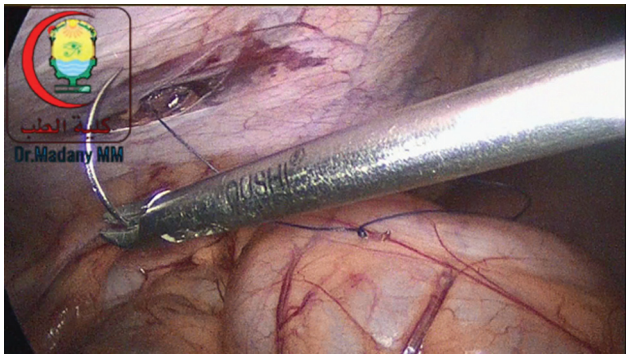


The laparoscopic needle holder is to be gotten from inside of the abdomen to the outside through the port intended to be closed.

Figure 3

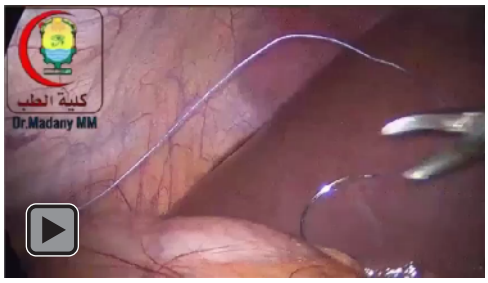
Get hold of the previously prepared 30 cm length Vicryl or PDS suture material 2 cm distal to the swaged end of the needle.

Figure 4



Grasp the needle at a suitable angle to close the port site.

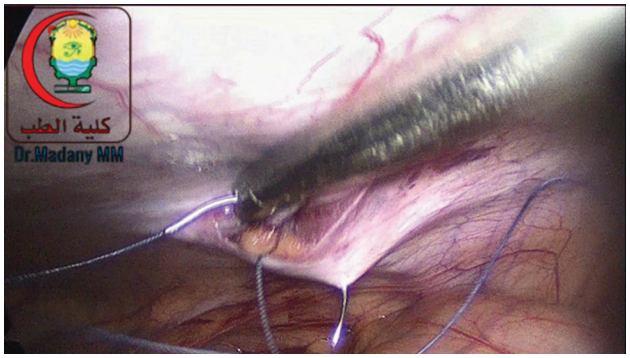
Video 1



Steps of Madany closure.

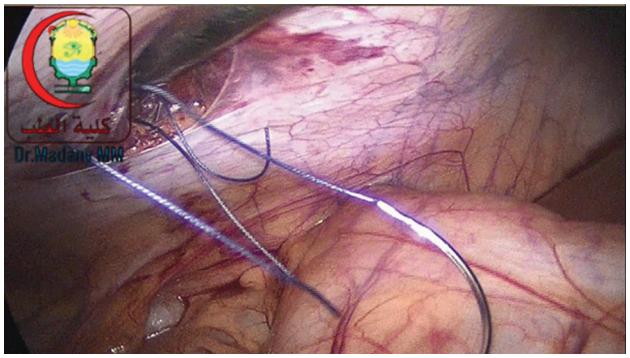
(4) We keep the sutured port loose to get the needle out through it. Using the needle holder, we grasp the thread 5 cm distal to the swaged end of the needle (Fig. 6), which enables the assistant to catch the thread to retrieve the needle outside the abdomen (Fig. 7). Afterward, we perform an extracorporeal surgical knot from the outside (Fig. 8). Finally, we cut the threads just above the knot (Fig. 9).

Figure 5



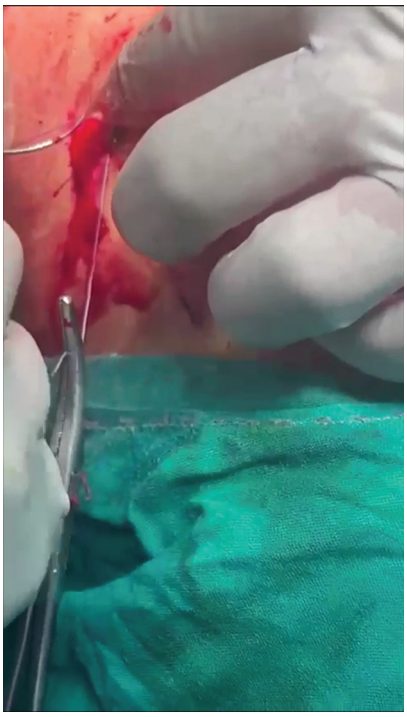
An intracorporeal suture is to be carried out to the opposite edges of the port.

Figure 6



Keep the sutured port loose to get the needle out through it. Using the needle holder, grasp the thread 5 cm distal to the swaged end of the needle.

Figure 7



An assistant is to catch the thread to retrieve the needle outside the abdomen.

Figure 8

An extracorporeal surgical knot is to be carried out from the outside.

Follow-up

All participants were followed up postoperatively for any emergent events related to the operation. Follow-up was made by seeing all the cases 1 day, 1 week, and 1 month after the surgery; then, a telephone call for all cases at months 3 and 6.

Objectives

This study's main goal is to assess the new method in terms of how long it takes for fascial closure. The surgical success, length of the procedure, complications (such as bleeding from the suture entry site or visceral injuries), postoperative discomfort [measured by visual analog scale (VAS) score], and complications (such as infection, seroma, hematoma, and port-site hernia) were the secondary outcome variables.

Statistical analysis

According to the study of Lasheen *et al.* [18], the average total time for fascial closure was 3.49 min. In the current study, with the aid of the Madany closure technique, we expect to reduce this time by 10%. Thus, with a significance level of 95% and a power of 80%, the calculated sample size was 33 participants. To allow for subgroup analysis, and with an expected dropout rate of 20%, the sample size will be 124 participants.

Continuous data were presented in mean±SD or median+interquartile range (IQR) according to the normality test of the variable distribution. For qualitative data, we used numbers and percentages. SPSS software (Statistical Package for the Social

Figure 9

Cut the threads just above the knot.

Sciences, version 25.0, SSPS Inc., Chicago, Illinois, USA) was used for the statistical analyses.

Results

In this study, 154 patients eligible for laparoscopic cholecystectomy were asked to participate; of them, 24 participants declined to participate, leaving 130 participants who enrolled and followed up.

Baseline characteristics

In this study, 130 participants were enrolled and followed up postoperatively, with an average age of 40.07±10.02 years. The majority of cases were female 121 (93.08%). Only 10 (7.69%) cases had normal weight, 49 (37.69%) were overweight, and 71 (54.62%) were obese.

The average BMI was 31.2±4.29 kg/m^2.

Only 14 (10.77%) had hypertension, 12 (9.23%) diabetes mellitus, and four (3.08%) ischemic heart disease. More than half of the cases, 71 (54.62%), were American Society of Anesthesiologists II, and the remaining 59 (54.38%) were American Society of Anesthesiologists I, as shown in Table 1.

Table 1 Baseline characteristics

Categorical variables		
Sex	Frequency	%
Male	9	6.92
Female	121	93.08
Obese		
Normal weight	10	7.69
Overweight	49	37.69
Obese	71	54.62
Hypertension	14	10.77
DM	12	9.23
IHD	4	3.08
ASA		
ASA I	59	45.38
ASA II	71	54.62
Continuous variables		
	Age	BMI
Valid number	127	130
Mean	40.07	31.32
SD	10.02	4.29
Minimum	20	24.50
Lower quartile	32	27.70
Median	39	30.70
Upper quartile	48	34.75
Maximum	65	39.00
Interquartile range	16	7.05

ASA, American Society of Anesthesiologists; DM, diabetes mellitus; IHD, ischemic heart disease.

Operative details

All cases underwent laparoscopic cholecystectomy (5-5-5-10 technique).

All the ports had a width of 5 mm except the lateral one (10–12 mm).

As depicted in Table 2, the mean±SD operative time was 88.90±28.30 min, and the median (IQR) was 83.5 min (32.5 min). Complete fascial and peritoneal closure was accomplished in each case as judged by palpation and endoscopic inspection.

The average±SD number of sutures needed was 2.62 ±1.14 with a median (IQR) of 2 (1). One suture was needed for complete closure of the port site in only 10% of cases, two sutures in 48.46%, three sutures 22.31%, four sutures in 7.69%, and five sutures in 11.54%.

Table 2 Operative details

Number of fascial sutures	Frequency	%
1	13	10.00
2	63	48.46
3	29	22.31
4	10	7.69
5	15	11.54
Bleeding (minimal)	3	2.31

	Total time for fascial closure (s)	Time (s) for closure of first suture	Time (s) for closure of second suture	Time (s) for closure of third suture	Time (s) for closure of fourth suture	Time (s) for closure of fifth suture	Operative time (min)	VAS	Sutures
Valid number	130	130	117	54	25	15	130	130	130
Mean	84.54	33.50	36.98	25.70	27.00	16.33	88.90	1.90	2.62
SD	31.61	21.49	24.02	12.58	13.17	3.52	28.30	0.74	1.14
Minimum	35	7	10	10	15	13	48	1	1
Lower quartile	64	17	17	14	18	13	69.25	1	2
Median	83.5	24	32	25	20	15	83.5	2	2
Upper quartile	108.75	47.5	50	35	33	21	101.75	2	3
Maximum	159	80	90	50	50	21	184	3	5
Interquartile range	44.75	30.5	33	21	15	8	32.5	1	1

As the variables of time of closure of sutures were not normally distributed, the median (IQR) was used to describe these data. The median (IQR) total time for the complete closure of the port site was 83.5 s (44.75 s). The time for closure of the first suture was 24 s (30.5 s), the second suture 32 s (33 s), the third suture 25 s (21 s), the fourth suture 20 s (15 s), and the fifth suture 15 s (8 s).

The only intraoperative complication noticed was minimal bleeding, with three (2.31%) cases during fascial closure. No bowel, vessel, or visceral injury occurred during fascial closure. The success rate of the surgery was 100%, with no case needing to be redone or converted to open surgery.

Postoperative follow-up

The postoperative pain (VAS score) was mean±SD 1.9 ±0.74, and the median (IQR) was 2 (1), with a minimum VAS of 1 and a maximum of 5.

Only two (1.54%) cases experienced seroma/hematoma and port-site infection during 1 month of the postoperative period. None experienced port-site hernia during the study's follow-up period (6 months).

Discussion

In this study, the novel manual facial closure technique, the Madany closure technique, was evaluated with a focus on its effectiveness and safety, as well as closure time. For evaluation of any new technique, the following should be evaluated: effectiveness, easiness, time factor, short-term safety, as well as long-term safety.

According to the results of the current study, the use of the newly developed fascial closure suturing technique resulted in a significantly lower failure rate (0%).

None of the cases needed any further intervention for closure. The only intraoperative complication noticed was minimal bleeding, with three (2.31%) cases during fascial closure. No bowel, vasculature, or visceral injury occurred during fascial closure. The success rate of the surgery was 100%, with no case needing to be redone or converted to open surgery.

The novel technique, the Madany closure technique, has the advantage of closing the port site with a traditional laparoscopic instrument, the needle holder, which is almost always available on any set of instruments for any laparoscopic procedure. The laparoscopic instruments set has, if any, only one fascial closure device. Malfunction of this device is common, and if it occurs during the procedure, what will the surgeon do?

In addition, the surgeon may plan to do a procedure through all 5 mm ports, but intraoperatively, a 10 mm or broader port may be needed. Also, when the laparoscopic instruments set does not contain a fascial closure device or when a fascial closure device is unavailable, as in most laparoscopic centers due to the high cost, the current novel technique can be used safely.

The Madany closure technique has a significant advantage in the minimal trauma of the tissues. Fascial closure devices have a caliber of more or less 2.7 mm, which may lead to tissue injury. Our technique uses the usual suture material with its needle, which respects the tissue as it is more tapered at its tip; its caliber is far smaller, so the surgeon can use the suitable size, length, and shape of the needle according to the case.

Also, some fascial closure devices may be introduced with slightly open jaws if the surgeon uses a larger size suture material like Vicryl 0 or one, and these open jaws will be impacted by tissues and cause more tissue damage.

In addition, our technique is easy to do correctly, even in morbidly obese patients, as suturing is from inside the abdomen, away from the subcutaneous fat.

Madany closure technique requires no skills apart from the laparoscopic suturing technique. There is also no need for intracorporeal knot tying. Only extracorporeal knot tying is employed in the novel technique.

Therefore, this technique was devised to be reasonable, free of complications, and used by an average surgeon during laparoscopic surgery. In this study, patients were observed during a 6-month postoperative follow-up, and no complications were reported. Our method requires no further instrumentation and can be used with or without visualization (no extra ports). We were unable to locate any literature that described a comparable method. This technique is quick to execute, requires little training or surgical expertise, does not require any new equipment, and does not incur any additional costs for the patient, surgeon, or institution. The technique is safe since the needle tip does not stab blindly into the peritoneal cavity, which may contain the intestine or other visceral organs. However, in other methods of fascial closure,

because the needle tip is exposed, there is a chance for visceral injury [18,19].

In the current study, the median (IQR) total time for the complete closure of the port site was 83.5 s (44.75 s) (mean=84.54 and SD=31.61 s).

This result is comparable to previous studies evaluating other suturing methods. The study by Jeon *et al.* [19] reported a closure time of 87.9±21.0 s.

An in-vitro study employing cadaver models found that the mean closure time for the typical Carter-Thomason system was 133.6 54.6 s [20]. Another study indicated that the Carter-Thomason needle method took an average of 8 min to seal two 10-mm port sites, even if the duration of complete skin closure was considered [21]. Nonetheless, a number of recently completed investigations revealed that the typical closure time of the Carter-Thomason device was within the range of 30–50 s. The significant variance in closure time, despite using the same conventional device in studies, was probably brought about by the different criteria used to measure suture time or the surgeon's level of experience [19].

Laparoscopic surgery involves a range of potential consequences, just like any other operation, as evidenced by existing literature. The trocar-site hernia is the most frequently reported [6,9]. Trocar-site hernia has three types: early-onset, late-onset, and particular varieties. The early-onset variation, which happens right after the surgery, frequently causes a Richter hernia or other minor bowel obstruction. A few months following the procedure, the late-onset form manifests as localized abdominal bulging without small intestine obstruction. The specific form is characterized by protrusion of the intestine and/or omentum and implies dehiscence of the whole abdominal wall [22].

Numerous methods were created to address this issue as laparoscopic trocar-site hernias became common. The port closure procedures were categorized into three primary groups by Shaher [23]. Techniques that require two extra ports and rely on assistance inside the abdomen fall into the first category. Techniques for extracorporeal support falling under the second category need one extra port. Methods that require no extra ports or visualization fall under the third category.

The second group can contain our novel technique. In addition to the accuracy and consistency of wound closure evaluated in this study, there was no trocar-site herniation during the short-term and long-term follow-up periods. Most previous studies on trocar-site closure techniques found no postoperative herniation in a small patient sample because trocar-site hernias are uncommon [24,25]. Effective fascial closure is significantly more critical in patients with conditions including obesity, lengthy surgery, age, diabetes mellitus, expansion of the incision, and wound infection [26].

This study has a number of limitations. First, it did not compare the novel procedure to a traditional manual closure technique. However, this pilot study's goal was to assess the effectiveness and safety of our unique method. To further bolster the evidence supporting its efficacy and safety, this novel method will be tested in a randomized controlled trial against alternative approaches.

Conclusion

The Madany closure is a revolutionary technique that we mentioned in our paper. The procedure has been shown to be safe and effective, with the exception of very slight bleeding. In addition, the methodology offers a quick procedure for port-site closure. We recommend conducting a randomized controlled trial against alternative approaches to reach a conclusive generalizable evidence.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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