Nasr fascial closure: a novel device for fascial closure in laparoscopic surgery

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Background
Laparoscopic surgery has become the gold standard approach for almost all abdominal surgeries with subsequent increase of its related complications mainly trocar-site hernia.
Patients and methods
This is a prospective interventional study aims to evaluate the efficacy and safety of Nasr fascial closure, time needed to close the trocar site and occurrence of bleeding or other postoperative complications. We included patients who underwent laparoscopic surgery in General Surgery Department, Aswan University Hospital.
Results
One hundred seventy patients were included in our study. Most of participants were females representing 94.1% of patients. The mean age of participants was 40.9 ±9.7 years and the median (interquartile range) total time for the complete closure of the port site was 63.0 s (76.8 s). After the follow-up period of 12–15 months, no patient developed trocar-site hernia.
Conclusion
Nasr device provides a safe, fast and effective technique for 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, which reduces perioperative problems, speeds up recovery, and produces better cosmetic results, has emerged as the gold standard of care for surgical operations in a variety of disciplines [1]. It has become the gold standard approach for almost all abdominal surgeries. It was first introduced in the early 1930s when American surgeon Ruddock described laparoscopic surgery as a superior diagnostic procedure to open surgery [2,3]. The first laparoscopic surgery was performed by Professor Mühe of Böblingen in 1985 [4]. Since then, laparoscopic surgery has been widely accepted due to its low incidence of morbidity and mortality. With the increasing use of laparoscopy in surgical interventions, some problems have been reported, such as hernia from the trocar site. However, it needs small incisions for trocars insertion. Trocar-site hernia is uncommon but remains a source of morbidity, with an incidence of 1–3% [5].

Since the invention of laparoscopic surgery, new technical difficulties have appeared. Fascial closure at port sites is one of them, particularly when big trocars are employed or when a port site has been dilated for organ extraction, like gallbladder extraction. Fascial closure is currently a problem due to new technologies like single-port laparoscopic surgery and the requirement for small cosmetic incisions. The risk of problems at the port site has been reduced significantly since the first report of herniation at a trocar site following laparoscopy was published. The typical closure method for the fascia at the port site can be difficult and tedious, frequently requiring bigger skin incisions or blind suturing of the fascial defect (with the risk of an imperfect suture and lesions of the intraperitoneal organs) [6].

Several methods for trocar site closure have been developed, as reported in Botea *et al.* [6], Carter [7], and Spalding *et al.* [8], but many of these are expensive and/or not easy to use. The objective of this study was to evaluate the effectiveness and safety, as well as the

applicability of a novel device invented locally, for trocar site closure.

Patients and methods

Study design

The study adopted the globally accepted standards of GCP and in conformity with the latest revision of the Declaration of Helsinki. In addition, it conformed to national laws and regulations and was approved by the Local Ethics Committee. This study was designed as a single-group quasi-experimental study following the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) Statement checklist [9]. The study was conducted from June 2022 to September 2023 (recruitment phase 3 months and follow-up phase 12–15 months) and on patients who attended the General Surgery Outpatient Clinic at Aswan University Hospital and approved by the institutional review board (IRB) (699/12/22), Faculty of Medicine, Aswan University. The purpose of this study and all information about the technique was clearly explained in Arabic to all participants attending the center before their enrolment in the study, and all of those enrolled signed an informed consent form.

All cases, male or female aged 18 years or more, who attend the center and are eligible for cholecystectomy were included in the study. On the other hand, all cases refused to participate, as well as those who are mentally impaired to be able to be subjected to the follow-up routine.

All patients were subjected to full history taking, including personal history (age, sex, and special habits), medical history, and surgical history (previous operations). Patients were admitted to the hospital and prepared for the operation.

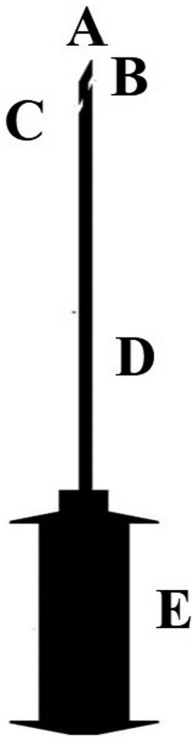
Device description

The instrument 'Nasr fascial closure' used in the procedure was invented by Dr MM. Nasr fascial closure has a unique design consisting of a single piece of a thin, needle-like solid metal rod of 2 or 2.5 mm in diameter and 17 cm in length with a pointed end. There are two consecutive slots with two reverse inclinations just above that end and on opposite sides of the metal rod. The distal or the front slot is used to insert the suture material, and the proximal or the back slot is used to pull the suture material (Figs 1 and 2). That makes it an easy-to-use, fast-performing, easy-to-sterilize instrument that can also be used to control bleeding from port sites if it occurs. That makes it distinguishable from others in its ease and speed in inserting and retrieving the suture material for making stitches.

Technique

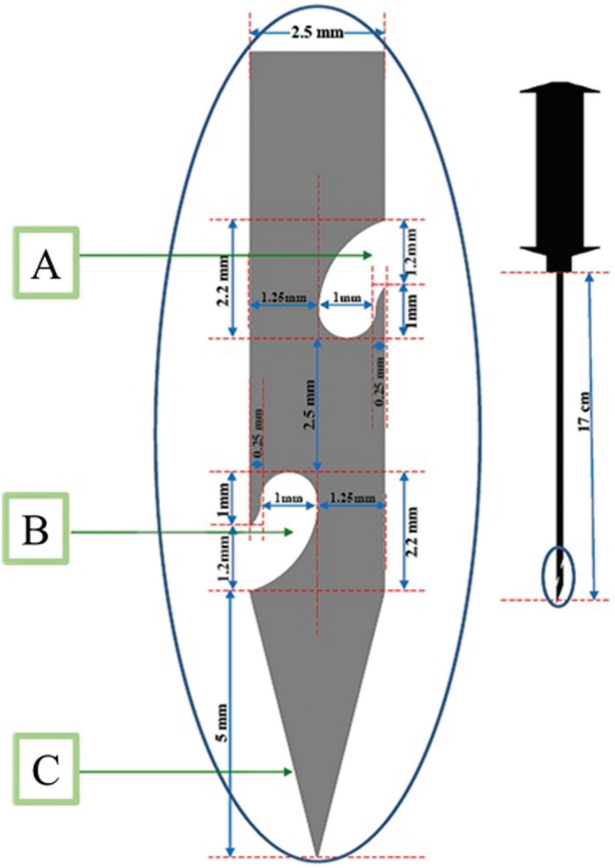
After finishing our laparoscopic maneuver inside the abdomen, we proceed with the port site fascial closure. We grasp the fascial closure device with our right hand and the suture material (vicryl) with the left hand and insert the suture material inside the distal slot of the device in a horse bridle-like shape, then insinuate the device with the thread inside it like a loop between the skin and the port to be in a reasonable distance from the edge (about 5 mm) to have a good grip of tissues and in a suitable position then we advance the device in the insufflated peritoneal cavity under vision, carefully to avoid injuring any intraabdominal structure such as viscera or solid organ then we withdraw it back leaving the loop of the thread inside the abdomen after dislodgement of the loop from the slot and then we insert the device again without the thread with our right hand in the opposite side of the port between it and the skin and manipulate it gently in the same way as before until reaching intraperitoneal then we proceed with the device to enter inside the loop inserted before. After that, we apply gentle traction with a laparoscopic device like a horse bridle with our left hands to make the loop inside the abdomen

Figure 1



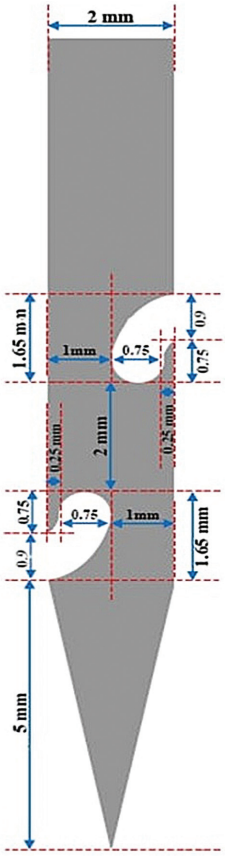
Explaining how to introduce and extract the thread.

Figure 2



The tip of fascial closure device. (a) The posterior slot. (b) The anterior slot. (c) The tip.

Figure 3



Other dimensions of the device.

impacted in the proximal slot of the device to retrieve it outside the abdomen with continuous gentle traction applied on the thread to avoid dislodgement of the loop outside the device slot (Figs 3–5, Video 1).

On both sides of the port, we have one side with the retrieved loop and the other side with the two cut ends of the thread. We can do a secure knot extracorporeally after the removal of the port. We can use our finger to close the port site to keep the pneumoperitoneum during this procedure instead of the port kept in place (Figs 3–5).

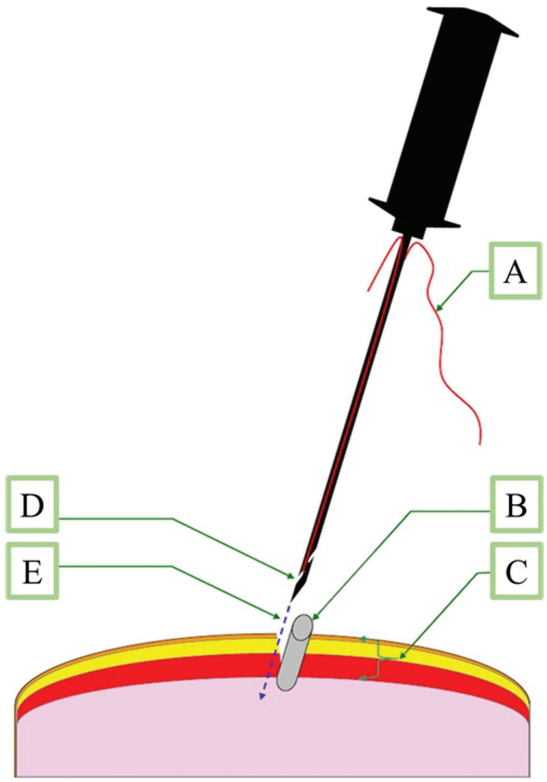
Follow up

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 month 3, month 6, month 9, and month 12 after the operation.

Objectives

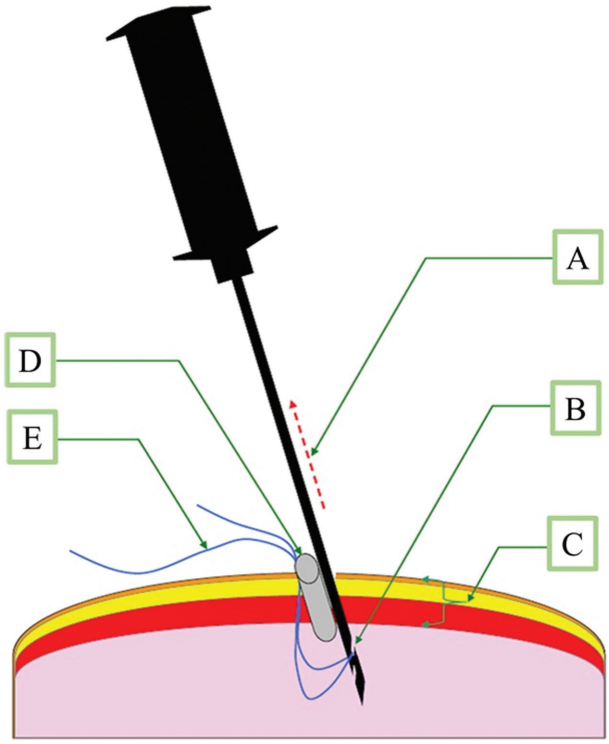
The primary outcome of this study is to evaluate the device in terms of the duration needed for fascial

Figure 4



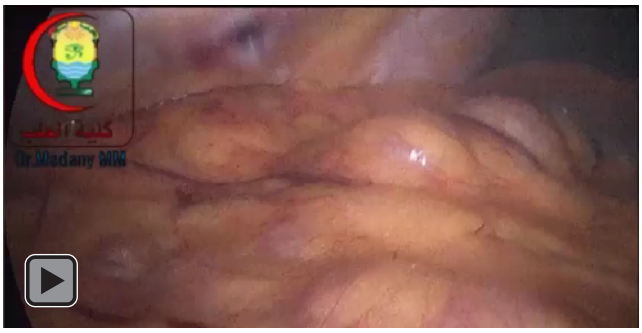
Explaining how to introduce the thread.

Figure 5



Explaining how to extract the thread.

Video 1



Explaining how to introduce and extract the thread.

closure. The secondary outcome variables were the success of the surgery, operative duration, operative complications (visceral injuries or bleeding from the site of entry of suture), postoperative pain [visual analog scale (VAS) score], and postoperative complications (infection, seroma, hematoma, port site hernia). The patients will be followed up clinically for 1 month.

Statistical analysis

According to the study of Lasheen *et al.* [10], the average total time for fascial closure was 3.49 min. In the current study, with the aid of the Nasr fascial closure device, we expect to reduce this time by 5%. Thus, with a significance level of 95% and a power of 80%, the calculated sample size was 134 participants, and with an expected dropout rate of 20%, the sample size will be 165 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 Sciences, version 25.0; SSPS Inc., Chicago, Illinois, USA) was used for the statistical analyses.

Results

In this study, from June 22 to September 22, 223 patients eligible for laparoscopic cholecystectomy were asked to participate; of them, 53 participants declined to participate, leaving 170 participants who enrolled.

Baseline characteristics

In this study, 170 participants were enrolled and followed up postoperatively, with an average age of 40.9±9.7 years. The majority of cases were female 160 (94.1%). Only five (2.9%) cases of them had normal weight, 54 (31.8%) were 'overweight,' and 111 (65.3%) were 'obese.' The average BMI was 32.1±4.1 kg/m^2. Only 15 (8.8%) had hypertension, 15 (8.8%) diabetes mellitus, and five (2.9%) ischemic heart disease. More than half of the cases, 90 (52.9%), were American Society of Anesthesiologists II, and the remaining 80 (47.1%) were American Society of Anesthesiologists I, as shown in Table 1.

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 from Table 2, the mean±SD operative time was 87.2±26.5 min, and the median (IQR) was 84 (31) min. Complete fascial and peritoneal closure was accomplished in each case as judged by palpation and endoscopic inspection.

In most cases, 120 (70.6%) needed only one suture for complete closure of the port site, 40 (23.5%) two sutures, and only 10 (5.9%) needed three sutures.

As the variables of time of closure of sutures were not normally distributed, the median (IQR) was used to

Table 1 Base line characteristics

Categorical variables		
Sex	Frequency	%
Male	10	5.9
Female	160	94.1
Obese		
Normal weight	5	2.9
Overweight	54	31.8
Obese	111	65.3
Hypertension	15	8.8
DM	15	8.8
IHD	5	2.9
ASA		
ASA I	80	47.1
ASA II	90	52.9
Continuous variables		
	Age	BMI
Valid number	168	170
Mean	40.9	32.1
SD	9.7	4.1
Minimum	25	24.5
Lower quartile	33	29
Median	41	32.15
Upper quartile	48	35.7
Maximum	65	39
Interquartile range	15	6.8

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

describe these data. The median (IQR) total time for the complete closure of the port site was 63.0 (76.8) seconds. The time for closure of the first suture was 60.5 (30.8) s, for closure of the second suture 59.5 (26.0) s, and for closure of the third suture it was 56.5 (8.5) s.

The only intraoperative complication noticed was minimal bleeding, with five (2.9%) 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 ±0.7, and the median (IQR) was 2 (1), with a minimum VAS of 1 and a maximum of 3.

Only two (1.2%) 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 (12–15 months).

Discussion

In this study, the novel device was evaluated with a focus on its effectiveness and safety, as well as closure time. For evaluation of any new device, 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 device 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 five (2.9%) cases during fascial closure. No bowel, vasculature, or visceral

Table 2 Operative details

Categorical variables					
Number of fascial sutures		Frequency		%	
1		120		70.6	
2		40		23.5	
3		10		5.9	
Bleeding (minimal)		5		2.9	
Continuous variables					
	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	Operative time (min)
Valid number	170	170	50	10	170
Mean	87.1	64.7	64.8	56.9	87.2
SD	50.2	21.2	20.5	16.7	26.5
Minimum	35.0	35.0	24.0	28.0	48
Lower quartile	48.3	48.0	52.0	51.5	67.25
Median	63.0	60.5	59.5	56.5	84
Upper quartile	125.0	78.8	78.0	60.0	98
Maximum	237.0	140.0	115.0	90.0	165
Interquartile range	76.8	30.8	26.0	8.5	31

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.

Nevertheless, caution should be exercised when employing a traditional trocar-site closure device to penetrate the fascia and peritoneum. The Carter-Thomason device (CooperSurgical Inc., Trumbull, Connecticut, USA), as well as BERCI fascial closure, are two examples of traditional instruments made for trocar-site closure. However, because the needle tip is exposed, there is a chance that they could harm internal organs. Although laparoscopic devices seldom cause visceral harm, an aortic injury brought on by a typical fascial closure device has been documented [11,12].

In the current study, the median (IQR) total time for the complete closure of the port site was 63.0 (76.8) s (mean=87.1 s and SD=50.2 s). This result is comparable to that of previously published studies evaluating conventional suturing devices. The study of Jeon *et al.* [11] reported for a new device EZ-Close the time of 87.9±21.0 s.

The standard Carter-Thomason system's mean closure time was 133.6 54.6 s, according to an in-vitro research using cadaver models [13]. Although the time of complete skin closure was considered, another study found that the Carter-Thomason needle approach required an average of 8 min to close two 10-mm port sites [14]. However, a number of lately conducted studies showed that the Carter-Thomason device's standard closure time was between 30 and 50 s [15,16]. Even though the same conventional device was employed in studies, the large variation in closure time was likely caused by the varied standards employed to gauge suture time or the level of expertise of the surgeon [11].

As known from the literature, laparoscopic surgery like any other intervention, has its spectrum of complications. Of these, the commonest reported is the trocar-site hernia [6,17]. There are three variants of trocar-site hernia: the early-onset, the late-onset, and the specific variant. The early-onset variant occurs immediately after the procedure and commonly results in a small bowel obstruction, particularly the Richter hernia. The late-onset variant occurs several months after the procedure and is characterized by local abdominal bulging but no small intestinal obstruction. The specific variant indicates dehiscence of the whole abdominal wall and is characterized by protrusion of the intestine and/or omentum [18].

As the incidence of laparoscopic trocar-site hernia increased, many techniques were developed to overcome this complication. Shaher classified the port closure techniques into three main categories. The first category includes techniques that use assistance inside the abdomen, requiring two additional ports. The second category includes extracorporeal assistance techniques requiring only one additional port. The third category includes techniques that do not require additional ports or visualization [19].

Our new device can be included in the second category. In this study, the precision and uniformity of wound closure were assessed; nevertheless, over the short-term and long-term follow-up periods, there was no trocar-site herniation. Due to the rarity of trocar-site hernia, the majority of earlier research examining trocar-site closure devices found no postoperative herniation in a small patient sample [14–16]. Obesity, length of surgery, age, diabetes mellitus, incision enlargement, and wound infection are all risk factors for trocar-site hernia, making effective fascial closure even more crucial in patients with those conditions [20].

The current study has several limitations. First, it did not evaluate the comparison between the novel device and a conventional device such as Carter-Thomason system. However, the objective of this pilot study was to evaluate the safety and efficacy of our novel device. In another research study, this novel device will be compared with other methods in a randomized controlled trial to further prove the evidence for its effectiveness and safety.

Conclusion

Our study discussed a novel device, namely Nasr fascial closure. The safety and efficacy of the device has been proven with no complication except minimal bleeding. Additionally, the device provides a rapid technique for port site closure compared with other methods.

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positively impact the lives of patients and transform the landscape of surgical innovation.

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Conflicts of interest
There are no conflicts of interest.

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