Effectiveness of a Novel Trocar Site Closure System: A Retrospective Evaluation

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Introduction:

Smaller and fewer laparoscopic incisions lead to decreased post-operative pain, rates of ileus, surgical site infections (SSI), ventral herniation, adhesive bowel obstruction, and shorter hospital stays as compared to the traditional open approaches[1-6]. Specifically, it has been established that when compared to open approaches, laparoscopic incisions lead to a lower rate of incisional herniation and pain[7]. Nonetheless, trocar site incisional hernia (TSIH) is a common complication after laparoscopic surgery. Rates of about 1% after laparoscopic cholecystectomy[8], 0.4% after robotic prostatectomy[9], 0.74% after gastrointestinal procedures, and up to 1.47% following colorectal procedures[10] have been reported for TSHI. However the true incidence of TSIH may be under reported in these studies due to their retrospective nature, loss of patient follow up and the presence of asymptomatic cases. In fact, a recent prospective observational study demonstrated a 25.9% incidence of TSIH at the umbilical site following elective laparoscopic cholecystectomy with 3 years of follow-up[11].

Trocar site incisional herniation is associated with significant morbidity including pain, bowel obstruction and bowel strangulation[12]. The factors associated with TSHI are both patient-related and technical. Incision enlargement to allow for specimen extraction, surgical site infection (SSI), diabetes mellitus (DM), and obesity are independent risk factors for TSIH[11]. Other factors such as advanced aged, poor nutritional status, connective tissue disorders, female gender, larger trocar diameter, prolonged surgical procedure time, and excessive trocar manipulation also increase the risk of TSHI [8, 13-18].

Multiple techniques and devices for port site closure have been developed with the goal to decrease TSIH prevalence and/or to minimize its effects[19 -22]. It has been shown that devices such as the Carter-Thomason have lower closure times and rates of TSHI, SSI, and seroma when compared to the hand closure technique[23]. The hand closure technique and the current closure devices require the deployment of loop transfascial sutures which are likely associated with increased complications due to local tissue ischemia, nerve entrapment and induction of inflammation.

NeoClose® is a novel trocar non-loop site closure system that achieves fascial approximation via the use of subfascial anchors affixed to both sides of the wound using a special guide system. The anchors approximate the defect without the need for a closed loop suture closure, thus decreasing fascial tension after closure. This system has been shown to be safe and effective in an animal model[12]. In fact, Walker et al demonstrated decreased closure times, decreased depth of needle penetration, and histologic superiority when using the neoClose® system as compared to the Carter-Thomason device[12]. We have been using neoClose® for over a year in our practice. Currently there is no data available regarding the application of this FDA approved device in human subjects.

The aim of this retrospective study is to evaluate the safety and effectiveness of the neoClose® trocar site closure system in patients undergoing a variety of abdominal surgical procedures. Measured outcomes included incidence of TSIH, SSI, post-operative pain at closure site, and re-admission rates related to port-site complications.

Methods:

Inclusion and exclusion criteria

This is a case series retrospective observational study. Patients included in the study were all consecutive patients who underwent a laparoscopic or robotic procedure in our practice from June 2015 to July 2016. There were no restrictions regarding age, gender, body mass index (BMI), or comorbidities including DM, chronic pulmonary disease, or smoking status. Patients with umbilical hernia or midline laparotomy scar were also included. Patients who were converted to laparotomy were excluded. Patients who were lost to follow-up were excluded from the final statistical analysis.

Study settings

Three surgeons (a single attending and 2 fellows) from a university associated private practice performed all the surgeries. The cases were done at Houston Northwest Medical Center or at Northwest Surgery Center Red Oak from June 2015 to July 2016.

Surgical technique

The neoClose® system (Figure 1A and B) was used following the manufacturer's protocol as follows: first, the laparoscopic trocar is removed and the surgeon's fingertip is inserted to maintain pneumoperitoneum. The neoClose® anchor guide (Figure 1A) is then inserted with its guide channels oriented orthogonal to the fascial incision (Figure 2). Under laparoscopic visualization, the anchor driver is deployed via the guide channel until it penetrates through the abdominal wall(Figure 3). Next, the anchor driver is removed, which engages the suture anchor in its position (Figure 4). The other suture anchor is deployed in similar fashion in the contralateral side of the incision (Figure 5). Lastly, the sutures are then tied after the abdomen is desufflated (Figure 6). Of note, a single set of neoClose is used for incisions 5 mm or less, while two sets are used for incisions greater than 5 mm.

Study variables

Patients were monitored for TSIH, SSI, and pain level. Re-admission rates related to port-site complications were also recorded. The time points analyzed were as follows: at discharge from hospital and at 1, 3, and 12 weeks after surgery. Data was obtained by a combination of review of medical records and telephone surveys. Trocar site incisional hernias were diagnosed by patient history and clinical examination. Pain was quantified using the visual analogue scale (VAS) from 0 (no pain) to 10 (worst possible pain). A SSI, as defined by The Centers for Disease Control and Prevention (CDC), is "an infection that occurs after surgery in the part of the body where surgery took place" with symptoms that include "redness and pain, drainage of cloudy fluid, and fever." All SSIs were confirmed by clinical exam and cultures were sent if opening of the wound for drainage was required. Re-admission events were recorded from medical record reviews.

Statistical Analysis

Given the study's retrospective observational nature, only descriptive statistics were employed. Gender was expressed as percentage of the total number of patients. Age was presented as a mean, range, and standard deviation (SD) when appropriate. Post-operative complications were recorded as number of cases and percentage of a total group. Pain scores were presented as a mean, range and standard deviation (SD) values.

Results:

Initial data was collected in 288 patients that underwent surgery requiring port site closure. The patient characteristics are presented in Table 1. Complete data sets were obtained for 158 patients all of whom were included in the final statistical analysis. Seventy-nine patients were lost to follow up, 1 patient suffered a stroke 6 months after surgery and was not able to respond to our survey, 1 patient died of unrelated causes. Furthermore, 49 patients had surgery within the 3 months at the time of data analysis; therefore, all data could not have been obtained from them. There were more female than male patients, but there were no significant differences between the groups (total group n=179, 62.2% and n=109, 33.8% and final group n=105, 66.4% and n=53, 33.5% respectively). There were no significant differences regarding age and BMI (range and average) between the total group of patients and the final group included in the statistical analysis (15-94, 46.5 and 15-92, 47.4 for age and 17.87-85.47, 34.96 and 17.87-85.47, 34.44 for BMI respectively). However, the final group had a greater percent of patients age > 65 years (27.2 % versus 18.4%) and BMI >30 (77.8% versus 47.2%).

Patients in the study underwent a variety of abdominal surgery procedures listed in Table 2. The most common procedures were laparoscopic cholecystectomy (n total group= 82 and n final group= 47), laparoscopic vertical sleeve gastrectomy (n total group=59 and n final group= 30), laparoscopic appendectomy (n total group=33 and n final group= 13), laparoscopic inguinal hernia repair (n total group= 36 and n final group= 20), and laparoscopic fundoplication (n total group= 26 and n final group= 21).

Patients were monitored for immediate postoperative complications at the time of discharge including TSIH, SSI, severe pain, hematoma, seroma, intestinal obstruction, or evisceration (Table 3). There were no immediate postoperative complications seen in any of the 288 patients (including the patients excluded in the final statistical analysis).

During the entire follow up period, there was a single TSIH in a patient who had undergone laparoscopic vertical sleeve gastrectomy (Table 4). The patient returned to our clinic at day 6 after surgery reporting mild to moderate pain and the presence of a “bulge” in the region of her 12 mm umbilical incision. The patient was

taken to the operating room for laparoscopic exploration. There was a small defect cephalad to the 2 intact sets of neoClose® sutures. There were adhesions in the periumbilical region from a prior surgery that were not taken down during the index surgery. There was a small amount of fatty tissue in the herniation. The case was deemed to be a technical error and would likely have been prevented by lysing of the adhesions and by using another set of neoClose® sutures to close the defect.

There was a SSI at the umbilical port in one patient after a sleeve gastrectomy (Table 4). The patient was seen in clinic a week after surgery. There was mild erythema and fluctuance at the umbilical site (i.e. the site of specimen extraction). The patient also reported moderate pain at the same site. The patient was taken to the operating room; the wound was opened, drained and packed. Cultures were taken. The patient was treated with antibiotics and did well afterwards. There was no need for readmission.

Mean quantification of pain using the VAS was 0.47 (range 0-8; SD 1.28) at 1 week, 0.14 (range 0-7, SD 0.75) at 4 weeks and 0.07 (range 0-4, SD 0.07) at 12 weeks (Table 5). Table 6 shows pain scores at 1, 4 and 12 weeks for the 5 most common procedures. There is a tendency of decreasing in pain scores as a function of time for all procedures listed in table 6. Laparoscopic cholecystectomy has the highest pain scores at all times followed in descending order by laparoscopic inguinal hernia repair, laparoscopic fundoplication, laparoscopic vertical sleeve gastrectomy and laparoscopic appendectomy (Table 6). It is important to note that the pain score levels are low across all intervention at all given times.

Discussion:

Trocar site incisional herniation is one of the most clinically significant complications after laparoscopic surgery[7-12]. Multiple factors contribute to development of TSIH and its etiology is complex. There are patient-related and technical factors linked to the presence of TSHI. Wound infection, DM, obesity, and incision enlargement to allow for specimen extraction have been found to be independent risk factors for TSIH[11]. Other factors such as advanced aged, poor nutritional status, connective tissue disorders, smoking, immunosuppressant drugs, steroids, female gender, larger trocar diameter, prolonged surgical procedure time, and excessive trocar manipulation also increase the risk of TSHI [8, 13-18, 24]. Comajuncosas et al[11] have suggested that TSIH is grossly under reported in the literature, with their own incidence of umbilical site TSIH reportedly as high as 25.9% following elective laparoscopic cholecystectomy after a median follow up period of 46.8 months. However, in a letter to the editor, Oliphant et al[24] find these results surprising for several reasons. They state the incidence if TSIH (and also SSI) is significantly higher in this study than what has been reported previously[10, 17]. They suggest that perhaps this population has high prevalence of smoking or other comorbid conditions such as asthma, chronic pulmonary disease, connective tissue disease, renal disease, or steroid or immunosuppressant use. They also note that these results could be due to the use of over sensitive diagnostic modalities (i.e. ultrasound) that can also be affected by inter-observer reliability. They also question the experience of the surgeons involved in the study. There is another recent study supporting the idea of TSIH being a significantly under recognized condition. The study by Armañanzas et al[25] is a randomized clinical trial in patients undergoing elective laparoscopic cholecystectomy with high risk factors including age >65 years, DM, chronic lung disease, and obesity. The authors proposed that prophylactic use of polypropylene mesh could reduce TSIH incidence. They randomized patients in two groups; one to have port-site closure with non-absorbable sutures (n= 47) and the other with polypropylene omega-3 mesh (n=45). The incidence of TSIH was 31.9% in the first group and 4.4% in the second group. These studies are in stark contrast with other studies [4-5, 8] reporting significantly lower incidence of TSIH after laparoscopic cholecystectomy. All of

these underscore the need for future studies, ideally multicenter, multi-institution randomized control trials, to help elucidate the true incidence of TSIH.

The association between TSIH and pain, bowel obstruction, bowel strangulation, and other post-procedure morbidities has been clearly established[12]. Several authors agree that the most frequent location of TSIH is the umbilical port[26-28]. This association can be related to the weaker anatomy at the midline of the abdomen, the larger incision diameter at that level and to the frequent need to dilate the fascia for specimen[25]. Surgical site infections have been shown to be an independent risk factor for TSIH[11]. Therefore, any strategy to reduce its incidence is of paramount importance. Shetty and Adiyat[23] demonstrated that closure devices such as the Carter-Thomason have lower closure times and rates of TSHI, SSI, and seroma when compared to the hand closure technique. However, both the hand closure technique and the current closure devices require the use of loop transfascial sutures which are likely associated with increased complications as a result of local tissue ischemia, nerve entrapment and induction of inflammation[12, 29] as compared to non-loop closure approaches. The neoClose® closure system has the advantage of attaining fascial approximation through subfascial anchors without the use of closed loop sutures minimizing tension and leading to less dead space and tissue trauma. This in turn can potentially lead to decreased nerve entrapment and local ischemia[12]. This system has been shown to provide lower closure times, being potentially safer (i.e. lower depth in needle penetration) and inducing less tissue trauma (i.e. less fibrosis and subperitoneal rather than intramuscular location) as compared to the Carter-Thomason device in well-conducted animal studies[12]. To the best of our knowledge, this is the first series studying the safety and effectiveness of the neoClose® closure system in humans.

The neoClose® system was found to be safe and efficient during a great variety of abdominal surgical procedures in a non-selected patient population (Table 1 and 2). One of the strengths of this series is the demonstration that this closure system can be used for port closure during any of the abdominal surgeries in table 2 and possibly others. In addition, we did not see an obvious patient-related contraindication to use the neoClose® port site closure system. We were able to

deploy the neoClose® sutures with no technical difficulty in all patients including patients with high BMIs. We believe this is a significant advantage of this system over other closure approaches. We did not measure depth of needle penetration, but suffice to say that as seen in Figures 3-5, the deployment takes place under direct visualization. Furthermore, there is no need to insert the driver/anchor any further once it penetrates the peritoneal layer. We did not experience any complication related to injury while deploying the neoClose® sutures. We did not measure closure times in a systematic fashion. However, it is our experience that port closure can be consistently achieved in about 25 seconds, possibly less, and with a short learning curve. We did not stratify our patient population regarding gender, age, procedure undergone, comorbidities, or any other variable. We included all the patients that were able to have a complete follow up in a retrospective manner as delineated in the methods section. Of significance, 27.2 % of our patient population were >65 years of age and 77.8% had a BMI >30.

No cases of TSIH, SSI, hematoma, seroma, intestinal obstruction, or evisceration were found during the immediate post-operative period in the initial 288 patients (i.e. time from surgery to discharge). Specific pain level at the port sites closed with the neoClose® system was not documented in the medical charts. However, none of the patients had severe pain preventing discharge. During the entire follow up period, there was a single TSIH in a patient who had undergone laparoscopic vertical sleeve gastrectomy (Table 4). The patient returned to our clinic at day 6 after surgery reporting mild to moderate umbilical pain associated with a bulge. A small defect cephalad to the neoClose® sutures was found, but the sutures were intact. The patient had periumbilical adhesions form a prior procedure that we did not take down. The most likely explanation is that a prior subclinical hernia (i.e. an asymptomatic, small hernia) was present and possibly aggravated during our intervention. There was a small amount of fatty tissue in the herniation. We believe this was a technical error in the sense that it could have been prevented by dissection and lysis of the adhesions and by using another set (s) of neoClose® sutures to close the defect. The patient did well after closure of the small hernia using the neoClose® system and was discharged on the same day. Given the fact that

we are not completely sure this to be the case, we counted this incident as a TSIH for statistical purposes. One case of SSI at the umbilical port (i.e. the site of specimen extraction) was found in a patient after a sleeve gastrectomy (Table 4). The patient was taken to the operating room; the wound was opened, drained and packed. The patient was treated with antibiotics and did well afterwards with no need for readmission.

Mean quantification of pain using the VAS showed a tendency of decreasing in pain scores as a function of time for all procedures. Our data also shows that laparoscopic cholecystectomy has the highest pain scores at all times. This could be due to the majority of such cases being done in the urgent rather than elective setting. It is difficult to explain why the pain scores in these patients were also higher at 12 weeks after surgery. On the other hand laparoscopic appendectomies had the lowest pain scores of all procedures despite being performed almost exclusively under urgent conditions. Therefore port site location (i.e near the ribs in the epigastrium versus the mid- or lower abdomen) may be a determinant factor for pain levels. The pain score levels in this series were low across all groups. It is also important to note that pain scores were obtained via a combination of modalities including physical exam by different physicians and telephone surveys. These can further introduce result variability of pain levels from patient to patient.

We cannot attribute change in length of hospital stay (LOS) during this study to port site closure with the neoClose® system. Nonetheless, we can report no increase in LOS due to any complication associated with its use. All of these observations strongly suggest the neoClose® closure system is safe in the majority of patients undergoing general surgery procedures, delivers adequate outcomes and is a good alternative to current port site closure approaches.

Conclusions:

Laparoscopic surgical interventions will continue to increase in the U.S and globally. Trocar site incisional herniation, SSI, and pain are significant complications associated with current port site closure modalities. This series demonstrates the safety of a non-loop trocar site closure device in humans undergoing a variety of general surgery procedures. In addition, it suggests the neoClose® closure system is an efficient approach as well. This study provides the basis for a prospective, randomized, controlled, multicenter clinical trial to rigorously test and validate these observations.

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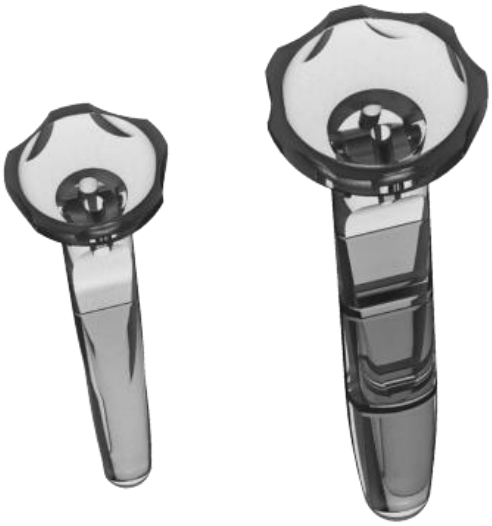
Figures:

A



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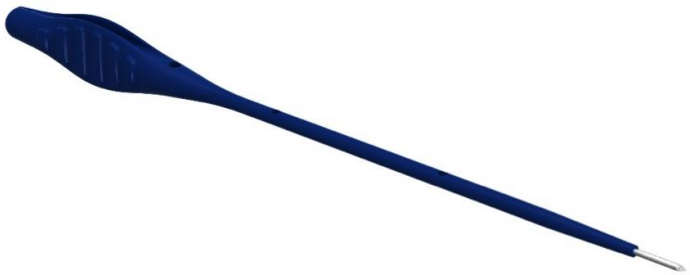

Figure 1. A) Picture of the neoClose® anchor guide system. B). Picture of the neoClose® anchor driver.

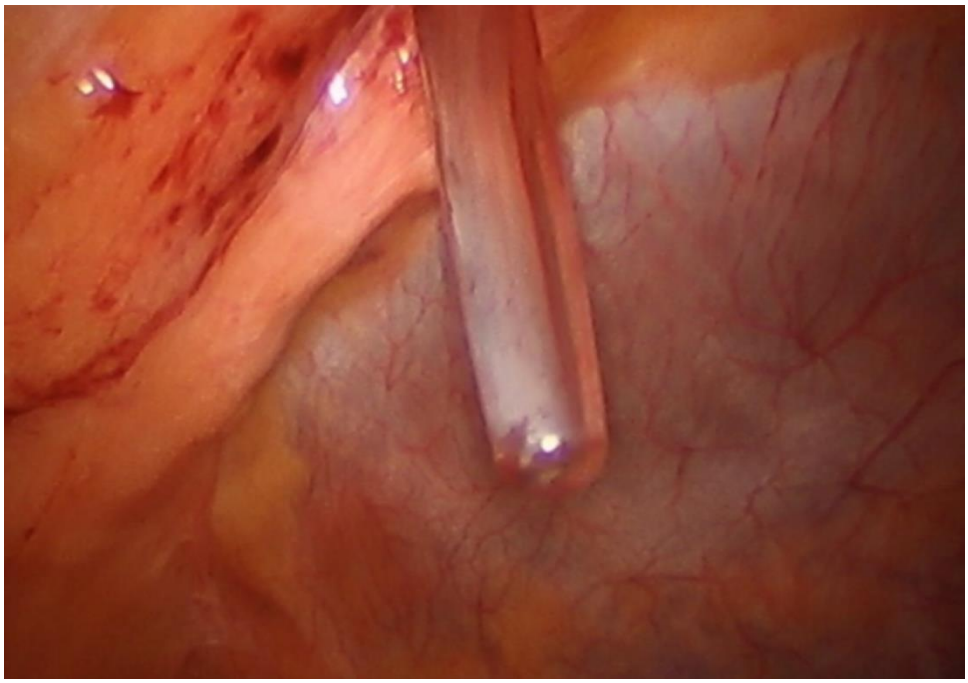

Figure 2. Intra abdominal view of the neoClose® anchor guide device after insertion in the trocar site.

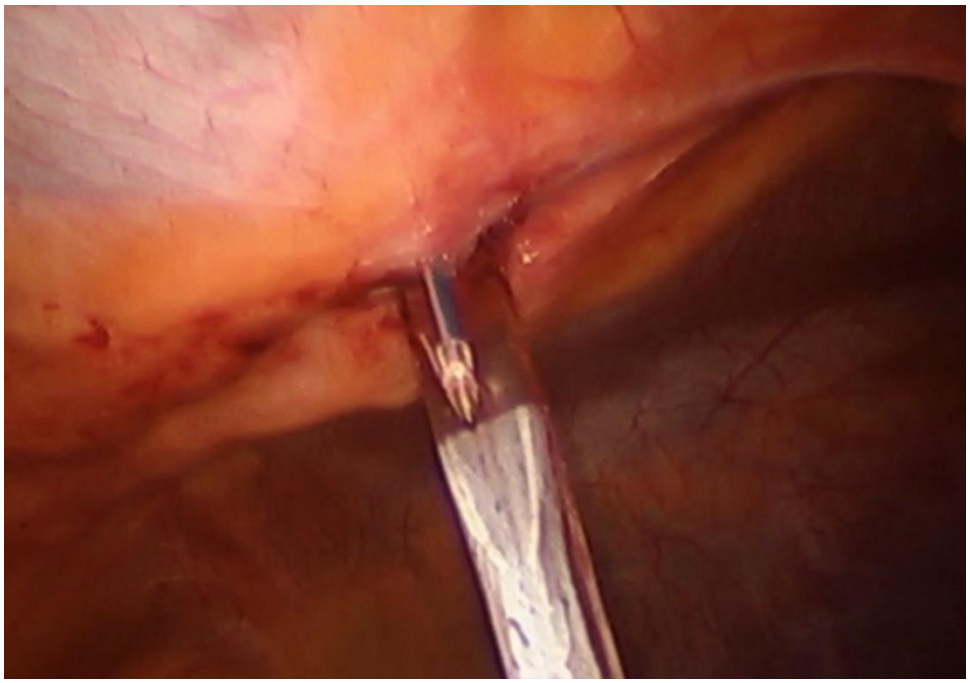

Figure 3. Deployment of neoClose® anchor driver via anchor guide channel under visualization.

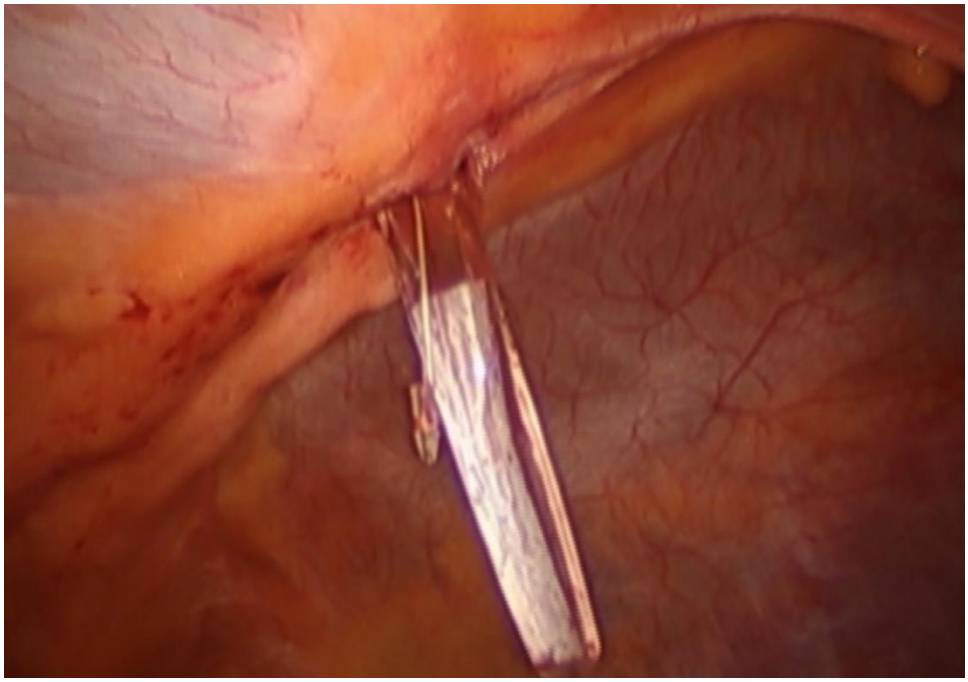

Figure 4. Suture release from anchor driver and removal of driver.

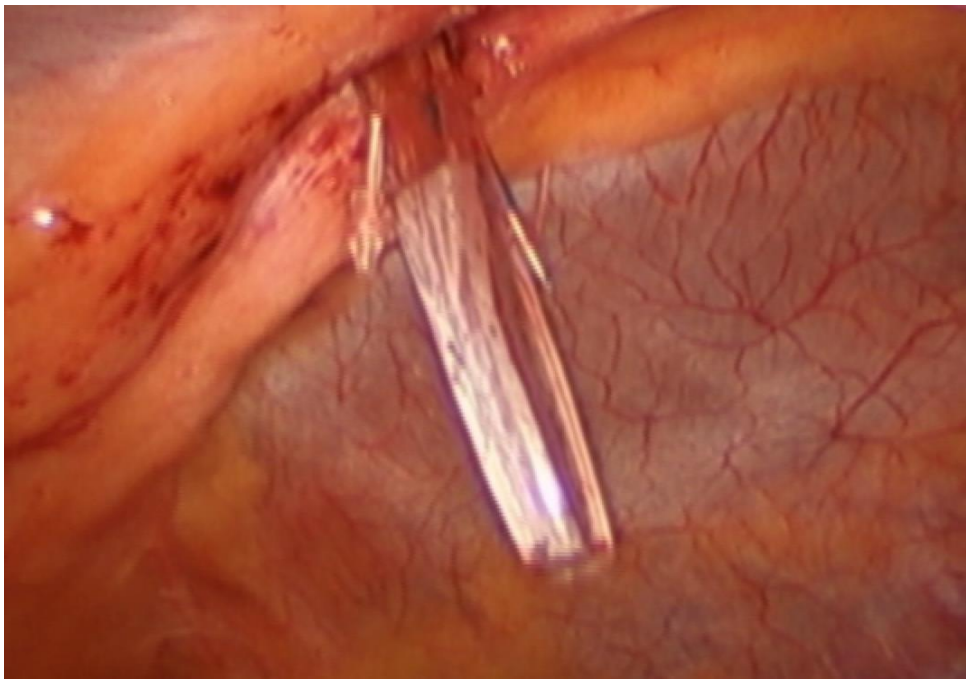

Figure 5. Insertion of the other anchor driver in the contralateral side.

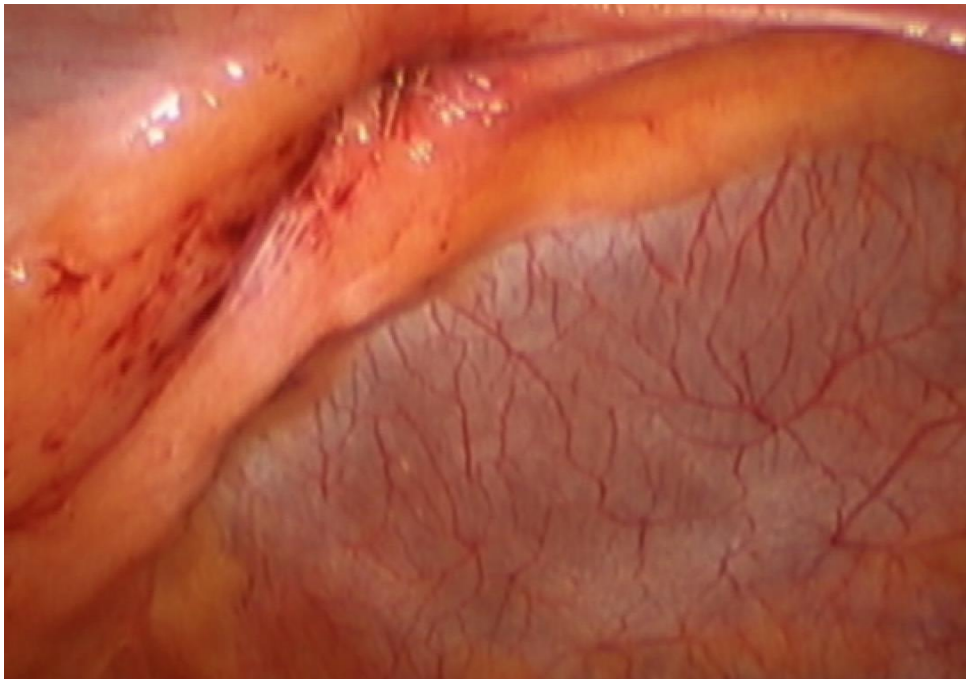

Figure 6. Removal of anchor guide and tying of the sutures to achieve port site closure.

Tables:

Table 1. Patient Characteristics.

Variable	**Total**	**Final**
Gender	Male 109 (37.8%) Female 179 (62.2%)	53 (33.5%) 105 (66.4%)
Age (years)	Range 15-94 Mean 46.5 (SD 17.1)	15-92 47.4 (SD 16.5)
BMI	Range 17.87-85.47 Mean 34.96 (SD 11.67)	17.87-85.47 34.44 (SD 10.22)
Age > 65 (years)	53 (18.4%)	43 (27.2%)
Obesity (BMI >30)	136 (47.2%)	123 (77.8%)
Total number of patients	288	158

BMI= body mass index

Table 2. Procedures Performed.

Procedure	Number of cases
Diagnostic laparoscopy	8
Laparoscopic appendectomy	33
Laparoscopic cholecystectomy	82
Laparoscopic colostomy reversal	2
Laparoscopic inguinal hernia repair	36
Laparoscopic fundoplication reversal	1
Laparoscopic fundoplication	26
Laparoscopic gastric band removal	16
Laparoscopic Heller myotomy	1
Laparoscopic hiatal hernia repair	3
Laparoscopic low anterior resection	1
Laparoscopic partial colectomy	3
Laparoscopic peritoneal dialysis catheter placement	6
Laparoscopic vertical sleeve gastrectomy	59
Laparoscopic ventral hernia repair	7
Robotic gastric band removal	1
Robotic sigmoidectomy	1
Robotic vertical sleeve gastrectomy	2

Table 3. Immediate Post-operative Complications in 288 cases.

Variable	Number of cases	Percent (%)
TSIH	0	0
SSI	0	0
Hematoma	0	0
Seroma	0	0
Intestinal obstruction	0	0
Evisceration	0	0

TSIH= trocar site incisional herniation
SSI= surgical site infections

Table 4. Complications at Follow up Intervals in 158 cases.

Complication	Number of Complications	Percent (%)
TSIH at 1 week	1	0.0063
TSIH at 1 month	0	0
TSIH at 3 months	0	0
SSI at anytime	1	0.0063
Re-admissions	0	0

TSIH= trocar site incisional herniation
SSI= surgical site infections

Table 5. Pain scores with neoClose® at follow up intervals in 158 cases.

Time interval	Mean	Range	SD
1 week	0.47	0-8	1.28
4 weeks	0.14	0-7	0.75
12 weeks	0.07	0-4	0.07

SD= Standard deviation

Table 6. Pain scores with neoClose® at follow up intervals in the most common cases.

Procedure	Time interval	Mean	Range	SD
Laparoscopic cholecystectomy (n=47)	1 week	0.68	0-6	1.35
	4 weeks	0.21	0-3	0.69
	12 weeks	0.11	0-3	0.52
Laparoscopic vertical sleeve gastrectomy (n=30)	1 week	0.17	0-3	0.59
	4 weeks	0.10	0-3	0.55
	12 weeks	0	0-0	0
Laparoscopic fundoplication (n=21)	1 week	0.57	0-4	1.25
	4 weeks	0.33	0-4	0.89
	12 weeks	0.19	0-4	0.87
Laparoscopic inguinal hernia repair (n=20)	1 week	0.65	0-8	1.66
	4 weeks	0.40	0-6	1.57
	12 weeks	0.10	0-2	0.45
Laparoscopic appendectomy (n=13)	1 week	0.08	0-1	0.28
	4 weeks	0	0-0	0
	12 weeks	0	0-0	0

SD= Standard deviation