Surgical Endoscopy (2020) 34:1270–1276
https://doi.org/10.1007/s00464-019-06891-y

Trocar site closure with a novel anchor-based (neoClose®) system versus standard suture closure: a prospective randomized controlled trial

Pouya Iranmanesh[1] · Angielyn R. Rivera[1] · Kulvinder S. Bajwa[1] · Mustafa Alibhai[2,3] · Brad E. Snyder[1] · Todd D. Wilson[1] · Melissa M. Felinski[1] · Sheilendra S. Mehta[4] · Kavita D. Chandwani[1] · Connie L. Klein[1] · Peter A. Walker[5] · Shinil K. Shah[1,6] · Erik B. Wilson[1]

Received: 17 March 2019 / Accepted: 4 June 2019 / Published online: 10 June 2019

Abstract

Background Patients with obesity have a higher risk of trocar site hernia. The objective of the present study was to compare a standard suture passer versus the neoClose® device for port site fascial closure in patients with obesity undergoing laparoscopic bariatric surgery.

Methods This is a randomized, controlled trial with two parallel arms. Thirty five patients with BMI ≥ 35 kg/m^2 and undergoing laparoscopic sleeve gastrectomy or Roux-en-Y gastric bypass were randomized to each group. Port site fascial closure for trocars ≥ 10 mm was performed with the neoClose® device in the study group and the standard suture passer in the control group. Primary outcomes were time required to complete closure and intensity of postoperative pain at the fascial closure sites. Secondary outcomes were intraabdominal needle depth and incidence of trocar site hernia.

Results The use of the neoClose® device resulted in shorter closure times (20.2 vs 30.0 s, $p = 0.0002$), less pain (0.3 vs 0.9, $p = 0.002$) at port closure sites, and decreased needle depth (3.3 cm vs 5.2 cm, $p < 0.0001$) compared to the standard suture passer. There was no trocar site hernia at the one-year follow-up in either group.

Conclusions Use of the neoClose® device resulted in faster fascial closure times, decreased intraoperative needle depth, and decreased postoperative abdominal pain at 1 week as compared to the standard suture passer. These data need to be confirmed on larger cohorts of patients with longer follow-up.

Keywords Incisional hernia · Trocar hernia · Port closure

Trocar site herniation (TSH) is a relatively uncommon complication after laparoscopic surgery, with an overall incidence estimated between 0.5 and 5.2%. [1–3] However, the actual incidence is probably underestimated, since TSH can remain unnoticed and patients do not always seek medical attention. TSH can negatively impact a patient's quality of life and can lead to serious acute complications such as bowel strangulation and necrosis. Fascial closure for trocar sites ≥ 10 mm is recommended in the literature to decrease TSH occurrence. [3–5]

Patients with obesity have an overall higher risk of incisional hernias, secondary to increased abdominal pressure and a weaker abdominal wall as compared to non-obese patients. [6–8] In this patient population, anterior access to the abdominal musculo-fascial layers is challenging due to thick subcutaneous fatty tissue. Fascial closure is often performed under laparoscopic vision using a suture passing device (Carter-Thomason® (Cooper Surgical, Inc, Trumbull, CT, USA) or similar device). Significant postoperative abdominal pain has been described with this technique,

✉ Shinil K. Shah
shinil.k.shah@uth.tmc.edu

1 Department of Surgery, McGovern Medical School, University of Texas Health Science Center at Houston, 6431 Fannin Street, MSB 4.156, Houston, TX 77030, USA

2 Surgical Group of North Texas, Grapevine, TX, USA

3 Surgical Group of North Texas, Irving, TX, USA

4 Texas Laparoscopic Consultants, Houston, TX, USA

5 Health First Medical Group, Rockledge, FL, USA

6 Michael E. DeBakey Institute for Comparative Cardiovascular Science and Biomedical Devices, Texas A&M University, College Station, TX, USA

potentially due to bridging of the fascial edges, excessive fascial tension, and potential nerve entrapment. [9] Recently, the neoClose® device (Neosurgical, Newton, MA, USA) has been approved for port site fascial closure by the US Food and Drug Administration. [10] This device uses a different suture pattern to achieve full-thickness fascial closure using two absorbable anchors. A preliminary porcine study demonstrated less intramuscular migration of suturing material, decreased fibrotic reaction, and faster closure times with the neoClose® device, with no short-term occurrence of TSH. [11]

The objective of the present study was to compare the standard needle passer versus the neoClose® device for port site fascial closure in patients with obesity undergoing laparoscopic bariatric surgery. The primary hypotheses were that the neoClose® device, as compared to standard sutured closure, would result in shorter closure times and less postoperative abdominal pain at port sites requiring primary fascial closure.

Materials and methods

Trial design and registration

The study was an interventional, single-blind, randomized trial with 2 parallel arms, conducted at the McGovern Medical School at University of Texas Health Science Center at Houston and Memorial Hermann—Texas Medical Center (Houston, TX, USA) between February 2016 and April 2018. Institutional Review Board approval of the study protocol was obtained prior to study initiation. The study was registered on the ClinicalTrials.gov website (NCT02589171).

Participants

Inclusion criteria for the study included patients ≥ 18 years of age with a body mass index (BMI ≥ 35 kg/m^2) who had undergone preoperative evaluation (esophagogastroduodenoscopy, nutritional and psychological evaluation and clearance, preoperative labs, preoperative weight loss, and medical and anesthesia clearance) and were scheduled for primary weight loss surgery (sleeve gastrectomy (SG) or Roux-en-Y gastric bypass (REYGB)).

Exclusion criteria included previous midline laparotomy, previous weight loss surgery, previous history of abdominal incisional hernia, intraoperative conversion to laparotomy, positive pregnancy test for female patients, and incapacity or refusal to give informed consent. Additionally, for patients undergoing sleeve gastrectomy, patients were excluded if they required dilation of the trocar site used for specimen extraction. Patients were recruited during their preoperative clinic visit by the research coordinator of the seven participating surgeons who participated in the study.

Interventions

In both control and intervention groups, patients underwent either multi-port robot-assisted laparoscopic SG or REYGB, performed by one of seven board-certified surgeons. All surgeons have received extensive training in minimally invasive laparoscopic robotic primary and revisional bariatric surgery, serve as training faculty of the UT Health McGovern Medical School minimally invasive surgery fellowship program, and meet the criteria as a proctor for robotic surgery. The operative technique for both procedures was standardized. For SG procedures, three 5-mm robotic trocars, a 12-mm camera trocar, and a 15-mm assistant/stapling/specimen extraction port were utilized. For REYGB procedures, two 5-mm trocars and one 8-mm robotic trocar, a 12-mm camera trocar, and a 15-mm assistant/stapling port were utilized. Our technique for robotic SG and REYGB has been published previously. [12]

In the control group, a traditional suture passer (Fig. 1) was used to place a 0 Vicryl suture across the fascial defects of the 12- and 15-mm port sites under direct vision. The peritoneal cavity was then desufflated and the suture was then tied extracorporeally. In the study group, a neoClose® port site closure device was used (Fig. 2) to close the 12 and 15 mm ports. Two small absorbable anchors attached to sutures and preloaded on drivers were passed through the abdominal wall using the guiding tract provided by the neoClose® trocar. These anchors were deployed intraperitoneally on both sides of the incision under direct vision. The peritoneal cavity was then desufflated and the sutures were tied together extracorporeally. In both groups, the surgeon determined the number of sutures needed to achieve port site closure, which was defined as the inability to palpate a fascial defect and the absence of intraabdominal CO2 leaking through the fascial incision.

Postoperative pain management

Patients in both arms received local anesthetics at all port sites during surgery and were given acetaminophen–codeine elixir and/or tramadol for pain control during the postoperative period.

Collected data, outcomes, and follow-up

During each procedure, an independent examiner recorded the time needed to achieve port site closure. In addition, a blinded systematic postoperative video review was performed to assess the depth of needle exposure and verify closure times. Follow-up visits were scheduled at 1 and

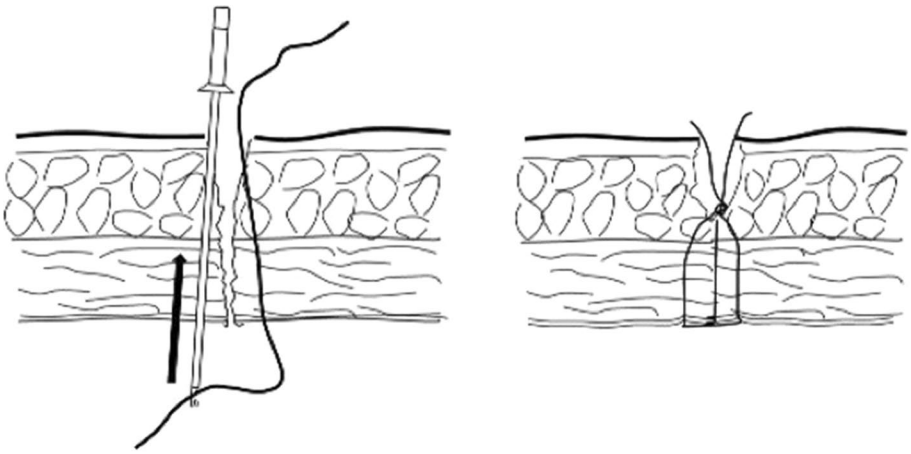

Fig. 1 Closed loop full-thickness closure

6 weeks as well as 1 year after surgery. Patients assessed their pain level using a visual analog scale on the first postoperative day and on each follow-up visit. To detect incisional hernias, a clinical examination and abdominal ultrasound was performed at each follow-up visit. The postoperative visits and ultrasound were all conducted by a surgeon blinded to the type of closure performed. Data collection was performed by research staff blinded to the method of fascial closure. Primary outcomes were time required to complete closure and intensity of pain at the fascial closure sites. Secondary outcomes were maximal needle depth during fascial closure and incidence of port site hernia.

Sample size

Based on the results of a preclinical porcine study [11] which showed average closing times of 18.2 s for the neoClose® device versus 32.5 s for the standard suture passer, in order to detect a similar difference in closure times when using a 2-sided alpha of 0.05 and a statistical power of 0.8, a sample size of 30 patients was required in each group. To compensate for a potential drop-out rate of 10%, 35 patients were included in each group.

Randomization and blinding

The randomization sequence was created using block randomization in sets of five. Allocation was performed upon induction of anesthesia using opaque, sealed envelopes, using a 1:1 ratio. Surgeons could not be blinded to the type of closure for obvious technical reasons. Patients, care providers, investigators, data collectors, and outcome assessors were blinded to the closure technique.

Statistical analysis

Comparison of primary and secondary outcomes between groups were done using an intention-to-treat analysis using Fisher's exact test and Mann–Whitney *U* test for discrete and continuous variables, respectively. Two-sided *p* values ≤ 0.05 were considered statistically significant. Analyses were performed using SPSS software (IBM, Armonk, NY, USA).

Results

Recruitment and follow-up

The CONSORT diagram is shown in Fig. 3. A total of 70 patients (35 patients in each arm) were recruited. In both arms, all patients received the allocated procedure and their data were analyzed for primary and secondary outcomes. A week after surgery (first follow-up visit), one patient in the control group who had undergone SG opted to leave the study (1/70, 1.4%). Six weeks after surgery (second follow-up visit), 7 patients in the study group (1 SG and 6 REYGB and 5 patients in the control group (4 SG and 1 REYGB) were lost to follow-up (12/70, 17.14%). A total of 23 patients in the study group (8 SG and 16 REYGB) and 24 patients in the control group (12 SG and 12 REYGB) were lost to follow-up after 1 year (47/70, 67.14%). There was no significant difference in drop-out rates when considering intervention (neoClose® versus standard device) or type of surgery (REYGB versus SG). Except the single patient who opted out of the study, all other patients were lost to follow-up because they either were unreachable or declined follow-up visits.

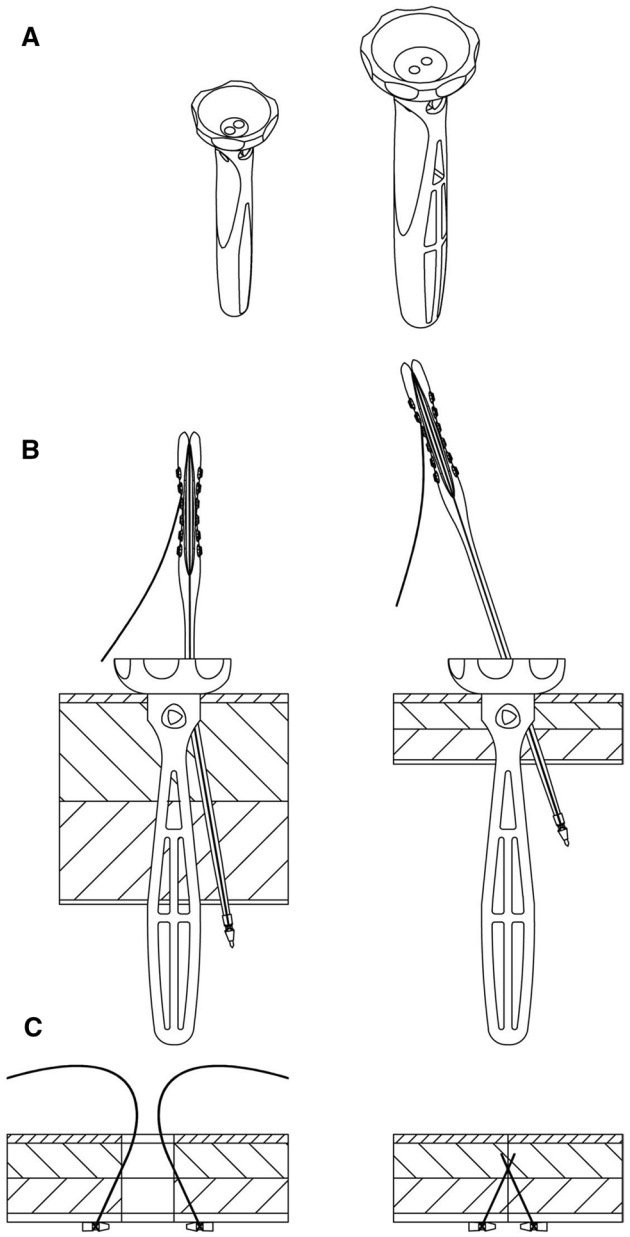

Fig. 2 **a** Special neoClose® trocars with guiding channels. **b** Diagram of the anchor drivers passing through guide. **c** Diagram of fascial closure without closed loop suture using anchors

Demographic and procedure data

Table 1 shows patients baseline data. There was no significant difference between groups regarding gender, age, BMI, and type of surgery. Overall, SG was performed for 34 patients (17 patients in each group) and REYGB for 36 patients (18 in each group).

Outcomes

Results of all primary and secondary outcomes are presented in Table 2. Closure time was significantly shorter for patients in the study group (mean time 20.2 vs 30.0 s, $p = 0.0002$). There was no statistically significant difference in mean pain scores between the two groups on the first postoperative day. During the 1-week follow-up visit, patients in the study group reported significantly less pain than those in the control group (0.3 vs 0.9, $p = 0.002$). At that time, 7/35 patients were still taking acetaminophen-codeine elixir or tramadol in the study group, versus 16/35 in the control group (20% versus 45.7%, $p = 0.04$). At the 6-week follow-up visit, the mean pain score in both groups was 0, with one patient in the control group still taking acetaminophen as needed. Mean needle depth was significantly greater when using the standard suture passer device (5.2 cm vs 3.3 cm, $p < 0.0001$). Performing subgroup analyses according to surgical procedure (SG versus REYGB) did not modify these results. Among the 23 patients who completed their 1-year follow-up visit, no incisional hernia was seen at port closure sites on clinical examination or abdominal ultrasound.

Discussion

The results of this trial demonstrate that in patients undergoing primary robotic-assisted laparoscopic weight loss surgery, the neoClose® device significantly decreased closure time, depth of needle penetration, and self-reported port site pain at one week after surgery. The shorter closure times with the neoClose® device are most likely linked to the design of the device, in which guiding channels facilitate placement of the anchors through the fascia. With the standard suture passer, multiple maneuvers are required to complete the looped closure of the fascia; this frequently requires the surgeon to work against the camera which can be technically difficult and time consuming. It is important to note that the mean closure times reported with the standard suture passer in this study (30 s) is far below what is frequently reported in the literature, and likely related to the advanced laparoscopic training and skill set of the participating surgeons. In the hands of highly experienced laparoscopic surgeons, there was still noted to be a significant decrease in time with the use of the neoClose® device. The differences in closure time are likely to be accentuated when comparing surgeons with less advanced laparoscopic experience.

Immediate postoperative pain scores were similar for both closure techniques, but patients had significantly less pain at the 1-week follow-up in the neoClose® device group. At that time, there were significantly fewer patients using acetaminophen-codeine elixir or tramadol in the study group. This

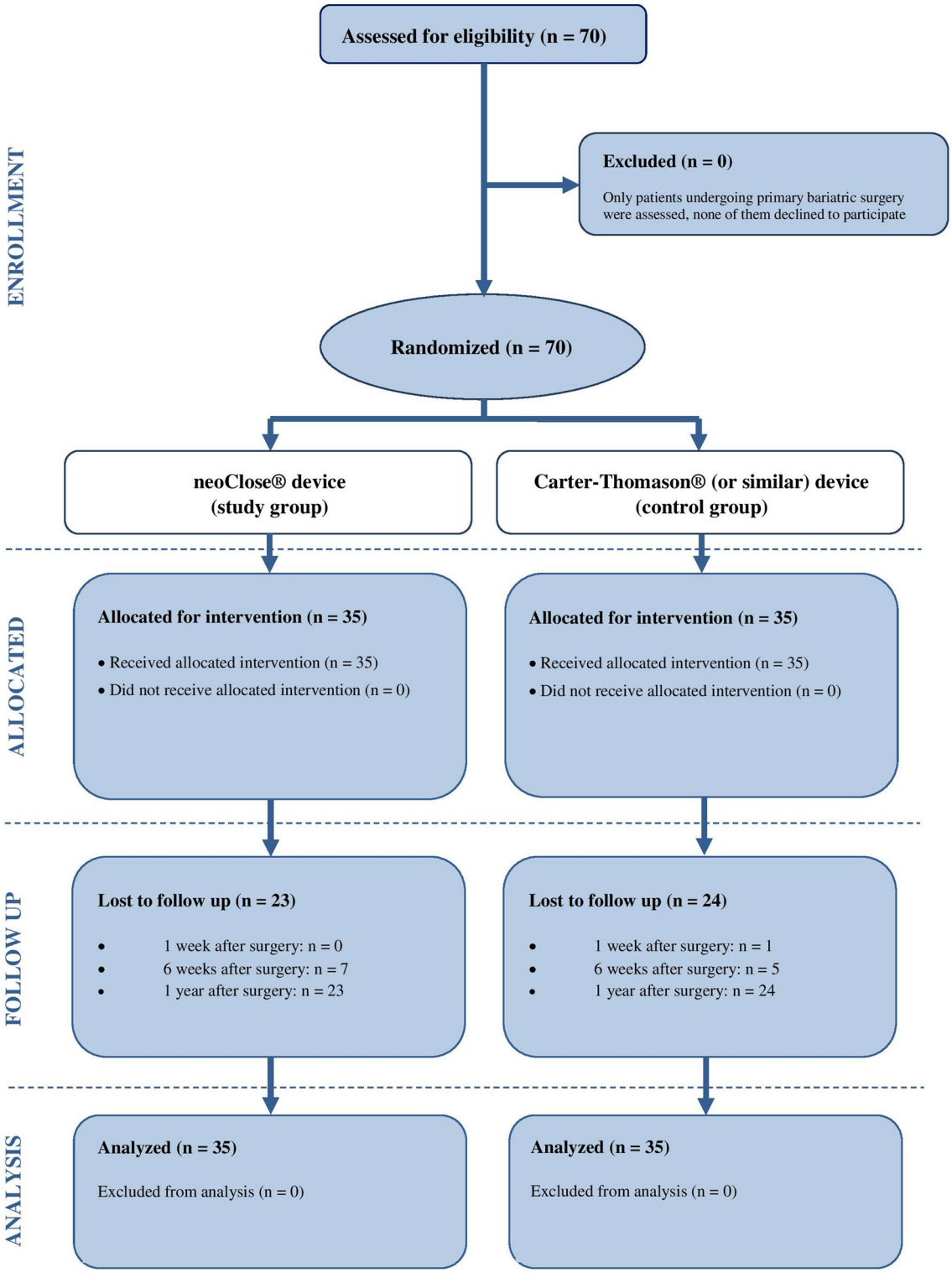

Fig. 3 Flow diagram according to CONSORT 2010 recommendations

delayed difference could be due to the systematic use of local anesthetics at port sites during surgery, which might have covered a potential difference in pain levels between groups for the first 24 h postoperatively. The suturing pattern obtained with the neoClose® device has been shown to diminish the tension on the incision edges as well as

Table 1 Baseline data

	Study group ($n=35$)	Control group ($n=35$)
Women-to-men ratio, ratio (n:n)	5:2 (25:10)	5:2 (25:10)
Age, mean (±SD), years	46.3 (±12.5)	43.6 (±12.4)
Preoperative BMI, mean (±SD), kg/m^2	44.5 (±7.9)	47.0 (±10.0)
Type of surgery, *n*		
Sleeve gastrectomy	17	17
Roux-en-Y gastric bypass	18	18

SD standard deviation, *BMI* body mass index

Table 2 Primary and secondary outcomes

	Study group ($n=35$)	Control group ($n=35$)	*p* value	Statistical test
Primary outcomes				
Closure time, mean (±SD), s	20.2	30.0	0.0002	MW
Intensity of pain on VAS, mean (±SD), *n*				
Postoperative day 1	0.8 (±1.6)	0.8 (±1.9)	0.87	MW
1-week follow-up	0.3 (±0.8)	0.9 (±1.4)	0.002	MW
6-week follow-up	0.0 (±0.0)	0.0 (±0.3)	0.33	MW
Secondary outcomes				
Maximal needle depth, mean (±SD), cm	3.3	5.2	<0.0001	MW
Incisional hernia at port site, *n*	0	0	0.99	F

SD standard deviation, *VAS* visual analog scale, *MW* Mann–Whitney U test, *F* Fisher's exact test

the intramuscular migration of suturing material in animal models [11], and the absence of a suture loop is thought to potentially result in less ischemia and possible lower likelihood of trapping nerve endings in the tied suture. These elements may potentially help to explain decreased overall pain scores and lower pain medication consumption. This difference faded away at the 6-week follow-up, with virtually all patients in both groups reporting no pain, suggesting a low rate of chronic pain in this particular study population.

Although both closure techniques are performed under direct laparoscopic vision, the greater intraperitoneal needle depth required when using the standard suture passing device may increase the risk of iatrogenic visceral injuries, which can sometimes go unnoticed and lead to disastrous postoperative complications. The shallower and oblique trajectory of the neoClose® anchor drivers may help to increase safety when performing fascial closure.

No patients in either group were diagnosed with an incisional hernia on clinical or ultrasonic examination after 1 year of follow-up. However, as this was not an endpoint, this trial was not sufficiently powered to reveal a potential difference between groups.

This study has several limitations. First, the number of enrolled patients was too small to stratify patients according to potential risk factors for TSH, such as associated diabetes mellitus or extreme BMI levels. Excluding patients requiring trocar site dilation for partial stomach removal during SG is another potential limitation. However, since these dilated sites usually require additional transfascial sutures, including these patients could have generated a bias when comparing pain levels. The authors therefore opted to exclude these patients in order to have comparable fascial closure lengths (15 mm and 12 mm) in all patients. In addition, assessing pain levels with a more refined tool than the visual analog scale, such as a quality of life questionnaire or a hernia-specific pain assessment tool, could have revealed more subtle pain level differences among groups. As mentioned in the previous paragraph, even though nearly all patients were seen at the 1-week follow-up visit, the drop-out rates were very high thereafter, especially for the 1-year visit (67%), despite several reminders and phone calls to patients. Although exact reasons remain unclear, the insurance reimbursement system (follow-up visits free of additional charges only up to 90 days after surgery) may have negatively influenced patient compliance. Additionally, there is historically a low rate of long-term follow-up in the post-weight loss surgery patient population. [13] The primary outcomes of this study, however, remained most likely unaffected by these high drop-out rates, because closure times and pain scores on postoperative day 1 and 7 were obtained for nearly all patients. Since almost all patients were pain-free at the 6-week follow-up visit, the 17% drop-out rate is thought less likely to have biased the results.

Although it is a reasonable criticism that the primary outcome of the study should have been incidence of incisional hernia, this would have required a substantially higher number of recruited patients and study budget, which was not feasible for this pilot randomized trial. Additionally, the objective of this study was to analyze intraoperative and immediate postoperative outcomes regarding the use of two different fascial closure devices after laparoscopy. Further studies evaluating long-term outcomes of this and other novel fascial closure systems are warranted.

In conclusion, this trial showed that the use of the neoClose® port site closure device resulted in faster fascial closure times, decreased intraoperative needle depth, and decreased postoperative abdominal pain at 1 week as compared to the standard suture passer. Larger randomized controlled trials with longer follow-up times are required to analyze a potential difference in other important outcomes such as incidence of delayed TSH.

Acknowledgements This research was supported by a research grant from Neosurgical (Newton, MA, USA). Neosurgical did not participate in data analysis, interpretation, or the writing of this manuscript.

Funding This research was supported by a research grant from Neosurgical (Newton, MA, USA).

Compliance with ethical standards

Disclosures Mustafa Alibhai, MD: Honoraria from Intuitive Surgical (Educational); Brad E. Snyder, MD: Honoraria from Intuitive Surgical (Proctor); Todd D. Wilson, MD: Consultant for Bard, EndoEvolution, and Olympus; Sheilendra S. Mehta, MD: Honoraria from Intuitive Surgical (Proctor); Peter A. Walker, MD: Research grant funding from Neosurgical; Shinil K. Shah, DO: Honoraria from Gore and C-SATS, and Research grant funding from Medigus and Intuitive Surgical; Erik B. Wilson, MD: Teaching honoraria from Intuitive Surgical, Olympus, Gore, Apollo, and Ethicon. Pouya Iranmanesh, MD; Angielyn R. Rivera; Kulvinder S. Bajwa, MD; Melissa M. Felinski, DO; Connie L. Klein, NP; and Kavita D. Chandwani, MD, DrPH have no conflict of interests or financial ties to disclose.

References

1. Erdas E, Dazzi C, Secchi F, Aresu S, Pitzalis A, Barbarossa M, Garau A, Murgia A, Contu P, Licheri S, Pomata M, Farina G (2012) Incidence and risk factors for trocar site hernia following laparoscopic cholecystectomy: a long-term follow-up study. Hernia 16(4):431–437. https://doi.org/10.1007/s10029-012-0929-y
2. Helgstrand F, Rosenberg J, Bisgaard T (2011) Trocar site hernia after laparoscopic surgery: a qualitative systematic review. Hernia 15(2):113–121. https://doi.org/10.1007/s10029-010-0757-x
3. Muysoms FE, Antoniou SA, Bury K, Campanelli G, Conze J, Cuccurullo D, de Beaux AC, Deerenberg EB, East B, Fortelny RH, Gillion JF, Henriksen NA, Israelsson L, Jairam A, Janes A, Jeekel J, Lopez-Cano M, Miserez M, Morales-Conde S, Sanders DL, Simons MP, Smietanski M, Venclauskas L, Berrevoet F, European Hernia S (2015) European Hernia Society guidelines on the closure of abdominal wall incisions. Hernia 19(1):1–24. https://doi.org/10.1007/s10029-014-1342-5
4. Swank HA, Mulder IM, la Chapelle CF, Reitsma JB, Lange JF, Bemelman WA (2012) Systematic review of trocar-site hernia. Br J Surg 99(3):315–323. https://doi.org/10.1002/bjs.7836
5. Tonouchi H, Ohmori Y, Kobayashi M, Kusunoki M (2004) Trocar site hernia. Arch Surg 139(11):1248–1256. https://doi.org/10.1001/archsurg.139.11.1248
6. Owens M, Barry M, Janjua AZ, Winter DC (2011) A systematic review of laparoscopic port site hernias in gastrointestinal surgery. Surgeon 9(4):218–224. https://doi.org/10.1016/j.surge.2011.01.003
7. Sugerman HJ, Kellum JM Jr, Reines HD, DeMaria EJ, Newsome HH, Lowry JW (1996) Greater risk of incisional hernia with morbidly obese than steroid-dependent patients and low recurrence with prefascial polypropylene mesh. Am J Surg 171(1):80–84. https://doi.org/10.1016/S0002-9610(99)80078-6
8. Lee DY, Rehmani SS, Guend H, Park K, Ross RE, Alkhalifa M, McGinty JJ, Teixeira JA (2013) The incidence of trocar-site hernia in minimally invasive bariatric surgery: a comparison of multi versus single-port laparoscopy. Surg Endosc 27(4):1287–1291. https://doi.org/10.1007/s00464-012-2597-5
9. Shin JH, Howard FM (2012) Abdominal wall nerve injury during laparoscopic gynecologic surgery: incidence, risk factors, and treatment outcomes. J Minim Invasive Gynecol 19(4):448–453. https://doi.org/10.1016/j.jmig.2012.03.009
10. (2014). https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142903.pdf. Accessed 7 Mar 2019
11. Walker PAS SK, Wilson EB (2016) Preclinical study evaluating a novel trocar site closure system. Open Access Surg 9:29–35
12. Shah SK, Walker PA, Snyder BE, Wilson EB (2015) Essentials and future directions of robotic bariatric surgery. In: Kroh MCS (ed) Essentials of robotic surgery. Springer, Switzerland, pp 73–80
13. Poole NA, Al Atar A, Kuhanendran D, Bidlake L, Fiennes A, McCluskey S, Nussey S, Bano G, Morgan JF (2005) Compliance with surgical after-care following bariatric surgery for morbid obesity: a retrospective study. Obes Surg 15(2):261–265. https://doi.org/10.1381/0960892053268499