Randomized Trial Evaluating Effectiveness of neoClose®Abdominal Closure Device versus Carter-Thomason® Needle Passer

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Version 6

SYNOPSIS

Study Title	Randomized Trial Evaluating Effectiveness of neoClose® Abdominal Closure Device versus CarterThomason® Needle Passer
Trial Design	A randomized trial intended to compare neoClose® abdominal closure versus standard Carter- Thomason® closure in a bariatric surgery gastric bypass and sleeve gastrectomy population. The primary objective of the study is to compare the technical effectiveness of the devices. A secondary outcome will be analysis of pain scores associated with the distinct closures. The study will be by a group of 6 Bariatric / General Surgeons at a high volume academic institution. Patients will be randomized upon induction of anesthesia and blinded to the closure technique performed. Video analysis of technical effectiveness will be performed as well as clinic follow up at 1 week ,6 weeks and 1 year after the procedure to assess pain scores. In addition, an abdominal ultrasound will be completed at 6 weeks and 1 year to evaluate the incidence of port site hernia.
Procedure	Both devices will be used to close 12 mm camera and stapler port sites upon completion of a robotic assisted laparoscopic gastric bypass and sleeve gastrectomy. The procedure requires a 12 mm port be placed in the midline approximately 3 cm cephalad to the umbilicus and a second in the right mid abdomen. Port sites will be closed as defined as the inability to palpate a fascial defect .

Study Population	Adults aged 18-70 years with BMI > 35 that have completed a multimodality bariatric workup (EGD, nutrition evaluation and psychological evaluation) and selected to have an elective gastric bypass and sleeve gastrectomy. Subjects who fail to complete extensive pre-operative work up including endoscopic surveillance, nutrition visit, psychological clearance will be excluded from the study. A pregnancy test will be done on female subjects as part of Standard of care. There will be 35 patients per group. A power analysis was completed using the data derived from our preclinical porcine study using primary endpoint of time (32 seconds for Carter- Thomason® and 18.5 seconds for neoClose®). The alpha utilized was 0.05. A total of 70 patients will be screened for the study.
Assessments	The study will allow for the evaluation of technical effectiveness and analysis of pain scoring: Technical Effectiveness • Number of sutures required to complete closure. • Time required to complete closure. • Depth of needle penetration to complete closure. • Evaluate for surgical site occurrences immediately post op as well as at 1 ,6 weeks and 1 year after closure procdure. • Evaluation for port site hernia at 6 weeks with abdominal ultrasound. Pain Evaluation • Visual analog pain scale will be used to assess pain at both port sites. • Amount of intravenous narcotics required during hospitalization. • Hospital stay duration. The study will allow for assessment of pain scores during hospitalization and at follow up visits approximately 1 week ,6 weeks and 1 year.
Data Collection	During the procedure, an independent examiner will record the amount of time and number of suture passes to obtain port site closure. In addition, an independent review of video from each procedure will be completed to record the time and depth of needle exposure. Patients will fill out pain analog scores

	during hospital stay and follow up visits. Care givers on the floor and in clinic will be blinded to the closure technique. Hospital records will be reviewed to record narcotic requirements.

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A. RATIONALE

Laparoscopic surgery requires the utilization of multiple ports with varying diameters. In the bariatric population, gastric bypass and sleeve gastrectomy requires 12 mm port placement for camera and stapler insertion. Many surgeons favor closure of the fascial defect in order to decrease the risk of hernia occurrence. Various type of port closure is available. The most popular closure device is the Carter-Thomason® needle. This device has inherent limitations:

(1) Insertion of the needle is associated with injury to the viscera and blood vessels.

(2) The width of the suture placed using the Carter-Thomason® needle can lead to compression of peritoneum and entrapment of underlying nerves, causing post-operative port site pain.

(3) Placement of the suture is challenging in the obese patient. [1]

Very few studies have been completed to compare novel devices to the Carter- Thomason® with equivocal data. [2][3]

Current practice requires fascial closure with a suture passing needle which passes the suture material through some amount of subcutaneous tissue, muscle, and fascia. This technique is often associated with elevated levels of discomfort which can remain weeks after the operation is complete. In addition, the technique of port site closure can be difficult to learn leading to prolonged times potential needle exposure to underlying viscera as well as times for port site closure.

The development of a novel closure device which relies upon the guided deployment of suture / fasteners could help improve the learning curve associated with port site closure. In addition, such a technique that would not require passage of suture material through adjacent muscle and isolated the posterior fascia could lead to an improvement in patient satisfaction secondary to a decrease in pain.

The neoClose ® device is an abdominal closure device that has been approved by the FDA in 2013 (510K) to use as such. The study aims to add to the existing knowledge about these kinds of devices and also to evaluate the effectiveness of the neoClose® device compared to the Carter-Thomason® device. Moreover, surveys will also be administered to patients using the Visual Analog Scale of pain to establish pain scores associated with individual closures.

B. STUDY DESIGN AND PROCEDURE

Patient Allocation

This is a randomized study consisting of 35 patients. This site will be the only site across the US doing the study. On the morning of the procedure, qualified subjects who were consented for the study will be randomized to fascial closure with either the neoClose® device or a Carter-

Thomason® suture passer. The floor team and the subjects will be blinded to the closure technique.

Small Pouch Gastric Bypass
Our model will include patients having robotic assisted gastric bypass. Briefly, the procedure involves the placement of 6 total trocars. Two large trocars (12 mm port placed 3 cm cephalad to the umbilicus and a 12 mm port in the right mid clavicular line) undergo fascial closure at the completion of the case. The dissection is started by making a small proximal gastric pouch with a linear stapler. A hand sewn gastrojejunostomy is then created approximately 50 cm distal to the ligament of Treitz. The small intestine is divided and then a 150 cm roux limb is created and a small bowel anastomosis is completed. No local anesthetic will be utilized in the study patients in order to avoid compounding variable to the assessment of pain scores.

Sleeve Gastrectomy
Patients having robotic assited sleeve gasterectomy will also be in the study. For this procedure, the same number of trocers and same locations will utilized. The stomach is visualized and fully mobilized. Sleeve gastrectomy is achieved with a linear stapler. The stomach is removed from the 15- mm port site in the right upper quadrant. Similar to the gastric bypass study patients, local anesthesia will not be used to avoid compounding variable in pain assessment.

Port Site Closure
Either the neoClose® device with provided suture/fasteners or a Carter- Thomason® suture passer with 0 Vicryl will be used to close the port sites. The port sites will be considered closed when no fascial defect can be palpated.

Data Collection
An autonomous recorder will document the number of sutures required to close each port site as well as the time required to obtain closure during the procedure. A video will be created of each procedure followed by careful analysis of the film by an independent reviewer to record the time of needle exposure to the abdominal cavity as well as depth of needle passage.

Each patient will be placed upon a Dilaudid pain pump immediately after the procedure and transitioned to oral narcotics upon initiation of liquid diet. Analog pain scoring will be completed on each hospital day as well as clinic visits approximately 1 ,6 weeks and 1 year after the operation. In addition, after patient discharge, the amount of narcotics required during hospitalization will be recorded. An abdominal ultrasound will be completed at 6 weeks and 1 year after the operation to evaluate the incidence of trocar site hernias.

The data will be stored on a password protected UT supplied computer in Excel files by MRN and without names. Upon analysis of the data, the MRN will be deleted thereby erasing all potential patient identifiers.

Data Analysis

Data will be analyzed using a simple T test within the Excel program as there will be only two groups with a single variable between them. Post Hoc analysis will not be required as with ANOVA secondary to the lack of a third group.

C. DEVICE USE AND TRAINING

Instructions for Use

A description of the neoClose® system and its components, intended use, technical details, warnings, precautions, and procedural steps will be provided to all users in the Instructions for Use. To operate the system, the operator must read the IFU and be fully trained and acquainted with the operation and function of each part of the system. To demonstrate the ease of product utilization, no prior large animal training will be required.

D. STUDY OBJECTIVES

Primary Outcome Measure

To compare technical effectiveness of neoClose® device versus classic Carter- Thomason® suture passer. This will completed by comparing:

- Time required to complete port closure.
- Number of sutures required to complete port closure.
- Time needle is within abdominal cavity.
- Depth of needle into the abdominal cavity.
- Evaluation of surgical site occurrences.
- Evaluation of trocar site hernia incidence with abdominal ultrasound.

Secondary Outcome Measures

- Comparison of perioperative and post operative pain via visual analog scoring while in the hospital and at follow up appointments 2 ,6 weeks and 1 year after discharge.
- Comparison of narcotic requirements during hospitalization.
- Comparison of hospital stay duration.

E. STUDY GUIDELINES

Patient Population

Subjects will be patients aged 18-70 that have been evaluated by a multimodality team including a surgeon, nutritionist, and psychiatrist then scheduled for a robotic assisted gastric bypass and

sleeve gastrectomy. Once surgery has been approved patient will be considered for the study if they have no prior history of midline laparotomy and are having a de novo gastric operation.

F. CLINICAL EVENTS

Risks

Risks to the patient are the same as the baseline procedure with Carter- Thomason® - visceral injury, hematoma, hernia, pain. There is no foreseeable additional risk when using the neoClose® device over the baseline treatment.

Adverse Events (AEs)

AEs clinically relevant to the patient will be recorded from the perioperative period through the sick week follow up period.

The following is a non-comprehensive list of possible adverse events:

- Hematoma or bleeding at port site.
- Iatrogenic visceral injury during port closure.
- Seroma at port site.
- SSI at port site.

G. ETHICAL AND REGULATORY CONSIDERATIONS

Confidentiality

Data that will be gathered for the study will be de-identified to protect patient information. Research charts and video recordings would be stored in a room under lock and key. No identifying markers would be included in the video recording of subjects in the study. Only the PI and designated staff would have access to the charts and video recordings. The video recordings will be kept for a maximum of 3 months to give ample time for review and analysis. The video recording will then be disposed in a manner that is according to UTHealth policy. Electronic security measures would also be taken. These are all done to minimize the inherent risk of breach of confidentiality.

Informed Consent

The background, purpose and potential risks and benefits of the proposed study will be explained to each subject under the care of the investigator. Subjects will be informed of their right to withdraw from the study at any time and for any reason without sanction, penalty, or loss of benefits to which the subject is otherwise entitled, and that withdrawal from the registry will not jeopardize their future medical care.

References

1. Shetty A, Adiyat K. Comparison between hand suture and Carter-Thomason® needle closure of port sites in laparoscopy. Urology J. 2014;11:1768-71.

2. Del Junco M, Okhunov Z, Juncal S, Yoon R, Landman J. Evaluation of a novel trocar-site closure and comparison with a standard Carter-Thomason® closure device. J Endourol. 2014;28:814-818.

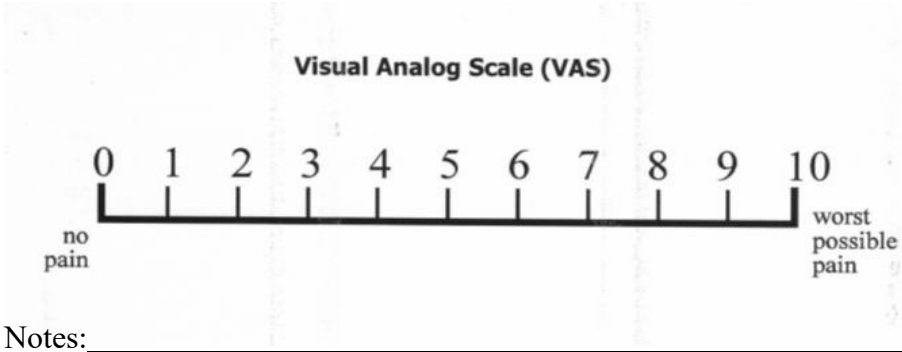
3. Guan X, Zurawin RK. Comparison of neat Stitch and Carter-Thomason® Trocar Port Closure Techniques. J Min Invasive Gynecology. 2011;19:175.

APPENDIX 1

Post Operation Data Form (Day1)

Study ID:	**Date:**
Date of Surgery:	**Duration of Surgery (min):**
No. of sutures to complete suture:	**Duration to complete closure:**
Length of Hospital Stay:	

Pain Medication (in Hospital) and dosage:_____
Pain Evaluation:



Notes:_____
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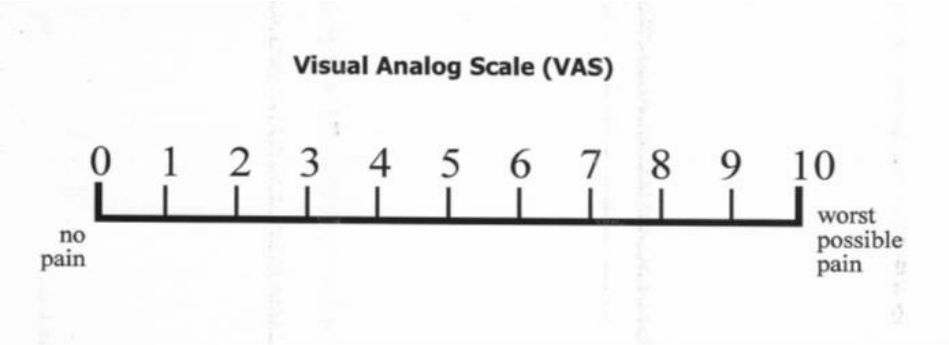
Follow-up Visit Data Form

Study ID:	**Date:**
Date of Surgery:	**Follow up visit no. :**

Pain Medication and dosage:_____
Pain Evaluation:



Notes:_____
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