The Role of the Robotic Platform in Inguinal Hernia Surgery

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INTRODUCTION

Inguinal hernia repair is the most commonly performed general surgery procedure in the United States.[1,2] Despite the prevalence of this procedure, there is no consensus regarding the optimal approach to this surgical procedure.[2] Since the advent of the laparoscopic inguinal hernia repair in 1990, there is a growing body of research that has investigated the efficacy of this minimally invasive surgical approach. To date, the laparoscopic approach to inguinal hernia repair has proven beneficial in reducing post-operative pain and allowing for earlier return to normal activity versus the traditional open inguinal hernia repair.[1-4] In addition, the laparoscopic approach to inguinal hernia repair has been advocated for recurrent inguinal hernia repairs and bilateral inguinal hernia repairs.[2]

Despite these advantages, however, there are several limitations of the laparoscopic inguinal hernia repair. Specifically, unstable camera platforms, two-dimensional imaging, rigid laparoscopic instruments, and poor surgeon ergonomics make the laparoscopic approach to inguinal hernia repair challenging.[5] Furthermore, the learning curve associated with a laparoscopic inguinal hernia repair has been prohibitive for many surgeons. Finally, the laparoscopic approach to inguinal hernia repair often requires the utilization of some form of fixation device, such as surgical tacks, which have been associated with chronic pain, vascular injury, as well as increased overall cost of the operation.[5-6] The robotic platform has been shown to help compensate for many of these short-comings of laparoscopic surgery as it provides three-dimensional imaging, improved instrument mobility, articulation, suturing capability (which allows for a more cost-effective procedure with decreased risk of post-operative chronic pain), and surgeon comfort.[5] Because of these reasons, it is important to determine the specific advantages the robotic approach will provide for inguinal hernia repairs.

The laparoscopic approach to inguinal hernia repair has proven beneficial in reducing post-operative pain and earlier returns to normal activity versus the traditional open inguinal hernia repair.[1-4] However, the overall penetrance of laparoscopic inguinal hernia repair has remained consistently below 20% of all inguinal hernia procedures performed in the United States.[1] The robotic platform provides several potential advantages over the laparoscopic inguinal hernia repair including three dimensional visualization, the ability to suture (rather than tack) the mesh, as well as the ability to suture the peritoneal defect closed. This technological platform could provide earlier adoption and proficiency for surgeons to perform a minimally invasive inguinal hernia repair with improved surgical outcomes. As more general surgeons begin to incorporate robotic surgery into their practice, the robotic platform might provide further improvements in the outcomes of minimally invasive inguinal hernia repair over even traditional laparoscopic inguinal hernia repair.

We propose a Randomized Clinical Trial comparing the robotic versus laparoscopic inguinal hernia repair techniques. We hypothesize that the robotic approach to inguinal hernia repair will result in improved post-operative outcomes compared to traditional laparoscopic inguinal hernia repairs.

Specific Aim #1: To determine if the robotic approach will result in a significant reduction in postoperative pain and earlier return to full function when compared to a laparoscopic inguinal hernia repair.

Specific Aim #2: To perform a cost analysis to determine the financial implications of performing a robotic versus a laparoscopic inguinal hernia repair.

Specific Aim #3: To determine the effect of surgeon reported ergonomics when performing laparoscopic versus robotic inguinal hernia repairs.

Specific Aim #4: Evaluate the long term hernia recurrence rates associated with laparoscopic versus robotic inguinal hernia repairs.

Specific Aim #5: Evaluate the cosmetic results of both surgical approaches.

STUDY DESIGN

A total of 100 patients will be enrolled in our study, 50 of whom will be randomized to standard laparoscopic inguinal hernia repair and 50 to robotic inguinal hernia repair. Patients will be blinded to their surgical procedure until they withdrawal their participation from the trial or they complete the two-year follow-up. Given the absence of any prior published data to appropriately perform a power calculation, we propose a pilot study to allow us to provide the first ever head-to-head comparison of laparoscopic versus robotic inguinal hernia repairs. There will be six sites performing the operation, including Cleveland Clinic, Virginia Commonwealth University, Mount Sinai Hospital, Washington University in St. Louis Medical Center, New Hanover Regional Medical Center, and Greenville Health System. All participating surgeons will be required to have performed a minimum of 25 robotic and 25 laparoscopic procedures in order to be eligible to participate. This will be a competitively enrolled trial, with each site capped at a maximum enrollement of 20 patients. All operations will be performed using the transabdominal pre-perionteal approach (TAPP). Patients will be randomized to one treatment group at the time of preoperative evaluation based on preoperative VAS pain scores. Patients in each cohort will be matched for age, gender, body mass index (BMI), and medical comorbidities in order to minimize confounding variables. Outcomes of interest to be investigated include post-operative pain, post-operative recovery period, cost, surgeon ergonomics, and recurrence.

Specific patient inclusion criteria include patients aged 21 years or older with no prior open abdominal surgery, presenting for primary or recurrent unilateral inguinal hernia repair, no previous preperitoneal mesh placement, with a BMI less than or equal to 40kg/m^2. Specific patient exclusion criteria include the need for an open inguinal hernia repair, patients presenting for evaluation of bilateral inguinal hernias, patients with previous open abdominal surgery at or below the umbilus, patients with previous preperitoneal mesh placement, patients requiring surgical repair of a strangulated inguinal hernia, patients with liver disease defined by the presence of ascites, patients with end-stage renal disease requiring dialysis, and patients who are unable to give informed consent.

Baseline patient demographics will be obtained at initial patient recruitment. All questionnaires will be filled out following patient recruitment for baseline comparison. Operative details will be collected from the medical record. Surgeon feedback will be collected immediately following the conclusion of each case using the NASA TLX and RULA ergonomic tools. Patient follow-up at seven days plus or minus three days, one month plus or minus one week, one year plus or minus one month, and two years plus or minus two months will be performed. Post-operative pain, including neuropathic pain, will be assessed using the visual analog scale (VAS) and the neuropathic pain score (NPS). Patient quality of life and functional mobility will be assessed using the short form 36 (SF-36) and activity assessment tool. Cosmesis will be evaluated using the Stony Brook Scar Evaluation Form. Patients will be required to fill out the VAS, NPS, SF-36 and physical activity assessment tool at each clinic visit and the Stony Brook Scar Evaluation form at one month and two years post-operatively to allow for monitoring of post-operative progression and overall effect of robotic versus laparoscopic inguinal hernia repair on quality of life measures. Hernia recurrence will be assessed by a member of the surgical team at each postoperative visit.

SURGICAL PROCEDURE

Regardless of surgical approach, the procedure to performed in this trial is a transabdominal preperitoneal(TAPP) inguinal hernia repair. The laparoscopic and robotic approaches vary only with respect to mesh fixation and peritoneal closure. A brief description of TAPP with specific reference to mesh fixation and peritoneal closure with respect to the laparoscopic and robotic approaches is detailed below. The type of mesh to be used, fixation of the mesh, and peritoneal closure have all been standardized for this trial and the procedure agreed upon by all participating surgeons. All procedures will be performed by Attending Physicians only without the involvement of fellows or resident physicians.

The patient is placed supine on the operating room table. General anesthesia is induced per the Anesthesia Team. Perioperative antibiotics should be administered per SCIP protocol, with all patients receiving Ancef (or Clindamycin if they have a penicillin allergy). Positioning of the patient should proceed based on standard surgeon practice. A foley catheter will not be used for bladder decompression. After patient positioning, an infraumbilical incision is used to access the peritoneal cavity, a 10-12 mm trocar placed, and pneumopertioneum is achieved. Two additional 5 mm ports are placed in the midclavicular line bilaterally. The hernia is visualized with the use of a laparoscope (size of laparoscope per the operating surgeon) and the peritoneum overlying it is incised sharply 3-4 cm superiorly from the medial umbilical ligament to the anterior superior iliac spine. Blunt dissection is used to peal the peritoneal flaps inferiorly, exposing the inferior epigastric vessels, the pubic symphysis and the Cooper's ligament, and the iliopubic tract. A direct hernia should be reduced if seen and an indirect dissected from the cord structures. Direct hernia defects will not be closed. If the patient is a female, the round ligament will be divded. Femoral and obturator hernias can also be visualized. If the patient has a femoral or obturator hernia, but not an inguinal hernia, or has bilateral inguinal hernias, repair should be performed at the surgeon's

discretion. However, that patient will be excluded from the trial at that time due to absence of an inguinal hernia. Care is taken to avoid the "Triangle of Doom" containing the external iliac vessels bordered by the vas deferens medially and the gonadal vessels laterally. A mesh ranging from 10 to 15 cm in diameter of flat, heavy weight polypropylene (>90 g/m^2) is introduced though the periumbilical trocar and positioned anterior along the pelvic wall with the center overlying the primary hernia defect. The mesh will not be key holed. Fixation of the mesh and closure of the peritoneum with the laparoscopic approach will occur with a permanent tacking device while fixation of the mesh will occur with permanent suture of the surgeon's choice. All ports will be removed under direct visualization and the fascial defect at the periumbilical incision will be closed based on standard surgeon practice. All surgeons will be required, in their operative report, to detail the size of the mesh used, the location of placement and number of tacks used (if a laparoscopic repair), the type of suture used (if a robotic repair), and the type of inguinal hernia repair according to the European Hernia Society's classification of inguinal hernias. Perioperative care should be performed per standard institutional practice and is left to the discretion of the Anesthesia and Surgery teams at the participating location.

OUTCOMES TO BE INVESTIGATED

Each outcome to be investigated is based on the specific aims of the study and are listed below:

Specific Aim #1: To determine if the robotic approach will result in a significant reduction in postoperative pain and earlier return to full function when compared to a laparoscopic inguinal hernia repair. This will be assessed at each postoperative visit with the use of the VAS, NPS, SF-36, and physical activity assessment tools. The

VAS will be determined based on a 10 centimeter scale with scores rounded to the nearest half centimeter.

Specific Aim #2: To perform a cost analysis to determine the financial implications of performing a robotic versus a laparoscopic inguinal hernia repair. This will be investigated with the assistance of the operating room staff at CCF who will generate cost per procedure. As cost is partially impacted by the duration of the procedure and the length of hospital stay, these variables will also be recorded for each patient.

Specific Aim #3: To determine the effect of surgeon reported ergonomics when performing laparoscopic versus robotic inguinal hernia repairs. This will be investigated with the use of the NASA TLX and RULA ergonomic tools. These tools require observation of the surgeon during the procedure (RULA) as well as their feedback (NASA TLX). Because of this, participating surgeons will also be required to sign a physician information sheet prior to participation in this study.

Specific Aim #4: Evaluate the long term hernia recurrence rates associated with laparoscopic versus robotic inguinal hernia repairs. A physical examination and concern for or known hernia recurrence will be documented by the participating surgeon in the patient's medical record during all postoperative clinic encounters. Suspicion for hernia recurrence will be pursued with the standard of care imaging modality for each participating institution. An inguinal hernia recurrence is defined as a fascial defect at the site of previous inguinal hernia repair as felt on physical examination or visualized on imaging.

Specific Aim #5: Evaluate the cosmetic results of both surgical approaches.

This will be performed using the Stony Brook Scar Evaluation Form at one month and two years postoperatively.

Additional outcomes to be investigated are those relating to the surgical wound itself. These definitions are per the Centers for Disease Control and were agreed upon by all participating surgeons and sites. These wound outcomes will be recorded in RedCAP and are as follows:

Superficial Incisional Surgical Site infection (SSI)

A **superficial incisional SSI** must meet the following criteria:

Infection occurs within 30 days after the operative procedure AND involves only skin and subcutaneous tissue of the incision AND patient has at least ONE of the following:

a. purulent drainage from the superficial incision.

b. organisms isolated from an aseptically-obtained culture of fluid or tissue from the superficial incision.

c. superficial incision that is deliberately opened by a surgeon and is culture-positive or not cultured AND the patient has at least one of the following signs or symptoms: pain or tenderness, localized swelling, redness, or heat. A culture-negative finding does not meet this criterion.

d. diagnosis of superficial incisional SSI by the surgeon or attending physician.

NOTE:

a. Do NOT report stitch abscess (minimal inflammation and discharge confined to suture penetration site) as an infection.

b. Do NOT report a localized stab wound or pin site infection. Instead, report these as skin or soft tissue infections, depending on their depth.

c. “Cellulitis" by itself does NOT meet criteria for superficial incisional SSI

d. If infection involves or extends into the fascial and muscle layers report as a deep incisional SSI.

Deep Incisional SSI

A **deep incisional SSI** must meet the following criteria:
Infection occurs within 30 or 90 days after the operative procedure AND the infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision AND patient has at least ONE of the following:

a. purulent drainage from the deep incision but not from the organ/space component of the surgical site

b. a deep incision spontaneously dehisces or is deliberately opened by a surgeon AND is culture-positive or not cultured AND the patient has at least one of the following signs or symptoms: fever (>38°C), or localized pain, or tenderness. A culture-negative finding does not meet this criterion.

c. an abscess or other evidence of infection involving the deep incision is found on direct examination, during invasive procedure, or by histopathologic examination or imaging test.

d. diagnosis of a deep incisional SSI by a surgeon or attending physician.

NOTE:

a. Classify an infection that involves both superficial and deep incision sites as a deep incisional SSI.

b. Classify infection that involves superficial incisional, deep incisional, and organ/space sites as deep incisional SSI. This is considered a complication of the incision.

Organ/Space SSI

An **organ/space SSI** must meet the following criteria:

Infection occurs within 30 or 90 days after the operative procedure AND infection involves any part of the body, excluding the skin incision, fascia, or muscle layers that is opened or manipulated during the operative procedure AND the patient has at least ONE of the following:

a. purulent drainage from a drain that is placed into the organ/space

b. organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space

c. an abscess or other evidence of infection involving the organ/space that is found on direct examination, during invasive procedure,, or by histopathologic examination or imaging test.

d. diagnosis of an organ/space SSI by a surgeon or attending physician and meets at least one criterion for a specific organ/space infection site listed in NHSN.

All study co-investigators agree to follow these CDC definitions of SSIs for study subjects enrolled in this trial to maximize objectivity of this study measure.

ANTICIPATED TIME FRAME

Estimated patient accrual time is one year with data collection to occur over two years from the last enrolled patient. Data analysis and manuscript production will occur within six months of completion of data collection.

PATIENT RISKS AND DISCOMFORTS

As with any surgical procedure, there are some risks associated risks and they will be discussed in a separate surgical consent form. The subjects may experience some pain, bleeding and discomfort; however this is with any surgical operation. Common occurrences following hernia repair include seroma or hematoma around the hernia repair, inflammation, opening of the wound, or infection. Subjects may also experience additional therapies or treatments, including the removal of the mesh to treat any of these events.

PATIENT BENEFITS

There are no direct benefits to subjects for participating in this study. Subject participation will help us better understand the role of the robotic platform for inguinal hernia surgery.

COSTS TO THE SUBJECTS

There are no extra costs to the subjects associated with the research. Procedures related to the preoperative evaluation and the hernia surgery are considered standard of care and will be the responsibility of the subject and the subject's insurance company.

ALTERNATIVES TO PARTICIPATION

Patients are under no obligation to participate in this study. A member of the research will discuss all available surgical options to the patients. Declining to particpate in this study will not impact any patient's ability to receive care at the participating institution or to undergo inguinal hernia repair at the participating institution.

PAYMENTS TO THE SUBJECTS

There are no extra costs to the subjects associated with the research and therefore it is not mandatory that participating institutions provide payment to the subjects.

PLAN FOR OBTAINING INFORMED CONSENT

The informed consent process will occur in accordance with each institution's standard operating procedures with respect to 21CFR-50. Written informed consent must be obtained prior to any protocol-related activities. As part of this procedure, a member of the research team must explain orally and in writing the nature, duration, and purpose of the study in such a manner that the subject is aware of the potential risks, inconveniences, or adverse effects that may occur. The subjects will be informed that they may withdraw from the study at any time. Subjects will receive all information that is required by federal regulations and per each institution's policies

PROVISIONS FOR SUBJECTS FROM VULNERABLE POPULATIONS

The population to be studied includes adults 21 years of age or over, so children are therefore excluded. Decisionally-impaired and cognitively-impaired persons will not be approached to participate in this study as we are seeking subjects who have the capacity to understand and actively consent to the procedure independently. Pregnant women will be excluded from participating in this study. Provisions should be taken according to each institution's policy regarding 21CFR-50 to protect all other patients that are considered a member of a vulnerable population.

SUBJECT PRIVACY AND DATA CONFIDENTIALITY

Anonymity and confidentiality of subjects participating in this study will be maintained. The only potential identifiers on any study documents submitted to the sponsor or designee will be subject study numbers, dates of birth, and dates of procedures. Every effort will be made to maintain the confidentiality of documents that identify the subject by name (e.g., signed informed consent documents, clinic charts), except to the extent necessary to allow monitoring by the Office of Research Compliance at the Cleveland Clinic, internal monitoring by any of the participating sites, or other regulatory authorities.

All information collectedwill be stored utilizing a customized Research Electronic Data Capture (REDCap®) database program. This is in a secure network/firewall protected electronic database to which only the investigator and the designated members of the study team will have access using an individual assigned login and password. Only approved study members listed on the IRB protocol will have access to the separately-stored master list. Only the Principal Investigator, Lead Research Coordinators, and Biostatisticians at CCF will be granted access to

retrieve patient data from all sites for routine data quality assessments and data analyses. All electronic records pertaining to the clinical study will be password-protected, and only approved study members listed on the IRB protocol will have password access.

ANALYSES OF PRIMARY OUTCOMES

The primary outcomes to be investigated are postoperative pain, time to return to full preoperative function, and long-term hernia recurrence rates. Simple chi-square tests will be used for unadjusted analyses and a logistic regression model will be used for adjusted analyses. As this is a randomized trial, differences in baseline demographic and clinical characteristics between the laparoscopic and robotic cohorts are expected to occur at random. Any significant differences found among the demographic or preoperative clinical characteristics between the two treatment groups will be controlled for in the final analysis to limit potential confounding of results.

ANALYSES OF SECONDARY OUTCOMES

Secondary outcomes of interest include the impact of surgical approach on surgeon ergonomics and the cost and financial implications of each surgical approach. Simple chi-square tests will be used for unadjusted analyses and a logistic regression model will be used for adjusted analyses. As this is a randomized trial, differences in baseline demographic and clinical characteristics between the biologic mesh cohort and the permanent synthetic mesh cohort are expected to occur at random. Any significant differences found among the demographic or preoperative clinical characteristics between the two treatment groups will be controlled for in the final analysis to limit potential confounding of results.

CLINICAL SIGNIFICANCE/INNOVATION

To date, very little published work has evaluated the robotic inguinal hernia repair. In fact, to our knowledge, all case series that describe the robotic approach for inguinal hernia repair are from Urologists who encounter and repair this clinical entity during robotic assisted radical prostatectomy (RARP).[7-12] These case series have found that concurrent repair of inguinal hernias during RARP is safe without increased perioperative morbidity or mortaly.[6-11] What remains to be known, and what we hope to determine, is the benefit of the robotic platform for inguinal hernia repair as an independent surgery.

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