

Safety and Feasibility of Single Port Robot in Colorectal Procedures
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SP Robot Study

1. Purpose:

The purpose of this study is to evaluate the safety and feasibility of using the SP robot to perform single port robotic colon resection and transanal robotic surgery. The hypothesis of the study is that the SP robot will prove a safe effective modality to perform these procedures.

2. Subject Recruitment and Selection:

The goal of the study will be to recruit 200 patients between the ages of 18 and 95 years of age, either male or female. Exclusion criteria would include emergency surgery and an inability to offer informed consent. There will be no inducement to the patients, pregnant women would be excluded as well.

3. Location:

The research would be conducted at the Lankenau Medical Center as well as the Marks Colorectal Surgical Associates practice.

4. Background:

Minimally invasive colorectal surgery was first described in 1991 and has been adopted steadily in the United States in the ensuing 25 years. Offshoots of a laparoscopic approach in a multiport fashion has led to the development of the single port colorectal surgery first described in 2008 performed by, Lankenau trained fellow, Dr. Daniel Geisler. Robotic surgery has been utilized for a full spectrum of abdominal surgery being performed. In the colorectal arena, the robotic approach for benign and malignant

disease is well established, with a great deal of literature generated regarding the safety and benefits of a colorectal robotic approach for benign and malignant disease. The section of colorectal surgery at the Lankenau Medical Center has been an active and robust contributor to surgical literature on laparoscopic surgery, robotic colorectal surgery, and single port laparoscopic surgery. Its one investigator has been involved in the development of clinical applications to the single port robotic platform where this has been utilized in cadaver work that has been published. Recently, the SP robot has gone through FDA clearance and is now available for clinical utilization. The FDA approval is for urologic surgery. The SP robot will be utilized in the same fashion to perform the same colorectal operations that we have been performing with multiple port placements in the past to accomplish robotic surgery in a single port platform in the colorectal arena. The principal investigator has worked on the SP robot over the past 3 years with extensive cadaver experience to develop its safe application in the colorectal field.¹ This study will entail a collection of demographics, preoperative, perioperative and postoperative outcomes of the patients into a database to follow this, report on the outcomes, and notably answer questions to demonstrate the feasibility and safety of this approach in colorectal patients.^{2,3,4,5}

5. Research:

All patients being considered for minimally invasive colorectal surgery will be evaluated for participation in the above study. The original goal will be 200 patients. All of these patients will undergo a standard minimally invasive resection in the same fashion as would be carried out with multiport laparoscopic or robotic surgery. The difference being that the operation would be performed with the single port robot as opposed to multiport robotic or laparoscopic surgery or single port-laparoscopic surgery. The exact same standard of operative care will be employed with these patients. Additional laparoscopic

ports would be utilized as needed to carry out the operation safely at the discretion of the principal investigator. The original target would be for 200 patients, this will then be continued based upon findings, safety and efficacy of this approach, and improved data in the database for further analysis. A preliminary safety analysis will be performed after 10, 20, and 40 patients and shared with the IRB to confirm the safety of this approach. Preoperative demographic information will be collected as well as perioperative outcomes and postoperative outcomes. Any preoperative data will include data related to age, gender, disease state, anatomic location, BMI, ASA classification, previous surgery and previous radiation therapy. The operative data will include time of surgery, total operative time, blood loss, disposable instrumentation utilized, cost data, assistants in the case, robotic console time, complications, IV fluids, blood transfusions, estimated blood loss, urine output, type of anastomosis, how the anastomosis was performed, and conversion rate to multiport surgery. In order to gauge the effect of the surgery on patients' quality of life, the following questionnaires will be administered pre-operatively and post-operatively: SF-36 and QoR-40. Because a validated survey for patient reporting of scarring outcomes does not currently exist, a comprehensive survey (known as the Patient Scar Assessment Questionnaire, PSAQ) whose validity and reliability has been reviewed will be utilized.⁶ A photo-series questionnaire, modeled after Dunker et al.'s widely used survey will also be used to help evaluate the cosmetic consequences of scarring and patient's preferences for future surgical approaches (open, laparoscopic, or single port).^{7,8,9}

Patients will be monitored for postoperative pain requirements (we will measure the total amount of narcotics used postoperatively per day), postoperative pain score, time to tolerating clear liquids, time to tolerating solid food, time to flatus, time to defecation, time to discharge, readmission rates will be tracked, as well as short term perioperative complications for 30 days or less. All these data will be compared to those from multiport

laparoscopic cases from previously published studies.^{10,11,12,13} Post-operative complication rates will be compared using the t-test. Subject data will be stored for the length of the IRB approved study and if we wish to continue using the data another IRB protocol will be submitted for approval. As an ongoing adjunct to this study long term complications including bowel obstruction, hernia rate and anastomotic problems will be noted. These data points will be noted for the length of the study, and we will seek another IRB approval to get longer term outcomes.

6. Risk Assessments to the Patient:

The risk to the patient would be the same as one with undergoing any major colorectal resection. This would include bleeding, infection, injury to other organs, bladder dysfunction, sexual dysfunction, the need for temporary stoma, permanent stoma and even death. These are inherent to this form of surgery represent the same risks done in an open, multiport laparoscopic, single port laparoscopic, or multiport robotic fashion. However this is the first time an SP robot will be used in humans for colorectal procedures. As such different complications rates may be encountered. Possible benefits to the subject would include decreased pain from less incisions and improved cosmesis with only one incision. Other potential benefits which have been seen in the single port literature have been decreased operative time, reduced blood loss, and a lower hernia rate.^{14,15,16} It does not seem to be any inherent risk singularly attributable to this robotic approach that would not be ongoing with other standard approaches currently employed. Potential risks would be minimized by the ability to add additional laparoscopic ports in the situation where adequate progress was not being achieved in a robotic single port fashion.

7. Confidentiality:

Data will be collected by the research assistant and will be kept in a file protected by a password. All data will be de-identified and upon publication there will not be any reference that could relate to patients identity. Information will be protected under the Health Information Portability and Accountability Act (HIPAA).

Citations

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- ² Fung AK, Aly EH. Robotic colonic surgery: is it advisable to commence a new learning curve? *Diseases of the Colon and Rectum* 2013; 56(6): 786-796.
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- ⁷ Dunker, M.S., Stiggelbout, A.M., van Hogezaand, R.A., Ringers, J., Griffioen, G., and Bemelman, W.A. Cosmesis and body image after laparoscopic-assisted and open ileocolic resection for Crohn's disease. *Surg Endosc*. 1998; 12: 1334–1340
- ⁸ Lind, M.Y., Hop, W.C., Weimar, W., and IJzermans, J.N. Body image after laparoscopic or open donor nephrectomy. *Surg Endosc*. 2004; 18: 1276–1279.
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- ¹² Carvello, M., de Groof, E., de Buck van Overstraeten, A., Sacchi, M., Wolthius, A., Buskens, C., D'Hoore, A., Bemelman, W., and Spinelli, A. Single port laparoscopic ileocaecal resection for Crohn's disease: a multicentre comparison with multi-port laparoscopy. *Colorectal Dis*. 2018 Jan;20(1):53-58.
- ¹³ Salem, J., Gummadi, S., and Marks, J. Minimally Invasive Surgical Approaches to Colon Cancer. *Surg Oncol Clin N Am*. 2018 Apr;27(2):303-318.

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¹⁵ Marks, J., Montenegro, G., Shields, M., Frenkel, J., and Marks, G. Single-port laparoscopic colorectal surgery shows equivalent or better outcomes to standard laparoscopic surgery: results of a 190-patient, 7-criterion case-match study. Surg Endosc. 2015 Jun;29(6):1492-9. d

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INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Feasibility and Safety of Single Port Robot in Colorectal Procedures

Principal Investigator: Dr. John H Marks

SUMMARY

The purpose of this study is to evaluate the safety and feasibility of using the Single Port (SP) robot to perform colorectal procedures. We want to see whether the SP robot will prove to be a safe and effective way to perform these procedures.

BACKGROUND

Minimally invasive colorectal surgery does not require a large incision, but is done using a laparoscope (a hollow tube), small incisions and miniaturized instruments. It was first described in 1991 and has been adopted steadily in the United States since then. Robotic surgery, a form of laparoscopic surgery using very small tools attached to a *robotic* arm, which the *surgeon* controls with a computer, has been utilized for many types of abdominal surgical procedures. Most laparoscopic surgery is performed using several small incisions (multiple ports), but single port (single incision) devices are being developed. The section of colorectal surgery at the Lankenau Medical Center has been active in research in laparoscopic surgery, robotic colorectal surgery, and single port laparoscopic surgery. Recently, the SP robot received FDA (Food & Drug Administration) “clearance” for procedures in the urinary system. This means that the FDA has determined that the SP robot is substantially equivalent to other previously FDA-cleared devices. This is the first study where the SP robot will be used in human

beings to perform colorectal procedures. The SP robot will be utilized in the same way to perform the same operations that we have been performing with multiple port placements in the past to do robotic surgery, using a single port device for colon and rectum surgeries. This study will involve collection of personal demographic information such as age, gender, height and weight, related medical history, and information during and after surgery. The information will hopefully answer questions to demonstrate the feasibility and safety of this approach in colorectal patients.

PROCEDURES

All colorectal procedures currently performed in a minimally invasive fashion can potentially be performed using the SP robot, including but not limited to: transanal local excision of rectal lesions (removal of abnormalities in the rectum through the anus), transanal resection of the rectum (removal of the rectum through the anus), removal of the left, right or entire (total) colon, and rectopexy (restoring the rectum to its normal position in the pelvis). Demographic data (e.g. age, gender, height and weight, related medical history, procedural data (such as procedure time, robotic console time, instruments utilized, blood loss, urine output, surgical techniques performed), postoperative treatment course (such as time to tolerating clear liquids and solid food, time to first bowel movement, time to discharge, and any readmissions) as well as complications will be collected. These data will be kept for the length of the study, which is expected to last 2 years and to enroll 200 patients. Participants will be asked to complete validated questionnaires pre- and postoperatively about their satisfaction with the procedure and body image. Completion of these questionnaires should take no longer than 30 minutes and can be done during the course of an office visits while

waiting to be seen. Administration of these questionnaires are therefore not expected to increase the length of patients' office visits.

RISKS AND SIDE EFFECTS

The risk to the patient would be the same as one with undergoing any major colorectal procedure. They include bleeding, infection, injury to other organs, problems with bladder function, the need for temporary stoma (an artificial opening of the bowel to the outside of the body), permanent stoma, and death. There are no known additional risks specific to the SP robot. However this is the first time an SP robot will be used in humans for colorectal procedures. As such different complication rates (higher or lower) may be encountered. The SP robot has not been approved by the FDA for this particular field (colorectal surgery) as of yet.

ALTERNATIVE TREATMENTS

You have the alternative to not participate in the study and receive standard surgical care. If you decide not to participate or to withdraw at any time, your medical care will not be affected. You do not waive or give up any legal rights when you sign this form.

BENEFITS

Possible benefits to the subject would include decreased pain from fewer incisions and improved cosmesis (appearance of the area after surgery) with only one incision. Other potential benefits which have been seen in the single port literature have been decreased operative time, reduced blood loss, and a lower hernia rate after surgery.

CONTACT PERSONS

If you experience any research related injuries during the study or if you have questions about the research, you should contact Dr. John H Marks at 610-645-9093 or Dr. Jean Salem, also at 610-645-9093.

In addition, if you have any problems, concerns and questions as a research subject, contact Albert A. Keshgegian, M.D., Ph.D., Chairman, Main Line Hospitals Institutional Review Board at 484-476-3552 or Anne Marie Hobson, J.D., Director, Office of Research Protections at 484-476-2692 to speak to someone independent of the research team.

CONFIDENTIALITY

You understand that your information is protected under the Health Information Portability and Accountability Act (HIPAA) and that you will be asked to sign a separate authorization form related to the permitted uses and disclosures of your information.

Your name or any identification information will not appear in any publication.

There is a risk of loss of confidentiality from your participation in this study. We will do our best to prevent the disclosure of your identity. All data collected from you will be stored in a password-protected database for the length of the study (2 years). Only the researcher and physicians affiliated with the study will have access to this database.

This is an FDA-regulated study, therefore the FDA may inspect the our records. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. If you have additional questions, please ask the Investigator.

Conflict of Interest Disclosure

The Principal Investigator has worked as a consultant with Intuitive Surgical, the manufacturer of the SP robot, to develop the use of the SP robot in colorectal surgery. He may benefit professionally depending on the results of this study. If you have additional questions, please ask the Investigator.

SIGNATURE OF RESEARCH SUBJECT

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I will be given a copy of this 4-page consent form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Subject Signature

Printed Name of Subject

Date

CERTIFICATION OF INVESTIGATOR

I have discussed this research study with the subject using a language that is understandable and appropriate. I believe that I have fully informed this subject of the nature of this study and its possible benefits and risks and I believe the subject understood this explanation.

Signature of Investigator

Printed Name of Investigator

Date