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Design of a comparative outcome analysis of open, laparoscopic, or robotic-assisted incisional or inguinal hernia repair utilizing surgeon experience and a novel follow-up model

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ABSTRACT

Background: In a recent publication, the International Guidelines for Groin Hernia Management by the European Hernia Society (EHS) recognized the need to individualize and tailor the surgical approach for hernia repair. There may be different opportunities for optimization of the surgical technique for surgeons performing open, laparoscopic, or robotic-assisted hernia repair. Robotic-assisted hernia repair is a relatively new minimally invasive surgical approach compared to laparoscopic and open repair. Currently, there is a lack of comparative prospective studies designed to evaluate long-term outcomes of patients undergoing robotic-assisted, laparoscopic, or open hernia repair.

Materials & methods: This manuscript presents an innovative study design with two study cohorts (incisional and inguinal hernia repair) that contain three arms (robotic-assisted, laparoscopic, and open). The trial objective is to collect short-term and long-term outcomes for patients undergoing robotic-assisted, laparoscopic, or open hernia repair. The present publication will discuss the trial design, methods used to ensure consistency in surgeon expertise, and provides strategies to obtain long-term (> 3 months) follow-up data for enrolled patients.

Results: One hundred subjects underwent incisional and one hundred underwent inguinal hernia repair at the time of this manuscript. Surgeon experience was analyzed across the three surgical techniques and follow-up compliance was assessed through 1 year. The follow-up completion rates for both study cohorts were > 80% for all visits.

Conclusions: The innovative trial design helped to improve the quality and quantity of long-term follow-up. More innovative options to improve patient retention may be tested in future trials of similar design.

1. Introduction

The surgical approach to hernia repair is ever evolving [1,2]. In a recent publication, the International Guidelines for Groin Hernia Management by the European Hernia Society (EHS) recognized the need to individualize and tailor the surgical approach for hernia repair [1]. Selection of the best surgical approach for each patient involves not just preoperative and intraoperative considerations, but also post-operative considerations including the risk of complications or recurrence and the quality of life [2]. Robotic-assisted hernia repair is a relatively new minimally invasive surgical (MIS) approach that may provide surgeons with additional MIS surgical options to hernia repair [3–6]. Several retrospective studies comparing robotic-assisted vs laparoscopic or open hernia repairs suggest that robotic-assisted hernia repair may result in decreased intraoperative blood loss, systemic complications, conversion rates to open surgery, length of hospital stay, and patient perceptions of pain [7–12]. Incisional and inguinal hernias remain relatively common procedures performed. Incisional hernia is one of the most common problems that arise from abdominal surgery across any surgical approach and may be the most common type of abdominal wall hernias [13,14]. Similarly, there are approximately 800,000 inguinal hernia repair surgeries that occur in the United States each year [15]. While the body of literature for robotic-assisted hernia repair is growing, there is limited data available for long-term comparative outcomes data for currently available surgical approaches, as the typical standard of care for follow-up for hernia repair is usually 30 days.

This publication presents an innovative clinical trial design of a prospective, multicenter, real world evidence study (NCT02715622) with two study cohorts (non-emergent incisional and non-emergent

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inguinal hernia repair) that contain three arms (robotic-assisted, laparoscopic, and open) in each study cohort. The objective of this trial is to prospectively collect uniform, evidence-based short-term (within 30 days) and long-term (up to 3 years) outcomes for patients undergoing robotic-assisted, laparoscopic, or open hernia repair to facilitate a pair-wise comparison between the robotic-assisted and open groups as well as the robotic-assisted and laparoscopic groups. The short-term and long-term follow-up post-procedure outcomes include evaluation of the rate of hernia recurrence in addition to patient-reported outcomes such as Hernia-Related Quality-of-Life (HerQles) Abdominal Wall Questionnaire for Incisional and Carolina Comfort Scale (CCS) for Inguinal Hernia Repair [16,17].

Large discrepancies in MIS hernia repair techniques including those for robotic-assisted hernia repair may introduce heterogeneity and bias that can impact the overall trial outcomes. Differences in robotic-assisted hernia repair techniques may arise from surgeon preference, and there may be wide variations in surgeon expertise (potentially due to learning curves associated with the adoption of new technologies or approaches, and the adequacy of technique in performing a hernia repair) [11]. Therefore, the present publication will discuss the methods used in participating surgeon selection to address these concerns. Another common source of bias that can offset the validity of a prospective trial is a large number of patients that are lost to follow-up [18,19]. Since the present trial aims to obtain quality long-term follow-up data, the strategies included in the study design for increasing subject compliance for long-term follow-up will be discussed. Preliminary compliance data on the first 100 patients enrolled in each of the incisional and inguinal hernia repair cohorts (200 patient total) who completed short-term (within 30 days) and long-term follow-up through 1 year will be presented.

2. Materials and methods

2.1. Study design

The Prospective Hernia Study is an ongoing, multicenter (17 study sites), observational (non-randomized) two-cohort trial (three arms in each cohort) evaluating the clinical outcomes and patient-reported outcomes from robotic-assisted, laparoscopic, and open non-emergent incisional and inguinal hernia repair (see Fig. A.1). This study does not have a specific hypothesis due to the paucity of data describing outcomes of robotic-assisted hernia repair at the time of study inception, but intends to enable a pair-wise comparison specficially between robotic-assisted subjects and the comparison arm in both cohorts. The study is designed to collect real-world, registry like data and therefore has limited inclusion/exclusion criteria. All patients undergoing a hernia repair who meet the inclusion/exclusion criteria could be selected to participate in the study. While there is literature that could potentially support a hypothesis for a comparison of MIS (robotic-assisted and laparoscopic) vs open hernia repair, during study design there was a lack of robust and high levels of evidence describing outcomes for robotic-assisted hernia repairs as well as a paucity of literature comparing robotic-assisted and laparoscopic incisional and inguinal hernia repair available that would support a hypothesis. Therefore, the sample size is not formally powered and a hypothesis supporting a robotic-assisted and laparoscopic comparison may be one impact of this study. Approximately 150 patients will be enrolled in all three arms (in both study cohorts) in order to target approximately 100 patients with follow-up data completed through 3 years. This is based upon the assumption that 30% of patients will be lost to follow-up, but is not based on nor was derived from specific outcomes or expected differences. By design and in recognition of two different types of hernias, the incisional and inguinal hernia repair cohorts will be analyzed separately. The two cohorts are included in a single study, however, as data on short-term quality of life and long-term recurrence is needed for both treatment cohorts. All robotic-assisted procedures are performed using the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA). After undergoing a hernia repair according to standard practice, subjects complete a short-term follow-up visit up to 30 days post-procedure and long-term follow-up visits at 3 months (± 14 days), 1 year (± 1 month), 2 years (± 1 month), and 3 years (± 1 month) post-procedure. The intent of this publication is to present the trial design methods that have helped increase patient follow-up compliance rates and the design factors included in the study to help mitigate against bias. The publication does not include clinical outcome data, as this data will be included in future publications.

2.2. Ethics and trial registration

Intuitional Review Board (IRB) approval was obtained for the study and the Informed Consent Form by each participating site prior to study enrollment. Informed Consent (along with HIPAA authorization) was obtained prior to any subject undergoing the surgical procedure for enrollment into this trial. In addition, all subject facing materials (including phone call and email scripts) received IRB approval prior to subject enrollment. This trial is registered on the ClincalTrials.gov website (NCT02715622).

2.3. Surgeon selection

Prior to subject enrollment and during trial site selection, participating surgeons who perform robotic-assisted hernia repair procedures from each selected study site underwent a video review of their robotic-assisted surgical technique to ensure consistency with respect to the technical aspects of an inguinal and incisional hernia repair. The video review process served as a means for surgeons to demonstrate sound technical expertise that is also in-line with accepted hernia repair techniques. A video review committee comprised of three key opinion leaders who are also experienced surgeons (two robotic-assisted and laparoscopic surgeons and one open/laparoscopic surgeon) and were selected based upon their expertise in their standard practice hernia repair method. Videos from each surgeon participating in the robotic-assisted arms (in both the incisional and/or inguinal cohorts) were submitted to the video review committee for review. The review process followed a double blind methodology, as reviewers were blinded to the surgeons submitting content for review, and surgeons were blinded to the identity of the reviewer; videos were de-identified and assigned a number identifier prior to submission.

Based on the pre-specified video review criteria (see Appendix A), the surgeon was approved if the majority of reviewers determined the technique used in the robotic-assisted hernia repair technique qualified for the trial. If the surgeon was not qualified from the initial video review, an additional video of their robotic-assisted hernia repair surgery was provided for a second review. If the surgeon did not qualify after the second video review, the surgeon was not allowed to participate in the trial.

A total of twelve surgeons submitted videos for review to participate in the robotic-assisted arm of the incisional study cohort, five of which underwent review by all three reviewers and seven of which underwent review by only two of the three reviewers. All surgeons who submitted incisional repair videos received approval, through consensus of two or more reviewers, to participate in the robotic-assisted arm of the incisional study cohort.

A total of nine surgeons submitted repair videos to participate in the robotic-assisted arm of the inguinal study cohort. Seven of the nine surgeons were reviewed by all three of the independent video reviewers, three of which required an additional repair video, as the initial review was inconclusive. Through consensus, all surgeons who submitted inguinal hernia repair videos were approved to enroll in the robotic-assisted arm of the inguinal study cohort. While all surgeons who submitted videos to participate in the robotic-assisted incisional and/or inguinal arms were approved, this process helped to ensure the

quality of technical repair for the surgeons participating in the study. These surgeons were chosen prior to the submission of the videos based upon the prior knowledge of each surgeons expertise in the robotic assisted hernia repair.

Since open hernia repair is well established and the learning curve for laparoscopic hernia repair has been well documented in publications, surgeons participating in the laparoscopic or open cohorts were required to complete a survey (see Appendix B) to assess their years of experience in performing open and/or laparoscopic hernia repairs, as well as to understand their standard practice for hernia repair. Surgeons were assigned their arm designation(s) as a results of the survey responses. The surgeons' experience is summarized in Table A.2. Refer to Appendix C for a list of participating sites/surgeons at the time of the data cut-off date.

All surgeons were selected according to their dominant surgical approach. The video review process and survey were designed to help mitigate bias in terms of expertise level and appropriate technique across the open, laparoscopic, and robotic-assisted arms, however, there may still be some degree of bias when selecting patients. The potential for bias is addressed in the discussion section of this manuscript. For the study results publication, differences in pre-operative outcomes may be addressed, as needed, through statistical analysis, such as propensity score matching.

2.4. Subject population

To ensure balance in subject enrollment across open, laparoscopic, and robotic-assisted arms, the incisional study cohort in the present trial design is limited to incisional hernia repair rather than any ventral hernia repairs. This design also prevents confounding data from comparing different hernia types (i.e. umbilical versus epigastric). Approximately 900 subjects (~450 subjects per study cohort of incisional vs inguinal hernia repair; ~150 subjects per study arm) will be enrolled in the study. Eligibility criteria for the study includes patients 18 years or older undergoing a robotic-assisted, laparoscopic, or open non-emergent incisional or inguinal hernia repair procedure (see Fig. A.1). Subjects with emergent cases are excluded in both the incisional and inguinal hernia repair cohorts. Additionally, subjects are excluded in the incisional cohort if the hernia is related to ostomy formation. Subjects are also excluded if the incisional hernia requires component separation, or myofascial release, (determined pre-operatively or intraoperatively), in order to reduce selection bias across any one surgical modality.

2.5. Data collected

Patient demographics, clinical characteristics, pre-operative medical history, and hernia specific patient-reported quality of life (QOL) questionnaires (HerQles for incisional and Carolinas Comfort Scale (CCS) for inguinal hernia repair) are all collected for each patient prior to their surgical procedure. Intraoperative assessments are collected for all subjects enrolled in either the incisional or the inguinal cohort. The location of incisional hernias is classified using the European Hernia Society (EHS) classification [20]. Inguinal hernias are classified using the NYHUS classification [21]. Additional data points collected include the inguinal hernia repair technique used, hernia defect size, primary defect closure for inguinal and incisional hernias, use of mesh, mesh fixation methods, concomitant procedures performed, complications, and conversions. Postoperative assessments include complications, readmissions, and reoperations (assessed at 30 days, 3 months, 1 year, 2 years, and 3 years post-procedure). Other postoperative assessments include length of stay and patient reported QOL questionnaire (HerQles and CCS assessed at 30 days, 3 months, and 1 year post-procedure).

2.6. Post-procedure follow-up

Post-procedure follow-up visits are conducted at 30 days, 3 months, 1 year, 2 years, and 3 years (see Table A.1). Follow-up visits completed at 30 days post-procedure are expected to be an office visit with the surgeon who performed the study-specific hernia repair. Follow-up visits completed after the 30 days follow-up visit will be completed by a third party. Two vendors are utilized for this study; a call center (Linical Accelovance, Patient Engagement Solutions) and email vendor (Clinovo ClinCapture, EDC vendor). Subjects indicate their preference of email or phone call follow-up visit at the time of study enrollment. The call center vendor is responsible for completion of the follow-up visit using an IRB approved follow-up script and data entry directly into the electronic database. Within the 3-month follow-up visit window, one dial attempt is made every week for five weeks (5 total) to contact subjects who preferred phone call follow-ups; one dial attempt is made every week for nine weeks (9 total) within window for the subsequent follow-up visits at 1 year, 2 years, and 3 years. The call center also mails a visit window reminder card to all patients upon enrollment in the study.

For subjects who selected email as their preferred contact method, an email is sent upon enrollment as a reminder of the follow-up schedule. Emails for completion of the survey are sent to the patient at the start of the visit window with an individual link to a website with follow-up questions. Each subject will receive up to three email reminders to complete their follow-up visit. If a patient does not complete the electronic survey after the three emails are sent and is within the 3 month follow-up visit window, an additional phone call attempt is made every week for 3 weeks (3 total) by the phone call center to contact the patients. The phone call center makes one phone call attempt per week for five weeks (5 total) for patients who are within their 1 year, 2 year, or 3 year follow-up visit windows and are non-compliant to the email reminders. The patient can then either complete the visit over the phone with the vendor, or request another follow-up visit questionnaire to be emailed and completed electronically.

If a patient cannot be reached during the visit window, a missed visit will be recorded; after two consecutive missed visits, a subject will be considered lost to follow-up. In addition, the sponsor representative alerts the study site research team via email if a patient provides responses indicative of a possible hernia recurrence. At the discretion of the treating surgeon, the patient may be seen in the office for an unscheduled follow-up visit; during which, the surgeon may perform hernia recurrence evaluation if it is deemed necessary according to their standard practice.

The data expected to be collected at follow-up visits include:

1. Any complications experienced post-procedure (including perioperative and postoperative complications by Clavien-Dindo Classification at up to 30 days post operation and patient-reported complications at the long-term follow-ups)
2. Patient reported readmission or reoperation post-procedure through long-term follow-up
3. Patient reported outcomes specific to complication and potential hernia recurrence
4. Post-operative pain medication characteristics
5. QOL survey responses (up to 1 year)

2.7. Data analysis

The current study is ongoing. The final data analysis and outcomes will be presented in a separate publication. For the present publication, descriptive analysis was performed for trial surgeon characteristics. The compliance for completion of the short-term (through 30 days) and long-term follow-up visits at 3-months and 1-year for the first 200 subjects enrolled in the incisional and inguinal hernia repair cohorts (100 patient in each cohort) is calculated as follows:

The compliance rate is determined by the number of expected visits for subjects within window compared to the number of completed visits. To calculate the number of visits completed at the 30-day, 3-month, and 1-year follow-up visits for the first 100 subjects enrolled in either arm, an enrollment report was pulled from the database that captures all enrollment in the study to date. The number of completed visits for each time point was used as a numerator, with the 100 expected patient visits as the denominator. This process was applied to calculate the visit completion rate for each follow-up time point through 1 year – 30 days, 3 months, and 1 year. Through this calculation, the follow-up compliance rates were determined separately for each study cohort.

3. Results

As of 25-Oct-2018 data cut off, 100 subjects underwent incisional and 100 subjects underwent inguinal hernia repair.

3.1. Surgeon experience

Table A.2 provides a summary of the experience level across surgeons participating in the study. The information is taken from the qualification survey that the surgeons completed prior to participation in the study. The sample size in the table below represents the total number of surgeons participating in that specific arm. The years of surgeon experience performing open or laparoscopic inguinal or incisional hernia repair is broken up into ranges (< 5 years, 5–10, 11–20, and > 20), as shown in the table below. Overall, the average number of years of experience for surgeons participating in the laparoscopic incisional arm is 13.02 years; 13.42 years in the laparoscopic inguinal arm, 17.56 years in open incisional, and 18.09 years in open inguinal. The table below summarizes the average experience levels across surgeons and study arms from the qualification surveys completed.

To further ensure consistency and reduce selection bias, surgeons who were approved for the trial could only enroll in a specific arm according to their primary approach for hernia repairs. For example, surgeons primarily performing inguinal hernia repairs using the open approach were approved to enroll in the open inguinal arm only. Arm designation in the incisional hernia repair cohort, however, was later updated from the original design, due to enrollment challenges, to allow surgeons to enroll across all three arms (robotic-assisted, laparoscopic, or open repair), provided they meet the specified qualifications.

3.2. Subject compliance to follow-up

Table A.3 provides a summary of the number of subjects from each of the study cohorts who have completed the 30-day short-term, 3-month, and 1-year long-term follow-up visits and the calculated compliance percentage overall. The table also indicates the percentage per visit completion method (electronic or by phone). A total of 191 subjects from both cohorts have completed the 30 days short-term follow-up visit. A total of 166 subjects across both cohorts completed the 3-month follow-up visit and 175 competed the 1-year long-term follow-up visit either electronically or by phone call. Overall, the subject population demonstrated high compliance to completion of the 30-day, 3-month, and 1-year follow-up visits and the level of compliance was similar between the two trial cohorts.

4. Discussion

The challenge of trials designed to evaluate surgical methods of treatment is obtaining consistent and high quality data to allow for adequate interpretation of that data. In this study, it was recognized that there would be variables in the selection of surgeons performing the hernia repair procedures, given the multiple surgical repair methods that were to be evaluated. Selection bias would exist both in the subject and surgeon arms alike.

Comparing the qualification survey results of surgeons participating in the open and laparoscopic incisional and/or open or laparoscopic inguinal arms, there did not seem to be a difference in experience level across arms. $> 50\%$ of all participating surgeons had > 10 years of experience performing open/laparoscopic incisional or inguinal hernia repairs. The similarity in experience levels helps to limit bias between these arms.

Because robotic-assisted hernia repair is a relatively recent addition to the surgical armamentarium, however, surgeons who perform robotic-assisted hernia repairs may not have the same years of experience compared to surgeons performing open or laparoscopic repairs. One challenge was the selection of experienced surgeons who perform robotic-assisted hernia repairs with appropriate technique, as inexperienced surgeons could impact the outcomes of this study. Therefore, an impartial review process was put in place. Surgeons participating in the robotic-assisted arms were required to submit hernia repair videos to the review committee to be reviewed in a blinded fashion.

The review committee consisted of three surgeons who reviewed the procedural videos that surgeons were to perform; a robotic-assisted repair (inguinal or incisional). These surgeons consisted of the study chair (with open, laparoscopic and robotic-assisted repair experience), a highly skilled laparoscopic and open surgeon, and a highly skilled surgeon who performs robotic-assisted hernia repairs. These surgeons were chosen as the review committee based on their experience levels across the surgical modalities and to provide an unbiased review of the repair videos submitted. Each surgeon completed the questionnaire (Appendix A) after review. Based upon the consensus, the surgeon "reviewed" was permitted to participate if the repairs were safe and appropriate to the criteria in the form. Two of the three reviewers needed to approve the surgeon's repair technique in order for the surgeon to participate in the study. Of the 12 video submissions for the incisional cohort and 9 submissions for inguinal, a total of 7 and 2, respectively, were only reviewed by two of the three reviewers. The qualification process required surgeons to demonstrate technical expertise, comparable to the expertise level of open and laparoscopic surgeons participating in the study.

To avoid bias in patient selection, the original design permitted surgeons to enroll patients in only one arm in either study cohort. For instance, surgeons approved for the open arm could not enroll in the laparoscopic or robotic-assisted arms. Due to challenges enrolling in the incisional cohort, however, arm designation was updated from the original design to allow surgeons to enroll across all three arms, provided they met the specified qualifications. Many inguinal hernia repair surgeons often perform more primary umbilical hernias, which are excluded from the study. Additionally, when these surgeons happen to do incisional cases, they are often complex cases requiring component separation, and were also excluded. By opening up the incisional cohort, surgeons could enroll patients in any of the three surgical modalities, as they would in their standard practice. As all surgeons met the experience criteria to enroll in both open and laparoscopic arms, this resulted in increased enrollment in the incisional cohort.

Another challenge in studies requiring long-term follow-up, is the ability for patients to comply with the protocol for follow-up visits. Several factors influence follow-up visit compliance, including cost to the patient, lack of desire to return if there are no complications, and loss of interest in the study as time progresses. Similar study designs that require patients to complete a questionnaire at different time points post-procedure have demonstrated approximately 60–70% response rate through 3–4 months [19]. The response rate tends to decrease the further out the patient is from the procedure. As follow-up compliance of $< 80\%$ can jeopardize the impact of study results, it is imperative that studies are designed to provide ample opportunity for the patients to complete the follow-up visits [22].

To mitigate against this in the study, the two vendors were utilized to provide subjects the option of electronic or phone call follow-up. Subjects who selected email follow-up received electronic reminders within each visit window to complete the visit. The patients also received a phone call from the call center if they were non-compliant to the email reminders. Several non-compliant subjects, who would not have completed the visit through email attempts alone, completed the visit as a result of the call center making an alternate attempt. Subjects who selected phone call follow-up received call attempts within each visit window from the call center. If the call center had difficulty reaching the subject, they would relay the issue to the sponsor, who would then contact the research staff for assistance reaching the patient. This interaction played a critical role in increasing compliance rates. Several patients who could not be reached by the call center initially were able to complete the visit with the site study coordinator's help. Utilizing two vendors and providing patients several opportunities to complete visits at their convenience appears to have contributed to increased compliance rates for follow-up. The additional subject material, including wallet cards with visit windows, QoL questionnaire magnets, and nominal reimbursement for each follow-up visit may also have served as a critical part of the trial design in terms of maximizing compliance rates.

Despite the success demonstrated by the follow-up rates, several limitations should be acknowledged. There is often an unequal distribution of enrollment in studies with multiple arms within multiple cohorts. The inguinal and incisional arms enrolled at very different rates, with the inguinal cohort enrolling faster. Within each cohort, one arm has been slower to enroll compared to the other two arms in that same cohort. It is anticipated that the imbalance noted at this time will be diminished as the study progresses and will be minimalized at the completion of patient enrollment.

During the site selection phase, there were difficulties in identifying institutions with qualified research personnel who would be dedicated to supporting the study. Many of the institutions, specifically community hospitals, did not have research programs with dedicated research personnel to assist with data collection. Several institutions were identified during site selection for potential participation, but the challenges with a lack of dedicated research personnel and familiarity with good clinical practices prevented the participation of these institutions in the study.

Additionally, the use of a third party to collect the data increases costs, especially when utilizing two separate vendors, as in this study. Although the utilization of two vendors has allowed for greater capture of patients data, the lack of in-person follow-up visits the study results are dependent upon verbal or email patient communications, rather than physical examination. As part of the study design, direct patient interaction has been foregone, which in the author's personal experience of over 30 years of research and challenges of adequate follow-up of post-operative hernia patients, may not be a consistently viable alternative to adequate evaluation of patients in research. On the contrary, there are recent articles that support the use of patient-reported outcomes, as they may lead to better communication from patients about their symptoms, quicker results, and less bias from patients answering the questions directly without the influence of research personnel [23]. Generally, researchers are pleased if they can achieve at least 60–75% patient response at one year. Beyond that, it is the experience of this author, there is a minimum loss of follow-up of at least 15–25% per year. The costs to the patient inhibits their interest in robust visits to their physician. The variation in follow-up modality across studies may impact the patients' responses and therefore introduce bias in outcomes. In this study, patients may have answered the follow-up questions differently over the phone versus via email. These factors combined may make the results difficult to replicate in other such research.

The study design focusing on the collection of the data through 3 years will be beneficial, as there is a need for quality, long-term data regarding the robotic-assisted repair technique and the comparison to open and laparoscopic hernia repair surgical approaches. The option for the patient to select email or telephone follow-up may increase participation. The use of gift cards also provides an incentive for the patients to complete visits. This has been noted in prior research by the study chair. It has also been demonstrated in another study comparing strategies to improve patient retention across randomized trials, in which the results indicated that including a nominal incentive for patients is more effective in improving retention than providing no incentive at all [24]. This study design provides opportunity to further explore options for patients to complete questionnaires via text message or with mobile phone applications and potentially enhance design replicability.

5. Conclusion

The present prospective trial design has implemented several innovative features to help improve the quality and quantity of long-term follow-up. Clinical long-term outcomes of recurrence, re-hospitalization and readmissions and patient-reported QOL outcomes in hernia repair allow the potential fulfillment of a current major unmet need in the medical field of robotic-assisted hernia repair. The full clinical findings will be presented in a future publication, and more innovative options to improve patient retention may be tested in future trials of similar design.

Author contributions

The author had full control of the study design and development of the manuscript.

Disclosure

The manuscript author, who is also the study chair, is a member of the Speaker's Bureau and is a course instructor for Intuitive Surgical, Inc. He is also on the Speaker's Bureau and consultant of W.L. Gore & Associates and C.R.Bard. He is a consultant to TAS Medical and a shareholder of Via Surgical, Inc.

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Appendix A

Reviewer Name: _____Surgeon #: _____
For an Incisional Hernia repair; the reviewers shall judge based on the following questions:

1. Was the defect appropriately measured? □Yes □No
2. Was the primary defect closed? (This may not be completed for every incisional hernia repair depending on the defect size) □Yes □No
3. If the defect was closed, was complete closure of the defect achieved?

   □Yes □No □ N/A.

4. Was the mesh positioned appropriately? □Yes □No
5. Was a three (3) to five (5) cm overlap of the mesh achieved? □Yes □No
6. If suprapubic incisional hernia, was fixation to Cooper's ligament done?

   □Yes □No □ N/A.

7. If subxyphoid incisional hernia, was there fixation to the diaphragm and/or 5 cm overlap? □Yes □No □ N/A
8. Was fixation of the mesh securely performed? □Yes □No
9. Overall, does this repair qualify for the Prospective Incisional Hernia Study cohort? □Yes □No

For an Inguinal Hernia repair; the reviewers shall judge based on the following questions:

1. Was a peritoneal incision placed from the anterior superior iliac spine (ASIS) to the medial umbilical ligament (MUL) around 4 cm above the inguinal canal? □Yes □No
2. Was the Medial extent of the dissection at least 2 cm beyond the symphysis pubis to the contralateral side? □Yes □No
3. Was the dissection extent cranially carried up to 4 cm above the transversalis arch or any direct defect? □Yes □No
4. Was the lateral extent up to the ASIS? □Yes □No
5. Was the dissection caudally carried down to 4 cm below the ileopubic tract at the level of psoas muscle, and 2 cm below the Cooper's ligament at the level of superior arch of the pubic bone? □Yes □No
6. Were spermatic cord structures, epigastric vessels and the triangle of Doom identified? □Yes □No
7. Was dissection carried out in the space between the internal and external layers of peritoneum? □Yes □No
8. Was the peritoneal sac and corresponding fat tissue from the hernia reduced towards the psoas muscle? □Yes □No
9. Were Lipomas and prolapsed fat in the enlarged hernia orifices retracted and resected routinely? □Yes □No
10. Was the defect appropriately measured for an Indirect hernia? □Yes □No □N/A
11. Was the defect appropriately measured for a Direct hernia? □Yes □No □N/A
12. Was the mesh positioned appropriately? □Yes □No
13. Was there a complete coverage of the myopectineal orifice? □Yes □No
14. Was fixation of the mesh securely performed? □Yes □No
15. Was a self-fixating mesh used? □Yes □No
16. Overall, does this repair qualify for the Prospective Inguinal Hernia Study cohort? □Yes □No

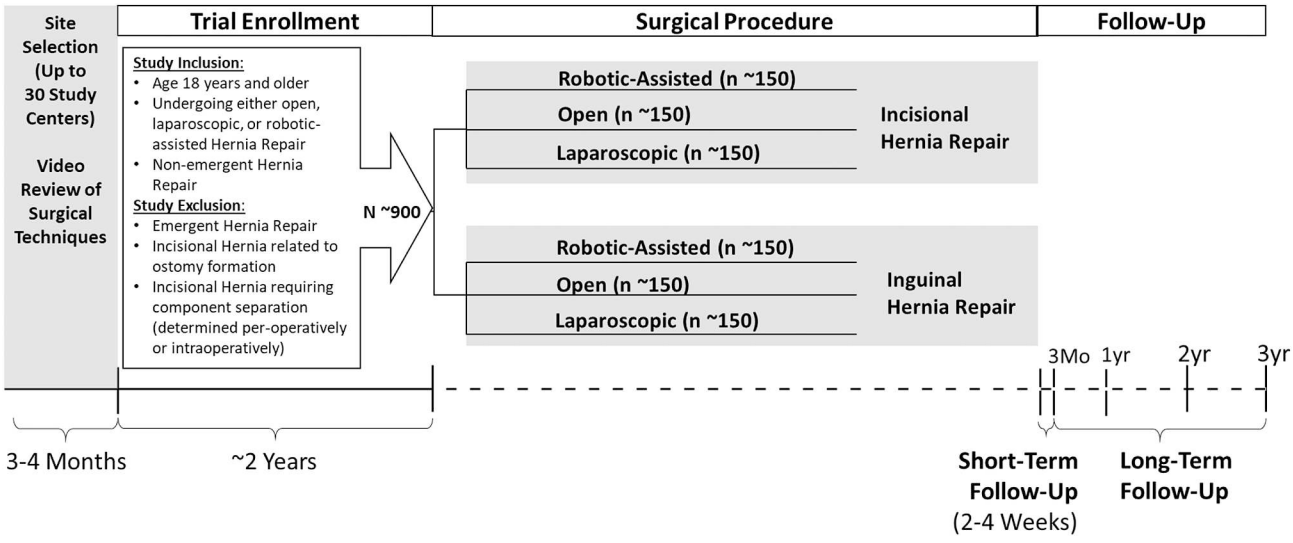

Fig. A.1. Study schema.
Abbreviation: mo = months; yr = year(s)

Table A.1 provides the post-procedure follow-up schedule of events.

Table A.1
Follow-up schedule of events

Time point	Informed consent	Office/clinic visit	Phone visit	HerQles questionnaire (incisional subjects)	Carolinas comfort questionnaire (inguinal subjects)
Pre-procedure[a]	X	X		X[a]	X[a]
Procedure		X			
30 days post-procedure		X		X	X
3 months (± 14 days) post-procedure			X	X	X
1 year (± 1 month) post-procedure			X[b]	X	X
2 years (± 1 month) post-procedure			X		
3 years (± 1 month) post-procedure			X		

[a] Pre-procedure questionnaires should be completed after informed consent is obtained but not > 5 days prior to the procedure.
[b] If physical exam warrants additional diagnostic testing for hernia recurrence, it can be completed at surgeon's discretion per standard practice.

Table A.2 provides a summary of the experience level across surgeons participating in the study.

Table A.2
Trial surgeon characteristics.

Years of experience	Open hernia repair (n, %)		Laparoscopic hernia repair (n, %)		Robotic-assisted hernia repair (n, %)	
	Inguinal (N = 17)	Incisional (N = 40)	Inguinal (N = 12)	Incisional (N = 39)	Inguinal (N = 9)	Incisional (N = 12)
< 5	2 (11.76%)	5 (12.50%)	2 (16.67%)	6 (15.38%)	6 (66.67%)	8 (66.67%)
5–10	4 (23.53%)	8 (20.00%)	2 (16.67%)	12 (30.77%)	3 (33.33%)	4 (33.33%)
11–20	4 (23.53%)	12 (30.00%)	6 (50.00%)	15 (38.46%)	0	0
> 20	7 (41.18%)	15 (37.50%)	2 (16.67%)	6 (15.38%)	0	0

Avg. cases completed	Open hernia repair (n)		Laparoscopic hernia repair (n)	
	Inguinal (N = 17)	Incisional (N = 40)	Inguinal (N = 12)	Incisional (N = 39)
Avg. number of hernia repair procedures performed over career:	1233.35	620.00	1475.00	389.28
Avg. number of hernia repair procedures performed over the past 2 years:	138.06	120.42	281.25	60.00

Table A.3 provides a summary of the number of subjects from each of the study cohortss who have completed the 30-day short-term, 3-month, and 1-year long-term follow-up visits and the calculated compliance percentage overall.

Table A.3
Preliminary percentage of compliance to short-term follow-up visit within 30 Days and long-term follow-up visits 3 month and 1 year in first 100 subjects enrolled.

Percent of subjects:	Incisional hernia repair (n = 100)	Inguinal hernia repair (n = 100)
Completed 30 Day Visit[a]	97 (97%)	94 (94%)
Completed 3 Month Visit	84 (84%)	82 (82%)
Completed 1 Year Visit	86 (86%)	89 (89%)
Compliance		
Electronic 3 Month Electronic 1 Year	(n = 46)	(n = 38)
	37 (80.43%)	29 (76.32%)
	41 (89.13%)	35 (92.11%)
Phone Call 3 Months[b] Phone Call 1 Year[b]	(n = 54)	(n = 62)
	47 (87.04%)	53 (85.48%)
	45 (83.33%)	54 (87.10%)
Combined 3 Month Combined 1 Year	(n = 100)	(n = 100)
	84 (84.00%)	82 (82.00%)
	86 (86.00%)	89 (89.00%)

[a] Standard practice office visit.
[b] Phone calls may result in completion of a visit or a reminder to complete the electronic follow-up visit.

Appendix B

Prospective Hernia study – Surgeon experience*

1. How many years have you been performing laparoscopic hernia repair procedures for the following:
   a. Inguinal hernia
   b. incisional hernia
2. Approximately how many laparoscopic hernia repair procedures (case volume) have you performed over your career for:

a. Inguinal hernia
b. Incisional hernia

3. Approximately how many laparoscopic hernia repair procedures (case volume) have you completed over the past 2 years for:
   a. Inguinal hernia
   b. Incisional hernia
4. How many years have you been performing open hernia repair procedures for the following:
   a. Inguinal hernia
   b. Incisional hernia
5. Approximately how many open hernia repair procedures (case volume) have you performed over your career for:
   a. Inguinal hernia
   b. Incisional hernia
6. Approximately how many open hernia repair procedure (case volume) have you completed over the past 2 years for:
   a. Inguinal hernia
   b. Incisional hernia

*Additional questions were included on the survey relating to site/surgeon specific information and patient population.

Appendix C

Prospective hernia participating sites/surgeons

#	Site name	Investigator names and arms	Incisional cohort	Inguinal cohort
1	Baptist Health Medical Center	**Anthony Gonzalez***	Robotic-assisted, open, laporoscopic	Robotic-assisted
		Jorge Rabaza	Robotic-assisted, open, laparoscopic	Robotic-assisted
		Juan-Carlos Verdeja	Open, laparoscopic	Laparoscopic
2	Celebration Health Research Institute	**Carlos –Ortiz-Ortiz***	Open, laparoscopic	Laparoscopic
		Dr. Eduardo Parra-Davila	Robotic-assisted, open, laparoscopic	Robotic-assisted
3	Progressive Surgical Associates	Reza Gamagami	Robotic-assisted, open, laparoscopic	Robotic-assisted
4	Vanderbilt University Medical Center	Richard Pierce	Open, laparoscopic	Open
5	Beverly Hills Hernia Center	Shirin Towfigh	Open, laparoscopic	Laparoscopic
6	University of Tennessee	**Guy Voeller***	Open, laparoscopic	Laparoscopic
		Nathaniel Stoikes	Open, laparoscopic	Laparoscopic
		David Webb	Open, laparoscopic	Laparoscopic
7	Mercy Medical Center	**Thomas Swope***	Robotic-assisted	Robotic-assisted
		Kelly Alexander	Open, laparoscopic	Laparoscopic
		Phuong Nguyen	Open	Open
8	Our Lady of Lake Hospital	**Karl LeBlanc***	Robotic, open, laparoscopic	Open
		Keith Rhynes	Open, laparoscopic	Open
9	Hillcrest Medical Center	**Eugene Dickens***	Robotic-assisted	Robotic-assisted
		Michael Mc.Gee	Open, laparoscopic	Open
10	Mount Sinai Medical Center	**Brian Jacob***	Open, laparoscopic	Laparoscopic
		Anthony Vine	Open, laparoscopic	Laparoscopic
		Mark Reiner	Open, laparoscopic	Laparoscopic
		Brian Katz	Open, laparoscopic	Laparoscopic
11	Southern Illinois Medical Center	Adrian Martin	Robotic-assisted, open, laparoscopic	None
12	Spectrum health Medical Group	**Amy Banks-Venegoni***	Open, laparoscopic	Laparoscopic
		Lora Silverman	Open, laparoscopic	None
		David Scheeres	Open, laparoscopic	Open
		Thomas Martin	Open, laparoscopic	Open
13	Louisville Surgical Associates	John Olsofka	Open, laparoscopic	None
14	Rush Presbyterian Hospital	Keith Millikan	Open, laparoscopic	Open
15	New Hanover Regional Medical Center	William Hope	Open, laparoscopic, robotic-assisted	Robotic-assisted
16	Kaiser Permanente (Northern CA)	**Elliott Brill***	Open, laparoscopic, robotic-assisted	Robotic-assisted
		Jemmy Hwang	Open, laparoscopic	Open
		Justin Choi	Open, laparoscopic	Open
		John Stevenson	Open, laparoscopic	Open
		Jong-Ping Lu	Open, laparoscopic	Open
		Amid Keshavarzi	Open, laparoscopic	Open
		Judith Keddington	Open, laparoscopic	Open
		Maureen Tedesco	Open, laparoscopic, robotic-assisted	Robotic-assisted
		Rouzbeh Mostaedi	Open, laparoscopic	Open
		David Nguyen	Open, laparoscopic	Open
17	Dallas VA	**Courtney Balentine***	Open, laparoscopic	Open
		Thai Pham	Open, laparoscopic	Laparoscopic

Note: Site PIs are indicated in bold with an asterisk.

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