Pilot Study to Establish Safety and Ease of Use of a TauTona Pneumoperitoneum Assist Device (TPAD) for Laparoscopic Surgery

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1. PURPOSE OF THE STUDY

a. Brief Summary

The purpose of this study is to assess the safety and ease of use of a trocar placement access device (TPAD, Tautona) for laparoscopic surgery. 10 patients will undergo laparoscopic surgery as planned, with their surgeon using the TPAD device to guide Veress needle insertion and primary trocar placement while gaining access to the peritoneal cavity. Surgeons will complete a questionnaire following use of the TPAD to evaluate the device feasibility. Ten patients will undergo standard of care without use of the TPAD device and also complete surveys.

b. Objectives

We hope to assess device feasibility and efficacy of the Tautona TPAD for clinical use.

c. Rationale for Research in Humans

The purpose of the study is to measure ease-of-use by surgeons in human patients. therefore, human patients are needed.

2. STUDY PROCEDURES

a. Procedures

Surgeons will identify patients scheduled to undergo laparoscopic surgery procedures and notify study staff. The patient will be met in the pre- operative holding area and informed consent will be obtained.

Patients will be randomized via block randomization.

Clinical information will be collected from participating patients including age, sex, demographic, past medical and surgical history, medications, allergies, diagnosis, and planned procedure. Clinical data will be de- identified and stored on a password protected spreadsheet on a PHI- safe server.

The surgeon will utilize the TPAD device to assist with Veress needle insertion (standard of care) to obtain access to the peritoneal cavity. The device will also be used to guide primary trocar placement.

Following induction of general anesthesia, the patient is prepped and draped in sterile fashion. Local anesthetic is infiltrated at the planned incision site and an incision is made with a scalpel. These steps are the same in any laparoscopic procedure. Next, the sterile TPAD, which is connected to a suction source, is centered over the incision, and the suction cups activated to non-invasively grasp the skin. The TPAD is pulled upward, and the Veress needle is advanced through the incision into the peritoneal cavity. Once the needle enters the cavity, the abdomen is insufflated as per usual standard of care. Once insufflated, the veress needle is withdrawn while maintaining the TPAD's suction on the skin. The primary trocar is then advanced through the incision into the abdominal cavity. The suction is then released and the TPAD taken away from the operating field.

The time needed to obtain laparoscopic access and the time needed for trocar placement will be recorded. Non-identifiable photos and/or video may be taken of the TPAD device during use. Acquired digital images may capture a portion of the patient's skin, however if a patient has any identifying features such as scars or tattoos, these areas will be cropped out of the images, or if this is not possible, no images will be recorded of that patient. There will be no other alterations to the planned surgery and it will proceed as planned. Following surgery, the surgeon will complete a questionnaire. Any adverse events will be recorded by medical record review.

Patients will undergo routine postoperative care as indicated by their surgery. no additional visits will be required due to their being enrolled in the study. The patient will participate in a questionnaire and may take non-identifiable photographs of the portion of the patients skin where the TPAD device acts, as described above.

b. Procedure Risks

Testing this device in human patients is necessary to establish its feasibility in a clinical setting. Identifying a safe, quicker method for obtaining peritoneal access has the potential to improve care for patients.

c. Use of Deception in the Study

No deception will be used.

d. Use of Audio and Video Recordings

Non-identifiable digital photos and/or videos will be taken of the TPAD during use and post-operatively. Acquired digital images may capture a portion of the patient's skin, however if a patient has any identifying features such as scars or tattoos, these areas will be cropped out of the images, or if this is not possible, no images will be recorded of that patient. Images will be kept on an encrypted, secure server, accessible only to study personnel. Some of these images may be used for publication or shared with the sponsor for providing instruction for other surgeons. Any images not used for these purposes will be erase.

e. Alternative Procedures or Courses of Treatment

The alternative is to not participate. No standard treatments will be withheld as a result of participating in the trial. Typically, surgeons use a Veress or Hasson technique to obtain laparoscopic peritoneal access. The risks and benefits are the same for all laparoscopic access techniques. The benefit of laparoscopic surgery over open surgery includes smaller incisions/scars, less postoperative pain and faster recovery, and reduced risk for incisional hernia

f. Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

Yes

g. Study Endpoint(s)

The study will terminate after 10 patients have been enrolled and have undergone surgery with use of the study device and 10 patients have undergone the standard of care and completed the survey. The primary outcome measure is device feasibility as measured by a surgeon questionnaire, which is completed at the end of every surgery. Secondary outcome measures include the time needed to obtain laparoscopic access using the device, as well as monitoring for adverse events. Another secondary outcome measure includes patient questionnaire to assess satisfaction.

If there is clear evidence of a lack of device feasibility through surgeon questionnaire review, or if there are any adverse events recorded that are related to the device and which endanger the health of a patient, the project leader will evaluate this information and decide whether any modifications or termination of the protocol are indicated.

3. BACKGROUND

a. Past Experimental and/or Clinical Findings

Gaining laparoscopic access to the abdomen is a clinical challenge due to the nature of inserting surgical instruments through small incisions. Laparoscopic entry is a blind procedure and thus it is not surprising that at least 50% of major complications of laparoscopic surgery occur prior to the commencement of the intended surgery. This complication rate has remained stable for the past 25 years. The Hasson technique (open) is considered safer, but is more time consuming with an average access time of 3-10 minutes (Hasson 1999). The Veress technique is a blind technique that has the advantage of being faster, however carries a risk of major vascular injury during insertion (Sangrasi et al, 2011). It is critical during

Veress needle access to upward tension on the abdominal wall so as to increase the distance between the abdominal wall fascia and major abdominal blood vessels. In order to address this need, Tautona developed
the TPAD, a device which applies suction to the abdominal wall skin to
facilitate easy upward traction during Veress needle insertion, thus improving speed and safety of peritoneal access.

Sangrasi et al. A safe quick technique for placement of the first access port for creation of pneumoperitoneum. Journal of the Society of Laparoscopic and Robotic Surgeons. 2011

Hasson HM. Open laparoscopy as a method of access in laparoscopic surgery. Gynaecol Endosc. 1999;8:353–62.

b. Findings from Past Animal Experiments

N/A

4. RADIOISOTOPES USED IN THE STUDY

N/A

5. DEVICES USED IN THE STUDY

a. Investigational Devices (Including Commercial Devices Used Off-Label)

Investigational Device 1	
Name:	Trocar placement access device (TPAD)
Description:	The TPAD can be used to assist in the passage of a Veress Needle to establish a pneumoperitoneum for laparoscopic surgical procedures. The TPAD can also be used to place the Primary Trocar, once the pneumoperitoneum has been achieved. The TPAD is comprised of 1) a pad with suction cups throughout the bottom surface, 2) a port with which to connect to a line coming from a sterile central vacuum source (central vacuum line), 3) a feature to activate or deactivate the central vacuum line, and 4) a handle to manipulate the TPAD when suctioned to skin. The pad has a middle layer that distributes the vacuum from the central vacuum line to each of the suction cups.
Significant Risk? (Y/N)	No
Rationale for Non-Significant Risk	The device applies suction via small vacuum powered suction cups to the abdominal wall skin. the risk of injury due to use of the device is minimal. Peritoneal access is still achieved using a Veress needle, which is the standard of care.

b. IDE-Exempt Devices

N/A

6. DRUGS, BIOLOGICS, REAGENTS, OR CHEMICALS USED IN THE STUDY

N/A

7. DISINFECTION PROCEDURES FOR MEDICAL EQUIPMENT USED ON BOTH HUMANS AND ANIMALS

N/A

8. PARTICIPANT POPULATION

a. Planned Enrollment

(i) 30
(ii) 30
(iii) participants are patients undergoing laparoscopic surgery. The indications for laparoscopic surgery are very broad and include appendicitis, gallbladder disease, inflammatory bowel disease, cancer, and others.

b. Age, Gender, and Ethnic Background

Patients >/= 18 years old of any gender and ethnicity will be recruited.

c. Vulnerable Populations

Patients who are economically/educationally disadvantaged, homeless, employees or students may be candidates to participate in the study. We will make it clear that participation is voluntary, that no part of their care is contingent on participating, and that there will be no compensation for participating. Decisionally impaired patients will not be included. Children and pregnant women will not be included in this pilot study.

d. Rationale for Exclusion of Certain Populations

No women or minorities will be excluded from participating. Children will not be included in this study as the device is primarily intended for use in adult patients.

e. Stanford Populations

We do not aim to recruit any particular number of laboratory personnel, employees and/or students. Participants may fall into these categories purely incidentally. All participants receive the same written informed consent.

f. Healthy Volunteers

There are no healthy volunteers as all participants have a clinical indication for undergoing laparoscopic surgery.

g. Recruitment Details

The surgeon will identify patients scheduled for laparoscopic surgery from their schedule and invite them to participate. if they are agreeable, study staff will be notified by the surgeon. The study staff will then meet the patient in the pre-operative area before their surgery to discuss the study and to obtain consent.

h. Eligibility Criteria

i. Inclusion Criteria

Age >/= 18
Scheduled for laparoscopic surgery
Able to understand and willing to sign a written informed consent form

ii. Exclusion Criteria

Age < 18
BMI > 35
Any situation where blind, peri-umbilical passage of a Veress needle is contraindicated.
Any situation where patients have suspected or confirmed intra-abdominal adhesions involving the peri-umbilical abdominal wall.
Any situation where patients have a suspected or confirmed umbilical hernia or peri-umbilical ventral hernia.
Any situation where there is not intact, uncompromised skin of the peri-umbilical region where the device is to be placed.

i. Screening Procedures

The surgeon will notify study staff of any patient meeting study inclusion criteria.

No personal health information will be collected prior to enrollment.

A waiver of authorization is provided in section 15. A data privacy attestation has been submitted.

j. Participation in Multiple Protocols

Patients will be asked if they are participating in any other studies prior to obtaining consent. If there is a potential that participation in either study may affect the outcome of the other, the patient will not be included.

k. Payments to Participants

No payment/reimbursement will be given for participation.

l. Costs to Participants

No additional costs are charged to the patient. the patient is still responsible for the cost of surgery.

m. Planned Duration of the Study

The study duration will be 1 year.

Total time per participant:
(i) screening: 1 week
(ii) active participation: <1 day (duration of surgery)
(iii) analysis of data: 1 month

9. RISKS

a. Potential Risks

i. Investigational devices

The TPAD device contacts the abdominal skin through a series of small vacuum powered suction cups. These are only in contact with the skin for a few minutes. The risk of damage to the skin is minimal.

Obtaining peritoneal access with a Veress needle, as well as laparoscopic surgery in general, carries risks including bleeding, damage to underlying structures including injury to bowel or major blood vessels, hernia, infection, scarring, pain, need for additional procedures.

The risks of laparoscopic surgery include:
• Infection
• Bleeding
• Damage to surrounding structures
• Need for additional procedures
• Hernia
• Pain
• Scarring
• Wound healing problems

The risks of veress needle insertion include:
• failed entry
• omental injury
• organ injury
• insertion site infection

The risks of TPAD include:
• skin discoloration/bruising

ii. Investigational drugs

N/A

iii. Commercially available drugs, biologics, reagents or chemicals

N/A

iv. Procedures

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Obtaining peritoneal access with a Veress needle, as well as laparoscopic surgery in general, carries risks including bleeding, damage to underlying structures including injury

to bowel or major blood vessels, hernia, infection, scarring, pain, need for additional procedures.

Health information is collected, and there is a risk of loss of confidentiality. however, this risk is low, as this information is kept on encrypted, password-secured servers.

Intra-operative photos/videos taken will similarly be kept on a password protected, encrypted server. these images may include a portion of the patient's skin, but this will be un-identifiable. If the patient has identifying scars or tattoos, this will be cropped out of the images, or, if this is not possible, no images will be stored for that patient. thus, the risk of identity exposure from these images is very low.

v. Radioisotopes/radiation-producing machines

N/A

vi. Physical well-being

The TPAD device contacts the abdominal skin through a series of small vacuum powered suction cups. These are only in contact with the skin for a few minutes. The risk of damage to the skin is minimal.

Obtaining peritoneal access with a Veress needle, as well as laparoscopic surgery in general, carries risks including bleeding, damage to underlying structures including injury to bowel or major blood vessels, hernia, infection, scarring, pain, need for additional procedures.

vii. Psychological well-being

N/A

viii. Economic well-being

N/A

ix. Social well-being

N/A

x. Overall evaluation of risk

Medium

b. International Research Risk Procedures

N/A

c. Procedures to Minimize Risk

Risks will be minimized by adhering to the inclusion/exclusion criteria.

Postoperatively, patients will be cared for by the Stanford general surgery service which has expertise in the management of patients undergoing laparoscopic surgery.

All clinical data and images will be stored on an encrypted server. If the patient has identifying scars or tattoos, this will be cropped out of the images, or, if this is not possible, no images will be stored for that patient. All data will be coded with an assigned study number. The study key will be kept in a password protected file that will be deleted at the conclusion of the study.

d. Study Conclusion

The experiment terminates for each participant at the end of their surgery. no additional follow up is needed. the general surgery service will care for the patients post-operatively and manage any adverse events that may occur.

e. Data Safety Monitoring Plan (DSMC)

i. Data and/or events subject to review

Aggregate Data Analysis
Progress toward Study endpoint(s)
AEs, SAEs, SUSARs
Participant consent forms

ii. Person(s) responsible for Data and Safety Monitoring

The PD will be responsible for Data and Safety Monitoring.

iii. Frequency of DSMB meetings

N/A

10. BENEFITS

We anticipate the TPAD could save anywhere from 1 to 10 minutes of anesthesia time. the patient may therefore benefit from shorter operative time (shorter duration of anesthesia). There could additionally be significant cost savings with shorter anesthesia. For example, the average cost for running an OR has been estimated at $62/minute, not counting personnel costs including Anesthesia fees. Therefore, we anticipate the potential for significant time and cost savings.

11. PRIVACY AND CONFIDENTIALITY

All participant information and specimens are handled in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and privacy policies of Stanford University, Stanford Health Care, and Stanford Children's Health.