NCT # 03043079

Protocol Number: 823896

Protocol Title: Ultra Sound Assessment of Ventral Hernia Defects

Document Date: December 09, 2015

Protocol Details

Basic Info

Confirmation Number:	**bjhhbige**
Protocol Number:	**823896**
Created By:	**LANNI, MICHAEL**
Principal Investigator:	**FISCHER, JOHN P**
Protocol Title:	**Ultrasound Assessment of Ventral Hernia Defects**
Short Title:	**ARFI Hernia**
Protocol Description:	**Through the use of ultrasound including sheer wave velocity measurements, the abdominal wall of 25 subjects scheduled to have ventral hernia repair will be compared to those of 25 healthy volunteers. The ultrasound measurements will elucidate if ventral hernia affects abdominal wall elasticity and reveal and effect on surgical outcomes.**
Submission Type:	**Biomedical Research**
Application Type:	**FULL**

Resubmission*
Yes

Study Personnel

Principal Investigator

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Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

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Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

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Training Expiration Date:	**04/25/2018**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

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Training Expiration Date:	**11/03/2016**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

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HS Training Completed:	**Yes**
Training Expiration Date:	**03/24/2018**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Biomedical Research

Clinical Trial*
Is this a clinical trial?

Investigator Initiated Trial*
Is this an investigator initiated trial?
No

Drugs or Devices*
Does this research study involve Drugs or Devices?
Yes: Investigational devices that may qualify as Non-Significant Risk.

IND Exemption

For studies that fall under an IND exemption, please provide the number below

For studies including IND or IDE's, please provide the number(s) below

IDE Review*
NOTE: For research involving investigational devices, you are required to review the guidance on Managing Research Device Inventory. Consult the Penn Manual for Clinical Research: https://somapps.med.upenn.edu/pennmanual/secure/pm/investigational-product-management Please check the box Yes if you have reviewed the guidance.

Yes

Research Device Management*
Please indicate how research device(s) will be managed.
Not Applicable (no investigational devices)

Drug, Herbal Product or Other Chemical Element Management *
Please indicate how drugs, herbal products or other chemical entities will be managed.
Not Applicable (no drugs, herbal products or other chemical entities)

Radiation Exposure*
Are research subjects receiving any radiation exposure (e.g. X-rays, CT, Fluoroscopy, DEXA, pQCT, FDG, Tc-99m, etc.) that they would not receive if they were not enrolled in this protocol?
No

Gene Transfer*
Does this research involve gene transfer (including all vectors) to human subjects?
No

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
No

CACTIS and CT Studies*
Does the research involve Center for Advanced Computed Tomography Imaging Services (CACTIS) and CT studies that research subjects would not receive if they were not part of this protocol?
No

CAMRIS and MRI Studies*
Does the research involve Center for Advanced Magnetic Resonance Imaging and Spectroscopy (CAMRIS) and MRI studies that research subjects would not receive if they were not part of this protocol?
No

Investigational Agent or Device within the Operating Room*
Does the research project involve the use of an investigational agent or device within the Operating Room?
No

Cancer Related research not being conducted by an NCI cooperative group*
Does this protocol involve cancer-related studies in any of the following categories?
No

Processing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

In-House Manufacturing of Materials*
Will the research involve processing (such as over encapsulating, or compounding)?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
Yes

If the answer is YES, indicate which items is is provided with this submission:

Modified research informed consent document that incorporates HIPAA requirements

CTRC Resources*
Does the research involve CTRC resources?
No

Pathology and Laboratory Medicine Resources*
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
No

Research Involves Apheresis, Cell Collection, and/or Blood Product Collection*
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

Research involving blood transfusion or drug infusions*
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

Trial in Radiation Oncology
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
N/A

Study in Radiation Oncology
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?
N/A

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
Yes

Primary Focus*
Clinical Trial (prospectively assigning subjects to health-related interventions to evaluate outcomes)

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
	Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)
	Surgical
x	**Diagnostic test/procedure (research-related diagnostic test or procedure)**
	Obtaining human tissue for basic research or biospecimen bank
	Survey instrument
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Department budget code

None

Multi-Site Research

Other Sites

No other sites

Management of Information for Multi-Center Research
na

The following documents are currently attached to this item:

There are no documents attached for this item.

Protocol

Abstract
Quantitative radiographic imaging holds promise as a novel and innovative strategy to assess ventral hernia patients. We will identify features of the abdominal wall that differ between healthy volunteers and subjects scheduled to have ventral hernia repair. We will assess abdominal wall changes surrounding ventral hernia using shear wave velocity values measured with ultrasound. Up to 25 subjects previously diagnosed with ventral hernia seeking surgical repair will receive ultrasound prior to repair and following repair and will be compared to up to 25 healthy volunteers.

Objectives

Overall objectives
Identify characteristic changes in the abdominal wall associated with ventral hernia. Determine elasticy of the abdominal wall in subjects known to have a hernia defect to those who are determined to have normal abdominal wall anatomy.

Primary outcome variable(s)
Sheer wave velocity measurements in the abdominal wall.

Secondary outcome variable(s)
Identification of any association between muscular elasticity/stiffness of the abdominal and surgical data/outcomes of the hernia repair.

Background
Significance of hernia and magnitude of the problem: Two million abdominal surgeries are performed annually in the United States, and ventral hernia (VH) is among the most common and serious complications(1, 2). The incidence of VH is approximately 13%(3), but as high as 70% in high-risk populations(1, 4-8). Despite improving surgical treatment strategies and mesh technology, long-term success rates of VH repair remain unacceptably low. The 348,000 VH repairs performed in 2006 cost over $3 billion (2). As a result of recurrence and morbidity, a disproportionately small subset (15%) of patients consumes more than 50% of expenditures(9), and become caught in the vicious cycle of hernia recurrence and morbidity. Failed repairs generate un-closable midline defects that require mesh bridging, meaning that native fascia cannot be closed and that mesh is bridged across the fascia. Bridging is a relevant and clinically meaningful outcome that occurs during the repair and has significant implications since these repairs fail in 44 to 100% of cases and are associated with significant cost (8, 10-13). Patients suffering from recurring hernia experience deterioration in quality- of-life, significant disability, and dysfunction; if un-closable defects can be identified using a point-of- care technology peri-operative decision-making could be substantially improved. Role of imaging in hernia care: There are currently no reliable data, standard imaging modalities, or guidelines available to predict successful fascial closure in hernia repair, which represents a substantial gap in knowledge and barrier to progress (4, 14-16). Surgeons are unable to adequately counsel patients and preoperatively plan complex VH repairs, which presents a clinical dilemma. The current state of hernia repair relies heavily on clinical evaluation of patients, which, as stated, is ultimately a poor predictor of patient outcome going into surgery for hernia repair. Additionally, there is a dearth of data regarding the use of various imaging modalities to diagnose and predict hernia outcomes of any kind. As of today, the only

recommended radiologic technique for the evaluation of hernia is CT, a costly and ultimately ineffective measure (17). If a technique leveraging the strengths of ultrasound (US) could be developed, it would be far superior to other modalities in terms of cost, time, and patient safety (Table 1) (18). There is little evidence regarding the role of ultrasound performed by surgeons in the diagnosis of hernias of any type Clearly, hernia ultrasound has the potential to be highly useful for surgical practice, however a well-designed trial needs to be carried out(14). Hernia leads to abdominal wall muscle fibrosis and decreased compliance, which presents an opportunity to quantify this change using specialized imaging techniques. Muscle fibrosis impedes closure (leading to bridging), and unloaded skeletal muscle undergoes architectural atrophic changes such as altered fiber composition, diminished cross-sectional area, and fibrosis that has been shown to be detectable and quantifiable (19, 20). Quantitative imaging using Acoustic Radiation Forced Impulse Shear Wave Velocity (ARFI-SWV) holds promise as a novel and innovative strategy to assess skeletal muscle pathology(21), and has already proven useful in evaluating fibromuscular disorders by quantitating stiffness and fibrosis (21, 22). Hernia repair outcomes are likely impacted by morphological changes that occur in the abdominal wall when significant fibrosis occurs. Clinically relevant target features include abdominal wall muscle thickness, pre-existing defects in the abdominal wall, or assessment of mechanical characteristics of muscular layers such as fibrosis or fatty infiltration (19, 20, 23). Clinical Implications and Future Directions: Completing this study will provide an opportunity to advance the applications of ARFI-SWV US imaging modalities for risk prediction of complex VH defects, translating this tool into the clinic as a point-of-care prognostic aid. The ability to preoperatively identify un-closable hernia defects represents an innovative strategy to an unmet clinical need with the potential to greatly impact thousands of patients. Following this critical, inter-disciplinary pilot, our team will have a reproducible and reliable quantitative tool. This translational research of proven concepts across multiple medical fields represents a significant collaborative effort and is just the first step that will be the foundation for future studies. The results of this proposal will be used to refine a protocol for preoperative shear wave velocity assessment in complex VH patients. The proposed translational research study represents a strong and promising collaborative effort between radiology, biomedical imaging, and surgery that will build upon recent work and cutting edge technology, setting in motion future research opportunities. The NIH states, The success of a potential shift from curative medicine, to predictive, personalized, and preemptive medicine could rely on the development of portable diagnostic and monitoring devices for point-of-care testing(25). It is with this notion in mind that we propose this work. We hope to develop a point-of-care technique that will allow the surgeon to pre-operatively assess the outcome of surgery at the bedside. Establishing a point-of-care test will allow surgeons to personalize their approach to each patient and avoid submitting patients to the spiral of hernia recurrence and morbidity. References 1. Candage R, Jones K, Luchette FA, Sinacore JM, Vandevender D, Reed RL, 2nd. Use of human acellular dermal matrix for hernia repair: friend or foe? Surgery. 2008;144(4):703-9; discussion 9-11. Epub 2008/10/14. doi: 10.1016/j.surg.2008.06.018. PubMed PMID: 18847657. 2. Poulose BK, Shelton J, Phillips S, Moore D, Nealon W, Penson D, et al. Epidemiology and cost of ventral hernia repair: making the case for hernia research. Hernia. 2012;16(2):179-83. doi: 10.1007/s10029-011-0879-9. PubMed PMID: 21904861. 3. Bosanquet DC, Ansell J, Abdelrahman T, Cornish J, Harries R, Stimpson A, et al. Systematic Review and Meta-Regression of Factors Affecting Midline Incisional Hernia Rates: Analysis of 14 618 Patients. PLoS One. 2015;10(9):e0138745. doi: 10.1371/journal.pone.0138745. PubMed PMID: 26389785; PubMed Central PMCID: PMCPMC4577082. 4. Franklin BR, Patel KM, Nahabedian MY, Baldassari LE, Cohen EI, Bhanot P. Predicting abdominal closure after component separation for complex ventral hernias: maximizing the use of preoperative computed tomography. Ann Plast Surg. 2013;71(3):261-5. Epub 2013/08/16. doi: 10.1097/SAP.0b013e3182773915
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Butler CE. Prospective study of single-stage repair of contaminated hernias using a biologic porcine tissue matrix: the RICH Study. Surgery. 2012;152(3):498-505. Epub 2012/07/06. doi: 10.1016/ j.surg.2012.04.008. PubMed PMID: 22763262. 11. Jin J, Rosen MJ, Blatnik J, McGee MF, Williams CP, Marks J, et al. Use of acellular dermal matrix for complicated ventral hernia repair: does technique affect outcomes? J Am Coll Surg. 2007;205(5):654-60. Epub 2007/10/30. doi: 10.1016/ j.jamcollsurg.2007.06.012. PubMed PMID: 17964441. 12. Purnell CA, Souza JM, Park E, Dumanian GA. Repair of recurrent hernia after biologic mesh failure in abdominal wall reconstruction. Am J Surg. 2014;208(5):788-93. Epub 2014/08/15. doi: 10.1016/j.amjsurg.2014.05.008. PubMed PMID: 25118163. 13. Patel KM, Nahabedian MY, Albino F, Bhanot P. The use of porcine acellular dermal matrix in a bridge technique for complex abdominal wall reconstruction: an outcome analysis. Am J Surg. 2013;205(2):209-12. Epub 2012/12/01. doi: 10.1016/j.amjsurg.2012.05.031. PubMed PMID: 23195145. 14. Beggs AD, Thomas PR. Point of use ultrasound by general surgeons: review of the literature and suggestions for future practice. Int J Surg. 2013;11(1):12-7. Epub 2012/12/05. doi: 10.1016/j.ijsu.2012.11.014. PubMed PMID: 23207511. 15. DiCocco JM, Magnotti LJ, Emmett KP, Zarzaur BL, Croce MA, Sharpe JP, et al. Long-term follow-up of abdominal wall reconstruction after planned ventral hernia: a 15-year experience. J Am Coll Surg. 2010;210(5):686-95, 95-8. Epub 2010/04/28. doi: 10.1016/j.jamcollsurg.2009.12.034. PubMed PMID: 20421031. 16. Wormer BA, Walters AL, Bradley 3rd JF, Williams KB, Tsirline VB, Augenstein VA, et al. Does ventral hernia defect length, width, or area predict postoperative quality of life? Answers from a prospective, international study. Journal of Surgical Research. 2013;184(1):169-77. doi: http://dx.doi.org/10.1016/ j.jss.2013.04.034. 17. Bittner R, Bingener-Casey J, Dietz U, Fabian M, Ferzli GS, Fortelny RH, et al. Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias (International Endohernia Society (IEHS)-part 1. Surg Endosc. 2014;28(1):2-29. Epub 2013/10/12. doi: 10.1007/ s00464-013-3170-6. PubMed PMID: 24114513; PubMed Central PMCID: PMC3872300. 18. Moore
CL, Copel JA. Point-of-care ultrasonography. The New England journal of medicine. 2011;364 (8):749-57. Epub 2011/02/25. doi: 10.1056/NEJMra0909487. PubMed PMID: 21345104. 19.
Culbertson EJ, Xing L, Wen Y, Franz MG. Reversibility of abdominal wall atrophy and fibrosis after primary or mesh herniorrhaphy. Ann Surg. 2013;257(1):142-9. Epub 2012/07/18. doi: 10.1097/ SLA.0b013e31825ffd02. PubMed PMID: 22801088; PubMed Central PMCID: PMC4492691. 20.
DuBay DA, Choi W, Urbanchek MG, Wang X, Adamson B, Dennis RG, et al. Incisional herniation induces decreased abdominal wall compliance via oblique muscle atrophy and fibrosis. Ann Surg. 2007;245(1):140-6. Epub 2007/01/02. doi: 10.1097/01.sla.0000251267.11012.85. PubMed PMID: 17197977; PubMed Central PMCID: PMC1867936. 21. Carpenter EL, Lau HA, Kolodny EH, Adler RS. Skeletal Muscle in Healthy Subjects versus Those with GNE-Related Myopathy: Evaluation with Shear-Wave US-A Pilot Study. Radiology. 2015;277(2):546-54. Epub 2015/06/03. doi: 10.1148/ radiol.2015142212. PubMed PMID: 26035587. 22. Drakonaki EE, Allen GM, Wilson DJ. Ultrasound elastography for musculoskeletal applications. Br J Radiol. 2012;85(1019):1435-45. Epub 2012/10/24. doi: 10.1259/bjr/93042867. PubMed PMID: 23091287; PubMed Central PMCID: PMC3500785. 23. Elsayes KM, Lammle M, Shariff A, Totty WG, Habib IF, Rubin DA. Value of magnetic resonance imaging in muscle trauma. Curr Probl Diagn Radiol. 2006;35(5):206-12. Epub 2006/09/05. doi: 10.1067/j.cpradiol.2006.06.003. PubMed PMID: 16949477. 24. Knops AM, Legemate DA, Goossens A, Bossuyt PM, Ubbink DT. Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis. Ann Surg. 2013;257(5):860-6. doi: 10.1097/ SLA.0b013e3182864fd6. PubMed PMID: 23470574. 25. National Institutes of Health 2013 FS-P-o- CDT, viewed 16 Nov 2015, http://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=112.

Study Design

Phase*
Not applicable

Design
Proposed Study Aims: Creating a protocol and using an existing technology to enhance informed risk counseling at the point-of-care will empower surgeons to personalize their approach to each patient, enhancing the informed decision process, fostering greater patient autonomy, and improving quality of care (24). ARFI-SWV US holds promise as an inexpensive, noninvasive, point-of-care diagnostic tool for pre-operatively predicting successful repair at the bedside. We will measure abdominal wall features suitable for predicting successful closure of the midline fascia. To accomplish these goals, we propose the following aims: Aim 1. To develop and refine a quantitative ultrasound protocol to assess mechanical changes in abdominal tissue. ARFI-SWV US represents a novel and intriguing modality for

real time visualization and characterization of changes in the biomechanical properties of diseased musculoskeletal tissues. We hypothesize that ARFI-SWV US can be used preoperatively to measure the stiffness in the lateral abdominal wall as an estimation for mobility during hernia repair. Demonstrating the utility of a cheap, point-of-care test for preoperatively evaluating hernia severity will prove to be a valuable, novel tool in surgical assessment of ventral hernia patients. Aim 2. To perform a prospective pilot ARFI-SWV US assessment of abdominal wall characteristics that predicts success of midline fascial re-approximation in hernia patients. A prospective comparative analysis of preoperative ARFI- SWV US exams in patients undergoing hernia repair (N=25) will be performed. We hypothesize that fibrosis and other identifiable mechanical characteristics of the abdominal wall musculature can predict ability to close fascia in VH patients. Preoperative identification of ultrasound features characteristic of severe hernia defects can be used to predict which hernias will be un-closable, resulting in poorer outcomes. The study proposes to compare ultrasound images and associated shear wave velocity measurements between healthy subjects and subjects undergoing surgical repair for ventral hernia. We will compare up to 25 healthy volunteers with up to 25 ventral hernia subjects. Any female patients of child-bearing age will be asked to take a urine pregnancy test prior to being included in the study at the time of consent. Subjects with ventral hernia will undergo imaging no earlier than two weeks prior to elective hernia repair and within six months following repair at a standard followup visit. Medical information related to their hernia or hernia repair from these subjects will remain available for analysis for the duration of the study. Statistical analysis will determine if there is a significant difference in the abdominal wall stiffness, represented by the ultrasound shear wave velocity measurements, between the healthy subjects and the subjects with ventral hernia. Further analysis will determine if there is any statistically significant relationship between abdominal wall stiffness of subjects with ventral hernia and surgical outcomes, including bridged repairs, as well as any change in abdominal wall stiffness following ventral hernia repair.

Study duration
All subjects will undergo about 40 minutes of ultrasound imaging. Subject who undergo hernia repair will have the same ultrasound imaging done at a standard follow up visit, within six months from the repair itself. following Subjects who undergo surgical repair for ventral hernia will have relevant information from their medical records included in the study for up to 1 year.

Resources necessary for human research protection
Describe research staff and justify that the staff are adequate in number and qualifications to conduct the research. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Please allow adequate time for the researchers to conduct and complete the research. Please confirm that there are adequate facilities for the research.
All members of the study team completed mandatory CITI research training and agree to follow established guidelines to ensure the privacy and respect for study participants. The PI will provide oversight for the study.

Characteristics of the Study Population

Target population
Up to 25 healthy, adult volunteer subjects and 25 adult subjects seeking surgical repair for ventral hernia between the ages of 20 and 70.

Subjects enrolled by Penn Researchers
50

Subjects enrolled by Collaborating Researchers
0

Accrual
Patients of Dr. John Fischer, Dr. Sean Harbison, Dr. Noel Williams, Dr. Daniel Dempsey, or Dr. Stephen Kovach seeking surgical repair for ventral hernia will be invited to participate in the study by members of the study team through word of mouth. Healthy volunteers will be invited through word of mouth by

study team members and will be composed for the most part, friends, family, and colleagues. It will be clearly stated that participation is completely voluntary and that their participation is for the purpose of research. Because ultrasound is such a common diagnostic tool, it is anticipated that participants will know what is involved and that it is a painless procedure that takes less than an hour.

Key inclusion criteria
Adults between the ages of 20 and 70. Healthy volunteer (25) or subject seeking elective ventral hernia repair (25).

Key exclusion criteria
Pregnant women will not be included in the study. Although ultrasound is a common procedure during pregnancy, our results regarding abdominal wall stiffness as they relate to hernia repair would be compromised by not controlling for other factors that affect the abdominal wall, such as physiologic changes during pregnancy.

Vulnerable Populations

Children Form

Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form

Fetuses and/or Neonates Form

Prisoners Form

Other

x **None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Populations vulnerable to undue influence or coercion
It will be clearly stated to any healthy volunteers who have an academic or professional relationship with UPENN/UPHS, that participation is voluntary and has no impact on position or care at the health system or academic institution

Subject recruitment
Patients of Dr. John Fischer, Dr. Sean Harbison, Dr. Noel Williams, Dr. Daniel Dempsey, or Dr. Stephen Kovach seeking surgical treatment for ventral hernia will be recruited through word of mouth. Healthy volunteers will be invited through word of mouth by study team members and will be composed for the most part, friends, family, and colleagues. It will be clearly stated that participation is completely voluntary and that their participation is for the purpose of research. Because ultrasound is such a common diagnostic tool, it is anticipated that participants will know what is involved and that it is a painless procedure that takes less than an hour.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

na

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
First Encounter: After informed consent is obtained by a member of the study team, each healthy volunteer and patient seeking ventral hernia repair will undergo ultrasound imaging for about 40 minutes as per the procedure outlined below. Any women of childbearing age will be asked to take a urine pregnancy test prior to enrollment. The ultrasound machine is the Siemens Acuson S3000 and our protocol is within its FDA approved label. The ultrasound imaging will focus on the abdominal wall and avoid areas with the potential for incidental findings, such as the gall bladder. Ultrasound Protocol:
1) Subject will be relaxed with shallow breathing and arm crossing over the chest. 2) Ultrasound transducer pressure will be minimal. 3) Ultrasound transducer will be perpendicular to the abdominal wall. 4) Transducer to be used: Linear or curved. 5) Grayscale Parameters: Abdominal wall musculature thickness in lateral mid abdomen (internal oblique, external oblique and transverse abdominis and rectus abdominis muscles. 6) Measurements will be in orthogonal planes 7) Repeat same procedure on the contra-lateral side 8) Color Doppler: Color Doppler image with optimum sensitivity along with grayscale images. Shear Wave Measurements: 1) A total of 10 measurements using quantification mode, with ROI placed within the musculature in lateral mid abdomen 2) Elastography using Color Map generation (two times in same region) within the musculature in lateral mid abdomen 3) Same measurements to be obtained for rectus abdominis muscle 4) Same measurements to be obtained for contralateral side Healthy volunteers will be thanked for their participation and subjects seeking ventral hernia repair return to their day and will eventually undergo standard treatment they would have otherwise done if they were not included in the study. Subjects who undergo ventral hernia repair will have followup care as per their standard treatment and information obtained through chart review regarding their medical course and surgical outcome/data (such as hernia defect size, if repair required components separation or mesh, complications) will be included in the study analysis. Follow up Encounter: Subject who underwent surgical repair will also be asked to repeat the exact same ultrasound evaluation at a standard follow up visit with their surgeon within six months of their hernia repair.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

Analysis Plan
Analysis will include comparing shear wave velocity measurements between healthy subjects and subjects with ventral hernia as well as correlating these measurements with the surgical outcome/data among patients with ventral hernia. Further, we will compare the measurements taken in subjects who underwent hernia repair before and after the hernia repair.

The following documents are currently attached to this item:

There are no documents attached for this item.

Are you conducting research outside of the United States?
No

Data confidentiality

x **Paper-based records will be kept in a secure location and only be accessible to personnel involved in the study.**

x **Computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords.**

Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

x **Wherever feasible, identifiers will be removed from study-related information.**

A Certificate of Confidentiality will be obtained, because the research could place the subject at risk of criminal or civil liability or cause damage to the subject's financial standing, employability, or liability.

A waiver of documentation of consent is being requested, because the only link between the subject and the study would be the consent document and the primary risk is a breach of confidentiality. (This is not an option for FDA-regulated research.)

Precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys.

Audio and/or video recordings will be transcribed and then destroyed to eliminate audible identification of subjects.

Subject Confidentiality
All computerized study databases will be housed on a secure Redcap database with deidentification capabilities. All information that is collected as part of this study will not be shared with other groups or investigators who are not part of the research team, except as required by the Institutional Review Board for the protection of human subjects. Further, data that is prepared for statistical analyses will be deidentified. Subjects are assigned uniques study IDs

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

Subject Privacy
Privacy refers to the person's desire to control access of others to themselves. Privacy concerns people, whereas confidentiality concerns data. Describe the strategies to protect privacy giving consideration to the following: The degree to which privacy can be expected in the proposed research and the safeguards that will be put into place to respect those boundaries. The methods used to identify and contact potential participants. The settings in which an individual will be interacting with an investigator. The privacy guidelines developed by relevant professions, professional associations and scholarly disciplines (e.g., psychiatry, genetic counseling, oral history, anthropology, psychology).
Study discussion will take place in a closed room. Pregnancy test will be administered using a study ID number that will be assigned to participants. All data/images will be stored securely using study ID numbers.

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
De-identified data results may be published in peer-reviewed journals

Data Protection*

x **Name**

Street address, city, county, precinct, zip code, and equivalent geocodes

x **All elements of dates (except year) for dates directly related to an individual and all ages over 89**

Telephone and fax number

Electronic mail addresses

Social security numbers

x **Medical record numbers**

Health plan ID numbers

Account numbers

Certificate/license numbers

Vehicle identifiers and serial numbers, including license plate numbers

Device identifiers/serial numbers

Web addresses (URLs)

Internet IP addresses

Biometric identifiers, incl. finger and voice prints

Full face photographic images and any comparable images

Any other unique identifying number, characteristic, or code

None

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Tissue Specimens Obtained as Part of Research*
Are Tissue Specimens being obtained for research?
No

Tissue Specimens - Collected during regular care*
Will tissue specimens be collected during regulator clinical care (for treatment or diagnosis)?
No

Tissue Specimens - otherwise discarded*
Would specimens otherwise be discarded?
No

Tissue Specimens - publicly available*
Will tissue specimens be publicly available?
No

Tissue Specimens - Collected as part of research protocol*
Will tissue specimens be collected as part of the research protocol?
No

Tissue Specimens - Banking of blood, tissue etc. for future use*
Does research involve banking of blood, tissue, etc. for future use?
No

Genetic testing
If genetic testing is involved, describe the nature of the tests, including if the testing is predicative or exploratory in nature. If predictive, please describe plan for disclosing results to subjects and provision

of genetic counseling. Describe how subject confidentiality will be protected Note: If no genetic testing is to be obtained, write: "Not applicable."
Not applicable

Consent

1. Consent Process

Overview
Consent will be obtained in person with a written consent form in plain English before any imaging. Consent may obtained by any research personnel listed in the IRB. Only subjects capable of consent will be included in the study. The consent process will inform the patient of the purpose of the study, study design, and possible risks and benefits of the study. Women of childbearing age will be ask to take a urine pregnancy test during the consent process.

Children and Adolescents
Not applicable

Adult Subjects Not Competent to Give Consent
Not applicable

2. Waiver of Consent

Waiver or Alteration of Informed Consent*
No Waiver Requested

Minimal Risk*

Impact on Subject Rights and Welfare*

Waiver Essential to Research*

Additional Information to Subjects

Written Statement of Research*
No

If no written statement will be provided, please provide justificiation

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit

Potential Study Risks
Small risk for breach in PHI, measure are in place to prevent this. Small potential for incidental finding upon ultrasound imaging, measures are in place to prevent this (avoiding areas where such findings are common such as the gall bladder and other abdominal organs).

Potential Study Benefits
Each time the medical team has the opportunity to learn information so that we may better serve our patients, there is a direct benefit to the medical community

Alternatives to Participation (optional)
Potential subjects may choose not to participate in the study with no effect on their medical care.

Data and Safety Monitoring
PI serves as study monitor

The following documents are currently attached to this item:

There are no documents attached for this item.

Risk / Benefit Assessment
There is a small risk of patient information breech and incidental ultrasound finding. Measures are in place to prevent these risks.

General Attachments

The following documents are currently attached to this item:

Additional forms (responsetostipulations.docx)

Additional forms (usconsenthipaaemrv2-clean.docx)

Additional forms (usconsenthipaaemrv2-tracked.docx)

Cover Letter (usherniairbcoverletter.docx)

Additional forms (12november2015ideexemptionapproved.pdf)

Investigator's brochure/product labeling (acuson_s3000_ultrasound_system_brochure-02428455.pdf)

HIPAA Authorization or Waiver (usconsenthipaaemr.docx)

Investigator's brochure/product labeling (siemensacusons3000.pdf)

Investigator's brochure/product labeling (k152369.pdf)