Assessment of the ability to predict fascial closure using shear-wave elastography in patients with midline incisional hernias.	
Principal Investigator	**Michael W Love, MD**
Co-Investigator(s)	**Jeremy A Warren, MD, FACS, Alfredo M Carbonell, DO, FACOS, Michael Devane, MD**
Study Location(s)	**Prisma Health Upstate (GMH, GrMH, HMH)**
Date	**01Jun2023**

Version: 1.0
Version date: 01May2021

TABLE OF CONTENTS

PRISMA HEALTH

I. ABSTRACT

Provide a concise summary (a few sentences) that includes objectives, population, design, and outcome measures:

The ability to achieve abdominal wall closure during ventral hernia repair depends on the compliance of the abdominal wall, and failure to achieve fascial closure results in inferior outcomes. There is currently no preoperative method to assess abdominal wall compliance and predict the ability to reconstruct the abdominal wall or the extent of myofascial release necessary to achieve this goal. Shear-wave elastography uses non-invasive ultrasound technology to measure the stiffness of abdominal wall muscles, potentially providing valuable data to support surgical decision making and patient informed consent.

II. INTRODUCTION

A. BACKGROUND

Describe the rationale for the study, including the disease or condition being studied, citations, and synthesized earlier preclinical and clinical research on the topic of the study:

Ventral hernia repairs (VHR) account for over 600,000 operations in the US each year [1]. While multiple options exist for repair, it is well established that fascial closure can reduce wound morbidity, decrease the risk of hernia recurrence, and improve physiologic parameters compared with bridging repair[2–4]. Depending on multiple patient and anatomic factors, a variable amount of tension is required to achieve closure, which can be offset by performing a myofascial release (MFR). This technique begins with incision of the posterior rectus sheath with progressive separation of the fascia from the rectus abdominis (RA) muscle, extending laterally to the linea semilunaris. The midline advancement afforded by this maneuver ranges from 3-5 cm per side[5]. Additional lateral release may include the external oblique myofascial release (EOR)[5], or transversus abdominis myofascial release (TAR)[6], which can provide additional medial advancement of the anterior fascia of up to 10 cm per side.

The majority of the data on myofascial advancement is derived from cadaver studies[5,7,8]. The advancement achieved *in vivo* can vary significantly according to defect width, abdominal wall compliance, and volume of herniated contents. Animal studies demonstrate hernia-induced histologic changes of the abdominal wall resulting in disuse atrophy and fibrosis, thus impairing compliance and impacting the ability to restore abdominal wall anatomy[9,10]. Our previous work evaluating computed tomography (CT) imaging in predicting the need for MFR beyond the rectus release (i.e. TAR or EOR) provides indirect insight into this phenomenon. We found a direct correlation of the rectus:defect ratio (RDR) to the need for TAR or EOR to achieve fascial closure. An RDR <1 required EOR/TAR in 78% of cases, while an RDR of >2 required EOR/TAR in just 10.8% and was found to be a more sensitive predictor of the need for additional release than hernia width alone[11]. For patients with loss of abdominal domain (LOD), progressive preoperative pneumoperitoneum (PPP) is sometimes required to lengthen the abdominal musculature and increase the abdominal cavity volume (ACV). The accommodating volume (AV) is calculated to determine if PPP enlarges the ACV enough to accommodate reintroduction of the initial hernia sac volume (HSV). A positive AV predicted fascial closure in 94.4% of patients, while a negative AV were closed in just 57.9% (data not yet published). Furthermore, a positive AV had significantly greater increase in oblique muscle length (5.4 vs 1.1cm). The AV is useful in predicting abdominal wall compliance and closure but is only calculable after a very invasive PPP procedure repair and is therefore not a useful preoperative assessment tool.

The tension required to achieve abdominal wall closure is a topic of ongoing research. Unpublished work from Cleveland Clinic clearly demonstrates a reduction in tension necessary to medialize the anterior fascia to the midline with MFR (personal communication; work submitted for publication and under review). Baseline tension to bring

fascia to the midline at the midpoint of the hernia defect was 6.78lbs. After complete release, this decreased to 3.12lbs. They also demonstrate a greater reduction in tension after MFR for patients with larger hernias. Other authors reported no correlation with intraoperative tension measurement and hernia width[12].

Any preoperative assessment tool needs to be readily accessible, affordable, accurate, and reproducible. Ultrasound shear wave elastography has the potential to provide this data. Elastography measures the physical properties of tissue by either mechanical deformation (strain elastography) or by analysis of shear wave propagation through the tissue (shear wave elastography – SWE). Fibrotic tissue is expected to be more stiff (less compliant), which is differentiated from soft, compliant tissue on an elastogram. Literature on SWE has primarily involved the assessment of hepatic fibrosis, though more recently been applied to breast, prostate, renal, and musculoskeletal diseases. SWE use for abdominal wall and in patients with ventral hernia is limited. Chaudhry, et al used SWE in a rat model of hernia repair as a means of detecting hernias and detecting prior VHR with either biologic or synthetic mesh. This study did not evaluate the muscle itself and all repairs were completed using a bridged repair without fascial closure[13]. Gabrielsen, et al have done important work in control patients without abdominal wall hernias, establishing normative data SWE values technical factors in the performance of SWE as a baseline for future study[14]. These baseline values were similar to those found by Wang, et al, who studied 14 control and 28 patients with incisional hernias. They found a decreased muscle thickness in the internal oblique and transversus abdominis and greater stiffness in hernia patients[15]. No study to date has correlated SWE with operative findings or tension.

B. IMPORTANCE / JUSTIFICATION FOR STUDY

Explain why the current research question is pertinent, important, interesting, or novel:

The ability to better predict the complexity of hernia repair and the extent of MFR needed has important implications in patient selection, informed consent, and selection of surgical approach. Complex VHR carries significant risk of morbidity, including a high risk of wound complications[2,16]. There is currently no objective preoperative method to determine abdominal wall compliance and predict the ability to achieve fascial closure, leaving this to the experience and judgment of the operating surgeon. Further, though MFR is standard in many high-volume specialty hernia practices, these techniques are often performed with much less frequency in other centers. Incorrect transition between MFR planes can result in devastatingly complex lateral hernias through the linea semilunaris[17]. Thus, for lower volume surgeons who may not feel comfortable performing these releases, the ability to reliably predict when they are needed adds to the potential benefit of SWE as a preoperative assessment tool.

III. HYPOTHESIS & OBJECTIVES

A. HYPOTHESIS

Describe the hypothesis/hypotheses that your study is intended to demonstrate, and your objectives are based:

Shear wave elastography can be used to predict abdominal wall compliance pre-operatively and can therefore be used as a tool to improve surgical outcomes.

B. OBJECTIVES

Describe the details of each objective that will lead to the achievement of the study goal including a summary of the outcome measures:

Specific Aim 1:

Determine the elasticity of abdominal wall muscles (rectus abdominis, external oblique, internal oblique, and transversus abdominis) through shear wave elastography in patients with midline incisional hernias of varying complexity and morphology.

Specific Aim 2:
Correlate shear wave elastography measurements of the abdominal wall with the extent of MFR required to achieve fascial closure.

Specific Aim 3:
Correlate SWE-determined elasticity of abdominal wall to intraoperative assessment of tension required to achieve fascial closure.

IV. DESIGN & METHODS

A. STUDY DESIGN

Briefly describe the study design (systematic review, randomized controlled trial, other controlled clinical trial, observational [cohort, case-control, cross-sectional], or case study):

Prospective cohort study of patients with midline ventral incisional hernia with a range of hernia morphology who plan to undergo open retromuscular VHR.

Study groups:
Study groups are selected across a range of morphology and based on factors known or suspected to affect the ability to achieve fascial closure.

Control groups: We plan to enlist 5 volunteers with no incisional hernia or prior laparotomy to establish internal baseline SWE values and interrater reliability. We will also plan to recruit 5 patients undergoing primary laparotomy in order to correlate SWE findings with closure tension.

B. SETTING

List the locations, with descriptions, of where procedures will be performed:

Prisma Health

1. Resources Available

List all research team members including contact details (e-mail addresses and telephone numbers):

Michael W Love, MD (wes.love@prismahealth.org)
Jeremy A Warren, MD, FACS (Jeremy.warren@prismahealth.org)
Alfredo M Carbonell, DO, FACOS (alfredo.carbonell@prismahealth.org)
Michael Devane, MD (mike.devane@prismahealth.org)

Briefly describe the qualifications (include approximate years of research experience) of the PI and co-investigators as well as their specific roles in the study:

Michael W Love, MD
Prisma Health Upstate Department of Surgery, Division of Minimal Access and Bariatric Surgery
Assistant Professor of Surgery, University of South Carolina School of Medicine Greenville

Sub-Investigators:

Jeremy A Warren, MD, FACS
Vice Chair of Academics, Prisma Health Upstate Department of Surgery, Division of Minimal Access and Bariatric Surgery
Associate Professor of Surgery, University of South Carolina School of Medicine Greenville

Alfredo M Carbonell, DO, FACOS
Prisma Health Upstate Department of Surgery, Division of Minimal Access and Bariatric Surgery
Professor of Surgery, University of South Carolina School of Medicine Greenville

Michael Devane, MD
Vice Chair of Academics, Prisma Health Upstate Department of Radiology, Division of Interventional Radiology

Describe availability/access to needed equipment and resources including access to the population of interest:

This study will utilize the ultrasound machine available in Radiology to perform the elastography. The tensiometers will be new equipment purchased by the investigator(s).

2. Multi-Site Research

If applicable, list sites involved in this study outside of Prisma Health and indicate the primary and satellite site(s):

N/A

C. PROPOSED INTERVENTION

1. Treatment

List the experimental treatment of interest and comparative treatment as applicable:

Imaging:

Ultrasound procedure will involve the following steps:

1. For control group 1 and group 2 patients, Images will be taken at two points along the bilateral RA; at the level of the umbilicus and midway between the umbilicus and xiphoid process. Bilateral external oblique (EO), internal oblique (IO), and transversus abdominis (TA) images will be performed at the level of the anterior axillary line midway between the costal margin and iliac crest.
2. For study patients, a single point of the bilateral RA will be selected at the longitudinal mid-point of the hernia defect. Bilateral EO, IO, and TA images will be performed at the level of the anterior axillary line midway between the costal margin and iliac crest.
3. Gray-scale imaging will first determine thickness and texture of each muscle layer. Texture analysis includes use of overlying subcutaneous fat as the internal control value.
4. SWE will be performed at each location with three successive maneuvers:
    a. With minimal external pressure applied by the ultrasound probe.
    b. Manual compression applied with the ultrasound probe (maximum pressure allowable without causing patient discomfort).
    c. During Valsalva.

Hernia repair:

All study patients will have an open retromuscular repair with/without additional lateral MFR (TAR or EOR at the discretion of the operating surgeon). All repairs beginning with retrorectus dissection to the level of the linea semilunaris. When needed, additional MFR progresses as follows:

1. For posterior myofascial release (TAR):
    a. Incision of the posterior lamella of the internal oblique (PLIO) just medial the intercostal neurovascular bundles and linea semilunaris
    b. Division of the transversus abdominis muscle / aponeurosisis

c. Lateral dissection to progressively separate the peritoneum from the transversus abdominis.

2. For anterior release (EOR):
   a. Subcutaneous flaps developed to the anterior or midaxillary line bilaterally.
   b. Division of the external oblique fascial and muscle 1cm or greater from the lateral border of the rectus sheath / linea semilunaris.
   c. Lateral dissection to progressively separate the external and internal oblique muscles.

All patients will have permanent mesh reinforcement of the abdominal wall (large-pore, midweight polypropylene). Fascia will be closed over the mesh with 0 or 2-0 polydioxanone slowly absorbable suture using a small-bite technique and a 4:1 suture length:wound length ratio.

Control group 1 patients will have no incisional hernia or prior laparotomy.

Control group 2 patients will have no hernia and will be undergoing elective midline laparotomy.

Tensiometry
For all study patients, an analog spring-tensiometer will be used to assess intraoperative tension required to bring the fascia to the midline for closure. The tensiometer is attached to a clamp attached to the fascia at the midpoint of the hernia defect. Tension required for medialization to the midline will be performed after adhesiolysis (baseline), retrorectus dissetion, incision of the PLIO (if performed), and after completion of TAR or EOR (if performed). Control group 2 patients will be undergoing first time laparotomy and will have tensiometry performed. As control group 1 is not having surgery, no tensiometry will be done.

2. Drugs

List the primary drug intervention of interest and any additional drugs used:

N/A

3. Devices

List the primary device intervention of interest:

N/A

D. POPULATION

Briefly describe the population of interest:

Patients with midline ventral incisional hernia with a range of hernia morphology who plan to undergo open retromuscular VHR.

Control: We plan to enlist 5 volunteers with no incisional hernia or prior laparotomy to establish internal baseline SWE values and interrater reliability. We will also plan to recruit 5 patients undergoing primary laparotomy in order to correlate SWE findings with closure tension.

1. Inclusion Criteria

Describe the inclusion criteria for the population of interest:

NOTE – inclusion criteria should, at a minimum: identify the disease or condition people must have to participate, define the acceptable age range, and delineate all other factors required to be in the study.

Patients >18 y/o.
Midline ventral / incisional hernia.
Plan for open retromuscular incisional hernia repair.

2. Exclusion Criteria

Describe the exclusion criteria:

NOTE – exclusion criteria should focus primarily on the protection of participants, with careful consideration of criteria needed to exclude those for whom participation would be unsafe.

Prior VHR with mesh.
Isolated subxiphoid (European Hernia Society (EHS) classification M1) or suprapubic hernias (EHS classification M5)
History of flank incisions. M1 (midline position 1) is defined as the xiphoid process down to a point 3cm below the xiphoid. M5 (midline position 5) is defined as the pubis to a point 3cm above the pubis.
Infected / contaminated cases.
Plan for robotic, laparoscopic, or open onlay repair, or plan for primary (non-mesh) repair.

3. Sample Size

If applicable, show the power calculation for the estimated sample size:

Group	Criteria	n
Control group 1:	No hernia or prior laparotomy	5
Control group 2:	No hernia undergoing elective midline laparotomy	5
Group 1: expected closure without additional myofascial release	RDR >2:1	25
Group 1a:	Xiphopubic hernias (M1-M5)	5
Group 2: expected need for additional myofascial release	RDR <1.5:1	25
Group 2a:	Xiphopubic hernias (M1-M5)	5
Group 3: Special circumstances		10
Group 3a:	Loss of domain (HSV:ACV >20%)	5
Group 3b:	History of open abdomen (unclosed)	5
Control: We plan to enlist 5 volunteers with no incisional hernia or prior laparotomy to establish internal baseline SWE values and interrater reliability. We will also plan to recruit 5 patients undergoing primary laparotomy in order to correlate SWE findings with closure tension.		

4. Local Number of Participants

List the number of expected participants within Prisma Health:
70 (see above table)
5. Study-Wide Number of Participants
For multi-site studies, list the number of expected participants in total (study-wide):
N/A
6. Recruitment Methods
Describe the recruitment process, including the source of participants:
NOTE – if the screening procedures are done as part of the study, they must be incorporated into this protocol with a description of the methods and their risks or discomforts. If participants are screened separately from the protocol, the method should be briefly acknowledged.
Participants will be patients with midline ventral incisional hernia with a range of hernia morphology who plan to undergo open retromuscular VHR. Control: We plan to enlist 5 volunteers with no incisional hernia or prior laparotomy to establish internal baseline SWE values and interrater reliability. We will also plan to recruit 5 patients undergoing primary laparotomy in order to correlate SWE findings with closure tension.

E. SPECIFICS OF STUDY PROCEDURES

Describe all participant research procedures, preferably in chronological order and from the participant's viewpoint. State where procedures will be done and if inpatient admission is required. Identify the required and optional study procedures. Identify the risks discomforts, and inconveniences of each procedure and intervention:
Imaging and tensiometry procedures are solely for the research study.
Describe all standard care procedures related to this study, preferably in chronological order and from the participant's viewpoint:
All surgical techniques/hernia repair are standard of care.
1. Study Timelines
List the duration of individual procedures and cumulative time commitment, including number and timing of visits and total duration of participation in the study:
NOTE – the duration of the study should reflect the disease or condition and intervention being studied. Define the frequency of study measurements needed to capture the primary outcome measure.
Study participation ends after surgery for those in the study group and control group 2. Study participation ends for control group 1 after they complete the ultrasound imaging procedures.
2. Study Endpoints
For clinical trials, list the study endpoints:
Specific Aim 1: Determine the elasticity of abdominal wall muscles (RA, EO, IO, and TA) through SWE in patients with midline incisional hernias of varying complexity and morphology.

Specific Aim 2:
Correlate SWE measurements of the abdominal wall with the extent of MFR required to achieve fascial closure.
Specific Aim 3:
Correlate SWE-determined elasticity of abdominal wall to intraoperative assessment of tension required to achieve fascial closure.

3. Outcome Measures/Data

List all outcome measures/data that will be collected including explanations/definitions of measures as necessary:

Patient demographics, MRN, DOB, date of surgery, date of US, operative details, comorbidities, hernia repair details, US elasticity measurements, tensiometry measurements, any post-operative outcomes/complications.

4. Data Collection Methods and Instruments Used

Describe how data will be collected including a copy of the data collection instrument/data collection form:

Clinical data on patient demographics, comorbidities, hernia characteristics, hernia repair details, and postoperative outcomes will be captured in the Abdominal Core Health Quality Collaborative (ACHQC). For control patients, demographic data and comorbid conditions will be captured separately in Redcap. Ultrasound SWE data will be collected and recorded in Redcap. Intraoperative tensiometry values will be recorded in Redcap. Only the investigators and study coordinator will have access to patient-level data. PHI in Redcap is used only to connect with the clinical data in the ACHQC.

5. Data Management

Describe the data monitoring procedures to assist in determining trends that affect the integrity of the study or participant safety. Include details on who will monitor, what they review, and how frequently data is reviewed. Also include any policies and procedures if a problem is identified, and the study needs to be suspended or stopped:

Clinical data on patient demographics, comorbidities, hernia characteristics, hernia repair details, and postoperative outcomes will be captured in the Abdominal Core Health Quality Collaborative (ACHQC). For control patients, demographic data and comorbid conditions will be captured separately in Redcap. Ultrasound SWE data will be collected and recorded in Redcap. Intraoperative tensiometry values will be recorded in Redcap. Only the investigators and study coordinator will have access to patient-level data. PHI in Redcap is used only to connect with the clinical data in the ACHQC.

6. Data and Specimen Banking

Describe the storage and management plan of research samples and/or data to assure their integrity and availability for analyses to fulfill the objectives of the study:

NOTE – clearly articulate if samples and data will be retained after the study is complete, whether data and/or samples may be shared with others, the purposes for which they may be used, and any restrictions on use. The protocol management plan must reflect information in the consent form on the additional use of data and samples. If participants are offered options, the participants' choices as to further use should be outlined.

Clinical data on patient demographics, comorbidities, hernia characteristics, hernia repair details, and postoperative outcomes will be captured in the Abdominal Core Health Quality Collaborative (ACHQC). For control patients, demographic data and comorbid conditions will be captured separately in Redcap. Ultrasound SWE data will be collected and recorded in Redcap. Intraoperative tensiometry values will be recorded in Redcap. Only the investigators and study coordinator will have access to patient-level data.

7. Statistical Analysis

Describe how the data and samples will be analyzed to achieve all study objectives:

Measures of central tendency (i.e., mean and standard deviation or median and interquartile range) will be used to describe continuous variables. Pearson or Spearman Rank correlation coefficients will be used to assess the linear

relationship between continuous variables. Differences in continuous variables between groups will be analyzed using Student's two-sample t-test or the Wilcoxon Rank Sum test. Analysis of variance techniques will be used to adjust for subgroup differences in continuous measurements if sample sizes allow. Statistical measures chosen for reporting will be based on the data distribution (i.e., parametric vs. nonparametric). SAS Enterprise Guide 8.3 software will be used for statistical analyses.

V. ETHICAL CONSIDERATIONS

A. RISKS AND POTENTIAL BENEFITS TO PARTICIPANTS

1. Risks to Participants

Define the study as "minimal risk" or "more than minimal risk" considering all risks and burdens of participation:

NOTE – If there are multiple study populations and the overall risk and benefit is different for individual populations, then define the risk for each population separately.

There are no medical risks related to participating in this study, as there are no known risks from the sound waves used in an ultrasound scan or the measurements done by the tensiometers. There is always a possible release of PHI; however numerous and appropriate steps will be taken to protect PHI, especially as this information may be used for presentations and publications.

2. Potential Benefits to Participants

Describe any benefits to participants:

NOTE – the classification of benefit should be weighed based on reasonable expectation of benefit for the individual participant. The possibility of indirect benefit, such as gaining generalizable knowledge may be sufficient depending on the nature and risks of the study.

There is no direct benefit to participants, but their participation will enhance future medical care.

B. PARTICIPANT CONFIDENTIALITY AND PRIVACY

1. Participant Confidentiality

Describe the plan to protect participant confidentiality including controls on storage, handling, and sharing of data. If applicable, include a schedule for destruction of identifiers associated with the data:

NOTE – confidentiality is the researcher's agreement with participants about how their identifiable private information (data) will be handled, managed, and disseminated. It protects the participants' personally identifying data and records. Confidentiality can be maintained by assigning records, data, and samples a code that does not embed personal identifiers and keeping the key to the code separately and securely. Further protections may include limiting access to identifiable data and the key to the code, and keeping records secured in double-locked storage and on secure, protected servers and computers.

Data from the study will be collected from Epic and stored in ACHQC or RedCap, both online databases that are HIPAA compliant. Only investigators involved in this study will have access to this information and investigators will access the minimum amount of data necessary to complete the study.

2. Provisions to Protect the Privacy Interests of Participants

Describe the plan to protect participant privacy, including how the investigator(s) will access information from or about participants:

NOTE – privacy refers to a person's desire to control the access of others to themselves (concerns people). Consider the methods used to identify and contact potential participants, the settings in which an individual will be interacting with an investigator, and the appropriateness of having all personnel present for research activities. Consider the methods used to obtain information about participants, the nature of the requested information, and how to access the minimum amount of information necessary to complete the study.
Investigators will access minimum amount of data necessary for study completion.

C. VULNERABLE POPULATIONS

Describe any vulnerable populations required to complete the study objectives as well as the plan to offer extra protection of confidentiality and privacy:
NOTE – for studies enrolling minors, it should also be determined if a "more than minimal risk" study is no more than a minor increment over minimal risk. For minors, the risk level of the study, along with consideration of whether there is direct individual benefit, determines whether the study fits into a category of approvable research.
N/A

D. CONSENT PROCESS

Describe the procedures to provide informed consent to potential participants:
NOTE – be sure to include any therapeutic alternatives (may include standard care). It should be acknowledged if the drug, device, or intervention under study can be obtained outside of the study, such as through a prescription for off label use. Clearly describe risks and potential benefits including confidentiality and privacy risks. Clearly delineate who will have access to the participant's information and under what circumstances data may be shared (i.e., with government agencies, sponsors, etc.).
The participants will be asked to sign a consent form prior to participation. The study doctor will consent the participants before any study procedures are completed. All communication will take place in a private setting. The participant will be given ample time to read the consent and have all questions answered prior to providing signature. The consent will be signed and dated by all parties and a copy will be provided to the participants at the time of consent.

E. PARTICIPANT ECONOMIC BURDEN/COMPENSATION & OTHER STUDY DETAILS

1. Economic Burden to Participants
If applicable, describe any potential economic burdens to participants:
N/A
2. Compensation for Research-Related Injury
If applicable, provide details on the amount, method, and timing of compensation:
NOTE – if there are more than one study cohort, include descriptions if they will be compensated differently.
Patients will be offered a small stipend of $25 to participate in the study and compensate the time required for SWE. Participants will be compensated after the completion of the ultrasound.
3. Debriefing Participants
If applicable, describe the procedures to debrief participants including what data and information will be released:

N/A
4. Community-Based Participatory Research
If applicable, describe the details on Community-Based Participatory involvement with this study:
Note – "Community-based Participatory Research (CBPR)" is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.
N/A

VI. BIBLIOGRAPHY

1. Schlosser KA, Renshaw SM, Tamer RM, Strassels SA, Poulose BK. Ventral hernia repair: an increasing burden affecting abdominal core health. Hernia. Published online 2022:1-7. doi:10.1007/s10029-022-02707-6

2. Scheuerlein H, Thiessen A, Schug-Pass C, Köckerling F. What Do We Know About Component Separation Techniques for Abdominal Wall Hernia Repair? Frontiers Surg. 2018;5:24. doi:10.3389/fsurg.2018.00024

3. Holihan JL, Askenasy EP, Greenberg JA, et al. Component Separation vs. Bridged Repair for Large Ventral Hernias: A Multi-Institutional Risk-Adjusted Comparison, Systematic Review, and Meta-Analysis. Surg Infect. 2016;17(1):17-26. doi:10.1089/sur.2015.124

4. Jensen KK, Backer V, Jorgensen LN. Abdominal wall reconstruction for large incisional hernia restores expiratory lung function. Surgery. 2017;161(2):517-524. doi:10.1016/j.surg.2016.08.015

5. Ramirez OM, Ruas E, Dellon AL. "Components Separation" Method for Closure of Abdominal-Wall Defects. Plast Reconstr Surg. 1990;86(3):519-526. doi:10.1097/00006534-199009000-00023

6. Novitsky YW, Elliott HL, Orenstein SB, Rosen MJ. Transversus abdominis muscle release: a novel approach to posterior component separation during complex abdominal wall reconstruction. Am J Surg. 2012;204(5):709-716. doi:10.1016/j.amjsurg.2012.02.008

7. Majumder A, Miller HJ, Campo LM del, Soltanian H, Novitsky YW. Assessment of myofascial medialization following posterior component separation via transversus abdominis muscle release in a cadaveric model. Hernia. 2018;22(4):637-644. doi:10.1007/s10029-018-1771-7

8. Afifi AM, Hartmann E, Talaat A, et al. Quantitative Assessment of Tension Reduction at the Midline Closure During Abdominal Component Separation. J Am Coll Surgeons. 2017;224(5):954-961. doi:10.1016/j.jamcollsurg.2016.12.052

9. Culbertson EJ, Xing L, Wen Y, Franz MG. Loss of mechanical strain impairs abdominal wall fibroblast proliferation, orientation, and collagen contraction function. Surgery. 2011;150(3):410-417. doi:10.1016/j.surg.2011.06.011

10. DuBay DA, Choi W, Urbanchek MG, et al. Incisional Herniation Induces Decreased Abdominal Wall Compliance via Oblique Muscle Atrophy and Fibrosis. Ann Surg. 2007;245(1):140-146. doi:10.1097/01.sla.0000251267.11012.85

11. Love MW, Warren JA, Davis S, et al. Computed tomography imaging in ventral hernia repair: can we predict the need for myofascial release? Hernia. 2021;25(2):471-477. doi:10.1007/s10029-020-02181-y

12. Hope WW, Williams ZF, Rawles JW, Hooks WB, Clancy TV, Eckhauser FE. Rationale and Technique for Measuring Abdominal Wall Tension in Hernia Repair. Am Surg. 2018;84(9):1446-1449. doi:10.1177/000313481808400947

13. Chaudhry A, Fernandez-Moure JS, Shajudeen PS, et al. Characterization of ventral incisional hernia and repair using shear wave elastography. J Surg Res. 2017;210:244-252. doi:10.1016/j.jss.2016.11.041

14. Gabrielsen DA, Carney MJ, Weissler JM, et al. Application of ARFI-SWV in Stiffness Measurement of the Abdominal Wall Musculature: A Pilot Feasibility Study. Ultrasound Medicine Biology. 2018;44(9):1978-1985. doi:10.1016/j.ultrasmedbio.2018.05.007

15. Wang X, He K, Zhu Y, et al. Use of Shear Wave Elastography to Quantify Abdominal Wall Muscular Properties in Patients With Incisional Hernia. Ultrasound Medicine Biology. 2020;46(7):1651-1657. doi:10.1016/j.ultrasmedbio.2020.03.027

16. Cobb WS, Warren JA, Ewing JA, Burnikel A, Merchant M, Carbonell AM. Open Retromuscular Mesh Repair of Complex Incisional Hernia: Predictors of Wound Events and Recurrence. J Am Coll Surgeons. 2015;220(4):606-613. doi:10.1016/j.jamcollsurg.2014.12.055

17. Zolin SJ, Fafaj A, Krpata DM. Transversus abdominis release (TAR): what are the real indications and where is the limit? Hernia. 2020;24(2):333-340. doi:10.1007/s10029-020-02150-5

VII. APPENDICES

None.