Official Title: A Comparison of the Outcomes in Fortiva and Strattice Mesh

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Background, Rationale and Context

Ventral hernia repair (VHR) is a common procedure performed by general surgeons with an estimated 400,000 per year performed in the United States [1]. Based on available literature, experts strongly recommend mesh reinforcement for all elective VHR of hernias at least 2cm in diameter with no contamination. There is currently no conclusive recommendation for mesh reinforcement in emergent VHR, VH < 2cm, or in the setting of contamination [2]. There are numerous types of mesh available, including biologic and synthetic. Because synthetic mesh has been associated with a host of complications including infection, adhesions, bowel obstruction, and enterocutaneous fistula, biologic meshes were developed and are widely available in various types. They provide an acellular collagen matrix on which the host tissue can regenerate [3]. Biologic meshes are generally significantly more expensive than their synthetic counterparts [4,5] although long-term cost analysis has suggested that biologic mesh may be more cost-effective due to the long-term complication rates for synthetic mesh [5]. Few studies have compared the various types of biologic mesh [6]. In this study, we aim to compare two different types of biologic mesh in VHR: Fortiva and Strattice to determine the difference in rates of hernia recurrence and mesh related complications. Fortiva is an FDA cleared (510(k)) biologic mesh that is "substantially equilvalent" to Strattice mesh but at a reduced cost making the mesh more cost efficient. The risks associated with this study are expected to be the same as those associated with a VHR utilizing Strattice mesh.

Goal

The goal of this research study is to show that Fortiva porcine dermis biologic mesh is equivalent to Strattice biologic mesh with respect to hernia recurrence rates and mesh related complication rates. Fortiva is an FDA cleared (510(k)) hernia mesh that is substantially equivalent to Strattice but at a reduced cost. The goal is to show similar equivalent outcomes to justify the use of Fortiva.

Objectives

Primary Objective: To determine the hernia recurrence rates for RTI Surgical biologic mesh (Fortiva) compared to Strattice
Hypothesis: Fortiva mesh will have equivalent rates of hernia recurrence compared to Strattice

Secondary Objective(s): To determine the mesh related complications for RTI Surgical biologic mesh (Fortiva) compared to Strattice
Hypothesis: Fortiva mesh will have equivalent rates of mesh related complications compared to Strattice

Methods and Measures

Design

This study will be a prospective, matched study of patients using Fortiva biologic mesh to determine the rates of hernia recurrence and mesh related complication compared to a retrospective cohort of patients who received Strattice mesh. The indication CLASP surgeons use for biologic mesh use is in contaminated/dirty cases; surgeons are sometimes unable to determine this until they are in the OR. To account for the nature of biologic mesh use in

ventral hernia repair, patients whom an attending surgeon uses Fortiva mesh in the OR when it was not otherwise planned (i.e. the surgeon changed the plan intraoperatively) will be approached in the postoperative space (i.e. follow-up clinic visits or phone calls) to be consented for inclusion in the study. In the event a subject cannot be reached in clinic prior to the end of their standard of care follow-up, a full waiver of consent will be requested to capture all patients and not unnecessarily skew the results. The rates of hernia recurrence and mesh related complications will be compared to determine equivalence. Patients who meet the inclusion and exclusion criteria will be prospectively enrolled to receive a Ventral Hernia Repair (VHR) using Fortiva biologic mesh and will be compared to a retrospective cohort of patients with a VHR that utilized Strattice mesh. All procedures and clinical care have already occurred for the participants who received a VHR with Strattice mesh. Participants will be propensity matched in a 1:3 (Fortiva : Strattice) fashion based on age, sex, and hernia defect size to control for confounding variables.

Setting

Hybrid Academic Medical Center

Subjects selection criteria

Patients who meet the following criteria will be included in the study.

- **Inclusion Criteria**
  - Aged at least 18 years
  - Ventral Hernia requiring surgical repair
- **Exclusion Criteria**
  - Pregnant women
  - Sensitivity to Polysorbate 20
- **Sample Size**

  This study will have a sample n=200 (n=50 Fortiva, n=150 Strattice). All participants may not be eligible for the study, so this study may consent up to 100 prospective participants to achieve the 50-participant sample size. This study will serve as a pilot study to compare rates of hernia recurrence and mesh related complications between Fortiva and Strattice. Our group has published research in press showing a 4% hernia recurrence rate for Strattice mesh. Based on an alpha level of 0.05 and a beta of 0.80 and a non-inferior limit of 2% the sample size per group would be 1188. Based on these numbers we would like to do a matched pilot study with a more feasible sample size of 200 participants (n=50 Fortiva(retrospective and prospective), n=150 Strattice(retrospective)).

Interventions and Interactions

This study will involve surgical ventral hernia repair utilizing a biologic hernia mesh (Fortiva). Fortiva mesh may be used by a CLASP surgeon in ventral hernia repair in patients even if they choose not to participate in the research study.

- This study will involve the implantation of RTI Surgical Fortiva biologic mesh in the reconstruction of the abdominal wall. Mesh size, position, location and procedure will be determined and performed by an attending surgeon from Carolinas Laparoscopic & Advanced Surgery Program (CLASP).
- Study participants will be asked to follow up for at least 36 months.
  - Follow up will include participants being seen back in clinic as part of our standard of care after a ventral hernia repair or contacted via telephone at 2-weeks, 6-months, 1-year, 2-year, 3-year to evaluate the participants progress and recovery using the Fortiva mesh

Data elements to be collected are listed below:

- Age
- Sex
- Race
- Body mass index (BMI)
- Comorbidities
    - Asthma
    - Cirrhosis
    - Congestive heart failure (CHF)
    - COPD
    - Coronary Artery Disease
    - Current Steroid Use
    - Current Anticoagulant Use
    - Diabetes history
    - Hemoglobin A1c
    - End Stage renal Disease
    - History of Cancer
    - Hypertension
    - Obstructive Sleep Apnea
    - Peripheral Vascular Disease
    - Smoking history
    - Current smoking status
    - Stroke History
    - Transplant patient
- Hernia defect size
- At the time of Surgery
    - Fistula present(y/n)
    - Mesh infection(y/n)
- Mesh size
- Mesh type
- Mesh location (preperitoneal, intraperitoneal, inlay/bridging, retrorectus, onlay)
- Number of hernia failures
- Number of hernia procedures
- Type of hernia procedures (emergent vs elective)
- Dates of Surgery
- Use of botox (y/n)
- American Society of Anesthesiologist (ASA) Classification
- Operative findings
    - Complete Fascial closure(y/n)
    - Enterotomy
- Use of component separation techniques (external oblique release or transversus abdominus release) to enable closure
- Length of Operation
- Recurrence(y/n)
- TAPP block
- Mesh resection
- Concomitant procedures
- Concurrent panniculectomy
- Mesh fixation (sutures/glue/none)
- Delayed primary skin closure(y/n)

- Wound complications(y/n)
    - Wound cellulitis
    - Wound infection
    - Surgical site infection (SSI)
    - Superficial wound breakdown
    - Intra-abdominal abscess
    - Seroma requiring intervention
    - Mesh infection
- Length of Stay
- Mortality
- 30-day readmission
- Pulmonary failure (y/n)
- Post-operative follow-up time

Outcome Measure(s)
This study will measure the rate of hernia recurrence and mesh related complications for patients undergoing VHR with RTI Surgical Fortiva biologic mesh compared with patients who underwent VHR with Strattice mesh.

Analytical Plan
Results will be analyzed initially using descriptive statistics. Comparison between groups will be done using chi square tests for proportions, and t-tests or ANOVA procedures for continuous variables. Regression analysis will be performed to identify independent outcome predictors. Other inferential statistical analysis will be conducted as appropriate.

Human Subjects Protection

Subject Recruitment Methods
Subjects will be recruited in the attending physician's clinic. The attending physician will present the study initially and if the patient is interested a member of the study team (attending physician, fellow, resident, research manager or research associate) will fully introduce the study via protocol and ICF. Subjects may also be recruited via telephone if they have already been seen in clinic and will not be seen again prior to surgery but may otherwise be a candidate for the study. Telephone calls will be made prior to the day of surgery. Patients contacted via telephone will be introduced to the study and, if interested, will be noted as such and asked to sign the ICF on the day of surgery.

No preference will be given to any sex, race, or ethnicity. Patients who meet the inclusion/exclusion criteria will be recruited with the same interest level. PHI will be kept confidential in the clinic as well as before and after telephone calls to gauge recruitment interest.

Informed Consent
Signed informed consent will be obtained from each subject in the prospective group. Informed consent will be obtained by a member of the research team (PI, Co-I, fellow, resident, research manager, or research associate) in the clinic prior to the date of surgery. Informed consent may be obtained on the day of surgery, if the patient has been contacted previously prior to the day of surgery, via telephone, and has stated an interest in participating in the research study.

A full waiver of consent/assent and a waiver HIPAA authorization will be requested for patients in the retrospective group as their procedures and outcomes have already happened and reporting on the procedures and outcomes will not adversely affect the patient's care. Access to age in years and

office/clinic notes will be requested. Access to patient name, phone number and MRN will be the only identifying information requested. The study material is identifiable; however, study data will be linked by an identifier assigned to each participant and the identifier will be the only information maintained in the study data. The standard operating procedure for our group is to keep all study data in a locked suite, locked file cabinet, or electronically via password protection on a secure computer, on a secure network. Identifiers will be kept as part of the participants' medical record indefinitely. Access to this information is requested to identify patients who have already undergone VHR with Strattice mesh and would be of the retrospective cohort.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed three years post study closure via overwriting and deleting electronic file and disposing of paper PHI in designated PHI destruction bins, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

References

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Appendix

1. Data collection form
2. ICF
3. 510(k) FDA Cleared as “Substantially Equilvalent” to Strattice Mesh