RESEARCH PROTOCOL

TITLE OF PROTOCOL: A Randomized, Prospective, Double Blind Clinical Trial of Non-Cross-Linked Porcine Dermis vs. Bioabsorbable Synthetic Mesh for the Repair of Abdominal Wall Defects in At-Risk Patients

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Summary

We propose a randomized, prospective clinical trial to evaluate the use of non-cross-linked porcine dermis (Strattice®) versus bioabsorbable tissue reinforcement (Gore® Bio-A®) for repair of abdominal wall defects in grade II or III hernia patients according to Ventral Hernia Working Group (VHWG) classification [1].

Purpose

The goal of the proposed study is to evaluate the outcomes of patients implanted with Strattice® (LifeCell Corporation, Branchburg, NJ, USA) and Gore® Bio-A® (W. L. Gore & Associates, Inc., Newark, DE, USA) for the repair of abdominal wall defects in at-risk patients. Primary endpoints of the study will include hernia recurrence, duration of postoperative drains, the incidence of systemic and wound-related complications, the need for percutaneous intervention or reoperation and quality-of-life with 3 years of follow-up. The study will be prospective and randomized, and the evaluator and patient will be blinded as to the type of mesh implanted.

Background and Significance

Over 150,000 ventral and incisional hernia repairs are performed annually in the United States [2]. Reinforcing the fascial closure with mesh has dramatically reduced recurrence rates by as much as 50-70%. Synthetic mesh has been shown to provide durable long-term outcomes; however, its use is contraindicated in contaminated fields. Contaminated and dirty wounds include a spectrum of operations involving opening or anastomosis of the GI tract, reoperation at the sites of on-going or previous infection, fistula, or abscess, infected foreign body, and major break in sterile technique. If a permanent synthetic mesh is used under such circumstances, there is greater than 50% risk of developing subsequent infection or persistent draining sinus as the synthetic mesh can harbor bacteria and prevent the host immune system from eradicating the infection even with adequate antibiotic treatment [3]. In the majority of these cases (50-90%), the mesh has to be surgically excised to enable the wound to heal [4].

To address the challenge of prosthetic reinforcement in contaminated fields, biologic grafts or meshes have been developed. Biologic mesh is made of an acellular collagen matrix derived from dermal, fascial, pericardial, or other tissues. Strattice® (LifeCell Corporation, Branchburg, NJ, USA) is a common biologic mesh originating from porcine dermal matrix. Biologic meshes allow the body to eradicate small amounts of bacterial contamination (up to 10^4 CFU/ml) by promoting tissue in-growth into the mesh collagen matrix. Porcine derived biologic meshes have been shown to clear bacterial infection with Staphylcoccus aureus. Strattice was demonstrated to be most effective among porcine meshes at lowering bacterial counts[5] and has been shown to provide equivalent integrity and strength of hernia repair in animal models[6]. However, in the same animal models followed over longer periods of time, we have seen both animal and human derived biologic meshes lose their integrity and tensile strength when exposed to bacterial loads at the time of implantation[7]. The impact of this phenomenon has been documented in humans, but its clinical relevance and impact on long term results has not been tracked.

In recent years, bioabsorbable, non-tissue derived products have been developed as an alternative to biologic mesh. Bioabsorbable mesh employs the same principals as biologic mesh by promoting tissue

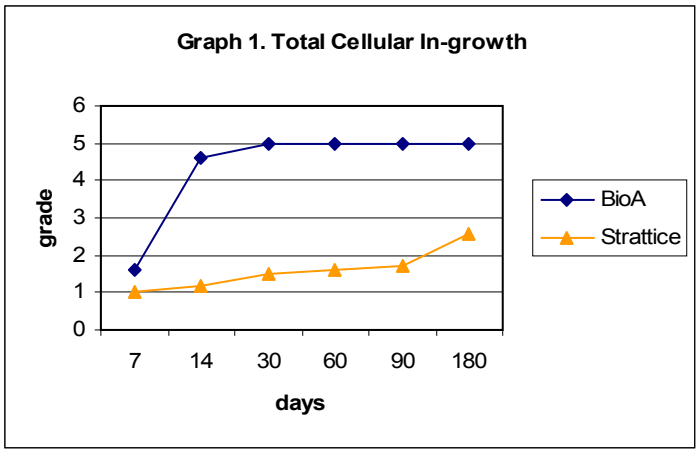
in-growth and neovascularization but was developed to address the weaknesses of biologics. Bio-A® (W. L. Gore & Associates, Inc., Newark, DE, USA) is a bioabsorble mesh composed of 67% polyglycolic acid and 33% trimethylene carbonate commonly used in the reinforcement of soft tissue. Identical chemical composition is used in making some sutures and Seamguard®, a product used in the reinforcement of staple lines. These are inert materials, neither of which has been known to stimulate allergic reactions in human subjects. Bio-A is constructed as a non-woven web that acts as a scaffold for tissue in-growth and is absorbed in the body within approximately 6 months.[8] Furthermore, the use Bio-A offers healthcare providers and patients significant cost savings over biologics, as much as 66% per square centimeter.[9]

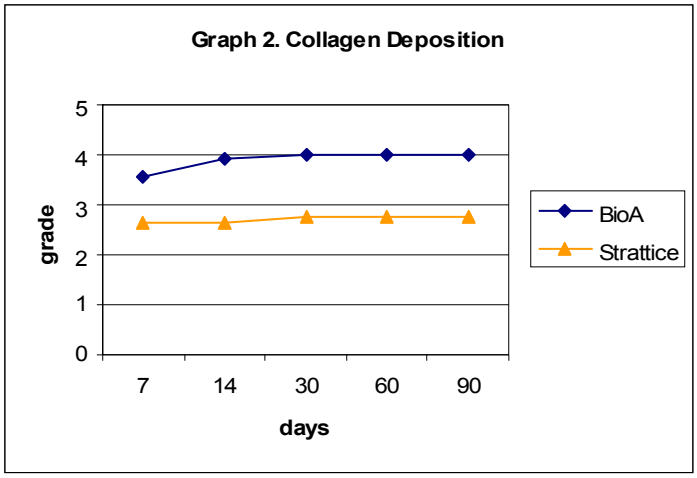
Although our own animal studies (see below) have demonstrated improved tissue in-growth and collagen deposition with bioabsorbable mesh compared to biologic porcine-derived material, no randomized, prospective, blinded study comparing these two mesh types is available nor has there been long term follow-up which includes quality of life measures in humans. Therefore, we propose a randomized, prospective, blinded clinical trial of patients with grade II or III ventral hernias according to Ventral Hernia Working Group (VHWG) classification that will compare outcomes of Strattice versus Bio-A. Grade II hernias are those in patients with certain comorbidities (diabetes mellitus, immunosuppression, current tobacco use, COPD, or BMI>30) that have been associated with higher rates of wound infections. Grade III hernias are considered to be potentially contaminated due to previous wound infection, presence of intestinal stoma, or violation of gastrointestinal tract[1]. Grade IV hernias are those in contaminated fields (current mesh infection, septic dehiscence), and these hernias will be excluded from this study.

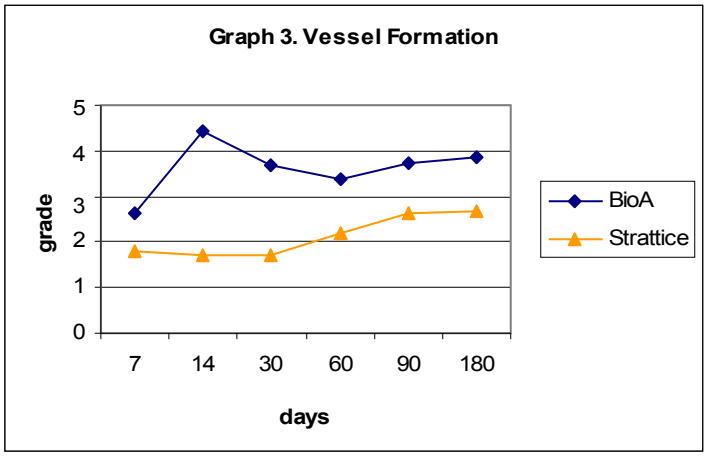
An appropriate prospective, randomized, double-blind clinical trial comparing the outcomes of Strattice and Bio-A in patients who would benefit from them most is absolutely needed and will allow surgeons to contrast results in an effort to decide which material will improve the outcomes of their patients with complicated abdominal wall defects.

Preliminary Data

We have previously evaluated tissue in-growth, collagen deposition and vessel formation of Bio-A and Strattice in sterile fields in a rabbit model. Grafts were implanted subcutaneously and harvested at 7, 14, 60, 90 and 180 days. The results are shown below.







Bio-A exhibited a higher degree of cellular in-growth, neovascularization, and collagen deposition than Strattice; however, we would like to evaluate use of both of these mesh types in at-risk patients to determine if one mesh produces superior outcomes in comparison to the other.

Materials and Methods - Patient Enrollment:

This is a prospective, randomized study. Study subjects will include patients classified as grade II and grade III according to VHWG classification scheduled for elective or non-emergent open ventral hernia repair.

Patients will qualify for this study if they meet the following criteria:

- Age 18 or older
- Grade II or III ventral hernia according to VHWG classification system
- Pre-operative informed consent is obtainable

Patients will be excluded from the study if they meet the following criteria:

- Return to the operating room within the next 1 year for additional open abdominal surgery is anticipated
- Absence of fascial defect or fascial defect less than 3 cm in greatest dimension
- Presence of previously placed mesh (synthetic or biologic) at the site of surgery, which will not be completely removed and will, in part or in whole, remain at the site of implantation of the study mesh
- Concurrent placement of another mesh (synthetic or biologic) at the site where the study mesh is placed
- Grade IV ventral hernia according to VHWG system
- ASA[1] score IV or above
- Any disease or condition along with the surgeon's clinical judgment that contraindicates the use of either study mesh
- Pregnancy
- Use of more than one of the same study mesh is not an exclusion criterion in and of itself, so long as the type of mesh is selected according to the randomization protocol

During pre-operative evaluation, patients will be informed about the details of the proposed study including the use of mesh, methods and possible risks of the procedure as well as possible side effects associated with the use of mesh. Implantation of either mesh product should not increase the risk of post-operative morbidity. The patients will be informed that the use of non-permanent mesh is clinically indicated in their condition and the determination to use a non-permanent mesh intra-operatively will be made entirely on clinical grounds and not based on the research protocol. If a non-permanent mesh is required (biologic or bioabsorbable), the randomization of the study will prescribe which type of mesh will be used. To date, there is no evidence to suggest that either one of the study meshes is superior or safer than the other. Patients willing to enroll must be able to give their informed consent to a research coordinator, which will include permission to collect data, distribute surveys and contact them after surgery for educational and research purposes.

Patient Randomization:

Randomization will be performed by a certified statistician using a computerized algorithm. Stratified randomization will be used based on the demographics, comorbidities and nature of any potential

[1] American Society of Anesthesiologists

contamination in order to maximize the likelihood of balanced groups. Patients will remain unaware of their group assignment or implanted mesh type throughout the duration of the trial.

Peri-Operative Care:
On the day of surgery, each patient will be randomized into one of two mesh groups. A group assignment letter in a sealed opaque envelope will be placed into patient's chart. The chart will be marked with a sticker indentifying the patient as part of proposed clinical study. Prior to taking the patient back to the operating room, the circulating nurse will check that the patient is appropriately consented and understands he/she is enrolled in the study. Furthermore, the circulating nurse is responsible for ensuring that the sealed envelope is in the chart and has not been opened. Following patient transfer to the operating room and induction of anesthesia, the circulating nurse will perform a "time-out", where he/she reads the consent form and notifies the operating room that the patient is part of the proposed study. As part of the time-out, the circulating nurse will open the sealed envelope and announce the mesh assignment to the surgical team prior to incision. This will give sufficient time for the staff to locate all necessary materials.

Materials:
The study meshes:

- Strattice® (LifeCell Corporation, Branchburg, NJ, USA)
- Gore®Bio-A® (W. L. Gore & Associates, Inc., Newark, DE, USA)

as well as adjunct fixation materials will be drawn from the Operating Room supply. A member of the research team will ensure adequate stock of both mesh types. The size of the mesh will be determined by the operating surgeon. Unless otherwise clinically indicated, surgeons will obtain at least a 5 cm mesh-fascial overlap for the hernia repair, except possibly at the pubis or xiphoid process. The mesh is to be secured to the fascia using Prolene™ Polypropylene Suture (Ethicon, Inc., Hamburg, Germany) size 0 or greater on a non-cutting needle. Alternatively, an equivalent size polypropylene monofilament suture may be used. If more than one piece of subject mesh is required, the pieces must be sewn together with a running 0 polypropylene suture with interrupted stitches of 0 polypropylene every 1.5cm. The mesh pieces may be of different sizes, however, all pieces must be of the same material as per the group assignment. Use of more than one type of mesh will result in disqualification from the study.

Procedure for Repair of Abdominal Defect:
In both groups, patients will receive underlay mesh tissue reinforcement followed by standard fascial closure with #1 PDS. This technique will require the surgeon to develop a plane between the rectus muscle and the posterior rectus sheath or the peritoneum and fascia for mesh placement. The mesh product will be placed in the developed space under the defect. As mentioned above, in a rare case when larger piece of mesh is required, a second packet of mesh will be opened and the mesh will be sutured together as previously mentioned. As described by Dr. Stoppa[10-12], the mesh will be secured via non-absorbable, full thickness, abdominal wall sutures. Two interrupted sutures will be used to anchor the mesh superiorly and two interrupted sutures will be used inferiorly. Additional full thickness sutures will be placed every 8 cm circumferentially. After securing the mesh in place, #1 PDS sutures will be used to close the fascia in a running fashion with 1.5-2 cm "bites" from the fascial edge and a 1cm "walk" between stitches. Skin will be closed with staples or monofilament suture

according to surgeon preference. One or two drains will be placed on the mesh in each case, and one or two drains will be placed in the subcutaneous tissues at the discretion of the surgeon depending on the amount of subcutaneous tissue dissected.

To qualify for the study, the fascia must be closed completely and without tension. A posterior rectus release to relax the fascial closure will be allowed, but a formal components separation, with laceration of the external oblique, will disqualify a patient from the study. A mesh bridge is not allowed and will result in disqualification from the study. Aside from this restriction, mesh may be placed in the preperitoneal or retrorectus position. Careful documentation by the operating surgeon of all of the repair components is imperative to avoid introducing bias, as well as precise description of the number of transfascial fixation sutures and additional fixation modalities.

Post-Operative In-Hospital Care:

All patients will be admitted to the hospital for postoperative monitoring. Depending on the preoperative diagnosis and concomitant procedures, patients will typically stay in the hospital for a period of 4-7 days. Intravenous antibiotics will be administered to patients with infected wounds and at the discretion of the attending surgeon following CDC guidelines. Early clinical outcomes will be documented as related to return of GI motility, respiratory status, renal function, pain control, and ambulatory status. Criteria for discharge will include absence of fever >100.5^{o}F, adequate oral intake to maintain hydration and nutrition, and sufficient pain control with oral analgesics as determined by the attending surgeon.

Safety Monitoring:

Safety issues that may terminate the study are significant differences in 30 day mortality and unplanned reoperative interventions, as well as mesh breakdown or wound dehiscence. Given the inherently high rates of infection of grade II and III wounds, any observed differences in complication rates will be rigorously investigated prior to any sanctions on study continuation. Any unexpected mortality will be reported directly to the IRB for their review. Any complications that are directly attributed to the implant will also be reported to the IRB. Ronald F. Sing, D.O. will perform the role of safety monitor for this study and will be informed of any untoward complication including a surgical site infection, seroma formation, wound dehiscence, postoperative evisceration, or mortality within 48 hours. Lot numbers for individual mesh products will be recorded in the operating room to reference for any complications. In concordance with operating surgeons, any untoward events or data as listed above will be reported to the IRB. Current plans are to perform a preliminary analysis at N=16 per group patients to evaluate for differences or concerning trends and this analysis will be repeated as deemed necessary by the operating surgeons and Dr. Sing. Documented meetings will take place every 4 months to discuss any complications and a written report will be summarized at the end of each meeting. If statistical significance is reached between the groups, or if one group is experiencing clinically worsened outcomes as defined above, we will discuss our results with the IRB and terminate the study as deemed necessary.

Outpatient Follow-Up:

Patients will undergo post-operative follow-up at 1 month, 6 months, and yearly for 3 years. Patients will receive reminders of their follow-up visits before each time period. If the patient is not receiving follow-up assessment from Dr. Heniford and his associates, we will also send a provider letter for the provider as well as a physician assessment that will be completed by the new provider. At each visit, patients will be asked to fill out a short questionnaire (Form A and Form B, attached) that will aid in assessing and documenting postoperative symptoms and quality of life. During each follow-up visit a board certified or board eligible surgeon, who is blinded with regard to the group assignment, will perform a physical examination to assess for the presence of a recurrent hernia, eventration and other findings detailed on Form C (attached). Any signs of wound complications will be noted, including seroma formation, erythema, drainage, break in the skin, purulence or tenderness to palpation. If a recurrent hernia defect is identified on the physical examination, imaging studies will be performed as indicated. Once a hernia defect is found, further management options will be discussed with the patient. Routine imaging will not be performed as the physical examination has been the gold standard for diagnosing abdominal hernias in previous large randomized multicenter studies[13-14].

Data Analysis and Statistics

Demographics, comorbidities, preoperative conditions and the nature of contamination will be recorded as well as post-operative hospital course and follow-up findings, including drain outputs, the use of antibiotics and drainage procedures, and postoperative quality of life surveys. The latter along with hernia recurrences and specific wound complications will be used as primary outcome variables.

A power analysis yielded a sample size of 96 patients. With an expected effect size of at least 0.85, it was determined that 40 patients in each group will be needed to show significance at the 0.05 level with 90% statistical power. In order to accommodate for a 20% attrition rate, 48 patients will be recruited into each group. Statistical analysis will be performed using SAS® System version 9.3 (SAS, Cary, NC, USA). Both intent-to-treat (ITT) and per protocol analysis will be performed. If the results of these two analyses significant differ, efficacy will be determined by the ITT analysis.

Interval outcome variables will be compared using the Wilcoxon-Mann-Whitney test. Serial quality-of-life survey results will be compared using repeat-measures ANOVA and non-parametric techniques. Frequencies of complications will be analyzed using Chi-square and Fisher's exact test. Differences in demographics and preoperative data will be controlled using linear and logistic statistical modeling techniques. Once confounders are determined, the effect of mesh type on patient outcomes and quality of life will be analyzed using multivariate logistic regression. The significance threshold will be set at $p<0.05$ and will be used for all analyses.

References

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Carolinas Comfort Scale™

Carolinas Medical Center

Division of Gastrointestinal and Minimally Invasive Surgery

Name: _____

Date of Surgery: _____

Date of Survey: _____

0 = No symptoms
1 = Mild but not bothersome symptoms
2 = Mild and bothersome symptoms
3 = Moderate and/or daily symptoms
4 = Severe symptoms
5 = Disabling symptoms

Please answer ALL questions for each of the 8 activities.
Use N/A if an activity was not performed.

1. While laying down, do you have							
a) sensation of mesh	0	1	2	3	4	5	N/A
b) pain	0	1	2	3	4	5	N/A
2. While bending over, do you have							
a) sensation of mesh	0	1	2	3	4	5	N/A
b) pain	0	1	2	3	4	5	N/A
c) movement limitations	0	1	2	3	4	5	N/A
3. While sitting up, do you have							
a) sensation of mesh	0	1	2	3	4	5	N/A
b) pain	0	1	2	3	4	5	N/A
c) movement limitations	0	1	2	3	4	5	N/A
4. While performing activities of daily living *(i.e. getting out of bed, bathing, getting dressed), do you have*							
a) sensation of mesh	0	1	2	3	4	5	N/A
b) pain	0	1	2	3	4	5	N/A
c) movement limitations	0	1	2	3	4	5	N/A
5. When coughing or deep breathing, do you have							
a) sensation of mesh	0	1	2	3	4	5	N/A
b) pain	0	1	2	3	4	5	N/A
c) movement limitations	0	1	2	3	4	5	N/A
6. While walking, do you have							
a) sensation of mesh	0	1	2	3	4	5	N/A
b) pain	0	1	2	3	4	5	N/A
c) movement limitations	0	1	2	3	4	5	N/A
7. When walking up the stairs, do you have							
a) sensation of mesh	0	1	2	3	4	5	N/A
b) pain	0	1	2	3	4	5	N/A
c) movement limitations	0	1	2	3	4	5	N/A
8. While exercising, do you have							
a) sensation of mesh	0	1	2	3	4	5	N/A
b) pain	0	1	2	3	4	5	N/A
c) movement limitations	0	1	2	3	4	5	N/A

Date of Surgery: _____

FORM B: Patient Questionnaire

Date of Follow-up: _____

Since surgery, have you noticed any of the following at your surgical site:

1. Bulges or protrusions? (No) (Yes) _____
2. Drainage? (None) (Clear) (Bloody) (Yellow) (Other) _____
3. Pain (excluding expected surgical pain) ?
   (None) (As expected) (Dull) (Stabbing) (Burning) (Numbness) Severity (0-10)_____
   Since surgery; (Improving) (Constant) (Worsening) _____

Since discharge from the hospital, have you had any of the following symptoms:

4. Fever (>100.4)? (No) (Yes) Max Temp: _____

   Bowel problems? (None) (Constipation) (Diarrhea) (Nausea) (Vomiting) _____

Since surgery, have you had any of the following:

5. Antibiotics by mouth? (No) (Yes) (Currently taking) (Completed)
   Why was it prescribed? _____

   Name of antibiotic: _____

   When and how long did you take it?_____
6. Topical antibiotics for your surgical wound? (No) (Yes) Specify _____
   (Bacitracin) (Neomycin) (Polymyxin) (Bactroban/mupirocin) (Silvadene)
7. An open wound requiring dressing changes? (No) (Yes)

   What kind and frequency? _____
8. ER or hospital visits (related to surgery)? (No) (Yes) Specify _____

   _____
9. Since surgery, have you seen a doctor or surgeon at another institution about your wound, abdomen, or other issues related to your surgery? (yes) (no).

   If yes, who? _____

FORM C: Abdominal Examination

Examiner: _____

Circle Appropriate Findings

Exam: Completely Normal

Incision: (clean/dry/intact) (necrosis) (breakdown) Describe other than normal findings: _____

_____

If open wound: (since surgery) (reopened) length: _____ width: _____ depth: _____
Condition: (infected) (necrosis) (improving) (exudate) (granulation) (mesh exposed)
Dressing: (plain gauze) (iodoform) (wound vac) Describe:_____

_____

Surrounding skin: (normal) (erythema) (cellulitis) (fluctuance) (induration)

Deep examination: (normal) (seroma) (granuloma) (abscess)

Drainage: (none) (serous) (serosang) (purulent) (other) _____

JP Drains:

1. (serous) (serosang) (purulent) last 24h output _____ (removed today)
2. (serous) (serosang) (purulent) last 24h output _____ (removed today)
3. (serous) (serosang) (purulent) last 24h output _____ (removed today)

Presence of Bulge: (none) (laxity) (hernia) size:_____x_____location: _____
Recurrent Hernia: (reducible) (incarcerated) Describe:_____

_____

Assessment

_____

Plan

_____

FORM D: Data Collection

Demographics
Age
Sex
Race
Financial Code
Case Type
Admission Date
Discharge Date
Length of Stay
OR Charges
Total Charges
Weight
Height
Body Mass Index
Comments
1° Diagnosis
2° Diagnoses
1° Procedure
2° Procedures

Laboratory / Radiology
CXR
Blood pressure
Pulse
Glascow Coma
Urea
Sodium
Potassium
Chloride
Bicarb
BUN
Creatinine
Glucose
Hemoglobin
WBC
Platelet Count
ECG

Medications
Steroids
Coumadin
Anti-Platelet
PPI
Other
No Medications

Comorbidities
Alcoholism
Arrythmia
Asthma
CHF
Cirrhosis
COPD
CAD
CVA
Diabetes
ESRD
HIV
Hypercholesterol
Illicit Drugs
History of Cancer
Hyperlipidemia
Hypertension
Hyperthyroidism
Hypothyroidism
Morbid Obesity
Pulmonary HTN
PVD
Sleep Apnea
Tobacco
Previous Intra-Abdominal Surgery
Abdominal Trauma
Renal Insufficiency
Preop Anemia
Other
No Commorbidities

Operative Record
Operation Severity
Number of Operations
Estimated Blood Loss
Peritoneal Malignancy
Time of Operation
ASA Score
Blood Transfusion
Number of Units
Estimated Blood Loss
Platelet Transfusion
Morphine Equivalents (mg)
Intra-Operative Ultrasound
Operation Time
Pathology
Procedure Identification
Concomitant Procedure
If Yes, type
Incarceration
If Yes, Organ
Enterotomy Made
Mesh Used
Current Mesh
Defect Size
Mesh Size
Fibrin Glue
Postop Persistant Pain
If Yes,Injected
times per site
sites injected
Prev Abd Surgery
Prev Hernia Repair
If Yes, how many
Previous Wound Complications
Surgical Technique
Previous Mesh
Ventral Location
TA Sutures

PostOperative Analgesia
Hydrocodone
Dilaudid
Demerol
Morphine
Other
Analgesia Type
Mechanism
PCA/Pump
Epidural
IV
Oral
Other

Complications
Air Embolous
Anast Leak
Anast Stenosis
Anesthesia Complication
Atelectasis
Bladder Injury
Bleeding
Bile Duct Injury
Bowel Injury
Cardiac Arrhythmias
Cardiac Failure
Chest Pain
Colitis
Constipation
CVA
Death
Deep Infection
DVT
Diarrhea
Enterotomy
Fever
Hematoma
Hernia Recurrence
Hypercarbia
Hypertension
Hypoxia
Ileus
Incisional Hernia
Incision
Numb/Ting
Infxn Unknown Origin
Intraabd Abscess
Kidney Infarction
Loss Pneumo
MI
Nausea
Pancreatitis
Enterotomy
Pneumonia
Pneumothorax
Postop Hypotension
Prolong Incision Pain
Mesh Infection
Pulmonary Embolism
Readmission 30 Days
Renal Failure
Reoperation
Resp Failure
Septicemia
Seroma
SBO
Splenic Injury
Subcutaneous Emphysema

Ureteral Injury
Urinary Retention
Urine Leak
UTI
Vomiting
Other

Follow-up Data
Drains
Wound Comp
Non-related Comp
Visual Analog Scale
Date Return to Work
Date Return Driving
Date Return Exercise
Preop Sym Returned
Oral Pain Med Amt
Patient Feels Mesh
Patient has Pain
Pain Location
Pain Exercise Only
Date No Postop Pain
Hernia Sites Injected
Sites Injected
Total Times Injected
Hernia Recurrence
Recurrence Date

Wound Complications
Antibiotics IV
Antibiotics PO
Cellulitis
Open wound
Wound Disruption
Wound Dehiscence
Wound Necrosis
Drain Placement
Drainage Clear
Drainage (nos)
Drainage Purulent
EC Fistula
Erythema
Inflammation
Fistula
Hematoma
Wound Infection
Local skin infection
Wound Abscess
Deep Infection
Mesh Infection
Infected Seroma
Intraabd Infection
Intraabd Abscess
Ischemia
Seroma
Seroma Intervention
Wound Intervention
Wound Vac

Carolinas Medical Center

Carolinas HealthCare System

Dear Patient:

You are receiving this letter because you have agreed to be in our study involving your recent hernia repair. We are contacting you in respect to 1 month follow up after your surgery.

The enclosed form is a questionnaire to be completed by a medical provider. We would prefer you come to Carolinas Medical Center to be seen by our surgical team, however due to time and distance we understand if this is not possible. We have outlined on the form enclosed specific questions about the healing of your surgical site. This form can be completed at the time of your next medical appointment you have scheduled and should take approximately 3 minutes of the appointment.

We have also included a letter to give to the provider who will be seeing you for this appointment to explain the need for this assessment from your involvement in the study. We hope you are doing well and please contact us at (704)-355-1813 for any questions or concerns you may want to discuss.

Thank you very much for your time. We hope to hear from you soon.

Sincerely,

B. Todd Heniford, MD
Principal Investigator

Carolinas Medical Center

Carolinas HealthCare System

Dear Patient:

You are receiving this letter because you have agreed to be in our study involving your recent hernia repair. We are contacting you in respect to 6 month follow up after your surgery.

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Principal Investigator

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Dear Patient:

You are receiving this letter because you have agreed to be in our study involving your recent hernia repair. We are contacting you in respect to 12 month follow up after your surgery.

The enclosed form is a questionnaire to be completed by a medical provider. We would prefer you come to Carolinas Medical Center to be seen by our surgical team, however due to time and distance we understand if this is not possible. We have outlined on the form enclosed specific questions about the healing of your surgical site. This form can be completed at the time of your next medical appointment you have scheduled and should take approximately 3 minutes of the appointment.

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Dear Patient:

You are receiving this letter because you have agreed to be in our study involving your recent hernia repair. We are contacting you in respect to 24 month follow up after your surgery.

The enclosed form is a questionnaire to be completed by a medical provider. We would prefer you come to Carolinas Medical Center to be seen by our surgical team, however due to time and distance we understand if this is not possible. We have outlined on the form enclosed specific questions about the healing of your surgical site. This form can be completed at the time of your next medical appointment you have scheduled and should take approximately 3 minutes of the appointment.

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Principal Investigator

Carolinas Medical Center

Carolinas HealthCare System

Dear Patient:

You are receiving this letter because you have agreed to be in our study involving your recent hernia repair. We are contacting you in respect to 36 month follow up after your surgery.

The enclosed form is a questionnaire to be completed by a medical provider. We would prefer you come to Carolinas Medical Center to be seen by our surgical team, however due to time and distance we understand if this is not possible. We have outlined on the form enclosed specific questions about the healing of your surgical site. This form can be completed at the time of your next medical appointment you have scheduled and should take approximately 3 minutes of the appointment.

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Principal Investigator

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Physician Assessment:

Patient Name: _____ Date of Operation: _____

Abdominal Exam: (check **ALL** that apply)

Incision?	☐ Clean/dry/intact
	☐ necrosis
	☐ breakdown
	☐ other specify:_____

Open Wound?	If yes:
☐ yes	☐ since surgery
☐ no	☐ reopened
	Length _____ width_____ depth_____

If yes to Open Wound, Condition of Wound:	☐ infected
☐ does not apply	☐ necrosis
	☐ improving
	☐ fibrinous exudate
	☐ granulation
	☐ mesh exposed
☐ other specify: _____	

If yes to Open Wound, Dressing applied:	☐ plain gauze (wet to dry)
☐ does not apply	☐ iodoform
	☐ wound vacuum
☐ other specify: _____	

Surrouding Skin:	☐ normal
	☐ erythema
	☐ cellulitis
	☐ fluctuance
	☐ induration

Deep Examination:	☐ normal
	☐ seroma
	☐ granuloma
	☐ abscess

Drainage?	☐ none
	☐ serous
	☐ serosanguinous
	☐ purulent
	☐ other specify:_____ ___

Presence of Bulge?	☐ none
	☐ laxity, does not feel like hernia but slight bulging
	☐ yes, feels like hernia
	☐ uncertain

If yes to bulge:	Location: _____
☐ does not apply	Length: _____
	Width: _____

If yes to bulge:	☐ reducible
☐ does not apply	☐ incarcerated (non reducible)
	☐ associated with pain

Please provide any additional comments/concerns about your examination today:

_____
_____
_____
_____
_____
_____

May **we** contact you for additional information on your assessment today?

- ☐ Yes (provide contact # below)
- ☐ No

Would **you** like to be contacted in regards to your assessment today?

- ☐ Yes (provide contact # below)
- ☐ No

Provider Name:_____

Provider Signature:_____ Date Examined:_____

Contact Number:_____

Thank you for your time and completion of the assessment.

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Dear Provider:

You are receiving this letter because your patient has agreed to be in our study involving their recent hernia repair. We are contacting the patient at this point in time for 36 month follow up after their surgery.

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Reminder for Follow Up

Patient Name:_____ Date of Surgery:_____

Please contact us approximately 2-3 weeks prior to the following follow up interval times to coordinate a clinic appointment with your surgeon.

1 month:_____ Appointment Time:_____

6 month:_____ Appointment Time:_____

12 month:_____ Appointment Time:_____

24 month:_____ Appointment Time:_____

36 month: _____ Appointment Time:_____

If you would prefer us to call you for the appointments, please check below and provide us a contact number.

- ☐ Please contact me for follow up reminders Contact #:_____
- ☐ Please contact me via email for follow up reminders E-mail:_____
- ☐ Please do not contact me, I will call 704-355-1813 for follow-up reminders.