Supplemental Online Content

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This supplemental material has been provided by the authors to give readers additional information about their work.

eMethods

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Inclusion and Exclusion Criteria

Inclusion Criteria

1. age $\geq$21
2. hernia defects $\geq$9 cm^2
3. contaminated wound class (CDC II or III)
4. elective single-staged repair
5. intraoperative achievement of fascial closure
6. candidates willing to receive either polypropylene or a biologic prosthesis

Exclusion Criteria

1. clean or dirty wound class (CDC I or IV)
2. BMI >45 kg/m^2
3. chronic immunosuppression (>10 mg of prednisone/day)
4. collagen vascular disorder
5. severe malnutrition (albumin <2.0 g/dL)
6. ascites refractory to medical management
7. end stage renal disease (on hemodialysis)
8. liver disease (hepatitis B and C or total bilirubin >3.0 mg/dL)
9. smoking within1 month of surgery
10. pregnancy
11. undergoing minimally invasive repair
12. active mesh infection. Mesh infection is defined as synthetic mesh that is not incorporated, exposed, or has chronic draining sinus with pus around the material.

Surgical Procedure Details

Standard Surgical Care Improvement Project (SCIP) protocol[1] was applied to all procedures with appropriate DVT prophylaxis and intravenous antibiotics preoperatively according to institution protocols and discontinued at 24 hours. A full midline laparotomy was performed, and the anterior abdominal wall was freed of adhesions. Concomitant procedures were performed as deemed necessary and appropriately recorded.

The hernia defect was measured according to European Hernia Society Guidelines[2].The abdominal wall was reconstructed by performing a release of the posterior rectus sheath. If deemed necessary by the surgeon, a release of the posterior lamella of the internal oblique and transversus abdominus muscle or the external oblique muscle was completed to achieve midline closure. The posterior components were then reapproximated to exclude the abdominal viscera from the prosthetic with a running slowly absorbable suture. Unless contraindicated due to drug allergies, a pulse lavage antibiotic irrigation using a 3-liter bag of normal saline with gentamicin (240 mg), cefazolin (3 gm), and bacitracin (50,000 units) was applied to the posterior rectus sheath and subcutaneous tissues prior to mesh deployment. In cases of drug allergy, pulse lavage irrigation using normal saline without antibiotics was applied. Final CDC wound classification was designated immediately prior to mesh placement. Notably, parastomal hernias were classified as a CDC class 2 if the stoma was covered at the beginning of the procedure and was not manipulated, and class 3 if the stoma was taken down and/or moved to another location. Randomization was performed by a clinical research nurse at the time of mesh placement to minimize bias. Those patients randomized to biologic mesh received porcine derived acellular dermal matrix (Strattice^{TM} Reconstructive Tissue Matrix, Lifecell Corp, Branchburg NJ), whereas those in the synthetic group had a medium weight (44 g/m^2) polypropylene mesh (Bard^{TM} Soft Mesh, CR Bard, Murray Hill, NJ) placed. Both materials were placed in a retromuscular position to avoid direct contact with the viscera with at least 5 cm of coverage on all sides of the defect. The mesh was fixated with trans-fascial #1 slowly absorbable sutures at 5-10 cm intervals. Closed suction drains were placed on the mesh and below the muscles and removed when the output was less than 30 cc/day for 48 hours. The anterior fascia was closed with a running or interrupted slowly absorbable #1 monofilament suture. The skin was closed with staples or sutures.

Hernia Recurrence Definition and Algorithm

Hernia recurrence was defined as a composite measure based on clinical exam, radiographic (abdominal CT/ultrasound) imaging or patient reported outcome of a bulge on the validated Hernia Recurrence Inventory (HRI)[5]. Patients with positive screening on HRI or clinical exam were offered a confirmatory radiologic study (CT/US). Hernia recurrence was further classified as radiologic recurrence (incisional hernia within 7 cm of original repair), clinical recurrence, or PRO only recurrence on HRI without further exam or imaging. For analysis purposes, a positive screening on HRI was overruled if imaging confirmed no recurrence. If HRI was positive for a recurrence, and no further evaluation was performed, the patient was considered to have a recurrence. Finally, the HRI was also used to rule out hernia recurrence, as a negative HRI without further follow up was considered as no recurrence. All CT radiographic images were reviewed by 3 enrolling surgeons who were blinded to the surgeon who performed the procedure, the type of mesh utilized and the postoperative course. Regarding CT interpretation, agreement between 2 of 3 or 3 of 3 surgeons signified consensus evidence of a hernia recurrence or not. Abdominal ultrasounds were the only radiologic study in 13 patients and were not reviewed by the panel. Hernia recurrences were additionally categorized as midline, parastomal, or both. Given the complexity of parastomal hernia repair, for analysis purposes, hernias at ostomy sites were not considered as a recurrent hernia in this analysis.

Primary and Secondary Endpoint Definitions and Reporting Structure

Surgical Site Occurrence Requiring a Procedural Intervention (SSOPI)

SSOPI was defined as any SSO (surgical site occurrence) that required opening of the wound, wound debridement, suture excision, percutaneous drainage, or partial or complete mesh removal[3]. A surgical site occurrence (SSO) included any surgical site infection (SSI) as well as wound cellulitis, non-healing incisional wound, fascial disruption, skin or soft tissue ischemia, skin or soft tissue necrosis, wound serous or purulent drainage, stitch abscess, seroma, hematoma, infected or exposed mesh, or development of an enterocutaneous fistula. SSI was further characterized according to CDC guidelines as a superficial, deep, or organ space infection[4].

Secondary Outcomes Definitions

Quality of Life Definitions

EQ5D Summary Score-

The EQ-5D descriptive system is comprised of five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety-depression) and three levels (no problems, some problems, and extreme problems). Patients completed the questionnaire based on how good or bad their health was for that day of administration relative to their ventral hernia repair from which a single-digit score described the patient's health state.

EQ5D VAS Score-

The EQ VAS is patient-rated assessment of health on a vertical, visual analogue scale on a spectrum of "best imaginable health state" and "worst imaginable health state" and is quantified as a measure of health outcome as judged by the individual respondents.

HerQles Score-

The HerQLes survey is a 12-question, validated, hernia-specific quality of life instrument with a focus on abdominal wall function and the impact of ventral hernia repair on quality of life. HerQles is scored from 0 to 100. Higher scores represent better quality of life.

Adverse Events Definitions

Adverse Events-any untoward medical event

Comprehensive Complications Index (validated score of 0-100, integrating the Clavien-Dindo Grades and number of complications and their severity)

Definitions and Treatment Plans for Surgical Site Occurrences

Surgical Site Occurrences Types and Consensus Treatment Plans:

SSO Type	Definition	Consensus Treatment Plan
wound cellulitis	inflammation of subcutaneous loose connective tissue, as evidenced by erythema, swelling, warmth, and/or tenderness	1. complete 10-day course of oral antibiotics: Clindamycin 300 mg PO TID OR Doxycycline 100 mg PO BID PLUS Cephalexin 500 mg PO QID OR Amoxicillin 500 mg PO TID OR TMP/SMX 1-2 double-strength tabs PO BID PLUS Amoxicillin 500 mg PO TID 2. reassess wound
non-healing incisional wound	skin and/or subcutaneous tissue of an incisional wound that do not heal within 90 days of procedure, without signs or symptoms of infection; fascia remains intact	dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 or negative pressure therapy until healed
wound dehiscence/fascial disruption	opening or disruption of fascia along the suture lines of a surgical site within 90 days of procedure	1. reoperation for surgical debridement and fascial closure; 2. dressing of skin and subcutaneous tissue with negative pressure therapy or at least daily dressings with saline-soaked wet-to-dry gauze until healed;

		3. mesh does not require removal
skin or soft tissue ischemia	local ischemia to the skin or soft tissue	watchful waiting to determine if skin or soft tissue ischemia progresses to skin or soft tissue necrosis
skin or soft tissue necrosis	pathologic death of the skin or soft tissue	allow skin or soft-tissue necrosis to demarcate, followed by sharp debridement
wound serous drainage	drainage of serum from the surgical site wound or drain	dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 until healed, Culture effluent
wound purulent drainage	drainage of pus from the surgical site wound or drain; surgical site infection	(See superficial, deep incisional, or organ/space surgical site infection corresponding to location)
chronic sinus drainage	a fistulous tract and/or cavity with drainage of fluid that persists beyond 90 days of procedure	1. dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 until 90 postoperative days 2. after 90 postoperative days, locally explore wound, debride unincorporated material, and dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 until healed
localized stab wound infection	a localized infection and/or inflammation restricted to the site of a transfascial fixation suture	1. locally explore stab wound 2. dress wound at least daily with ¼" packing tape until healed 3. complete 10-day course of oral antibiotics: Clindamycin 300 mg PO TID OR Doxycycline 100 mg PO BID PLUS Cephalexin 500 mg PO QID OR Amoxicillin 500 mg PO TID

		OR TMP/SMX 1-2 double-strength tabs PO BID PLUS Amoxicillin 500 mg PO TID 4. reassess wound 5. If localized stab wound infection persists beyond 30 postoperative days, open wound, remove offending transabdominal fixation suture, and dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 until healed
stitch abscess	a localized superficial collection of pus and/or inflammation restricted to the skin and subcutaneous tissue around a suture, with confirmed presence of suture in wound	1. locally explore wound and remove offending suture 2. dress wound at least daily with ¼" packing tape until healed
seroma	a localized collection of serum within a tissue or space	asymptomatic seroma: watchful waiting symptomatic seroma: percutaneous drainage of fluid with or without drain placement, cultures obtained.
infected seroma	a localized collection of serum within a tissue or space that has become infected and has converted to an abscess; surgical site infection	(See superficial, deep incisional, or organ/space surgical site infection corresponding to location)
hematoma	a localized collection of extravasated blood within a tissue or space	1. evaluate for active bleeding and need to immediately establish hemostasis; 2. evaluate blood counts for possible need for transfusion of blood products as per clinical standard of care; 3. asymptomatic hematoma: watchful waiting of fluid collection

		symptomatic hematoma: percutaneous drainage of fluid collection with or without drain placement. If hemodynamically unstable, might require return to OR for surgical control.
infected hematoma	a localized collection of extravasated blood within a tissue or space that has become infected and has converted to an abscess; surgical site infection	(See superficial, deep incisional, or organ/space surgical site infection corresponding to location)
exposed biologic mesh	an implanted biologic scaffold (xenograft) that has become exposed to the extracorporeal space	1. dressing of skin and subcutaneous tissue with negative pressure therapy or at least daily with saline-soaked wet-to-dry gauze until healed 2. mesh does not require removal 3. may consider split thickness skin graft when granulation bed is present
exposed synthetic mesh	an implanted synthetic material scaffold that has become exposed to the extracorporeal space	1. dressing of skin and subcutaneous tissue with negative pressure therapy or at least daily with saline-soaked wet-to-dry gauze until healed; mesh does not require removal 2. may consider split thickness skin graft when granulation bed is present
contaminated biologic mesh	pathogen presence on a biologic scaffold (autograft, allograft, or xenograft) without signs or symptoms of local or systemic inflammation of the host; pathogen presence confirmed by culture-positive fluid around mesh	1. contamination source control with: percutaneous drainage with or without drain placement OR operative drainage with irrigation or pulse lavage;

		2. mesh does not require removal
contaminated synthetic mesh	pathogen presence on a synthetic material scaffold without signs or symptoms of local or systemic inflammation of the host; pathogen presence confirmed by culture-positive fluid around mesh	1. contamination source control with: percutaneous drainage with or without drain placement OR operative drainage with irrigation or pulse lavage 2. mesh does not require removal
infected biologic mesh	pathogen presence on a biologic scaffold (autograft, allograft, or xenograft) with signs or symptoms of local or systemic inflammation of the host; pathogen presence confirmed by culture-positive fluid around mesh; surgical site infection	1. intravenous or oral antibiotics as determined by culture results and evidence-based standard of care 2. infectious source control with percutaneous drainage with or without drain placement OR operative drainage with irrigation or pulse lavage 3. mesh does not necessarily require removal. Remove mesh if not incorporated into surrounding soft tissue bed, or if signs or symptoms of local or systemic infection newly develop, persist, or worsen. 4. if mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
infected synthetic mesh	pathogen presence on a synthetic material scaffold with signs or symptoms of local or	1. intravenous or oral antibiotics as determined by

	systemic inflammation of the host; pathogen presence confirmed by culture-positive fluid around mesh; surgical site infection	culture results and evidence-based standard of care 2. infectious source control with: percutaneous drainage with or without drain placement OR operative drainage with irrigation or pulse lavage 3. mesh does not necessarily require removal. Remove mesh if not incorporated into surrounding soft tissue bed, or if signs or symptoms of local or systemic infection newly develop, persist, or worsen 4. if mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
mucocutaneous anastomosis disruption	opening or disruption in a surgically-created communication between the enteric mucosa and cutaneous soft tissue	1. if signs or symptoms of local or systemic inflammation or infection, intravenous antibiotic treatment with broad-spectrum coverage of enteric organisms, as per evidence-based standard of care 2. reoperation for wound exploration, irrigation, and stoma revision 3. If mesh not exposed to enteric contents, mesh does not require removal. 4. If mesh is not incorporated into surrounding soft tissue bed when exposed to enteric contents, remove mesh. 5. If mesh is incorporated into surrounding soft tissue bed when exposed to enteric contents, attempt to salvage mesh. If signs or symptoms of local or systemic infection newly develop, persist, or worsen, remove mesh.

		6. If mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed.
enterocutaneous fistula	a pathologic tract or cavernous communication between the enteric viscera and cutaneous soft tissue	1. intravenous antibiotic treatment with broad-spectrum coverage of enteric organisms, as per evidence-based standard of care 2. reoperation for wound exploration, irrigation, and correction of underlying problem 3. If mesh not exposed to enteric contents, mesh does not require removal. 4. If mesh is not incorporated into surrounding soft tissue bed when exposed to enteric contents, remove mesh 5. If mesh is incorporated into surrounding soft tissue bed when exposed to enteric contents, attempt to salvage mesh. If signs or symptoms of local or systemic infection newly develop, persist, or worsen, remove mesh. 6. If mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed.
enteric serosal tear	a superficial injury to the serous layer of the enteric viscera	1. repair serosal injury with vicryl sutures 2. mesh does not require removal
enterotomy	a full-thickness incision into or injury to the enteric viscera	1. intravenous antibiotic treatment with broad-spectrum coverage of enteric organisms, as per evidence-based standard of care 2. If enterotomy occurs and is recognized during index operative procedure, repair enterotomy with two layers of suture or resect and re-anastomose bowel 3. If mesh is not exposed to enteric contents, proceed with mesh placement and/or mesh does not require removal

		4. If recognition of enterotomy is delayed until after the index operative procedure, and reoperation through midline incision necessary for re-exploration, irrigation, and correction of the underlying problem, mesh will require removal 5. If mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
enteric ischemia	local anemia to enteric tissue due to compromise or disruption of the blood supply	1. intravenous antibiotic treatment with broad-spectrum coverage of enteric organisms, as per evidence-based standard of care 2. Address underlying cause of enteric ischemia 3. Resect non-viable portions of the gastrointestinal tract as necessary 4. Mesh does not require removal. 5. If enteric ischemia occurs after index operative procedure, and reoperation is necessary, mesh may be removed if obstructive to reoperation through midline incision. 6. If mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
enteric necrosis	pathologic death of the enteric tissue	1. intravenous antibiotic treatment with broad-spectrum coverage of enteric organisms, as per evidence-based standard of care 2. Address underlying cause of enteric necrosis 3. Reoperation to resect necrotic portions of the gastrointestinal tract 4. If mesh not exposed to enteric contents, mesh does not require removal 5. If mesh is not incorporated into surrounding soft tissue bed when exposed to enteric contents, remove mesh

		6. If mesh is incorporated into surrounding soft tissue bed when exposed to enteric contents, attempt to salvage mesh If signs or symptoms of local or systemic infection newly develop, persist, or worsen, remove mesh 7. If mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
enteric leak	pathologic drainage of enteric contents into surrounding tissue or space	1. intravenous antibiotic treatment with broad-spectrum coverage of enteric organisms, as per evidence-based standard of care 2. possible percutaneous drainage if well-contained leak OR reoperation for wound exploration, irrigation, and correction of underlying problem 3. If mesh not exposed to enteric contents, mesh does not require removal 4. If mesh is not incorporated into surrounding soft tissue bed when exposed to enteric contents, remove mesh 5. If mesh is incorporated into surrounding soft tissue bed when exposed to enteric contents, attempt to salvage mesh. If signs or symptoms of local or systemic infection newly develop, persist, or worsen, remove mesh 6. If mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed.
superficial surgical site infection	(see CDC definition; Appendix 4)	1. intravenous or oral antibiotics as determined by culture results and evidence-based standard of care 2. infectious source control:

		open, debride, and irrigate or pulse lavage wound 3. dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 or negative pressure dressing until healed 4. mesh does not necessarily require removal. Remove mesh if not incorporated into surrounding soft tissue bed, or if signs or symptoms of local or systemic infection newly develop, persist, or worsen 5. if mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
deep incisional surgical site infection	(see CDC definition; Appendix 4)	1. intravenous or oral antibiotics as determined by culture results and evidence-based standard of care 2. infectious source control: percutaneous drainage with or without drain placement OR operative drainage, debridement, and irrigation or pulse lavage 3. if operative management, dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 or negative pressure therapy until healed 5. mesh does not necessarily require removal. Remove mesh if not incorporated into surrounding soft tissue bed, or if signs or symptoms of local or systemic infection newly develop, persist, or worsen 6. if mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
organ/space surgical site infection	(see CDC definition; Appendix 4)	1. intravenous or oral antibiotics as determined by

		culture results and evidence-based standard of care 2. infectious source control: percutaneous drainage with or without drain placement if well-contained infection/abscess OR operative drainage, debridement, irrigation or pulse lavage, and address underlying source of infection 4. if operative management, dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 or negative pressure therapy until healed 5. mesh does not necessarily require removal. Remove mesh if not incorporated into surrounding soft tissue bed, or if signs or symptoms of local or systemic infection newly develop, persist, or worsen 6. if mesh is removed, subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
unanticipated surgical site occurrence	surgical site occurrence not defined here	Communicate to all multi-site co-investigators within 24 hours of occurrence, and determine consensus management or treatment plan

eResults

Expanded Hernia Recurrence Assessments

Of the 204 (81%) patients available for 6 months follow up, clinical exam was performed in 100% of patients in both groups and 31% had supplemental radiographic imaging (13% biologic versus 18% synthetic). There was a total of 3 recurrences in the biologic mesh group and 0 recurrences in the synthetic group (p=0.25).

At one year follow up, of the 193 (78%) patients with completed follow up, 170 (88%) had a clinical exam (87 biologic vs 83 synthetic; 93% vs 84% respectively), 131 (68%) had additional radiographic imaging (65 biologic vs 66 synthetic; 69% vs 67% respectively), and 10 (5%) patients had PRO (HRI) only follow up (3 biologic vs 7 synthetic; 3% vs 7% respectively). There were 8 hernia recurrences in the biologic group and 2 in the synthetic group (p=0.10). All patients with PRO only follow up did not report a bulge and were considered to have an intact repair.

At two years follow up, 241 patients remained alive for the analysis and 8 were lost to follow up (biologic n=3 vs synthetic n=5). Of the remaining 233 (97%) patients, 118 (97%) were available for biologic mesh and 115 (95%) for the synthetic mesh cohort. A total of 192 (76%) patients had a clinical exam (100 biologic vs 92 synthetic; 85% vs 80% respectively), 138 (58%) had additional radiographic imaging (69 biologic vs 69 synthetic; 59% vs 60% respectively), and 30 (13%) patients had PRO (HRI) only follow up (14 biologic vs 16 synthetic; 11% vs 13% respectively). There were 14 hernia recurrences in the biologic group and 5 in the synthetic group (p=0.06). At 2 years follow up, of the 30 patients with PRO only follow up, 27 patients reported no bulge and were considered to have an intact repair (12 biologic vs 15 synthetic). Three patients who reported a bulge (2 biologic vs 1 synthetic) and did not return for further clinical or radiographic follow up were considered to have a recurrence.

Full Details Regarding Reoperations:

Eight patients required a reoperation in the first 30 days and there was no significant difference between the two groups. In the biologic mesh group, one patient was re-explored for a missed enterotomy and the mesh was explanted due to generalized sepsis, two patients had erosions of a mesh associated with a (keyhole) parastomal hernia repair into the bowel and required bowel resection and revision of the repair, and one patient required re-exploration for postoperative hemorrhage and one patient for a major wound complication. In the synthetic mesh group, there were two patients that required surgical wound debridement and one had mesh erosion into a (keyhole) parastomal hernia repair requiring surgical revision; all retained their mesh. During follow up (6 months to 2 years), 39 patients (15%) required a reoperation. There were no differences in the rate or severity of reoperations between the two groups or mesh related complications (eTable 5). At 6 months follow up, 14 patients required an abdominal reoperation. Indications for re-exploration in the biologic mesh group included surgical debridement for deep surgical site infections in 3 patients, two patients were re-explored secondary to a small bowel obstruction unrelated to the hernia repair, and one patient had an elective takedown of a loop ileostomy. In the synthetic mesh group, 2 patients required surgical debridement for non-healing wounds that did not involve the mesh. One patient developed a mesh erosion from a keyhole repair of a parastomal hernia requiring surgical revision, and one patient developed an enterocutaneous fistula that was remote to the mesh at a prior leak from a small bowel anastomosis, but ultimately required surgical correction. No patients required mesh removal. Four additional reoperations occurred for a retained foreign body, scar revision, and two patients had recurrent parastomal hernias that required re-repair. At 12 months, 10 patients had reoperative abdominal surgery. In the biologic mesh group, 3 patients had surgical re-exploration. Indications included a non-healing wound in one patient, re-repair of a parastomal hernia in one patient, and another one for a midline recurrence. In the synthetic mesh group, 7 patients had another abdominal surgery. Two patients had wound issues requiring surgery which were a suture granuloma/abscess and non-healing wound all unrelated to the mesh. One patient with ulcerative colitis had her retained rectum removed and another patient had a scar revision. The remaining 3 patients were re-explored for recurrent parastomal hernias. At 24 months, 15 patients had further surgery. There was one suture granuloma/abscess requiring re-exploration in each group with retained permanent sutures identified from prior surgeries not involving the current repair or mesh. Otherwise, one patient in the biologic mesh group underwent a panniculectomy and all other re-operations at 2 years were related to symptomatic hernia recurrences (biologic n=8, synthetic n=4). There were 2 isolated midline

recurrences, 4 parastomal recurrences, and 2 parastomal and midline recurrences requiring reoperations in the biologic group. The synthetic group had 3 midline recurrences and one parastomal hernia recurrence that required further surgery. Notably, after 6 months, no mesh infections or long term chronic draining sinuses involving the prosthetics occurred in either group.

eTable 1 Mesh Sizes Utilized for the Trial

Mesh Size (cm)	Biologic (n)	Synthetic (n)
30x40	6	0
30x30	81	110
25x30	0	5
20x30	24	0
15x30	0	4
20x20	10	3
16x20	4	0
15x13	0	1
10x12	0	1
9x13	1	0
7x13	0	1
8x10	0	1
6x10	1	0

eTable 2: Multivariate Cox model for hernia recurrence rate with cluster analysis adjusted by Site

2a Cluster analysis adjusted by site

	Time to Recurrence Regression Model		
Predictors	*Hazard Ratio*	*95% CI*	*p*
rand factor: Synthetic vs Biological	0.31	0.23 – 0.42	**<0.001**
site factor: Hospital (01)	0.90	0.69 – 1.17	0.434
site factor: Hospital (02,03,04)	1.33	1.18 – 1.39	**<0.001**
Age (25^{th} to 75^{th}: 55.4 to 70.1)	1.15	0.86 – 1.54	0.336
ethnicity factor: Non Caucasian vs Caucasian	1.40	0.79 – 2.49	0.255
sex factor: Female vs Male	1.24	0.82 – 1.87	0.302
BMI(25^{th} to 75^{th}: 28.6 to 35.5):	1.006	0.7 – 1.45	0.975
ever smoked factor: No vs Yes	0.65	0.45 – 0.92	**0.016**
mesh defeat ratio(25^{th} to 75^{th}: 2.14 to 3.83)	1.02	0.98 – 1.07	0.350
mesh size(25^{th} to 75^{th}: 60 to 1600)	0.53	0.14 – 2.02	0.348
Observations	253		
R^2 Nagelkerke	0.066		

eTable 3: Multivariate Cox model for hernia recurrence rate with cluster analysis adjusted by surgeon

	Time to Recurrence Regression Model		
Predictors	*Hazard Ratio*	*95% CI*	*p*
rand factor: Synthetic vs Biological	0.31	0.13 – 0.75	**0.009**
site factor: Hospital (01)	0.90	0.32 – 2.58	0.848
site factor: (02,03,04)	1.33	0.24 – 7.37	0.742
Age (25^{th} to 75^{th}: 55.4 to 70.1)	1.15	0.61 – 2.19	0.661
ethnicity factor: Non Caucasian vs Caucasian	1.40	0.33 – 5.90	0.649
sex factor: Female vs Male	1.24	0.62 – 2.49	0.544
BMI(25^{th} to 75^{th}: 28.6 to 35.5):	1.006	0.63 – 1.62	0.981
ever smoked factor: No vs Yes	0.65	0.33 – 1.28	0.210
mesh defeat ratio(25^{th} to 75^{th}: 2.14 to 3.83)	1.02	0.95 – 1.09	0.549
mesh size(25^{th} to 75^{th}: 60 to 1600)	0.53	0.13 – 2.13	0.368
Observations	253		
R^2 Nagelkerke	0.066		

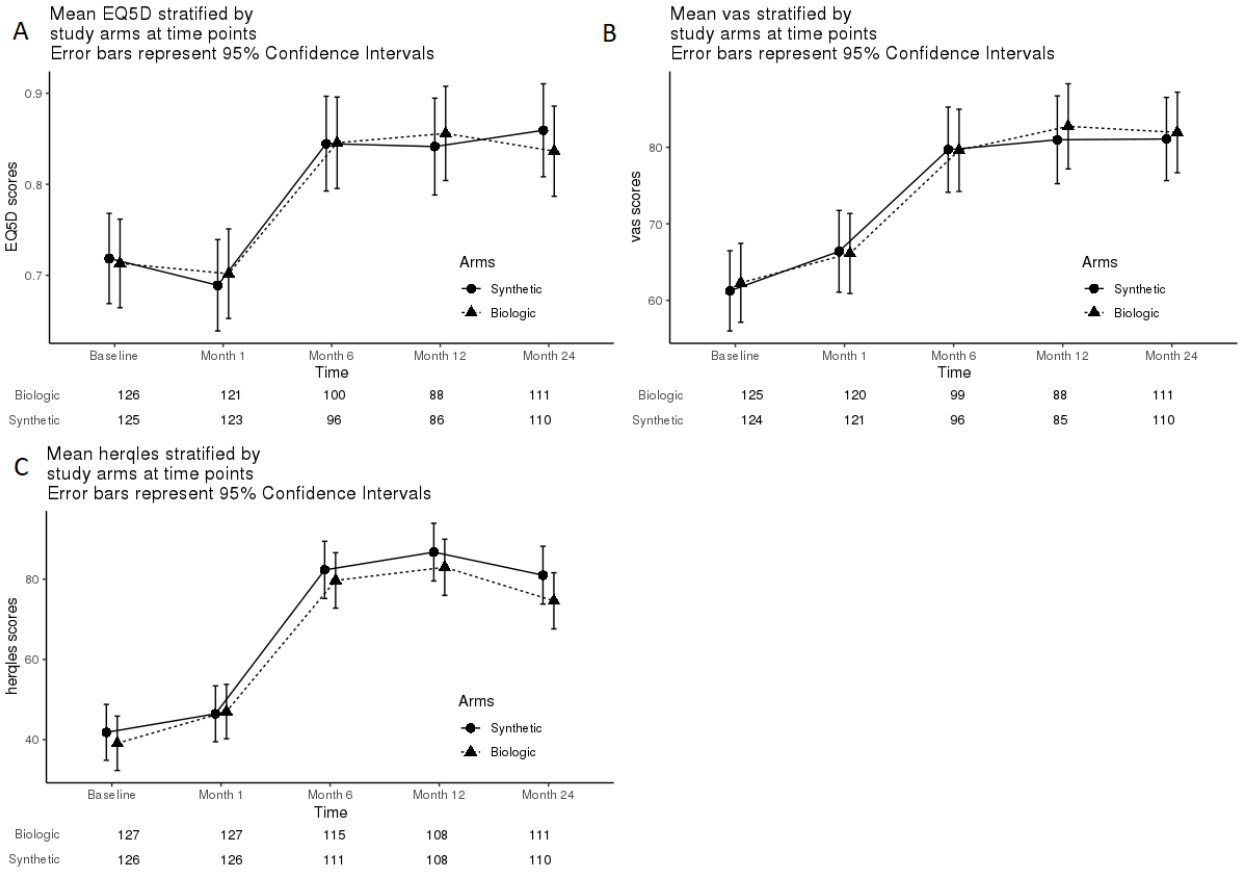
eTable 4: 30-day adverse events and complications.

Outcome	All N=253	Biologic N=127	Synthetic N=126	Absolute Difference Percentage points (95% CI)	P Value
Adverse Events	149 (58.9%)	84 (66.1%)	65 (51.6%)	14.6 (1.7 to 27)	0.026
Comprehensive Complications Index	20.9 [0.0;24.2]	20.9 [0.0;28.2]	8.7 [0.0;22.6]		0.050
Other Complications	111 (44%)	63 (50%)	48 (38%)		0.09
Ileus	51 (20.2%)	24 (19%)	27 (21.4%)		0.73
Bowel Obstruction	9 (3.6%)	7 (5.5%)	2 (1.6%)		0.17
Pulmonary Embolism	5 (2.0%)	3 (2.4%)	2 (1.6%)		1.0
DVT	3 (1.2%)	1 (0.8%)	2 (1.6%)		0.62
Sepsis	2 (0.8%)	2 (0.8%)	0 (0%)		1.0
MI	1 (0.4%)	0 (0%)	1 (0.8%)		0.50
Cardiac Arrest	1 (0.4%)	1 (0.8%)	0 (0%)		1.0
Urinary Retention	1 (0.4%)	1 (0.8%)	0 (0%)		1.0
UTI	21 (8.3%)	13 (10.2%)	8 (6.4%)		0.37
Acute Renal Failure	6 (2.4%)	4 (3.2%)	2 (1.6%)		0.68
Pneumonia	6 (2.4%)	3 (2.4%)	3 (2.4%)		1.0
Ventilator (>48 Hours)	3 (1.2%)	1 (0.8%)	2 (1.6%)		0.62
Post op transfusion	18 (7.1%)	12 (9.5%)	6 (4.8%)		0.23
Death	1 (0.4%)	1 (0.8%)	0 (0%)		1.0
Other	21 (8.3%)	12 (9.5%)	9 (7.1%)		0.66

eTable 5. Indications for reoperations throughout the study period.

Time	Reoperation Reason	All N=253	Biologic N=127	Synthetic N=126	P value
1 month	Overall	8 (3.1%)	5 (3.9%)	3 (2.4%)	0.72
	Missed Enterotomy	1 (0.4%)	1 (0.8%)	0 (0%)	1.0
	Major Wound Complication	3 (1.2%)	1 (0.8%)	2 (1.6%)	0.62
	Bleeding	1 (0.4%)	1(0.8%)	0 (0%)	1.0
	Mesh Erosion	3 (1.2%)	2 (1.6%)	1 (0.8%)	0.62
6 months	Overall	14 (6.8%)	6 (5.8%)	8 (7.8%)	0.77
	Major Wound Complication	7 (2.8%)	3 (2.4%)	4 (3.1%)	0.72
	Small Bowel Obstruction	2 (0.8%)	2 (1.6%)	0 (0%)	0.25
	Enterocutaneous fistula	1 (0.4%)	0 (0%)	1(0.8%)	1.0
	Mesh Erosion	1 (0.4%)	0 (0%)	1(0.8%)	1.0
	Hernia at New Ostomy Site	2 (0.8%)	0 (0%)	2 (1.6%)	0.25
	Other (Intra-abdominal pathology)	1 (0.4%)	1 (0.8%)	0 (0%)	1.0
	Mesh Infection/Removal	0 (0%)	0 (0%)	0 (0%)	1.0
12 months	Overall	10 (5.5%)	3 (3.3%)	7 (7.8%)	0.21
	Non healing wound (not mesh related)	3 (1.2%)	1 (0.8%)	2 (1.6%)	0.62
	Scar Revision	1 (0.4%)	0 (0%)	1 (0.8%)	1.0
	Hernia at New Ostomy Site	4 (1.2%)	1 (0.8%)	3 (2.4%)	0.37
	Midline Recurrence	1 (0.4%)	1 (0.8%)	0 (0%)	1.0
	Other (Intra-abdominal pathology)	2 (0.8%)	0 (0%)	2 (1.6%)	0.25
	Mesh Infection/Removal	0 (0%)	0 (0%)	0 (0%)	1.0
24 months	Overall	15 (6.0%)	10(7.8%	5 (4.0%)	0.31
	Non healing wound (not mesh related)	0 (0%)	0(0%)	0(0%)	1.0
	Suture Granuloma	2 (0.8%)	1 (0.8%)	1 (0.8%)	1.0
	Scar Revision	0(0%)	0(0%)	0(0%)	1.0
	Small Bowel Obstruction	0(0%)	0(0%)	0(0%)	1.0
	Hernia at New Ostomy Site	7 (3.4%)	6 (5.8%)	1 (0.8%)	0.38
	Midline Recurrence	7 (3.4%)	4 (3.2%)	3 (2.4%)	0.38
	Panniculectomy	1 (0.4%)	1(0.8%)	0(0%)	1.0
	Mesh Infection/Removal	0(0%)	0(0%)	0(0%)	1.0

Supplemental Figure 1: EQ5D, 3B EQ5D VAS, and 3C HerQles estimates from mixed effect regression model throughout the study period adjusted for baseline differences.



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