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Long-term outcomes of ventral hernia repair using a new prosthetic mesh

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Abstract

BACKGROUND: Recently, use of hybrid meshes has been proposed owing to its different mesh-related properties. This study reviews our longer term experience with a hybrid mesh.

MATERIALS AND METHODS: We retrospectively reviewed all patients undergoing ventral hernia repair at our single medical center using a hybrid mesh from April 2016 through September 2019. Demographic, perioperative, and short- and long-term outcomes, reoperation, and recurrence rates were reviewed, and descriptive statistics were calculated.

RESULTS: A total of 48 patients who underwent ventral hernia repairs using a hybrid mesh were included. The average age of participants was 58 years (range 42–77 years), 85.7% were Caucasian, and 51% female. A minimally invasive approach was performed in 63.3%, with 20.4% converting to open hernia repair. Eighteen patients (36.7%) underwent open hernia repair. Thirty-day complications occurred in 12 patients (24.5%), with the most common complication being seroma formation. Hernia recurrence occurred in four of 49 (8.2%) patients. Results of a univariate analysis comparing groups of patients who did and did not experience recurrence resulted with body mass index (BMI) (45.85 vs. 30.70) as the only statistically significant risk factor. All recurrences occurred in open (three) or laparoscopic converted to open (one) cases. Over the full follow-up period, 11 patients (22.4%) underwent abdominal reoperation.

CONCLUSIONS: We report longer-term outcomes of a new permanent synthetic hybrid mesh with long-term hernia recurrence rates comparable to reported national averages. This study found BMI to be a statistically significant predictor of hernia recurrence. Synecor mesh appears to be safe and offers potential benefits of both bioabsorbable and permanent synthetic meshes.

Keywords:

Composite mesh, hernia recurrence, hernia repair, long-term outcomes, Synecor

Introduction

Hernia repairs are one of the most common general surgical procedures performed worldwide. A 2016 study suggested that watchful waiting of ventral hernias is a safe option; however, around 19% of patients eventually underwent surgery at a later point.[1] For those undergoing surgery, recurrence rates for ventral hernias range from 10% to 50% after initial repair.[2] This variation depended on patient characteristics, comorbidities, and method of surgical repair.[1] Recurrent ventral hernias pose increased risk to patients as they have been associated with increased complications, more extensive surgical procedures, and an increased risk for further recurrence.[3] Over the last several decades, multiple studies have found the use of mesh repair compared to suture repair to significantly reduce the risk of hernia recurrence, while not increasing the risk of surgical-site infections or postoperative pain.[4-6] Based on these early studies, The European Hernia Society (EHS) now recommends the use of a mesh in virtually all hernia repairs, with exceptions for defects <1 cm.[4] Even though these studies support

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the use of a mesh in ventral hernia repair, there is no clear consensus on which type of mesh should be used.

Hernia repairs with mesh were first performed in 1958; however, the initial mesh designs were heavyweight and had small pores, leading to intense fibrosis.[7] While the weight of these first-generation meshes helped support hernia repair against high intra-abdominal pressure, they generated an intense fibrotic reaction during the healing process, which led to pain and movement restriction.[8] This led to the creation of lightweight meshes. While their large pores and smaller size decrease postoperative pain, they had higher complication rates, including increased recurrence, infection, and adhesion after repair.[8] As research continued, it became clear that an ideal mesh would have the benefits of heavyweight and lightweight meshes, while minimizing the problems associated with earlier-generation meshes. Composite meshes were created for intraperitoneal use and came in both absorbable and permanent forms.[7] While they reduced infection and inflammation, adhesion was still prevalent.[7] Biomaterials have recently been incorporated into composite meshes for enhanced mesh absorption.[8] While no ideal mesh exists yet, new composite meshes will require more robust investigation, given some concern that the repair may weaken as biomaterials are incorporated into the host tissue.[8]

This study aims to further understand how composite meshes may be able to reduce hernia recurrence after surgery by reviewing a single medical center's long-term outcomes in ventral hernia repair using the GORE Synecor composite mesh. It is expected that composite meshes combine the benefits of prior mesh iterations to reduce long-term recurrence and complication rates.

Materials and Methods

This is an IRB-approved retrospective review of prospectively collected data from a single surgeon at minimally invasive surgery practice at a regional referral facility. Consecutive patients with any type of abdominal wall hernia, as defined by the EHS (primary, incisional, and recurrent incisional), repaired with preperitoneal or intraperitoneal GORE Synecor mesh during the study period were included. Demographic, patient, and surgical data were retrieved from a local hernia surgical database, abdominal core health quality collaborative registry data, and the healthcare system electronic medical records. Data of outcomes, including short- and long-term complications, recurrence, and reoperation, were obtained from a retrospective chart review. Recurrence was defined as a physical exam documenting a hernia, computed tomography scan of a recurrence, or reoperation for hernia recurrence. The time from last chart review to the index surgery date was recorded.

GORE Synecor is a hybrid composite mesh made of three components: a proprietary copolymer layer (polyglycolic acid [PGA]: trimethylene carbonate [TMC]), a monofilament polytetrafluoroethylene (PTFE) layer, and a nonporous bioabsorbable PGA: TMC film.[9] PGA and TMC are both biodegradable polymers which have differing strength and degradation rates. PGA is slightly more rigid but degrades more rapidly than the more flexible, elastic and slower-degrading TMC. These biodegradable layers are intended to maximize tissue ingrowth and revascularization surrounding the repair and permanent PTFE layer. The PTFE layer is macro-porous and has high strength but has a diameter similar to that of lightweight polypropylene so that minimal amount of the material is left behind.[9]

Descriptive statistics were used to report the recurrence and reoperation rates. For secondary analysis, characteristics of patients with recurrence and reoperation were compared to those of patients without the respective complication. All continuous variables were assessed with t tests or non-parametric equivalents, while categorical variables were analyzed using the chi-squared or Fisher's exact test where appropriate. Statistical significance was defined as $P < 0.05$. All statistical analyses were performed using R Statistical Software, R Foundation for Statistical Computing, Vienna, Austria (v4.3.1; R Core Team 2023).

Clinical trial registry

This work is a retrospective study. No clinical trials were involved.

Results

Forty-nine patients underwent ventral hernia treatment with Synecor mesh from April 2016 to September 2019. About half of patients were female (51%), most were Caucasian (85.7%), had a mean age of 58.86 (S.D. 12.22), and with a median body mass index (BMI) of 30.90 (28.00, 36.50) [Table 1]. Over half of patients had at least one comorbidity, with hypertension (HTN) (57.1%) being most common, followed by diabetes (24.5%). Nearly a quarter of patients were current smokers (20.4%) or had quit in the last year (2.0%).

Over a third of hernias were recurrent incisional hernias (36.7%), and 14 of 18 (77.8%) of these hernias were previously repaired with a mesh [Table 2]. The median hernia width and height were 5.00 (3.00, 8.00) and 8.00 (5.00, 12.00), respectively. Treatment in most cases began with a minimally invasive approach (63.3%), with 10 (20.4%) laparoscopic cases converting to open hernia repair. Of open and converted to open cases, component separation, either a Rives–Stoppa or transversus abdominus release were performed 19 of 28

Table 1: Patient characteristics

Patient characteristics		Overall
		49
Age		58.86 (12.22)
Sex	F	24 (49.0)
	M	25 (51.0)
Ethnicity	Caucasian	42 (85.7)
	African American	6 (12.2)
	Hispanic	1 (2.0)
BMI		30.90 (28.00, 36.50)
HTN		28 (57.1)
DM		12 (24.5)
A1c	Not recorded	5 (41.7)
	<6.5	1 (8.3)
	6.5 to 8.0	3 (25.0)
	>8.0	3 (25.0)
COPD		5 (10.2)
Smoking	Never	22 (44.9)
	Current	10 (20.4)
	Quit <1 year	1 (2.0)
	Quit >1 year	16 (32.7)
CHF		1 (2.0)
ASA	1	2 (4.1)
	2	16 (32.7)
	3	29 (59.2)
	4	2 (4.1)

Table 2: Surgery characteristics

Hernia type	Primary	7 (14.3)
	Incisional	24 (49.0)
	Recurrent incisional	18 (36.7)
Recurrent: number of prior repairs	One	10 (21.3)
	Two or more	8 (17.0)
Hernia location	Umbilical	13 (26.5)
	Epigastric	11 (22.4)
	Epigastric and umbilical	11 (22.4)
	Suprapubic	3 (6.1)
	Umbilical and infraumbilical	3 (6.1)
	Epigastric, umbilical, and infraumbilical	3 (6.1)
	Subxiphoid	1 (2.0)
	Subcostal (lateral)	3 (6.1)
	Iliac (lateral)	1 (2.0)
Hernia width (cm)		5.00 [3.00, 8.00]
Hernia height (cm)		8.00 [5.00, 12.00]
Hernia area (cm^2)		42.00 [16.00, 100.00]
Surgical approach	Open	18 (36.7)
	Laparoscopic	13 (26.5)
	Robotic	8 (16.3)
	Laparoscopic converted to open	10 (20.4)
	Robotic to open	0 (0.0)
Open component separation	Not performed	21 (42.9)
	Retrorectus	11 (22.4)
	TAR	8 (16.3)
Mesh placement location	Preperitoneal	10 (20.4)
	Intraperitoneal	21 (42.9)
	Retrorectus	17 (34.7)
	Onlay	1 (2.0)
Fascial closure	Yes	42 (85.7)
	No	7 (14.3)
Drain placed	Yes	22 (44.9)
	No	27 (55.1)

(67.8%) times. Mesh placement is also shown in Table 2, and the intraperitoneal GORE Synecor mesh was used in all 21 cases where the mesh was positioned in the intraperitoneal space. A preperitoneal mesh was used in all other cases. Fascial closure was achieved in as many cases as abdominal wall tension would allow (85.7%). Drains were left in 22 cases, all of which were open, 17 of 22 (77.3%) had component separation, where the median hernia width was 8.5 cm.

Complications occurred within 30 days of surgery in 12 (24.5%) patients [Table 3]. The most common complication was seroma, three of 12 (25.0%); two after open repairs with retrorectus release and one after laparoscopic repair with intraperitoneal sublay. There were three reoperations within this early period, two for missed enterotomy with subsequent repair or short segment bowel resection and both with mesh removal. One patient had an early small bowel obstruction (SBO) where there were light adhesions from the small bowel to the abdominal wall, although the mesh was in a retromuscular position and not directly involved in the adhesion. Over the full follow-up period, 11 (22.4%) patients underwent abdominal reoperation. Two underwent hernia recurrence for a first operation, and a third recurrence was repaired as a second surgery (this patient had the early SBO requiring laparoscopic lysis of adhesions as a first reoperation). Two patients had mesh infections with partial mesh excision. Of the 11 patients who underwent a first reoperation, five (45.5%) underwent a second operation, three for an infection and two for hernia recurrence. One patient underwent three operations. The patient's first operation was for partial removal of the infected mesh, the second operation was for soft tissue incision and drainage of an abscess, and the final operation was for complete removal of the infected mesh.

Hernia recurrence occurred in four of 49 (8.2%) patients [Table 4]. Three patients had recurrent hernia repair, and one of these three had a recurrence after the first recurrent repair and subsequent second repair. Results of a univariate analysis comparing groups of patients who did and did not experience recurrence resulted with BMI (median recurrent 45.85 vs. non-recurrent 30.70) as the only statistically significant risk [Table 5]. Of the recurrent hernias, three (75.0%) occurred in patients with

Table 3: 30-day complications and re-operations

30-d complication	Yes	12 (24.5)
	No	37 (75.5)
30-d complication type	Seroma	3 (25.0)
	Draining sinus	1 (8.3)
	SSI	3 (25.0)
	Post op ileus	1 (8.3)
	Post op syncope	1 (8.3)
	Missed enterotomy	2 (16.7)
	Post op bowel obstruction	1 (8.3)
Reoperation	Yes	11 (22.4)
	No	38 (77.6)
Reoperation procedure	Stitch abscess excision	2 (18.2)
	Partial removal of the infected mesh	2 (18.2)
	Complete removal of the infected mesh	0 (0.0)
	Soft tissue incision and drainage	2 (18.2)
	Small bowel resection and mesh removal	1 (9.1)
	Diagnostic laparoscopy and lysis of adhesions	1 (9.1)
	Recurrent hernia repair	2 (18.2)
	Laparoscopic to open enterotomy repair and mesh removal	1 (9.1)
Second reoperation	Yes	5 (45.5)
	No	6 (54.5)
Second procedure	Stitch abscess excision	1 (20.0)
	Complete removal of the infected mesh	1 (20.0)
	Soft tissue incision and drainage	1 (20.0)
	Recurrent hernia repair	2 (40.0)
Third reoperation	Yes	1 (20.0)
	No	4 (80.0)
Third procedure	Complete removal of the infected mesh	1 (100.0)

Table 4: Hernia recurrence and follow-up

Hernia recurrence	Yes	4 (8.2)
	No	45 (91.8)
Reoperation for hernia	Yes	3 (6.1)
	No	46 (93.9)
Median follow-up		992.00 [374.00, 1398.00]

prior recurrences ($P = 0.343$). All recurrences occurred in open (three) or laparoscopic converted to open (one) cases ($P = 0.41$). There were no other significant risk factors included in our results.

Discussion

It has been well-studied that the use of mesh for treating incisional hernias relates to a significant decrease in the rate of hernia recurrence when compared to suture repair.[2] Though a well-studied and researched field, there is no consensus for which the mesh is ideal for ventral hernias. While there may be proposed advantages of certain types of mesh categories for specific hernia and patient characteristics, there have been few studies with direct comparisons of mesh products in a randomized controlled fashion, which limits our understanding of when to use these products. Currently, non-hybrid permanent meshes remain the standard of care for the majority of hernia repairs and are easily accessible. However, no mesh is suitable for all hernia repairs, and as new

Table 5: Hernia recurrence risk univariate analysis

		No recurrence	Recurrence	*P*
n		45	4	
Age		57.98 (12.33)	68.75 (4.11)	0.091
Sex	F	22 (48.9)	3 (75.0)	0.609
	M	23 (51.1)	1 (25.0)	
Ethnicity	African American	6 (13.3)	0 (0.0)	1
	Caucasian	38 (84.4)	4 (100.0)	
	Hispanic	1 (2.2)	0 (0.0)	
Ethnicity		30.70 (28.00, 35.80)	45.85 (38.12, 50.95)	0.039
HTN	No	21 (46.7)	0 (0.0)	0.125
	Yes	24 (53.3)	4 (100.0)	
DM	No	34 (75.6)	3 (75.0)	1
	Yes	11 (24.4)	1 (25.0)	
COPD	No	40 (88.9)	4 (100.0)	1
	Yes	5 (11.1)	0 (0.0)	
Smoking	Never	18 (40.0)	4 (100.0)	0.199
	Current	10 (22.2)	0 (0.0)	
	Quit <1 year ago	1 (2.2)	0 (0.0)	
	Quit >1 year ago	16 (35.6)	0 (0.0)	
ASA	1	2 (4.4)	0 (0.0)	0.494
	2	16 (35.6)	0 (0.0)	
	3	25 (55.6)	4 (100.0)	
	4	2 (4.4)	0 (0.0)	
Hernia type	Incisional	23 (51.1)	1 (25.0)	0.343
	Primary	7 (15.6)	0 (0.0)	
	Recurrent	15 (33.3)	3 (75.0)	
Hernia width		5.00 [3.00, 8.00]	7.50 [6.50, 11.00]	0.122
Approach	Open	15 (33.3)	3 (75.0)	0.41
	Laparoscopic	13 (28.9)	0 (0.0)	
	Robotic	8 (17.8)	0 (0.0)	
	Laparoscopic to open	9 (20.0)	1 (25.0)	
Open component separation	None	5 (23.8)	2 (50.0)	0.646
	Rectrorectus	9 (42.9)	1 (25.0)	
	TAR	7 (33.3)	1 (25.0)	

hernia meshes become commercially available, they require the study to evaluate longer-term outcomes and ultimately can compare them to more traditional meshes.

With more than 70 different types of meshes available to surgeons, it is important to look at short- and long-term outcomes when choosing to use a new mesh for hernia repair.[9] Gore Synecor® (W.L. Gore and Associates, Flagstaff, AZ) is a permanent synthetic mesh made of an absorbable synthetic component and a permanent synthetic component that can be used intraperitoneally or within the abdominal wall layers. As a composite mesh, it is ideal for advanced repairs that require a non-absorbable material to facilitate successful reconstruction.[10] This study's preliminary evaluation of this composite mesh in 2020 found comparable short-term outcomes after 30 days when compared to other mesh products on the market.[11] These preliminary results included a 30-day complication rate of 24.5%. Twenty-five percent of these complications were seromas, 25% were surgical-site infections, and 16.7% were missed enterotomy cases. We also reported our short-term outcomes with this mesh previously including a complication rate of 29% and recurrence rate of 4% at 3 months of follow-up.[12]

Longer-term outcomes for this novel hybrid mesh have recently been reported. Linn and colleagues reported on 459 patients undergoing mostly laparoscopic or robotic repairs and reported a 5% complication rate at 30 days and a 0.9% recurrence rate at a mean follow-up of 32 months.[13] Another recent study reported on 278 patients and report outcomes based on different techniques of repair and planes of mesh placement, with an overall recurrence rate of 1.4% at a mean follow-up of 24.1 months. They reported a mesh infection rate of 5% with no meshes requiring complete explantation.[14]

The goal of this study was to evaluate the long-term outcomes with the hybrid mesh Synecor and an update on our previously published short-term results.[12] The demographic characteristics were found to be representative of the population, and the wide variety of ASA scales of study participants suggests that this study included a variety of patients, including some healthy patients and some with serious chronic illnesses. The recurrence rate of 8.2% with Synecor mesh is lower than recurrence rates of ventral incisional hernias (30%–40%) reported in other studies.[2,15] BMI was found to be the only statistically significant factor that predicted recurrent ventral incision rates in this study. Other factors in evaluating mesh viability including a 30-day complication rate of 24.5% and a reoperation rate of 22.4% suggest that Synecor is a viable mesh alternative for ventral hernia repair. HTN was found to be a statistically significant comorbidity when assessing the re-operation rate in patients who underwent repair with Synecor, but this is likely not clinically significant and likely due to comparison of few patients.

Limitations of the study include limited sample size. Ideally, more than 49 patients would be used for data analysis as this makes the power of our statistics smaller. However, this sample size was likely due to the nature of a single-center, single-surgeon study, and longer-term follow-up. These types of studies may encounter issues with external validity as their populations may be unique to their geographic area or the specific patient population of the surgeon whose outcomes were documented. However, the use of a single surgeon removes possible confounders such as surgeon experience and technical ability.

Conclusion

We report longer-term outcomes of a new permanent synthetic mesh with long-term hernia recurrence rates comparable to reported national averages. This study found BMI to be a statistically significant predictor of hernia recurrence. This novel mesh appears to be safe and offers potential benefits of both bioabsorbable and permanent synthetic meshes. Further study with longer-term outcomes and larger patient samples are needed to evaluate ideal indications for the use of this novel hybrid mesh.

Author contributions

WH: Concept design, data analysis, manuscript editing and review, guarantor; AC: Literature review, data analysis, manuscript preparation; AW: Concept design, data analysis, manuscript preparation; JL: Concept design, data analysis, manuscript editing and review; JB: Literature review, data analysis, manuscript preparation.

Ethical policy and institutional review board statement

The study was approved by the Novant Health - New Hanover Regional Medical Center Institutional Review Board, approval number 23-2482, dated on October 2nd, 2023. Procedures followed were in accordance with the Helsinki Declaration of 1975.

Declaration of patient consent

All patients signed consents for surgical treatment and were aware of placement in the registry that would be used for research purposes.

Data availability statement

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Financial support and sponsorship
Nil.

Conflicts of interest
Dr. William W. Hope is an Editor-in-Chief of *International Journal of Abdominal Wall and Hernia Surgery*. The article was subject to the journal's standard procedures, with peer review handled independently of this Editor and their research groups.

Abbreviations
BMI	Body mass index
CT	Computer tomography
EMR	Electronic medical records
ASA scale	American Society of Anesthesiologists scale

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