The Role of a Biosynthetic Hybrid Mesh in Abdominal Wall Hernia Repair in High Risk Patients with Multiple Comorbidities

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Background

The influx of more high-risk and obese patients in need of abdominal wall hernia repair naturally leads to larger, more complex hernia cases and the need for strong mesh. Strength of the mesh itself has become critical in hernia repair as body mass indices (BMI) continue to increase. To help support a single-stage repair, the strength of the biomaterial mesh must be able to maintain strength over the life of the patient.

Biosynthetic surgical mesh technology is designed to address some of these complex patient characteristics, and leverage the benefits of biologic and synthetic meshes, while reducing the associated risks of those devices, and may provide some of the advantages of these meshes.[1] GORE® SYNECOR Biomaterials, with their unique combination of materials and tri-layer design, are considered a hybrid surgical mesh device, within the Biosynthetic mesh category. GORE® SYNECOR Biomaterial offers a unique value proposition as a device for abdominal wall hernia repair.

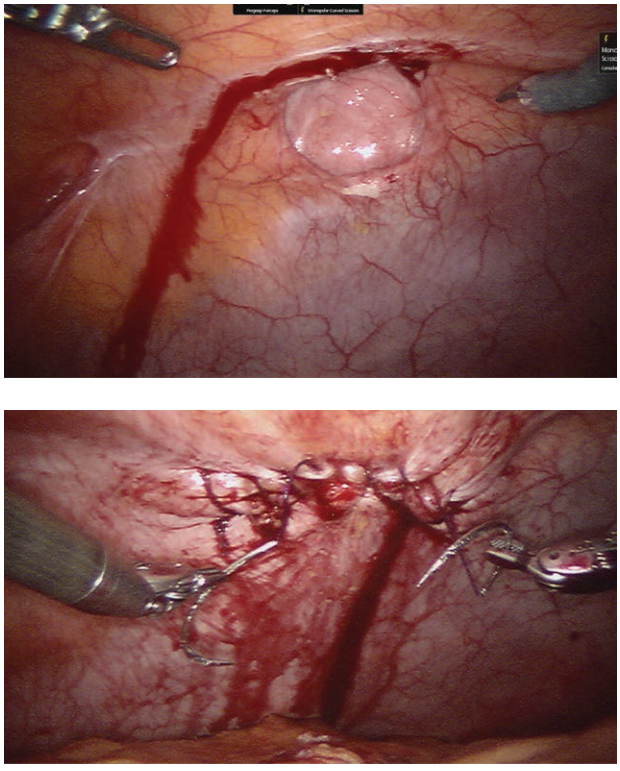
Hybrid Biosynthetic Mesh

GORE® SYNECOR Intraperitoneal Biomaterial is a combination of a macroporous knit of dense, monofilament polytetrafluoroethylene (PTFE) fibers for permanent strength, a bioabsorbable layer of Gore 3D polyglycolic acid (PGA): Trimethylene carbonate (TMC) web scaffold on the parietal surface and a PGA:TMC nonporous film on the visceral surface. GORE® SYNECOR Preperitoneal Biomaterial is a macroporous knit of dense, monofilament PTFE fibers for permanent strength embedded between two web scaffolds.

The PGA:TMC web, which serves as the scaffold in GORE® SYNECOR Biomaterials, forms interconnected pores that are similar in structure to a collagen fiber network. The 3D web layer provides optimal porosity for rapid cellular infiltration and vascularization.[2] The PTFE knit layer of GORE® SYNECOR Biomaterials is a macroporous knit (average pore size of 1.6 mm). This combination of materials allows rapid cellular migration and vascularization, which can facilitate healing after a hernia repair.

Methods

A retrospective review of 22 patients who underwent abdominal wall hernia repair with a biosynthetic GORE® SYNECOR Biomaterial by a single surgeon at a single institution was conducted between 2016–2018. Considerations for using the GORE® SYNECOR Device included the following pre-operative patient characteristics, which posed risks for potential complications: A BMI greater than 40; multiple recurrent hernias and hernia repair requiring panniculectomy. Types of procedures performed include laparoscopic, robotic and open repairs with underlay, onlay or retromuscular mesh placement with or without myofascial release, with or without panniculectomy. Patients were followed up post-operatively at two weeks and at 30 days.



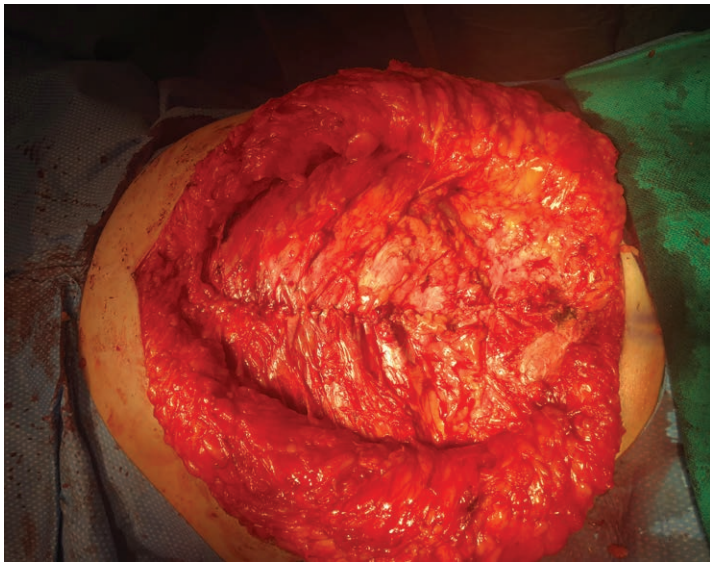
Retromuscular abdominal wall reconstruction.
Photo courtesy of Jacob Roberts, D.O.

Of the 11 patients who had primary hernia repairs, three underwent a laparoscopic procedure with underlay mesh placement. Seven patients had an open procedure; six with retromuscular mesh placement with myofascial release and one with an onlay mesh. Four patients had concomitant panniculectomies.

Of the 11 patients who underwent repair for a recurrent hernia, two had a laparoscopic procedure with underlay mesh. Nine had an open procedure; two with onlay mesh, one with underlay mesh placement, six with retromuscular placement following myofascial release. Four patients had concomitant panniculectomies.

In this series, the following was also observed:

- One patient that had a robotic umbilical hernia repair experienced a recurrence but this was unrelated to the mesh
- One patient experienced a seroma requiring intervention by interventional radiologist (IR); seroma was drained and subsequently resolved. After, the patient did extremely well.



Abdominal wall reconstruction for high-risk patient presenting with multiple comorbidities. Photo courtesy of Jacob Roberts, D.O.

Table 1. Case series summary*

Number of patients	22 patients from 2016–2018 retrospectively reviewed
Procedure types	Abdominal wall hernia repairs with biosynthetic, hybrid mesh products, GORE® SYNECOR Intraperitoneal Biomaterial or GORE® SYNECOR Preperitoneal Biomaterial including: Laparoscopic, robotic and open repairs
Mesh placement	Onlay, retromuscular or intraperitoneal mesh placement with or without abdominal wall reconstruction
Patient factors	BMIs over 40
	Primary or recurrent hernias
	Comorbidities that increased their risk factors

Table 2. Key clinical findings, observations and recommendations

Observational outcomes over a three-year time period with clinical utilization of GORE® SYNECOR Biomaterial—both GORE® SYNECOR Intraperitoneal Device and GORE® SYNECOR Preperitoneal Device configurations	0% infection rate in over 20 complex cases
	Biosynthetic hybrid mesh replaced biologic mesh in this type of high risk / complex ventral hernia cases
	GORE® SYNECOR Biomaterial has provided great financial savings over biologic mesh
	Utilized both GORE® SYNECOR Intraperitoneal Biomaterial and GORE® SYNECOR Preperitoneal Biomaterial in multiple types of cases, such as open (underlay, onlay, component separation) laparoscopic and robotic repairs
	Our surgical team always changes gloves following dissection in open cases, before handling the mesh, to reduce risk of infection
	Drains were placed in all open cases

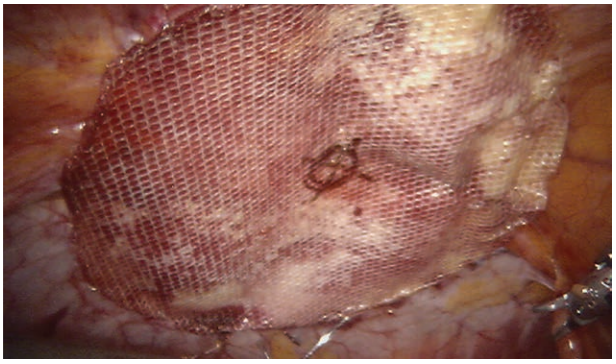
* Data includes both GORE® SYNECOR Intraperitoneal Biomaterial and GORE® SYNECOR Preperitoneal Biomaterial.

Surgeon Observations and Conclusions

In our practice, we have successfully utilized GORE® SYNECOR Biomaterials in different surgical approaches for hernia repair, including retromuscular, intraperitoneal and onlay mesh placements. We have used it in patients who would be considered at high-risk for surgical site infections (SSIs), surgical site occurrences (SSOs) and other complications, patients with multiple past hernia recurrences, patients who had previously undergone bariatric procedures, obese patients and patients that presented with comorbid conditions, such as requiring a panniculectomy. We have not observed any mesh infection, complications attributable to the mesh or any need to explant GORE® SYNECOR Biomaterials.

The performance of GORE® SYNECOR Biomaterials in our series of high-risk patients undergoing abdominal wall hernia repair was clinically acceptable. Based on our observations at the time of this case series, we reported that none of the devices became infected or required removal, and the reported recurrence in one patient was not device related. The handling properties of the material are excellent and it is ready to use on removal from its packaging without the need for additional preparation time or storage. It is very easy to trim or tailor the device to the defect or anatomy, allowing for precise tissue approximation, reducing the risk for "dead space" and potentially reducing the risk of seroma formation. The device is easy to manipulate and fixate when performing robotically-assisted laparoscopic ventral hernia repairs.

As unique biosynthetic hybrid meshes, GORE® SYNECOR Biomaterials provide compelling alternatives in complex cases where biologic mesh has been traditionally utilized, such as in the presence of obesity, multiple comorbidities, recurrent hernias and high-risk patients. Our early data demonstrates acceptable outcomes in complex cases specific to recurrence rates and postoperative morbidity and mortality.



Robotic ventral hernia repair with intraperitoneal onlay mesh (IPOM). Photo courtesy of Jacob Roberts, D.O.

1. Afaneh C, Cobb WS. From the bench to the bedside. Mesh selection for hernia repair: expert review of biologic, synthetic, and bioabsorbable types. Presented at the International Hernia Congress; March 12-15, 2018; Miami, FL. *General Surgery News* 2018:1-4. BB184. AX0892-EN1.
2. Crawford N. *Assessment of Vascularity via Micro CT in Various Patch Devices*. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2016. [Final study report]. 2344TL.

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