

Case Study Report

Reinforcement with Gentrix® Surgical Matrix Thick following ventral hernia repair: durable repair at 3 years

Age: 65 **Sex:** Female

Comorbidities: Type-2 diabetes, hypertension, hyperlipidemia, anemia.

Procedure Used: Laparoscopic Ventral Hernia Repair.

ACell Product(s) Used: Gentrix® Surgical Matrix Thick 10 cm x 20 cm.

Outcome: Patient has demonstrated no signs of recurrence 38 months post-op. A CT scan at 38 months showed robust, intact fascia at the site of the Gentrix-reinforced repair.

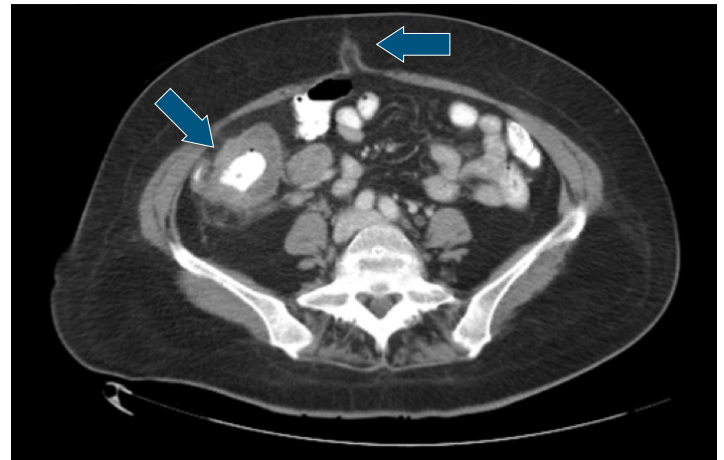


Figure 1. CT scan demonstrating colon cancer (left arrow) and ventral hernia (right arrow).



Figure 2. CT scan three years after repair of ventral hernia with Gentrix Surgical Matrix Thick showing intact repaired fascia.

Clinical Presentation and Case Background

A 65-year-old female patient presented with fatigue and profound anemia. Patient mentioned to her doctor that she had been experiencing an increasingly uncomfortable protruding ventral hernia that had started as an umbilical hernia. Past medical history included insulin-dependent Type 2 diabetes mellitus, hypertension, hyperlipidemia, and a prior right below-knee amputation. She underwent colonoscopy and was found to have two synchronous carcinomas, one in the sigmoid colon, and one in the cecum.

A CT scan was performed for cancer staging, and it demonstrated the colonic neoplasia and the ventral hernia (Figure 1).

Management of Ventral Hernia

At surgery, a laparoscopic resection of both tumors was performed and the ventral hernia was repaired. A laparoscopic technique was employed for the resections and the ventral hernia repair utilizing an intraperitoneal placement of a 10 cm x 20 cm Gentrix Surgical Matrix Thick device through a 15 mm trocar* with transfascial Vicryl suture fixation.

The patient recovered uneventfully and was discharged home on post-operative day five. Her wounds and hernia repair healed without incident, and she required chemotherapy for the colorectal carcinoma.

Outcome of Management and Follow-up

The patient has continued to follow up annually and has had no recurrence of the hernia and is cancer-free. A CT scan was performed 38 months after surgery as part of ongoing cancer surveillance, and it showed a robust intact repaired fascial layer (Figure 2).

Why this Patient was a Candidate for ACell Product

In the physician's opinion, the patient was an appropriate candidate for hernia reinforcement with a biologically-derived mesh. Synthetic mesh was avoided because of the concomitant resection of two colon segments and the patient's advanced diabetes.

ACell Product Summary

A single 10 cm x 20 cm Gentry Surgical Matrix Thick device was hydrated for 30 minutes and placed laparoscopically.

Source

This case was performed by Kent Sasse, MD, at an urban teaching hospital in Nevada, USA. Dr. Sasse is a board certified general and colorectal surgeon. Dr. Sasse maintains a financial relationship with ACell, Inc. as a member of ACell's Consultants Bureau and Scientific Advisory Board.

**Unlike other configurations of the Gentry Surgical Matrix product family, Gentry Surgical Matrix Thick is available in sizes 10 cm x 20 cm and larger. These larger sizes of Gentry Surgical Matrix Thick are not generally recommended for insertion through a trocar. However, ACell has data on file to support that Gentry Surgical Matrix sizes 10 cm x 15 cm and smaller can be safely inserted through a trocar (see IFU).*

MatriStem UBM™ Technology

Urinary Bladder Matrix (UBM) is an extracellular matrix (ECM) scaffold derived from porcine urinary bladder. The bladder is harvested and processed so that only the lamina propria and epithelial basement membrane remain. It is then disinfected, packaged, and sterilized. The resulting product is non-crosslinked, completely resorbable, and acellular. Non-crosslinked UBM, unlike crosslinked materials, reduces encapsulation associated with a chronic foreign body response¹.

MatriStem UBM, manufactured by ACell, Inc., is the only commercially available form of UBM. Commercial manufacturing methods differ from published methods utilized by academic institutions.

Characteristics of UBM

UBM contains a collection of collagens and proteins arranged in a natural three-dimensional structure with features including:

- Laminin²
- Numerous growth factors³
- Numerous collagens²
- Glycosaminoglycans (GAGs)³

UBM appears to facilitate the body's naturally adaptive or accommodative immune response, which facilitates the remodeling of biomechanically functional tissue.² In the presence of UBM, in pre-clinical studies, the host has been observed to:

- Demonstrate an anti-inflammatory response¹
- Completely resorb and incorporate the material^{1,4}
- Mobilize site-appropriate and progenitor cells^{1,5,6}
- Promote the formation of site-appropriate tissue through remodeling^{1,4,7,8}



ACell, Inc.
6640 Eli Whitney Drive
Columbia, MD 21046
www.acell.com
800-826-2926

Note: The data presented here contain the opinions of and personal techniques practiced by the treating physician(s). The techniques presented herein are for informational purposes only. The decision of which techniques to use in a particular clinical application lies with the treating physician(s) based on patient profile, particular circumstances surrounding the procedure, and previous clinical experiences.

Note: MatriStem® Surgical Matrix Thick was rebranded as Gentry Surgical Matrix Thick in January 2017.

Note: Gentry Surgical Matrix devices are composed of a porcine-derived extracellular matrix, also known as Urinary Bladder Matrix. The devices are supplied in multi-layer sheet configurations (including 3-Layer, 6-Layer, & 8-Layer) in sizes up to 10cm x 15cm. Gentry Surgical Matrix Thick (8-layer) is intended for implantation to reinforce soft tissue where weakness exists in patients requiring urological, gastroenterological, or plastic & reconstructive surgery. Reinforcement of soft tissue within urological, gastroenterological, and plastic & reconstructive surgery includes, but is not limited to, the following procedures: hernia and body wall repair, colon and rectal prolapse repair, tissue repair, and esophageal repair.

Rx ONLY Refer to IFU supplied with each device for indications, contraindications, and precautions. US Toll-Free 800-826-2926 • www.acell.com © 2018 ACell, Inc. All Rights Reserved.

1. Brown BN, Londono R, Tolley S, et al. *Acta Biomater.* 2012 Mar;8(3):978-87.
2. Brown B, Lundberg K, Reina J, et al. The basement membrane component of biologic scaffolds derived from extracellular matrix. *Tissue Eng.* 2006 Mar; 12(3):519-26.
3. Growth factor and GAG data on file.
4. Gilbert TW, Nieponice A, Spiewack AR, et al. Repair of the thoracic wall with an extracellular matrix scaffold in a canine model. *J Surg Res.* 2008 Jun; 147(1):61-7.
5. Reing JE, Zhang L, Myers-Irvin J, et al. Degradation products of extracellular matrix affect cell migration and proliferation. *Tissue Eng Part A.* 2009 Mar; 15(3):605-14.
6. Agrawal V, Johnson SA, Reing J, et al. Epimorphic regeneration approach to tissue replacement in adult mammals. *Proc Natl Acad Sci USA.* 2010 Feb; 107(8):3351-5.
7. Nieponice A, Gilbert TW, Badylak SF. Reinforcement of esophageal anastomoses with an extracellular matrix scaffold in a canine model. *Ann Thorac Surg.* 2006 Dec; 82(6):2050-8.
8. Boruch AV, Nieponice A, Qureshi IR, et al. Constructive remodeling of biologic scaffolds is dependent on early exposure to physiologic bladder filling in a canine partial cystectomy model. *J Surg Res.* 2010 Jun 15; 161(2):217-25.