

Case Study Report

Reinforcement with Gentrix[®] Surgical Matrix Plus following incisional hernia repair: 2-year follow up of complex hernia

Age: 55 **Sex:** Female

Procedure Used: Laparoscopic Incisional Hernia Repair.

ACell Product(s) Used: Gentrix[®] Surgical Matrix Plus 10 cm x 15 cm.

Outcome: Patient had no recurrence of the hernia two years post-op. A CT scan at 6 months post-op showed robust, intact fascia at the site of the Gentrix-reinforced repair.

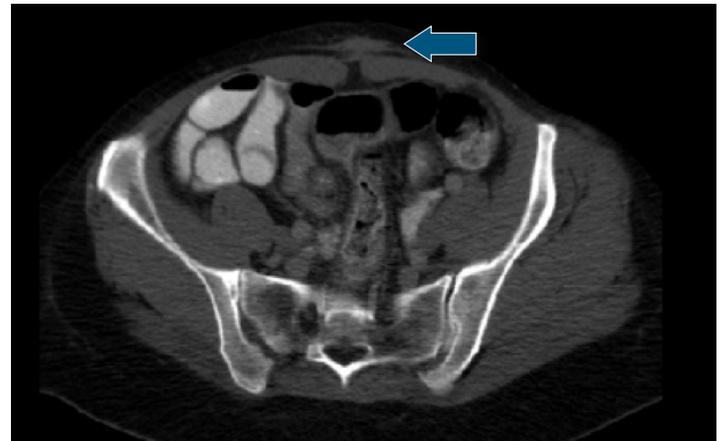


Figure 1. CT scan image demonstrating incisional hernia, inflamed tissue, and deep subcutaneous fistula.

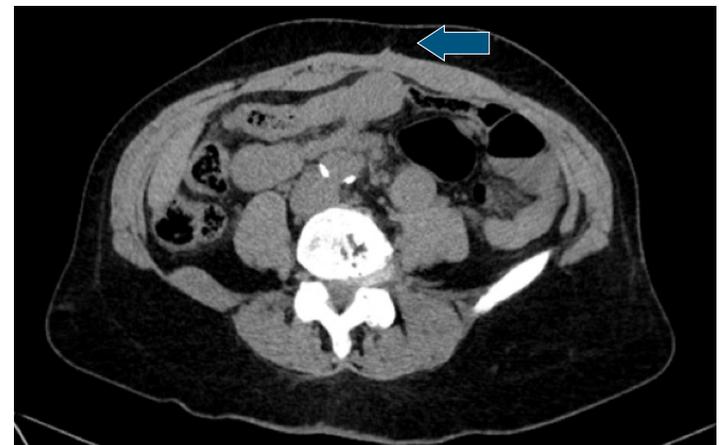


Figure 2. CT 6 months post-op showing intact abdominal wall repair without recurrence or fistula.

Clinical Presentation and Case Background

A 55-year-old female patient presented with three years of continuous purulent abdominal wall drainage and an incisional hernia. Past surgical history consisted of a Cesarean-section, a laparoscopic gastric bypass, and a mesh ventral hernia repair more than three years earlier. In addition, three years before presentation, the patient had undergone an abdominoplasty procedure at an outside hospital. A review of the operative notes indicated that the abdominoplasty was performed with Prolene sutures.

Subsequent to the abdominoplasty, the patient had suffered with persistent purulent drainage and a non-healing abdominal wall despite multiple debridement procedures and more than 20 courses of antibiotics. A CT scan was performed, demonstrating the incisional hernia and a soft tissue lucency consistent with a deep subcutaneous fistula (Figure 1).

Management of Incisional Hernia

The patient underwent exploratory laparotomy with excisional debridement of a chronic abdominal wall infection and excision of foreign body material including previously-implanted mesh, scar, suture material, and granulomatous tissue. The incisional hernia was repaired laparoscopically with intraperitoneal placement of a 10 cm x 15 cm Gentrix

Surgical Matrix Plus device and sutured closure of the fascia in layers using Vicryl suture, then with full thickness retention sutures, with drains.

Post-operatively, the patient remained in the hospital for two nights and was discharged home with two drains. The drains were removed at the second post-operative visit, two weeks after surgery, when the output was noted to be less than 20 cc per day and serosanguinous in character. One area of the incision had serous drainage appear on the dressings for another three weeks and then resolved. The patient recovered uneventfully and resumed full, normal activities.

Outcome of Management and Follow-up

6 months post-op, the patient reported pain in the abdominal wall when lifting grocery bags. A CT scan was obtained which showed a robust, intact fascia without recurrence or abscess. The patient has had no further events and no sign of recurrence, drainage, or fistulization (Figure 2). The patient remained free from recurrence two years after surgical reinforcement of the hernia repair per a regular follow-up visit in October 2017.

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 not considered appropriate due to the high expected risk of mesh contamination and potential need for future explantation.

ACell Product Summary

A single 10 cm x 15 cm Gentrix Surgical Matrix Plus device was hydrated for 20 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.

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

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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 J, 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.
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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.

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 Plus was rebranded as Gentrix Surgical Matrix Plus in January 2017.

Note: Gentrix 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. Gentrix Surgical Matrix Plus (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.