Strattice™ Reconstructive Tissue Matrix

BECAUSE EVIDENCE MATTERS

Acellular Dermal Matrix Provides Durable Long-Term Outcomes in Abdominal Wall Reconstruction: A Study of Patients With Over 60 Months of Follow-up

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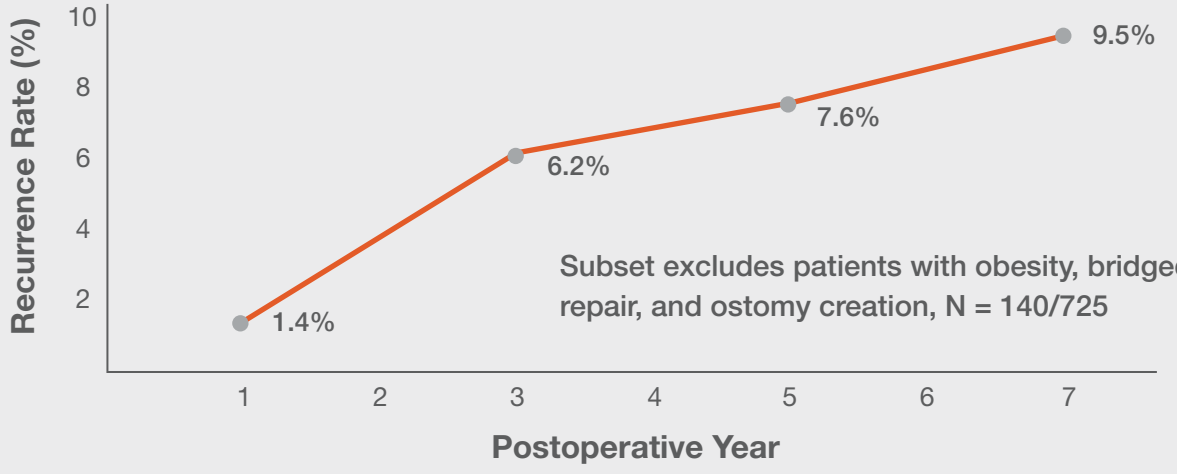
In the study, STRATTICE™ Reconstructive Tissue Matrix (RTM) provided "very favorable" outcomes in complex AWR

Study Setup

- Retrospective analysis of 725 patients who underwent abdominal wall reconstruction (AWR) using either porcine ADM or bovine ADM from March 2005 to June 2019 at The University of Texas at MD Anderson Cancer Center
- **Inclusion criteria:** Patients who underwent AWR for hernia or reconstruction of midline oncologic resection defects using an underlay (retrorectus, preperitoneal, or intraperitoneal) biologic mesh were considered for this study
- **Exclusion criteria:** Patients with lateral abdominal wall hernias or resection defects, primary closure of abdominal wall fascia without mesh placement, performance of posterior component separation, reconstruction with synthetic mesh or onlay mesh placement, or who had less than 6 months of follow-up
- Primary outcome measure was hernia recurrence (HR) diagnosed by physical examination or abdominal imaging
- Secondary outcome measure was defined as having the presence of at least 1 surgical site occurrence (SSO)
  - Surgical site occurrences identified were: surgical site infection, wound dehiscence, fat necrosis, seroma/hematoma, and enterocutaneous fistula (ECF)
- Imaging studies were available for 93% of patients in the overall sample (N = 677/725) and 96% of patients in the "long-term follow-up" (N = 156/162) group having a minimum of 60 months follow-up
- Authors excluded risk factors for hernia recurrence (shown in graph below) and evaluated recurrence rates for patients with 7 years of follow-up (N = 140)

Cumulative Hernia Recurrence Rates With CT Imaging



ADM = acellular dermal matrix; AWR = abdominal wall reconstruction.

STUDY STRENGTHS AND LIMITATIONS

- Strengths of this study include a large patient cohort, long-term follow-up time, inclusion of data for both overall cohort as well as long-term follow-up (LTF) patients, and routine use of serial CT scans for most patients
- Limitations of this study include single-center retrospective design, high number of complex cases may limit generalizability, and lack of randomization and a synthetic mesh comparator group

THE AUTHORS FOUND BIOLOGIC MESH PROVIDES VERY FAVORABLE AWR OUTCOMES WHEN COMPARED TO PUBLISHED REPORTS OF A PATIENT POPULATION WITH SIMILAR COMORBIDITIES AND DEFECT CHARACTERISTICS WHO USED SYNTHETIC MESH

- The current study reports the longest follow-up outcomes to date for all AWR using ADM
- When compared to outcomes in synthetic mesh patients exhibiting similar comorbidities and defect characteristics, biologic mesh remains a reliable long-term option for complex AWR

INDICATIONS

STRATTICE™ Reconstructive Tissue Matrix (RTM), STRATTICE™ RTM Perforated, STRATTICE™ RTM Extra Thick, and STRATTICE™ RTM Laparoscopic are intended for use as soft tissue patches to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. Indications for use of these products include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. STRATTICE™ RTM Laparoscopic is indicated for such uses in open or laparoscopic procedures. These products are supplied sterile and are intended for single patient one-time use only.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

These products should not be used in patients with a known sensitivity to porcine material and/or Polysorbate 20.

WARNINGS

Do not resterilize. Discard all open and unused portions of these devices. **Do not use** if the package is opened or damaged. **Do not use** if seal is broken or compromised. After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Do not reuse once the surgical mesh has been removed from the packaging and/or is in contact with a patient. This increases risk of patient-to-patient contamination and subsequent infection.

For STRATTICE™ RTM Extra Thick, **do not use** if the temperature monitoring device does not display "OK."

PRECAUTIONS

Discard these products if mishandling has caused possible damage or contamination, or the products are past their expiration date. Ensure these products are placed in a sterile basin and covered with room temperature sterile saline or room temperature sterile lactated Ringer's solution for a minimum of 2 minutes prior to implantation in the body. Place these products in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.

These products should be hydrated and moist when the package is opened. If the surgical mesh is dry, do not use.

Certain considerations should be used when performing surgical procedures using a surgical mesh product. Consider the risk/benefit balance of use in patients with significant co-morbidities; including but not limited to, obesity, smoking, diabetes, immunosuppression, malnourishment, poor tissue oxygenation (such as COPD), and pre- or post-operative radiation.

Bioburden-reducing techniques should be utilized in significantly contaminated or infected cases to minimize contamination levels at the surgical site, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy prior and in addition to implantation of the surgical mesh. In large abdominal wall defect cases where midline fascial closure cannot be obtained, with or without separation of components techniques, utilization of the surgical mesh in a bridged fashion is associated with a higher risk of hernia recurrence than when used to reinforce fascial closure.

For STRATTICE™ RTM Perforated, if a tissue punch-out piece is visible, remove using aseptic technique before implantation.

For STRATTICE™ RTM Laparoscopic, refrain from using excessive force if inserting the mesh through the trocar.

STRATTICE™ RTM, STRATTICE™ RTM Perforated, STRATTICE™ RTM Extra Thick, and STRATTICE™ RTM Laparoscopic are available by prescription only.

For more information, please see the Instructions for Use (IFU) for all STRATTICE™ RTM products available at www.allergan.com/StratticeIFU or call 1.800.678.1605.

To report an adverse reaction, please call Allergan at 1.800.367.5737.

Reference: 1. Asaad M, Kapur SK, Baumann DP, Liu J, Butler CE. Acellular dermal matrix provides durable long-term outcomes in abdominal wall reconstruction: a study of patients with over 60 months of follow-up. *Ann Surg.* DOI: 10.1097/SLA.0000000000004454. Published ahead of print.

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