

STRATTICE™ Reconstructive Tissue Matrix Clinical Case Study

Gross and histologic examination of STRATTICE™ Reconstructive Tissue Matrix three years postimplantation

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Patient: A 65-year-old gentleman with a history of ulcerative colitis, subtotal colectomy, and subsequent incisional hernia repair presents with clinical bulging, pain, and poor functional status. His prior ventral hernia repair had been performed with an underlay (intraperitoneal) STRATTICE™ Reconstructive Tissue Matrix in a bridged fashion in 2010. At our institution, a CT scan showed the patient had an intact STRATTICE™ Tissue Matrix repair, an unrepaired incisional hernia superior to the prior ventral hernia repair, and central bulging/ventration where the fascia had been bridged.

Procedure: A midline incision was made through the prior surgical incisions and through the STRATTICE™ Tissue Matrix. There were no adhesions to the posterior abdominal wall where the STRATTICE™

Tissue Matrix had been placed. Biopsies were taken of the STRATTICE™ Tissue Matrix at multiple locations for histologic evaluation. A retrorectus STRATTICE™ Tissue Matrix repair was performed with complete primary fascial closure. A 20cm x 30cm piece of STRATTICE™ Tissue Matrix was trimmed to fit the 13cm x 30cm exposed retrorectus space.

Outcome: Biopsies taken from the previously implanted STRATTICE™ Tissue Matrix demonstrated neovascularization and collagen deposition with minimal foreign body reaction. The patient was seen three weeks postoperatively and contacted via phone at nine weeks; at both time points, the patient was doing well. He reported a high degree of satisfaction with the surgical repair, resolution of his preoperative pain, and regain of functional status.

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The surgical techniques described herein are suggested techniques for using STRATTICE™ Reconstructive Tissue Matrix. Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the technique based on his or her own medical training and expertise.

Mike K. Liang, MD is a paid consultant for LifeCell Corporation.

Patient History

A 65-year-old male presented with symptomatic ulcerative colitis to an outside hospital in 2004. He underwent an open subtotal colectomy with re-anastomosis. He developed an incisional hernia from that laparotomy and underwent an open incisional hernia repair with an underlay (intraperitoneal) STRATTICE™ Tissue Matrix. During this procedure, primary fascial closure was not achieved and a bridged repair was performed with STRATTICE™ Tissue Matrix. Three years postoperatively, the patient presented to our institution with bulging and complaints of a recurrent incisional hernia. On examination, the patient had central bulging underlying the prior incision. He felt that this bulging affected his day-to-day ability to function. CT scan demonstrated that the patient had a small incisional hernia superior to the prior repair in the epigastrium (**Figure 1**), an intact STRATTICE™ Tissue Matrix, and eventration/bulging from the bridged repair (**Figure 2**).



Figs. 1 & 2 CT scan imaging demonstrating an incisional hernia superior to the prior surgical repair (Figure 1) and eventration/bulging where prior fascial closure had not been achieved during the prior repair (Figure 2).

Surgical Intervention

Following discussion of the patient's options/alternatives, risks, and benefits, he underwent an open ventral incisional hernia repair. The patient's postoperative risk of surgical site infection and occurrence was calculated and it was determined that he was at high risk of postoperative wound occurrence. An incision was made through the prior STRATTICE™ Tissue Matrix placement. There were no adhesions to the posterior abdominal wall where the STRATTICE™ Tissue Matrix had been placed. The STRATTICE™ Tissue Matrix was intact and appeared contiguous with the posterior fascia and abdominal wall (**Figure 3**).

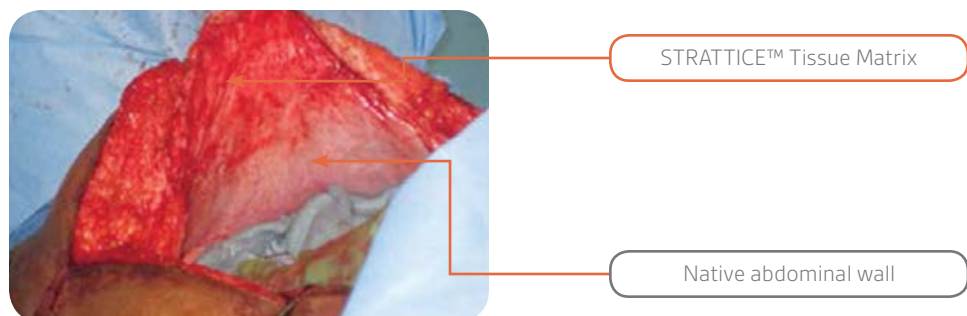


Fig. 3 Intraoperative image of posterior abdominal wall three years after an underlay; STRATTICE™ Tissue Matrix repair demonstrating no adhesion formation and continuous interface between STRATTICE™ Tissue Matrix and native fascia.

The retrorectus space was entered and developed. The posterior rectus sheath was closed with a running 0-polygalactate suture (**Figure 4**). The exposed space measured out to be 13cm x 30cm. A 20cm x 30cm piece of STRATTICE™ Tissue Matrix was trimmed to fit this space in a non-bridged repair and the matrix was secured with 12 0-PDS transfascial sutures (**Figure 5**). A drain was placed. The anterior fascia was closed with running 0-PDS sutures and the skin was closed.



Fig. 4 Retrorectus dissection and space with the posterior fascia closed.

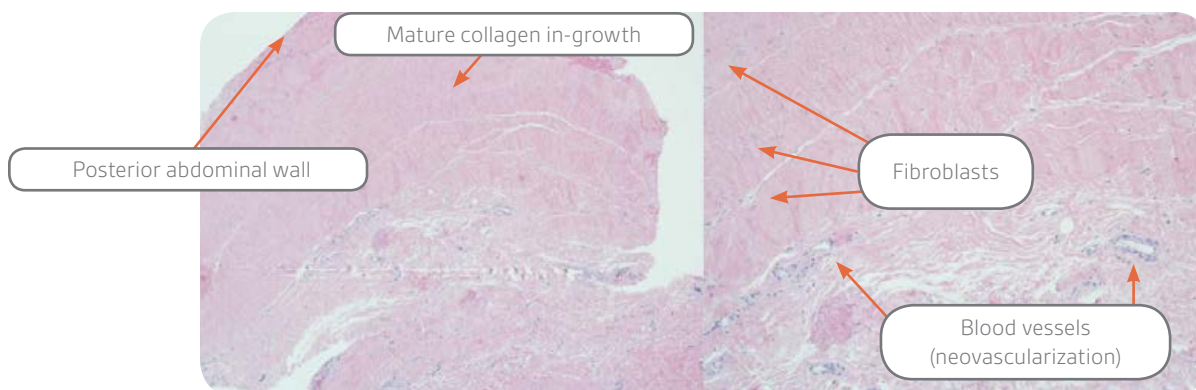


Fig. 5 STRATTICE™ Tissue Matrix placed in the retrorectus space with a drain in place.

Histologic Examination

Biopsies taken of the STRATTICE™ Tissue Matrix used in the 2010 bridged ventral incisional hernia repair were evaluated histologically. Mature collagen was noted and minimal foreign body reaction seen (**Figure 6**). There was evidence of neovascularization and fibroblast infiltration of the matrix, markers of integration (**Figure 7**). The pathologist stated that the matrix had transitioned into host tissue with a fully integrated repair at three years.

The patient left the hospital on postoperative day four and the dressing was removed. He returned to postoperative follow-up three weeks later and was contacted by phone six weeks later. On both visits, the patient reported a high degree of satisfaction with his surgical repair and function.



Figs. 6 & 7 STRATTICE™ Tissue Matrix and native abdominal wall interface 36 months postoperative at 4x and 10x magnification.

Before use, physicians should review all risk information, which can be found in the *Instructions for Use* attached to the packaging of each STRATTICE™ Tissue Matrix graft. Rx only.

CONTRAINDICATIONS: STRATTICE™ is derived from a porcine source and should not be used in patients with known sensitivity to porcine material, or in patients with a known sensitivity to Polysorbate 20.



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