The procedure started with diagnostic laparoscopy and laparoscopic adhesiolysis. Findings from diagnostic laparoscopy included a cirrhotic liver, ascites, and a fistula of the distal jejunum through the synthetic mesh, which was the source of the periumbilical drainage and NSTI. Due to these complex findings, the procedure was converted to an open operation. Part of the distal jejunum with the fistula, the infected mesh, and the umbilicus were resected, followed by a stapled end-to-end anastomosis of the jejunum. Necrotic abdominal wall tissue was debrided, resulting in a full-thickness 12 x 10 cm abdominal wall defect. Primary closure of the abdominal wall muscles was achieved using running 0 Prolene® suture following release of the lateral aponeuroses of the external obliques. Onlay mesh placement was chosen due to violation of the retrorectus space during prior surgeries. A hydrated OviTex 1S Resorbable Reinforced BioScaffold (10 x 20 cm) was brought onto the field and sutured to intact surrounding anterior abdominal wall fascia with interrupted 0 PDS sutures (Ethicon®). The primary repair was reinforced by the OviTex 1S with several centimeters of overlap beyond the edge of the primary repair in all directions. Three 10-mm fully perforated Jackson-Pratt drains were placed. A T-shaped skin incision was closed primarily and PREVENA™ dressing was placed.

Clinical Case Study:
Open Abdomen Incisional Herniorrhaphy in Contaminated (CDC Class IV) Operative Field
Performed by Dr. Michael Sawyer, general surgeon at Comanche County Memorial Hospital, Lawton, OK

This case study demonstrates the utility of an OviTex 1S Reinforced BioScaffold with Resorbable Polymer for incisional herniorrhaphy in a contaminated (CDC Class IV) operative field.

- 56-year-old male presented with draining purulent periumbilical wound.
- Patient previously had 3 midline incisional hernia recurrences; the last hernia defect was repaired with a synthetic mesh that became infected.
- Patient developed a fistula producing intestinal content and a necrotizing soft tissue infection (NSTI).
- Medical history includes alcoholism, liver cirrhosis, esophageal varices, hypertension, type II diabetes, and chronic congestive heart failure.

Important Safety Information
OviTex Reinforced BioScaffolds are intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome.

Caution: Federal law restricts this device to sale by or on the order of a physician.
Do not use OviTex in patients known to be sensitive to materials of ovine (sheep) origin.
For additional important safety information, please see the OviTex Reinforced BioScaffold Instructions for Use.
On postoperative day 3, cellulitis was noted around the dressing, and the wound was opened and packed due to a superficial wound abscess. Two days later, a vacuum-assisted closure (VAC) dressing was placed.

At day 17, there was no swelling or redness of the wound. The exposed surface of the OviTex implant showed signs of neovascularization and granulation tissue (Figure 4).

The patient slowly but steadily progressed overall and was discharged on day 23 with home healthcare and a home wound VAC. The wound granulated and filled progressively as observed on subsequent follow-up visits (Figure 5).

At day 131, his last visit, the repair remained intact and the wound had healed sufficiently for the VAC to be discontinued (Figure 6).

No antibiotics were used postoperatively.

Incisional herniorrhaphy in contaminated operative fields is a challenging undertaking associated with high rates of surgical site infection and other surgical site occurrences, such as seroma, hematoma, or wound dehiscence. OviTex Reinforced BioScaffold performed well in an incisional hernia in a contaminated operative field:

- OviTex 1S Resorbable Reinforced BioScaffold helped maintain the integrity of the repair over 4 months of follow-up.
- OviTex performed well in a hostile, contaminated (Class IV) field of a complex recurrent abdominal wall hernia in a patient with numerous significant comorbidities.
- OviTex supported wound repair, granulation, and revascularization throughout the observed time period.

Consider OviTex BioScaffolds for complicated hernia repair cases.

Discover the OviTex portfolio of products at www.TELABIO.com.
Contact us at 1-844-TELABIO (1-844-835-2246) or customerservice@telabio.com.
Clinical Case Study:
Repair of Incisional Hernias in 2 Patients With More Than 1 Year of Follow-up
Performed by Dr. Michael Sawyer, general surgeon at Comanche County Memorial Hospital, Lawton, OK

These case studies present the use of OviTex™ 1S Reinforced BioScaffolds with resorbable polymer in abdominal wall reconstruction (AWR) for the repair of incisional hernia in 2 patients with more than 1 year of follow-up.

Patient 1
- 44-year-old female with type 2 diabetes, previous gastric bypass surgery, and a body mass index (BMI) of 28 at presentation
- Patient had previously undergone laparoscopic cholecystectomy, developing a central abdominal bulge that exhibited progressive enlargement and increasing abdominal discomfort, beginning 6 months post-surgery
- CT scan revealed incisional hernia containing portion of transverse colon
- Ventral Hernia Working Group (VHWG) grade 2; CDC wound class I

Material and Technique
- The procedure involved AWR with creation of bilateral transversus abdominis release (TAR) myofascial advancement flaps
- Operative findings revealed a dominant defect measuring approximately 10 cm in transverse diameter, as well as several smaller “Swiss cheese” defects along the patient’s upper vertical midline abdominal incision; estimated aggregate size of the defects was 150 cm (Figure 1)
- Following the TAR, the posterior rectus sheaths were approximated in the midline with running 0-Prolene

Patient 2
- 82-year-old female with chronic congestive heart failure and obesity. BMI of 31 at consultation
- Patient had previously undergone hysterectomy, bladder suspension, and laparoscopic cholecystectomy
- Patient first noted incisional hernia ~2 years prior to consultation, with noticeable and rapid growth over the past 6 months
- Physical examination demonstrated a relatively large, reducible hernia at the superior aspect of the prior incision
- VHWG grade 2; CDC wound class I

Materials and Technique
- The procedure involved AWR with creation of bilateral TAR myofascial advancement flaps
- Operative findings revealed a defect ~12 cm in transverse diameter and 11 cm in length (132 cm²) (Figure 2)
- Following the TAR, the posterior rectus sheaths were approximated in the midline with running 2-0 Prolene

Figure 1
- [Image of patient 1's abdomen with incisional hernia]

Figure 2
- [Image of patient 2's abdomen with incisional hernia]
Materials and Technique (cont.)

Postoperative Results with OviTex

• An OviTex 1S Resorbable Reinforced BioScaffold (20 x 10 cm) was placed into the retrorectus space and secured with a total of 8 0-PDS sutures (Figure 3)
• The anterior rectus sheaths were approximated in the midline with running 0-Prolene, completing the AWR
• Three #10 Jackson-Pratt drains were placed

• No surgical site infections or other surgical site occurrences were observed during the 5-day postoperative hospital stay
• Drain output progressively decreased to less than 20 cc per day via each drain during hospitalization
• Prior to discharge on postoperative day 5, drains were removed
• Postoperative follow-up via office visits and telephone interviews demonstrated continued durability of the OviTex Reinforced BioScaffold at 17 months
  o No lingering postoperative discomfort reported
  o No signs of recurrence observed
  o No seromas reported or observed

Patient 1 (cont.)

• An OviTex 1S Resorbable Reinforced BioScaffold (20 x 10 cm) was placed into the retrorectus space and secured with a total of 8 0-PDS sutures (Figure 4)
• Three #10 Jackson-Pratt drains were placed

• No surgical site infections or other surgical site occurrences were observed during the 6-day postoperative hospital stay
• Drain output progressively decreased to less than 20 cc per day via each drain during hospitalization
• Prior to discharge on postoperative day 6, drains were removed
• Postoperative follow-up via office visits and telephone interviews demonstrated continued durability of the OviTex Reinforced BioScaffold at 15 months
  o No signs of recurrence observed
  o No signs of other surgery-related complications observed
  o No seromas reported or observed

Patient 2 (cont.)

Conclusion

AWR techniques involving the use of synthetic or biologic mesh have become more commonly used to effect durable repairs and to aid in restoring abdominal wall integrity and function.1 Although synthetic meshes have been associated with decreased incidence of hernia recurrence when compared with primary suture repair, these materials have been linked with severe mesh-related complications, including mesh infection, seromas, contracture, erosion, and fistulas.1,2 On the other hand, biologic and biosynthetic repair materials are purported to be more resistant to infection and usually do not require explantation when exposed to infectious sources. However, biologics and biosynthetics have been criticized for their cost and lack of long-term durability.3

OviTex Reinforced BioScaffolds represent the first reconstructive bioscaffold combining the beneficial properties of both biologic and synthetic materials. The OviTex portfolio has been recognized as unique and designated in a newly created and distinct category of soft tissue reinforcement materials called biological tissue–derived reinforced.4 In the 2 cases presented here in which OviTex was used as the reinforcement material, both patients have been satisfied with their repairs and exhibited no signs of surgery-related recurrence or other complications after more than 1 year of follow-up.
Important Safety Information

OviTex Reinforced BioScaffolds are intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome. Do not use OviTex in patients known to be sensitive to materials of ovine (sheep) origin. For additional important safety information, please see the OviTex Reinforced BioScaffold Instructions for Use. The statements made or results achieved by TELA Bio customers described herein were achieved in their specific setting. Due to variations in clinical experience and technique, there is no guarantee that these results are typical. For prescription use only.

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References


