OVITEX®

REINFORCED TISSUE MATRIX

Midline Incisional

Open

OviTex 1S Resorbable

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 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.

TELA BIO® INC
SURGICAL RECONSTRUCTION COMPANY

SCIENCE. VALUE. INNOVATION.

Patient History

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

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

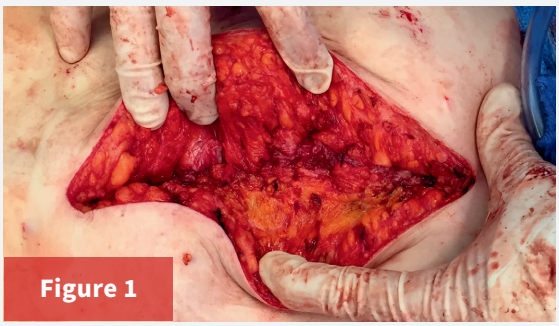

Figure 1

- 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

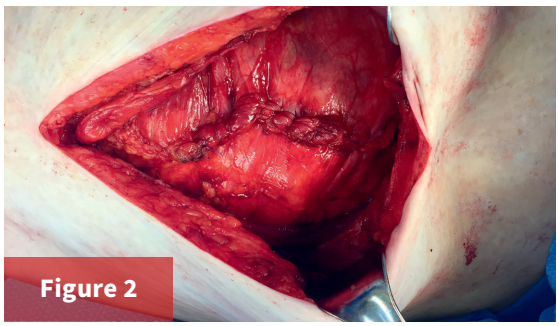

Figure 2

- 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 cm^2) **(Figure 2)**
- Following the TAR, the posterior rectus sheaths were approximated in the midline with running 2-0 Prolene

Materials and Technique (cont.)

Patient 1 (cont.)

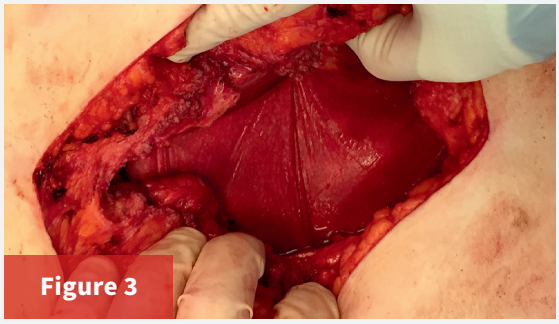

Figure 3

- An OviTex 1S Resorbable (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

Patient 2 (cont.)

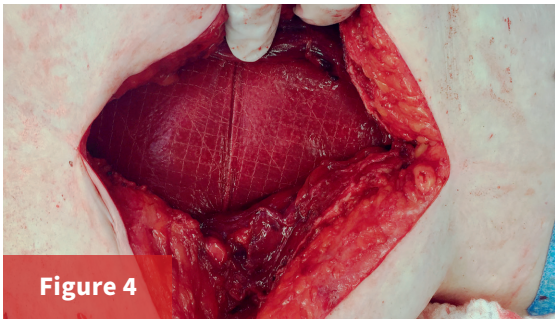

Figure 4

- An OviTex 1S Resorbable (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

Postoperative Results with OviTex

- 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 implant at 17 months
  - o No lingering postoperative discomfort reported
  - o No signs of recurrence observed
  - o No seromas reported or observed

- 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 implant at 15 months
  - o No signs of recurrence observed
  - o No signs of other surgery-related complications observed
  - o No seromas reported or observed

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 represents the first reconstructive biologic 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.

TELA BIO® INC
SURGICAL RECONSTRUCTION COMPANY
SCIENCE. VALUE. INNOVATION.

To discover the OviTex portfolio of products:

Visit:
www.TELABIO.com

Call:
US: 1-844-835-2246 (1-844-TELABIO)
EU: 00800 03577753

Email:
US: customerservice@telabio.com
EU: customerserviceEU@telabio.com

Important Safety Information

OviTex is 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 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.

A surgeon must use his or her own clinical judgment when deciding which products are appropriate for treatment of a particular patient. Always refer to the package insert, product label, and/or instructions for use before using any TELA Bio product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your TELA Bio representative if you have questions about TELA Bio products.

Aroa Biosurgery. 2 Kingsford Smith Place, 2 Airport Oaks, Auckland 2022, New Zealand
EC REP S4M EUROPE, 59, rue Castellion, 01100 Oyonnax, France
Literature number: MK-PM-0013 Revision 03 (May 2021)

References

1. Burger JWA, Luijendijk RW, Hop WCJ, Halm JA, Verdaasdonk EGG, Jeekel J. Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. *Ann Surg*. 2004;240(4):578-583; discussion 583-585.

2. Luijendijk RW, Hop WC, van den Tol MP, et al. A comparison of suture repair with mesh repair for incisional hernia. *N Engl J Med.* 2000;343(6):392-398.

3. Ferzoco SJ. A systemic review of outcomes following repair of complex ventral incisional hernias with biologic mesh. *Int Surg*. 2013;98(4):399-408.

4. Deeken CR, Lake SP. Mechanical properties of the abdominal wall and biomaterials utilized for hernia repair. *J Mech Behav Biomed Mater*. 2017;74:411-427.

TELA BIO® INC SURGICAL RECONSTRUCTION COMPANY
SCIENCE. VALUE. INNOVATION.