OVITEX®
REINFORCED BIOSCAFFOLDS


Midline Incisional


Open


OviTex 1S Resorbable

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.

Patient History

- 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.

Materials and Technique

- 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 **(Figure 1)**.
- 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 **(Figure 2)**.
- Three 10-mm fully perforated Jackson-Pratt drains were placed.
- A T-shaped skin incision was closed primarily **(Figure 3)** and PREVENA™ dressing was placed.

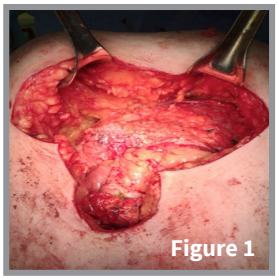
Figure 1

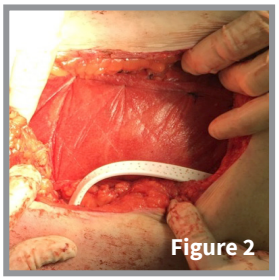
Figure 2

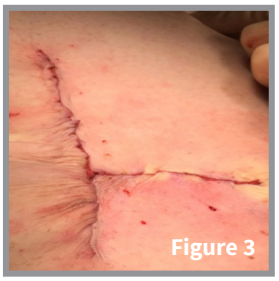
Figure 3

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.

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Postoperative Results with OviTex

- 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.

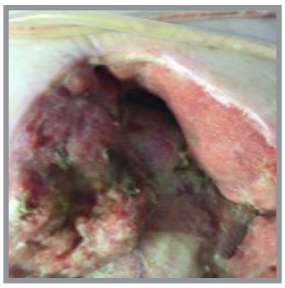
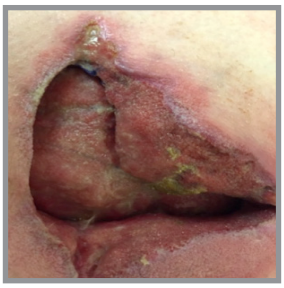
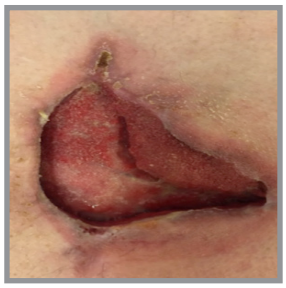


Figure 4: 17 days





4 weeks **8 weeks**

Figure 5

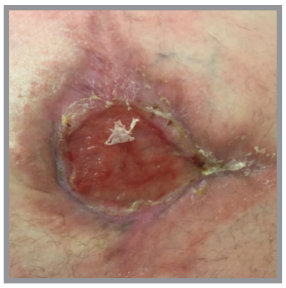


Figure 6: 131 days (19 weeks)

Conclusion

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 GD Medical; exclusive distributor for TELA Bio products in the Netherlands.
Contact GD Medical at 040- 3031 090 or visit gdmedical.nl

Important Safety Information (continued)

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.

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.

Manufactured by: Aroa Biosurgery. 2 Kingsford Smith Place, Auckland 2022, New Zealand.

Authorized Representative in the European Community: HealthLink Europe Services BV. De Tweeling 20-22, 5215 MC ‘s-Hertogenbosch, The Netherlands.

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