OVITEX®

REINFORCED TISSUE MATRIX

EVIDENCE SUMMARY

TELABIO®

TELA Bio, Inc. is focused on providing innovative soft-tissue reconstruction solutions that optimize clinical outcomes by prioritizing the preservation and restoration of the patient's own anatomy. We are committed to delivering our advanced technologies with a strong economic value proposition to assist surgeons and health care institutions in providing next-generation soft-tissue repair solutions to more patients worldwide.

TELABIO®

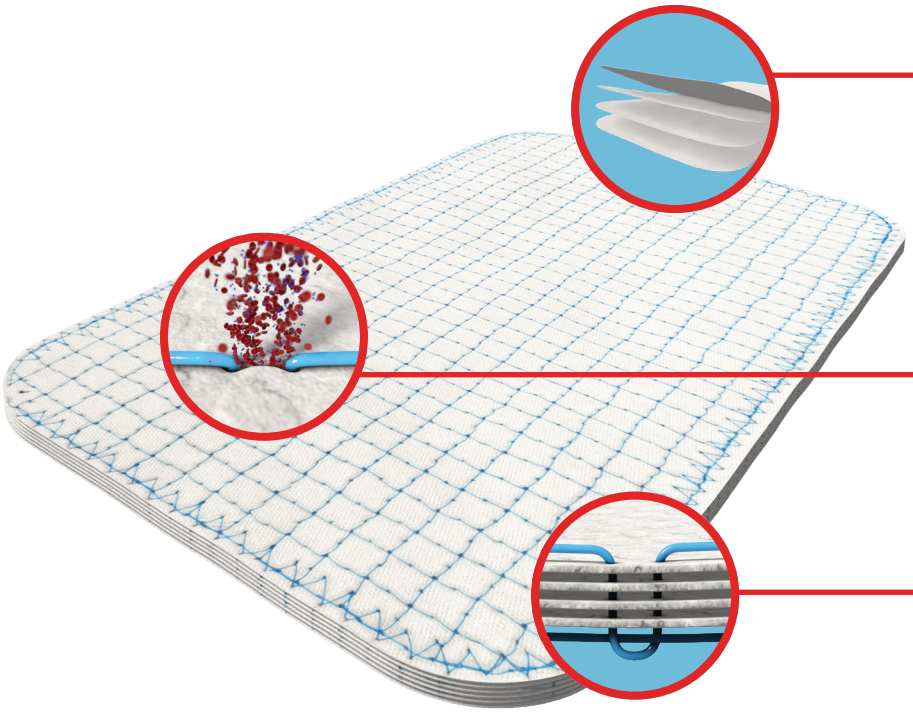
SCIENCE. VALUE. INNOVATION.

OVITEX®
REINFORCED TISSUE MATRIX

A PURPOSEFULLY DESIGNED SOLUTION

The result of extensive and exhaustive research and development, OviTex Reinforced Tissue Matrix is a true technological revolution in soft tissue repair, bringing together science, value, and innovation to address the unmet needs of surgeons and their patients.

OviTex is purposefully designed as a biologic tissue reinforced with minimal suture material to optimize the strength and compliance of the entire construct while facilitating tissue remodeling.



Layered Biologic

Layers of ovine (sheep) extracellular matrix provides a 3-D scaffold for rapid cellular infiltration and angiogenesis to enable functional tissue remodeling.

Permeable Design

Facilitates fluid transfer and movement of cells throughout the matrix.

Polymer Reinforcement

Interwoven polymer suture for added strength and improved handling. Lockstitch embroidery pattern creates ripstop effect and prevents unraveling when cut.

EVIDENCE: PURPOSEFUL DESIGN

	Citation	Procedure Type	Evidence Type
Bravo Clinical Study	DeNoto, G., III, Ceppa, E. P., Pacella, S. J., Sawyer, M., Slayden, G., Takata, M., Tuma, G., & Yunis, J. (2021).* **A Prospective, Single Arm, Multi-Center Study Evaluating the Clinical Outcomes of Ventral Hernias Treated with OviTex® 1S Permanent Reinforced Tissue Matrix: The BRAVO Study 12-Month Analysis.** Journal of clinical medicine, 10(21), 4998. https://doi.org/10.3390/jcm10214998	Ventral Hernia	Journal Publication
2016	Ferzoco, Stephen.* **Biomechanical Evaluation of Reinforced BioScaffolds: A New Approach to Hernia Repair.** Poster presented at: Abdominal Wall Reconstruction Conference; June 9-11, 2016; Washington, D.C.	Hernia	Conference Poster Presentation
2017	Abell, Bruce., Awad, Samir., Bastidas, J. Augusto., Denoto, George., III, Ferzoco, Stephen., Franz, Michael., Golla, Dinakar.* **Mesh Performance in Hernia Repair in 2017: A Surgical Review of Progress to Improve Outcomes.** www.telabio.com. 2017. Tela Bio.	Hernia	White Paper
	Ferzoco, Stephen.* **OviTex Reinforced BioScaffolds are More Permeable than Other Market-Leading Hernia Repair Materials.** Poster presented at: Abdominal Wall Reconstruction Conference; June 8-10, 2017; Washington, D.C.	Hernia	Conference Poster Presentation
2018	Ferzoco, S. (2018).* **Early Experience outcome of a reinforced Bioscaffold in inguinal hernia repair: A case series.** International Journal of Surgery Open, 12. 9-11. https://doi.org/10.1016/j.ijso.2018.06.001.	Inguinal Hernia	Journal Publication
	Sawyer M. (2018).* **New Ovine Polymer-Reinforced Bioscaffold in Hiatal Hernia Repair.** JSLS : Journal of the Society of Laparoendoscopic Surgeons, 22(4), e2018.00057. https://doi.org/10.4293/JSLS.2018.00057	Hiatal Hernia	Journal Publication
	Sawyer, Michael A J.* **Ovine Polymer-Reinforced BioScaffold in Abdominal Wall Reconstruction.** Poster presented at: American Hernia Society International Hernia Congress; March 18, 2018; Miami, FL	Abdominal Wall Reconstruction	Conference Poster Presentation
2019	Awad, Samir et al.* **Resilience and Healing of a Novel Reinforced BioScaffold (RBS) Matrix in the Setting of High-Risk Incisional Hernia Repair After Enterocutaneous Fistula (ECF) Takedown.** Poster presented at: Americas Hernia Society Annual Meeting; March 11-14, 2019; Las Vegas, NV	Incisional Hernia	Conference Poster Presentation
	Langstein, Howard et al.* **A Study of Mesh Compliance: Implications for Proper Splinting for Fascial Repair in Abdominal Wall Reconstruction.** Poster presented at: Americas Hernia Society Annual Meeting; March 11-14, 2019; Las Vegas, NV	Abdominal Wall Reconstruction	Conference Poster Presentation
	Sawyer, Michael A J.* **Ovine Polymer-Reinforced BioScaffold in Abdominal Wall Reconstruction.** Poster presented at: Americas Hernia Society Annual Meeting; March 11-14, 2019; Las Vegas, NV	Abdominal Wall Reconstruction	Conference Poster Presentation

**Indicates one or more surgeons are paid consultants of TELA Bio, Inc.*

	Citation	Procedure Type	Evidence Type
2020	Overbeck, N., Nagvajara, G. M., Ferzoco, S., May, B., Beierschmitt, A., & Qi, S. (2020).* **In-vivo evaluation of a reinforced ovine biologic: a comparative study to available hernia mesh repair materials.** Hernia: the journal of hernias and abdominal wall surgery, 24(6), 1293–1306. https://doi.org/10.1007/s10029-019-02119-z	Abdominal Wall Reconstruction	Journal Publication (pre-clinical study)
	Szotek, Paul et al.* **Using a Reinforced Biologic Mesh in a Minimally Invasive Technique for Ventral Hernia Repair.** Poster presented at: Americas Hernia Society Annual Meeting; September 25-26, 2020; Virtual	Ventral Hernia	Conference Poster Presentation
	Szotek, Paul et al.* **Using a Reinforced Biologic Mesh in a Minimally Invasive Technique for Ventral Hernia Repair.** Poster presented at: Minimally Invasive Surgery Symposium; June 9-24, 2020; Virtual	Ventral Hernia – Minimally Invasive (MIS)	Conference Poster Presentation
	Towfigh, Shirin et al.* **Choice of Hernia Mesh for Patients at Higher-Than-Average Risk for Mesh-Material Complications.** Poster presented at: Americas Hernia Society Annual Meeting; September 25-26, 2020; Virtual	Hernia	Conference Poster Presentation
2021	Ankney C, Banaschak C, Sowers B, Szotek P.* **Minimizing Retained Foreign Body in Hernia Repair Using a Novel Technique: Reinforced Biologic Augmented Repair (ReBAR).** J Clin Med Res. 2021;3(4):1-11. https://doi.org/10.37191/Mapsci-2582-4333-3(4)-073	Hernia (Multiple) – ReBar	Journal Publication
	Banaschak, Cory., Szotek, Paul.* **Robotic Assisted ReBAR of 111 Inguinal Hernias.** Poster presented at: Society of American Gastrointestinal and Endoscopic Surgeons; August 31 - September 3, 2021; Las Vegas, NV	Inguinal Hernia	Conference Poster Presentation
	Parker, M. J., Kim, R. C., Barrio, M., Socas, J., Reed, L. R., Nakeeb, A., House, M. G., & Ceppa, E. P. (2021).* **A novel biosynthetic scaffold mesh reinforcement affords the lowest hernia recurrence in the highest-risk patients.** Surgical endoscopy, 35(9), 5173–5178. https://doi.org/10.1007/s00464-020-08009-1	Ventral Hernia	Journal Publication
	Denoto, George, III.* **Use of Ovine Reinforced Tissue Matrix in Bridged Incisional Hernia Repair.** Poster presented at: Society of American Gastrointestinal and Endoscopic Surgeons; August 31 - September 3, 2021; Las Vegas, NV	Hernia – Bridged	Conference Poster Presentation
	Sawyer, M., Ferzoco, S., & DeNoto, G., III (2021).* **A Polymer-Biologic Hybrid Hernia Construct: Review of Data and Early Experiences.** Polymers, 13(12), 1928. https://doi.org/10.3390/polym13121928	Hernia	Journal Publication

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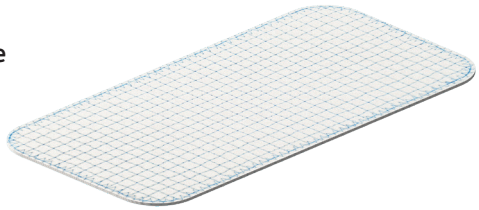
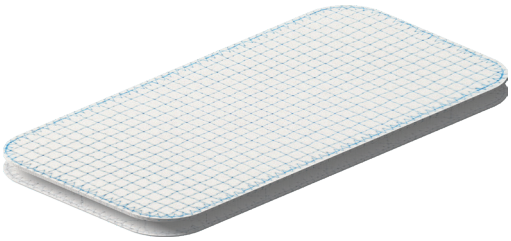
	Citation	Procedure Type	Evidence Type
2022	Fernandez, Luis.* **Definitive Closure Using an Ovine Reinforced Tissue Matrix in the Complex Open Abdomen after Penetrating Thoraco-Abdominal Trauma**. Poster presented at: Abdominal Wall Reconstruction Conference; June 8-11, 2022; Virtual	Abdominal Trauma	Conference Poster Presentation
	DeNoto, G., III (2022).* **Bridged repair of large ventral hernia defects using an ovine reinforced biologic: A case series.** Annals of medicine and surgery (2012), 75, 103446. https://doi.org/10.1016/j.amsu.2022.103446	Ventral Hernia – Bridged	Journal Publication
	Sivaraj, D., Henn, D., Fischer, K. S., Kim, T. S., Black, C. K., Lin, J. Q., Barrera, J. A., Leeolou, M. C., Makarewicz, N. S., Chen, K., Perrault, D. P., Gurtner, G. C., Lee, G. K., & Nazerali, R. (2022).* **Reinforced Biologic Mesh Reduces Postoperative Complications Compared to Biologic Mesh after Ventral Hernia Repair.** Plastic and reconstructive surgery. Global open, 10(2), e4083. https://doi.org/10.1097/GOX.0000000000004083	Ventral Hernia	Journal Publication
	Shaknovsky, Thomas.* **Role of Biologic Mesh in Elective Repair of Ventral Hernia: Retrospective Analysis.** Poster presented at: Society of American Gastrointestinal and Endoscopic Surgeons; March 16-19, 2022; Denver, CO.	Ventral Hernia	Conference Poster Presentation

OviTex Core



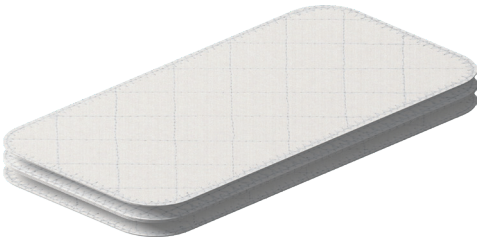
OviTex LPR

OviTex 1S



OviTex PRS

OviTex 2S



SCAN QR TO LEARN MORE ABOUT THE SCIENCE BEHIND OVITEX

**Indicates one or more surgeons are paid consultants of TELA Bio, Inc.*

EVIDENCE MATTERS

OVITEX®

REINFORCED TISSUE MATRIX

BRAVO CLINICAL STUDY

A PROSPECTIVE, SINGLE ARM, MULTI-CENTER STUDY EVALUATING THE CLINICAL OUTCOMES OF VENTRAL HERNIAS TREATED WITH OVITEX® 1S PERMANENT REINFORCED TISSUE MATRIX: THE BRAVO STUDY 12-MONTH ANALYSIS

DENOTO, G., III, CEPPA, E. P., PACELLA, S. J., SAWYER, M., SLAYDEN, G., TAKATA, M., TUMA, G., & YUNIS, J.

Study Design: Prospective, single arm, multi-center study designed to evaluate evaluating the clinical outcomes of primary and ventral hernias in CDC Class 1-3, VHWG Grade 1-3 wounds and 80% with high risk for complications treated with OviTex 1S Permanent.

- **Study Size and Duration:** 92 patients with up to 1-year follow-up.

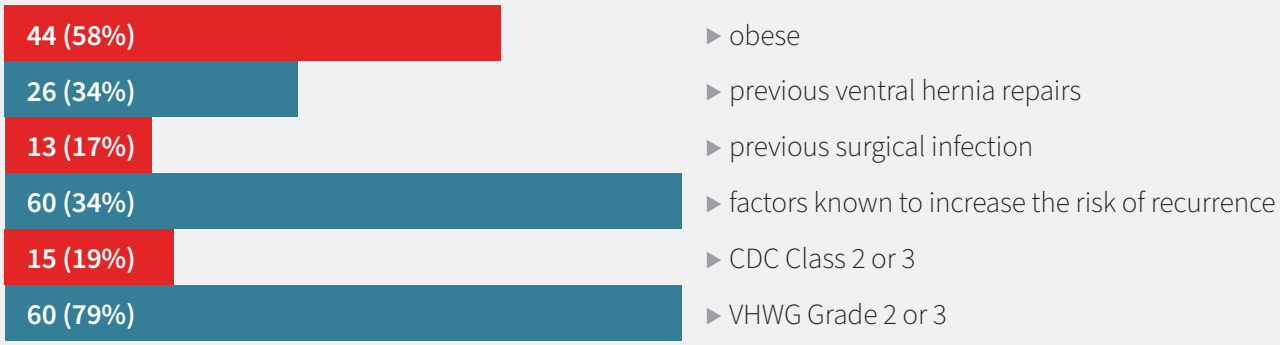
Primary Endpoints: Incidence of post-operative surgical site occurrences (SSO) or wound related events noted at the hernia repair site and the incidence of other early post-operative complications occurring within the first 90 days after index surgery. In addition complications were also recorded.

Secondary Endpoints: Incidence of hernia recurrence at the site of repair, the incidence of post-operative surgical site occurrences and wound related events noted at the hernia repair site occurring at time points later than 90 days after index surgery, and the incidence of other late post-operative complications occurring at time points later than 90 days after index surgery. The EQ-5D, EQ-5D VAS, and HerQLes surveys were used for a disease specific assessment of patient reported quality of life (QoL).

92 patients were enrolled in the study of whom 76 reached the 12-month follow-up.

PATIENT CHARACTERISTICS AT 12 MONTHS. (76 PATIENTS)

Avg. BMI 31



OPERATIVE CHARACTERISTICS AT 12 MONTHS

APPROACH

Open 47 (62%)
Laparoscopic 11 (14%)
Robotic 18 (24%)

PLANE OF PLACEMENT

Intraperitoneal
36 (47%)
Retrorectus /TAR 38 (50 %)
Retrofascial/ Pre-Peritoneal 1 (1%)
Onlay 1(1%)

CLOSURE

Primary Closure
70 (92%)
41 (54%) required component separation
Bridged 6 (8%)

12- MONTH RESULTS

ADVERSE EVENTS

SSO 20 (26%)

SSI 13 (17%)
SSO/SSI Requiring Procedural Intervention
10 (13%)

RECURRENCE RATE

Hernia Recurrence
2 (3%)

CONCLUSION

The low rate of hernia recurrence and SSOs requiring intervention illustrates the potential that reinforced tissue matrices, and OviTex 1S, in particular, have to improve outcomes in VH repairs.

JOURNAL ARTICLES

BRIDGED REPAIR OF LARGE VENTRAL HERNIA DEFECTS USING AN OVINE REINFORCED BIOLOGIC: A CASE SERIES

Annals of Medicine and Surgery, March 2022

DENOTO G., III

Single surgeon, retrospective, study of bridged repair with a reinforced with permanent polymer ovine rumen biologic in 19 consecutive high-risk patients over a 5-year period was performed. In all cases the reinforced biologic was used as an underlay.

Inclusion criteria: Bridged hernia repair required, VHWG grade 2 and 3 with complicating factors.
Exclusion criteria: VHWG grade 1 and 4, or VHWG 2 without complicating factors.

Mean follow up was 23 months (range of 5 to 61). Of the 19 patients:

- 6 (32%) experienced a surgical site occurrence including infection (26%), seroma, abscess, fistula, bioloma, or bowel obstruction.
- 3 (16%) had recurrences with two out of three of the recurrences occurring within 6 months of surgery. Key correlation to recurrence was obesity. BMI of 3 recurrences was 39, 50, and 55. No infections nor need to explant the mesh.

Rates of SSO's and recurrences using OviTex Reinforced Tissue Matrix (RTM) were in line with or better than other published studies of bridged repair utilizing biologic or synthetic mesh reinforcement. OviTex RTM's should therefore be considered in complex large ventral hernia repairs.

Other studies have even higher rates of recurrence with other mesh types.

- A previous study, with the same mean follow up time of 24 months, that the senior author participated in found a recurrence rate of 44% when patients with complex hernias were bridged with a porcine acellular dermal matrix (PADM).
- Patel et al. and Abdelfatah et al. found that 89% (mean follow up time 18 months) and 80% (mean follow up of 60 months) of patients, respectively, had recurrences when PADM was used in bridged repair. In addition, the SSI rate for Patel was 44%, vs only 26% in this series.
- Blatnik et al. had a recurrence rate of 80% using a human ADM with a mean follow up of 23 months.
- Holihan et al. A metanalysis of bridged cases in which synthetic mesh was used 36% of the time and biologic mesh used 64% of the time found an average recurrence rate of 25% at a shorter follow up time of 16 months. Also, the SSI rate was similar at 29%.

REINFORCED BIOLOGIC MESH REDUCES POSTOPERATIVE COMPLICATIONS COMPARED TO BIOLOGIC MESH AFTER VENTRAL HERNIA REPAIR

Plastic and Reconstructive Surgery, February 2022

SIVARAJ, D., HENN, D., FISCHER, K. S., KIM, T. S., BLACK, C. K., LIN, J. Q., BARRERA, J. A., LEEOLOU, M. C., MAKAREWICZ, N. S., CHEN, K., PERRAULT, D. P., GURTNER, G. C., LEE, G. K., & NAZERALI, R.

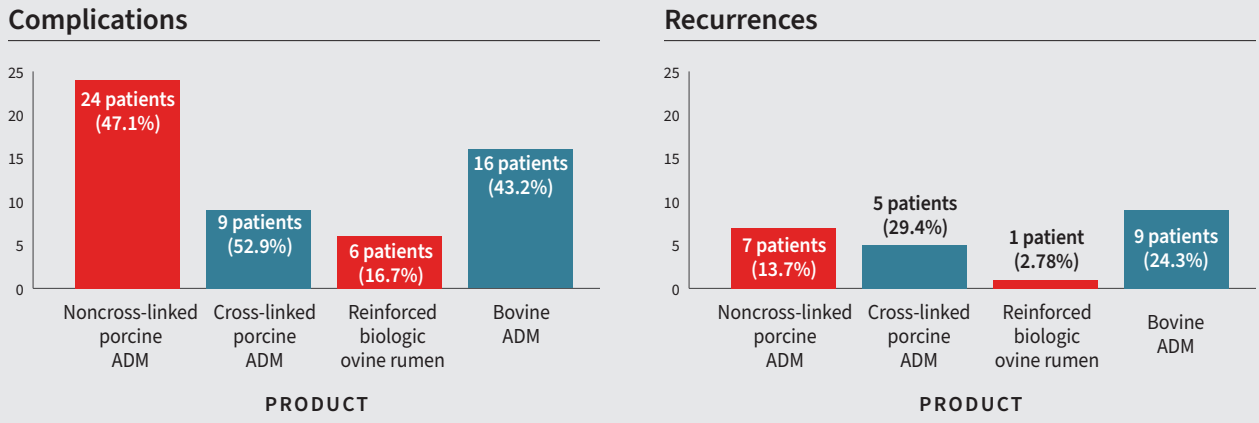
Single Center Retrospective analysis of 141 patients who had undergone ventral hernia repair with biologic mesh between 2002 and 2020. No financial interest; funding solely institutional.

- Mesh types included:
  - Noncross-linked porcine ADM (NC-PADM) (n = 51).
  - Cross-linked porcine ADM (C-PADM) (n = 17).
  - Reinforced biologic ovine rumen (RBOR) (n = 36).
  - Bovine ADM (BADM) (n = 37).
- No statistically significant differences in patient demographics or comorbidities per group. No statistically significant differences in degree of defect contamination according to CDC class and VHWG.
- This was also the case among patients for hernia defect size, the presence of a con-comitant procedure, median follow-up time, hernia types, and hernia etiology. All patient's repair was open approach.

Our data indicates that in patients undergoing abdominal wall repair, RBOR mesh decreases overall complications and hernia recurrence compared to those receiving NC-PADM, C-PADM, and BADM. Utilizing reinforced biologic meshes for VHR may lead to improved outcomes relative to current biologic mesh types.

OVERALL COMPLICATION AND RECURRENCE RATES

Complications and recurrence occurred less often in patients that had undergone reconstruction with RBOR, compared to patients that had received C-PADM, NC-PADM, and BADM.



MINIMIZING RETAINED FOREIGN BODY IN HERNIA REPAIR USING A NOVEL TECHNIQUE: REINFORCED BIOLOGIC AUGMENTED REPAIR (REBAR)

Journal of Clinical and Medical Research, July 2021

ANKNEY C, BANASCHAK C, SOWERS B, SZOTEK P.

As a result of exposure to the growing litigious environment surrounding synthetic mesh products, patients are demanding hernia repairs with minimal or no foreign body.

Retrospective, single surgeon cohort of 619 patients representing a variety of hernia types and using multiple methods underwent repair using the ReBAR technique (data summarized in table).

- The repair leverages the surgeon's existing tissue repair strategies with the goal of defect closure and primary repair reinforcement which augments traditional techniques using the reinforced biologic material to create what we have labeled the Reinforced Biologic Augmented Repair (ReBAR) technique.

Instead of using traditional synthetic or biologic mesh materials individually, the investigators chose to use a permanent reinforced biologic material (OviTex® Reinforced Tissue Matrix) to produce a more natural repair while maintaining data-driven principles.

Procedure (ReBAR)	Number of Cases	Number of Recurrences	Percentage Recurrences	Average Follow Up
Total Implants	**619**	**8**	**1.2**	**1.5 yrs**
Robotic Inguinal: TAPP	259	3	1.2	1.5 yrs
Open Inguinal	47	2	4.3	1.5 yrs
Robotic Ventral: TAPP	59	1	1.7	1 yr
Stapled Single Incision Retrorectus	32	0	0	2 yrs
Open AWR: TAR/ACS	54	1	1.8	1.7 yrs
Open Ventral: Onlay	48	1	2	1.2 yrs
Open Ventral: Preperitoneal	95	0	0	1.8 yrs
Open Ventral: Bridged	2	0	0	61 days and 610 days
eTEP Ventral	2	0	0	1.1 years
Open Umbilical	21	0	0	3.3 years

The total number of recurrences for all patients undergoing ReBAR to date is 8 (1.3%) with an average follow up of 1.5 years.

The outcomes in this single surgeon series suggest that by following the defining ReBAR technique principles of defect closure and reinforced biologic augmentation, surgeons can provide both safe and durable results while addressing patient fears and desires. In doing so, surgeons can safely offer a shared decision-making model of care delivery to their patients and confidently offer a more natural hernia repair using the ReBAR technique in their practices.

A NOVEL BIOSYNTHETIC SCAFFOLD MESH REINFORCEMENT AFFORDS THE LOWEST HERNIA RECURRENCE IN THE HIGHEST-RISK PATIENTS

Surgical Endoscopy, September 2021

PARKER, M. J., KIM, R. C., BARRIO, M., SOCAS, J., REED, L. R., NAKEEB, A., HOUSE, M. G., & CEPPA, E. P.

Retrospective review of two cohorts (100 total) of 50 consecutive patients who underwent ventral hernia repair with OviTex or synthetic mesh at Indiana University Medical Center.

Endpoints included surgical site occurrences (SSO), readmission rate, and hernia recurrence at 12 months postoperatively.

- OviTex group had significantly more high-risk patients (VHWG grade 3: 68% vs. 6%). (CDC Class 1-2: 74% vs. 98%).
- OviTex group had a significantly higher % of concomitant surgeries (70% vs. 10%).

OviTex performed comparably overall to synthetic mesh in terms of incidences of SSOs (36% vs. 22%), readmission rates (24% vs. 14%), and hernia recurrence (6% vs. 12%).

Patients who developed SSO with OviTex (18 subjects vs. 11) had an Avg. LOS of 11 days vs. 3 days and a readmission rate of 61% vs. 64%

- Also, CDC>1 was 61% vs. 9%, Tobacco use 78% vs 73%, and concomitant surgeries 67% vs. 9%.
- SSO recurrence rates with OviTex were 17% recurrence vs. synthetic mesh 55% recurrence.

"OviTex mesh offers durable defect reinforcement with a decreased risk for hernia recurrence in comparison to synthetic mesh options in high-risk patients."

	OviTex TELA Bio	Synthetic Mesh
	50	50
Gender	21 M (42%) 29 F (58%)	27 M (54%) 23 F (46%)
Age (years)	55±14	52±12
BMI (kg/m²)	34±6	33±7
VHWG Grade	2 (32%) 3 (68%)	2 (94%) 3 (6%)
CDC Wound Class	I (30%) II (44%) III (10%) IV (16%)	I (94%) II (4%) III (2%) IV (0%)
Repair Method	Open	Open
Mesh Location	Underlay (68%) Sublay (20%) Onlay (12%)	Underlay (62%) Sublay (34%) Onlay (4%)
Concomitant Surgeries	70%	10%
Average Hospital LOS (days)	11	2
SSO	36%	22%
Readmission Rate	24%	14%
Hernia Recurrence	6%	12%

A POLYMER-BIOLOGIC HYBRID HERNIA CONSTRUCT: REVIEW OF DATA AND EARLY EXPERIENCES

Polymers, June 2021

SAWYER, M., FERZOCO, S., & DENOTO, G., III

Review of OviTex Reinforced Tissue Matrix in several types hernia repair:

- **Ventral Hernia:**
  Single institution retrospective review by Parker et al. published in September of 2020 showed OviTex to be effective in high-risk patients who underwent VHR.
  - Study compared the surgical outcomes when OviTex was used to repair ventral hernias in high-risk patients compared to lower risk patients in which synthetic polypropylene mesh with a barrier was utilized.
  - After 12 months, the hernia recurrence rate was lower in the OviTex group despite having amore challenging population than the synthetic group, 6 vs. 12% for OviTex and synthetic groups.
- **Hiatal Hernia:**
  Retrospective study conducted to document surgical experience in using resorbable OviTex to repair symptomatic hiatal hernias.
  - Surgical repair was performed on 25 patients who had a high incidence of co-morbidities and 52% who had type III and IV hiatal hernias.
  - After a mean follow-up time of 14.2 months, there were no recurrences.
- **Inguinal Hernia:**
  Single surgeon study, Ferzoco investigated whether use of OviTex in inguinal hernia repair was effective in repairing the defect, reducing recurrence,and preventing chronic postoperative pain.
  - 31 patients, treated on an outpatient basis, underwent inguinal hernia repair with OviTex.
  - There were no reported surgical site infections (SSI) during the initial 30 days postoperatively.
  - At an average 12.6 month follow-up there were no reported recurrences.

Use of OviTex RTM results in a decrease in chronic postoperative inguinal pain, improvement of preoperative hiatal hernia symptoms, and a lower incidence of recurrence compared to use of synthetic mesh in a more challenging ventral hernia repair population.

- The authors have found that the use of RTM in hernia repair is effective in limiting foreign body response, promoting wound healing, and providing reinforcement to lower the risk of hernia recurrence.
- OviTex resorbable and permanent clinical biopsies at 6, 7 and 23 months exhibit low inflammation and end stage remodeling with the repair exhibiting mature, lamellar and aponeurosis-like connective tissue.
- OviTex tends to be fully surrounded by functional tissue, have low inflammation, and no typical delamination or loose, connective tissue that is normally seen in polymer devices.

IN-VIVO EVALUATION OF A REINFORCED OVINE BIOLOGIC: A COMPARATIVE STUDY TO AVAILABLE MESH REPAIR MATERIALS*

Hernia, December 2020

OVERBECK, N., NAGVAJARA, G. M., FERZOCO, S., MAY, B., BEIERSCHMITT, A., & QI, S.

Pre-clinical study comparing two innovative reinforced biologic materials to seven clinically used biologic and synthetic meshes in a non-human primate hernia full thickness defect repair model.

- To evaluate performance of the inflammatory response, healing kinetics, integration, and remodeling into functional host tissue.

Synthetics (including Phasix) demonstrated most contraction, extended FBR, and chronic inflammation. They also developed a layer of reactive tissue above and separate from the contracted mesh structure.

- Foreign body response persisted at 24 weeks with the synthetics.
- Developed less organized collagen, separate in space from the actual mesh.

Biologics had minimal inflammation, but due to dense network of dermal collagen, demonstrated a superficial, peripheral layer of cells at early time points. By later time points, remodeled into mostly functional host tissue.

- Strattice stretched to 110% of it's original size by 6 months in some samples.
  Adverse remodeling of mineralized and osseous metaphasia tissue was also demonstrated.

Reinforced biologics best aspect ratio showing minimal contraction, and permanent version with initial inflammatory response higher than biologics. Earlier, more rapid and diffuse cellular infiltration jump started the remodeling process.

- As early as 12 weeks, the collagen networks associated with the reinforced biologics remodeled into organized host collagen.

By 24 weeks, both reinforced biologics and biologics had low levels of inflammation.

Study shows a favorable response to reinforced biologics, which were associated with an initial inflammatory response, resolving by later time points, followed by active remodeling, and the formation of new morphologically functional collagen more reminiscent of fascia

**Animal test results may not necessarily be indicative of human clinical performance*

EARLY EXPERIENCE OUTCOMES OF A REINFORCED BIOSCAFFOLD IN INGUINAL HERNIA REPAIR A CASE SERIES

International Journal of Surgery Open, June 2018

FERZOCO, S.

Key objective was to evaluate the role of OviTex in reducing the incidence of Chronic Postoperative Inguinal Pain (CPIP).

Data collected retrospectively from 31 consecutive patients who had an inguinal hernia repair using OviTex Permanent (4x8 cm).

- All hernia repaired using open Lichtenstein technique.
- Average follow up of 12.6 months (range: 3 – 18 months).

No reported surgical site infections during initial 30 days postoperatively.

No reported recurrences or explanations.

No postoperative complications (seromas or hematomas) requiring surgical intervention.

No reported incidence of Chronic Postoperative Inguinal Pain.

No requests for pain medication refills (all patients prescribed standard postoperative narcotics).

NEW OVINE POLYMER-REINFORCED BIOSCAFFOLD IN HIATAL HERNIA REPAIR

Journal of the Society of Laparoendoscopic Surgeons, September 2018

SAWYER M.

Retrospective review of OviTex Resorbable 4 and 6 layers used in laparoscopic repair of Types I, II, III and IV hiatal hernias, both primary and recurrent, in 25 patients.

- Average follow-up: 14.2 months (range: 1-20 months).

Various fixation methods used, including suture only, suture + fibrin glue, and fibrin glue only. Fibrin glue was predominant method.

OviTex features included excellent strength, ease of handling and suturing, and conformation to the hiatal space.

Good to excellent symptom control reported for all preoperative symptoms.

No clinical recurrences reported.

CONFERENCE POSTER PRESENTATIONS

DEFINITIVE CLOSURE USING AN OVINE REINFORCED TISSUE MATRIX IN THE COMPLEX OPEN ABDOMEN AFTER PENETRATING THORACO-ABDOMINAL TRAUMA

2022 Abdominal Wall Reconstruction Conference

FERNANDEZ, L.

Two trauma cases involving penetrating thoraco-abdominal trauma.

Case 1: A 35-year-old male patient with a right thoraco-abdominal stab wound to the right side of the chest and upper abdomen, resulting in damage to the diaphragm epicardium, liver, and duodenum.

- Results: A 8-layer OviTex ovine RTM with permanent polymer was effective in providing definitive abdominal fascial closure in a hostile environment. Despite exposure to bile, this one piece of ovine RTM was able to retain its integrity in this one patient. No additional surgeries were required, and the patient was discharged on hospital day 29.

Case 2: A 22-year-old male patient presents with a skull fracture ,exposed brain, major lacerations to the shoulder, right lateral chest wall and abdomen causing a large right flank hernia, due to an automated trencher farm accident.

- Results: A 6-layer OviTex ovine RTM with resorbable polymer was effective in maintaining abdominal wall closure as part of the initial repair of a right flank hernia. A second procedure was done on hospital day 2, showed optimal wound healing. The patient did not develop any wound complications and was discharged on hospital day 13. No recurrence is reported to date.

CONCLUSION

The ovine RTM delivered an effective and durable fascial repair. In a cost comparison to other common biologic matrices, use of an ovine RTM saved the author's institution:

$1,874 – $10,473 per case

ROLE OF BIOLOGIC MESH IN ELECTIVE REPAIR OF VENTRAL HERNIA: RETROSPECTIVE ANALYSIS

2022 Society of American Gastrointestinal and Endoscopic Surgeons

SHAKNOVSKY, T.

OviTex 1S mesh is a biologic material is derived from ovine rumen interwoven with permanent polymer fiber through the layers in “lockstitch pattern.”

The authors evaluated the 1S which is comprised of 6 layers interwoven by 5-0 prolene suture completely.

Utilized the OviTex 1S product on patient cohort requiring elective hernia repair which elected to avoid synthetic mesh.

- 15 total cases performed using robotic approach (XI Platform) with primary closure of fascial defect and intraperitoneal onlay mesh (IPOM) technique.
    - 9 ventral hernia.
    - 6 incisional hernia.

Patients were evaluated postoperatively at 2 weeks and 8 weeks on outpatient basis.

No readmissions, wound infections or other complications noted.

No hernia recurrence was found in this short term post operative follow up period.

ROBOTIC ASSISTED REBAR OF 111 INGUINAL HERNIAS

2021 Society of American Gastrointestinal and Endoscopic Surgeons

BANASCHAK, C., SZOTEK, P.

Retrospective, single surgeon review of 111 hernias in 86 consecutive patients. The objective of this study is to evaluate the utilization of the reinforced biologic augmented repair (ReBAR) with the robotic transabdominal preperitoneal (rTAPP) technique.

- All patients received the same reinforced biologic mesh (Ovitex® Core) which was shaped and placed into the abdomen through an 8mm robotic port.
- All repairs were completed utilizing the same rTAPP technique which included placement of a permanent anchoring stich in Cooper's ligament and two interrupted anchoring sutures on the anterior abdominal wall for fixation after deployment of the mesh.

From June 2018 to September 2019, a total of 86 patients undergoing rTAPP were identified.

2 SSOs

- 1 small bowel obstruction
- 1 seroma

6 patients had previous repair.

INGUINAL HERNIAS TOTAL

111

Some patients also had simultaneous repair of other conditions at the time of rTAPP, including ventral hernia repair (n=7), hydrocelectomy (n=6), and mesh excision (n=2).

Average follow-up was 376 days.

Hernia recurrences = 3 (2.7% of implants / 3.4% of patients) – 2 occurred within weeks of procedure due to technical issues.

- 1st – improper mesh cut
- 2nd – no lateral fixation
- 1 true recurrence after 1 year almost immediately post op / 1 occurred 345 days post-op.

The use of a reinforced biologic mesh appears to be a viable option for rTAPP inguinal hernia repairs in patients who desire the robotic assisted minimally invasive technique while avoiding traditional permanent synthetic mesh and yielding acceptable recurrence rates within 1 year.

USE OF OVINE REINFORCED TISSUE MATRIX IN BRIDGED INCISIONAL REPAIR

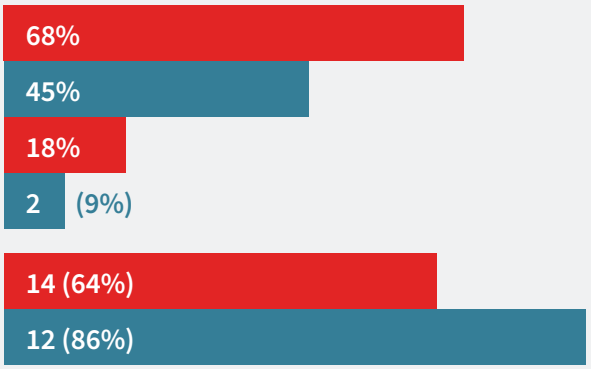
2021 Society of American Gastrointestinal and Endoscopic Surgeons

DENOTO, G., III

In complex, bridged AWR, especially in high risk of infection where synthetic meshes are avoided, Biologics are preferable as they are able to remodel, but they have shown to be prone to stretching and possibly leading to recurrences.

In the single-center, retrospective review of bridges cases; 6 or 8 layered RTMs with polypropylene suture reinforcement were used (1S-P or 2S-P).

22 PATIENTS HAD SIGNIFICANT CO-MORBIDITIES AND HISTORY OF PRIOR VENTRAL HERNIA RECURRENCES



- obese
- hypertensive
- diagnosed with a type of cancer
- previously bridged because of abdominal wall tumor removal
- history of prior ventral hernia repair
- previously repaired with synthetic (58%) or porcine ADM (25%) mesh. Prior synthetic mesh led to infection in 86% of patients. While ADM did not result in infection, all recurred.

Average follow up was 13 monrhs

3 recurrences (14%) (all 6 months post op).

- 1 pateint with BMI 38, who developed a wound infection.
- 2 patients with BMI of 50 and 55.

No infections of removal of OviTex itself.

Human and Porcine acellular dermal matrices have been shown to have recurrence rates in bridged patients of 80% and 40% respectively. The recurrence rate of 14% in the investigators practice is an improvement. They believe the reinforcement of the biologic mesh with polypropylene suture offers a stronger, more resilient repair.

USING A REINFORCED BIOLOGIC MESH IN A MINIMALLY INVASIVE TECHNIQUE FOR VENTRAL HERNIA REPAIR

2020 American Hernia Society and 2020 Minimally Invasive Surgery Virtual Symposium

SZOTEK, P.

Retrospective review of prospectively collected data from a single person of 27 patients from a single surgeon using single incision retrorectus (SIRR) or single incision preperitoneal (SIPP) technique (small 3cm incision) for repair of ventral hernia between 2018-2019.

- 25 cases completed with SIRR technique, 2 with SIPP, Avg. BMI 31.8.
- Average follow-up: ~ nine months (36 to 459 days).
- OviTex 1S Permanent – 19 patients.
- OviTex LPR – 4 patients.
- OviTex Core Permanent – 4 patients.

No reported cases of recurrence.

1 reported surgical site occurrence (3.7%).

- Post-operative hematoma identified in a patient on chronic anticoagulation.

The use of a reinforced biologic mesh during the minimally invasive SIRR or SIPP procedure for ventral hernia appears to be an effective and safe option.

CHOICE OF HERNIA MESH FOR PATIENTS AT HIGHER THAN AVERAGE RISK FOR MESH-MATERIAL COMPLICATIONS

2020 American Hernia Society

TOWFIGH, S.

The certain patient subgroups that could be considered higher than average risk includes patients with mesh reaction, mesh-related inflammatory pain, and autoimmune disorder.

32 patients underwent hernia repair with reinforced biologic mesh (RBM) (aka OviTex Reinforced Tissue Matrix).

Post operatively, 31 (97%), with a mean long-term follow up of 5.5 months, had resolution of their preoperative mesh-related symptoms.

Greatest improvement in pain score was among patients who underwent replacement of their synthetic mesh with RBM at the same operative setting.

RESILIENCE AND HEALING OF A NOVEL REINFORCED BIOSCAFFOLD (RBS) MATRIX IN THE SETTING OF HIGH-RISK INCISIONAL HERNIA REPAIR AFTER ENTEROCUTANEOUS FISTULA (ECF)TAKEDOWN

2019 Americas Hernia Society Annual Meeting

AWAD, S.

Incisional hernia repairs with mesh after ECF takedown exhibit high SSI rates. Synthetics not routinely used.

Single patient case study with 20x20 cm OviTex Permanent 6-layer used in retrorectus position in 66-year-old male with COPD and severe malnutrition presenting for enterocutaneous fistula takedown and incisional hernia repair.

- One week postop, a deep SSI with dehiscence of skin and anterior rectus sheath closures developed, exposing the OviTex, which was left in place with wound care initiated.

OviTex "seamlessly and effectively incorporated within the wound with rapid granulation."

- According to the presentation, the patient is 12 months post-op with a completely healed incision and no recurrence

OviTex allowed robust wound healing without recurrence of the hernia.

A STUDY OF MESH COMPLIANCE: IMPLICATIONS FOR PROPER SPLINTING FOR FASCIAL REPAIR IN ABDOMINAL WALL RECONSTRUCTION

2019 Americas Hernia Society Annual Meeting

LANGSTEIN, H.

This study was performed to test the initial compliance of two mesh systems – reinforced biologic mesh (OviTex, TelaBio) and resorbable monofilament mesh (Phasix, Bard) in order to measure their suitability to offload fascial repairs.

The ideal mesh for abdominal wall repair should provide ongoing support without altering the native compliance (elasticity) of the abdominal wall, which ranges between 11% and 32%.

OviTex (4 layers), OviTex 1S (6 layers), OviTex 2S (8 layers), and Phasix were tested for uniaxial compliance.

OviTex exhibited a compliance ranging from 10.9% to 14.2%, within the native range of the abdominal wall, while Phasix exhibited a compliance of 52.5%.

OviTex demonstrated significantly less compliance than Phasix, and appear to be better suited to offload or splint a primary fascial repair.

OVINE POLYMER-REINFORCED BIOSCAFFOLD IN ABDOMINAL WALL RECONSTRUCTION

2019 Americas Hernia Society Annual Meeting and 2018 Americas Hernia Society International Hernia Congress

SAWYER, M.

Prospectively collected and reviewed retrospectively. OviTex used in 23 consecutive patients undergoing abdominal wall reconstruction with myofascial advancement flap creation (78% TAR, 22% Anterior).

- Highly complex patient base where less than half the patients were VHWG Grade 1 or Grade 2.
- Patients generally had multiple comorbidities, with an average of 3.4 per patient.
- Nearly two-thirds of patients had recurrent hernias, with 15 synthetic/biologic mesh explantations.
- Enterocutaneous fistula resection in 13% of patients.

"Acceptably low" rates of recurrence (9%) and complications and excellent patient satisfaction at an average of 18.7 months of follow up (range of 9 to 33 months).

OVITEX REINFORCED BIOSCAFFOLDS ARE MORE PERMEABLE THAN OTHER MARKET LEADING HERNIA REPAIR MATERIALS

2017 Abdominal Wall Reconstruction Conference

FERZOCO, S.

To evaluate the permeability of various hernia repair materials, including OviTex™ Reinforced BioScaffolds, Parietex™ Composite, Physiomesh®, and Strattice™ Firm. Unimpeded movement of fluids and cells is believed to reduce incidence of seroma and other post-operative complications, as well as promote tissue integration and remodeling.

Early preclinical experiments in non-human primates have shown Ovitex implants to integrate within 4 weeks with no evidence of interlayer seroma.

In a standardized water permeability testing, water was introduced at a pressure of 120 ± 2 mmHg on one side for 60 seconds. In other experiments, red-dyed water was applied at physiological pressure to one side of OviTex implants and appeared on the other side within 2 seconds, visually demonstrating OviTex's permeability.

Results demonstrate that Ovitex devices are permeable, in contrast to market-leading biologic material and coated synthetic meshes.

BIOMECHANICAL EVALUATION OF REINFORCED BIOSCAFFOLDS: A NEW APPROACH TO HERNIA REPAIR

2016 Abdominal Wall Reconstruction Conference

FERZOCO, S.

To evaluate the strength and directional compliance of all OviTex devices and compare the results to those obtained with current synthetic implants and the target values described in the literature.

- Ball burst, uniaxial tensile strength, and suture retention strength tests on Permanent and Resorbable Ovitex 4-, 6-, and 8-layers vs Phsyiomesh, Phasix, and Ventralight
- Uniaxial compliance strain test was done in 3 orientations (horizontal, vertical, and diagonal) to text ability to maintain compliance properties and resist stretching and elongation.

RESULTS

All Ovitex products have sufficient ball burst, uniaxial tensile, and suture retention strength to support abdominal wall recon. Ovitex was equal to or stronger in some configurations than the compared synthetic and resorbable synthetics.

OviTex implants exhibited more isotropic compliance and more appropriate compliance strains than widely used synthetics across different device orientations. The compliance strain values of Ovitex are purposely designed to the lower end of the physiological range of 11 – 32% to allow Ovitex to maintain physiological compliance while resisting stretch and elongation.

All 3 compared meshes had higher levels of stretch in all, or at least 1, of the 3 directional planes

WHITE PAPER

MESH PERFORMANCE IN HERNIA REPAIR IN 2017: A SURGICAL REVIEW OF PROGRESS TO IMPROVE OUTCOMES

ABELL, B., AWAD, S., BASTIDAS, A., DENOTO, G., III, FERZOCO, S., FRANZ, M., GOLLA, D.

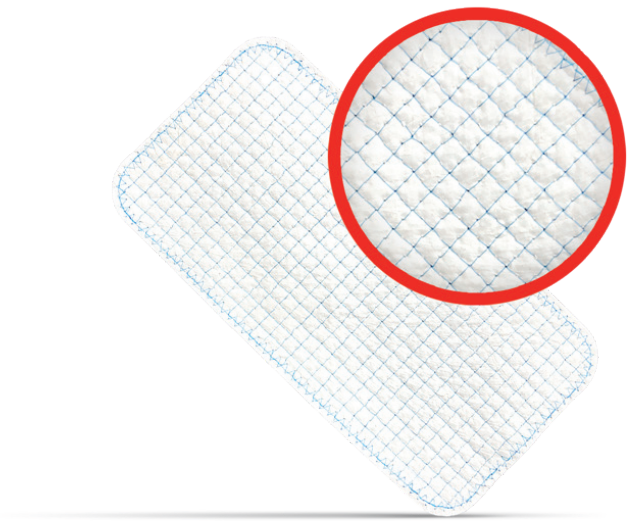
TELA Bio convened a panel of 7 expert surgeons to review the current landscape of mesh-based hernia repair.

The surgeons had experience in over 200 cases using OviTex.

Early outcomes in demanding cases have been very promising, and to date, no adverse events were possibly or definitely related to the implant.

- Surgeons commented that OviTex RBSs handle well compared to biologic implants and are suited for use in open and minimally invasive surgeries.
- Surgeons agreed that their usage reflected the versatility of the OviTex RBS product portfolio for a wide range of ventral hernias.

LOW RECURRENCE ALL APPLICATIONS



HIATAL 0%

Sawyer – 2018
25 patients
Average follow up 14 months

BRIDGED 14%

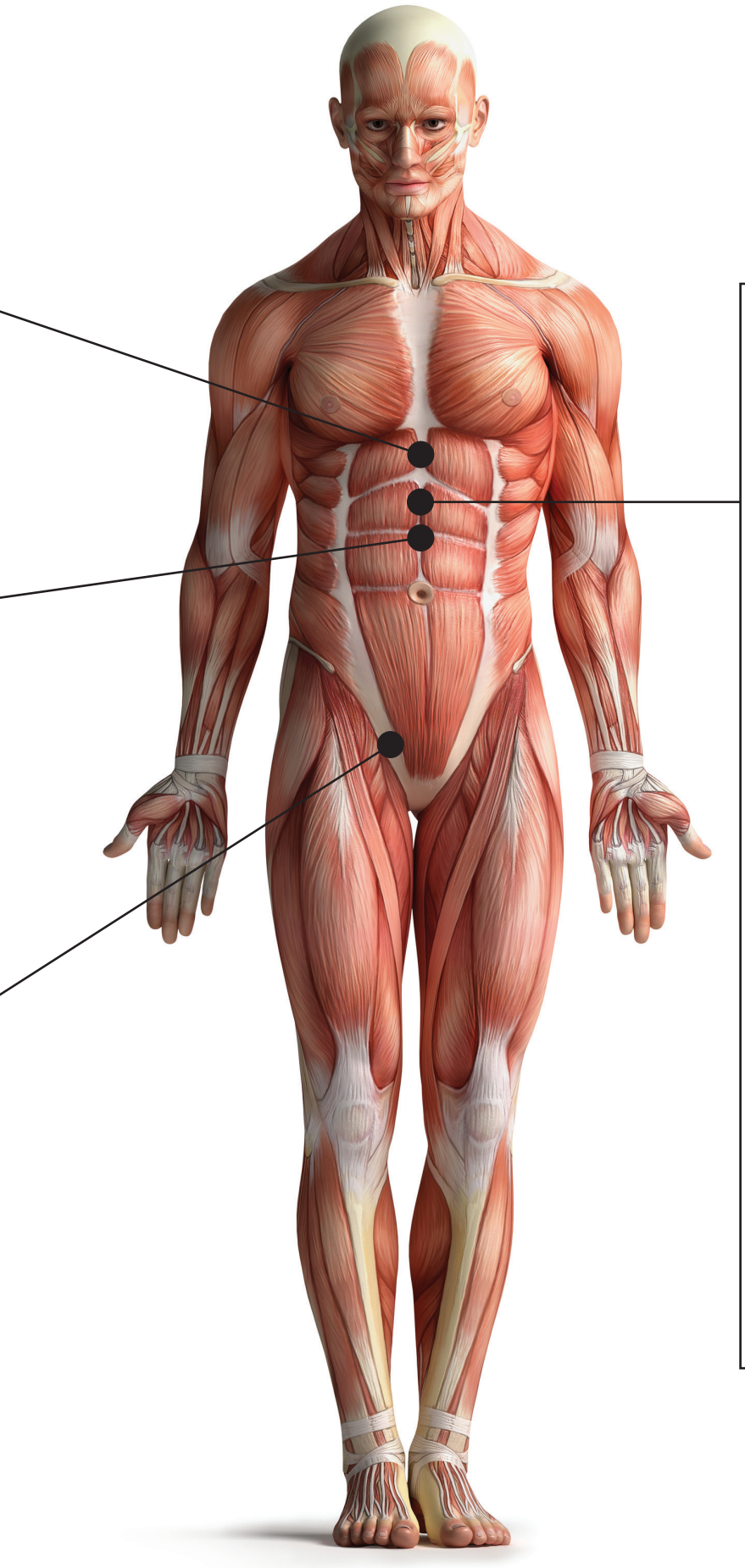
DeNoto – 2021
22 patients
Average follow up 13 months

INGUINAL 0%

Ferzoco – 2018
31 patients
Average follow up 13 months

INGUINAL 1.6%

Ankey, Szotek et al. – 2021
306 patients
Follow up 1-36 months



2.8% **VENTRAL**
Sivaraj, Nazerali et al. – 2022
36 patients
Average follow up 29 months

1.8% **AWR**
Ankey, Szotek et al. – 2021
54 patients
Follow up 3-38 months

1.9% **VENTRAL**
Ankey, Szotek et al. – 2021
107 patients
Follow up 1-25 months

2.7% **VENTRAL**
DeNoto – 2021
76 patients
Follow up 12 months

6% **VENTRAL**
Parker – 2020
50 patients
Follow up 12 months

8.7% **AWR**
Sawyer – 2019
23 patients
Average follow up 19 months

OviTex Reinforced Tissue Matrix 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.

Caution: Federal (US) law restricts this device to sale by or on order of a physician.

Do not use OviTex in patients known to be sensitive to materials of ovine (sheep) origin. Use of OviTex in this patient population may result in an allergic or immunological reaction.

The following adverse events have been reported for surgical repair of hernias (with or without the use of surgical mesh): pain, infection, hernia recurrence, adhesion, bowel obstruction, bleeding, fistula, seroma, perforation, mesh migration, and mesh contraction. For additional important safety information, please see the OviTex Instructions for Use.

Healthcare professionals must use their own clinical judgment in evaluating appropriate treatment options for a particular patient. Treatment of a specific patient should be based on individual needs and the medical care deemed necessary by the patient's treating physician and institutional protocols. Always refer to the package insert, product label, and/or instructions for use before using any TELA Bio 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.

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.

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