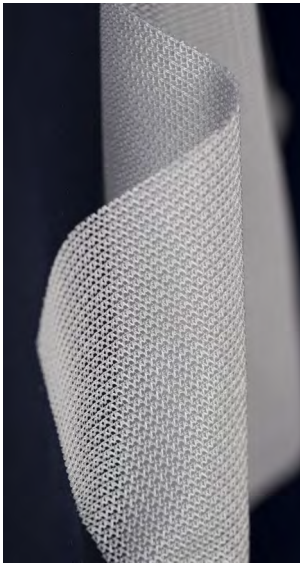
SYNTHETIC RESORBABLE SCAFFOLD

TIGR® matrix

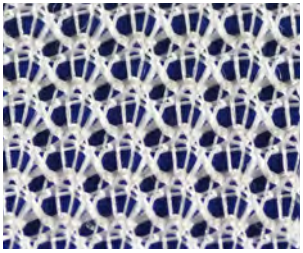
WHAT IS TIGR® MATRIX?

TIGR® Matrix is the world's first long-term resorbable, 100% synthetic surgical mesh. Its unique technology consists of dual-stage degradation and full resorption.



ABOUT THE PRODUCT

- Copolymers of lactide, glycolide and trimethylene carbonate. Same type of polymers that have been in clinical use since the 1970s. [1]
- Macro-porosity, >1 mm2, allows for good tissue integration. [1,2]
- Strong for at least 6 months and complete resorption over time. [1,5]
- A viable alternative to acellular dermal matrices, at a lower cost. [2,3,4]



ABOUT THE USE

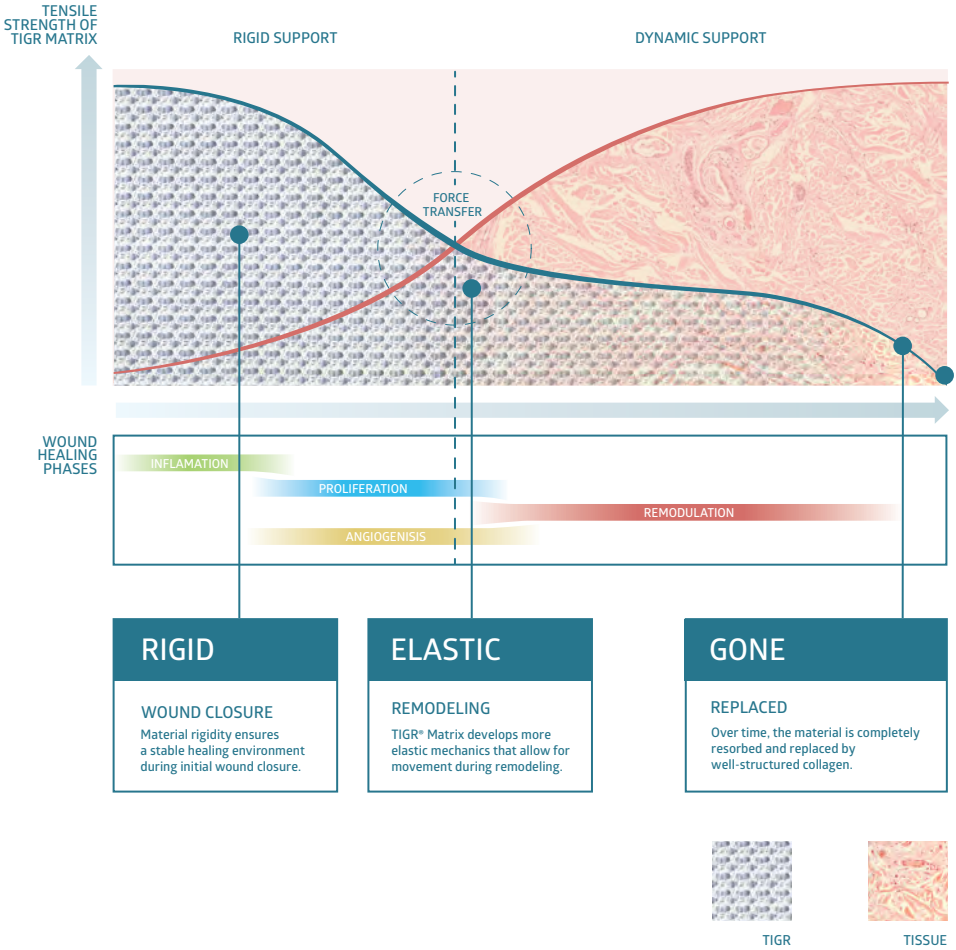
- Ready to use directly out of the package, without rinsing.
- Warp-knitted multifilament fibers make it easy to handle, pliable and easy to cut. [4]

References

1 - Three-year results from a preclinical implantation study of a long-term resorbable surgical mesh with time-dependent mechanical characteristics H. Hjort, T. Mathisen, A. Alves, G. Clermont, J. P. Boutrand, Hernia, 16(2):191–197, 2012 **2 -** The use of synthetic mesh in reconstructive, revision, and cosmetic breast surgery H. Becker, J. G. Lind II, Aesth Plast Surg, 37(5):914–921, 2013 **3 -** Value-based Clinical Quality Improvement (CQI) for Patients Undergoing Abdominal Wall Reconstruction. B. Stephan, B. Ramshaw, B. Forman, Surg Technol Int, 26:135-142, 2015 **4 -** Immediate implant based breast reconstruction using the TIGR® Matrix. P. Schrenk, Breast Cancer Manag, 5(2), 53–59, 2016 **5 -** Data on file, in vitro resorption.

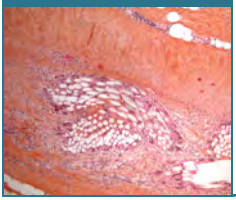
HOW IT WORKS

TIGR® Matrix works in two phases, in which it gradually transfers the load from the scaffold to tissue. In phase 1 it gives strength and stability in the mesh is high during initial wound-healing. [5] In phase 2 it gradually increases the elasticity and transfer of load to the tissue stimulates regeneration of well-structed collagen. [1]



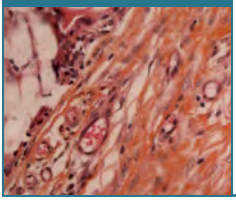
TIGR® MATRIX 3 YEAR PRE-CLINICAL DATA

9 MONTH



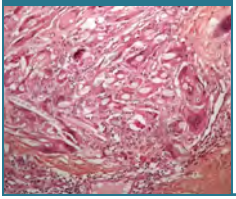
The inflammatory response is limited to the location of the mesh fibers. No sign of granuloma. New blood vessels and connective tissue are evident close to the matrix filaments.

15 MONTH



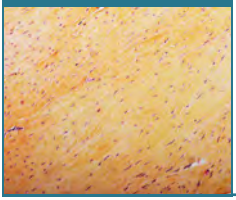
TIGR® Matrix well integrated in connective tissue. Fibroblasts are present among mesh fibers. New blood cells visible.

24 MONTH



TIGR® Matrix filaments are surrounded by giant cells indicting on-going fiber degradation. Collagen cells are infiltrating the matrix.

36 MONTH



TIGR® Matrix resorbed and replaced with collagen. Few inflammatory cells and no foreign body reaction. Well distributed fibroblasts.

CLINICAL EXPERIENCE USING TIGR® MATRIX SYNTHETIC RESORBABLE SCAFFOLD

Bruce Ramshaw, MD, Brandie Forman, Michelle Preston, Briana Alvoid-Preston.

OPEN VENTRAL HERNIA REPAIR (INCLUDING AWR)

18 Month Post-op Comparison Charts

PATIENT DEMOGRAPHICS

	TIGR - 2015 (61 patients)	Phasix - 2017 (121 patients)	BioA - 2017 (104 patients)	Strattice - 2012 (80 patients)
BMI (Avg.)	33.1	32.2	28	23% Obese (BMI 35-40)
CST (%)	92%	44%	65%	65%
Onlay (%)	0%	26%	0%	4%
Retrorectus (%)	100%	73%	90%	36%
Intraperitoneal (%)	0%	0%	10%	60%
Hernia Defect Size (cm^2)	283.6	115.7	137.0	236.0

Inclusion/Exclusion Criteria

TIGR CQI program- No exclusions | Other prospective studies: Exclusion for more than three recurrences, BMI > 40, cirrhosis, ascites, HIV or on steroids.

PATIENT OUTCOMES

	TIGR - 2015 (61 patients)	TAR: Approach (46 patients)	Phasix - 2017 (121 patients)	BioA - 2017 (104 patients)	Strattice - 2012 (80 patients)
Recurrence	9.8%	1/46 (2.2%)	9.1% Retrorectus 5.7%	15.4%	28%
SSI	13%	3/46 (6.5%)	9.1%	18%	30%
Seroma Requiring Intervention	1.6%	1/46 (2.2%)	5.8%	6%	6%
Mesh Removal Required	0	0	0	0	0

Results

Extremely low rate of mesh related complications | No mesh removal or mesh related complications in complex abdominal wall patients, even in the setting of contaminations and wound complications. | Long-term outcomes and experience demonstrating long-term durability.

TIGR® MATRIX SUPERIOR HANDLING CHARACTERISTICS

- Knitting process allows mesh to be cut to optimal size without fraying.
- Slight memory allowing fixation under gentle stretch preventing buckling of the mesh.
- With mesh taut, no buckling when anterior fascia is closed in TAR and other sub-lay techniques.

TO ORDER

Size	Reference number
10x15 cm	NSTM1015
15x20 cm	NSTM1520
20x30 cm	NSTM2030

InterMed Resources
TENNESSEE

1-800-224-6113
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TIGR® matrix

Clinical Literature Synopsis

"THE USE OF A NOVEL SYNTHETIC RESORBABLE SCAFFOLD (TIGR® Matrix) IN A CLINICAL QUALITY IMPROVEMENT (CQI) EFFORT FOR ABDOMINAL WALL RECONSTRUCTION (AWR)"

R. Lewis, B. Forman, M. Preston, E. Heidel, B. Alvoid-Preston, B. Ramshaw
Hernia, May 2020

Key Takeaways

In this group of 91 patients, the use of TIGR® Matrix resorbable synthetic mesh for AWR as part of a CQI process improvement was evaluated in place of a variety of biologic meshes. With no mesh-related complications and no mesh removals required, there was an improvement in value due to the decrease in mesh cost and improved outcomes over time. Long-term follow-up demonstrated the durability of the repair with TIGR Matrix for AWR.

BACKGROUND & METHODS

Use of surgical mesh in abdominal wall reconstruction (AWR)

Open ventral hernia repair is one of the most common general surgery procedures performed. A postoperative wound complication, including infection, is one of the most common complications related to this procedure. For large, complex open ventral hernia repairs, biologic hernia meshes have been common practice over the past decade in abdominal wall reconstruction (AWR) operations due to the perceived tolerance to the open environment, including contaminated and/or infected fields. At an extremely high average selling price, the high cost of biologic mesh has raised questions about the value of its use in AWR. Resorbable synthetic mesh may have the potential benefits of biologic mesh, minimizing the need for removal when infected, at a lower cost.

[1]The use of a novel synthetic resorbable scaffold (TIGR Matrix) in a clinical quality improvement (CQI) effort for abdominal wall reconstruction (AWR) Ramshaw, B., Lewis, R., Forman, B., Preston, M., Heidel, E., Alvoid-Preston, B. Hernia, 2020 May 25

Continuous Quality Improvement (CQI) tools

Demonstrating the value of care is becoming an increasing priority in healthcare. Value-based continuous quality improvement (CQI) tools can simplify patient care by designing care around definable patient groups, diseases, and/or problems (patient care processes). The information generated by these care processes can then be used to continually improve outcomes over time, resulting in improved overall quality, safety, and patient satisfaction, along with decreased costs, resulting in improved value. Using the principles of CQI is often more appropriate for developing an understanding of the factors that drive improvements in patient care than are randomized controlled trials that aim to prove or disprove a hypothesis. Specifically, traditional randomized controlled trials may not be appropriate for studying complex dynamic processes, such as patients with ventral/incisional hernias undergoing open abdominal wall reconstruction (AWR), because there are many inherently uncontrollable variables that can influence interpretation of trial results.

Purpose

The main purpose is to evaluate if a novel resorbable synthetic mesh (TIGR Matrix) may have the potential benefits of biologic mesh, while minimizing the need for removal when infected, at a lower cost.

Methods

A hernia program has implemented the principles of CQI to improve patient outcomes. One process improvement attempt was implemented in an effort to improve the value of care by decreasing the use of biologic mesh and using a less costly alternative, a newly available two-polymer

synthetic resorbable scaffold (TIGR Matrix), for patients who underwent AWR. As part of the CQI process, a transversus abdominus release (TAR) approach was implemented as an attempt at process improvement involving the AWR technique. To determine the long-term performance of this mesh in the single-surgeon hernia program, follow-up beyond 3 years was obtained as a part of the CQI process.

MAIN RESULTS

91 consecutive patients underwent open AWR with placement of TIGR Matrix. 66 of these patients underwent a TAR approach. As part of the CQI approach all patients were included, without inclusion or exclusion criteria. There were 52 patients (57%) with a recurrent hernia and contamination was present in 27/91 (30%) patients. Baseline outcomes included a mean length of stay of 7.5 days (0–49), a recurrence rate of 12% (11/91) and a wound complication rate of 27% (25/91). There were no mesh-related complications and no mesh removal (partial or total) was required. The mean follow-up length was 42.4 months.

Outcomes comparison TIGR Matrix vs Phasix™ Mesh trial

As all patients were included as part of the CQI effort, 30% had contamination. Therefore, a comparison of TIGR Matrix patients without exclusions was made vs the published results from a trial with Phasix Mesh (a single-polymer resorbable synthetic mesh)[2]. Overall the outcomes are similar. However, when exclusion criteria are applied to the TIGR Matrix study patients, 49/91 (54%) patients would have been excluded. In comparing the remaining 42 TIGR Matrix mesh patients with a more similar group of patients in the Phasix Mesh trial, there is some improvement in outcomes in the TIGR Matrix group of patients. (Table 8).

Outcomes comparison TIGR Matrix (no exclusions, incl CQI improvements) vs Phasix Mesh trial

To see the impact of CQI attempts at improvement, a comparison was made with 66 TIGR Matrix patients, no exclusion criteria, who had the TAR approach as well as other process improvement attempts. This comparison showed a further decrease in recurrence rate with the TIGR Matrix patients to 4.5% (3/66). (Table 10).

[2]Roth JS, Anthone GJ, Selzer DJ et al (2018) Prospective evaluation of poly-4-hydroxybutyrate mesh in CDC class 1/high-risk ventral and incisional hernia repair: 18 month follow-up. Surg Endosc 32(4):1929–1936

Table 8. Outcome comparison between TIGR Matrix, with exclusions, and Phasix Mesh trial

	TIGR Matrix *n*=42	Phasix Mesh *n*=121	*p* values
OR time	Average = 191 min ± 66.3	Average = 168 min ± 84	0.02
Length of stay	Average = 6.7 days ± 9.6	Average = 5.3 days ± 5.3	0.36
Recurrence	4 patients (9.5%)	11 patients (9%)	0.93
Wound infection	3 patients (7%)	11 patients (9%)	0.70
Seroma requiring intervention	1 patient (2%)	7 patients (13%)	0.38
Wound VAC	0 patients (0%)	11 patients (13%)	0.15
Mesh-related adverse event	0 patints (0%)	11 patients (9%)	0.19

Table 10. Outcomes after quality improvements implemented

	TIGR Matrix and TAR approach No exclutions *n*=42	Phasix Mesh *n*=121	*p* values
OR time	Average = 230 min ± 100.5	Average = 168 min ± 84	< 0.001
Length of stay	Average = 6.5 days ± 6.4	Average = 5.3 days ± 5.3	0.15
Recurrence	3 patients (4.5%)	11 patients (9%)	0.26
Wound infection	3 patients (4.5%)	11 patients (9%)	0.26
Seroma requiring intervention	1 patient (1.5%)	7 patients (6%)	0.17
Wound VAC	1 patient (1.5%)	11 patients (13%)	0.04
Mesh-related adverse event	0 patints (0%)	11 patients (9%)	0.04

TIGR Matrix Surgical Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as for the repair of hernias or other fascial defects that require the addition of a reinforcing material to obtain the desired surgical result.
Caution: Please read instructions for use which accompany the product for indications, contraindications, warnings and precautions.
TIGR Matrix Surgical Mesh received 510(k) clearance by the FDA in 2010.