Five Years of Learning and Improving with a Reinforced Tissue Matrix Used in Inguinal Hernia Repair*

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INTRODUCTION

Several FDA-cleared options are available for hernia repair. Reinforced Tissue Matrices (RTMs) are an alternative device solution to permanent synthetic, resorbable synthetic, and biologic meshes. They are comprised of non-dermal sourced layers of extracellular matrix, paired with a minimal suture footprint. This selection of RTMs (OviTex®) may provide clinical value due to the unique design of the RTM.

The choice of reinforcement device for inguinal hernia repair is one variable that may lead to a difference in outcomes. Other contributing factors can include fixation type, size of defect, direct vs. indirect, among others. This investigation focused on changes in inguinal hernia recurrence rate using OviTex® Core Permanent as the variables of templated cutting, device size, and defect closure evolved over time in a single surgeon practice.

METHOD

A clinical quality improvement (CQI) project is a way to analyze outcomes using real-world clinical data. In this CQI project, one clinical site evaluated this reinforced tissue matrix for inguinal hernia repair over five years (2018 – 2022). A combination of manual and technological solutions were used to obtain clinical and follow-up data. Clinical data were obtained from the electronic medical record through manual extraction and GenAI data acquisition software tools. Follow-up data were obtained from direct patient contact using a HIPAA-compliant patient-facing text application.

Table 1: Outcomes for inguinal hernia repair with OviTex for each year demonstrating continuous improvement through size, shape and technique adjustments.

Year	Total Patients	Bilateral	Total Hernias	Recurrent (%)	Mean Follow-up (months)	Follow-up Range (months)
2018	40	12	52	4 (7.7%)	48.8	1 - 75
2019	90	18	108	6 (5.6%)	37.1	1 - 67
2020	60	11	71	3 (4.2%)	29.1	1 - 56
2021	115	47	162	4 (2.5%)	21.3	1 - 39
2022	105	40	145	3 (2.1%)	16.8	1 - 27

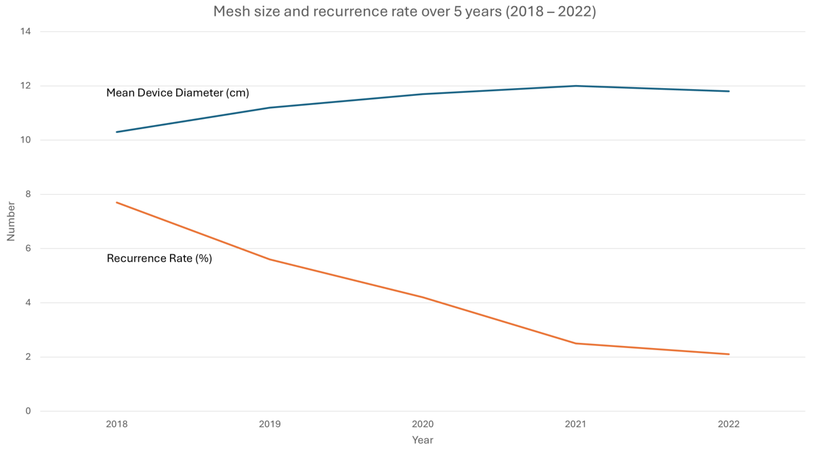


Figure 1. Device width and recurrence rate for patients who underwent inguinal hernia repair with OviTex during a 5-year period (2018 – 2022) demonstrating continuous improvement.

RESULTS

- 538 inguinal hernias were repaired using OviTex Core Permanent in 410 patients over five years (2018-2022).
- The approaches included robotic, laparoscopic, and open repairs for unilateral (262) and bilateral (148) inguinal hernias.
- Mean follow-up was 27.4 months, and the range was 1 – 75 months.
- Several adjustments were made during this time frame in an attempt to improve outcomes:
  1. a new template was employed to facilitate in cutting devices,
  2. larger size devices were made available (10cm x 15cm and 10cm x 16cm vs only 10cm x 12cm), and
  3. defect closure was implemented.

Outcomes:

- Recurrence rates improved after implementing the adjustments as shown in Table 1. The majority of recurrences occurred at 20 months or less post-op.
- There were no known device-related complications, nor were device removals required.
- Over time there was an increase in device diameter (height and width) and a reduction in recurrence rates (Figure 1).

CONCLUSION

Surgeons can improve outcomes using feedback methodologies when implementing new techniques into their clinical practice. Improved outcomes, specifically recurrence, were observed over five years by evaluating a four-layer reinforced tissue matrix as part of a CQI project. The CQI data collection methodology (a combination of automated and manual entries) for clinical and patient follow-up identified that adjustments to a surgeon's clinical practice over time can improve patient outcomes.

*This CQI Project was funded by TELA Bio through a collaborative partnership with Caresyntax and The Indiana Hernia Center.