A Novel Polypropylene Mesh (T-Line®) for Abdominal Wall Repair: Early Experience at Three Centers in the United States

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ABSTRACT

Mesh suture was initially developed and investigated to overcome suture pull-through in hernia repair. It has a large area compared to standard suture which distributes the load in tissue, reducing stress at the suture/tissue interface and preventing suture from cutting through tissue or the mesh. This report describes our early experience using the new T-line® mesh (Deep Blue Medical Advances, Durham, NC, USA) in patients with incisional and primary ventral hernia repairs. This is a descriptive, retrospective study in 18 patients who underwent abdominal wall repair with T-Line® mesh from November 2020 to November 2021 in three academic centers. T-Line® is a novel moderate-weight macroporous, polypropylene mesh with extensions that are 29 times the cross-sectional area of #0 polypropylene suture. They can be sewn into fascia to anchor the mesh with no need for suture tackers or other devices to fixate the mesh. The median age of the patients was 56.5 years (range 25-83) and the median BMI was 31.7 kg/m^2 (range 23.6-51). Twelve patients (66.7%) had primary hernias, and 11 (61.1%) had a recurrent hernia. The median defect area was 117.5 cm^2 (range 4-390) and the median mesh area was 449.5

cm² (range 130-600). The mesh position was onlay in 16 cases (88.9%) and sublay in 2 cases (11.1%). The median operative time was 247 minutes (range 104-395). The median length of stay was six days (range 0-21) with no significant in-hospital complications. One patient had a surgical site infection (5.5%) and two patients developed seromas (11.1%). There were no early hernia recurrences with a median follow-up of 28 days (range 8-307). The T-Line® mesh was shown to be safe and effective for patients with ventral hernia in the short term.

INTRODUCTION

The incidence of primary ventral hernias is increasing in the United States.[1] The incidence of incisional hernias after laparotomy ranges between 11 and 20%, and ~400,000 ventral hernia repairs are performed annually in the United States. Randomized controlled trials and large database studies have demonstrated the safety and efficacy of mesh reinforcement compared to primary suture repair in primary ventral hernias and incisional hernias to improve long-term outcomes.[2-5]

Several different approaches to fixate mesh to tissue are available, and the most common method involves the use of sutures. However, despite its many benefits, suture can fail due to breakage, the unraveling of knots, or perhaps, most commonly, excessive tension, which can cause the suture to cut through tissue.[6-8] When suture fails, meshes can contract or tear away from tissue, allowing hernias to recur. To overcome these failures, mesh suture was developed by Dumanian et al., under the assumption that mesh suture has a larger surface area than standard suture and distributes tension better, thus reducing stress at the suture/tissue interface to prevent mesh suture from cutting through tissue.[9] With the same principles of tension distribution as those underlying Dumanian's mesh suture, a new type of mesh has recently been introduced into the marketplace with mesh extension sutures integrated into the mesh body (i.e., mesh and mesh suture comprise a single unit) to enhance anchoring strength and mesh placement; the T-Line® Hernia Mesh (Deep Blue Medical Advances, Durham, NC, USA).[10] T-Line® Hernia Mesh blends the traditional benefits of polypropylene mesh with the superior anchor point-fixation features of mesh suture (Fig. 1A). The extensions are secured to tissue by a simple and easy-to-apply lock stitch (Fig. 1B-E), without knots. Mesh extensions provide 275% greater anchoring strength than suture alone.[10-12]

This is the first multi-institutional case series that describes the use of T-Line® Hernia Mesh in patients with abdominal wall defects. This report describes the early experience with this mesh at three academic centers in the United States in patients with ventral hernia repairs.

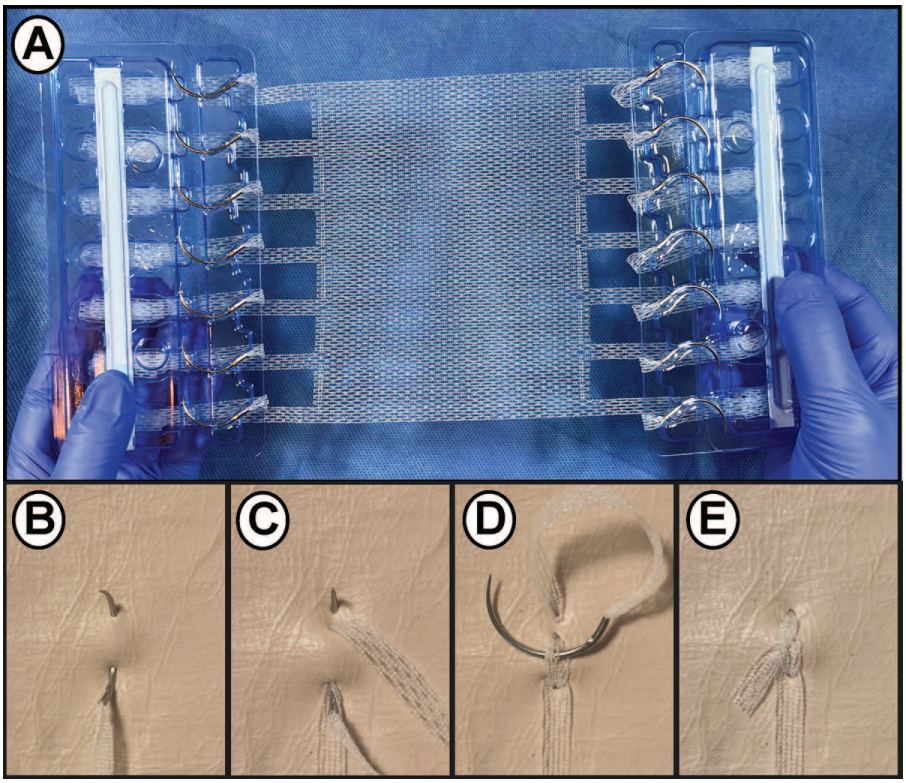

Figure 1. (A) T-Line® Hernia Mesh (13.5cm x 10cm) (Deep Blue Medical Advances, Durham, NC, USA) with integrated mesh extensions terminating with GS-21 needles secured on lateral trays containing the extensions. (B) The first bite of the self-locking stitch can be a shallow bite (e.g., 1cm to 1.5cm) lateral to the edge of the mesh. The extension is then pulled to create the desired amount of tension on the mesh body. (C) The needle is then passed through a center pore of the extension where the first bite entered the fascia and placed slightly deeper through the tissue exiting 1mm to 2mm lateral to the exit of the first bite. The second bite is pulled to create a snug loop around the fascia. (D) The needle is then passed through a center pore of the extension where it exits on the first bite. The extension is drawn snug to complete the self-locking stitch. (E) The extension is cut with scissors 1cm to 1.5cm from the last point of pass-through, thus removing the needle and excess extension. Image used with permission from Deep Blue Medical Advances.

METHODS

Study Design

This was a descriptive, retrospective study of patients who underwent abdominal wall repair using T-Line® mesh in three academic medical centers from November 2020 to November 2021. All eligible patients who underwent abdominal wall reconstruction by three surgeons (FM, HH, YO) were followed prospectively for postoperative outcomes, and data were collected retrospectively. Inclusion criteria were age greater than 18 years and ventral hernia repair with the use of T-Line® mesh. Patients in whom a primary fascial repair could not be achieved or who received a second, different mesh were excluded. This study was approved by the Institutional Review Boards of all the institutions and all HIPPA regulations were followed. This case series is reported according to the PROCESS checklist of 2018.[13]

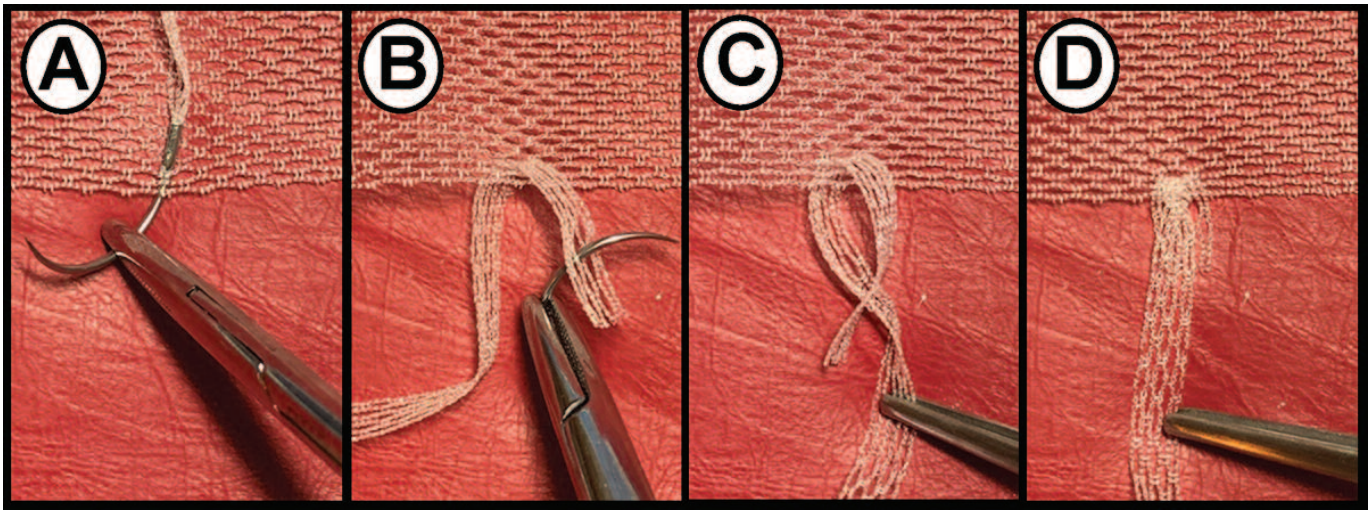

Figure 2. "Zip-tie" re-attachment of a mesh extension. (A) The free extension is re-attached by passing the needle through a pore in the mesh. (B) The needle is passed through a pore >1cm from the cut end of the extension, similar to starting a "zip-tie". (C) The extension is worked through itself similar to a zip-tie until it is snug on the mesh body (D) The re-attached extension is used in the same way one would use an extension attached to the mesh. Image used with permission from Deep Blue Medical Advances.

Characteristics of the Mesh

T-Line® Hernia Mesh is a novel, macroporous, polypropylene mesh with an areal density of 90.40±0.50 g/m^2 and extensions that are 15 times the cross-sectional area of #0 polypropylene suture.[11] The extensions are 0.6 cm wide with swaged-on taper needles. They can be sewn into fascia without bulky knots to anchor the mesh with no need for sutures, tackers, or other fixation technologies, or used as free mesh extensions for additional fixation or wound closure. Besides coming in several different sizes, the mesh can be trimmed into different shapes.

Placement of the mesh

Abdominal wall hernia repair with the T-Line® mesh involved placement of the prosthetic in the onlay or sublay position. Different widths and lengths of the mesh were used as appropriate for the specific patient, with a minimal overlap of 5 cm in all directions from the closed defect. While the onlay technique varied slightly between surgeons, in general, skin flaps were raised bilaterally out to the semilunar line. After the midline was closed, the centerline of the mesh was aligned over the fascia defect and the left array of mesh extensions was sewn into the fascia using a lock stitch (Fig. 1B-E). The right side of the mesh was then sewn into place in a corresponding manner, where each extension was pulled taut prior to being locked to set tension according to the surgeon's preference. The mesh lay flush with the tissue and there were no crinkled edges. Sublay techniques included methods that secured the mesh in the sublay space with bites at the lateral aspects of the retrorectus space anterior to the semilunar line and the extensions were secured with an anterior lockstitch at that location, or with the extension woven back into the mesh body. When mesh was cut and trimmed to specific sizes, previously cut free extensions were used at the cut edge in a "zip-tie" free-hand fashion, analogous to mesh suture (Fig. 2) to secure the mesh to tissue.[12] Once the mesh was secured, drains were placed and the skin was closed in layers.

Data collection

Data were collected and divided into patient characteristics, hernia characteristics, intraoperative data, and patient outcomes. The following patient demographics and comorbidities were analyzed: age, sex, body mass index (BMI), diabetes mellitus (DM), hypertension, chronic obstructive pulmonary disease (COPD), liver disease, use of anticoagulants or antiplatelets, and ASA class.

Preoperative data included information regarding the history and chronicity of hernia, type of hernia (e.g., ventral,

Table I
Patients' characteristics (n=18)

	Median (range)	n (%)
Age (y)	56.5 (25-83)	
BMI (kg/m^2)	31.7 (23.6-51)	
Sex		
Female		12 (66.7)
Male		6 (33.3)
ASA		
Class II		7 (39)
Class III		11 (61)
Comorbidities		
Hypertension		7 (39)
Diabetes Mellitus		6 (33.3)
COPD		1 (5.6)
Smoking		2 (11.1)
Liver disease		2 (11.1)
Anticoagulation medication		1 (5.6)
Antiplatelet medication		3 (16.7)

incisional), panniculectomy, and recurrence. Intraoperative and postoperative data consisted of size/location of hernia defect, mesh area, the use of drains, duration of surgery, length of stay, complications, readmissions, and follow-up.

Table II
Hernia characteristics (n=18)

	n (%)
Hernia Type	
Primary ventral	12 (66.7)
Incisional	6 (33.3)
EHS Classification	
M1	0
M2	6 (24)
M3	13 (52)
M4	3 (12)
M5	0
L1	1 (4)
L2	2 (8)
L3	0
L4	0
Recurrent Hernias	11 (61.1)
Recurrent incisional	6 (33.3%)
Recurrent primary ventral	5 (27.8%)
EHS Width Classification	
W1	1 (5.6)
W2	11 (61.1)
W3	4 (22.2)
Unknown	2 (11.1)

Table III
Intraoperative data (n=18)

	Median (range)	n (%)
Wound classification		
Clean		17 (94.4)
Clean Contaminated		1 (5.6)
Diastasis		5 (27.8)
Defect Length (cm)	13.5 (2-26)	
Defect Width (cm)	9 (2-15)	
Area of the Defect (cm^2)	117.5 (4-390)	
Mesh Area (cm^2)	449.5 (130-600)	
Mesh position		
Onlay		16 (88.9)
Sublay		2 (11.1)
Anterior Component Separation		4 (22.2)
Associated Procedure		
Panniculectomy		5 (27.8)
Small bowel resection		1 (5.6)
Omentum resection		1 (5.6)
Intraoperative complication		
Serosal tear		2 (11.1)
Drain use		17 (94.4)
Operative Time	247 (104-395)	
EBL	100 (25-400)	

Statistical analysis

A descriptive analysis was performed. Continuous variables (age, BMI, length of stay, duration of surgery, follow-up) are reported as median and range. Categorical variables are reported as frequencies and percentages. Data were analyzed using SPSS v.28 (SPSS, Inc., Chicago, IL, USA).

RESULTS

A total of 18 patients underwent abdominal wall repair with T-Line® mesh between November 2020 and November 2021. The median age was 56.5 years (range 25-83) and the median BMI was 31.7 kg/m^2 (range 23.6-51)(Table I). Twelve patients (66.7%) had primary hernias, whereas 11 (61.1%) had a recurrent hernia (Table II).

The median defect area was 117.5 cm^2 (range 4-390) and the median mesh area was 449.5 cm^2 (range 130-600) (Table III). Mesh position was onlay in 16 cases (88.9%) and sublay in 2 cases (11.1%). Anterior component separation was performed in 4 (22.2%) patients and five patients (27.8%) underwent a combined hernia repair plus panniculectomy. The median operative time was 247 minutes (range 104-395).

The median length of stay was six days (range 0-21) with no significant in-hospital complications (Table IV). One patient had a surgical site infection (5.5%) (Clavien-Dindo grade I), and three patients developed seromas (16.7%) (Clavien-Dindo grade I). There were no early hernia recurrences with a mean follow-up of 28 days (range 8-307).

DISCUSSION

This study demonstrates the safety and early efficacy of a novel polypropylene hernia prosthetic that uses mesh extensions as suture anchors. While these results are too early to address long-term efficacy, they are sufficient to assess 30-day outcomes. Prior preclinical studies in pigs indicated that the T-Line® mesh outperformed standard polypropylene mesh anchored with sutures in terms of mechanical and biomechanical performance with equivalent biocompatibility.[11]

Incisional hernia is one of the most common complications after abdominal surgery. The current treatment of choice for ventral and incisional hernias is mesh repair. Randomized clinical trials and meta-analyses have demonstrated the

Table IV
Postoperative outcomes (n=18)

	Median (range)	n (%)
LOS (days)	6 (0-21)	
ED presentation within 30 days		2 (11.2)
Readmission		2 (11.2)
Complications		
Seroma		3 (16.7)
SSI		1 (5.5)
Follow-up (days)	28 (8-307)	

superiority of mesh repair over primary suture repair.[4,5] Mesh repair significantly reduces recurrence compared to primary suture repair. A recent trial by Kaufmann et al. showed that, for small primary umbilical hernias (1-4 cm in diameter), mesh repairs were associated with less recurrence compared to primary suture repairs after a median follow-up of 25 months.[4]

However, the literature is still uncertain regarding the optimal placement for mesh repair. Onlay mesh repair and retromuscular repair are the most common techniques for ventral hernias.[6] Each technique presents a unique set of advantages and disadvantages. Some studies have shown that onlay repairs are associated with more seroma formation and wound infection compared to retromuscular repairs,[7,8,14] as supported by a recent meta-analysis by Beckers Perletti et al.[1] On the other hand, retromuscular repairs are associated with a longer operative time.[14,15] However, a retrospective study by Haskins et al. using the ACHQC database showed no significant difference between onlay and sublay repairs in low-risk patients regarding 30-day surgical site infection, surgical site occurrences or surgical site occurrences requiring procedural intervention.[16] This inconsistency in the literature makes it difficult to develop strong recommendations regarding best techniques for ventral hernia repairs.

In our cohort, most patients underwent onlay repair, and only two patients received sublay repair. Primary fascia closure was achieved in all cases. Furthermore, four patients had anterior component separation, which might increase morbidity in the postoperative period. In this series, patients presented with complex and challenging hernias (grade II and III VHWG) with previous repairs in >60% of cases. Two patients developed seroma in the postoperative period, both type I according to the Morales Conde seroma classification,[17] and were managed conservatively. One patient developed a superficial surgical site infection and was also managed conservatively with oral antibiotics.

Two patients were readmitted due to incisional pain. One received supportive care and pain control with a one-day length of stay. The other had a seroma that was drained at bedside with a length of stay of 3 days.

Limitations of the study

The limitations of our study are its retrospective nature and the use of historical comparisons to evaluate outcomes (n=18). The short follow-up did not allow us to properly evaluate recurrence or surgical site occurrences. Patients with a concomitant panniculectomy may have a longer operative time and this may be a confounding factor.

CONCLUSION

The T-Line® mesh was shown to be safe in the short term when used for the repair of complex ventral hernias. Notably, this case series demonstrated onlay and sublay repairs with mesh extension fixation, thereby supporting versatility of the product. New studies with larger samples and comparison groups should be performed to better understand the outcomes with the mesh. STI

AUTHORS' DISCLOSURES

HH is an unpaid member of the Scientific Advisory Board of Deep Blue Medical Advances, Inc. JY and FM are paid consultants for Deep Blue Medical Advances, Inc. The other authors declare that there are no other conflicts of interest.

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