A Reprint from Surgical Technology International Volume 40

The T-Line® Hernia Mesh, A Novel Mesh Uniquely Designed to Prevent Hernia Recurrence and Occurrence

Seth T. Beeson, DO
General Surgery Resident

Brandon Casas, MS
Medical Student

Justin D. Faulkner, MD
General Surgery Resident

William W. Hope, MD
Associate Professor of Surgery
General Surgery Residency Program Director

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SETH T. BEESON, DO
GENERAL SURGERY RESIDENT

BRANDON CASAS, MS
MEDICAL STUDENT

JUSTIN D. FAULKNER, MD
GENERAL SURGERY RESIDENT

WILLIAM W. HOPE, MD
ASSOCIATE PROFESSOR OF SURGERY
GENERAL SURGERY RESIDENCY PROGRAM DIRECTOR

DEPARTMENT OF SURGERY, NOVANT NEW HANOVER REGIONAL MEDICAL CENTER, WILMINGTON, NORTH CAROLINA

ABSTRACT

Ventral hernia repair (VHR) fixation techniques with current meshes on the market are prone to failure from intra-abdominal pressure spikes due to coughing or lifting, for example. The T-Line® Hernia Mesh (Deep Blue Medical Advances, Durham, North Carolina) is a new mesh with a novel fixation mechanism to enhance anchoring strength addressing hernia occurrence and recurrence. Used similarly to traditional mesh, the new mesh uses incorporated mesh sutures that are 15 times the surface area of sutures for fixation rather than monofilament sutures, providing ~275% stronger anchoring strength. The increased surface area of the mesh extensions decreases tension on the mesh and tissue and increases the strength of the repair overall. There is also the likelihood that anchoring gains strength over time as the extensions undergo bioincorporation. This novel mesh specifically addresses the most common complication of VHR and has the potential to significantly improve outcomes.

INTRODUCTION

Ventral hernia repair (VHR) is one of the most common surgeries performed in the United States. The reasons for this are because first-time ventral hernias occur in 20–30% of laparotomy cases and hernia repairs fail in >30% of VHR cases, leading to recurrent ventral hernias.[1,2] One reason for ventral hernia recurrence is that sutures used to secure mesh to fascia pull through, allowing the mesh to migrate or contract, analogous to how a cheese-wire cuts through cheese. Suture cheese-wiring is an inevitable event in many VHR cases, despite our best efforts to optimize patient care or utilize methodical surgical techniques.[3] Given these issues with present methods of mesh fixation, a better performing mesh and anchoring or fixation system is needed.

Small bite, small travel technique, and 4:1 suture to wound length ratio are abdominal wall closure strategies that have been shown to decrease hernia rates. These technical concepts are predicated on increasing surface area of the suture-tissue interface, thus decreasing tissue stress.[1] This is analogous to cross strand tendon repair techniques where four suture strand repairs yield a more reliable repair than two suture strand repairs.[4] In the last several years, Dumanian has advanced the concept of using mesh suture strips to distribute abdominal tension and reduce ventral hernia. Early results have demonstrated these to be an effective option for

abdominal wall closures in complex ventral wall defects.[2]

The Food and Drug Administration (FDA)-cleared T-Line® Hernia Mesh (Deep Blue Medical Advances, Durham, North Carolina) utilizes mesh extension suture integrated into familiar flat sheet polypropylene mesh. When sewn into tissue, these extensions allow for a broad anchor surface area which reduces stress and ensures the mesh is secure. The T-Line® mesh is highly versatile and designed to meet surgeon and patient needs in all cases of VHR. The purpose of this paper is to describe the mesh and illustrate technical detail on how to use the mesh in the OR, with case examples. Furthermore, we will discuss how the mesh may further evolve to fit into the hernia surgeons' armamentarium as advanced versions of the mesh reach the market with different biomaterials or assist devices.

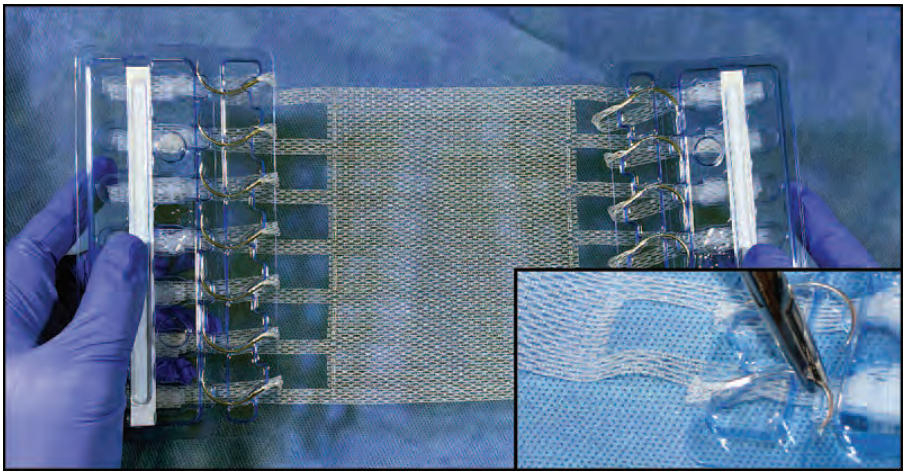

Figure 1. 10.5mm x 13.5mm T-Line® Hernia Mesh with integrated mesh extensions. Each lateral array of extensions is contained with the GS-21 needle secured on a cassette so that each extension can be individually pulled from while keeping the remaining extensions organized and out of the way during implantation.

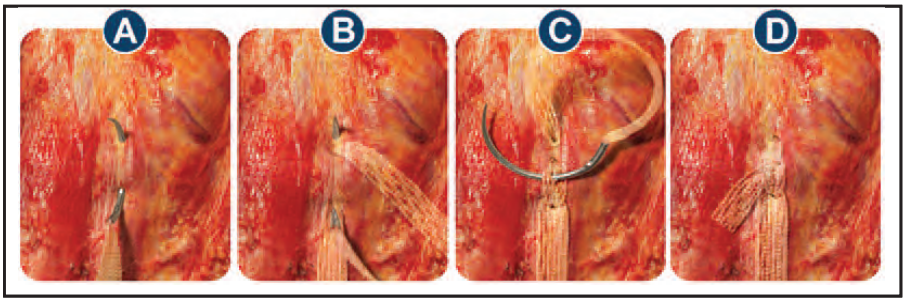

Figure 2a) First, shallow, bite (1cm to 1.5cm) of the lock stitch lateral to the edge of the mesh pulled to create the desired amount of tension on the mesh body. (b) Needle is passed through a center pore of the extension where the first bite entered the fascia and placed slightly deeper through the tissue exiting 1 to 2mm lateral to the exit of the first bite. The extension is pulled snug creating a fascia loop. (c) The needle is passed through a center pore of the extension where it exits on the first bite and is drawn snug to complete the lock stitch. (d) The extension is cut 1 to 1.5cm from the last point of pass-through removing the excess extension and needle.

MESH DESIGN

The T-Line® hernia mesh (Fig. 1) is a macroporous (2.82mm^2), moderate weight (90.4g/m^2), monofilament polypropylene mesh with excellent pliability for implanting in the abdominal wall to achieve exceptional long-term reinforcement of soft tissue.[5] Large pore sizes (~3mm^2) similar to this mesh have been shown to increase collagen deposition and maturation compared with mesh with smaller pores.[6] The mesh is available in eight sizes—four medial-lateral width (5.5, 10.5, 15.5, and 20.5mm) and two cephalocaudal lengths (13.5 and 29mm)—to provide the desired defect overlap. The medial-lateral width is chosen to provide sufficient wound overlap while allowing space to sew the extensions into tissue to anchor the mesh. The cephalocaudal length can be easily trimmed to create the required overlap. Extensions may be removed from the mesh or residual extensions may be used as free mesh suture with the mesh to further anchor the mesh on cephalocaudal borders or as quilting sutures. The mesh can be cut on its lateral borders and the free mesh sutures used to anchor the mesh.

The mesh comes packaged in two plastic trays. The mesh has integrated 5mm wide, 30cm long mesh extensions spaced 2cm apart along the lateral edges. Each extension has a GS-21 needle swaged on the end so the extension can be sewn into the fascia in lieu of suture. The extensions resist cheese-wiring because they have about 15 times the surface area of a typical #1 suture, analogous to how a snowshoe allows people to walk on top of snow rather than sink in. In addition, bioincorporation into the extensions increases with time and should lead to increased extension anchoring strength—a unique property of the mesh extension sutures.[7] This mesh anchoring system has been shown to have up to 275% greater load carrying

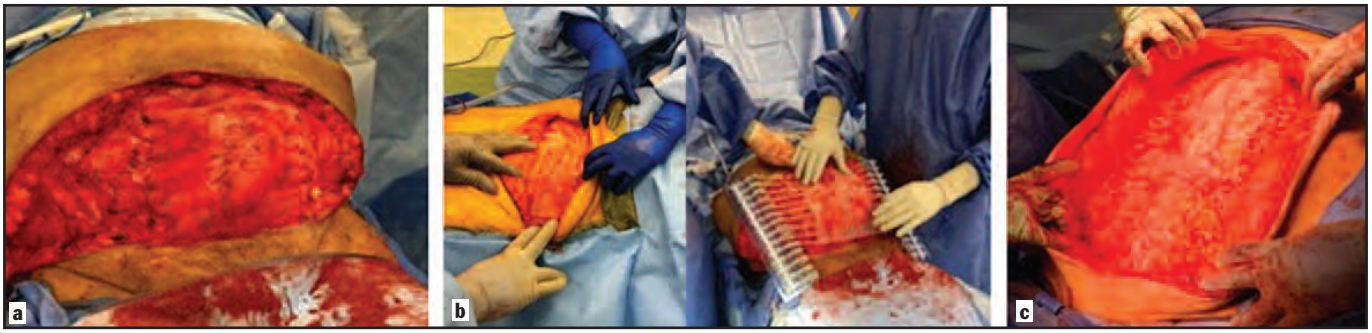

Figure 3. T-Line® Mesh has many clinical uses including abdominal wall reinforcement following panniculectomy (a) and open ventral hernia repair (b and c).

capabilities perioperatively compared to suture, allowing for the mesh to support increased abdominal tension of >32N/cm from lifting or coughing without tearing through the fascia.[5,8] The extensions are designed to resist mesh contraction or migration.

Instead of tying the extension with a bulky knot, the mesh is anchored with a novel stitch pattern that locks the mesh in place once the desired tension is achieved. The extension is secured with a two-bite lock stitch (Fig. 2a–d). The stitch is created by first taking a shallow bite (e.g., 1 to 1.5cm) lateral to the edge of the mesh and pulling the extension to create the desired amount of tension on the mesh body. A second, slightly deeper bite is taken by passing the needle through a center pore of the extension where the first bite enters the fascia and exiting ~1mm to 2mm lateral to the exit of the first bite. This second bite is pulled to create a snug loop around the fascia. This loop does not further constrict on the tissue when the mesh is subsequently loaded avoiding tissue strangulation. The stitch is completed by passing the needle through a center pore of the extension where it exits on the first bite and draws snug. The excess extension is cut leaving a 1 to 1.5cm tail which lays flat along the fascial plane. The residual extension can then be discarded or used for additional fixation.[9]

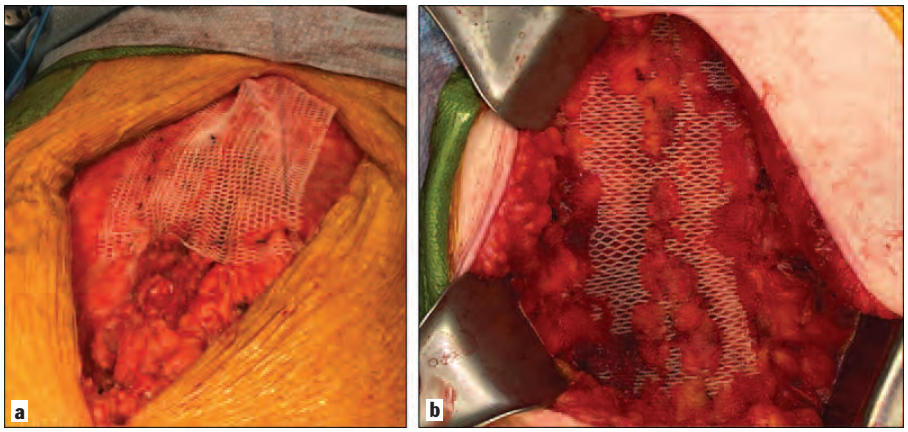

Figure 4a and b. Sutures placed through adjacent pores cause mesh wrinkling. Mesh extensions pull the mesh flat and in apposition to the fascia.

CLINICAL APPLICATION

Introduced in the fall of 2020, the T-Line® Hernia Mesh is relatively new to the market. Initially cleared by the FDA for onlay use only, it has been used in open ventral hernia repair, diastasis repair, abdominal wall reinforcement following Deep Inferior Epigastric Perforator (DIEP) flap reconstruction, reinforcement after panniculectomy, and reinforcement of off-midline repairs (Fig. 3). FDA clearance for sublay use is currently in process.

Besides the obvious advantages of enhanced anchoring strength, there are additional beneficial performance characteristics unique to the T-Line® Hernia Mesh. When sewn into tissue, the mesh lays particularly flat without wrinkling because the extensions tautly pull the mesh laterally. This is different from suture because sutures are placed through adjacent pores and when tied, cause mesh to wrinkle (Fig. 4a and b). The perceived advantages of a flat mesh is that it is believed to be more likely to bioincorporate; whereas, a wrinkled mesh will not necessarily be in contact with tissue and may be more susceptible to infection and seromas. Superior tension adjustment is another advantage of this mesh. Tension setting is achieved by anchoring one complete side of the mesh first and then sewing in the contra-lateral extensions and pulling them taut one at a

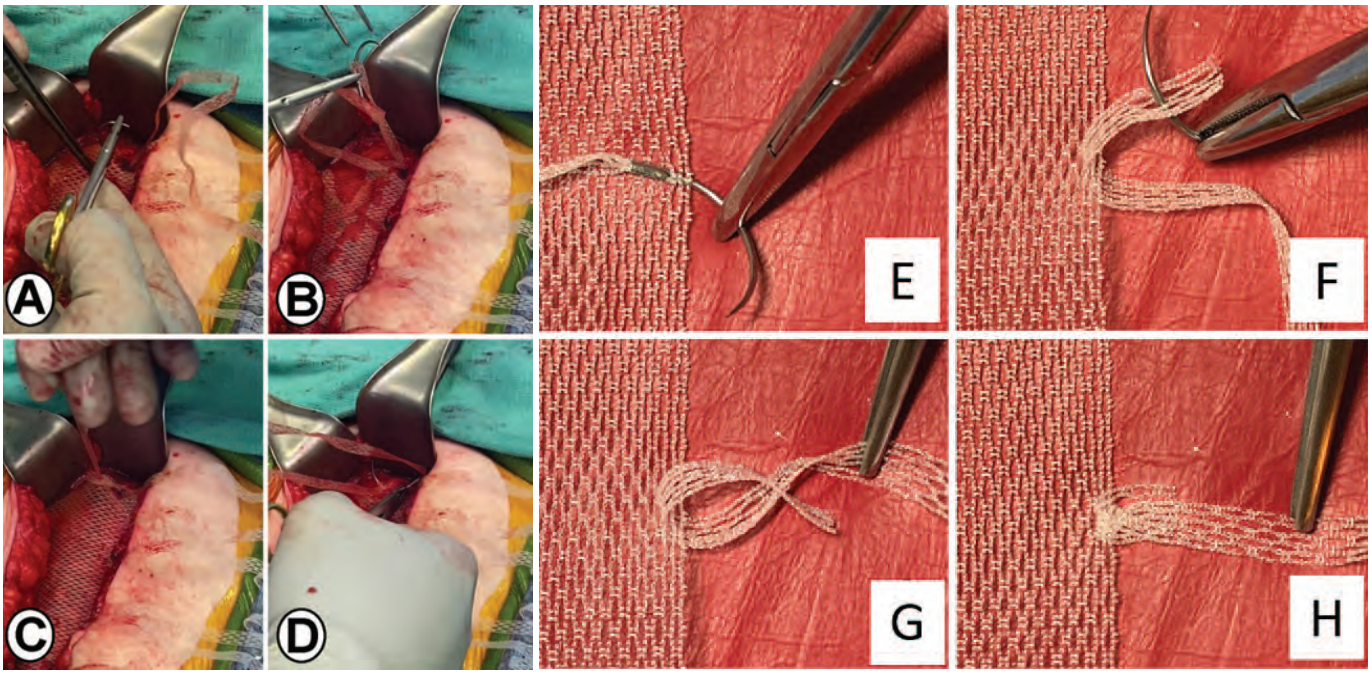

Figure 5. "Zip-tie" re-attachment of mesh extension. (a–d) Clinical images highlighting the "zip-tie" method of mesh insertion technique. (e) Take a bite of the mesh a few pores in from the edge, (f) pass the needle through a center pore 1–1.5cm from the bitter end of the free extension, (g) pull the extension through itself similar to a zip-tie until snug on the mesh body, and (h) re-attached mesh extension is now ready to sew in to fascia using the two-bite lock stitch.

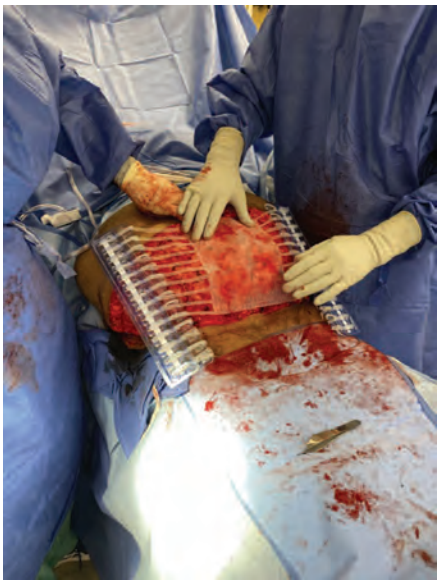

Figure 6. T-Line® Hernia mesh after initial removal from packaging. Mesh is cut cranial-caudal to fit defect with desired amount of superior-inferior overlap.

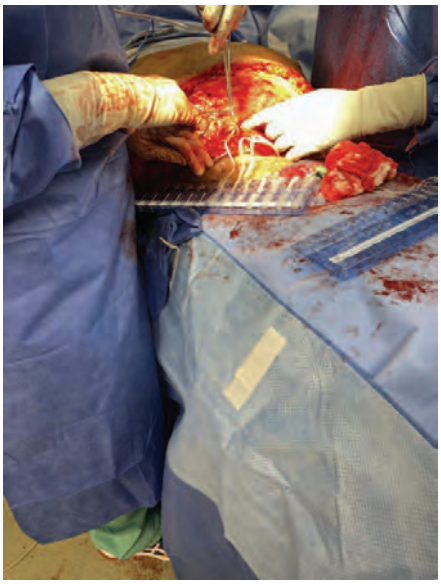

Figure 7. The right side of the mesh is secured to the fascia utilizing the mesh extensions and lock-stich technique.

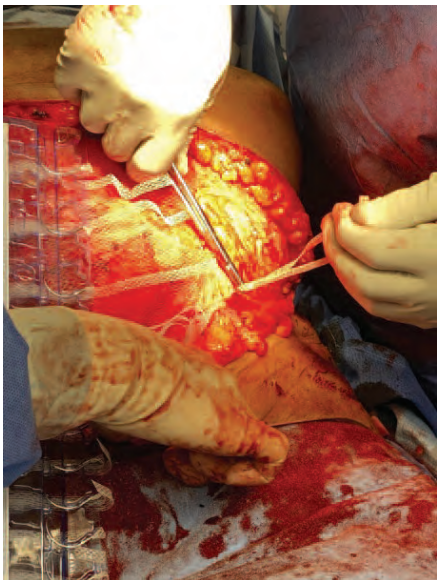

Figure 8. Mesh is then pulled taught and the contralateral extensions are secured to the fascia.

time to set the desired tension and then locking each extension in place by the lock stitch (Fig. 4). The cut and free extensions can be used independently with the mesh by sewing a free extension through tissue in one pass and then passing the needle through a pore of the mesh at the tail of the extension and pulling.[9] This is analogous to a zip-tie. With the tail of the extension secured, the mesh suture can be used as the surgeon sees fit and ultimately secured with a lock stitch (Fig. 5a–h).

Case example of placing the T-Line® mesh as an onlay

The case is of a 56-year-old female presenting with a symptomatic ventral/incisional hernia from a previous open hysterectomy in the setting of a large pannus was examined. Surgical options were discussed with the patient who elected to undergo open repair of her hernia in conjunction with a panniculectomy. Surgery was uncomplicated and the patient was found to have a 10 x 10cm incisional hernia. After skin flaps were elevated and trimmed, a 15 x 25cm T-Line® Hernia Mesh (Catalog # TL3015) was applied. The mesh was taken from the package and the trays were gently pulled away from the body of the mesh to allow for mesh placement (Fig. 6). The mesh was trimmed on the caudal border to fit the wound. #0 PDS sutures were temporarily used to tack the mesh body in place. The trays were further positioned laterally for comfort and the right side of the mesh was sewn into place one extension at a time using the lock stich (Fig. 7). The temporary #0 PDS sutures were removed and the mesh was pulled taut along the left side. The left-sided extensions were sewn in one at a time for desired tension. In instances where the fascia was weak, the extensions were sewn as a running stitch, providing additional mesh overlap and secured anchoring (Fig. 8). Once the mesh was secured, two drains were placed above the mesh and the abdominal skin flaps closed (Fig. 9). The patient tolerated the procedure well and was discharged home on postoperative day two. She was seen during follow up for drain and staple removal, and at three months follow up she had no surgical site occurrences.

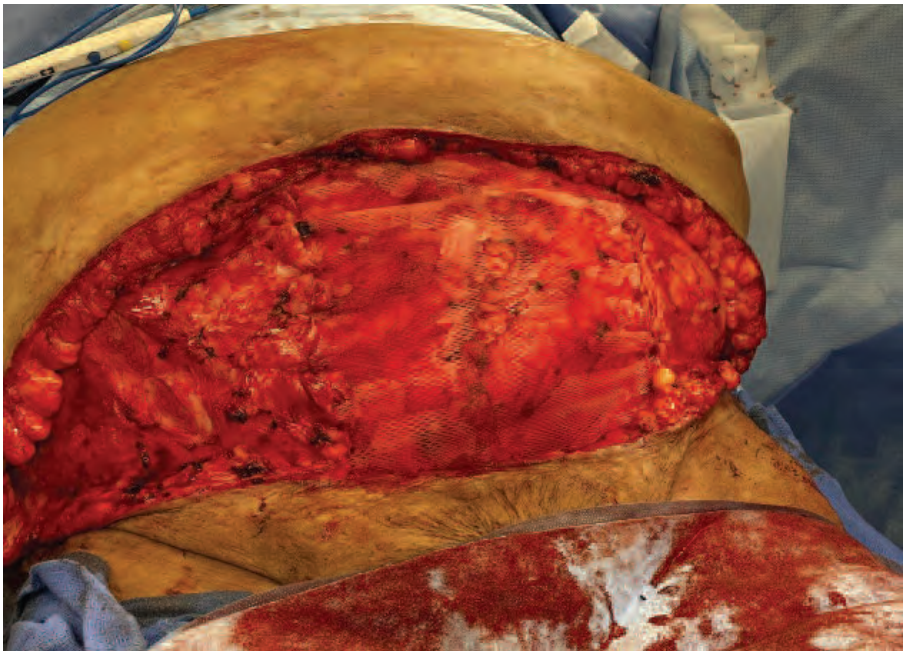

Figure 9. Mesh extension tails are cut once the mesh is secured to the fascia. Drains are placed overlying the mesh to prevent seroma formation and the skin is closed.

FUTURE MESH USE

There are potentially many other future technical approaches to applying the mesh in the onlay, retrorectus, and pre-peritoneal planes with or without

the attached needles. In certain instances, the extensions can be used to assist with mesh positioning. Free mesh extension sutures open a world of possibility with soft tissue anchoring. There are an infinite number of suture patterns to place the extensions. The needles can be removed from the extensions and suture passers used to sew the extensions into tissue. Tacks, glue, or screws could be used as adjuncts to assist with securing the extensions and no fixation techniques are possible. In the future, the mesh can be used in open or minimally invasive cases.

The T-Line® mesh is being studied for MIS transabdominal preperitoneal (TAPP) or totally extra peritoneal (TEP) techniques, in which the mesh is placed in the retro-rectal or pre-peritoneal space.[10] After reducing the hernia and ensuring no exposure of bowel to the polypropylene mesh, the unwanted extensions are trimmed, needles cut from remaining extensions, and mesh and extensions rolled and introduced into the desired space in the abdominal wall through a cannula. The mesh center is fixed with a tack to keep it in place. A percutaneous suture grasper is introduced through the skin and used to grab the end of one of the remaining mesh extensions, pull it into the supra-aponeurotic space, and back in again. In this way, a loop of mesh traverses the abdominal wall from inside out and goes in again. Once inside, the extension is folded back over itself and fixed to the abdominal wall with one to three tacks. This is repeated with the other mesh extensions. Additional tacks may be used to stretch and fix the mesh to the abdominal wall.

Of course, with the advent of a biosynthetic or anti-adhesive T-Line® Hernia Mesh, there are many tissue planes and many cases where this mesh may be safely applied including intraperitoneal or in cases where there is a high risk of contamination. The mesh could eventually be used for all types of hernias such as ventral, umbilical, paraesophageal, inguinal, flank, back, and para stomal hernias. Because of its simplicity in design, versatility, and ease of application, the mesh is also a great device for use in prophylactic hernia prevention cases.

DISCUSSION

The T-Line® Hernia Mesh is an entirely novel mesh which is designed to prevent hernia recurrence or occurrence by directly addressing anchor point failure. The integration of mesh with mesh extension sutures into one device for enhanced performance is based on fundamental engineering principles that have been studied and proven safe and effective.[2,11,12] The clinical rationale for utilizing a medical device to distribute force and provide superior soft tissue anchoring strength through tension-free repair is based on decades of experience in tendon reconstruction, where tendon rupture is analogous to hernia recurrence.[13,14] The T-Line® Hernia Mesh is new on the market and we can expect to see adoption over time, particularly as surgeons develop their own application techniques and the mesh is manufactured from different materials.

CONCLUSION

Hernia recurrence and occurrence are significant problems which we should all acknowledge. It is time we accept the fact that prehabilitation and surgical technique modifications are insufficient for success. As with many other advancements in surgery, we need better performing devices to achieve improved surgical outcomes—more tools in our toolbox. The T-Line® Hernia Mesh might be a significant advancement in hernia repair. STI

AUTHORS' DISCLOSURES

Dr. William Hope is on the surgeon advisory board for Deep Blue and receives honorarium from Medtronic, WL Gore, Intuitive, and Becton Dickinson for consulting and research.

All other authors have no conflicts of interest to disclose.

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Tel. +1 415 704 3160
Email: info@surgicaltechnology.com
Internet: www.surgicaltechnology.com
Surg Technol Int. 2022, Feb 14; 40. pii: sti40/1535