# Improved Anchoring Mechanism for Hernia Repair Mesh

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## INTRODUCTION

Approximately 345,000 ventral hernia repairs are performed annually in the US and recurrence is the leading complication (~30% ten-year recurrence rate)[1,2]. While the exact mechanisms of hernia recurrence are unknown, anchor point failure at the mesh, suture, tissue interface from mechanical forces is believed to be a leading cause, leading to mesh migration, mesh contraction, and mesh tearing from tissue.[3] To overcome this problem, we developed a hernia mesh (T-line Hernia Mesh) with integrated anchoring mesh extensions, akin to suture, that are 30cm long, 2 cm on center, **Figure 1**. The mesh extensions are sewn into tissue and distribute forces better than narrow suture. In benchtop testing, extensions lead to ~275% stronger hernia mesh fixation. This study investigates T-line Hernia Mesh anchor point fixation in the peri-operative period compared to a predicate mesh when mesh anchoring is most susceptible to failure. We also tested bio-incorporation for safety according to FDA standards to demonstrate substantial equivalence to a predicate mesh.

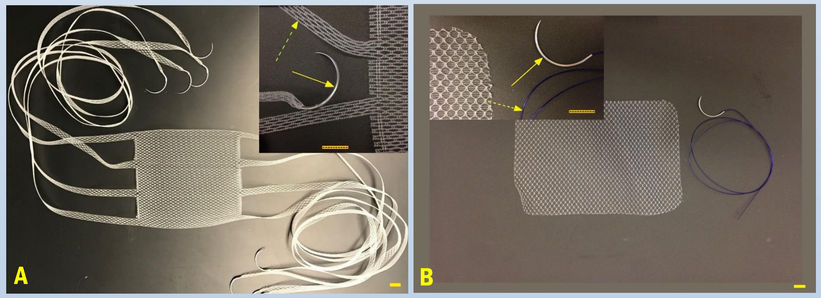


**Figure 1. T-line Hernia Mesh and predicate control mesh.** (A) T-line: 0.5cm wide extensions emanating from body of textile w/ GS21 needles swaged on the ends of extensions. (B) Predicate polypropylene mesh and #0 prolene sutures w/ GS21 needles for anchoring mesh to fascia with interrupted stitches. Scale bar = 1 cm, ⟶ = GS-21 needle, and ⇢ = extension/suture.

## MATERIALS AND METHODS

- T-line Hernia Mesh was warp knitted from polypropylene and evaluated for physical and mechanical characteristics
- Implanted in swine as ventral hernia onlay, **Figure 2**, (n=4/group: 1, 30 and 90 days)
- 1 day postoperative anchoring strength evaluated by distraction to failure @100mm/min on servo-hydraulic materials testing system
- Gross pathologic observations by board-certified veterinary pathologist on ventral wall containing hernia repair
- H&E staining to evaluate inflammation, bio-incorporation, & fibrosis

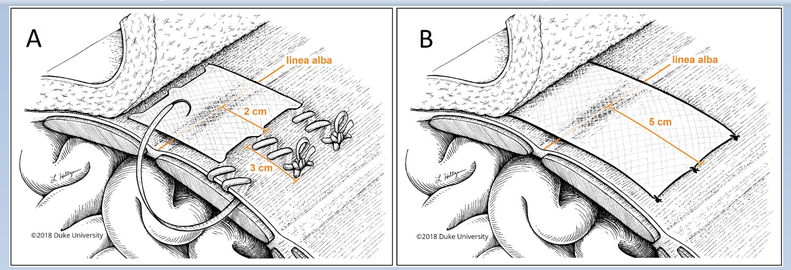


**Figure 2. Application techniques for onlay placement.** (A) T-line mesh placement, body extends 2 cm beyond fascia incision on both sides for adequate overlap onto healthy fascia. Extensions are sewn into fascia for up-to an additional 3 cm (total mesh body + extensions ≥5 cm overlap away from the fascia incision). (B) Predicate mesh placed directly over incision and body of mesh extends 5 cm beyond fascia incision on both sides and is secured with #0 polypropylene suture. **40% less T-line mesh is needed.**

## RESULTS

### T-Line Hernia Mesh Physical & Mechanical Characterization

- T-line mesh = moderate-weight, macroporous mesh (**Table 1**)
- T-line mesh outperforms predicate in benchtop mechanical tests (**Table 2**)

**Table 1. T-line Hernia Mesh Physical Characteristics (mean ± SD).**

| Dimension | T-line Mesh | Predicate Mesh | Predicate Suture |
|---|---|---|---|
| Thickness (mm) | 0.55 ± 0.01 | 0.50 ± 0.01 | NA |
| Pore Area (mm²) | 2.82 ± 0.19 | 0.56 ± 0.06 | NA |
| Areal Density (g/m²) | 90.40 ± 0.50 | 36.80 ± 0.35 | NA |
| Extension Interspace Distance - center to center (cm) | 2 | NA | NA |
| Extension Width (mm) | 11 | NA | 0.38 ± 0.01 |
| Needle Size | GS21 equivalent | NA | GS21 |

**Table 2. Benchtop Mechanical Performance of T-line Hernia Mesh (mean ± SD).**

| | T-line Mesh | Predicate Mesh | Predicate Suture |
|---|---|---|---|
| Suture Retention Strength (N) | 26.09 ± 5.24 | 9.15 ± 3.72 | NA |
| Ball Burst (N) | 474.41 ± 23.75 | 233.92 ± 15.38 | NA |
| Tongue Tear Resistance (N) | 14.46 ± 1.74 | 11.71 ± 0.61 | NA |
| Tensile Strength (N) | 691.93 ± 73.48 | 111.92 ± 7.50 | NA |
| Extension Tensile Strength (N) | 217.39 ± 6.87 | NA | 50.46 ± 0.60 |

### Bio-Mechanical Analysis in Perioperative Period

- T-line mesh ~275% (P<0.001) stronger anchoring **Figure 3**
- T-line mesh consistent failure mode / predicate multiple failure modes

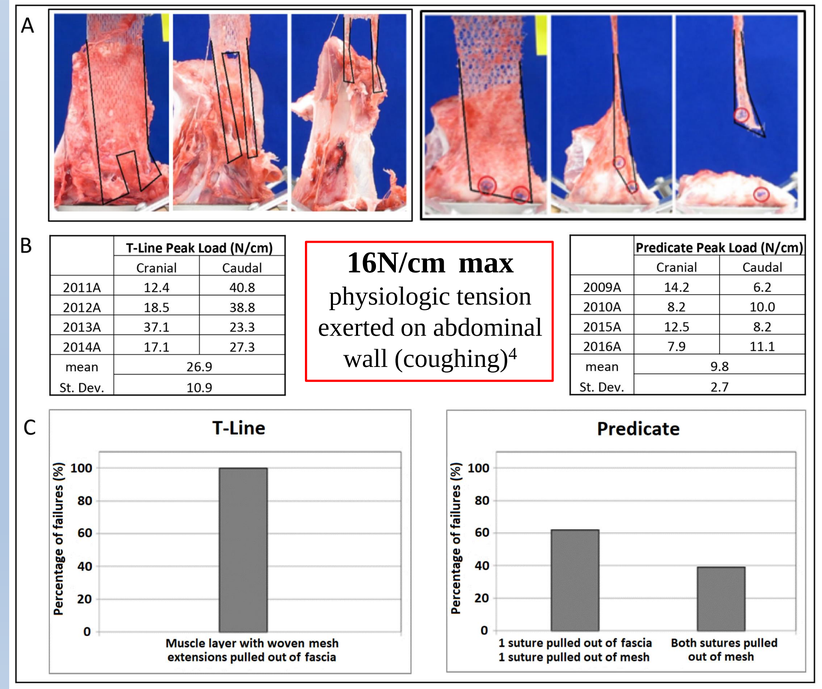


**Figure 3. Perioperative mechanical analysis – day 1.** (A) Gross images of representative samples during bio-mechanical testing for T-line mesh (left) and predicate mesh (right). Meshes outlined in black, standard of care #0 sutures outlined with red circles. (B) T-line mesh ~275% stronger per unit length (P<0.001) than standard of care on peak load performance with no significant difference between cranial and caudal locations. (C) Failure modes; T-line mesh demonstrated one failure mode (extensions pulled out of fascia), while predicate mesh demonstrated two failure modes (one suture pulled out of fascia and other out of mesh; or both sutures pulled out of mesh.

## RESULTS

### Bio-incorporation Analysis at day 30 & 90

- No significant macroscopic differences between T-line mesh and predicate mesh
- No significant differences found through H&E, **Figure 4**
- Same decrease in inflammation seen from 30 to 90 days

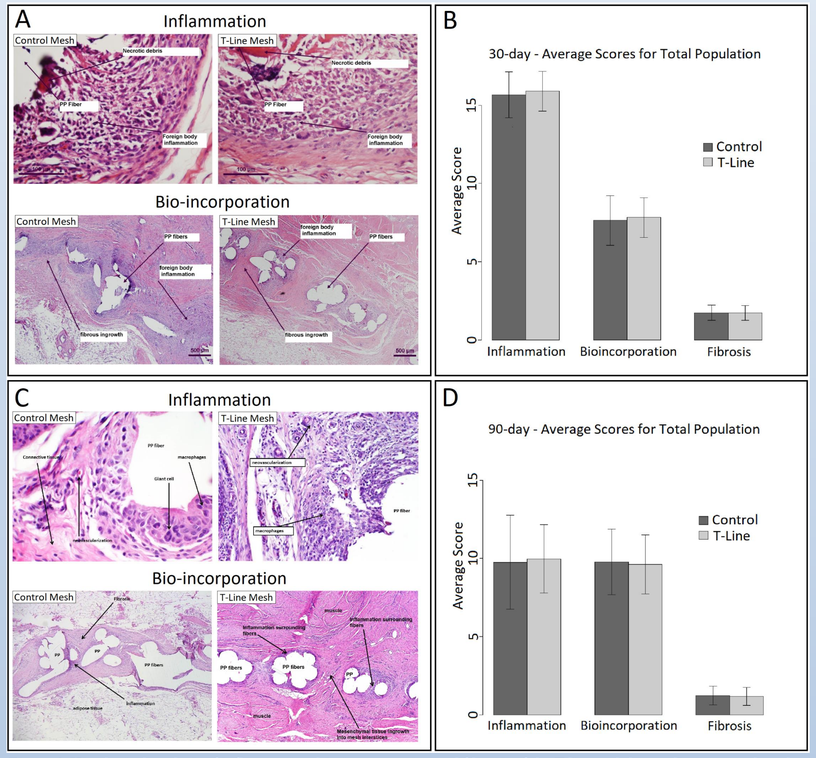


**Figure 4. Histological analysis of inflammation, bio-incorporation and fibrosis of the T-line and the predicate control mesh.** Microscopic images demonstrating inflammation and bio-incorporation after (A) 30 days and (C) 90 days. Quantification of the average scores of inflammation, bio-incorporation and fibrosis of the T-line mesh and the control predicate mesh after (B) 30 days and (D) 90 days. There was no statistically significant difference between T-line and control mesh (P>0.05).

## CONCLUSION

- T-line Hernia Mesh exhibits supra-physiologic anchoring strength overcoming the most common failure mode of current hernia meshes

| Maximum Physiologic Force | T-line Hernia Mesh Anchoring | Predicate Mesh Anchoring |
|---|---|---|
| 16 N/cm | 26.9 N/cm | 9.8 N/cm |

- Meets early safety standards for implantation in humans
- Results support ongoing commercial development of a novel T-line mesh with enhanced tension-free repair for durable hernia repair and prevention

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Dr. Levinson is a founder of Deep Blue Medical Advances Inc (DBMA) which has licensed the technology from Duke University. Dr. Ruppert is employed by DBMA and is an equity stakeholder.

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