Novel Mesh Anchoring Extensions Address Hernia Recurrence

Howard Levinson, MD and David S. Ruppert, PhD

INTRODUCTION: ~345,000 ventral hernia repairs performed annually in the US and recurrence is the leading complication (~30% ten-year recurrence rate)[1,2]. Anchor point failure at mesh/suture/tissue interface from abdominal tension believed to be a leading cause, resulting in mesh tearing from tissue, mesh migration, and mesh contraction.[3] T-line® Hernia Mesh with integrated anchoring mesh extensions, replacing suture, that are 30cm long, 2 cm on center (**Figure 1**) has been developed to overcome this problem. Mesh extensions are sewn into tissue distributing forces better than narrow suture. In ex-vivo benchtop testing, extensions lead to ~275% stronger peri-operative mesh fixation compared to predicate mesh when mesh anchoring is most susceptible to failure.[4] This study investigates T-line Hernia Mesh bio-incorporation for safety according to FDA standards to demonstrate substantial equivalence to a predicate mesh.

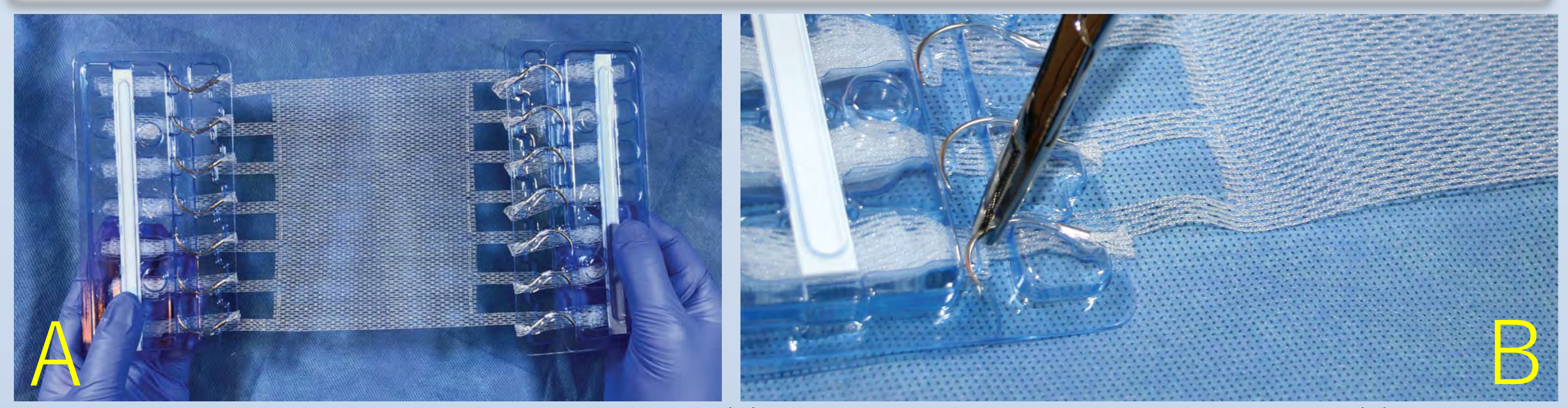


Figure 1. T-line Hernia Mesh and predicate control mesh. (A) T-line mesh with extensions in deployment trays (B) 0.5cm wide extensions emanating from body of textile w/ GS21 needles swaged on the ends of extensions.

MATERIALS AND METHODS:

- T-line Hernia Mesh was warp knitted from polypropylene and evaluated for physical and mechanical characteristics
- Lock-stitch (**Figure 2**) anchoring performance evaluated in swine abdominal tissue by distraction @100mm/min to failure on a servo-hydraulic materials testing system
- Implanted in swine as ventral hernia onlay (**Figure 3**) (n=4/group: 1, 3 and 6 months)
- Gross pathologic observations by board-certified veterinary pathologist on ventral wall containing hernia repair
- H&E staining to evaluate inflammation, bio-incorporation, & fibrosis

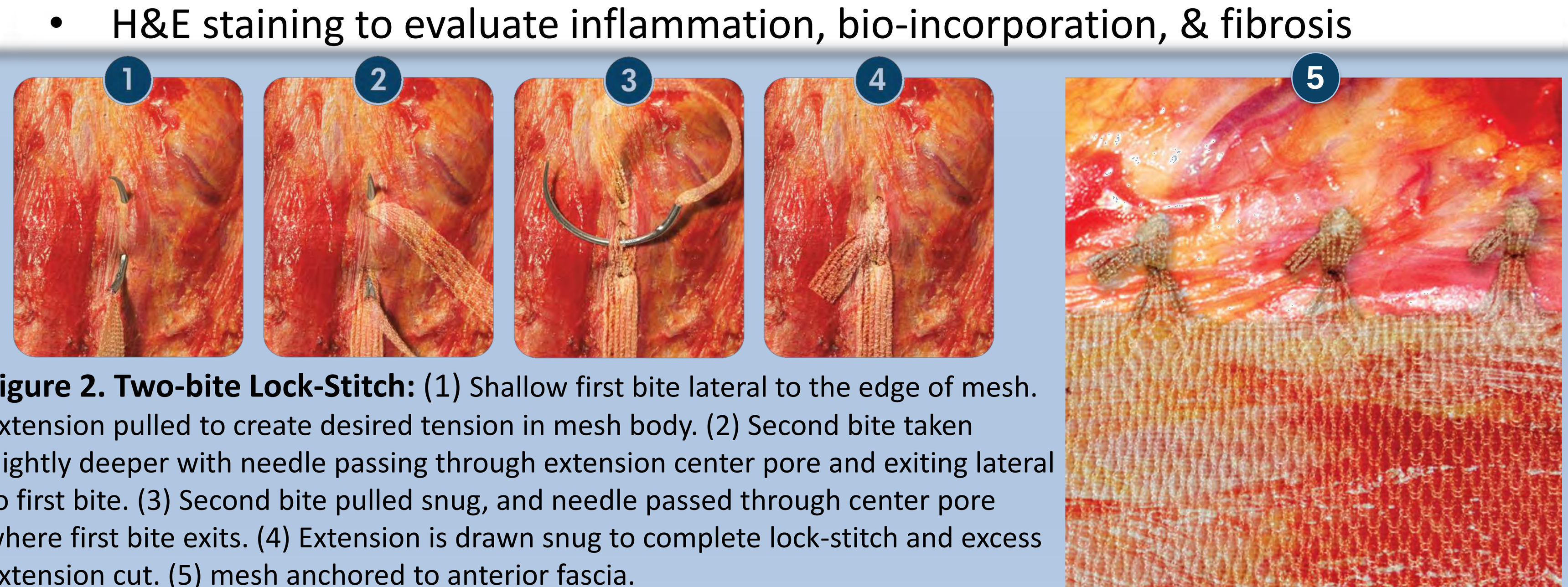


Figure 2. Two-bite Lock-Stitch: (1) Shallow first bite lateral to the edge of mesh. Extension pulled to create desired tension in mesh body. (2) Second bite taken slightly deeper with needle passing through extension center pore and exiting lateral to first bite. (3) Second bite pulled snug, and needle passed through center pore where first bite exits. (4) Extension is drawn snug to complete lock-stitch and excess extension cut. (5) mesh anchored to anterior fascia.

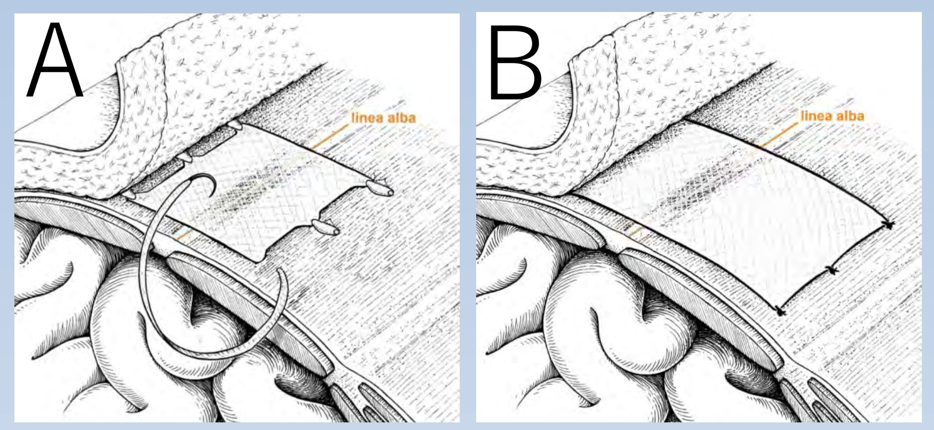


Figure 3. Application techniques for onlay placement. (A) T-line mesh body extends at least 2.5+ cm beyond fascia incision on all sides for adequate overlap onto healthy fascia. Extensions are sewn into fascia with two-bite lock-stitches (total mesh body + extensions ≥5 cm overlap from fascia incision). (B) Predicate mesh body extends 5 cm beyond fascia incision on both sides and 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 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
Equivalent Needle Size	GS21	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 of Lock Stitch

- T-line lock-stitch mesh >250% (P<0.001) stronger anchoring than suture and exceeded **32N/cm max** physiologic tension exerted on abdominal wall (e.g. coughing, jumping, lifting, etc.)[5]
- Failure modes: T-line mesh demonstrated one failure mode (textile failure), while predicate demonstrated two failure modes (>40% suture tearing completely through fascia and sutures breaking at the knot)

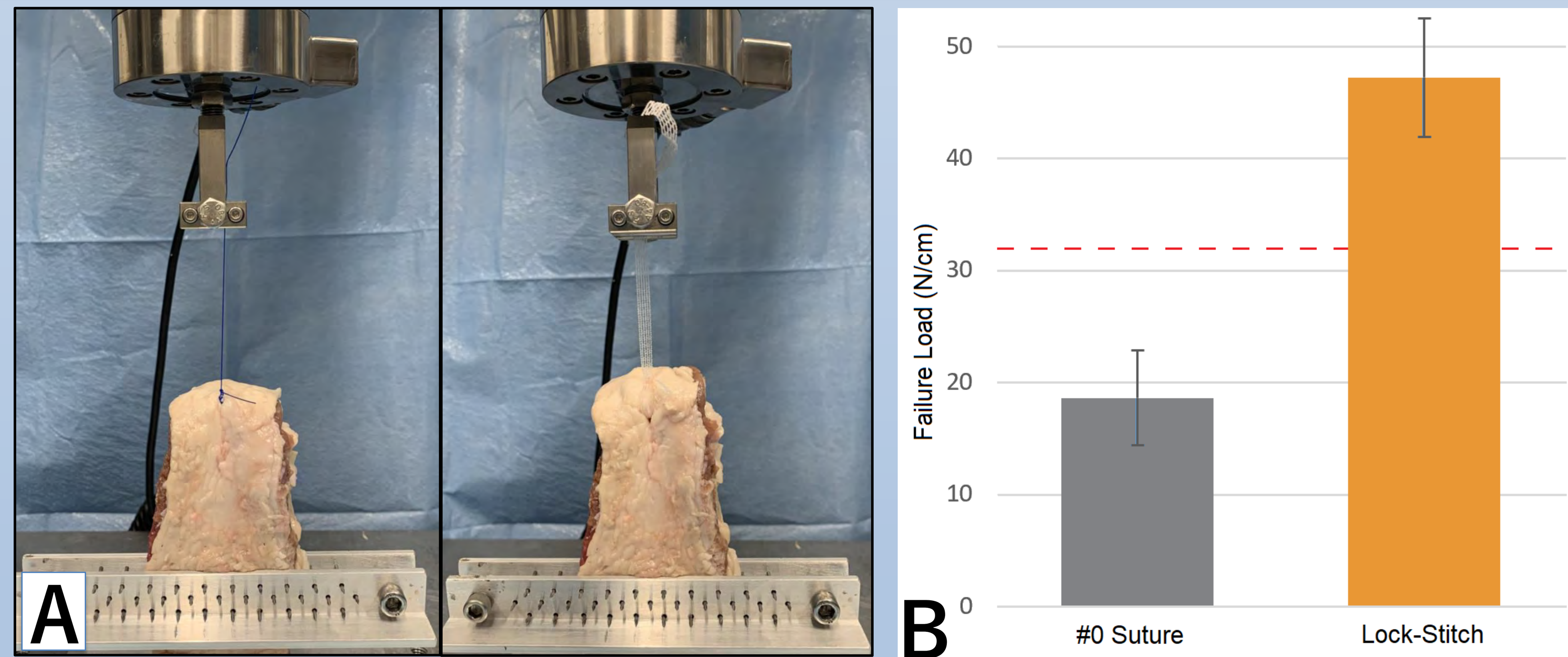


Figure 4. Bio-Mechanical Analysis of T-line Lock Stitch compare to predicate. (A) Gross images of representative samples during bio-mechanical testing for T-line mesh (right) and predicate mesh (left). (B) T-line mesh >250% stronger per unit length (P<0.001) than standard of care on peak load performance.

Bio-Incorporation Analysis at month 1, 3, & 6

- No significant macroscopic differences between T-line and predicate mesh
- H&E of GLP swine study (**Figure 5 & 6**) showed no statistical differences in inflammation, bio-incorporation and fibrosis at 1 month; however, greater bio-incorporation (P<0.005) and fibrosis (P<0.05 @ 3 months & P<0.005 @ 6 months) at 3 & 6 months in the T-Line group. Finally, there was significantly less inflammation at 6 months (P<0.001) in the T-Line group (**Figure 7**)
- Continual decrease in inflammation seen over time

Acknowledgements:
This work was supported by grants: 2R44GM117657-02 and 4UL1TR001117-04 from the National Institutes of Health (NIH); an NC Biotechnology Center Technology Enhancement Grant; a MedBlue Translational Grant; and an NC Biotechnology Center Small Business Research Loan. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or other funding agencies.
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.

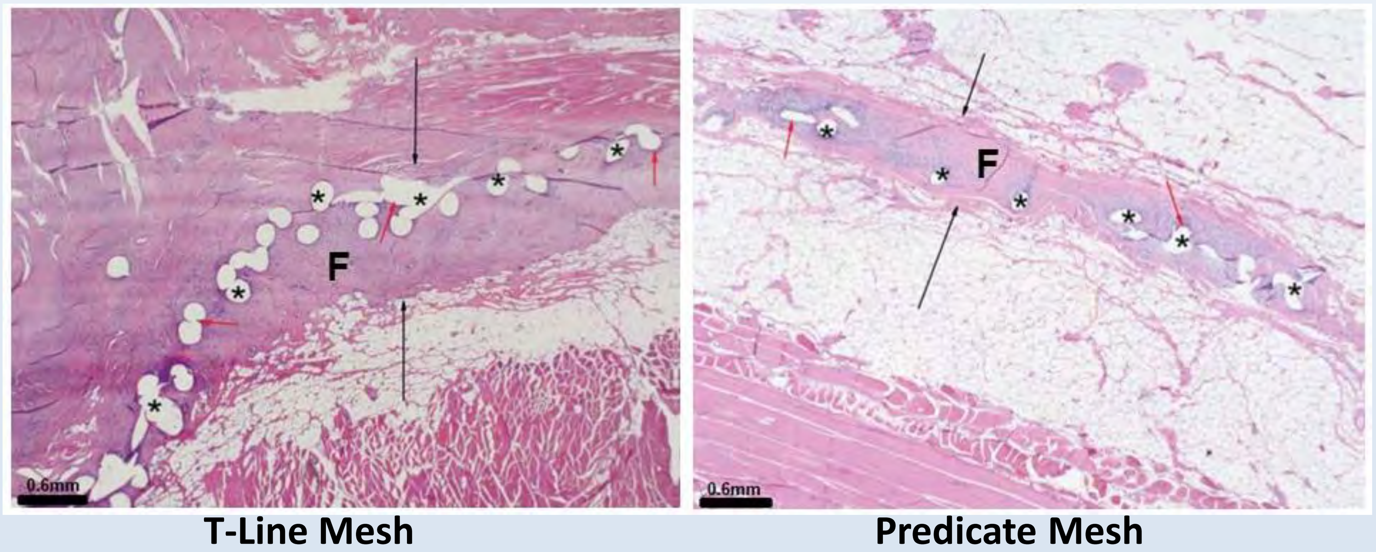


Figure 5. The mesh was composed of PP fibers (*). It was embedded in a fibrous tissue capsule (F) and surrounded by a narrow band of granulomatous inflammation (basophilic tissue at the tip of red arrows). Scale bar = 0.6mm under 2X magnification.

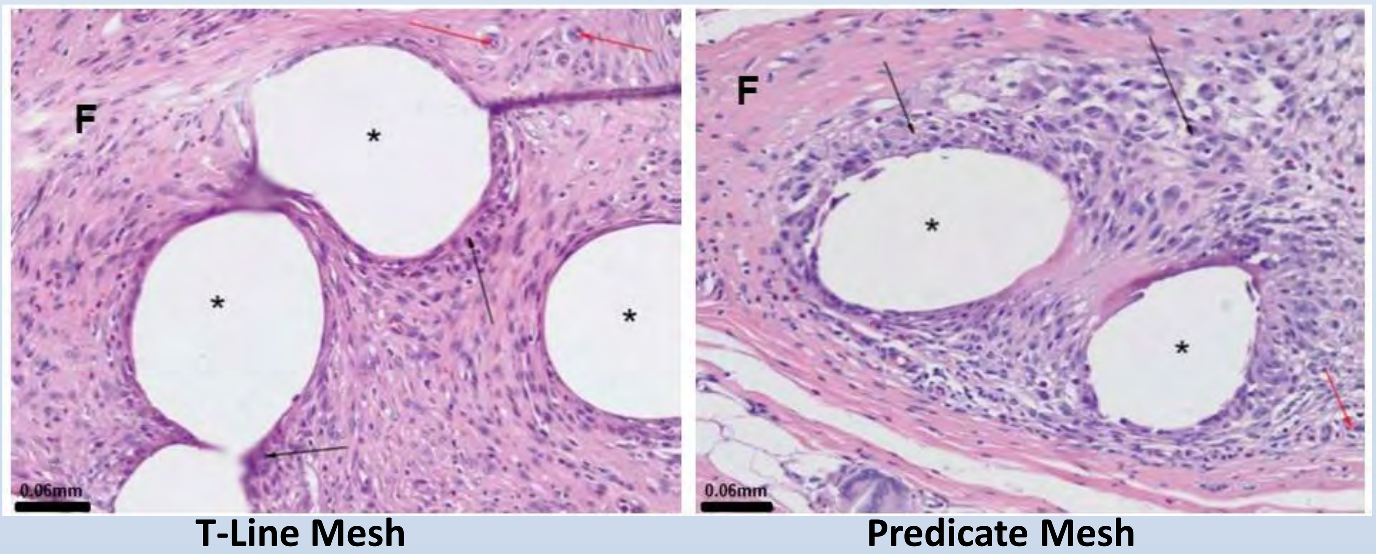
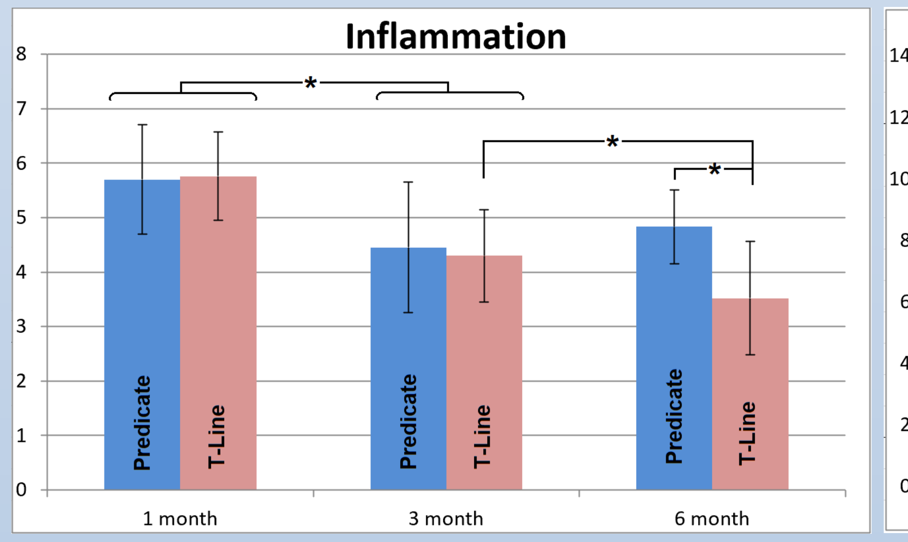


Figure 6. Fibrous tissue ingrowth (F) and a granulomatous inflammatory response (black arrows) were observed around and between the PP mesh fibers (*). Neovascularization (red arrows) was also visualized. Scale bar = 0.06mm under 20X magnification.



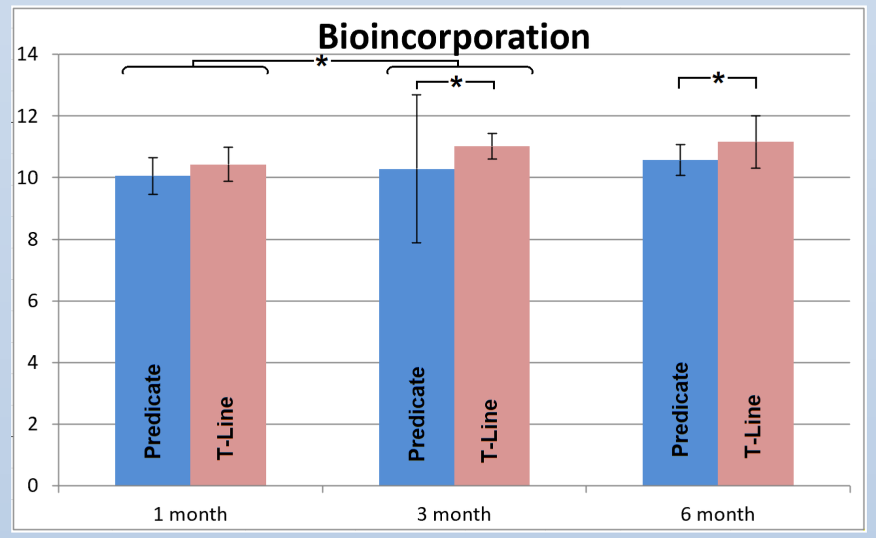
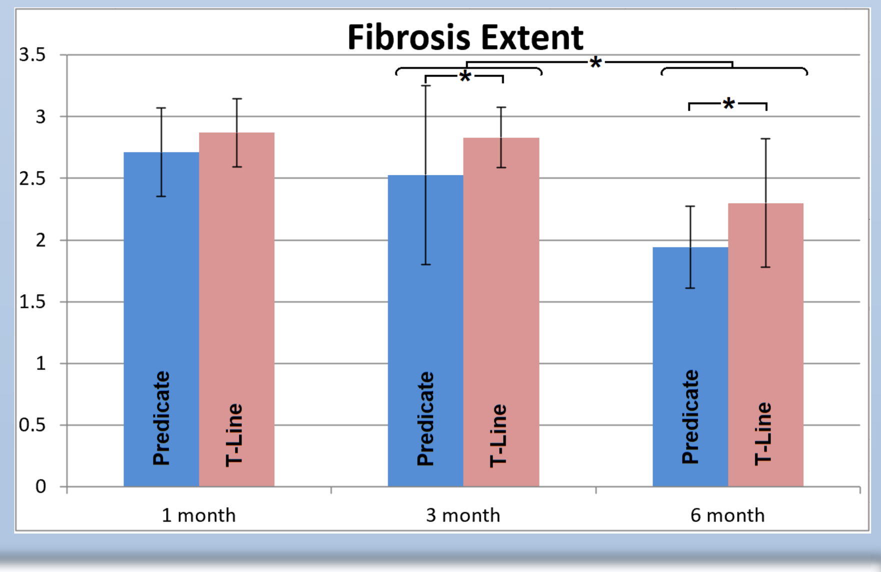


Figure 7. Histological analysis of inflammation, bio-incorporation and fibrosis of the T-line and the predicate control mesh. Quantification of the average scores of inflammation, bio-incorporation and fibrosis of the T-line mesh and the predicate mesh after 1, 3, & 6 months.
* indicates statistical differences (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[5]	T-line Hernia Mesh Anchor Strength	Predicate Mesh Anchor Strength
32 N/cm	47 N/cm	19 N/cm

- Meets early safety standards for implantation in humans
- Results supported FDA clearance of a novel T-line mesh with enhanced tension-free repair for durable hernia repair and prevention

References:
1. Hernia, US Market Report. Smart TRAK, 2017. (Accessed Oct 9th, 2017, 2017, at https://app.smarttrak.com/markets/qs/6561.)
2. Peralta R, Latifi R. Long-term outcomes of abdominal wall reconstruction. What are the real numbers? J World journal of surgery 2012;36:534-8
3. Lanier ST, Dumanian GA, Jordan SW, Miller KR, Ali NA, Stock SR. Mesh Sutured Repairs of Abdominal Wall Defects. Plast Reconstr Surg Glob Open. 2016; 4(9): e1060
4. Ibrahim M, Green J, Everitt J, et al. Soft Tissue Anchoring Performance, Biomechanical Properties, and Tissue Reaction of a Now Hernia Mesh Engineered to Address Hernia Occurrence and Recurrence. J Med Device. 2019; 13(4): 21-29.
5. Pott PP, Schwarz ML, Gundling R, et al. Mechanical properties of mesh materials used for hernia repair and soft tissue augmentation. *PLoS One* 2012; **7**: e46978