

Bioscaffold Mesh: Comparison Between Gore Bio-a And Ovitex

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Introduction

The objective of this study is to compare two types of bioscaffold meshes: OviTex from Tela Bio and Gore Bio-A from Gore Medical.

First generation mesh is based on polypropylene which has high tensile strength but creates a sustained inflammatory response, increased susceptibility to infection, and pain. Second generation mesh is based on combinations of synthetic materials. These meshes have initial low cost, high biomechanical strength and durability but increased inflammation, risk of infection, and pain response. Third generation mesh is made from biologic materials which have better biocompatibility and allows for revascularization but at a high cost and increased laxity.

Newest meshes include OviTex and Gore Bio A. OviTex is a combination of biologic layers with interwoven synthetic material to capitalize on the benefits of both products. Gore Bio A is a web of biocompatible synthetic polymers with a matrix of 3D pores to promote rapid cellular infiltration and vascularization.

Methods and Procedures

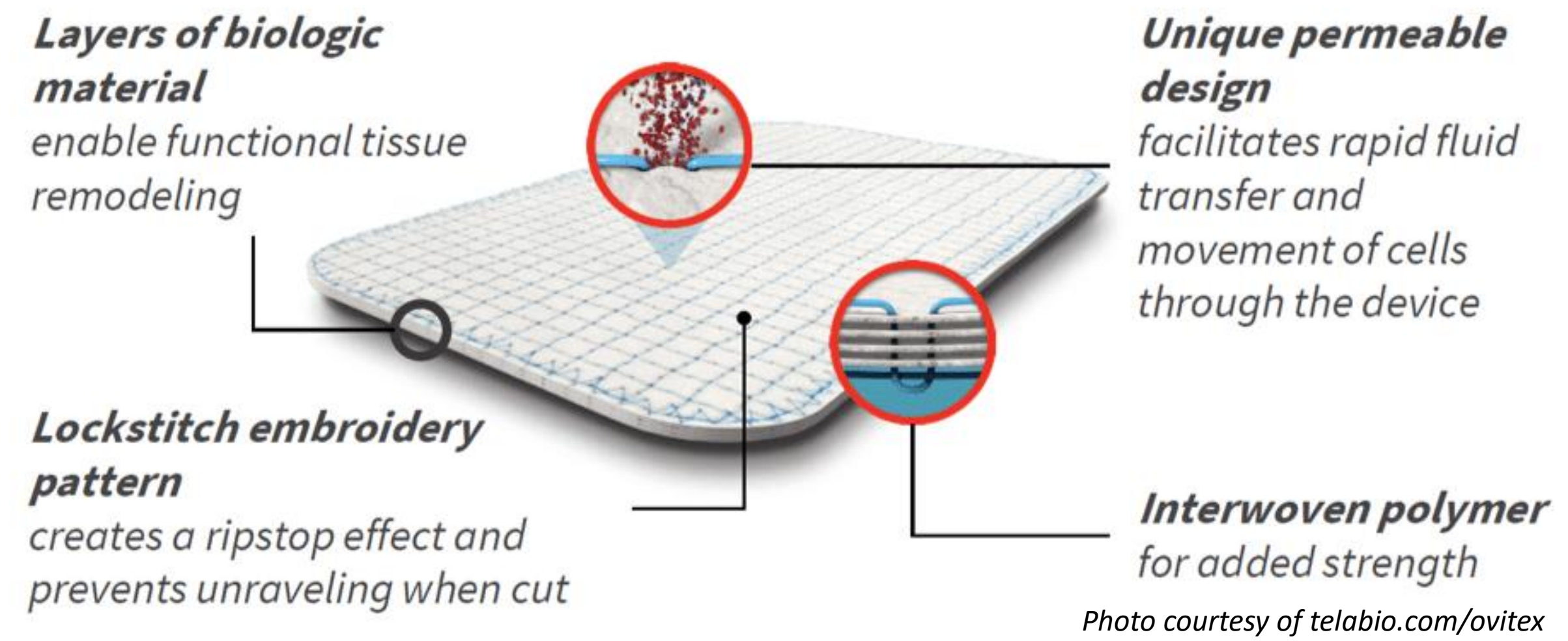
A literature search across PubMed, Tela Bio, and Gore Medical was performed using the following search terms: "OviTex", "Gore Bio A" and "Mesh Hernia Repair". Articles corresponding to these search terms were individually reviewed by the primary and secondary author, then selected based on relevance.

Results

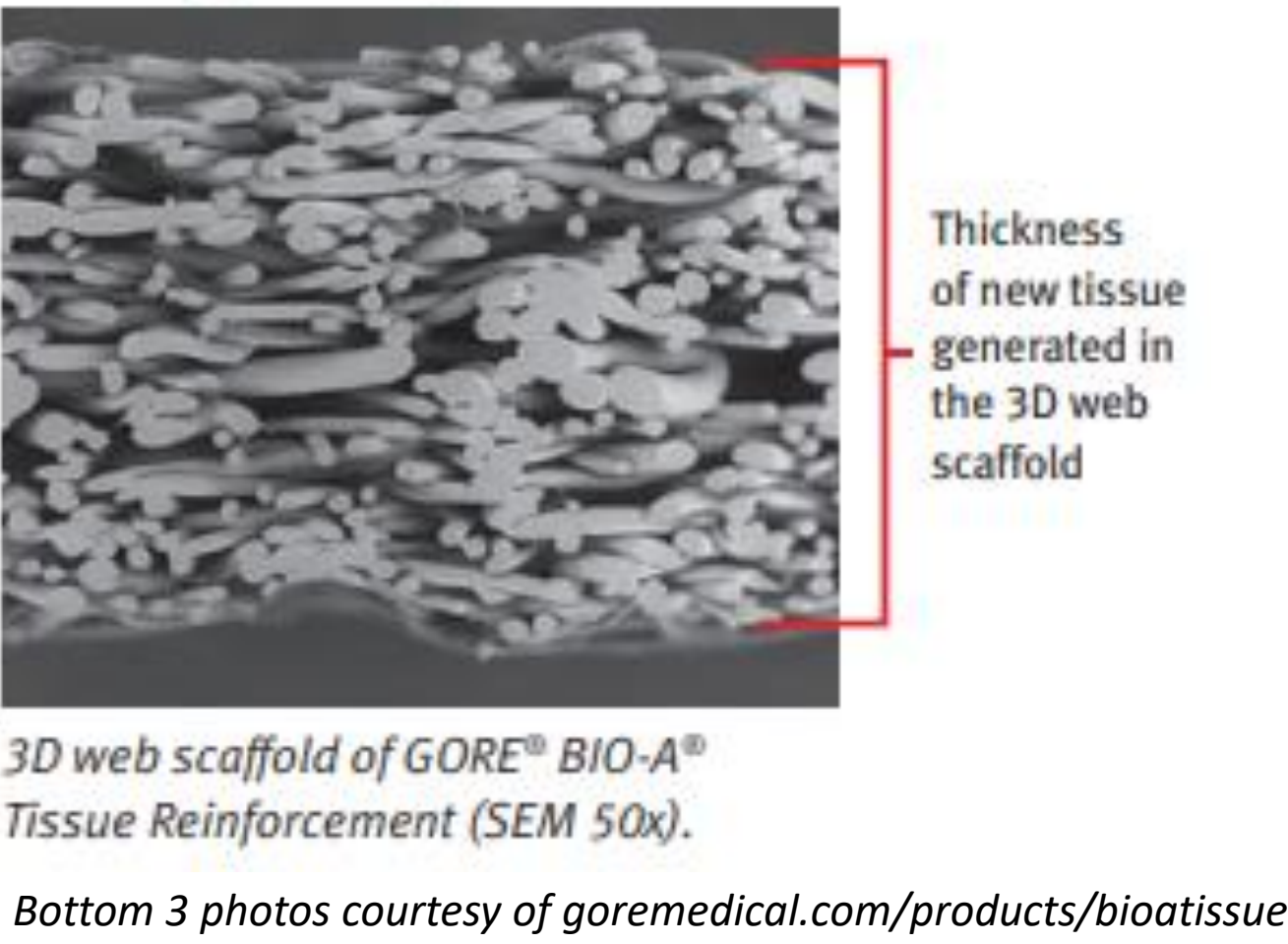
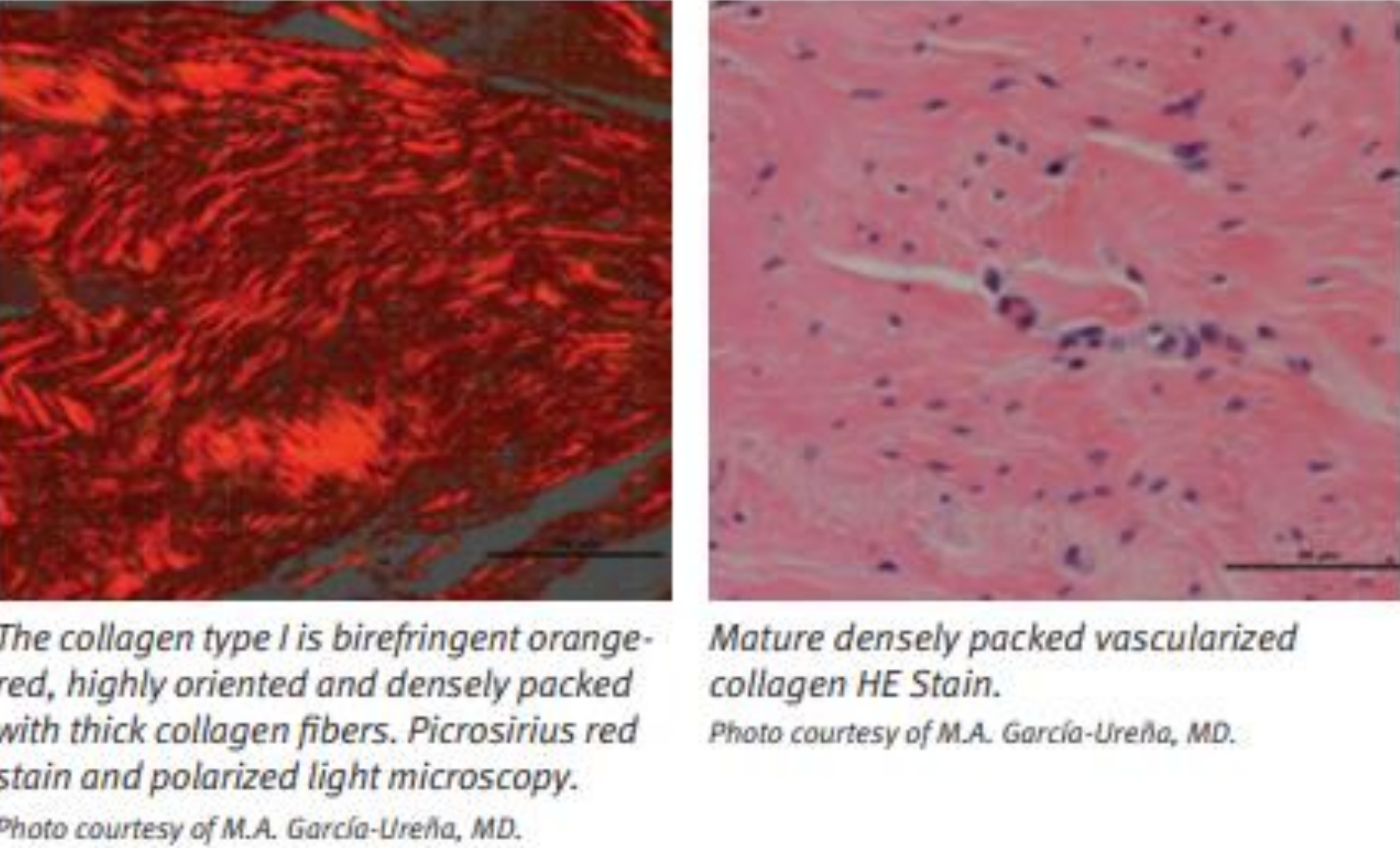
As OviTex is a newer product, majority of findings were case report series. Overall, The BRAVO study and several case series were compiled to analyze the performance of OviTex used in various hernia repairs ranging from incisional to abdominal wall reconstruction. The cases encompassed 69 patients with follow up ranging from 4-17 months and showed no recurrence, infection, explantation, or complications. Select cases below:

- Bravo Study
 - 32 patients that underwent ventral hernia repairs with an average of 1 year follow up
 - No recurrence, explantations, device failures
- Ventral Hernia Published Case Series
 - 1 repair of open abdominal incisional herniorrhaphy
 - 2 incisional hernia repairs
 - At an average of 16 months post-op, no post-op discomfort, no signs of recurrence, no seromas
- Mesh Performance in Hernia Repair 2017
 - Case 1
 - incarcerated parastomal hernia, midline incisional hernia
 - 17-month follow-up, repairs of both midline and parastomal hernias remained intact, with no evidence of recurrence.
 - Case 2
 - repair of an incisional hernia of her long midline incision, and abdominal wall reconstruction
 - At 4 months – no issues, on narcotic pain medications
 - At 9 months – no issues, off narcotic pain medications

OviTex, Tela Bio



Gore Bio-A, Gore Medical



Results Continued...

OviTex

- Mesh Performance in Hernia Repair 2017
 - Case 3
 - Recurrent incarcerated right lower quadrant incisional hernia and left upper quadrant incisional hernia
 - 15-month follow-up, both hernia repairs remained intact, with no evidence of recurrence

Gore Bio-A had more cases and studies available regarding its performance as it has been on the market longer. Cases ranged from incisional repair to abdominal reconstruction and complex repair. Data includes several case series as well as a Bench-to-Bedside report from the 2018 International Hernia Congress. In total, 289 patients with follow up ranging from 6 months to 1 year showed no cases of early recurrence or complications. Select cases below:

- Crura augmentation with Bio-A mesh for laparoscopic repair of hiatal hernia
 - 100 patients followed over a median of 30 months showing recurrence free probability at 1 and 5 years of 0.99 (CI 0.97 – 1.00) and 0.84 (CI 0.74-0.97)
- Safety and efficacy of prophylactic resorbable biosynthetic mesh following midline laparotomy in clean/contemned field
 - 92 patients, ≥10 cm incision, followed for incisional hernia at 1- and 2-years post-op
 - Group A: closed in double layer with PDS 0 and WL/SL of 1:4, incisional hernia rate 11/47 (22%)
 - Group B: closure in double layer with PDS 0 and sub-lay of 3cm wide Gore BIO A strip for the length of incision, incisional hernia rate 3/45, 6%
- Mesh Selection for Hernia Repair: Expert Review Of Biologic, Synthetic, and Bioabsorbable Types
 - Paper documenting 10 ventral hernias, 33 complex repairs, 32 inguinal hernias, and 66 non-specific hernia repairs
 - At an average of 1 year follow up, no mesh related complications or chronic pain were reported by patients

Conclusions

In conclusion, the use of biosynthetic mesh in hernia repair appears to safe, effective, and durable over a medium-term follow up. Based on available data, Gore Bio-A is recommended as it encompasses a larger study population in addition to having a published cost management study showing a \$340,000 (66%) cost savings in comparison to biologic mesh, with no change in quality outcomes at a leading Midwest medical center.