OviTex

January, 2023

Device

OviTex by TelaBio is a sterile, reinforced, bioscaffold matrix comprised of ovine (sheep) rumen (forestomach) extracellular matrix (ECM).[1,2] The matrix is approximately 95% biologic material and 5% polymer. The mesh is made of intertwined polymer fibers in a pattern stitch that creates an embroidered construction. This structure provides additional reinforcement for better handling and load-sharing ability to support abdominal wall function in hernia repair as well as plastic and reconstructive surgery. The polymer holds the biologic layers together and provides additional strength in the early healing phase. The scaffold is either made of permanent and/or resorbable material interwoven with the ECM.[1]

OviTex, OviTex 1S, OviTex 2S, OviTex LPR are used in reconstruction of abdominal wall deformities and hernia repair, while OviTex PRS is recommended for use in plastic and reconstructive surgery.[1] The OviTex 1S and OviTex LPR consist of a smooth side and a textured side. The textured side is a blue polypropylene which provides a surface conducive for tissue ingrowth. The smooth side contains a clear polypropylene designed to minimize tissue attachment.[1]

U.S. Food and Drug Administration Approval and Indications for Use

OviTex received FDA 510(k) clearance (K141053) in December of 2014 for the intended use in reinforcing and repair in soft tissue, abdominal wall hernia, and other body wall weakness repairs.[3]

Clinical Data

There are a number of industry sponsored studies that demonstrate safety and effectiveness of the OviTex product. A search for non-industry sponsored studies regarding the use of OviTex revealed the two studies outlined below.

- A 2020 cohort study was completed on 50 patients undergoing ventral hernia repair with TELA Bio OviTex biosynthetic or synthetic mesh.[4] Overall readmission rates were 24% for OviTex and 14% with synthetic mesh ($p = 0.31$). For those that experienced OviTex, recurrence rates were lower at 6% compared to 12% ($p = 0.74$) with synthetic mesh. The study authors concluded that biosynthetic mesh performed better in higher risk patients. Limitations of the study included selection bias as it related to mesh used, single institution, and limited 1-year study.[4] Additional independent prospective studies to confirm and to further validate study findings are needed.
- A retrospective study was completed on 141 ventral hernia repair patients between 2002 and 2020. Mesh used included noncross-linked porcine acellular dermal matrix (ADM) ($n = 51$), cross-linked porcine ADM ($n = 17$), reinforced biologic ovine rumen ($n = 36$), and bovine ADM ($n = 37$). Recurrence rates for patients who received reinforced biologic ovine rumen mesh were the lowest at 2.78%, compared to the other meshes with rates ranging from 13.7% to 29.4% ($p = 0.022$). Limitations included a small sample size and the study being of retrospective type. [5]

References

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3. Food and Drug Administration. FDA Approval. Published December 11, 2014. Accessed December 28, 2022. https://www.accessdata.fda.gov/cdrh_docs/pdf14/K141053.pdf
4. Parker MJ, Kim RC, Barrio M, et al. A novel biosynthetic scaffold mesh reinforcement affords the lowest hernia recurrence in the highest-risk patients. Surgical endoscopy. 2021;35(9):5173-5178. doi:10.1007/s00464-020-08009-1
5. Sivaraj D, Henn D, Fischer KS, et al. Reinforced Biologic Mesh Reduces Postoperative Complications Compared to Biologic Mesh after Ventral Hernia Repair. Plast Reconstr Surg Glob Open. 2022;10(2):e4083. Published 2022 Feb 7. doi:10.1097/GOX.0000000000004083

Initial or Update	Date	Completed by	Changes Made
Updated	12/28/2022	JU	Updated