



Risk Profiles of Surgical Mesh for Transvaginal Pelvic Organ Prolapse

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Disclosures

Currently employed by and owns stock in ACell, Inc., which commercializes urinary bladder matrix (UBM) under the brand names MatriStem[®], MatriStem UBM[™], Cytal[®], Gentrinx[®] and MicroMatrix[®].

The purpose of the presentation is scientific education, not promotion. Any off-label discussion is only intended describe a scientific principle.

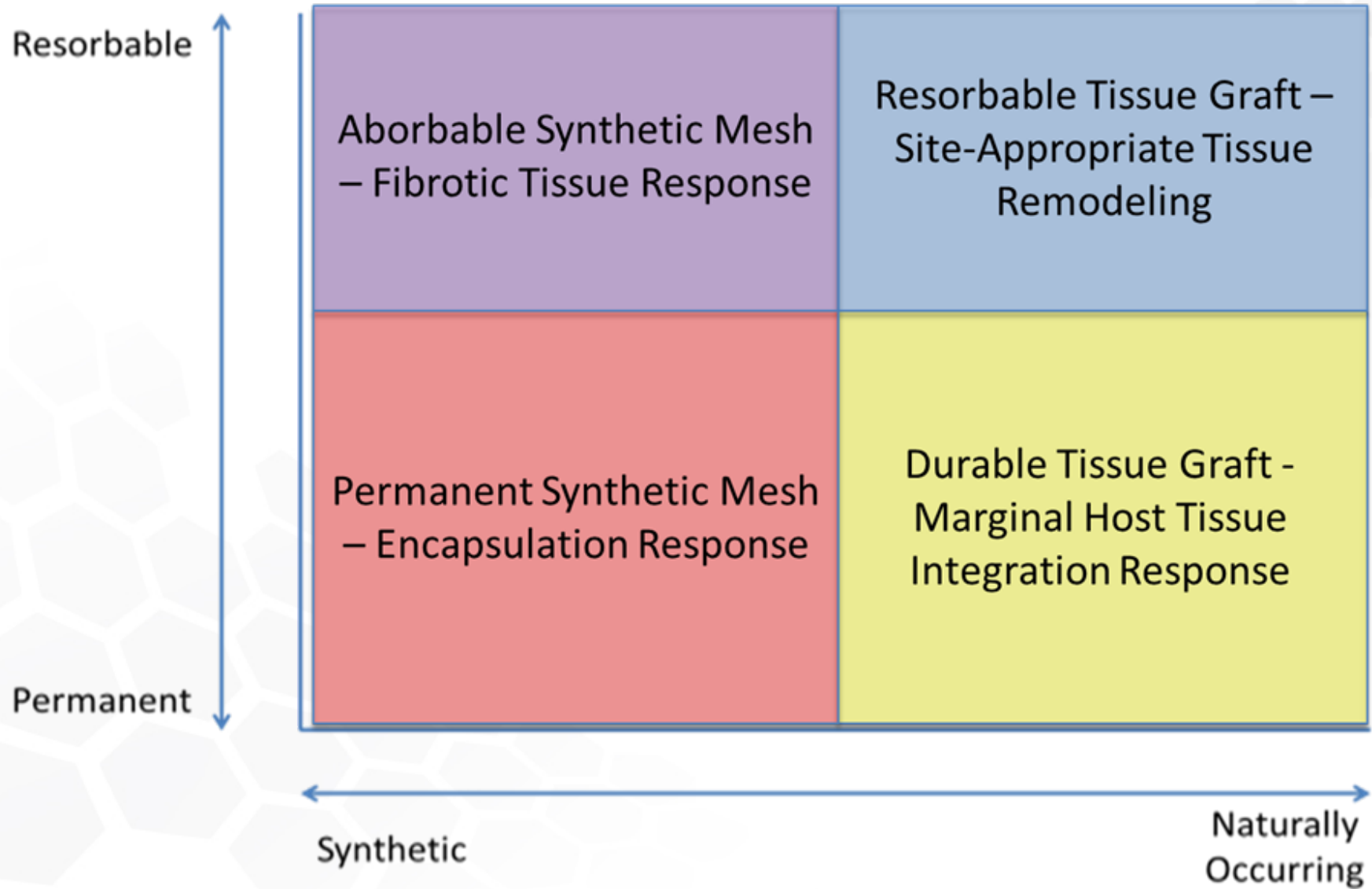
Preclinical data may not reflect clinical results.

Classification of Surgical Mesh

- There are terms being utilized to describe new surgical mesh, but there are simple definitions that summarize all products
- Durability
 - Permanent – Always present, biologically inert
 - Resorbable – Temporary scaffold, subject to hydrolytic or enzymatic degradation
- Source
 - Synthetic – Manufactured by chemical processes, especially to imitate a natural product
 - Naturally-derived – Biological scaffold processed to preserve native structure and composition



Classification of Surgical Mesh

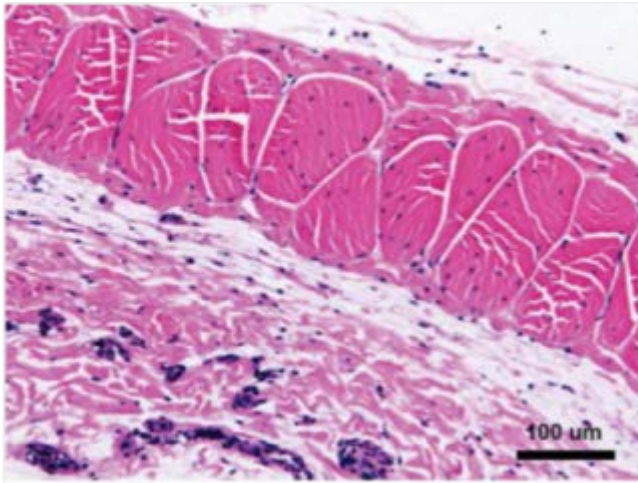


Approximate; Not to Scale

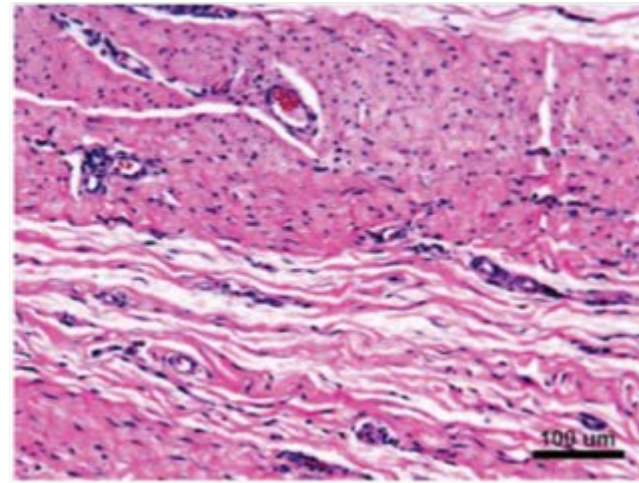
Various Material Types Elicit Different Host Responses

Native
Tissue

Native Fascia

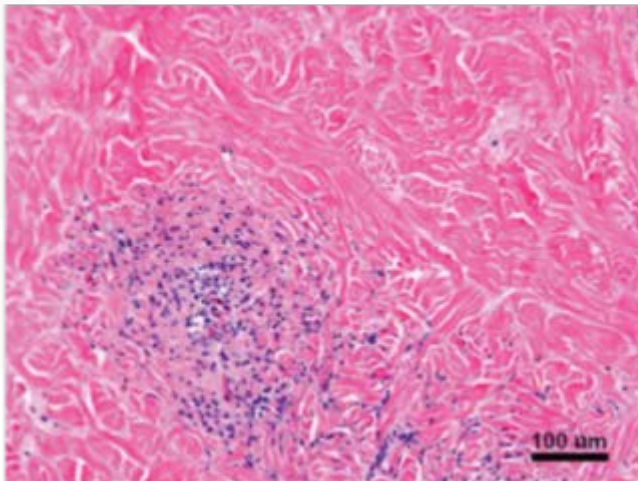


Gentrix



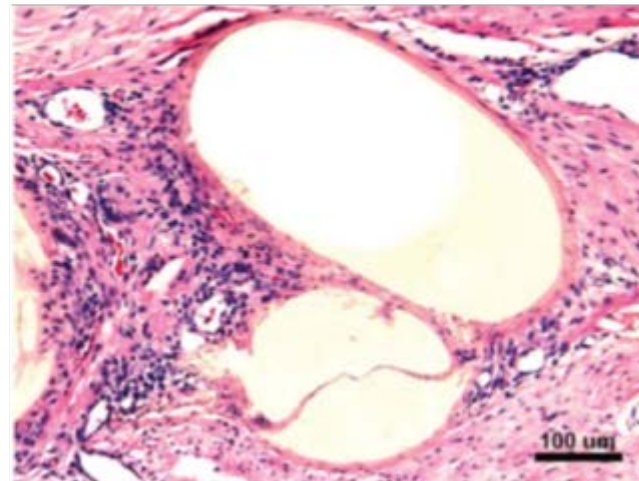
Resorbable
Tissue
Graft

Strattice



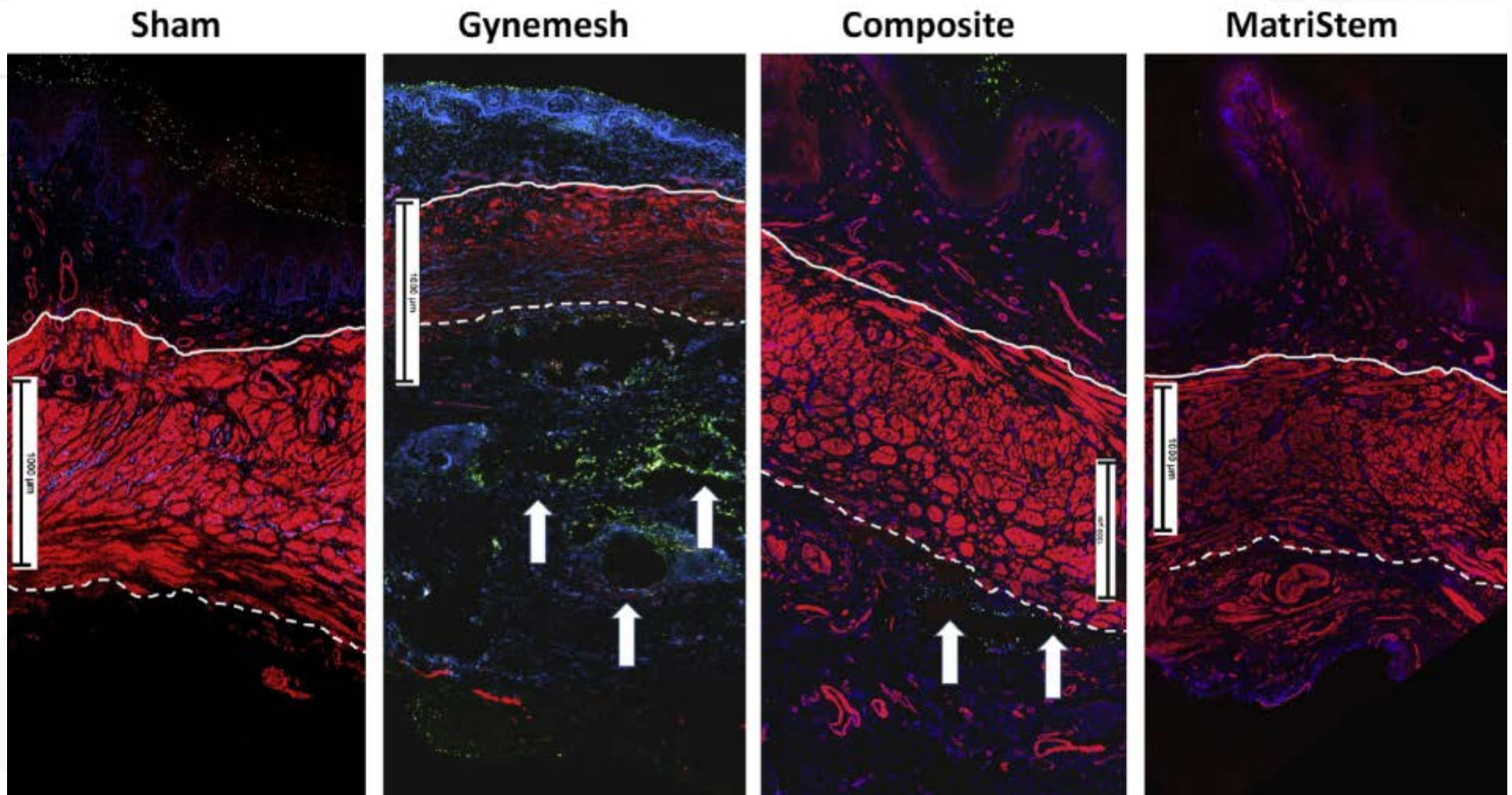
Durable
Tissue
Graft

Phasix

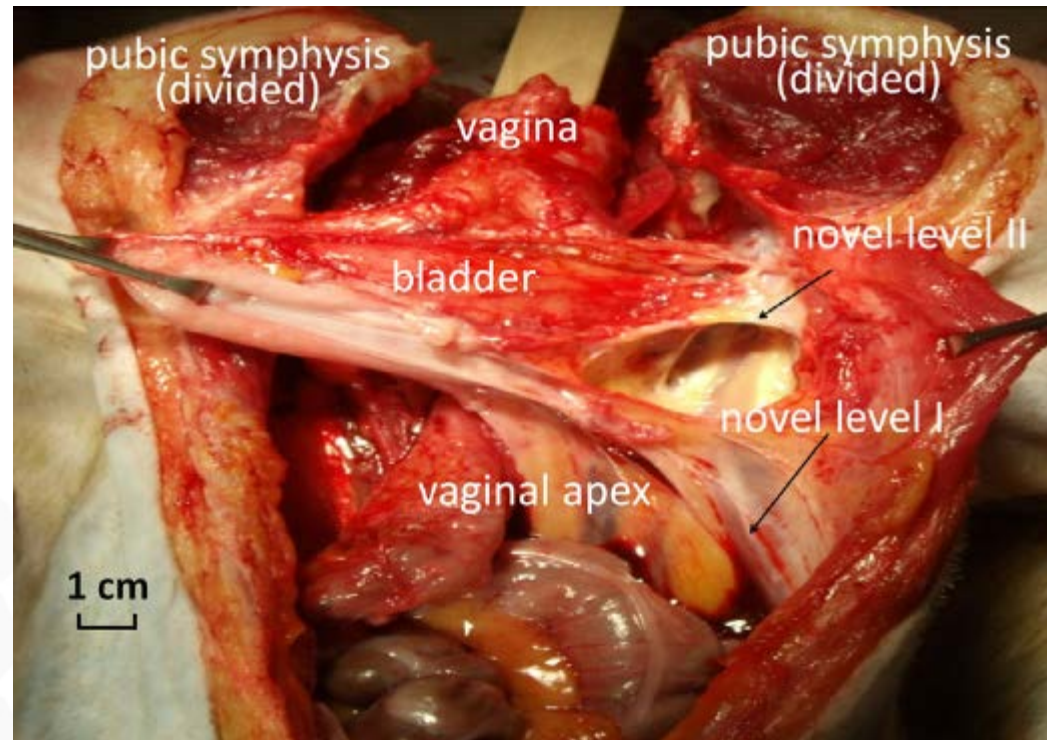


Absorbable
Synthetic
Mesh

Vaginal Tissue Response to Permanent Synthetic and Resorbable Tissue Graft



Resorbable Tissue Graft Remodeled into Robust Support Tissue



	Stiffness (N/mm)	Ultimate Load (N)	Extension (mm)	Energy Absorbed (N/mm)	Thickness (mm)
Sham	35.8 (30.6, 49.5)	154.9 (95.8, 172.2)	11.7 (10.0, 12.8)	413.5 (248.1, 495.7)	4.7 (2.5, 9.2)
MatriStem TA	32.5 (30.2, 61.6)	163.1 (106.4, 222.9)	20.6 ^a (20.6, 24.0)	544.6 (289.1, 625.0)	5.8 (4.9, 6.6)
MatriStem TV	19.7 ^a (10.9, 24.6)	61.7 (36.1, 116.5)	19.4 (18.2, 23.2)	201.7 (141.5, 311.9)	4.5 (2.5, 6.6)
P*	0.061	0.127	0.035	0.12	0.50

Different Host Responses Lead to Different Risk Profiles

- Permanent Synthetic Mesh, Absorbable Synthetic Mesh, and Durable Tissue Grafts have a higher risk of erosion or extrusion due to geometry and persistence
- Absorbable Synthetic Mesh and Resorbable Tissue Grafts have a higher risk of recurrence
- We encourage the FDA not to take a one size fits all approach, but rather define the appropriate rigor and duration of investigational studies based upon the reasonable risks for each device.