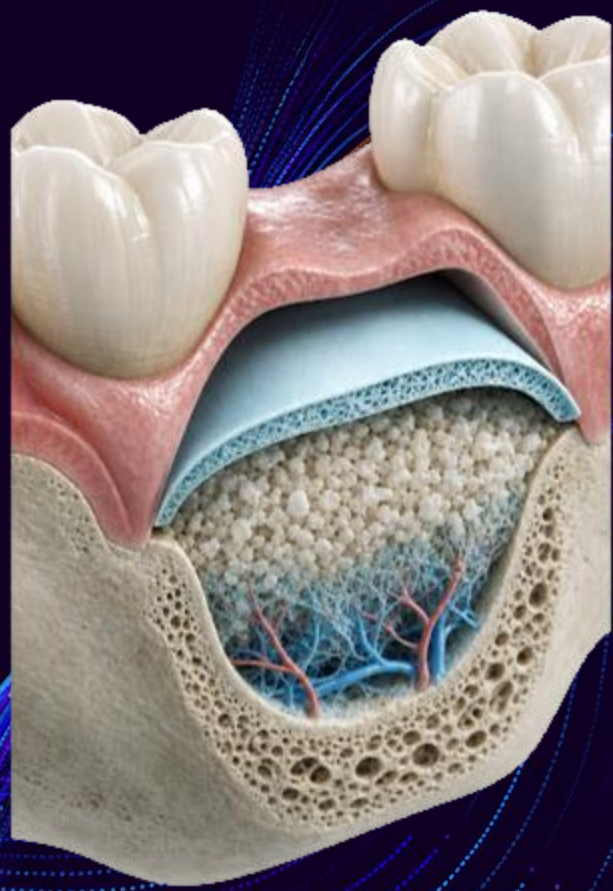
Translational Evaluation of Novel Amino-acid based Membrane for GBR

Designable microarchitecture, preclinical performance, and operational relevance

MHSRS-26-4553 · CRITICAL CONCERNS IN OPERATIONAL DENTISTRY

Sherif Soliman, PhD, MBA
Matregenix, Inc. · MHSRS 2026



Disclosure, Investigational Status, and Disclaimer

Financial disclosure

Dr. Sherif Soliman is Founder and Chief Executive Officer of Matregenix, Inc. and has an equity and financial interest in the PEU membrane technology discussed.

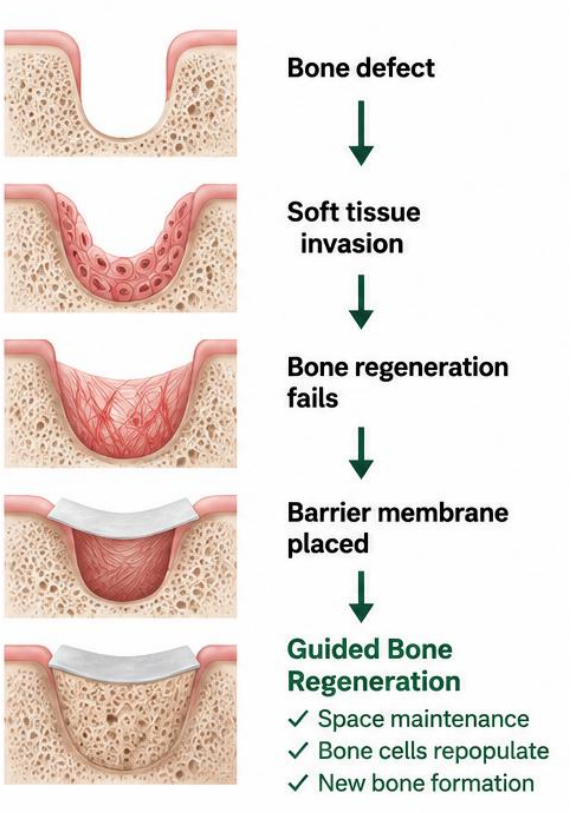
Investigational technology

The barrier membrane is investigational and is not cleared by the U.S. Food and Drug Administration. This presentation includes preclinical, in vitro, and company-supplied feasibility data.

Required disclaimer

The views expressed are those of the presenter and do not necessarily reflect the official policy of the Department of Defense, Defense Health Agency, Uniformed Services University, National Institutes of Health, or the U.S. Government. Mention of commercial products does not imply endorsement.

Barrier Membranes: The Foundation of Guided Bone Regeneration



Five classic design criteria (Scantlebury, 1993)

Biocompatibility	Low tissue reactivity; avoids inflammation-driven dehiscence
Cell occlusivity	Blocks soft-tissue cell ingrowth into the compartment
Space maintenance	Resists collapse to preserve regenerative volume
Tissue integration	Anchors to host tissue and supports vascular contact
Clinical manageability	Handles, conforms, and stays stable when wet

Optimizing one criterion usually forces a compromise in another — no single existing material wins on all five.

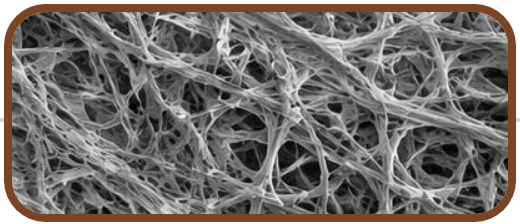
GBR/GTR principles synthesized from Elgali et al., Eur. J. Oral Sci. 2017; Scantlebury, J. Periodontol. 1993. No comparative outcome claim.

Why Do We Still Need Better GBR Membranes?

Current Barrier Membranes

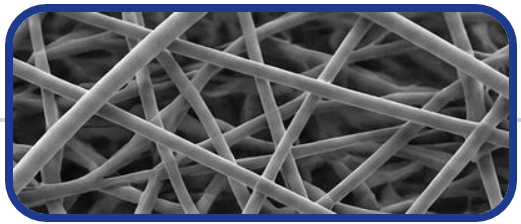
COLLAGEN MEMBRANES

- ✓ Excellent biocompatibility
- ✓ Native ECM-like structure
- ✗ Low mechanical strength
- ✗ Rapid degradation
- ✗ Animal-derived variability



SYNTHETIC MEMBRANES

- ✓ Better mechanical properties
- ✓ Controlled manufacturing
- ✗ Acidic degradation products
- ✗ Potential inflammatory response
- ✗ Difficult to handle

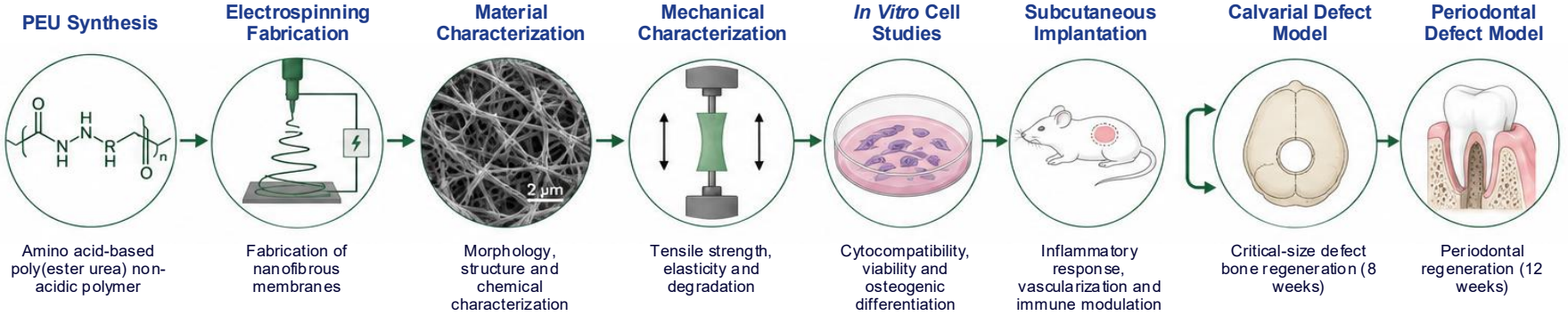


Study Hypothesis and Design

Study Hypothesis

“An electrospun amino acid–based PEU barrier membrane will achieve non-inferior biocompatibility and bone-regenerative performance compared with clinically used collagen membranes, while demonstrating superior handling characteristics and a more favorable cost–performance profile”

Study Design



Electrospinning: A Scalable, Animal-free Manufacturing Route

Minutes, not days

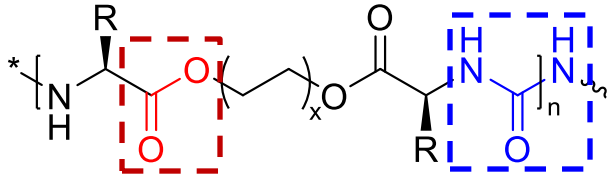
A 1 m² synthetic sheet is produced in minutes; equivalent donor tissue takes days to weeks to source and process.

Why it matters operationally

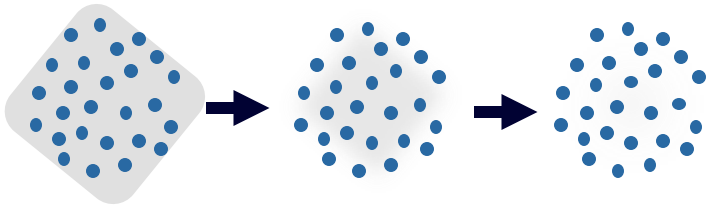
Scalable	Roll-to-roll deposition supports reproducible, higher-throughput production.
Cost-effective	Synthetic feedstock avoids costly tissue sourcing, purification, and screening.
Animal-free	No xenogeneic or donor material — no associated ethical or disease-transmission concerns.
Tunable	Fiber-scale control of mechanics, porosity, and degradation for a target indication.

Amino-acid–based poly(ester urea): A Novel Barrier Chemistry

Amino Acid-Based Poly(ester urea)s



Ester bonds **Urea bonds**



Uniform degradation & Non-acidic byproducts

Progress in Polymer Science **2024,** *156*, 101866.

Advantages

Versatile thermoplastic	• Many validated form factors • Film, tube, suture, mesh, scaffold
Synthetic Flexibility	• Tunable mechanical properties • Customizable degradation (weeks to months)
Biocompatible	• Non-toxic byproducts • Limited inflammatory response
Controlled drug delivery	• Drug stabilization • Uniform and sustained (days to weeks)

> 30 Publications w/ multiple Issued U.S. Patents: 9,988,492; 10,537,660; 10,280,261; 11,103,613 w/ others pending

Technology and Material Platforms Created MatriNova

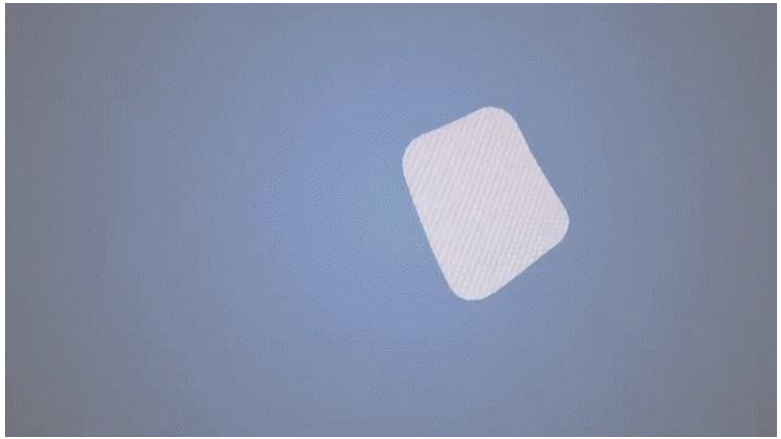
MatriNova: Electrospun PEU Platform for Tissue Repair

MATRINOVA SYNTHETIC MEMBRANE

A synthetic bilayer barrier membrane designed for GTR and GBR applications

Animal-free — no disease-transmission risk
Easier to handle
Designed for lower cost than biologics

SAFER • Easier Handling • LOWER COST



THE PLATFORM

One Material, Multiple Operational Indications

The amino-acid PEU platform is programmed at the fiber scale — thickness, pore size, and degradation tuned per indication

Dental GBR

Excludes soft tissue; guides alveolar bone and cementum regeneration.

Pre-clinical complete

Wound healing

Full-thickness wound matrix; ECM-mimetic, antimicrobial support.

Pre-clinical complete

Rotator cuff

Reinforcement scaffold for load-bearing tendon repair.

ovine feasibility

Ophthalmic

Synthetic "amniotic membrane" for the ocular surface.

program-stage

Dural repair

Watertight barrier for neurosurgical defects.

concept-stage

ONE CHEMISTRY · TUNED ARCHITECTURE · TISSUE FUNCTION

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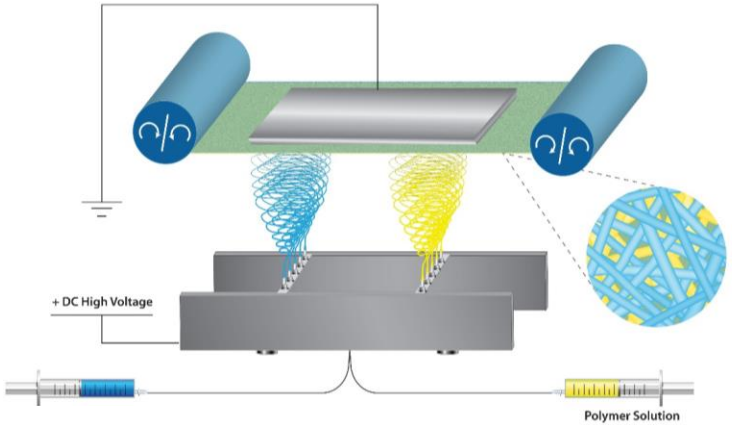
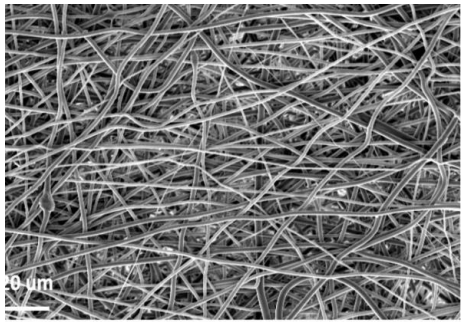
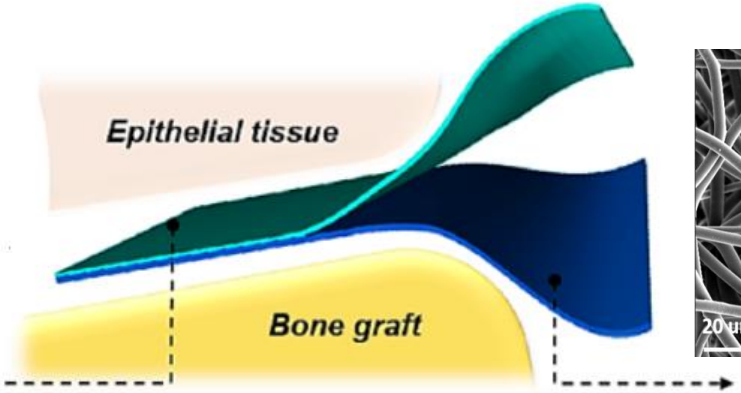
Electrospun PEU Bilayer Membrane Design

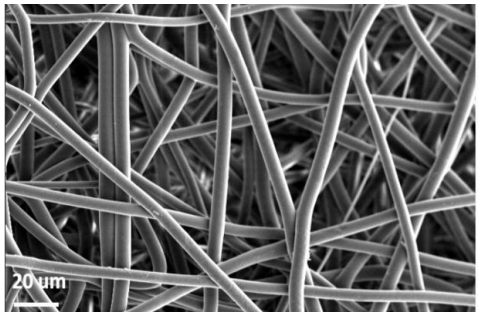
Bilayer Design

- **Small pore layer (SPL):** achieve the prevention of epithelial tissue ingrowth
- **Large pore layer (LPL):** encourage cell infiltration and guide bone tissue formation



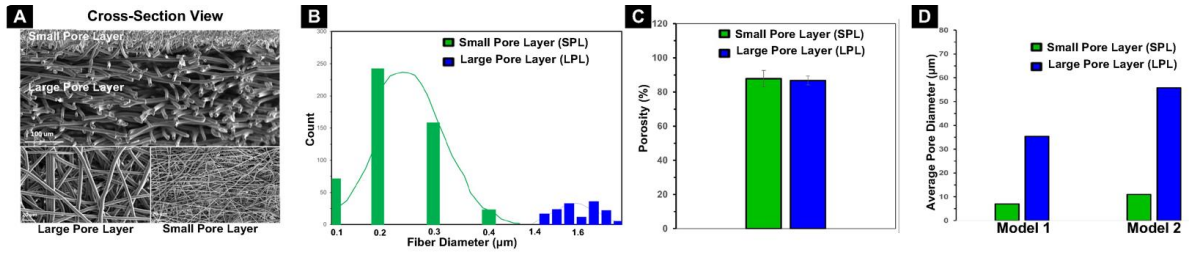






DESIGN FEASIBILITY

The Bilayer Architecture Separates Tissue Exclusion from Osteogenic Support

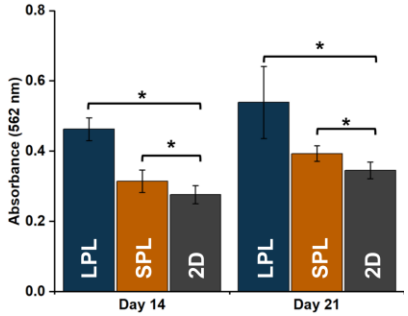


>90% porosity

in both small- and large-pore layers

≤10 / ≥50 μm

target pore regimes for barrier and regenerative faces



The large-pore layer increased mineral deposition

LPL exceeded SPL and 2D controls at days 14 and 21 (Alizarin Red; n=5; $p<0.05$). Proliferation differences were not significant.

The final bilayer still requires in vivo efficacy validation.

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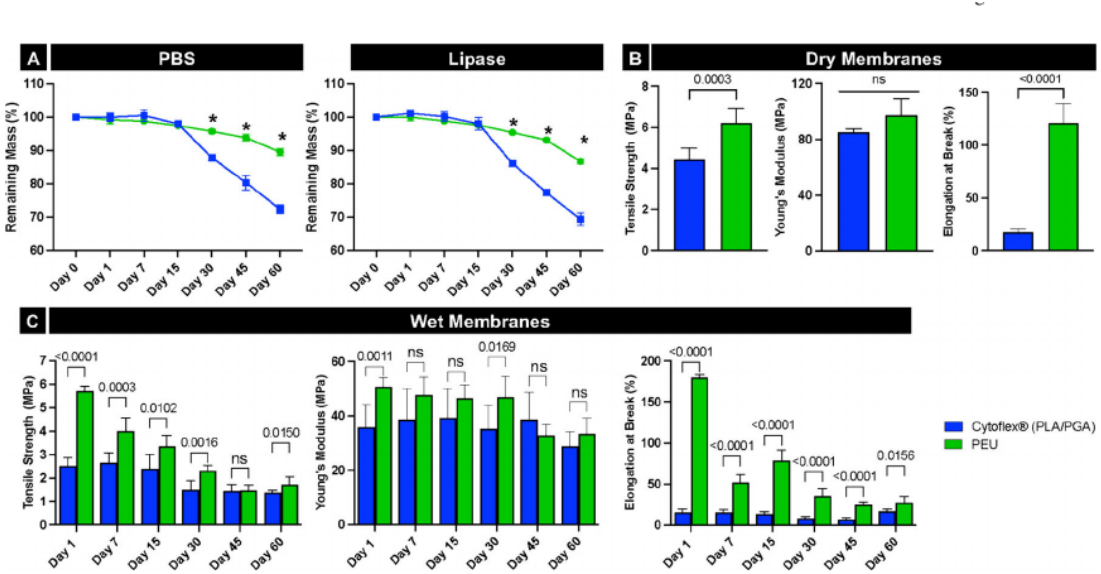
PEU Retained Mass and Mechanical Competence During the Early Healing Window



≈90% mass

remained at day 60 in the reported in vitro degradation study

6 MPa

dry tensile strength versus 4 MPa for Cytoflex® (p=0.0003)

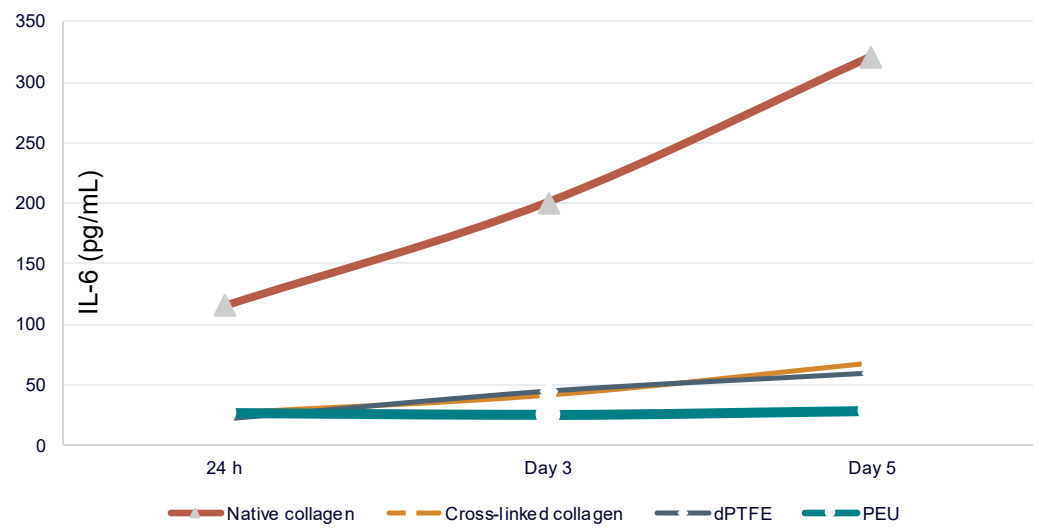
≈120%

elongation at break versus ≈17% for Cytoflex® (p<0.0001)

Interpretation: PEU combined persistence, strength, and conformability—properties relevant to placement and early space maintenance.

COMPLEMENTARY HOST RESPONSE

PEU Elicited a Lower Epithelial IL-6 Response than Native Collagen in-vitro



Stable through Day 5

PEU mean IL-6: 26.9 → 25.1 → 28.3 pg/mL

Lower than native collagen

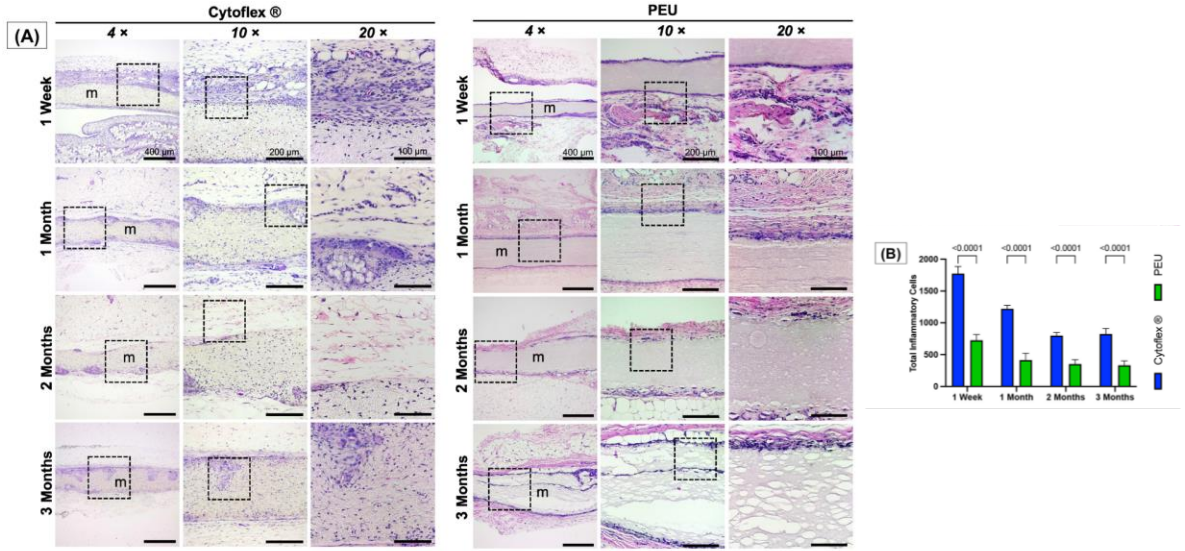
Native collagen increased to 321.0 pg/mL by Day 5; $p<0.05$ versus PEU at every timepoint.

In vitro epithelial model · n=9 per condition/timepoint

This complementary study supports a low pro-inflammatory epithelial signal; it is not a clinical outcome.

BIOCOMPATIBILITY

PEU Degradation was Accompanied by a Lower Inflammatory Cell Response



m = membrane

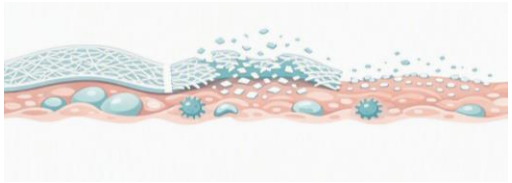
Subcutaneous rat model; single-sheet PEU.

Lower at every timepoint

PEU had fewer inflammatory cells than Cytoflex® from 1 week through 3 months.

p<0.0001

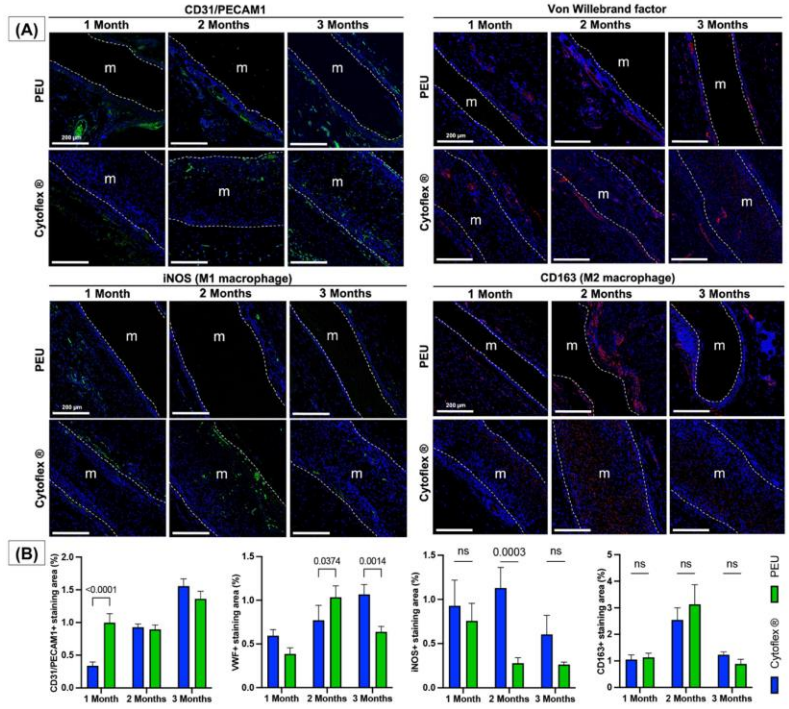
for PEU versus Cytoflex® at each reported interval.



Representative H&E and quantitative inflammatory-cell analysis: Dal-Fabbro et al., 2024.

MECHANISM

PEU Supported Angiogenesis with Reduced pro-Inflammatory Polarization



Vascular markers

CD31 was higher with PEU at 1 month ($p<0.0001$); VWF was higher at 2 months ($p=0.0374$).

M1 macrophages

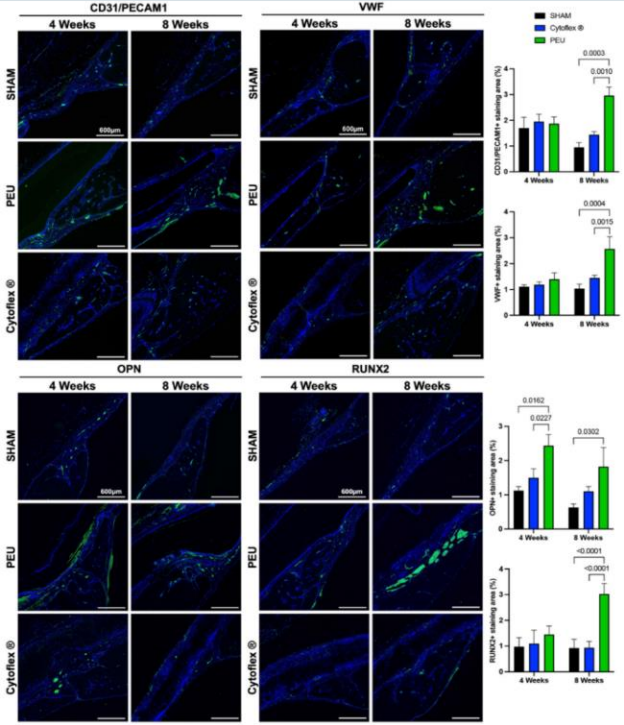
iNOS staining was lower with PEU at 2 months ($p=0.0003$).

M2 macrophages

CD163 differences were not significant at the reported timepoints.

Subcutaneous rat model; immunofluorescence results from Dal-Fabbro et al., 2024.

At 8 Weeks, PEU Increased Vascular and Osteogenic Markers within Calvarial Defects



CD31 / PECAM1

Higher than sham and Cytoflex® at 8 weeks
p=0.0003 and p=0.0010

VWF

Higher than sham and Cytoflex® at 8 weeks
p=0.0004 and p=0.0015

RUNX2

Higher than sham and Cytoflex® at 8 weeks
p<0.0001

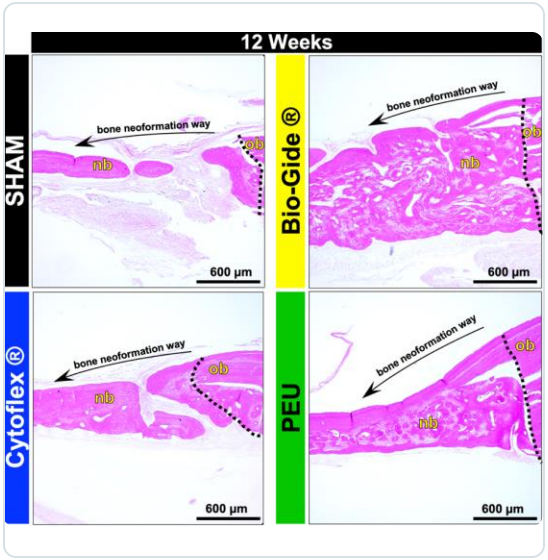
OPN

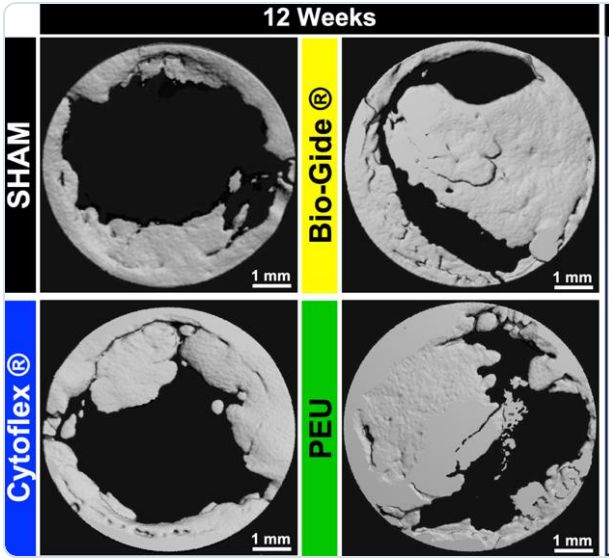
Higher than sham at 4 and 8 weeks; higher than Cytoflex® at 4 weeks

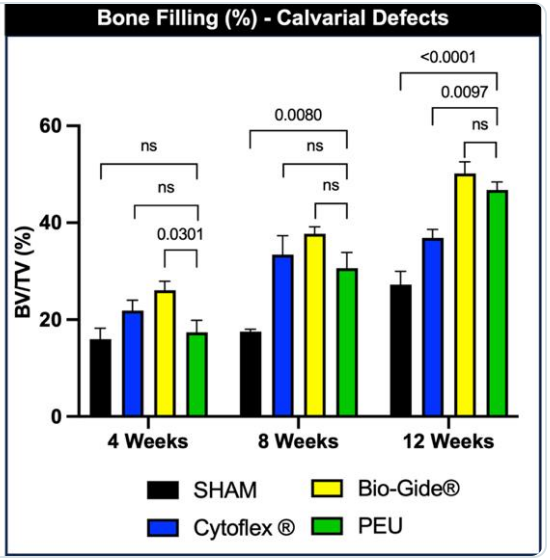
Mechanistic correlates support—but do not replace—quantitative bone-volume outcomes.

Critical-size rat calvarial model; Dal-Fabbro et al., 2024.

PEU Performed Comparably to Bio-Gide® at 8–12 Weeks and Exceeded Cytoflex® at 12 Weeks







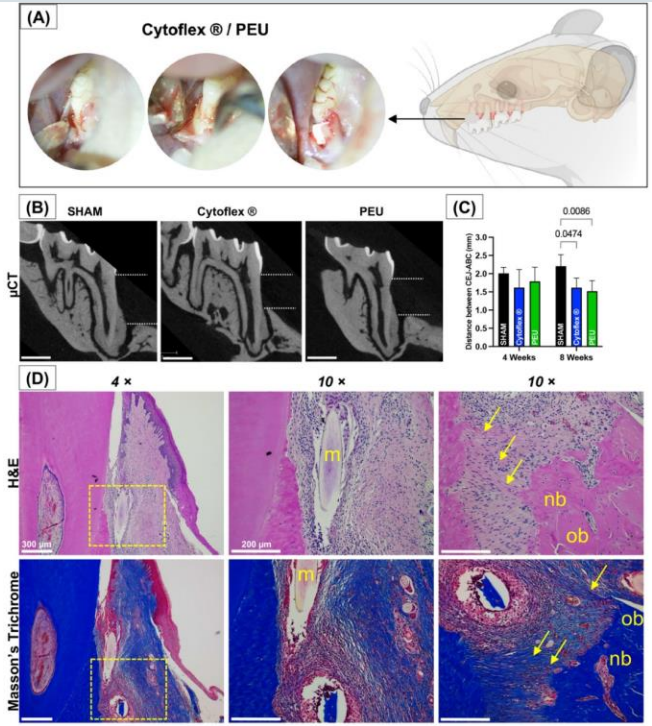
8 weeks
PEU not different from Bio-Gide® or Cytoflex®

12 weeks
PEU not different from Bio-Gide®
PEU > Cytoflex® (p=0.0097)

Bone fill
PEU and Bio-Gide® both > sham at 12 weeks

ORTHOTOPIC MODEL

PEU Restored Alveolar Bone and Supported Periodontal Tissue Regeneration



≈31% recovery

of alveolar bone loss versus sham at 8 weeks; CEJ–ABC p=0.0086.

Functional tissue architecture

Histology showed new cementum and Sharpey's fiber insertion adjacent to newly formed bone.

Barrier function maintained

PEU and Cytoflex® limited soft-tissue ingrowth within the defect.

Rat one-wall periodontal defect; single-sheet PEU; Dal-Fabbro et al., 2024.

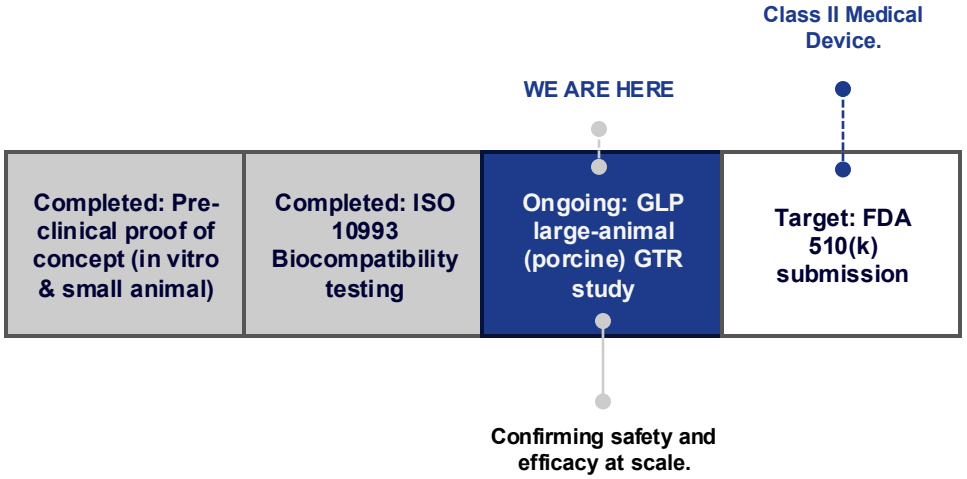
Conclusions and Future Prospectives

Advantages of PEU barrier membrane

Superior mechanical properties	Higher tensile strength, greater elasticity, and improved dimensional stability compared to the commercial membrane.
Excellent cytocompatibility	High cell viability and enhanced osteogenic differentiation of human mesenchymal stem cells.
Lower inflammatory response	Reduced pro-inflammatory cytokine production and favorable immune modulation.
Enhanced angiogenesis	Increased vessel formation and M2 macrophage polarization, supporting tissue regeneration.
Effective bone regeneration *in vivo*	Significantly more new bone formation and greater bone volume in a clinically relevant calvarial model.

Translational pathway to clinics

Advancing the PEU bilayer membrane though final regulatory milestones to deliver a scalable, clinical-grade solution to the DoW and civilian markets.



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NIH / NIDCR
Dental barrier membrane program

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Broader platform: wound healing, rotator cuff, ophthalmology

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Army collaborator studies

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Renan Dal-Fabbro · Caroline Anselmi · W. Benton Swanson · Lais Medeiros Cardoso · Priscila T. A. Toledo · Arwa Daghrery · Darnell Kaigler · Alexandra Abel · Marco C. Bottino

Army Postgraduate Dental School / DDEAMC — COL Thomas M. Johnson group

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Army collaborators' views are their own and do not necessarily reflect official policy of the U.S. Government, DHA, or USU.
Key references: Dal-Fabbro et al., ACS Appl. Mater. Interfaces 2024, 16:53419–53434.

Appendix

Little Innovation in Degradable Polymers in the Last 2 Decades

1971

PGA Dexon™ (Davis & Geck) Absorbable Suture

1987

Polyglyconate Maxon™ (Davis & Geck) Suture

1994

PLA BioScrew™ (Linvatec Corporation) Absorbable Interference Screw

PCL Monocryl™ (Ethicon) Suture

BD Acquired 2021

TEPHA MEDICAL DEVICES

2005

Polyarylate-Coated TYRX PivitAB™ (TyRx Pharma) Surgical Mesh

2015

Polyurethane Tissuglu™ (Cohera Medical Inc.) Adhesive Glue

Lots of Room & Demand For Innovation

1982

PDS™ II (Ethicon) Suture

1991

Polyglyconate Suretac™ (Acufex Microsurgical) Absorbable Fixation Device

1996

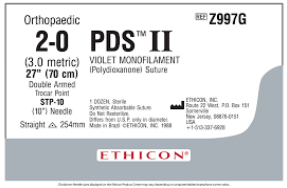
Polyanhydride Gliadel™ (Gilford Pharmaceuticals) Intracranial Implant

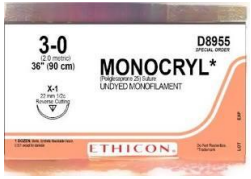
2007

P4HB Tephaflex™ (Tepha Inc.) Surgical Mesh

2020

CBB Citregen™ (Acuitive Technologies) Tendon Interference Screw

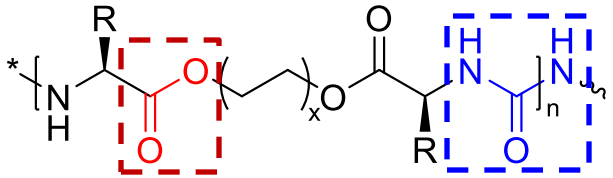




Almost exclusively polyesters w/ acidic byproducts

Amino-acid–based poly(ester urea): a novel barrier chemistry

Amino Acid-Based Poly(ester urea)s



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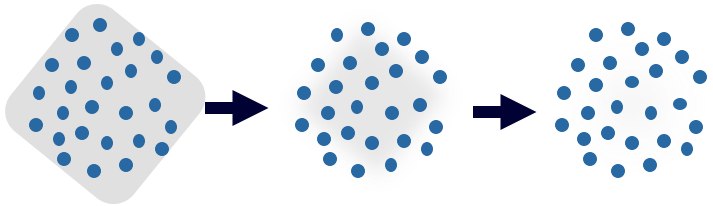

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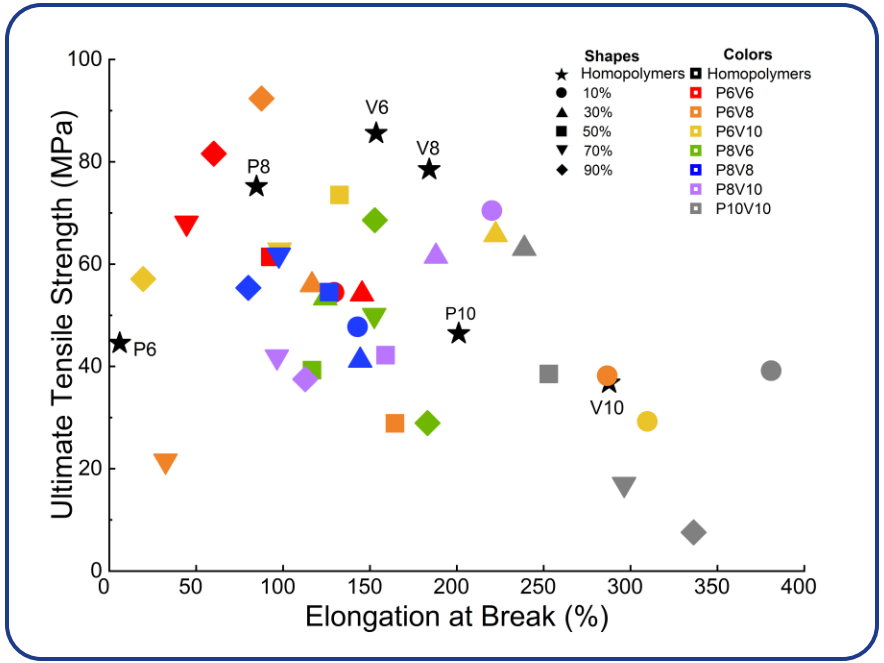

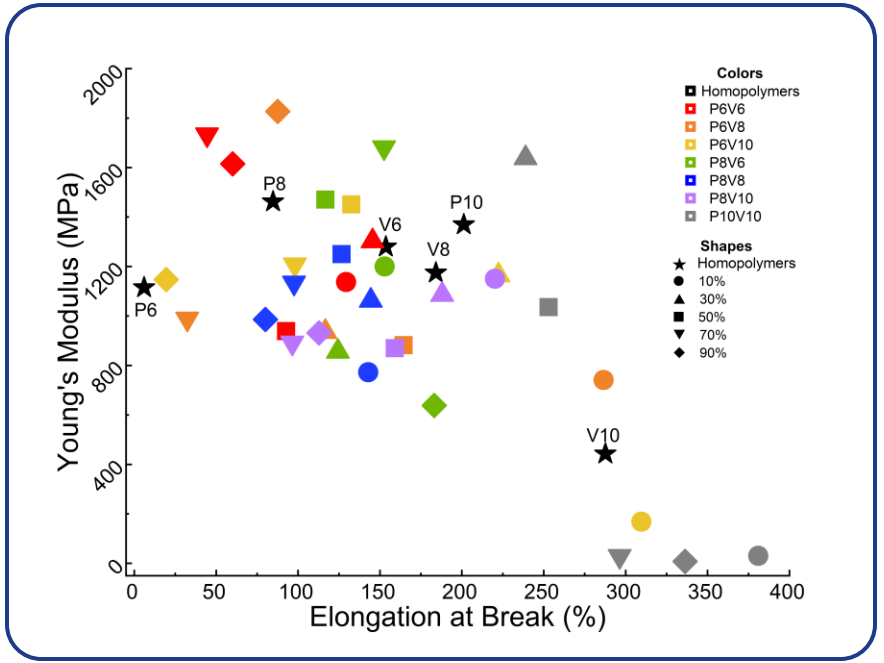

CI Dziewior#, K Godwin#, NG Judge, NZ Dreger, ML Becker* “Poly(ester urea)s: synthesis, material properties, and biomedical applications” *Progress in Polymer Science* **2024,** *156*, 101866.

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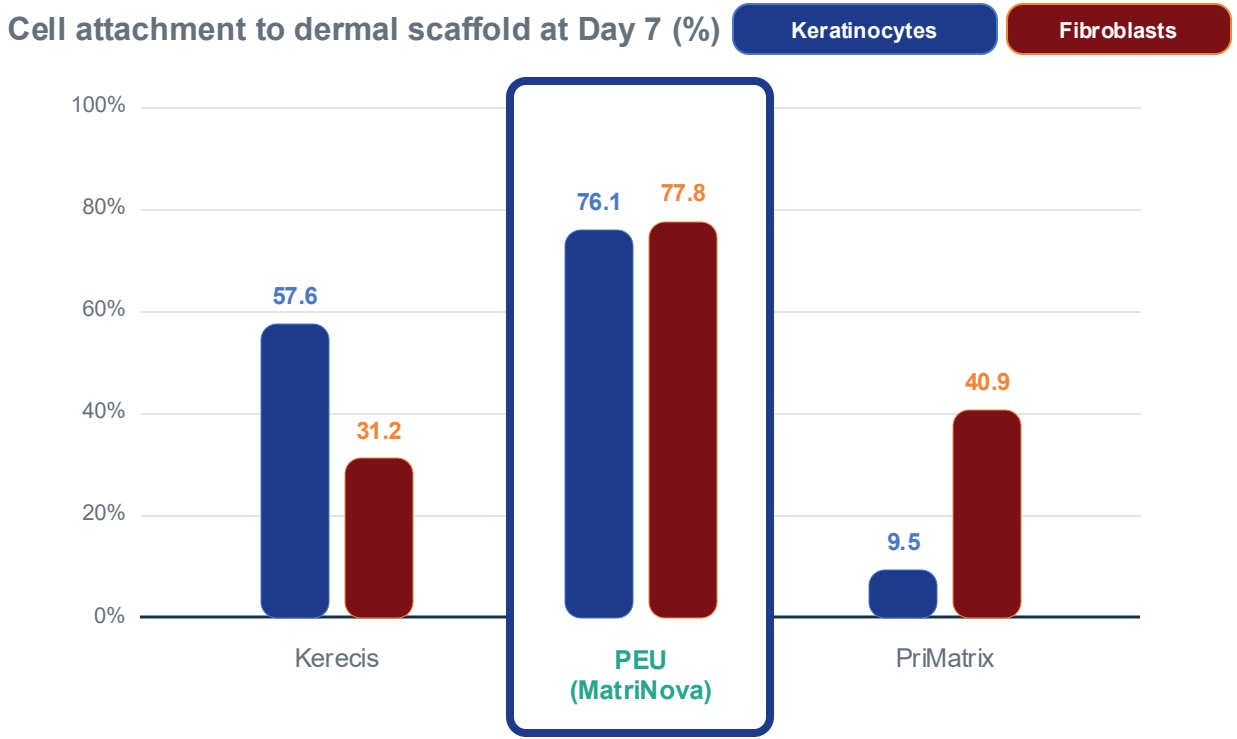
PEU Had the Highest Cell Attachment Against Commercial Skin Substitutes

IN VITRO DERMAL-SCAFFOLD COMPARISON · DESCRIPTIVE SOURCE DATA



76–78%

attachment on PEU at Day 7

KERATINOCYTES

1.3× / 8.0×

vs Kerecis / vs PriMatrix

FIBROBLASTS

2.5× / 1.9×

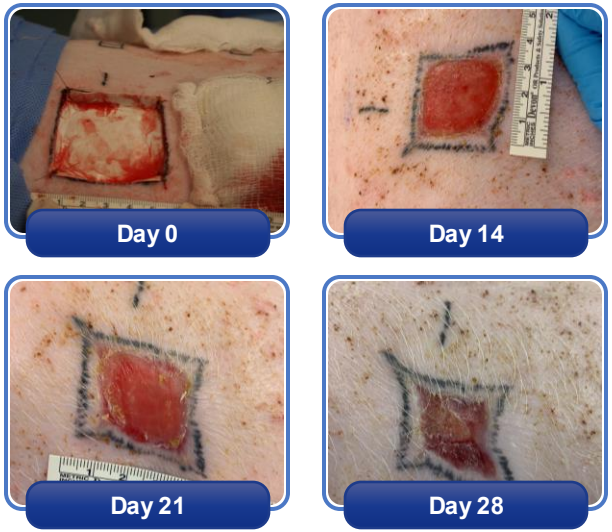
vs Kerecis / vs PriMatrix

Wound: PEU-treated Wounds were Smaller at Days 14–28

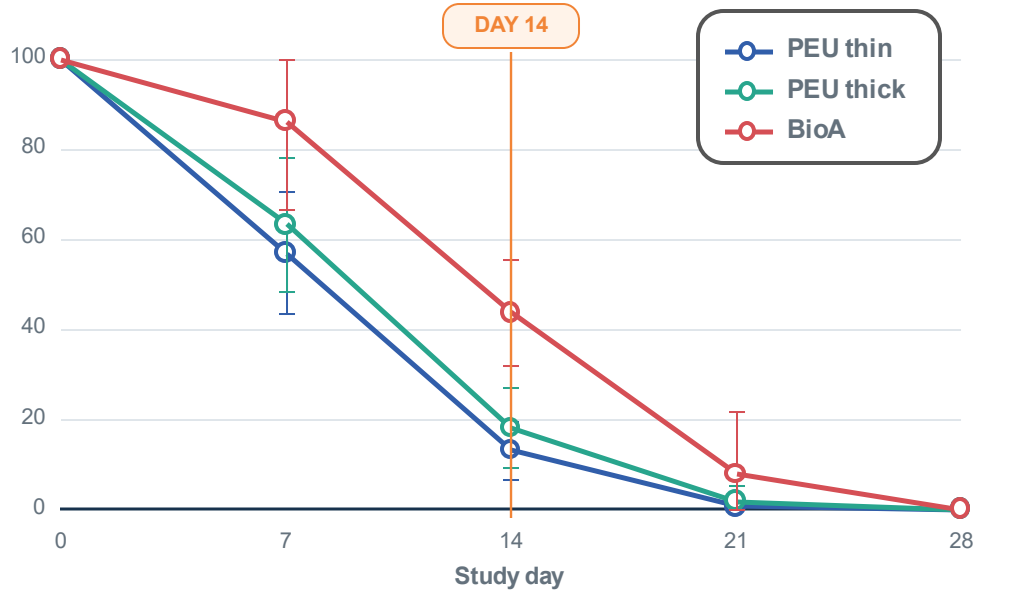
PIVOTAL PORCINE STUDY · 2 × 2 CM FULL-THICKNESS WOUNDS · n=6 ANIMALS

Representative PEU wound sequence

Separate 4 × 4 cm MatriNova series

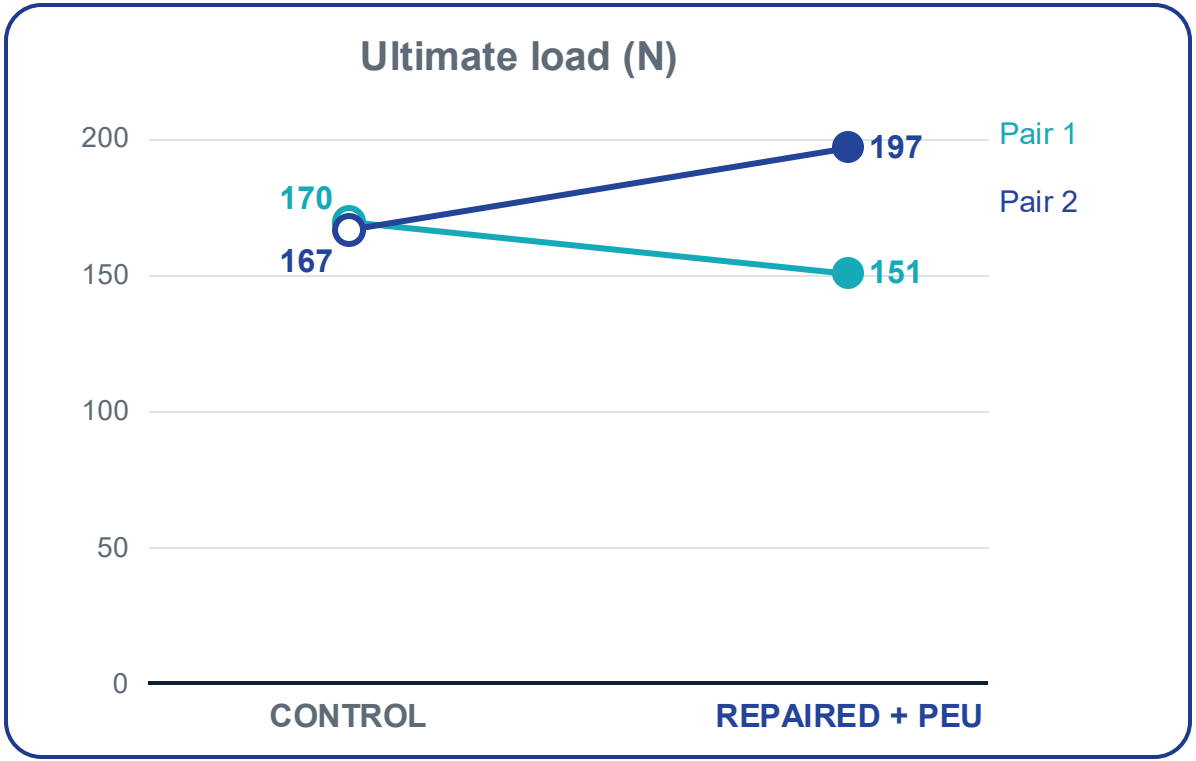


Wound area (% of Day 0) · mean ± SD



DAY 14 · PEU thin 13% · PEU thick 18% · BioA 44% remaining wound area

Rotator Cuff: Repair-site Mechanics Held at 90 Days in Ovine Model



THE REPAIR SITE HELD

Both repaired tendons failed within tendon fibers—not at the surgical repair site.

READ AS FEASIBILITY

n=2 paired shoulders · 90 days
No statistical power or inferential claim

Failure-to-load test after cyclic preconditioning. Control: 170, 167 N; repaired + PEU: 151, 197 N.