From Donor Dependence to Scalable Synthetic Scaffolds

Biomanufacturing resilience for operational tissue repair

2026 MHSRS · BIOMANUFACTURING FOR SUPPLY CHAIN RESILIENCE

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

Disclosure, Investigational Status, and Disclaimer

Financial disclosure

Founder, CEO, and shareholder of Matregenix, Inc.; financial interest in the technologies discussed. Matregenix owns or licenses related electrospinning, amino-acid PEU, and scaffold IP.

Investigational technology

All products and applications discussed are investigational and are not FDA cleared or approved unless specifically stated. Evidence spans preclinical, in-vitro, feasibility, and proposal-stage work.

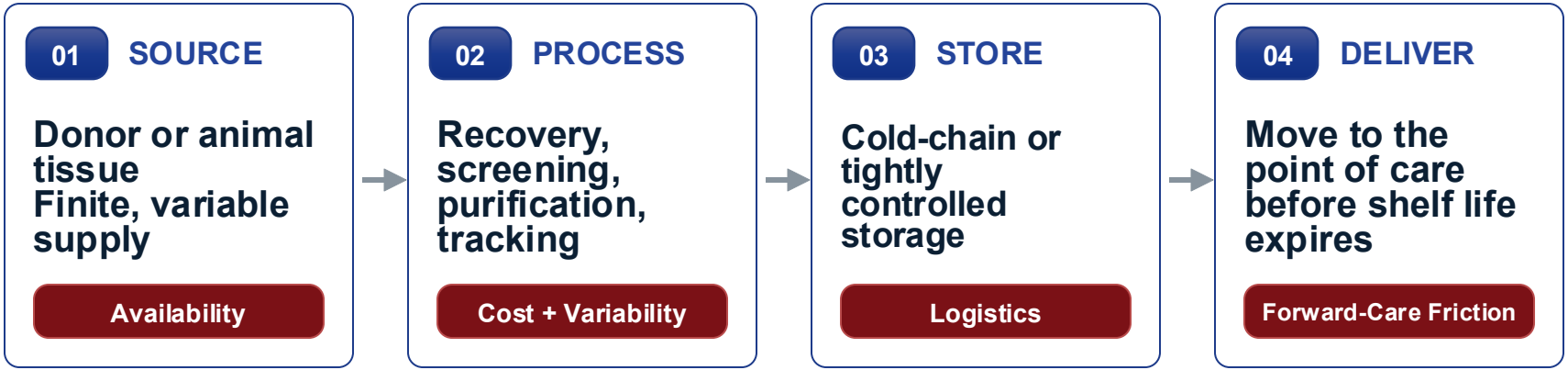
Required disclaimer

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.

Biological Grafts: Clinical Value, Logistical Dependency

THE OPERATIONAL GAP

Biological grafts can be clinically valuable—and still be operationally fragile.



Operational medicine needs regenerative capacity that can be stocked, moved, and surged—not sourced one patient at a time.

Synthetics Promised the Fix- Two Barriers Stopped Them

TWO COUPLED BARRIERS

BARRIER 1 MANUFACTURING

Electrospinning stayed at laboratory scale

Needle-by-needle production
→ low throughput
→ difficult process control

A great scaffold is not a supply chain.

BARRIER 2 BIOMATERIALS

Many synthetics rely on lactide/glycolide chemistry

Hydrolysis can create acidic products
→ local pH reduction
→ inflammatory risk in some settings

Scale alone cannot rescue the wrong chemistry.

TRANSLATION REQUIRES BOTH BARRIERS TO FALL

Barrier 1: Industrialize Electrospinning

ROLL-TO-ROLL SCALE

Minutes, not days

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

Scalable

Roll-to-roll deposition supports reproducible, higher-throughput production.

Cost-effective

Synthetic feedstock avoids costly tissue sourcing, purification, and screening.

Animal-free

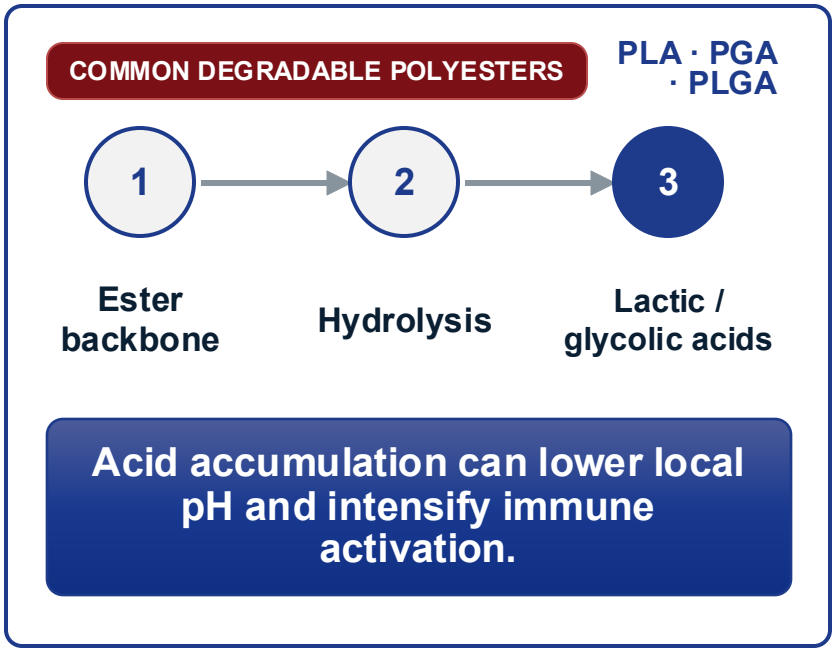
No xenogeneic or donor material — no associated ethical or disease-transmission concerns.

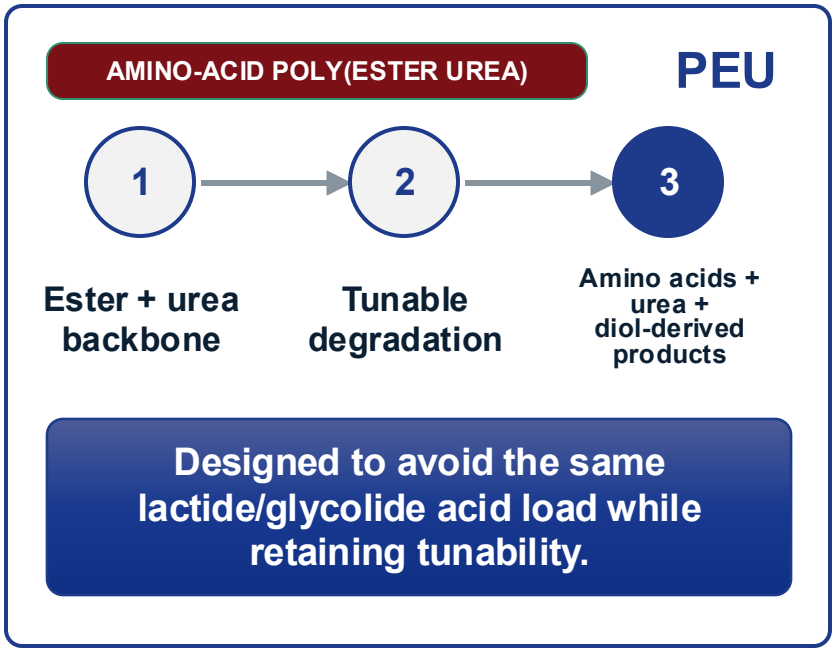
Tunable

Fiber-scale control of mechanics, porosity, and degradation for a target indication.

Barrier 2: Redesign Degradation Chemistry

AMINO-ACID POLY(ESTER UREA)





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

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Solving Both Barriers Created MatriNova

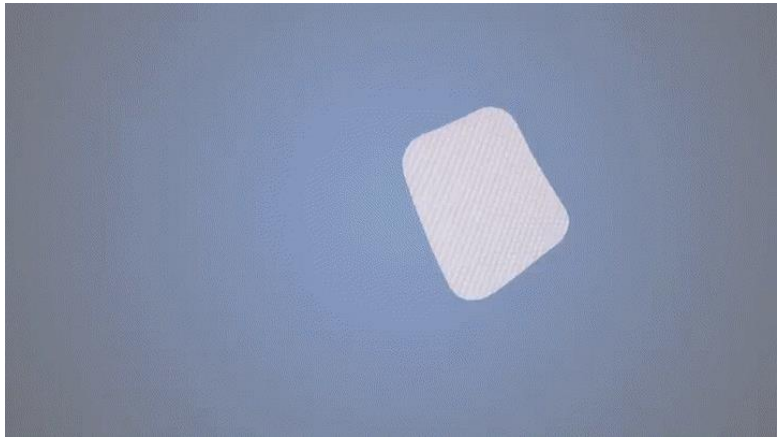
THE MATRINOVA PLATFORM

MATRINOVA SYNTHETIC ECM

A synthetic tissue scaffold designed to regenerate tissue by mimicking the human extracellular matrix.

Animal-free — no disease-transmission risk
Shelf-stable — no refrigeration
Designed for lower cost than biologics

SAFER • SHELF-STABLE • LOWER COST



ONE SYNTHETIC PLATFORM • MULTIPLE TISSUE-REPAIR APPLICATIONS

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

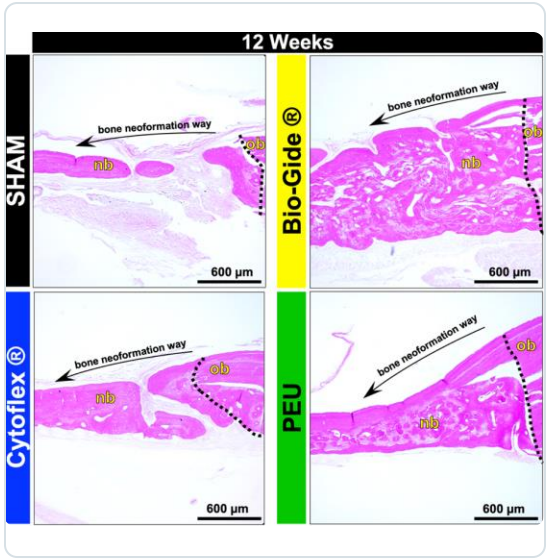
Watertight barrier for neurosurgical defects.

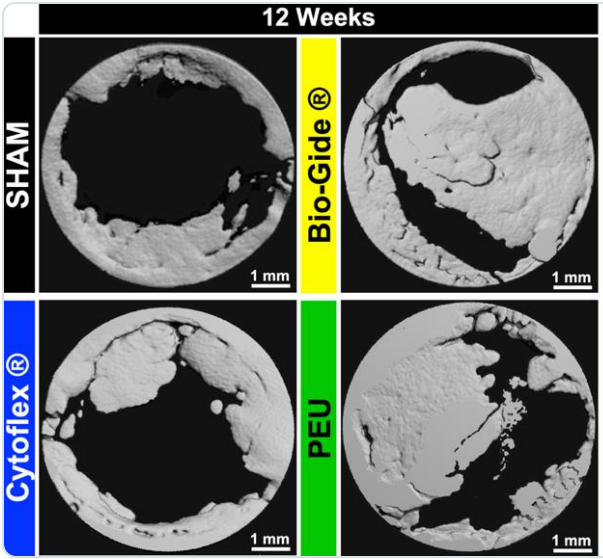
concept-stage

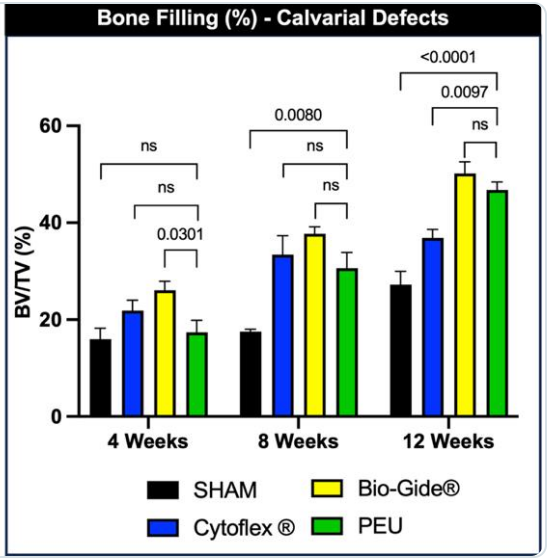
ONE CHEMISTRY · TUNED ARCHITECTURE · TISSUE FUNCTION

EVIDENCE · RAT CALVARIAL MODEL

Dental: PEU Matched Collagen at 8–12 Weeks







8 WEEKS

PEU ≈ collagen (ns)
PEU ≈ lactide synthetic (ns)

12 WEEKS

PEU ≈ collagen (ns)
PEU > lactide synthetic (p=0.0097)

INTERPRETATION

Collagen-equivalent bone fill at 12 weeks.
Internal rat study; n not stated.

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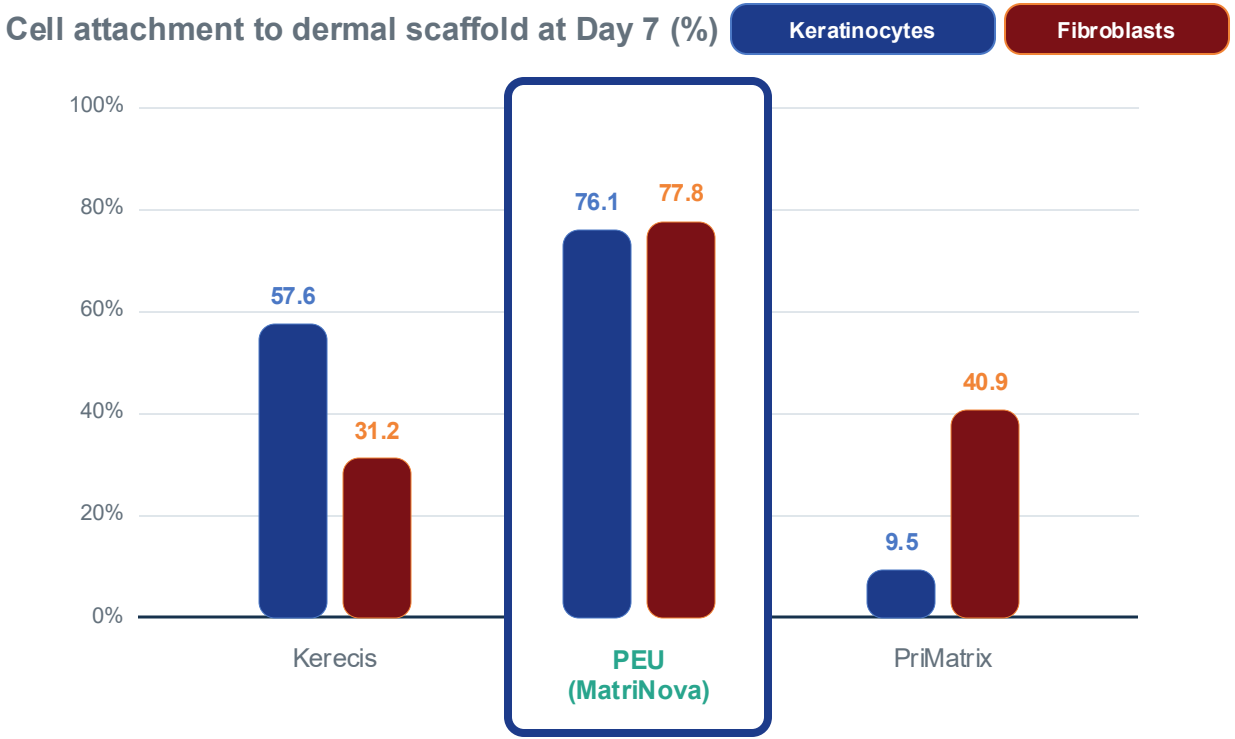
EVIDENCE · IN-VITRO FEASIBILITY

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

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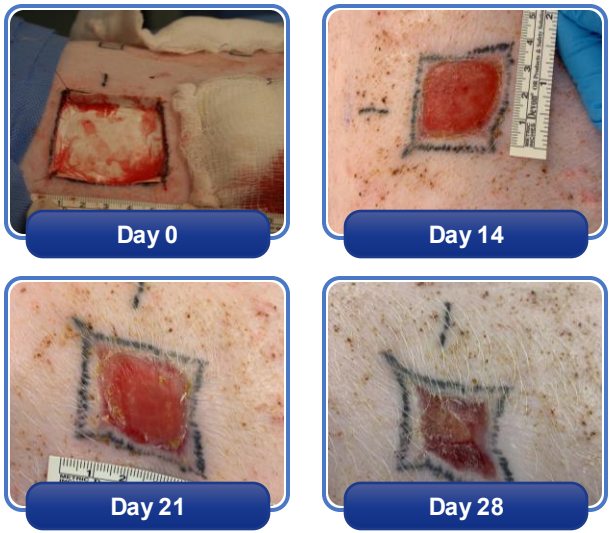
EVIDENCE · PORCINE FULL-THICKNESS FEASIBILITY

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

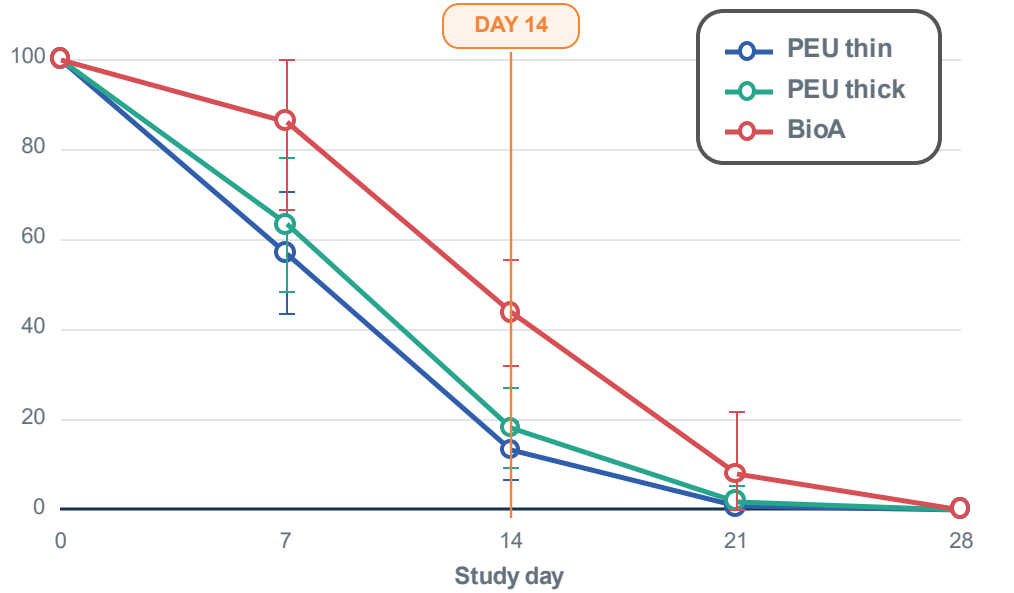
PIVOTAL PORCINE STUDY · 2 × 2 CM FULL-THICKNESS WOUNDS · n=6 ANIMALS

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

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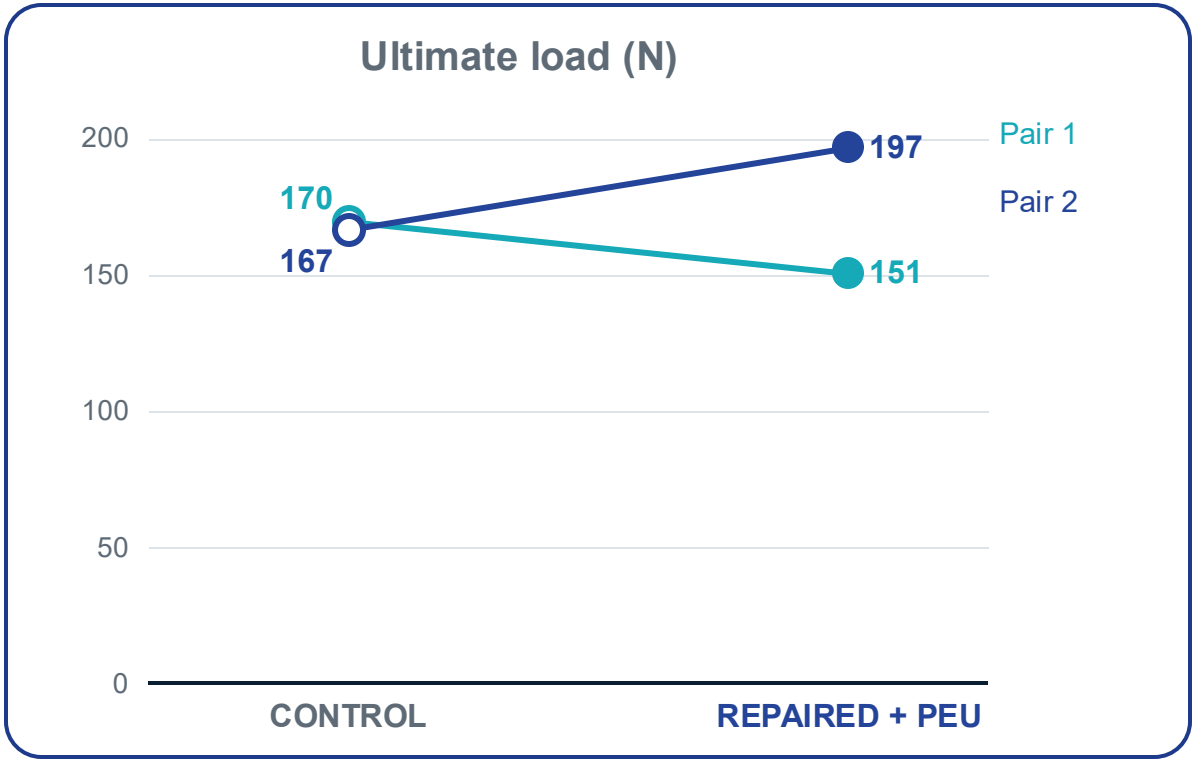
OVINE FEASIBILITY · n=2 PAIRS

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



THE REPAIR SITE HELD

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

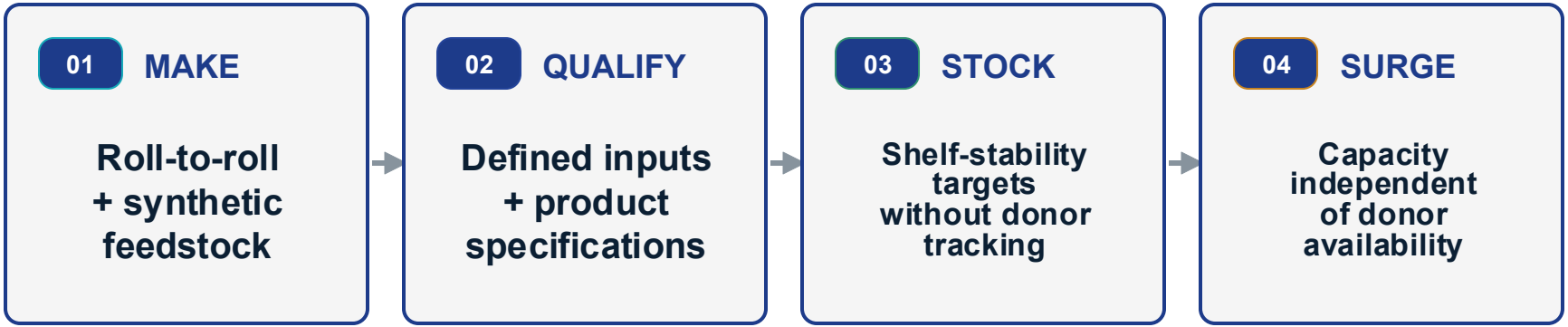
READ AS FEASIBILITY

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.

Translation Progress: Make, Qualify, Stock, and Surge

Resilience is engineered across the full product system.



TAKE-HOME

Biomanufacturing resilience comes from decoupling regenerative capacity from donor tissue—and making the synthetic alternative at industrial scale.

ACKNOWLEDGMENTS

Funding, Collaborators, and Contributors

NIH / NIDCR
Dental barrier membrane research

AFWERX
Wound, tendon, and ocular translation

U.S. Defense Health Agency
Army collaborator studies

University of Michigan — Prof. Marco C. Bottino group

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

Andrew W. Egger · Denise M. Cacho · Toria L. Koutras · Jennifer B. Hawie · Kristen E. Quartararo · Adam R. Lincicum · Kimberly A. Inouye · Kenneth M. Hussey · Sanjiv Kumar · Laura E. Riddle · Michael A. Washington · Michael E. Walsh · Thomas M. Johnson

Poly(ester urea) chemistry

Matthew L. Becker and collaborators · Matregenix scientific, engineering, quality, and regulatory teams

Questions

Scalable synthetics can turn regenerative materials into a stockable, surge-capable capability.

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Sherif Soliman, PhD, MBA

Thank you

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

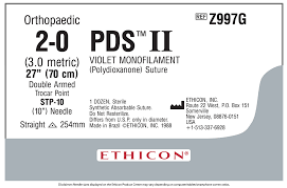
Polyanhydride Gliadel™ (Gilford Pharmaceuticals) Intracranial Implant

2007

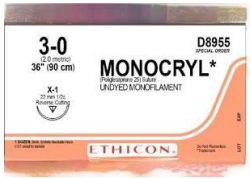
P4HB Tephaflex™ (Tepha Inc.) Surgical Mesh

2020

CBB Citregen™ (Acuitive Technologies) Tendon Interference Screw



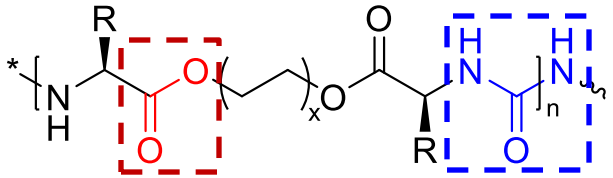
Almost exclusively polyesters w/ acidic byproducts



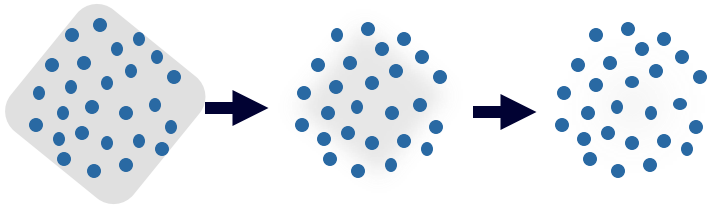
MATERIAL PLATFORM

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

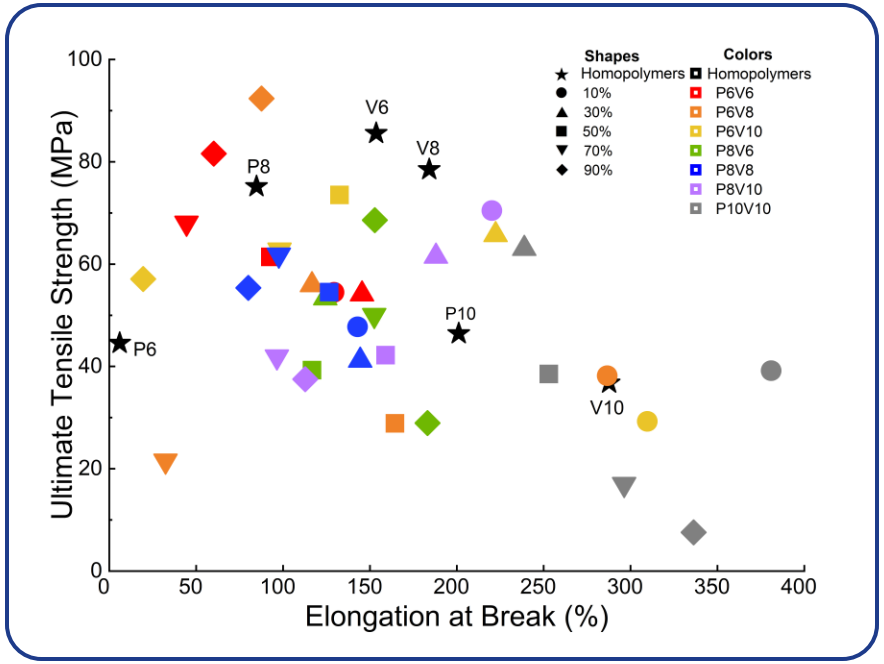
Progress in Polymer Science **2024,** *156*, 101866.

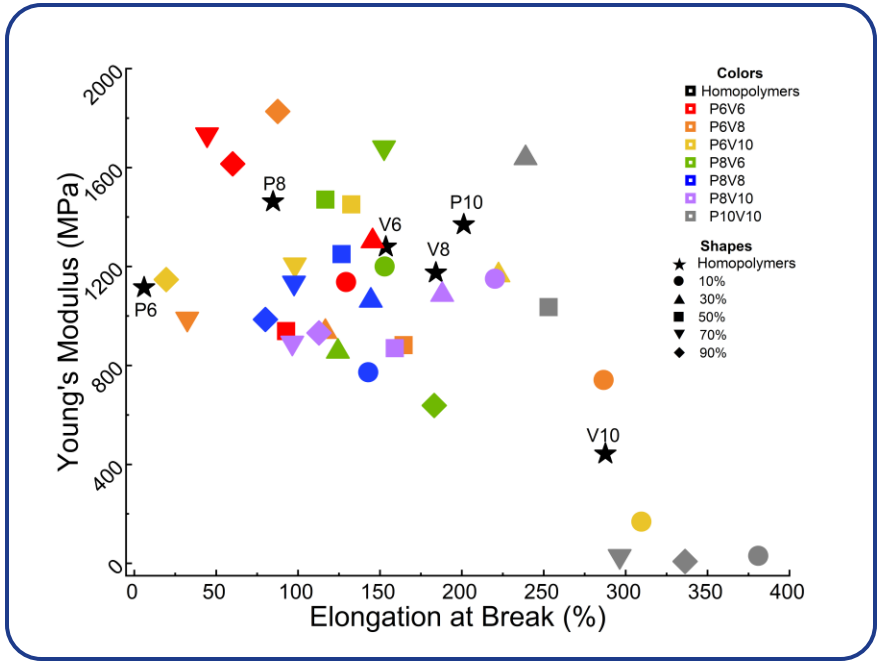
Advantages

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

Library of Poly(ester urea)s is Diverse Chemically & Mechanically

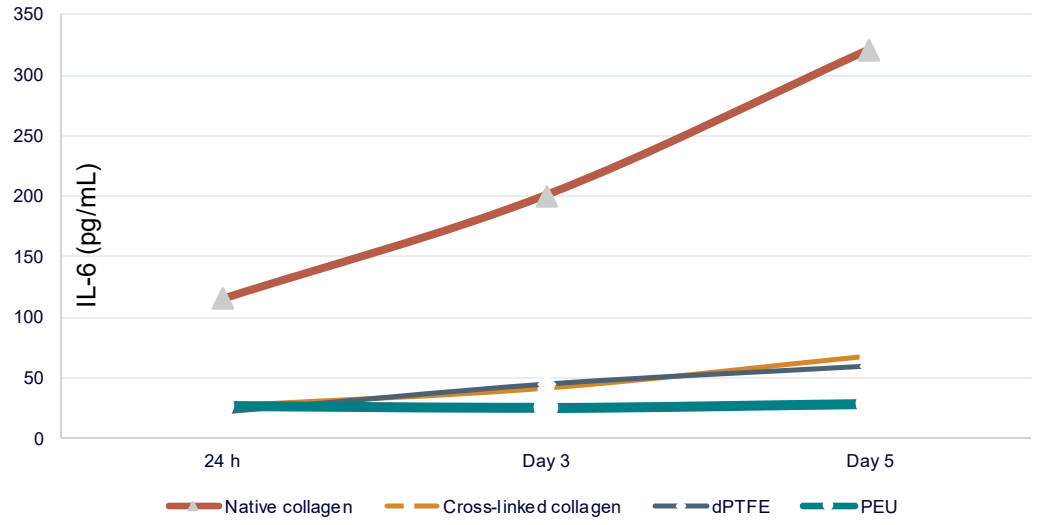




CI Dziewior#, K Godwin#, NG Judge, NZ Dreger, ML Becker* “Poly(ester urea)s: synthesis, material properties, and biomedical applications” *Progress in Polymer Science* **2024,** *156*, 101866.

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

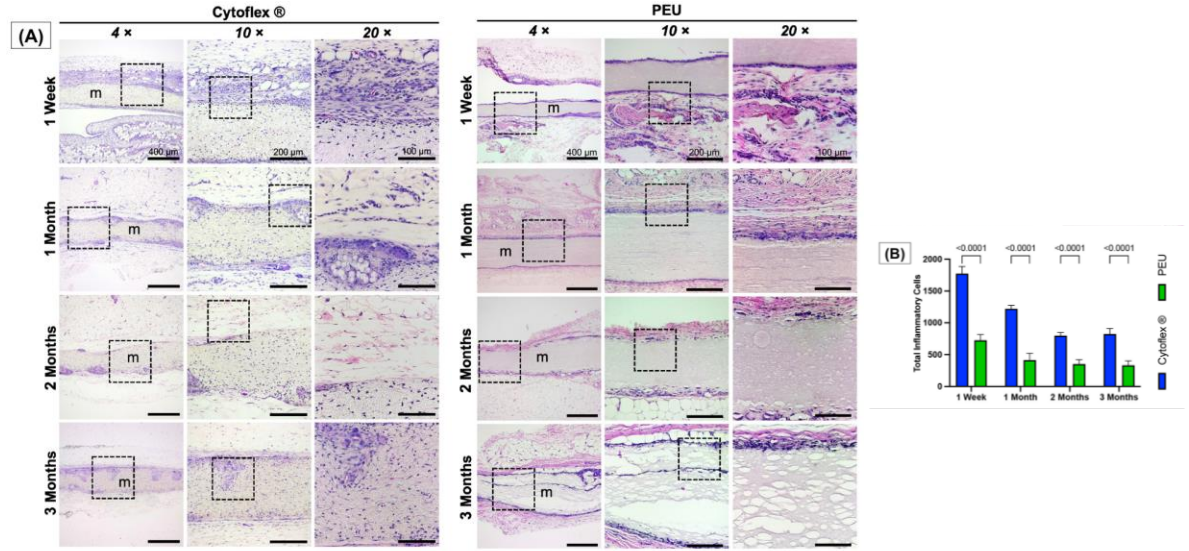
Native collagen increased to 321.0 pg/mL by Day 5; $p<0.05$ versus PEU at every timepoint.

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

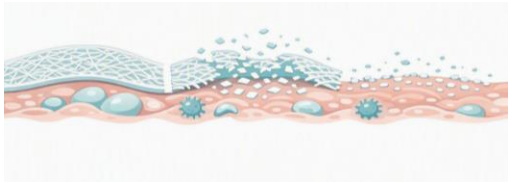
Subcutaneous rat model; single-sheet PEU.

Lower at every timepoint

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

p<0.0001

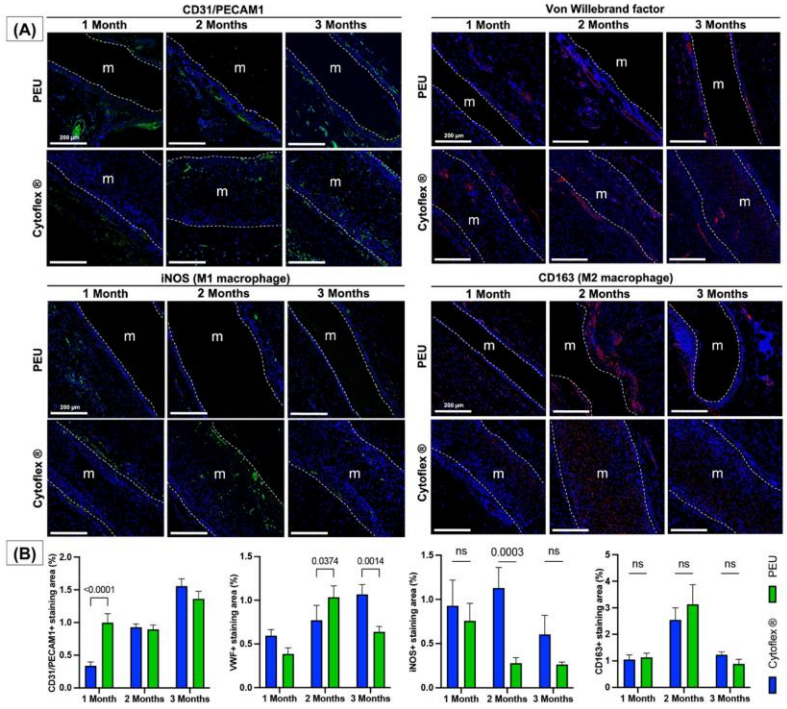
for PEU versus Cytoflex® at each reported interval.



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 ($p=0.0003$).

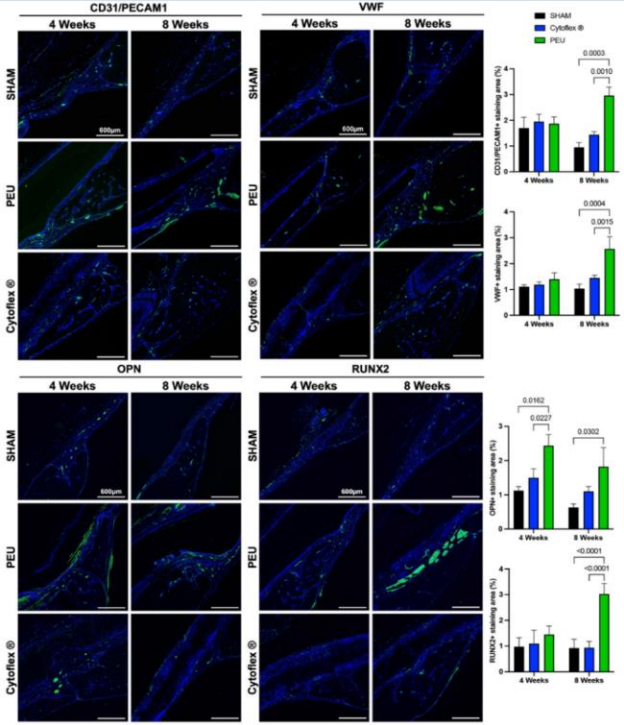
M2 macrophages

CD163 differences were not significant at the reported timepoints.

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

GUIDED BONE REGENERATION

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

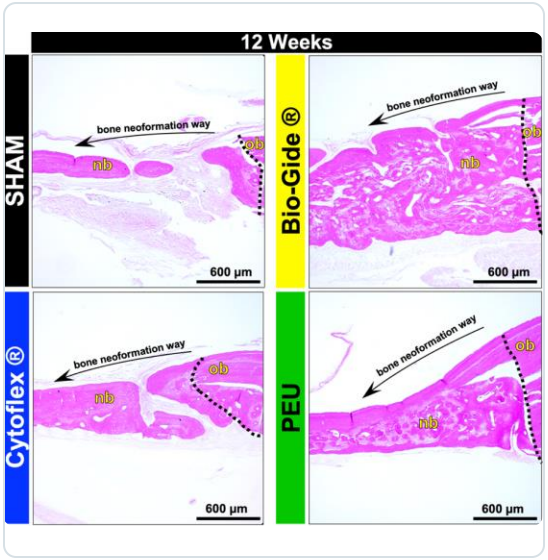
Higher than sham at 4 and 8 weeks; higher than Cytoflex® at 4 weeks

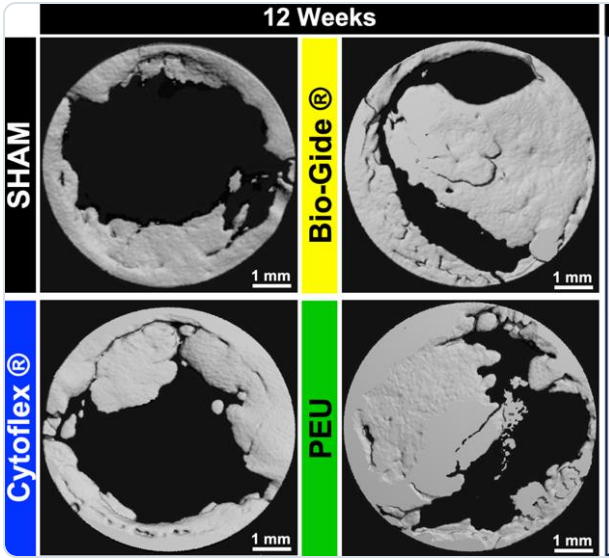
Mechanistic correlates support—but do not replace—quantitative bone-volume outcomes.

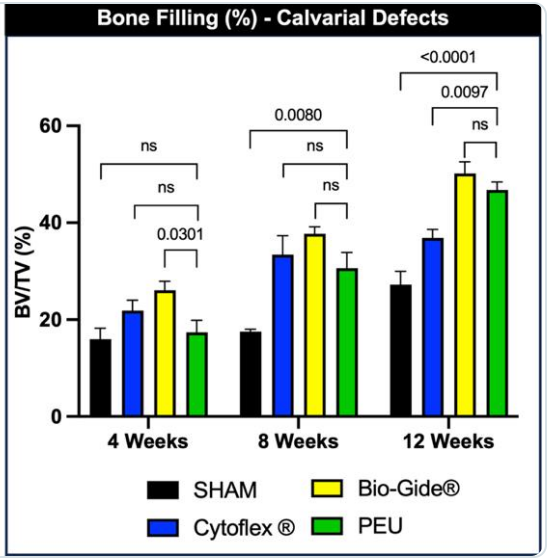
Critical-size rat calvarial model; Dal-Fabbro et al., 2024.

UPDATED COLLAGEN COMPARISON

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







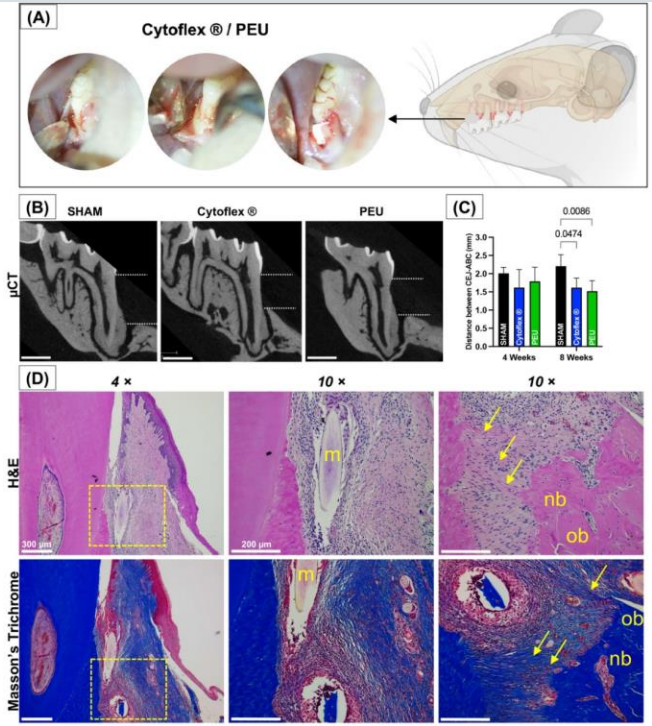
8 weeks
PEU not different from Bio-Gide® or Cytoflex®

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.