

SYNTHETIC BIODEGRADABLE POLYMERS IN BIOMEDICAL APPLICATIONS

**SIGNIFICANCE OF PHOSPHORYLATED TYPE I COLLAGEN IN TISSUE
REGENERATION AND WOUND HEALING**

BIOMATERIALS FORUM



OFFICIAL NEWS MAGAZINE OF THE SOCIETY FOR BIOMATERIALS

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ALSO INSIDE

OFFICE OF MANAGEMENT AND BUDGET'S PROPOSED RULE AND APPROPRIATIONS UPDATE

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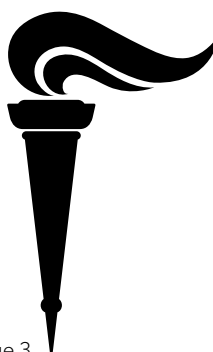
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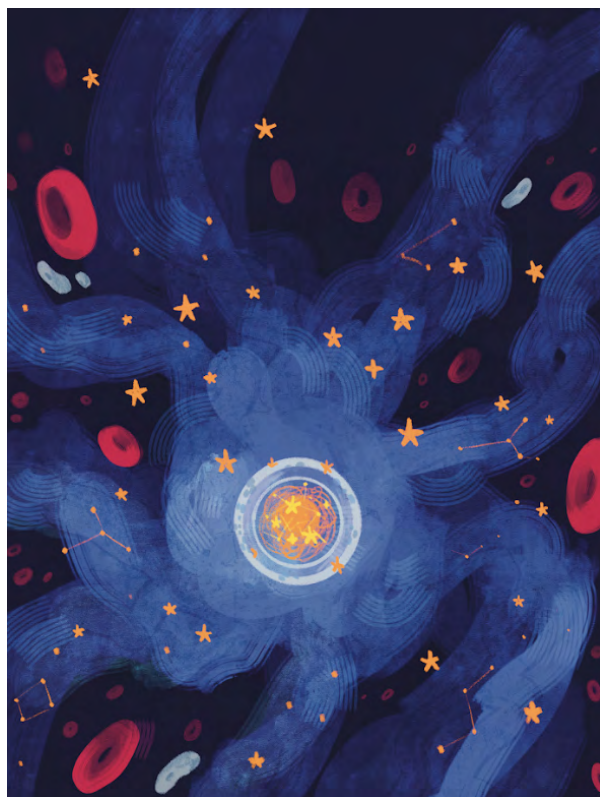
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ON THE COVER

Nanomedicine: Inspired by nanomedicine, this artwork portrays therapeutic delivery through the bloodstream, blending nanoscale science with the wonder of the cosmos.

Credit: Betül Karanfil, PhD Candidate, Chemical Engineering Department at Virginia Tech

From the Editor

By Roger Narayan, MD, PhD, Biomaterials Forum Executive Editor



Welcome to the Third Quarter 2026 issue of *Biomaterials Forum*! The cover image, provided by Betül Karanfil, a PhD candidate in the Department of Chemical Engineering at Virginia Tech, is inspired by nanomedicine and depicts therapeutic delivery through the bloodstream.

In his From the President letter, Timmie Topoleski notes progress on the 2027 Annual Meeting and the 2028 World Biomaterials Congress. He also appeals to members to serve as manuscript reviewers for the Society's journals, the *Journal of Biomedical Materials Research Part A* and the *Journal of Biomedical Materials Research Part B: Applied Biomaterials*. The AIMBE update provides details on the 2027 AIMBE Annual Event scheduled for March 6-8 in Washington, DC, the Public Policy Training Institute for Rising Leaders, and the second BEMA Roundtable on combination products. The update also describes AIMBE and SFB advocacy regarding proposed changes to the OMB Uniform Guidance, the \$5 billion federal commitment to the Genesis Mission for AI-driven science, and the OSTP report "Science: A New Golden Age."

Our two feature articles consider synthetic biodegradable polymers and collagen biochemistry. Seungil Kim at Mississippi State University provides an overview of the development of synthetic biodegradable polymers for biomedical applications through three material classes (poly(amino acid)s, polyesters, and polyurethanes). He also describes efforts to

balance degradation with mechanical function and biological integration. Subramanian Gunasekaran at Encoll Corporation describes the significance of phosphorylated type I collagen in tissue regeneration and wound healing. He considers how the addition of phosphate groups alters physicochemical properties and biological functionality.

Member News recognizes achievements from John Fisher, Donny Hanjaya-Putra, Ahsanul Kaiser, Bingyun Li, Ramesh Singh, Norah Sivasubramaniam and Andrey Zakharchenko. Student News introduces readers to the 2025-2026 National Student Section officers and outlines continuing initiatives, including the Industry Tour, PhD-to-Postdoc Poster Session, Student Luncheon and Student and Young Scientist Group Mixer. Industry News provides an overview of the U.S. biomaterials market, which is estimated at approximately \$70 billion in 2026. It also discusses the FDA's implementation of the Quality Management System Regulation and the growing role of AI and additive manufacturing in the field.

As always, I would like to thank the contributors to this issue. Please feel free to reach out to me at roger_narayan@ncsu.edu if you and members of your group would like to share biomaterials research, education, translation and outreach activities that may be of interest to the Society For Biomaterials community.

**CALLING ALL
BOOKWORMS!**

If you'd like to contribute a review of your recent favorite read to the Biomaterials Forum, send it for consideration to the Editor at Roger_narayan@ncsu.edu. If it's approved, it will be published in a future Forum Book Review column!

From the President

By Timmie Topoleski



Hello SFB!

You've likely seen a bunch of emails about our 2027 Annual Meeting and WBC 2028. We're making progress on both! There are still opportunities to help plan and implement both meetings. This is an enormous service contribution to the SFB, as well as the national and international biomaterials field.

Speaking of service — note the segue into the main topic! — I want to talk about something that probably annoys and frustrates all of us every once in a while. You know when you submit a paper to a journal for review and then wait — and wait — *and wait* — to hear about the status of your paper? Then, you wonder about the appropriate time frame to contact the editor to point out that science is decidedly *not* marching forward, and ask, "When will I get my reviews back?" I know that many of us have experienced this. I also know that many of you contribute your valuable time and expertise to review papers submitted to our Society's two premier journals, *JBMR-A* and *JBMR-B*, as well as other journals. Even so, I want to make an appeal as both the President of the SFB and an Associate Editor of *JBMR-B*: We need reviewers! Most of the time, the bottleneck in returning reviews to authors is finding enough reviewers to give manuscripts a fair and forthright peer review. There is a time lag in finding reviewers. We send out invitations and then wait for replies. If the replies are negative or non-existent (yeah, we get ghosted), then we have to start again and send out another set of invitations. And time marches on.

All manuscript reviewers are volunteers who provide a great service to our Society and our profession. This aspect of the scientific endeavor, dissemination of knowledge, cannot efficiently or effectively proceed without this (i.e., *your*) volunteer participation. To those colleagues who have contributed mightily as reviewers (i.e., the "peers" in the peer review process), thank you!

I would like to appeal to those who do not regularly participate in the process, or who would like to review papers but aren't sure how to start. Here's the essence of my appeal: Review papers! Review papers! Review papers! When you're invited, please respond! Most preferably, please agree to review the manuscript, but if you absolutely are not able, let your inviter know quickly. Suggest alternative reviewers or hand it off to one of your grad students or postdocs — yes, that's allowed, and a great way for them to build a service record on their CVs. If you've not been involved as a reviewer but would like to be, contact our amazing editors and let them know (Kent Leach, *JBMR-A*, and Danielle Benoit, *JBMR-B*). They'll make sure you receive the information you need to join in the process.

To conclude, I want to again say *thank you* to everyone who continues to contribute, or plans to contribute, their valuable time to moving the SFB's mission forward.

If you have any questions,

require any information or have suggestions for improved services,
please feel free to contact the Society's Headquarters office:

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AIMBE Updates

By Dawn Beraud, PhD

SAVE THE DATE: 2027 AIMBE ANNUAL EVENT

Mark your calendars: On March 6–8, the 2027 AIMBE Annual Event will be held in Washington, D.C. Each year, the AIMBE community, including several members and leaders from the Society For Biomaterials, comes together to connect with colleagues, advance advocacy and explore the ideas and innovations shaping the future of biomedical engineering. More details about the 2027 program and registration will be shared soon.

AIMBE PUBLIC POLICY INSTITUTE HOLDS WORKSHOP

AIMBE brought back its highly acclaimed “Public Policy Training Institute for Rising Leaders” on Oct. 15–16, in Washington, DC. This science policy workshop trains undergraduate and graduate students and postdocs about the public policy landscape surrounding the scientific enterprise. Top government officials and science policy experts led small group discussions.

AIMBE BIOMEDICAL ENGINEERING MULTIDISCIPLINARY ALLIANCE (BEMA) ROUNDTABLE ON COMBINATION PRODUCTS

On May 18, AIMBE hosted its second BEMA Roundtable meeting, this time focused on “Regulatory, Technical and Scientific Frontiers in Combination Products.” This event convened more than 40 cross-sector experts from 27 companies and organizations across fields including medical devices, pharmaceuticals, materials suppliers, academia and the federal government. [Click here](#) to view the roundtable agenda, which includes invited speakers, roundtable participants and the AIMBE Fellows who comprise the BEMA Working Committee.

POLICY UPDATE OMB PROPOSED RULE AND APPROPRIATIONS UPDATE

AIMBE and its Council of Societies (CoS) Members, including SFB, have been actively advocating against proposed changes to the Office of Management and Budget’s (OMB) Uniform Guidance governing federal financial assistance. AIMBE submitted [public comments](#) and coordinated a [joint CoS response](#), with SFB among the signatories, highlighting concerns about the potential impact of the proposed changes on federally supported research. AIMBE also developed a [suite of advocacy resources](#) to help researchers and scientific societies engage in the public comment process.

The strong response from the research community helped elevate concerns about the proposed rule. That advocacy has yielded progress: The [Senate passed legislation](#) including language that would prevent implementation of the proposed OMB rule through Dec. 11, 2026, while maintaining Fiscal Year (FY)2026 funding levels. The legislation still must pass the House and be signed into law, but it represents an important step toward protecting the research enterprise.

These safeguards would be temporary, and continued advocacy will be critical as Congress develops the FY2027 appropriations bill. AIMBE will continue working with policymakers and CoS member societies, including SFB, to advocate for lasting protections and will keep the research community informed as this issue evolves.

GENESIS MISSION ACCELERATES AI-DRIVEN SCIENCE

On July 22, White House Office of Science and Technology Policy (OSTP) Director Michael Kratsios [announced a \\$5 billion federal commitment to the Genesis Mission](#) in response to [Executive Order 14363](#). The 15-agency initiative will use artificial intelligence (AI) to accelerate scientific discovery, address national science and technology challenges and strengthen U.S. leadership in AI.

The National Institutes of Health (NIH) and U.S. National Science Foundation (NSF) are key participants, with new opportunities emerging for biomedical researchers. The NIH has launched the [Bio Genesis Mission](#), with more than \$1.2 billion committed in FY2026 and additional FY2027 funding planned. Priorities include using AI to model and forecast the behavior of complex biological systems; advancing domestic biomanufacturing and biosecurity; and applying AI to tackle pediatric cancer and chronic disease.

The NSF has also invested in the [Programmable Cloud Laboratories \(PCL\) Test Bed](#), providing up to \$20 million over four years to 20 teams to develop automated, AI-enabled laboratories accessible remotely for scientific and engineering research. The NSF has also announced an additional \$83 million investment in data systems and services and anticipates investing \$100 million to unlock the value of scientific datasets.

NSF’s FY2026 PCL Test Bed awards have already been announced, while the NIH’s Genesis-related funding is expected to roll out in FY2027. Researchers working in these priority areas should monitor NIH and NSF funding announcements for new opportunities.

AIMBE Updates

WHITE HOUSE OUTLINES NEW DIRECTION FOR U.S. SCIENCE POLICY

On July 26, the OSTP released "[Science: A New Golden Age](#)," outlining reforms intended to strengthen U.S. leadership in science and technology. The report calls for changes to the federal research funding system, institutional structures and the scientific workforce, including reducing administrative burdens, expanding alternative funding models, strengthening public-private partnerships and broadening pathways into research careers.

The report also places AI at the center of the future research enterprise, while emphasizing the need for rigorous, reproducible science. It recommends shifting how researchers and institutions are evaluated, including placing greater emphasis on scientific milestones and outcomes rather than publication counts.

The report was followed by the [White House FY2028 R&D priorities memorandum](#), which directs federal agencies to begin implementing these priorities, including increased focus on national science and technology priorities, AI integration, research infrastructure, new funding approaches and identifying scientific talent. Federal agencies are expected to outline how they will implement these priorities within 90 days.

CALL FOR COVER ART

WE WANT TO FEATURE YOUR EXCITING BIOMATERIALS ARTWORK ON THE COVER OF *BIOMATERIALS FORUM*!

Deadline: Accepted on a rolling basis.

Instructions: Please email artwork (digital images, artistic creations, etc.) to info@biomaterials.org, to the attention of the Executive Editor of the *Biomaterials Forum*. All artwork with biomaterials relevance that has not appeared as a *Forum* cover are welcome. Multiple submissions are permissible.

Description: Selected artwork will appear as the cover of a future issue of *Biomaterials Forum* along with a brief "On the Cover" description of the subject and name/affiliation of the creator.

Format: High-resolution electronic version in .gif, .tiff or .jpeg file format.



Synthetic Biodegradable Polymers in Biomedical Applications

By Seungil Kim, PhD, Biomedical Engineering at Mississippi State University

Throughout my early academic career, I have had the opportunity to engage in the development of synthetic biodegradable polymers for biomedical applications and to observe the field's ongoing evolution (Figure 1). Over the past two decades, biodegradable polymer systems — including poly(amino acid)s, polyesters and polyurethanes — have advanced from simple resorbable materials to increasingly sophisticated platforms capable of meeting demanding mechanical, biological and translational requirements.

These advances reflect a broader shift in biomaterials design, moving beyond the initial goal of material resorption toward integration of mechanical compliance, controlled degradation, bioactivity and application-specific performance. While early biodegradable polymers were primarily evaluated on their ability to degrade safely in vivo, subsequent biomedical applications, particularly in cardiovascular systems, have highlighted the need to balance degradation behavior with functional durability, device deliverability and interaction with complex biological environments.

I am reflecting on the historical development of biodegradable polymers through the lens of three major material classes: poly(amino acid)s, polyesters and polyurethanes. Here, I draw on personal research experience across academic training and early independent work. Rather than providing a comprehensive

review, this perspective emphasizes key conceptual advances, practical challenges and design lessons that have shaped the evolution of biodegradable polymer systems for biomedical applications.

POLY(AMINO ACID)S: EARLY BIODEGRADABLE POLYMERS AND BIOMOLECULAR INSPIRATION

Among the earliest classes of biodegradable polymers explored for biomedical applications, poly(amino acid)s and synthetic polypeptides occupy a unique position. Their structural resemblance to natural proteins and peptides made them especially attractive during the formative years of biomaterials research, when the central challenge was to design materials that could interact favorably with biological systems while degrading into non-toxic degradation products. Unlike purely synthetic aliphatic polymers, poly(amino acid)s offered a molecular architecture inherently familiar to biological environments, providing an early bridge between polymer chemistry and biology.

Initial efforts in this area were strongly influenced by the desire to mimic or harness biological function through synthetic means. By adopting amino acid-based backbones, researchers sought to combine biodegradability with molecular-level tunability, enabling control over charge density, hydrophilicity,



Figure 1. My journey with synthetic biodegradable polymers.

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functionality and biological interactions through side-chain modification. These features were particularly attractive for applications such as drug delivery, surface modification and tissue-interactive systems, where fine control over molecular interactions was required.

From a practical standpoint, poly(aspartic acid) and related poly(amino acid) derivatives emerged as representative platforms because of their synthetic accessibility and the chemical versatility of their pendant functional groups.^{1,2} Conjugation strategies enabled these materials to serve not only as degradable carriers but also as active participants in biological processes, including controlled drug release and molecular recognition. In many cases, incorporating amino acid motifs or bioactive conjugates was seen as a way to move beyond passive material behavior toward functional bio-interfaces.

However, experience with poly(amino acid)-based systems also revealed fundamental limitations that would later shape the evolution of biodegradable biomaterials more broadly. While these polymers offered excellent biocompatibility and molecular design flexibility, their mechanical properties were often insufficient for load-bearing or mechanically dynamic environments. Rapid hydrolytic degradation, combined with relatively low mechanical robustness, constrained their applicability in applications requiring structural integrity over extended time scales. These challenges became particularly apparent as interest shifted from molecular and pharmaceutical systems toward devices exposed to mechanical stress, fluid flow or cyclic deformation.

Importantly, the lessons learned from poly(amino acid)s extended beyond any single material platform. They highlighted an enduring theme in biomaterials development: Biological inspiration, while powerful, does not automatically translate to functional sufficiency in complex biomedical applications. Instead, successful biodegradable polymer systems must reconcile molecular-level biological compatibility with macroscopic performance requirements dictated by application context. In this regard, poly(amino acid)s served as an essential proving ground, demonstrating both the potential and the constraints of bio-molecularly inspired polymer design.

The exploration of poly(amino acid)s laid critical conceptual foundations for other biodegradable polymers. The emphasis on structure-property-function relationships, side-chain engineering and degradation-controlled behavior directly informed work on polyesters and polyurethanes, even as those materials departed from strict biomimicry. The shift away from exclusively amino acid-based backbones did not represent a failure of the approach, but rather an evolution toward hybrid

design philosophies that integrate chemical versatility with application-driven performance.

In this way, poly(amino acid)s occupy a pivotal role in the history of biodegradable polymers for biomedical applications. They represent an early, instructive chapter in which biological inspiration guided material design, revealing key design principles that continue to influence contemporary biomaterials research.

POLYESTERS: FROM RESORBABLE SCAFFOLDS TO TRANSLATIONAL WORKHORSES

Following early exploration of bio-molecularly inspired polymers such as poly(3-hydroxybutyrate), polyesters emerged as the most widely adopted class of biodegradable materials for biomedical applications. Aliphatic polyesters such as poly(lactic acid), poly(glycolic acid), poly(ϵ -caprolactone) and their copolymers offered a combination of synthetic simplicity, predictable degradation behavior and scalable manufacturing that aligned well with translational and regulatory needs.^{3,4} As a result, polyesters rapidly became the default choice for resorbable medical implants, drug delivery systems and tissue engineering scaffolds.

The appeal of polyesters stemmed in part from their relatively straightforward structure-property relationships. Hydrolytic degradation through ester bond cleavage enabled predictable mass loss and resorption profiles, while copolymerization and molecular weight control provided tunability across a wide range of stiffness, crystallinity and degradation kinetics. These characteristics made polyesters particularly suitable for applications where controlled temporal support was desired, including sutures, fixation devices, scaffolds and particulate drug carriers.

As the field matured, polyesters transitioned from laboratory materials to clinically accepted platforms. Their processability into diverse forms, including films, fibers, porous scaffolds, microspheres and coatings, enabled broad adoption across biomedical disciplines. Importantly, this versatility facilitated early clinical translation, reinforcing the perception of polyesters as reliable, “workhorse” biodegradable polymers. In contrast to poly(amino acid)s, whose use was often confined to molecular or pharmaceutical contexts, polyesters could readily support macroscopic structure and function.

However, widespread adoption also revealed important limitations. While mechanically adequate for many static or low-load applications, many polyester systems exhibited intrinsic stiffness that was poorly matched to soft-tissue environments. In cardiovascular and other mechanically dynamic

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settings, this mismatch often manifested as altered healing responses, stress shielding or incomplete functional integration. Additionally, bulk degradation and acidic degradation products raised concerns related to localized inflammation and tissue compatibility, particularly in confined or poorly perfused environments.

These challenges prompted extensive efforts to modify polyester systems through blending, copolymerization, surface engineering and structural design. Researchers explored topographical modification, surface chemistry control and incorporation of bioactive cues as strategies to improve biological performance without abandoning the translational advantages of polyester backbones. Such approaches underscored an important shift in biomaterials thinking: Performance could no longer be judged solely by degradation timelines or mechanical strength, but rather by how materials interacted with biological systems over time and under physiological loading conditions.

Despite their limitations, polyesters played a critical role in establishing biodegradable polymers as legitimate alternatives to permanent solutions for temporary clinical problems. Their success demonstrated that degradable materials could meet regulatory standards, be manufactured at scale and function reliably in vivo. At the same time, the shortcomings encountered in more demanding applications revealed the need for new classes of biodegradable polymers with enhanced mechanical compliance, fatigue resistance and interface adaptability.

Polyesters represent a pivotal stage in the evolution of biodegradable biomaterials. They bridged the gap between biologically inspired but mechanically limited polymers and the subsequent pursuit of elastomeric and multifunctional biodegradable systems. The lessons learned from polyester-based devices, particularly in cardiovascular and load-bearing applications, directly stimulated the development of biodegradable polyurethanes and related elastomeric materials designed to better match the mechanical and functional demands of living tissues.

Thus, while polyesters remain indispensable translational workhorses, their historical significance extends beyond their continued use. They gave the field a reference point against which newer biodegradable polymers could be evaluated, clarifying both what degradable materials could achieve and where innovation was most urgently needed. This evolution set the stage for polyurethane-based systems, which sought to reconcile degradability with elasticity, durability and functional integration in complex biomedical environments.

POLYURETHANES: ELASTOMERIC AND FUNCTIONAL BIODEGRADABLE SYSTEMS

The limitations of the other biodegradable polymer classes, particularly their inability to combine controlled degradation with sustained mechanical performance, ultimately motivated the exploration of polyurethanes for biomedical applications. Unlike poly(amino acid)s and polyesters, which are largely defined by a single dominant backbone chemistry, polyurethanes are inherently modular. This modularity allows independent tuning of mechanical properties, degradation behavior and biological interactions, making polyurethanes uniquely suited for applications requiring both structural function and biological integration.

Historically, polyurethanes were first adopted in biomedical devices as biostable elastomers, valued for their flexibility, fatigue resistance and durability in dynamic physiological environments. Their segmented molecular architecture, comprising soft and hard domains, enabled mechanical compliance across a wide range of stresses, a property particularly relevant to cardiovascular and soft-tissue applications. As interest in biodegradable systems grew, this same architectural flexibility became the basis for designing resorbable polyurethanes that maintain elastomeric behavior throughout the device's functional lifetime.

The transition from biostable to biodegradable polyurethanes marked a conceptual turning point in biomaterials design. Rather than prioritizing degradation alone, biodegradable polyurethanes were engineered to preserve mechanical integrity during critical healing or therapeutic windows, followed by gradual and predictable resorption. By tailoring soft-segment chemistry, hard-segment content and chain extenders, these materials enabled decoupling of mechanical performance from degradation rate, an achievement not readily attainable with earlier biodegradable polymers.⁵

Equally important was polyurethane systems' ability to accommodate functionalization without compromising bulk properties. The incorporation of bioactive motifs, antioxidant components or responsive segments could be achieved through backbone design or side-chain modification, allowing bioactivity to be integrated directly into the material rather than applied as an afterthought. This capability addressed a key limitation observed with many bioactive coatings on polyesters, where surface modification often came at the expense of deliverability, flexibility or long-term stability.

In mechanically demanding environments, such as cardiovascular devices, these features proved decisive. Elastomeric biodegradable polyurethanes offered improved

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compliance with native tissue mechanics, reduced stress concentrations and enhanced fatigue resistance under cyclic loading. At the same time, controlled degradation profiles minimized abrupt loss of structural support while mitigating adverse tissue responses associated with rapid mass loss or acidic degradation products. As a result, polyurethane-based systems began to fill an important gap between molecularly inspired polymers and rigid resorbable scaffolds.

The evolution of biodegradable polyurethanes also reflected a broader shift toward application-driven materials design.⁵ Rather than adapting existing polymers to new clinical problems, polyurethane chemistry enabled the deliberate construction of materials around specific performance requirements such as low-profile delivery, shape recovery, controlled release or hybrid integration with metallic components. This flexibility proved particularly valuable for minimally invasive and implantable devices, where material behavior directly influences procedural success and patient outcomes.

Polyurethanes represent a maturation of the biodegradable polymer field. They embody lessons learned from earlier materials while extending the design space to include elasticity, multifunctionality and system-level integration. Importantly,

their success underscores a key insight: Biodegradability alone is insufficient as a design goal; instead, next-generation biodegradable polymers must be evaluated by how effectively they balance degradation with mechanical function, biological interaction and translational practicality.

As biodegradable biomaterials continue to evolve, polyurethane-based systems illustrate how structure-property-function relationships can be strategically leveraged to address complex clinical needs. Their development signals a shift from single-parameter optimization toward holistic material design, positioning elastomeric and functional biodegradable polymers as central components of future biomedical devices.

LESSONS LEARNED ACROSS BIODEGRADABLE POLYMERS

Examining biodegradable polymers (poly(amino acid)s, polyesters and polyurethanes) reveals that progress in the field has been shaped as much by limitations as by innovation (**Table 1**). Each class emerged in response to unmet needs, and together they illustrate a gradual shift from molecule-centric design toward performance-driven, application-aware materials engineering. Several overarching lessons have emerged from this historical progression.

Table 1. Representative synthetic biodegradable polymers

	Poly(amino acid)s	Polyesters	Polyurethanes
Representative polymers	Poly(aspartic acid), poly(glutamic acid), poly(L-lysine), polypeptides	PLA, PGA, PLGA, PCL, PLCL	Polyester urethane, polycarbonate urethane, PU-urea
Design origin	Biomolecular inspiration (protein mimicry)	Synthetic aliphatic polymers	Modular, segment-based synthetic polymers
Primary motivation (historical)	Biocompatibility and bio-functionality	Resorbable structural materials and translation	Mechanical compliance and functional integration
Degradation mechanism	Enzymatic and hydrolytic	Hydrolytic (ester bond cleavage)	Tunable (hydrolytic $\pm$ oxidative depending on chemistry)
Mechanical properties	Generally low strength and stiffness	Moderate strength, relatively stiff	Highly tunable; elastomeric to semi-rigid
Mechanical compatibility with tissue	Poor for load-bearing applications	Limited (stiffness mismatch in soft tissues)	Excellent (tailorable compliance and elasticity)
Control of degradation	Moderate; often rapid	Well-established, predictable	Highly tunable via segment chemistry
Biofunctionalization	Intrinsic (side-chain modification)	Often requires surface modification	Readily integrated into bulk polymer
Processability	Limited for device-scale fabrication	Excellent (films, fibers, scaffolds, particles)	Versatile (coatings, elastomers, hybrid systems)
Typical applications	Drug delivery, gene delivery, bio-interfaces	Sutures, scaffolds, drug carriers, implants	Cardiovascular devices, coatings, flexible implants
Translational maturity	Limited (primarily research/biological platforms)	High (widespread clinical use)	Emerging to advanced (device-level applications)
Key limitations	Low mechanical robustness, rapid degradation	Stiffness mismatch, acidic degradation products	Complexity of synthesis and design optimization
Key advantage	Molecular-level tunability and bioactivity	Scalability and clinical reliability	Combination of elasticity, degradability and functionality
Role in field evolution	Established biomolecular design principles	Enabled large-scale clinical translation	Enabled function-driven, device-integrated biomaterials

Synthetic Biodegradable Polymers in Biomedical Applications

First, biodegradability alone is not a sufficient design criterion. Early enthusiasm for degradable polymers often prioritized resorption over function, implicitly assuming that biodegradability would translate to clinical benefit. Experience across all discussed polymer classes shows that degradation must be carefully coordinated with mechanical integrity, biological response and the intended functional lifetime of the device. Premature loss of strength, rapid mass loss or uncontrolled degradation products can undermine therapeutic outcomes as much as permanent implants can. Successful biodegradable systems are therefore those in which degradation is treated as a time-dependent design parameter, not an endpoint.

Second, mechanical compatibility with native tissue is as critical as chemical compatibility. Poly(amino acid)s highlighted the importance of molecular-level biomimicry, while polyesters demonstrated the feasibility of scaled translation. However, both polymers revealed that stiffness mismatch, limited elasticity and fatigue vulnerability can dominate biological outcomes, particularly in mechanically dynamic environments such as the cardiovascular system. The development of elastomeric biodegradable polyurethanes underscored a key insight: Materials must be mechanically matched to the physiological context they inhabit, not merely tolerated by the body.

Third, surface bioactivity must be integrated rather than appended. Across polymer systems, attempts to improve biological performance through post-fabrication coatings or surface treatments frequently introduced new challenges, including altered friction, compromised flexibility or reduced deliverability. These experiences highlighted the importance of materials-integrated bio-functionality, in which biological signaling, antifouling behavior or therapeutic capability is embedded within the polymer architecture itself. Polyurethanes demonstrated how modular chemistry can enable this integration without sacrificing bulk performance.

Fourth, structure-property-function relationships must be evaluated at the device and system levels. Much of early biomaterial development focused on material properties in isolation such as modulus, degradation rate or cytocompatibility. Over time, it became clear that these metrics are only meaningful when considered in the context of device geometry, manufacturing method and procedural use. Polyester scaffolds and elastomeric polyurethane devices alike showed that identical materials can perform very differently depending on form factor, loading conditions and interaction with biological flows. This realization reinforced the need for holistic design frameworks that connect polymer chemistry to end-use performance.

Finally, translational success requires alignment between materials innovation and practical constraints. Polyesters became translational workhorses not because they were ideal in every respect, but because they balanced performance with manufacturability, reproducibility and regulatory familiarity. Subsequent polymer systems benefited from these lessons, emphasizing scalability and consistency alongside innovation. The history of biodegradable polymers thus underscores that scientific novelty must coexist with processing, quality control and clinical workflow considerations if materials are to move beyond the laboratory.

Taken together, these lessons illustrate the synthetic biodegradable polymer field's maturation. What began as a search for resorbable alternatives to permanent implants has evolved into a nuanced discipline focused on dynamic performance, biological integration and system-level functionality. By understanding how different polymer classes succeeded or fell short in addressing these challenges, the biomaterials community is better equipped to design next-generation biodegradable systems that are not only resorbable, but also functional, reliable and clinically relevant.

PERSPECTIVES

Again, the historical evolution of synthetic biodegradable polymers, including poly(amino acid)s, polyesters and elastomeric polyurethanes, demonstrates that progress in the field has been driven less by the discovery of a single "ideal" material than by refinement of design philosophies. As biodegradable biomaterials continue to mature, future advances are likely to depend on how effectively materials scientists, engineers and clinicians integrate lessons learned from prior generations into cohesive, application-driven, human-centered strategies.

Hopefully, the future of biodegradable biomaterials will continue to be shaped by interdisciplinary training and collaboration. The challenges ahead extend beyond science, engineering and medicine, touching upon broader dimensions of humanity and philosophy. Preparing the next generation of biomaterials researchers to think across these boundaries will be as important as any specific material discovery. Feature-level reflections on history, such as those presented here, can play a valuable role in providing context for this training by highlighting not only successes, but also the lessons learned from pioneers in the field.

As a polymer and biomedical engineer engaged in the design and synthesis of polymeric biomaterials, I am witnessing a new era in biomaterials science, driven by artificial intelligence (see Figure 2, an AI-generated flowchart about using Machine Learning for new synthetic biodegradable polymers in

Synthetic Biodegradable Polymers in Biomedical Applications

biomedical applications). Although this perspective did not discuss the moral or emotional implications of these advances, it reflects a personal commitment to remain grounded in human-centered, fundamental insights. In an increasingly data-driven field, I view my role as contributing to the development of the next generation of problem-solvers, who are upright human beings equipped with foundational understanding and practical insight, to guide the responsible advancement and medical application of polymeric biomaterials.

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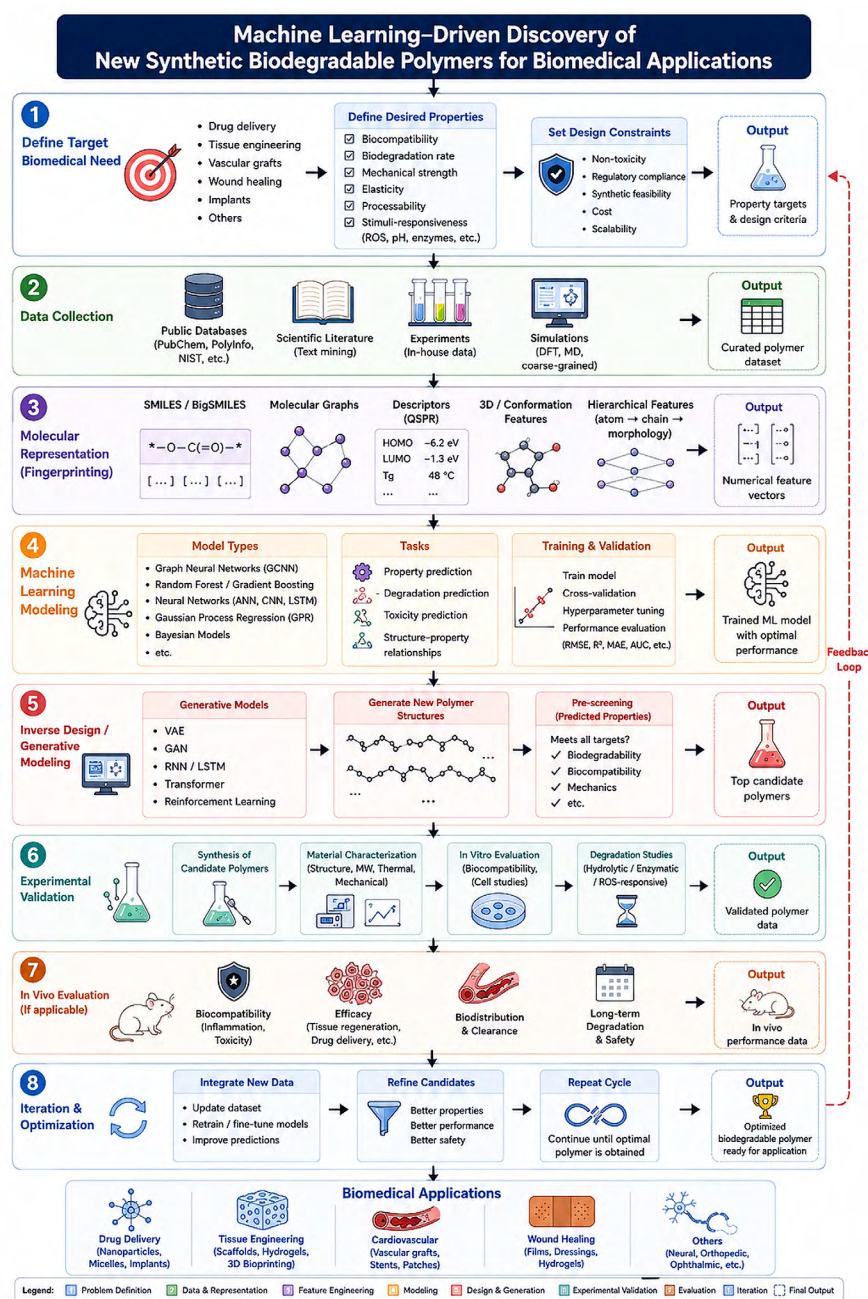


Figure 2. Machine Learning–Driven Discovery of New Synthetic Biodegradable Polymers for Biomedical Applications — generated by AI.

Significance of Phosphorylated Type I Collagen in Tissue Regeneration and Wound Healing

By Subramanian Gunasekaran, PhD

Collagen serves as the principal structural protein of the extracellular matrix (ECM) and plays a central role in tissue repair, regeneration and remodeling. Beyond its structural function, collagen undergoes several post-translational modifications that influence its biological activity. Among these modifications, phosphorylation represents an important biochemical process that can significantly enhance collagen's regenerative properties. Adding phosphate groups to specific amino acid residues modifies collagen's physicochemical characteristics, alters cellular interactions and activates signaling pathways involved in tissue repair.

Phosphorylated type I collagen has been associated with improved cellular recruitment, enhanced angiogenesis, increased extracellular matrix remodeling and accelerated tissue regeneration. By influencing kinase-mediated signaling pathways, phosphorylation contributes to stem cell attraction, cellular differentiation and the restoration of damaged tissues. These biological mechanisms have important implications for regenerative medicine, tissue engineering, wound healing and biomaterial design.¹

This article reviews the molecular basis of collagen phosphorylation, its biological significance in tissue regeneration, its role in cell signaling and angiogenesis and its potential importance in the development of advanced regenerative biomaterials. Understanding these mechanisms may provide valuable insights into the design of next-generation collagen-based scaffolds intended to support more effective tissue repair and clinical outcomes.

Tissue regeneration is a highly coordinated biological process involving cellular communication, extracellular matrix remodeling, vascular development and tissue-specific differentiation. Successful healing requires restoring structural integrity while simultaneously re-establishing the biological microenvironment necessary for normal tissue function.

The extracellular matrix serves as the primary structural framework for tissue repair. Among its various components, type I collagen is the most abundant and biologically important structural protein in the human body. It provides mechanical support, regulates cellular behavior, facilitates growth factor interactions and serves as a scaffold for tissue reconstruction.

Historically, collagen has been viewed primarily as a passive structural biomaterial. However, advances in molecular biology and biomaterials science have demonstrated that collagen actively participates in cellular signaling and tissue regeneration. The biological functionality of collagen is influenced not only by its molecular composition and structural architecture but also by post-translational modifications that occur naturally within tissues.

One such modification is phosphorylation. Protein phosphorylation is recognized as one of the most important regulatory mechanisms in cellular biology. Through the addition of phosphate groups to specific amino acid residues, proteins can undergo significant changes in their biochemical activity, molecular interactions and signaling capabilities.

While phosphorylation has been extensively studied in intracellular proteins, increasing evidence suggests that phosphorylation of extracellular matrix proteins, including collagen, may contribute substantially to tissue regeneration and wound healing. Understanding the role of phosphorylated collagen therefore represents an important area of interest in regenerative medicine and biomaterials science.^{2,3}

MOLECULAR BASIS OF COLLAGEN PHOSPHORYLATION

Phosphorylation is a reversible biochemical process involving the attachment of phosphate groups to specific amino acids, most commonly serine, threonine or tyrosine residues. This reaction is catalyzed by protein kinases and can be reversed through phosphatase activity (Figure 1).³

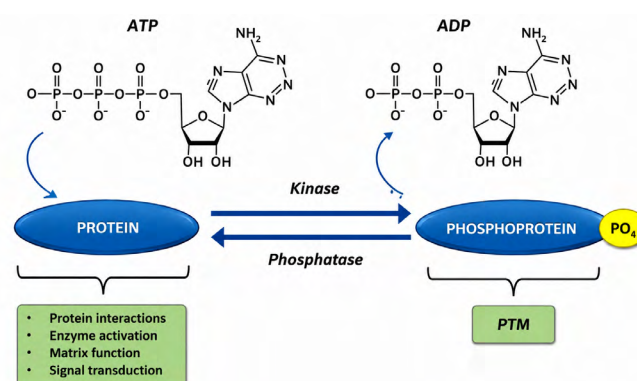


Figure 1. Phosphorylation transforms type I collagen into a bioactive scaffold that enhances cellular signaling and tissue regeneration.

Significance of Phosphorylated Type I Collagen in Tissue Regeneration and Wound Healing

When collagen undergoes phosphorylation, several important molecular changes occur. The introduction of negatively charged phosphate groups alters the electrical characteristics of the collagen molecule and shifts its isoelectric point. This modification affects molecular interactions, protein conformation and solubility under physiological conditions.

From a biomaterials perspective, phosphorylation can increase collagen's functional activity by exposing or modifying binding sites that interact with biological molecules. These changes influence cellular attachment, migration, proliferation and differentiation.

The significance of phosphorylation may be compared to preparing a structural framework for reconstruction. Just as a construction material must possess the appropriate physical properties before supporting a new structure, collagen must exhibit the appropriate biochemical characteristics before serving as an effective regenerative scaffold.

In physiological tissues, phosphorylation contributes to matrix organization and plays a role in regulating interactions between collagen and surrounding cellular components. During tissue repair, these interactions become particularly important because they influence the recruitment of inflammatory cells, stem cells, fibroblasts, endothelial cells and other key participants in the regenerative process.

BIOLOGICAL SIGNIFICANCE IN TISSUE REGENERATION

The regenerative significance of phosphorylated collagen extends beyond its molecular modifications and becomes evident through its influence on multiple biological processes involved in tissue repair:

- **Enhanced Matrix Functionality**

One of the primary consequences of phosphorylation is the enhancement of collagen functionality under physiological conditions. The modified collagen matrix becomes more biologically interactive, allowing improved communication between the extracellular environment and resident cells.

- **Stem Cell Recruitment and Differentiation**

Tissue regeneration depends heavily on the recruitment of undifferentiated progenitor and stem cells to sites of injury. Phosphorylated collagen may facilitate this process through the activation of signaling pathways that promote cellular migration toward damaged tissues.^{2,5}

Once recruited, these cells undergo differentiation into tissue-specific lineages required for repair. Depending on local physiological conditions, stem cells may contribute to the formation of soft tissues, vascular structures, connective tissues or mineralized skeletal tissues.

- **Matrix Remodeling**

Successful healing requires continuous remodeling of the extracellular matrix. Phosphorylation appears to influence matrix turnover and organization, enabling collagen scaffolds to adapt to changing biological requirements throughout the healing process.

- **Bone Formation and Mineralization**

The role of phosphorylation is particularly evident during skeletal tissue regeneration. During bone formation, collagen serves as the structural template upon which mineralization occurs (Figure 2).

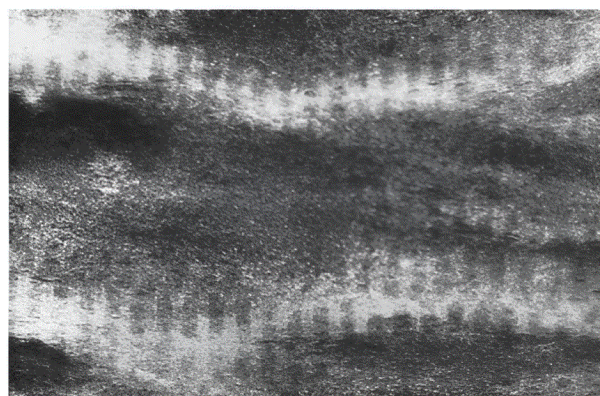


Figure 2. Electron micrograph of compact lamellar bone of chick diaphysis. Note that the apatite crystals are not only distributed axially along the long axis (horizontal in the photograph) of the individual collagen fibrils but that they are also in lateral register (vertical dimension of photograph) as well.

Phosphorylated regions of collagen can interact with calcium ions, facilitating the formation of calcium phosphate complexes that ultimately contribute to bone mineral development. This process demonstrates how phosphorylation can influence not only soft tissue repair but also hard tissue regeneration.¹

Collectively, these biological activities highlight the importance of phosphorylation as a mechanism that transforms collagen from a structural matrix into a biologically active regenerative scaffold.

CELL SIGNALING AND BIOACTIVITY

Perhaps the most significant contribution of collagen phosphorylation lies in its role in cellular signaling. Cell signaling governs virtually every aspect of tissue repair, including inflammation, angiogenesis, cellular migration, matrix deposition

Significance of Phosphorylated Type I Collagen in Tissue Regeneration and Wound Healing

and tissue remodeling. The activation of these pathways depends upon highly coordinated molecular interactions occurring between cells and their extracellular environment.

Phosphorylation is a fundamental component of signal transduction mechanisms. Through activation of kinase-mediated pathways, phosphorylated proteins regulate gene expression, cellular behavior and tissue-specific responses.^{3,4}

When collagen participates in phosphorylation-mediated signaling processes, it may enhance interactions with numerous biological mediators involved in wound healing, including:

- Platelets
- Macrophages
- Monocytes
- Fibroblasts
- Endothelial cells
- Growth factors
- Cytokines
- Extracellular matrix proteins

These interactions help coordinate the complex cascade of events necessary for successful tissue repair.

Importantly, phosphorylation may facilitate communication between collagen matrices and growth factors such as Platelet-Derived Growth Factor (PDGF), Epidermal Growth Factor (EGF), Insulin-Like Growth Factor (IGF), Fibroblast Growth Factors (FGFs) and Vascular Endothelial Growth Factor (VEGF).^{4,5}

Because these signaling molecules regulate cellular recruitment, proliferation, angiogenesis and matrix synthesis, enhanced interaction with collagen may amplify regenerative responses and improve healing efficiency.

PHOSPHORYLATION AND ANGIOGENESIS

Angiogenesis, the formation of new blood vessels, is among the most critical processes in tissue regeneration. Without adequate vascularization, newly forming tissues cannot receive sufficient oxygen, nutrients or cellular components necessary for repair. Poor blood supply is recognized as a major factor contributing to delayed healing and chronic wound development.

Emerging evidence suggests that phosphorylated collagen may support angiogenesis by activating signaling pathways associated with endothelial cell migration and vascular development.^{2,5}

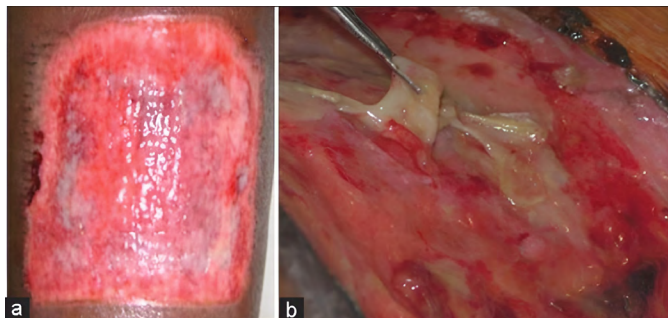


Figure 3. Type I collagen incorporated into deeper structures (a); capillary bleeding and incorporation of type I collagen (b). Reprinted from "Healicoll: An Alternate to Flap Cover for Bare Bones and Tendons," by Prema Dhanraj, N Naveen, K Ramesh Babu, M. S Mahesh, K. S Hanumanthaiah, 2016, Acta Medica International, 3(1):p 146-150, Jan-Jun 2016. CC BY-NC-SA 4.0.

Enhanced neovascularization contributes several important regenerative benefits:

- Improved oxygen delivery
- Enhanced nutrient transport
- Increased immune surveillance
- Accelerated waste removal
- Better integration of newly formed tissues

Clinically, rapid vascular incorporation of collagen matrices is often associated with improved tissue viability and more efficient wound closure (Figure 3). Because angiogenesis serves as a foundational event in tissue repair, biomaterials that support vascular development may offer significant advantages in regenerative applications.

IMPLICATIONS FOR REGENERATIVE BIOMATERIALS

Modern regenerative medicine increasingly recognizes that successful biomaterials must provide more than mechanical support. Advanced biomaterials must actively participate in biological processes that guide tissue repair and regeneration.

Phosphorylated collagen illustrates how biochemical modification can enhance biomaterial performance.^{5,6,7}

An ideal regenerative scaffold should possess:

- High biocompatibility
- Low immunogenicity
- Structural integrity
- Cellular interaction capability
- Growth factor responsiveness
- Angiogenic potential
- Remodeling capacity

Significance of Phosphorylated Type I Collagen in Tissue Regeneration and Wound Healing

Phosphorylation contributes to several of these characteristics by enhancing the biological activity of collagen matrices while maintaining their structural role within the extracellular matrix.

As biomaterials science continues to evolve, attention is increasingly turning toward bioactive matrices that influence cellular behavior through controlled molecular interactions. Understanding phosphorylation may therefore provide valuable guidance for the design of future tissue-engineered products.

Type I collagen phosphorylation represents an important post-translational modification that significantly enhances the biological functionality of collagen within regenerative tissues. By altering molecular interactions and activating critical signaling pathways, phosphorylation contributes to cellular recruitment, stem cell differentiation, angiogenesis, extracellular matrix remodeling and tissue regeneration.^{1,2,3}

Beyond its structural role, phosphorylated collagen functions as a biologically active component of the regenerative microenvironment, helping coordinate the complex cellular events necessary for tissue repair. These properties have important implications for wound healing, tissue engineering, orthopaedic regeneration and the development of advanced biomaterials.

As scientific understanding of extracellular matrix biology continues to expand, phosphorylation may emerge as an increasingly important factor in the design of next-generation regenerative technologies. Integrating biomaterials science with molecular biology will be essential to fully realize the therapeutic potential of bioactive collagen matrices in clinical medicine.

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ATTENTION MEMBERS!

WE WOULD LOVE TO HEAR FROM YOU.

IF YOU HAVE NEWS TO SHARE WITH FORUM READERS, LET US KNOW. EMAIL YOUR NEWS AND ANY PHOTOS TO INFO@BIOMATERIALS.ORG AND YOU COULD BE FEATURED IN THE NEXT ISSUE.

Member News

By Tatiana Segura, PhD



Norah Sivasubramaniam, Student Member

Norah Sivasubramaniam presented her project, “Improving Current Procedures in Pediatric Pulmonary Heart Valve Replacements Using 3D-Printed PGD and IPAAG Scaffold,” at the UC Berkeley BioEHSC™ competition. The project describes a bioresorbable, 3D-printed pulmonary valve scaffold designed to support fibroblast integration and grow alongside pediatric patients.

This approach has the potential to reduce the need for repeated open-heart surgeries in children born with congenital heart defects by enabling a regenerative approach to pediatric pulmonary valve replacement.



Donny Hanjaya-Putra, PhD, Associate Professor,
University of Notre Dame

Donny Hanjaya-Putra has received an inaugural Emerging Health Innovators (EHI) award from the Advanced Research Projects Agency for Health (ARPA-H) to advance research on lymphatic disease. The award will provide up to \$1.6 million over three years to support the multi-institutional Transforming Lymphatic Disease and Management (TRANSFORM-L) project.

Led by Hanjaya-Putra at the University of Notre Dame, the project will develop new diagnostic technologies and treatments for lymphatic filariasis. Notre Dame was one of only three institutions nationwide represented in the inaugural EHI cohort.



Ahsanul Kaiser, PhD, Independent Nano and
Biomedical Researcher

Ahsanul Kaiser has received the Best Professional Award (BPA) 2026 and the Star Excellence Award 2026 in the category of Biomedical Research and Innovation. The awards recognize his contributions to biomedical and nanotechnology research in Bangladesh and Malaysia.

Kaiser received the BPA at the ceremony on June 20 in Dhaka, Bangladesh, and the Star Excellence Award at a ceremony also held in Dhaka on July 11. His research focuses on cancer nanomedicine and theranostic nanoparticles.



Ramesh Singh, PhD, Postdoctoral Fellow,
George Mason University

Ramesh Singh and colleagues published a research article titled “Hierarchical Peptide Functionalized Titania Nanotubes: Improving Stability, Promoting Osteogenesis, and Reducing Infection Risk” in *Small* in July 2026.

The study introduces a hierarchical, dual-mode peptide functionalization strategy for titania nanotubes that addresses the stability limitations of conventional peptide coatings while promoting osteogenic stem cell differentiation and disrupting bacterial membranes. The approach may provide a strategy for simultaneously improving bone integration and reducing implant-associated infection.

Member News



Andrey Zakharchenko, PhD, Instructor, Department of Pediatrics,
Division of Cardiology, Children's Hospital of Philadelphia

Andrey Zakharchenko and colleagues have reported a new approach for improving the durability of bioprosthetic heart valve materials in *Acta Biomaterialia*. The study investigated Pyrphenone, a vitamin B6-based, photoresponsive molecule designed to become stably attached to valve materials following light activation.

In laboratory and animal studies, Pyrphenone modification reduced several processes associated with bioprosthetic valve deterioration, including glycation, calcification, serum albumin accumulation and interactions with platelets and white blood cells. The team is continuing to investigate Pyrphenone-modified bioprosthetic valves in a sheep model.



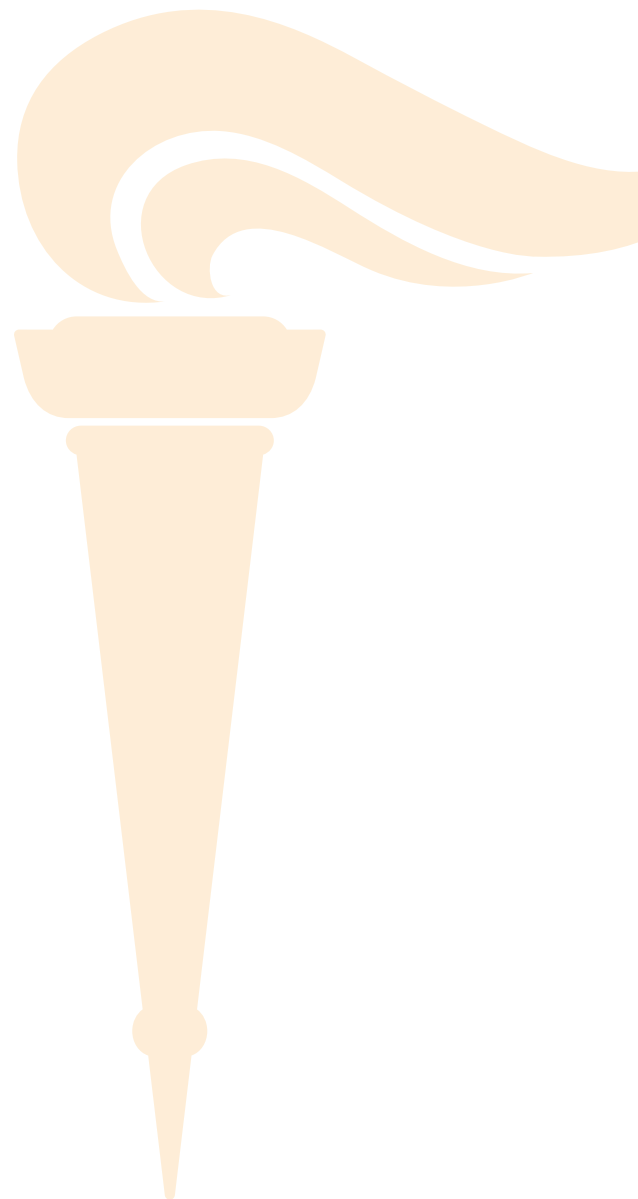
Bingyun Li, PhD, Professor, Department of Orthopaedics,
West Virginia University

Bingyun Li has received the 2026 West Virginia University Faculty Award for Distinction in Graduate Research Mentoring. The university-wide award recognizes faculty members who demonstrate exceptional commitment to graduate student mentorship.

During his 21 years at West Virginia University, Li has mentored more than 130 undergraduate, graduate, postdoctoral and visiting trainees. His mentorship spans research development, scientific and professional growth and continued career support for former trainees.

John Fisher, PhD, has moved to the University of Notre Dame to lead a new university-wide initiative in bioengineering and life sciences. Fisher, a biomedical engineer whose research spans biomaterials, tissue engineering and regenerative medicine, will help expand interdisciplinary research and education across engineering and the life sciences at Notre Dame.

In his new leadership role, Fisher will direct efforts to strengthen collaborations across the university and advance research at the intersection of engineering, biology and medicine.



Student News

THE NATIONAL STUDENT SECTION CONNECTS EMERGING BIOMATERIALS SCIENTISTS AND ENGINEERS THROUGH RESEARCH, EDUCATION, PROFESSIONAL DEVELOPMENT AND MULTIDISCIPLINARY COLLABORATION

BUILDING CONNECTIONS AND EXPANDING OPPORTUNITIES — A MESSAGE FROM THE PRESIDENT



Shatil Shahriar

President, SFB National Student Section

It is an honor to serve as President of the Society For Biomaterials (SFB) National Student Section. Our student community brings together emerging scientists and engineers from diverse backgrounds who share an interest in advancing biomaterials research and improving human health.

During the coming year, our leadership team hopes to make the Student Section more connected, active and valuable to its members. We will focus on strengthening collaboration among local chapters, supporting research and professional development and creating opportunities for students to connect with leaders in academia and industry.

I look forward to working with our officers, local chapters and student members to build an inclusive and supportive community. I encourage students to share their ideas, participate in upcoming activities and help shape the future of our Section.

MEET THE 2025–2026 STUDENT SECTION OFFICERS

The National Student Section is pleased to introduce its 2025–2026 leadership team. Together, the officers will support the Section's mission to promote student research, education, professional development and interaction across the biomaterials community.

Role	Officer	Institution
President	Shatil Shahriar	University of Nebraska Medical Center
President-Elect	MD Salauddin SK	Clemson University
Secretary/Treasurer	Nicole Racca	University of Michigan
Secretary/Treasurer-Elect	Rao Fu	Worcester Polytechnic Institute
Bylaws Chair	Kayle Riley	University of Michigan

CONTINUING SUCCESSFUL STUDENT INITIATIVES

Since the most recent SFB conference, the National Student Section has submitted four Calls for Ideas proposals to continue initiatives introduced at the previous conference. These proposals are intended to sustain opportunities for career exploration, scientific exchange, mentorship and community building:

- Industry Tour
- PhD-to-Postdoc Poster Session
- Student Luncheon
- Student and Young Scientist Group Mixer

Collectively, the proposed activities would help students learn about biomaterials careers, navigate transitions between training stages, exchange research ideas and build relationships with peers and professionals across the Society.

LOOKING AHEAD

In the coming year, the leadership team will work to strengthen communication among local student chapters, expand professional development opportunities and encourage broader student participation in SFB activities. The Section also aims to highlight student accomplishments and create more opportunities for students to connect with peers, postdoctoral researchers, academic scientists and industry professionals.

We welcome ideas, accomplishments and updates from local chapters and individual student members. By working together, we can continue building an active, connected and supportive community for the next generation of biomaterials scientists and engineers.

Share. Connect. Participate.

Industry News

By Subra Gunasekaran, PhD

MARKET GROWTH, INNOVATION AND COMMERCIAL OUTLOOK

The U.S. biomaterials industry continued its strong growth trajectory during Q3 2026, driven by expanding applications in **regenerative medicine, advanced wound care, orthopaedic and dental implants, cardiovascular devices and tissue engineering**.

The U.S. biomaterials market is estimated at approximately **US \$70 billion in 2026** and projected to reach nearly **US \$183 billion by 2035**, representing a CAGR of approximately **11.3 percent**.¹ Although estimates vary according to market definitions, industry analyses consistently indicate sustained long-term growth.

Q3 2026 also highlighted increasing convergence among **biomaterials science, regenerative medicine, additive manufacturing, artificial intelligence (AI) and advanced medical-device technologies**. At the same time, the U.S. Food and Drug Administration's (FDA) implementation of the **Quality Management System Regulation (QMSR)** has increased emphasis on manufacturing consistency, risk management and quality-system compliance.²

KEY GROWTH DRIVERS

Growth during Q3 2026 continued to be supported by:

- Increasing adoption of **regenerative medicine and tissue-engineering technologies**
- Expanding utilization of biomaterials in **advanced wound care**
- Rising orthopaedic, dental, cardiovascular and reconstructive procedures
- Greater use of **bioactive, biodegradable and bioresorbable materials**
- Increasing demand for **patient-specific implants**
- Continued development of **hydrogels, collagen-based matrices and regenerative scaffolds**
- Growing adoption of **3D printing and advanced manufacturing**

Aging populations and the increasing prevalence of chronic diseases remain important structural drivers. Healthcare systems are also placing greater emphasis on technologies that improve healing, reduce complications and revision procedures and provide measurable clinical and economic benefits.¹

INNOVATION AND EMERGING TECHNOLOGIES

Innovation is increasingly shifting biomaterials from passive structural materials to **bioactive and regenerative platforms** capable of interacting with cells and tissues, controlling local

biological responses and delivering therapeutic agents.

Key technology areas include:

- Regenerative scaffolds for wound, bone, cartilage and soft-tissue repair
- Smart and stimuli-responsive biomaterials
- Hydrogel-based drug-delivery systems
- Bioactive implant surfaces
- 3D-printed patient-specific implants and scaffolds
- Biomaterial-assisted tissue-engineering platforms
- Biosensing and implantable therapeutic devices
- AI-assisted material and scaffold design

NIH-supported research programs specifically identify smart biomaterials, regenerative and multi-tissue repair, implantable devices, biosensing, advanced manufacturing and data-driven design as important areas of translational development.³

AI, ADDITIVE MANUFACTURING AND PERSONALIZED MEDICINE

The integration of **AI and advanced manufacturing** represents an important emerging opportunity for biomaterials. AI-based modeling can potentially accelerate material selection, scaffold optimization, prediction of material–tissue interactions, manufacturing-process development and patient-specific implant design.

In August 2026, the FDA sought public feedback regarding regulatory considerations for **generative AI-enabled medical devices**, highlighting the increasing importance of AI across medical-device development and post-market monitoring.⁴

Meanwhile, 3D printing continues to expand opportunities for producing **patient-specific medical devices directly from anatomical imaging**, while tissue-engineered printed constructs remain an important area of regenerative research.⁵

REGULATORY AND COMMERCIAL ENVIRONMENT

A major 2026 regulatory development is the FDA's implementation of the **QMSR**, effective **February 2, 2026**. The QMSR amended 21 CFR Part 820 and incorporated **ISO 13485:2016** by reference.²

For biomaterial manufacturers, this increases the importance of:

- Material characterization and biocompatibility
- Risk-based product development
- Manufacturing consistency and process validation
- Supplier and quality-system controls

Industry News

- Clinical and performance evidence
- Post-market quality surveillance

The FDA evaluates biomaterials within the context of the **finished medical device and its intended use**, making product-specific safety, performance and manufacturing evidence essential for commercialization.⁵

CHALLENGES AND COMMERCIAL OPPORTUNITIES

Despite strong market fundamentals, the sector still faces **high research and development and clinical-validation costs, complex regulatory requirements, reimbursement uncertainty, manufacturing scale-up challenges and shortages of specialized biomaterials expertise**.

However, significant commercial opportunities remain in:

- Advanced wound-care and regenerative matrices
- Orthopaedic and dental regeneration
- Bioactive implant coatings
- Patient-specific implants
- Drug-delivery biomaterials
- Smart biomaterials and biosensors
- Tissue-engineering scaffolds

Regenerative medicine remains particularly important. The NIH continues to support approaches combining **materials science, bioengineering, cell biology and therapeutic delivery** to repair or replace damaged tissues.⁶

Successful commercialization increasingly requires more than technological novelty. Companies must demonstrate a combination of **biological performance, clinical evidence, manufacturing consistency, regulatory compliance, reimbursement viability and health-economic value**.

OUTLOOK

The Q3 2026 environment reinforces a broader transition from conventional structural biomaterials toward **bioactive, regenerative, patient-specific and digitally integrated therapeutic platforms**.

Continued advances in regenerative medicine, tissue engineering, additive manufacturing, smart biomaterials, AI-assisted design and personalized medicine are expected to sustain industry growth through the remainder of 2026 and beyond.

With the U.S. biomaterials market projected to approach **US \$183 billion by 2035**,¹ the sector remains positioned as a foundational technology platform for next-generation medical devices and regenerative therapies.

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