SYNTHESIS, CHARACTERIZATION AND PROCESSING OF NEW MATERIALS FOR INNOVATIVE APPLICATIONS
Jul-Dec 2024, VOL. 2, ISSUE 1, pp. 35-39
https://doi.org/10.61577/scpnmia.2024.100009

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REVIEW

OPEN ACCESS

Biomedical applications of silk fibroin: Progress, potential and limitations

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ABSTRACT

Silk fibroin (SF), predominantly sourced from Bombyx mori, has gained prominence as a protein-based biomaterial due to its tunable secondary structure, biocompatibility, mechanical robustness, and biodegradability. Advances in fabrication techniques have enabled the development of SF-based constructs such as films, nanofibers, hydrogels, sponges, and bioinks for diverse biomedical applications, including bone and cartilage repair, skin regeneration, ocular implants, and controlled drug delivery. Comparative analysis reveals that SF composites especially when blended with hydroxyapatite, gelatin, or bioactive ceramics exhibit superior mechanical integrity and cellular compatibility over traditional synthetic polymers. Moreover, recent progress in recombinant spider silk production through bacterial and yeast expression systems addresses scalability limitations while preserving high tensile properties. Post-processing modifications, such as methanol-induced β-sheet formation and polymer crosslinking, allow tailoring of degradation kinetics and structural resilience. Emerging applications include SF-based biosensors, neural interfaces, and microneedle arrays integrated with conductive or antimicrobial agents. Despite these advances, clinical translation is constrained by batch-to-batch variability, lack of regulatory standardization, and sensitivity to sterilization-induced conformational changes. Incorporating artificial intelligence and machine learning approaches has shown promise in optimizing scaffold design and predicting degradation and mechanical outcomes. To bridge the gap, interdisciplinary research integrating material science, molecular biology, and regulatory frameworks is essential. This review studies recent advancements and identifies translational barriers, offering a critical perspective on the clinical and commercial feasibility of silk-based biomaterials for regenerative medicine, therapeutic delivery, and bio-integrated devices.

KEYWORDS

Silk fibroin; Bombyx mori; Polymer crosslinking; Drug delivery; Biomaterials

ARTICLE HISTORY

Received 20 November 2024; Revised 19 December 2024; Accepted 27 December 2024

Introduction

Silk, a natural fibrous protein produced by various arthropods, has long been utilized in textiles and is now increasingly explored for biomedical applications. The most widely studied variant is derived from the domesticated silkworm (Bombyx mori), which produces silk fibroin (SF), a structural protein characterized by its unique combination of strength, flexibility, and biological compatibility [1]. Other sources such as non-mulberry silks (Antheraea mylitta, Samia cynthia ricini) and spider silk contribute additional mechanical and biochemical features, expanding the material's potential for diverse applications [2].

Silk fibroin is particularly attractive in the biomedical field due to its high tensile strength, controlled biodegradation, and minimal immunogenicity. Unlike many synthetic polymers, SF degrades into non-toxic amino acids and supports cellular adhesion and proliferation, making it suitable for applications in regenerative medicine, wound healing, and drug delivery. Furthermore, SF can be processed into various formats including films, hydrogels, fibers, sponges, and 3D-printed scaffolds using both aqueous and organic solvent systems [3].

Recent advancements in material processing and functionalization have enhanced the versatility of SF-based biomaterials. Techniques such as controlled β-sheet formation, blending with nanoparticles or polymers, and surface modification have enabled the fabrication of scaffolds with tunable mechanical properties, degradation rates, and bioactivity [4,5]. These improvements have led to successful demonstrations in bone regeneration, neural tissue engineering, controlled therapeutic release, and biosensing devices.

However, certain challenges persist. Variability in silk source, batch-dependent differences, and lack of standardization in processing can affect reproducibility and scalability. Additionally, achieving regulatory compliance and clinical translation remains a hurdle due to limited long-term in vivo data and production bottlenecks [6].

This review aims to critically assess the structure, processing techniques, and biomedical applications of silk-based biomaterials. By highlighting both the advances and limitations, we seek to provide a focused perspective on the translational potential of silk fibroin in clinical and material science domains.

Molecular Structure and Physicochemical Properties

Silk is a natural fibrous protein composed primarily of fibroin and sericin, produced by various insects. In Bombyx mori, silk fibroin (SF) forms the core structural protein, while sericin acts

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as a hydrophilic glue-like coating. SF consists of a heavy chain (~390 kDa), a light chain (~26 kDa), and a glycoprotein P25 (~30 kDa) in a 6:6:1 molar ratio, stabilized by disulfide bonds and hydrophobic interactions. The repetitive amino acid sequences—mainly glycine (Gly), alanine (Ala), and serine (Ser) enable the formation of ordered secondary structures, notably antiparallel β-sheets [7-9].

These β-sheet domains contribute significantly to the semi-crystalline nature of SF, imparting high tensile strength, stiffness, and slow degradation. In contrast, amorphous regions confer elasticity and extensibility. This dual-phase architecture allows silk to exhibit remarkable toughness and energy-dissipation properties, desirable for load-bearing and dynamic biomedical applications [10,11].

The amphiphilic nature of SF due to its distinct hydrophobic (β-sheet) and hydrophilic (amorphous) segments affects both solubility and biological behavior. Hydrophilic domains enhance cell adhesion, proliferation, and hydrogels' water retention, while hydrophobic domains contribute to mechanical integrity and reduced water solubility under physiological conditions [12].

Comparatively, spider silk possesses higher tensile strength and extensibility than Bombyx mori silk, attributed to its unique spidroin sequences and spinning mechanisms. Spider silk also contains polyalanine and glycine-rich blocks forming extensive β-sheets with greater alignment, resulting in enhanced load-bearing capacity. Non-mulberry silks such as tasar and muga, derived from Antheraea species, exhibit varied amino acid profiles, higher moisture regain, and inherent antimicrobial and antioxidant properties, making them particularly useful for wound healing and skin-contact materials [13,14] [Table 1].

Table 1. Composition and Properties of Different Silk Types.

Silk Type	Source Species	Primary Amino Acids	β-sheet Content	Tensile Strength (MPa)	Elasticity (%)	Degradation Rate	Notable Properties
Mulberry Silk	*Bombyx mori*	Glycine, Alanine, Serine	Moderate	300–600	~15	Slow	Biocompatible, low immunogenicity, well-studied, consistent supply
Tasar Silk	*Antheraea mylitta*	Glycine, Alanine, Aspartic Acid	Low–Moderate	150–250	~8–12	Moderate	Antioxidant, antimicrobial properties; higher sericin content
Eri Silk	*Samia cynthia ricini*	Serine, Alanine, Glycine	Low	100–200	~10	Moderate	High thermal stability; suitable for slow-releasing drug carriers
Muga Silk	*Antheraea assamensis*	Serine, Glycine, Alanine	Moderate	250–350	~12–15	Moderate	High luster and moisture regain; antimicrobial activity
Spider Silk	*Nephila clavipes, Araneus spp.*	Glycine-rich, Polyalanine blocks	High	1000–1500	~30–40	Very Slow	Highest strength-to-weight ratio; recombinant versions in development
Recombinant Spider Silk	Engineered microbes	Gly-Ala-Gly motifs	High	~500–800 (varies)	~15–20	Customizable	Tunable mechanical properties; scalable; free from batch variability

Processing Techniques

SF, undergoes a series of processing steps to enable its use in biomedical materials. These include degumming, dissolution, material fabrication, and post-processing modifications, each contributing to the final material properties and performance [Figure 1].

Degumming process

The initial step involves the removal of sericin, a hydrophilic glycoprotein coating that can elicit inflammatory responses in vivo. Degumming is typically achieved by boiling silk cocoons in a 0.02 M sodium carbonate (Na_2CO_3) solution for 30-60 minutes [Figure 2]. This process separates sericin from fibroin while preserving the native structure of the fibroin protein. Over-degumming, however, can lead to chain scission and a reduction in molecular weight, which adversely affects mechanical properties and processability [15].

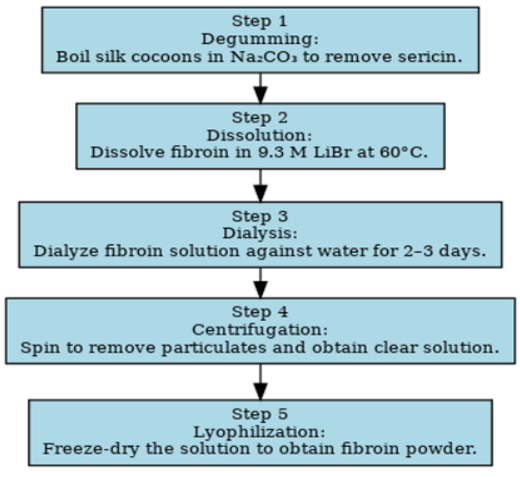

Figure 1. Silk Fibroin Extraction Flowchart.

https://doi.org/10.61577/scpnmia.2024.100009

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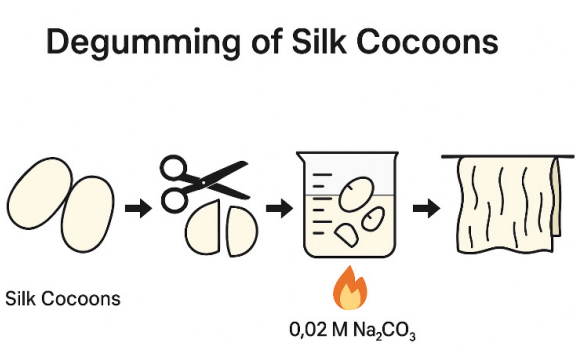

Figure 2. Degumming of Silk Cocoons.

Dissolution of silk fibroin

Following degumming, SF must be solubilized for downstream fabrication. As native SF is insoluble in water, dissolution requires denaturing solvents such as 9.3 M lithium bromide (LiBr) at 60°C for 4 hours or Ajisawa's reagent ($CaCl_2$:ethanol:water in a 1:2:8 molar ratio). After dissolution, dialysis against ultrapure water for72 hours removes salts, yielding an aqueous SF solution. The final concentration and viscosity of the regenerated SF solution are critical parameters for determining suitable fabrication methods [16].

Fabrication methods

Films

SF films are produced by casting aqueous fibroin solutions onto flat substrates followed by slow drying under ambient or controlled humidity. These films exhibit optical clarity, flexibility, and tunable permeability, which makes them suitable for wound dressings, drug delivery coatings, and ocular implants [17].

Hydrogels

SF hydrogels can be prepared through physical or chemical crosslinking. These networks mimic the extracellular matrix, providing hydration, porosity, and mechanical support for tissue growth. Gelation kinetics and pore size can be tuned by adjusting SF concentration and environmental parameters [18].

Electrospinning

Electrospinning of SF yields nanofibrous scaffolds with high surface area-to-volume ratios, favorable for cell attachment and proliferation. Parameters such as voltage, flow rate, and needle-to-collector distance affect fiber morphology. SF nanofibers have been explored in vascular grafts, nerve conduits, and antimicrobial wound mats [19].

Freeze-drying

Freeze-drying of SF solutions allows the formation of 3D porous scaffolds with tunable pore size, porosity, and mechanical strength. These structures are particularly useful for cartilage and bone tissue engineering, where nutrient diffusion and vascular ingrowth are essential [20].

3D printing and bioprinting

Recent advances in additive manufacturing have enabled the development of SF-based bioinks for 3D printing. These approaches allow fabrication of complex, patient-specific constructs with spatially controlled porosity and mechanical gradients, supporting the regeneration of anatomically precise tissue models [21].

Post-processing modifications

Methanol treatment

Immersing SF constructs in methanol induces β-sheet formation, increasing crystallinity, mechanical stability, and resistance to aqueous degradation.

Physical crosslinking

UV irradiation or thermal treatment can enhance structural integrity without chemical additives, minimizing cytotoxicity.

Polymer blending

Blending SF with polymers such as polyethylene glycol, gelatin, or chitosan allows fine-tuning of biodegradation, mechanical performance, and bifunctionality to meet specific biomedical requirements [22,23].

Biomedical Applications

Tissue engineering

Bone regeneration

SF scaffolds, particularly when combined with hydroxyapatite (HA), have demonstrated enhanced osteoconductive and mechanical properties suitable for bone tissue engineering. These composites support osteoblast adhesion, proliferation, and differentiation, making them promising candidates for orthopedic applications [24].

Cartilage and tendon repair

The mechanical properties of SF can be tailored to match those of cartilage and tendon tissues, making it suitable for their repair. SF-based scaffolds have shown to support chondrocyte and tenocyte proliferation and extracellular matrix production, facilitating tissue regeneration in these load-bearing applications [25].

Skin regeneration

SF matrices have been developed as wound dressings due to their biocompatibility, biodegradability, and ability to promote cell adhesion and proliferation. These dressings can maintain a moist wound environment, support re-epithelialization, and reduce scarring, making them effective for treating various skin injuries [26].

Drug and gene delivery

SF's ability to form various structures, such as films, hydrogels, and nanoparticles, allows for versatile drug delivery applications. Its β-sheet content can be manipulated to control degradation rates and drug release profiles. SF has been used to encapsulate a range of therapeutics, including proteins, antibiotics, and anticancer drugs, enabling sustained and controlled release. Additionally, SF-based microneedle patches have been developed for transdermal drug delivery, offering a minimally invasive method for administering therapeutics with controlled release kinetics [27].

Wound healing and hemostatic applications

SF-based dressings have been enhanced with antibacterial agents like silver nanoparticles (AgNPs) and zinc oxide (ZnO)

https://doi.org/10.61577/scpnmia.2024.100009

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to prevent infections and promote healing. These composites exhibit antimicrobial properties while maintaining the beneficial characteristics of SF. For hemostatic applications, SF sponges and pads have been developed to rapidly induce blood clotting. These materials can be functionalized with pro-coagulant agents to enhance their efficacy in controlling bleeding during surgical procedures [28].

Sutures, implants, and ophthalmology

SF has a long history of use in surgical sutures due to its strength and biocompatibility. Biodegradable SF sutures have been developed, offering controlled degradation rates suitable for various surgical applications. In ophthalmology, SF has been explored for corneal implants and contact lenses. Its transparency, mechanical strength, and biocompatibility make it an ideal material for these applications, potentially improving outcomes for patients with corneal diseases [29].

Bioelectronics and neural interfaces

SF's flexibility and biocompatibility have been leveraged in the development of bioelectronic devices and neural interfaces. Conductive SF composites have been created for use in flexible electronics that can conform to biological tissues, enabling applications such as brain implants and biosensors. These devices aim to provide stable, long-term interfaces with neural tissue, potentially improving treatments for neurological disorders [30].

Limitations and Challenges

Despite the growing interest in SF for biomedical applications, several critical limitations must be addressed to enable consistent clinical translation and commercial scalability.

Batch-to-batch variability

Silk fibroin derived from Bombyx mori shows natural variability due to differences in silkworm strain, rearing conditions, and cocoon processing. These factors influence the molecular weight distribution, secondary structure, and amino acid composition of the extracted protein. Such batch-to-batch variation can result in inconsistent mechanical strength, degradation kinetics, and biological responses, thereby complicating reproducibility in downstream applications [31].

Scalability and reproducibility

Most SF processing techniques, including degumming, dissolution, and regeneration, are optimized at laboratory scale. Scaling these protocols to industrial levels while maintaining protein integrity and consistent properties is challenging. Process deviations, such as incomplete sericin removal or inconsistent β-sheet content, can alter scaffold performance and biocompatibility. There is also a lack of standardized protocols for manufacturing SF-based medical devices, which hinders regulatory approval [32].

Regulatory and standardization gaps

Currently, silk biomaterials lack specific regulatory classifications under the U.S. FDA or ISO standards. This regulatory uncertainty impedes clinical adoption. Moreover, standard test methods to evaluate SF's physicochemical properties and in vivo performance are still under development, leading to inconsistent characterization across studies [33].

Sterilization-induced alterations

Sterilization is a prerequisite for clinical use, but common methods such as autoclaving and gamma irradiation can induce structural modifications in SF. For instance, autoclaving significantly increases β-sheet content, thereby enhancing crystallinity and stiffness but reducing degradation rate and elasticity [34].

Conclusion

Due to its tunable secondary structure, biocompatibility, and processability into diverse material formats, it has emerged as a leading natural polymer for biomedical applications. Its structural flexibility allows fabrication into films, sponges, hydrogels, nanofibers, and 3D-printed constructs, which have been successfully applied in tissue engineering, wound healing, drug delivery, and biosensing. These features, combined with its controlled degradability and favorable cell-material interactions, position SF as a key candidate in translational biomaterials research.

Looking ahead, several technological advances are expanding the biomedical utility of silk-based systems. Genetic engineering approaches have enabled production of recombinant spider silk proteins in bacterial and yeast systems, overcoming the scalability limitations of native spider silk and offering superior mechanical resilience for sutures and implants. Concurrently, smart biosensors fabricated from silk-based composites-often integrated with carbon nanotubes or metallic nanoparticles-have been demonstrated for real-time physiological monitoring, including pH, glucose, and strain sensing in implantable and wearable devices.

Further potential lies in combining SF with synthetic polymers to produce hybrid scaffolds with customizable mechanical, chemical, and degradation profiles. Additionally, artificial intelligence (AI)-driven design frameworks are being developed to model structure–function relationships, predict material behavior, and optimize fabrication strategies, thereby accelerating innovation in silk biomaterials.

Despite these advances, clinical translation will require coordinated progress in standardizing fabrication protocols, defining regulatory benchmarks (ISO/ASTM), and validating long-term performance. Interdisciplinary collaboration among materials scientists, molecular biologists, and clinicians remains essential to address these challenges and realize the full potential of silk-based biomaterials in precision medicine and therapeutic device platforms.

Disclosure statement

No potential conflict of interest was reported by the author.

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