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Research Article

DESIGN AND MECHANISMS OF BIODEGRADABLE MATERIALS FOR IMPLANTABLE STENT DEVICE APPLICATION

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Abstract

The increasing demand for biocompatible and more functional medical devices has led to the development of biodegradable materials, which offer promising alternatives for implantable applications. Recently, many promising approaches have been suggested based on biodegradable materials in various medical applications. This article explores the various biodegradable materials currently utilized in medical stent devices, focusing on their chemical composition, mechanical properties, and degradation mechanisms. We introduce material approaches ranging from biodegradable polymers to metallic materialsfor implantable devices, emphasizing their biocompatibility and controlled degradation profiles. The mechanisms of degradation, including hydrolysis, decomposition of metal, are discussed in detail, illustrating how these processes influence the performance and safety of biodegradable implants. Additionally, the article addresses the challenges associated with the design and implementation of biodegradable materials in clinical settings, including sterilization, mechanical integrity, and regulatory compliance. Emerging applications, such as bioresorbable stents integrated with diverse functions demonstrate the versatility of novel stent for improving outcomes of patients. Ultimately, this article aims to provide a comprehensive overview of the current state of biodegradable materials and their mechanisms, paving the way for future innovations in implantable stent that align with the evolving needs of healthcare.

Keywords: Mechanisms, device.

INTRODUCTION

The field of biomedical engineering has been fundamentally transformed by the development of implantable medical devices, which offer therapeutic (1), diagnostic (2,3), and monitoring capabilities (4-6) for a variety of medical conditions. Traditionally, these devices have been developed using non-degradable materials designed for long-term implantation, which, although effective, present significant drawbacks including the risk of infection, immune response, and the potential need for secondary surgeries to remove the device after its functional lifetime. Recently, there have been significant interests in biodegradable materials as an innovative solution for temporary implantable devices, as they offer the distinct advantage of fulfilling a biological or therapeutic function for a set period before gradually degrading into biocompatible by-products that can be safely absorbed or expelled by the body. The promise of biodegradable materials is vast, as they not only reduce the risks associated with permanent implants but also eliminate the need for device removal surgeries, making them a minimally invasive and patient-friendly option (7). As a result, biodegradable materials are being explored for various medical applications, such as tissue scaffolding, temporary cardiovascular stents (8, 9), drug delivery systems, wound healing, and short-term diagnostic tools (Figure 1). These materials must meet strict biocompatibility requirements, ensuring that they perform their intended function without eliciting harmful immune responses while also offering predictable and controllable degradation kinetics. Biodegradable materials can be categorized into three primary types: polymers, metals, and ceramics, each with distinct properties and degradation mechanisms.

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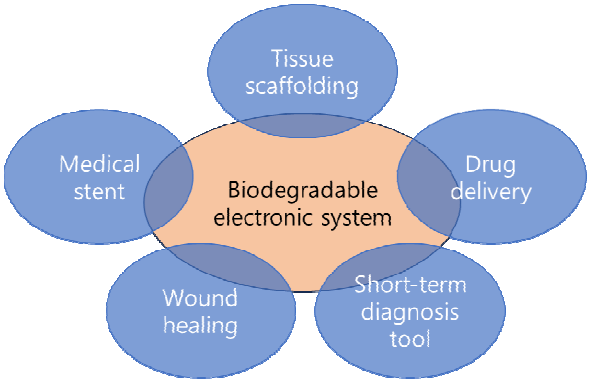

Figure 1. Medical applications based on biodegradable materials

Polymers, which include widely studied materials such as polylactic acid (PLA), polyglycolic acid (PGA), polycaprolactone (PCL), and poly(lactic-co-glycolic acid) (PLGA), degrade primarily through hydrolysis, where water molecules interact with polymer chains, breaking them into smaller fragments that are metabolized by the body. PLA, for instance, degrades into lactic acid, which is naturally processed by the body, making it a popular choice for biodegradable sutures, drug delivery devices, and tissue scaffolds. The rate of degradation can be fine-tuned by adjusting the molecular structure of these polymers or by creating copolymers. In contrast, biodegradable metals, particularly magnesium (Mg) and its alloys, degrade through corrosion in the physiological environment. Magnesium-based implants, such as temporary vascular stents or orthopedic fixation devices, degrade by interacting with bodily fluids to form magnesium hydroxide, which eventually dissolves and is excreted, leaving no trace of the implant. The corrosion of magnesium can be further controlled through alloying or surface modification to optimize its degradation rate for specific medical applications. Biodegradable ceramics, such as calcium phosphate and

bioactive glass, offer a slower degradation rate, making them ideal for bone regeneration and reconstruction applications where mechanical support is needed for extended periods as the natural bone gradually heals. The degradation of these ceramics is typically controlled by resorption mechanisms that mimic the natural turnover of bone tissue, and their bioactivity encourages the formation of new bone at the implant site. Despite their promise, there are several challenges that need to be addressed in the design and application of biodegradable materials for implantable devices. One of the most critical challenges is achieving precise control over the degradation rate. The material must maintain its structural integrity and mechanical strength for the required duration before beginning to degrade at a predictable pace. This is particularly important for load-bearing applications, where the premature degradation of a device could compromise its mechanical support. Conversely, if a material degrades too slowly, it may cause long-term complications, such as chronic inflammation or fibrotic encapsulation, similar to those associated with permanent implants. Another challenge lies in ensuring the biocompatibility of the degradation by-products. While many biodegradable materials, such as PLA and PGA, degrade into naturally occurring metabolites, the accumulation of these by-products in localized areas could lead to adverse effects such as tissue irritation or an imbalance in the local pH. Careful material selection and design can mitigate these issues by ensuring that degradation occurs at a rate that allows the body to effectively metabolize or excrete the by-products. Additionally, the mechanical properties of biodegradable materials are typically inferior to those of traditional non-degradable materials like titanium or stainless steel, limiting their use in high-load applications. Researchers are actively exploring strategies to enhance the mechanical properties of biodegradable materials, such as using composite materials or applying surface treatments to strengthen the material without compromising its degradability. Finally, understanding the physiological environment in which the material will degrade is critical to predicting its behavior in vivo. Factors such as the pH, enzyme activity, and local blood flow at the implantation site can significantly influence the rate and manner of degradation, necessitating the development of sophisticated models and in vivo testing protocols to accurately predict material performance. Here we review the importance of biodegradable materials to clinical application, especially stent intervention. Then, chemical mechanisms of biodegradable materials that have been reported will be addressed in next section. Moreover, design and material approaches to achieve mechanical robustness as well as compatibility with blood vessel will be discussed. With advances in material science, particularly in the synthesis of novel polymers, metals, and ceramics with tailored degradation profiles, biodegradable materials are set to play a central role in the future of personalized medicine and minimally invasive healthcare solutions. By harnessing the inherent biocompatibility and biodegradability of these materials, engineers and clinicians can design devices that meet the body's changing needs, offering temporary solutions that disappear once their work is done, paving the way for safer, more effective, and less invasive medical interventions.

Clinical requirement of biodegradable materials to medical system

Biodegradable materials have become increasingly significant in the medical system due to their unique ability to decompose naturally within the body, eliminating the need for surgical removal and offering a range of benefits across various medical applications. These materials, primarily composed of polymers, for examples, poly(lactic-co-glycolic acid) (PLGA), polylactic acid (PLA), and magnesium-based alloys, must meet stringent clinical requirements to ensure they are both biocompatible and effective. One of the most important requirements is biocompatibility, which ensures that the material does not trigger adverse immune responses, such as inflammation or toxicity, during its interaction with biological tissues. Another important aspect is the control of the degradation rate, where materials need to degrade at a pace that complements tissue healing or regeneration, maintaining mechanical support until the biological structures can independently handle the physiological loads. For instance, biodegradable stents and bone fixation devices must provide initial strength while gradually transferring mechanical load to the healing tissue (10). This highlights the necessity for mechanical integrity, as the materials must possess properties tailored to their specific functions, whether intended for use as scaffolds in tissue engineering, sutures, or implants. The structural integrity of materials must remain stable during the requirement period before degrading in a predictable manner without early breakdown, which could cause complications such as structural collapse or premature release of embedded drugs. Furthermore, products result from degradation must be non-toxic and easily metabolizable or excretable by the body. For example, PLGA degrades into lactic and glycolic acid, both of which are naturally processed by the body without causing harm. With increasing applications in areas like controlled drug delivery, tissue engineering, and wound healing, biodegradable materials must not only fulfill these clinical requirements but also adapt to emerging medical needs. In drug-eluting stent systems, for instance, biodegradable polymers are being engineered to provide sustained release of drugs over extended periods, effectively preventing the regeneration of cells near the blood vessel. In tissue engineering, biodegradable scaffolds play a pivotal role in supporting cell growth and tissue formation for complex structures like bone, cartilage, and skin, eventually degrading as the tissue regenerates. The advent of bioresorbable stents and grafts in cardiovascular treatments has also highlighted the potential of biodegradable materials in reducing long-term complications and eliminating the need for secondary surgeries. While the future of biodegradable materials in the medical field is promising, it is crucial that these materials continue to evolve with innovations that ensure their degradation rate, mechanical properties, and biocompatibility align with specific medical applications to optimize patient outcomes, safety, and effectiveness.

Basic mechanism of biodegradable materials

The basic mechanism of biodegradable materials revolves around their ability to naturally decompose into non-toxic byproducts through the action of biological agents such as microorganisms, enzymes, or environmental factors like moisture and temperature. These materials are designed to break down into water, carbon dioxide, methane, biomass, and inorganic compounds, depending on the environmental conditions and the composition of the material. At the core of this mechanism is the molecular structure of the material, often featuring hydrolytically or enzymatically cleavable bonds, such as ester, amide, or glycosidic linkages. For example, polylactic acid (PLA), a commonly used biodegradable

polymer, degrades through hydrolysis of its ester bonds, resulting in lactic acid, which is further metabolized by microbes in the environment (Figure 2) (11).

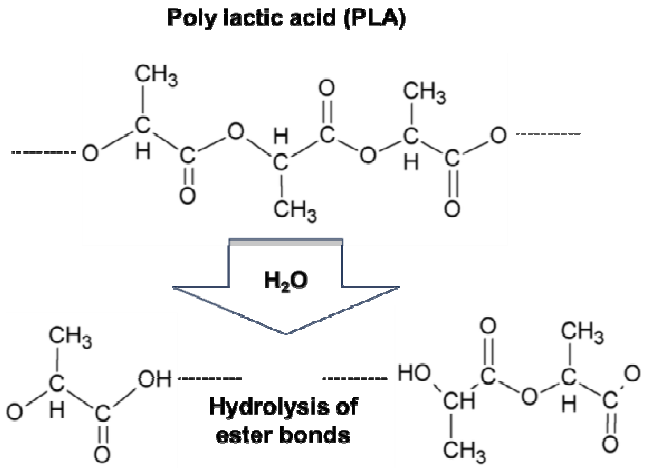

Figure 2. Schematic showing chemical structure of PLA and its decomposition through hydrolysis

Similarly, polyhydroxyalkanoates (PHAs), naturally occurring biopolymers, are enzymatically broken down into monomers that microbes utilize as an energy source. The degradation process typically occurs in stages: initial depolymerization where the polymer chains are cleaved into smaller fragments, followed by bioassimilation where these fragments are consumed by microorganisms, and finally mineralization, where the byproducts are converted into simple inorganic compounds. The rate and efficiency of biodegradation depend on several factors, including the chemical structure of the material, environmental conditions such as oxygen availability, and the presence of suitable microbial populations. For instance, anaerobic environments, like those in landfills, facilitate methane production, whereas aerobic conditions, such as composting, primarily yield carbon dioxide and biomass (12). Advances in biodegradable material design focus on tailoring these mechanisms for specific applications, such as creating starch-based bioplastics or cellulose derivatives for packaging, and bioresorbable polymers like polyglycolic acid (PGA) for medical sutures that degrade safely within the human body. Understanding and optimizing the mechanisms of biodegradation are essential for developing materials that effectively address environmental challenges while maintaining functionality in their intended applications.

Mechanics and materialapproaches for soft biodegradable system

During the tissue healing process, minimal mechanical requirements are critical to prevent elastic recoil during balloon expansion. These include a low yield strength (YS) of approximately 200 MPa, high ultimate tensile strength (UTS) exceeding 300 MPa, and a high Young's modulus (E) to manage deformation within <4% during expansion. An elongation range of 15-18% is recommended, though higher values can trade off against YS and UTS. Alongside balancing these mechanical properties, stent design must account for factors such as low-profile configurations, flexibility, radial strength, open or closed cell geometry, and longitudinal force distribution.Stent development involves careful consideration of material, geometry, and metal microstructure. Metals are often preferred due to their superior strength, allowing thinner designs that minimize tissue injury while reducing the need for additional surgeries. Among various studies, Omega and Driver stents required less force for compression and extension, demonstrating improved mechanical efficiency. The commonly used 316L stainless steel (316LSS) stents initially faced challenges with low radiopacity. However, innovations such as material composition adjustments have led to successful modern versions.Polymer materials were explored as alternative stent materials to address the clinical limitations of metals. Despite some advancements, polymers still face significant drawbacks, including low radiopacity, reduced radial force, and limited plasticity. To achieve the necessary rigidity, polymers must be thicker, which can be addressed by increasing molecular weight or optimizing degradation rates (e.g., PLLA degrades in 2-3 years). Fiber-coated PLA has shown promise in improving tensile strength while reducing elasticity. For example, Magnitude-BRS demonstrated a wall thickness of 98 μm while maintaining tensile strength, elastic recoil, and radial strength.Bioresorbable metals such as iron (Fe), magnesium (Mg), and zinc (Zn) represent a promising alternative for stent applications (13). These metals not only enhance stent strength but also offer biocompatibility, serving essential roles in the human body. However, their corrosion rates differ significantly under in vitro and in vivo conditions (Mg < Fe < Zn). Alloying strategies address challenges such as Fe's slow degradation, which can interfere with surrounding tissues (14). For instance, Fe alloys with Mg or silver (Ag) enhance corrosion rates and mechanical strength.Magnesium-based alloys are also advancing, with the addition of calcium (Ca) or polymer coatings extending their degradation from 60 days to approximately 9 months while improving elongation to 26% (15). Recently, zinc has emerged as a bioresorbable material, though its initial performance fell short of stent requirements. Alloying Zn with Mg and lithium (Li) has demonstrated improved mechanical strength and a controlled degradation duration of around 6 months (16).In conclusion, effective stent design requires balancing factors such as strut thickness and polymer crystallinity. Thinner stents are generally more favorable for compatibility within the body. Bioresorbable metal alloys, combining optimal strength, controlled degradation rates, and reduced profiles, are emerging as the most promising candidates for next-generation stents.

Multi functions for future stent technology

The evolution of stent technology has profoundly impacted the field of interventional medicine, particularly in treating cardiovascular diseases. Future stent designs are increasingly moving beyond the traditional role of maintaining vascular patency to incorporating multifunctional features that address a broader spectrum of clinical needs. One of the most significant advancements is the development of bioresorbable stents, which gradually degrade after restoring blood flow, eliminating the need for permanent implants and reducing long-term complications like restenosis or late thrombosis. Alongside this, drug-eluting stents (DES) are undergoing innovations to deliver site-specific therapy. These stents are being engineered to release anti-inflammatory, antiproliferative, or even gene-therapy agents in a controlled manner to prevent restenosis. Another promising direction is the integration of sensors within stents to enable real-time monitoring of vascular conditions. Smart stents equipped with sensors could measure parameters such as blood flow,

pressure, or biomarkers indicative of inflammation or clot formation, providing critical data for clinicians (Figure 3).

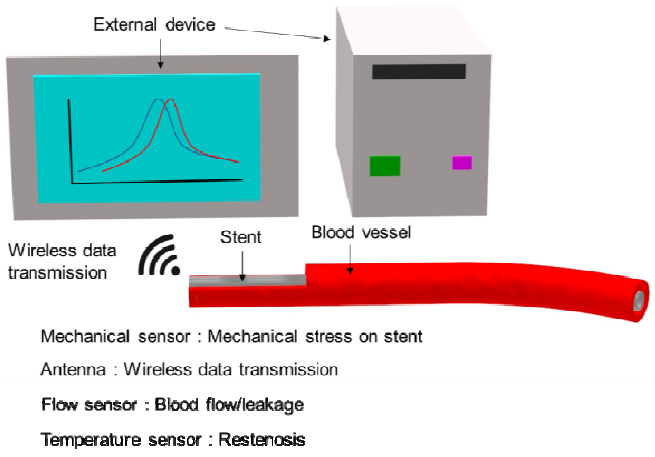

Figure 3. Schematic of future multi-functional stent

These features could be linked to wireless communication systems, creating a feedback loop for immediate therapeutic interventions. For example, if a stent detects early signs of restenosis or clot development, it could trigger a signal to the physician or activate an embedded drug-release mechanism to counteract the condition. The incorporation of sensors also has potential applications in chronic disease management, allowing continuous patient monitoring without the need for invasive procedures.Future stents maycontribute to regenerative medicine. Researchers are investigating the incorporation of stem cell-attracting compounds or growth factors into stent surfaces to promote natural tissue regeneration and vascular repair. These regenerative stents could reduce dependence on external therapies and facilitate self-healing processes within the body. Additionally, hybrid designs combining mechanical support with bioelectronic components are emerging. These could provide electrical stimulation to enhance tissue healing, improve cell signaling, or even act as a platform for interfacing with neural pathways in cases involving neural-vascular interactions.Finally, future stent technology will likely embrace artificial intelligence and machine learning for improved design and post-implantation management. Computational models could optimize stent geometry and placement strategies for each patient, enhancing procedural success rates. Similarly, AI-driven systems could analyze sensor data to predict complications, enabling preemptive measures. These multi-functional stents will not only treat cardiovascular diseases more effectively but also expand their applications to other areas, such as gastrointestinal, neurological, or respiratory systems. By combining structural, therapeutic, and diagnostic functionalities, the next generation of stents will redefine their role in medicine, making them a cornerstone of personalized and precision healthcare.

Conclusion

Biodegradable materials mark a significant advancement in the design of implantable stent devices, addressing critical challenges such as long-term complications and the necessity of secondary removal surgeries. These materials are engineered to degrade into biocompatible byproducts, offering a promising approach to enhance patient outcomes by mitigating risks of inflammation, restenosis, and thrombosis. The degradation mechanisms hydrolytic, enzymatic, or oxidative are meticulously tailored to match the physiological environment and the stent's functional lifespan. Despite notable progress, challenges remain, including precise control of degradation rates, retention of mechanical strength, and ensuring biocompatibility, which are key areas for ongoing research. Innovations in material science and engineering continue to drive the development of biodegradable stents, paving the way for next-generation medical implants that seamlessly integrate functionality, safety, and sustainability.

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