

Review Article 

A Review of Advances in the Development of Bioresorbable Nano Stents: Part (II)

Abdul Razak Mohamed Sikkander^{1,*} , Hazarathaiah Yadav² , Manoharan Meena³ , V. Vidya Lakshmi⁴ 

¹Department of Chemistry, Velammal Engineering College, Chennai, India

²Department of Chemistry, Vel Tech Rangarajan Dr. Sakunthala R&D Institute of science&Technology, Avadi, Chennai, India

³Department of Chemistry, R.M.K. Engineering College, Kavaraipeetai, Chennai, India

⁴Department of Electronics&Communication Engineering, R. M. K. Engineering College, Chennai- India



Citation: A.R.M. Sikkander, H. Yadav, M. Meena, V.V. Lakshmi, A Review of Advances in the Development of Bioresorbable Nano Stents: Part (II). *J. Chem. Rev.*, 2024, 6(3), 304-330.

 <https://doi.org/10.48309/JCR.2024.432947.1287>

**Article info:**

Received: 29 December 2023

Revised: 10 March 2024

Accepted: 08 May 2024

ID: JCR-2312-1286

Checked for Plagiarism: Yes

Language Editor Checked: Yes

Keywords:

Critical healing phase,
Thrombosis persist,
Biocompatibility, Drug delivery

ABSTRACT

Bioresorbable nano stents represent a revolutionary advancement in the field of interventional cardiology, offering a novel approach to address the challenges associated with traditional stent technologies. These innovative devices are designed to provide temporary structural support to blood vessels during the critical healing phase following interventions, such as angioplasty. The key feature of bioresorbable nano stents lies in their ability to gradually degrade over time, aligning with the natural healing processes of the body. Nanotechnology plays a pivotal role in the development of bioresorbable nano stents, allowing for precise control over material properties, degradation kinetics, and biocompatibility. The customization afforded by nanomaterials enables tailoring stent characteristics to match the specific needs of individual patients and diverse clinical scenarios. This level of customization contributes to enhanced safety, reduced risk of complications, and improved patient outcomes. The controlled degradation of bioresorbable nano stents eliminates the long-term presence of foreign materials in the body, potentially mitigating late complications associated with permanent stents, such as in-stent restenosis and thrombosis. This abstract explores the potential benefits of bioresorbable nano stents, including their role in minimizing inflammatory responses and adverse reactions. In addition, the integration of nanotechnology enables the incorporation of imaging agents, antimicrobial coatings, and other functionalities, further expanding the capabilities of these innovative medical devices. The dynamic nature of nanomedicine, coupled with interdisciplinary collaboration, continues to drive advancements in bioresorbable nano stents, positioning them as a transformative technology in the landscape of cardiovascular interventions.



Abdul Razak Mohamed Sikkander: He is serving as an Associate Professor and Head, Department of Chemistry, Velammal Engineering College, Chennai- 600066 India. He has earned his UG, PG Chemistry Degrees from Jamal Mohamed College, Trichy, M. Phil from Bharathidasan University, Trichy and Ph.D. from Periyar University, Salem. He was 20th Ph.D. scholar of Dr. P. Mani Sankar, Former Vice Chancellor, Bharathidasan University Tiruchirappalli. He has taught for thirty years and has written 12 books.

*Corresponding Author: Abdul Razak Mohamed Sikkander (ams240868@gmail.com)



Hazarathaiah Yadav: He is serving as a Professor and Head, Department of chemistry, Veltech Rangarajan Dr. Sakunthala R&D Institute of Science and Technology, Avadi, Chennai India. His research focused areas are chromatography, Synthesis, Characterization, and Nano materials.



Manoharan Meena: She works as a Professor in the Department of Science and Humanities (Chemistry Division), at R.M.K. Engineering College, Kavaraipettai, Thiruvallur district, Tamil Nadu since 1997. She obtained her Master's Degree in Applied Chemistry from Anna University, Master of Philosophy from J.N.T University, and Doctorate in Chemistry from Anna University, Chennai. She started her teaching career in the year 1996 and serving with passion in the same field for the past 27 years. Her areas of interest are phase transfer catalysis, polymer chemistry, and environmental science. She has published many research papers in both national and international journals. She has published 11 patents to her credit and acts as a reviewer in a few national journals. She also presented papers at many conferences, seminars, and workshops. In addition, she co-authored books on Engineering Chemistry and Environmental Issues and Sustainable Development.



V. Vidya Lakshmi: She is currently working as Assistant Professor in Velammal Engineering College, Chennai in the Department of Electronics and Communication Engineering. She has 20 Years of teaching and research experience. She received her B.E (ECE) degree, from Adhiparasakthi Engineering College in the year 2002 and received her M.E. degree from Velammal Engineering College in the year 2010. She received her Ph.D. degree from Anna University, in information and Communication in the year 2022. She has published over 10 research publications in refereed international journals and international conferences. Her areas of research include image processing, signal processing, wireless communication.

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1. Introduction

Cardiovascular diseases remain a leading cause of morbidity and mortality worldwide, necessitating continual advancements in interventional cardiology. Traditional metallic stents have significantly improved the outcomes of coronary interventions; however, concerns regarding long-term complications such as in-stent restenosis and thrombosis persist [1]. In response to these challenges, bioresorbable nano stents have emerged as a groundbreaking technology, poised to redefine the landscape of vascular interventions. Bioresorbable nano stents are designed to offer temporary structural support to blood vessels

while addressing the limitations associated with permanent stents [2-11] (Figure 1). The integration of nanotechnology in stent development provides a level of precision and customization that was previously unattainable. This innovation leverages nanomaterials to engineer stents with tailored degradation kinetics, enhanced biocompatibility, and multifunctional capabilities (Table 1).

Nanotechnology enables the design of stents that not only provide mechanical support, but also dissolve gradually, aligning with the natural healing processes of the body. The controlled degradation of bioresorbable nano stents eliminates concerns related to the long-

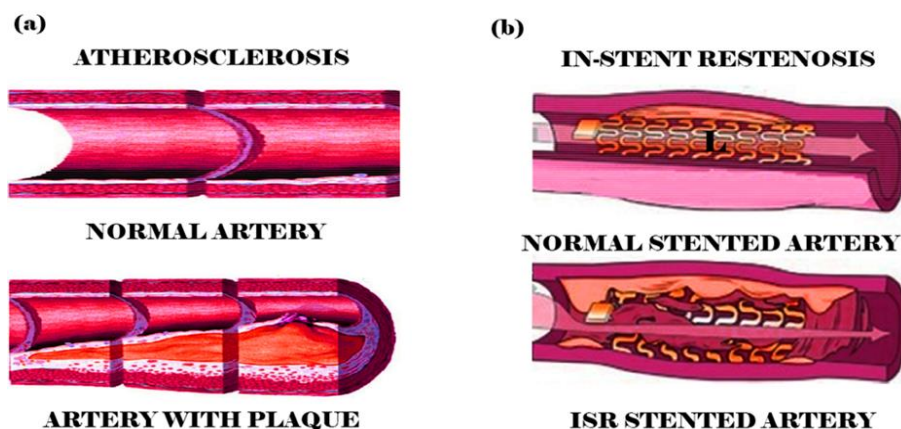


Figure 1. Bioresorbable stents: (a) Abbott ABSORB stent; (b) DESolve stent; (c) Fantom stent; and (d) Igaki-Tamai stent

Table 1. The tailored degradation kinetics, enhanced biocompatibility, and multifunctional capabilities of Bare-Metal Stent, Drug Eluting Stent and Bioresorbable Stent

Properties	Bare-Metal Stent	Drug Eluting Stent	Bioresorbable Stent
Mechanical stress	permanent	permanent	temporary
Tensile strength	high	high	high (metallic stents) low (polymeric stents)
Coatings	none	possessed	possessed
Risk of thrombosis	low	late	transient
In-stent restenosis	high	low	moderate
Inflammation	low	moderate/high	High
Vessel size mismatch	none	none	Possible

term presence of foreign materials and opens new possibilities for minimizing complications associated with permanent implants. This introduction explores the key features and potential advantages of bioresorbable nano stents, including their ability to reduce inflammation, optimize biocompatibility, and facilitate a more natural vascular response. The integration of imaging agents and other functionalities further enhances the diagnostic and therapeutic capabilities of these advanced medical devices. While the promise of bioresorbable nano stents is substantial, their successful clinical translation requires rigorous validation through preclinical studies and clinical trials. This comprehensive exploration of bioresorbable nano stents aims to provide an understanding of their potential impact on cardiovascular interventions, emphasizing the need for ongoing research, interdisciplinary collaboration, and regulatory approvals to usher in a new era in interventional cardiology [12-35].

2. Research and Methodologies

Research on bioresorbable nano stents involves a multidisciplinary approach, integrating principles from materials science, nanotechnology, biomechanics, pharmacology, and clinical research. The methodologies employed in studying bioresorbable nano stents are diverse, encompassing both *in vitro* and *in vivo* experiments, preclinical studies, and clinical trials. Researchers explore various nanomaterials, such as biocompatible polymers, to design stents with optimal mechanical properties and degradation characteristics. Techniques like scanning electron microscopy (SEM), atomic force microscopy (AFM), and spectroscopy are used to analyze the surface morphology, mechanical strength, and chemical composition of the nanomaterials. Nanotechnology is applied to fabricate nano stents using methods like electrospinning, lithography, or self-assembly, allowing precise control over the stent's structure at the nanoscale. Nanoparticles loaded with therapeutic agents are integrated into the stent design for controlled drug release. Encapsulation methods and drug

loading techniques are studied to optimize drug delivery kinetics. *In vitro* studies involve exposing bioresorbable nano stents to cultured cells to assess their biocompatibility. Cell viability assays, gene expression analysis, and cytokine release assays are conducted to evaluate the cellular response. Implantation of bioresorbable nano stents in animal models helps assess the stent's interaction with living tissues, examining inflammatory responses, tissue integration, and overall biocompatibility. Researchers simulate physiological conditions *in vitro* to study the degradation kinetics of nano stents.

Factors such as temperature, pH, and enzymatic activity are controlled to mimic the *in vivo* environment. Implantation of bioresorbable nano stents in animal models for extended periods allows researchers to monitor the degradation process over time, ensuring it aligns with the natural healing timeline. *In vitro* Drug Release Studies: Researchers conduct controlled drug release studies in simulated physiological conditions to understand and optimize the release profiles of therapeutic agents from the nano stent.

In vivo studies assess the systemic and local pharmacokinetics of drugs released from bioresorbable nano stents, providing insights into the therapeutic efficacy and safety. Nano stents undergo mechanical testing using techniques such as tensile testing and radial compression to evaluate their mechanical properties, including strength, flexibility, and recoil. Computational modeling, such as FEA, is employed to predict the mechanical behavior of bioresorbable nano stents under various conditions. Nanotechnology allows for the integration of imaging contrast agents into nano stents, enabling enhanced visualization during imaging modalities such as MRI or CT scans. *In vivo* imaging studies assess the visibility, location, and behavior of bioresorbable nano stents within blood vessels, providing valuable diagnostic information [36-65] (Figure 2).

Clinical trials involving human subjects are conducted to assess the safety, efficacy, and performance of bioresorbable nano stents. These trials follow a phased approach, gradually progressing from small-scale safety

studies to larger-scale efficacy trials. Continuous monitoring of patients who have received bioresorbable nano stents provides long-term data on their safety and performance in real-world clinical settings. Researchers collaborate with regulatory agencies to ensure that bioresorbable nano stents comply with established standards and undergo the necessary approvals before entering the market. The research on bioresorbable nano stents involves a combination of laboratory-based experiments, animal studies, computational modeling, and clinical trials. This multifaceted approach aims to comprehensively understand the behavior of bioresorbable nano stents, from their material characteristics to their performance in clinical settings, with the ultimate goal of advancing cardiovascular interventions. Some researchers are investigating bioresorbable stents at the nanoscale. These stents are designed to gradually dissolve over time, reducing the long-term presence of a foreign material in the body. Bioresorbable nano stents represent a notable development in stent technology [66] (Table 2). The goal of bioresorbable stents is to provide temporary support to a blood vessel or

other tubular structures, and then gradually dissolve, eliminating the need for a permanent implant. Bioresorbable stents are designed to break down over time, eventually being absorbed by the body. At the nanoscale, the materials used for these stents can be engineered to degrade into biocompatible byproducts that are easily absorbed or excreted [67].

2.1. Temporary structural support

The initial purpose of a bioresorbable nano stent is to provide temporary structural support to a vessel or duct, such as an artery. This support is crucial during the initial healing phase when the vessel is at risk of collapsing or becoming blocked.

The statement accurately captures the primary purpose of bioresorbable nano stents. Bioresorbable stents are designed to provide temporary structural support to a vessel or duct, such as an artery, during a critical healing phase. The primary function of a bioresorbable nano stent is to offer temporary mechanical support to a vessel, providing stability during

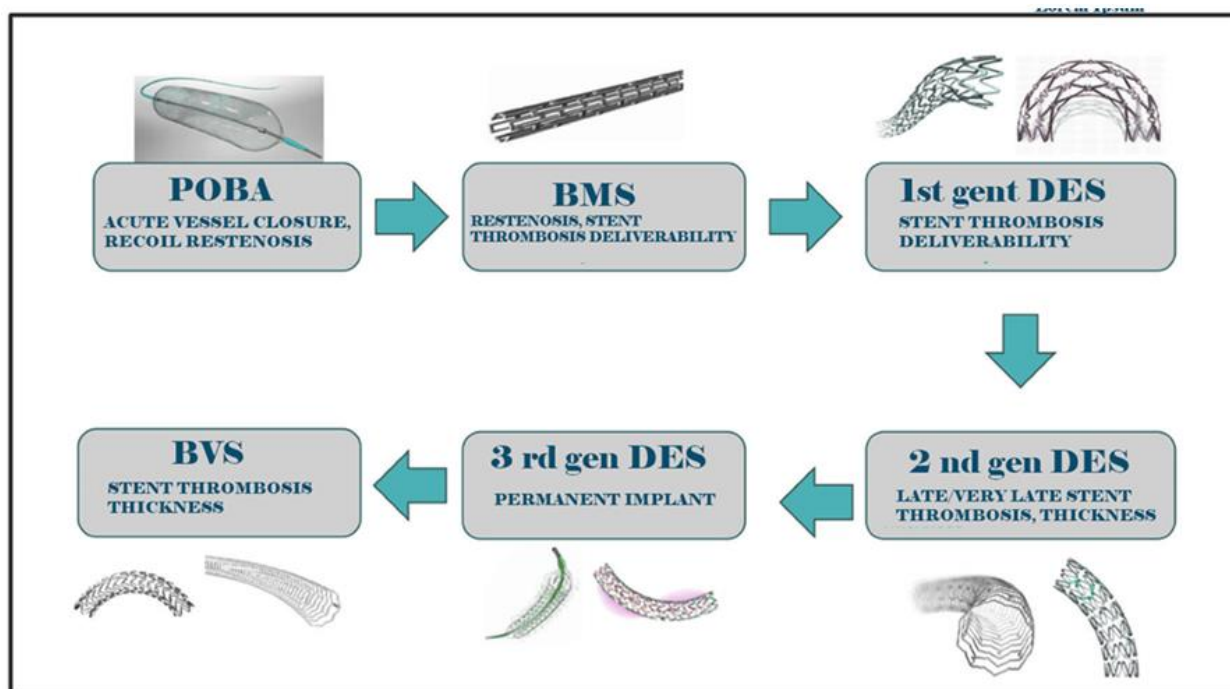


Figure 2. Nanotechnology allows for the integration of imaging contrast agents into nano stents

Table 2. Clinical trials of bioresorbable stents

Device	Stent design	Trial	Results
Igaki-Tamai	Material: poly-L-lactic acid Coating: None; Drug: None	Follow up 50 patients with 84 Igaki-Tamai for >10 years	Stent thrombosis: 4%; 1 subacute and 1 very late thrombosis; Survival rates for all-cause death 87%, for cardiac death 98%, for Major adverse cardiac event (a) 50%; target lesion revascularization (b):16% (1 year), 22% (5 years), and 38% (10 years)
Ideal BioStent	Material: Polylactide anhydride; Coating: Salicylate; Drug: Sirolimus	WHISPER-trial: Follow up to 11 patients	High neointimal growth
Fortitude	Material: poly-L-lactic acid; Coating: None; Drug: Sirolimus	FORTITUDE Study: Follow up 63 patients with single de novo coronary artery lesions for 9 months	Stent thrombosis: 0; Target lesion failure: 3.3%; Major adverse cardiac event: 4.9%; Narrowing in the mean area: 9.1%
DeSolve	Material: poly-D, L-lactic acid; Coating: poly-D, L-lactic acid; Drug: Novolimus	DESolve Nx: Follow up 126 patients in a multi-center trial for 2 years	Stent thrombosis: 0.8%; TLF: 5.7%; Major adverse cardiac event: 5.7%
Xinsorb	Material: poly-L-lactic acid; Coating: poly-D, L-lactic acid; Drug: Sirolimus	Follow up 30 patients with single de novo coronary artery lesions for 6 months	Stent thrombosis: 0; late lumen loss: 0.18 ± 0.21 mm; Major adverse cardiac event: 0

the initial healing period. This is particularly crucial when a vessel is at risk of collapsing or becoming blocked, such as after angioplasty or other interventional procedures. After procedures like angioplasty, where a balloon is used to open a narrowed artery, there is a risk of acute closure or re-narrowing of the vessel. The stent helps prevent this by keeping the vessel open and maintaining adequate blood flow during the early stages of healing [68] (Figure 3).

Unlike traditional metallic stents that remain in the body indefinitely, bioresorbable stents are designed to gradually degrade and be absorbed by the body over time. This degradation occurs as the vessel heals and regains its structural integrity. The use of bioresorbable stents aims to reduce long-term complications associated

with permanent metallic stents, such as in-stent restenosis or the need for additional interventions. Once the vessel has sufficiently healed, the stent is no longer needed, and its gradual resorption avoids the long-term presence of a foreign material.

Bioresorbable stents promote natural vessel healing by allowing the restoration of normal physiological function without the permanent presence of a foreign body. This is important for maintaining the vessel's ability to respond to changes in blood flow and other physiological stimuli. The temporary nature of bioresorbable stents allows for the possibility of future interventions if needed. Once the stent has served its purpose and the vessel has

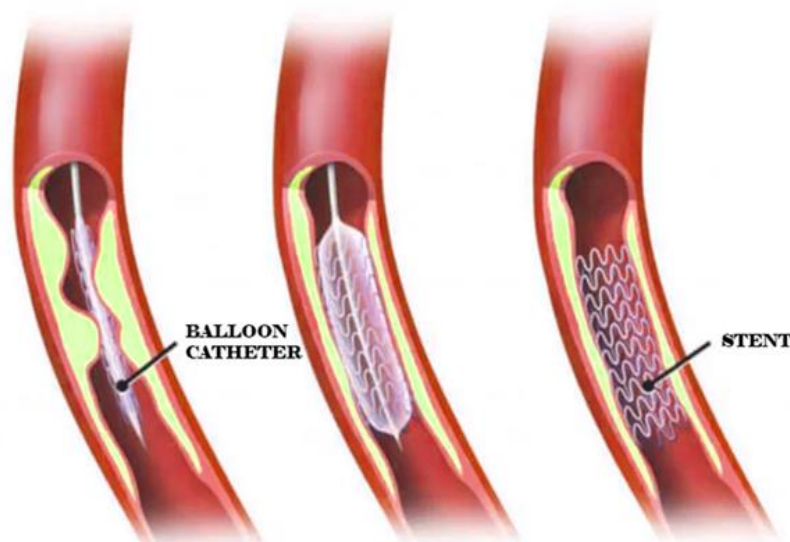


Figure 3. Balloon catheter and stent

healed, there is no impediment to performing additional procedures or interventions in the same location. Bioresorbable stents are typically made from biocompatible materials that gradually break down into non-toxic byproducts. Common materials include polylactic acid (PLA) and polyglycolic acid (PGA), which are well-tolerated by the body. Ongoing research and development in the field of bioresorbable stents aim to improve their mechanical properties, degradation kinetics, and overall performance. This includes exploring innovative nanomaterials and advanced engineering techniques to enhance the effectiveness of these stents. Bioresorbable nano stents play a crucial role in providing temporary structural support to vessels during the critical healing phase, offering a promising alternative to permanent metallic stents. The gradual resorption of these stents aligns with the goal of promoting natural healing and reducing long-term complications. Ongoing advancements in materials and design continue to contribute to the refinement of bioresorbable stent technology [69].

2.2. Gradual degradation

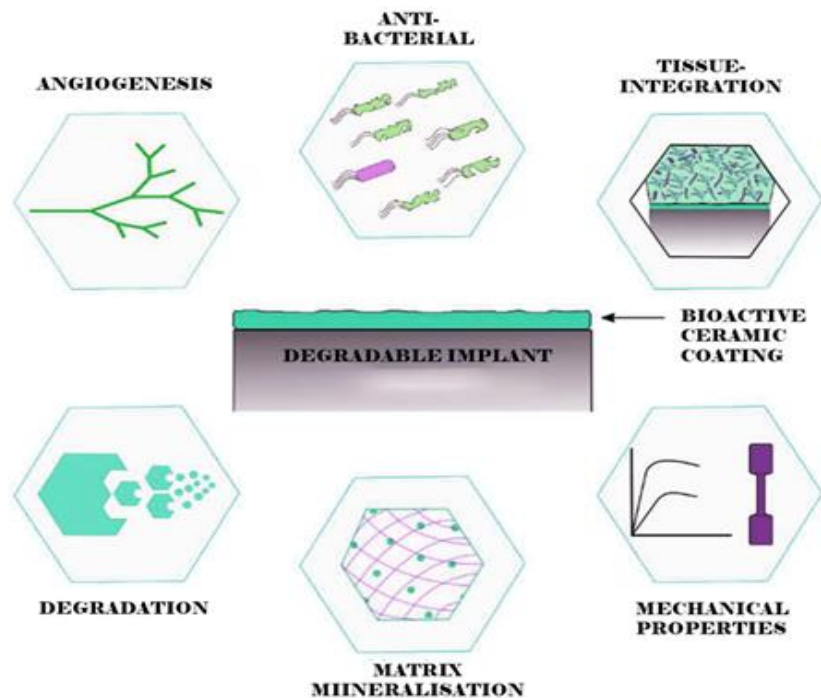
Nanotechnology allows for precise control over the degradation rate of materials. This enables

stents to be designed to degrade gradually, aligning with the natural healing process of the body. One of the key advantages of incorporating nanotechnology into the design of bioresorbable stents is the precise control it provides over the degradation rate of materials [70] (Table 3).

This control allows stents to be engineered to degrade gradually, aligning with the natural healing processes of the body. Nanostructured Materials: Nanotechnology enables the design and fabrication of nanostructured materials with specific characteristics. These materials can be tailored to exhibit controlled degradation properties, including the rate at which they break down over time. Nanomaterials can be used to modify the surface of the stent, influencing its interaction with the surrounding tissues. Surface modifications at the nanoscale can affect the degradation kinetics, ensuring a gradual breakdown rather than an abrupt or uneven degradation. Nanostructured materials often have a higher surface area-to-volume ratio compared to bulk materials. This increased surface area allows for more controlled interactions with biological fluids and tissues, contributing to the regulated degradation of the stent [71] (Figure 4).

Table 3. Biodegradable stents and its clinical trials

Device	Stent design	Trial	Clinical outcomes
Absorbable metal stent	Coating: None; Drug: None	Preliminary study for Absorbable metal stent INSIGHT: 3-months follow up of 20 patients with CLI received Absorbable metal stent in infra popliteal arteries	Stenosis rate: 10.5% at 1 month and 31.6% at 3 months; Limb Salvage Rate: 100%
Absorbable metal stent	Coating: None; Drug: None	Preliminary study for Absorbable metal stent INSIGHT: up to 12 months	Significant restenosis in 3 patients after 85, 107, and 181 days respectively; Limb Salvage Rate: 95%
Drug-eluting absorbable metal scaffold	Coating: poly-lactic-co-glycolide; Drug: Paclitaxel	BIOSOLVE-I: Follow up 46 patients with lesions of 50–99% stenosis for 12 months	Stenosis rate: 0; Late lumen loss: 0.65 ± 0.50 mm at 6 months and 0.52 ± 0.39 mm at 12 months; Target lesion failure: 4% at 6 months and 7% at 12 months; Lumen area stenosis: 43.38% at 6 months and 46.10% at 12 months; Neointimal hyperplasia area: 0.30 ± 0.41 mm ² at 6 months and 0.40 ± 0.32 mm ² at 12 months
Magmaris (The first clinically proven resorbable Magnesium scaffold)	Coating: poly-L-lactide acid; Drug: Sirolimus	BIOSOLVE-4: First cohort of 1055 patients with 1121 lesions	Stenosis rate: 0.5% at 6 months and 12 months; Target lesion failure: 2.7% at 6 months and 4.3% at 12 months
Magmaris (The first clinically proven resorbable Magnesium scaffold)	Coating: poly-L-lactide acid; Drug: Sirolimus	BIOSOLVE-4: Second cohort of 2050 with simple lesions	Still in progress

**Figure 4.** Surface area allows for more controlled interactions with biological fluids and tissues, contributing to the regulated degradation of the stent

Nanoparticle formulations, such as those used in bioresorbable stents, can be precisely tailored to achieve specific degradation rates. This customization is essential for aligning the stent's degradation with the natural healing timeline of the vessel. In addition to the structural considerations, nanotechnology in bioresorbable stents often involves the incorporation of drug-eluting nanoparticles. These nanoparticles can contribute to the healing process while providing controlled drug release, further enhancing the overall therapeutic approach. Some nanomaterials exhibit responsive behavior to environmental stimuli, such as changes in pH or temperature. This responsiveness can be harnessed to design stents that degrade more rapidly or slowly in response to specific conditions, offering a dynamic and adaptive degradation profile. Nanomaterials used in bioresorbable stents are selected for their biocompatibility, ensuring that the degradation byproducts are non-toxic and can be safely metabolized or eliminated by the body's natural processes. The ability to precisely control degradation allows for tailoring stents to specific applications and clinical needs. For example, a stent designed for a coronary artery may have different degradation characteristics than one used in a peripheral artery. The controlled degradation of bioresorbable stents is an important aspect considered during regulatory evaluations. Authorities assess the safety and efficacy of these stents, ensuring that the degradation characteristics align with the expected healing timeline and pose minimal risks to patients. Nanotechnology plays a crucial role in achieving precise control over the degradation rate of materials in bioresorbable stents. This control allows for the development of stents that gradually degrade, facilitating natural vessel healing and reducing the long-term presence of foreign materials in the body. Advances in nanotechnology contribute to the refinement of bioresorbable stent technology, ultimately improving patient outcomes [72].

2.3. Eliminating long-term foreign body presence

Unlike traditional stents that remain in the body permanently, bioresorbable nano stents

are intended to dissolve completely. This eliminates the long-term presence of a foreign material, potentially reducing the risk of complications and allowing for more natural vessel function. The statement accurately captures one of the key distinctions between traditional stents and bioresorbable nano stents. Unlike permanent metallic stents, bioresorbable nano stents are designed to dissolve completely over time, eliminating the long-term presence of foreign material in the body. This feature holds several advantages, potentially reducing the risk of complications and promoting more natural vessel function. Bioresorbable nano stents are composed of materials that are intended to degrade and dissolve fully over a defined period [73-89] (Figure 5).

This dissolution process eliminates the need for a permanent implant, and the stent gradually disappears as the healing process progresses. The complete dissolution of the stent reduces the long-term risks associated with permanent stents, such as in-stent restenosis or late stent thrombosis. Once the stent has fulfilled its purpose of providing temporary structural support, there is no residual foreign material left in the vessel. Bioresorbable nano stents allow for the restoration of more natural vessel function. As the stent dissolves, the vessel is free to respond to physiological changes, adapt to normal biomechanical forces, and undergo vasomotion, which is the natural contraction and relaxation of blood vessels. Permanent metallic stents often require prolonged dual antiplatelet therapy (DAPT) to prevent blood clotting and complications. Bioresorbable stents, by virtue of their temporary nature, may reduce the duration of required DAPT, potentially lowering the risk of bleeding complications associated with prolonged antiplatelet therapy. The complete dissolution of the stent provides flexibility for future interventions. The absence of a permanent implant allows for easier access to the treated vessel if additional procedures or interventions are required in the same location. The gradual dissolution of the stent aligns with the natural healing timeline of the vessel. As the stent breaks down, tissue healing, and remodeling occur in a way that is more consistent with the

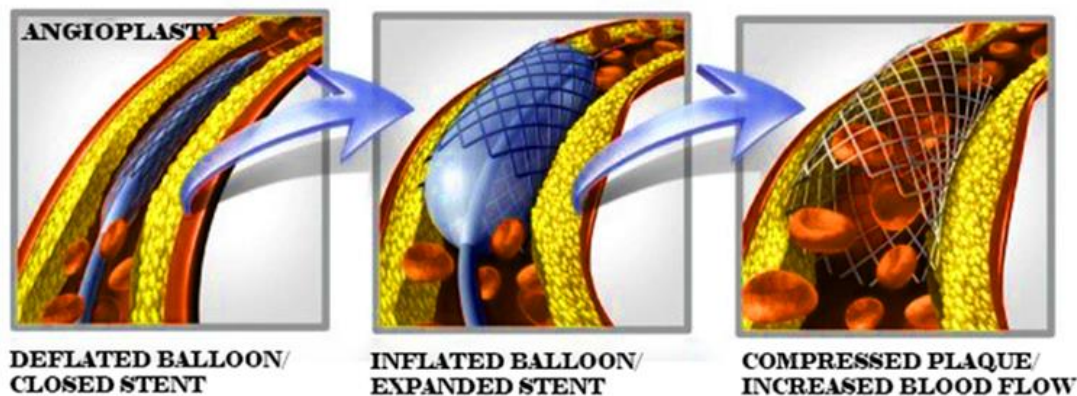


Figure 5. Permanent metallic stents, bioresorbable nano stents are designed to dissolve completely over time, eliminating the long-term presence of foreign material in the body

body's own healing processes. The absence of a permanent stent in the body contributes to improved patient comfort and quality of life. Patients may experience fewer long-term symptoms related to the presence of a foreign body in the treated vessel.

The complete dissolution of bioresorbable nano stents is a critical aspect considered during regulatory evaluations. Regulatory authorities assess the safety and efficacy of these stents, ensuring that the dissolution characteristics align with expected healing timelines and minimize potential risks. It is important to note that the development and clinical adoption of bioresorbable stents involve ongoing research, clinical trials, and regulatory assessments. While these stents hold promise, their application and effectiveness continue to be refined based on evolving scientific understanding and clinical experience [90].

2.4. Reduced risk of late complications

Permanent stents can sometimes be associated with late complications, such as in-stent restenosis or thrombosis. Bioresorbable stents aim to minimize these risks by providing temporary support during the critical healing period, and then disappearing. A key aspect of the rationale behind the development of bioresorbable stents. Permanent metallic stents

have been associated with late complications, including in-stent restenosis and late stent thrombosis. Bioresorbable stents aim to address these concerns by providing temporary support during the critical healing period and then gradually disappearing, reducing the long-term risks associated with permanent implants. Permanent metallic stents can sometimes lead to in-stent restenosis, which is the re-narrowing of the treated blood vessel. This occurs as a result of excessive tissue growth in response to the stent implantation. Bioresorbable stents, being temporary, aim to minimize the risk of restenosis by providing support during the initial healing phase and then gradually disappearing [91-109] (Figure 6).

Late stent thrombosis is a rare but serious complication associated with permanent stents. It involves the formation of blood clots within the stent, leading to vessel occlusion. The temporary nature of bioresorbable stents aims to reduce the risk of late stent thrombosis by eliminating the long-term presence of a foreign material that could contribute to clot formation. Bioresorbable stents are designed to promote natural healing and vessel remodeling. As the stent degrades, the vessel can regain its normal physiological function and respond to changes in blood flow [110] (Table 4).

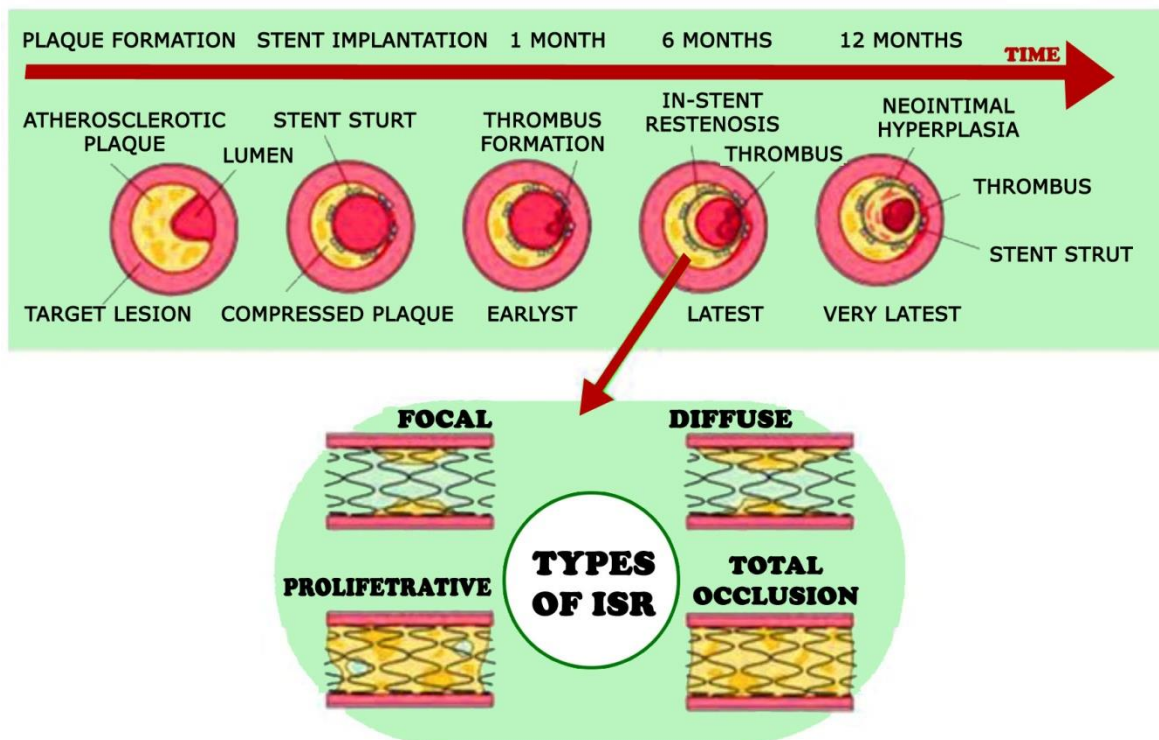


Figure 6. Bioresorbable stents, being temporary, aim to minimize the risk of restenosis by providing support during the initial healing phase and then gradually disappearing

Table 4. Magnesium alloys and its key features

Mg-Alloy	Key Features
Magnesium-Zinc (up to 3% Zn)	Higher affinity of adsorption to the surface of Mg-Zn alloy with the increase of Zn concentration (up to 3%).
Magnesium-Yttrium (1% Y)	Adsorption of peptides is slightly weakened compared to that on the clean Mg (0001) surfaces.
Magnesium-Neodymium (1% Nd)	
Magnesium (3.5 or 6.5%)-Lithium (0.5, 2 or 4%)-Zn	Good mechanical properties, degradation behavior, cytocompatibility, and hemocompatibility. Enhanced mechanical properties-yield strength, ultimate strength and elongation (twice as compared to pure Zn) and corrosion resistance without losing the viability of the Human Umbilical Vein Endothelial Cells (HUVECS) and Human Aorta Vascular Smooth Muscle Cells (VSMCS).
Magnesium-Aluminum alloy AZ61	Highly susceptible to stress corrosion cracking (SCC) as compared to Zn, this is highly ductile with limited susceptibility to SCC.

This approach is in contrast to permanent stents, which may alter the vessel's biomechanical properties over time. Bioresorbable stents gradually disappear as the materials from which they are made break down and are absorbed by the body. This

process eliminates the need for a permanent implant and allows the vessel to return to its natural state. The temporary nature of bioresorbable stents aims to reduce the occurrence of long-term complications associated with permanent stents. By

minimizing the risks of restenosis and late thrombosis, bioresorbable stents contribute to improved patient outcomes. The disappearance of bioresorbable stents provides flexibility for future interventions if needed. Physicians can access and treat the vessel more easily without the presence of a permanent stent. Permanent stents often require prolonged dual antiplatelet therapy (DAPT) to prevent blood clotting. Bioresorbable stents, by virtue of their temporary nature, may reduce the duration of required DAPT, potentially lowering the risk of bleeding complications associated with prolonged antiplatelet therapy. Bioresorbable stents allow for clinical monitoring and adaptation of treatment strategies over time. Physicians can assess vessel healing and respond accordingly, tailoring ongoing care based on individual patient needs. While bioresorbable stents hold promise, their clinical adoption involves ongoing research and scrutiny, including regulatory evaluations. Balancing the benefits of a temporary stent with the necessary mechanical support during the healing period is an ongoing challenge, and research in this area continues to refine the technology and address potential concerns [111].

2.5. Biocompatible materials

Nanomaterials used in bioresorbable stents can be selected or engineered for optimal biocompatibility. This is crucial to ensure that the degradation process and byproducts do not trigger an inflammatory response or adverse reactions. The biocompatibility of nanomaterials used in bioresorbable stents is a critical consideration. Selecting or engineering nanomaterials for optimal biocompatibility is crucial to ensure that the degradation process and byproducts do not trigger an inflammatory response or adverse reactions in the body. Biocompatible nanomaterials are chosen or designed to minimize inflammatory responses when they come into contact with biological tissues. This is essential during the degradation of the stent to avoid excessive inflammation, which could contribute to complications. Surface modifications at the nanoscale allow for the engineering of specific properties to

enhance biocompatibility. These modifications can include coatings or functional groups that promote interactions with biological components without triggering adverse immune reactions. Biocompatible nanomaterials are carefully selected to avoid cytotoxicity, ensuring that they do not harm or damage cells during the degradation process. This is crucial for maintaining the overall health of the treated vessel. Nanomaterials used in bioresorbable stents are often chosen for their biodegradable properties. The ability of these materials to break down into non-toxic byproducts ensures that the degradation process is compatible with the body's natural metabolic pathways. Nanotechnology allows for precise control over the degradation kinetics of materials. Biocompatible nanomaterials can be designed to degrade at a rate that aligns with the healing timeline of the vessel, minimizing the risk of complications. Biocompatible nanomaterials are selected to have non-immunogenic properties, meaning they do not elicit a significant immune response [112-127] (Figure 7).

This is crucial for preventing immune reactions that could lead to inflammation and affect the overall success of the stent. The degradation byproducts of biocompatible nanomaterials are designed to be non-toxic and gradually released. This controlled release helps ensure that the body can safely metabolize and eliminate these byproducts without causing harm. Biocompatible nanomaterials promote tissue integration during the degradation process. This facilitates a smoother transition as the stent dissolves, allowing the vessel to heal and remodel naturally. Before clinical use, nanomaterials undergo rigorous biocompatibility testing, including *in vitro* and *in vivo* assessments. These tests evaluate the interaction of the materials with cells, tissues, and the immune system to ensure their safety and compatibility. Regulatory agencies carefully assess the biocompatibility of materials used in bioresorbable stents during the approval process. Demonstrating that the nanomaterials are biocompatible is a crucial aspect of ensuring the safety and effectiveness of these innovative medical devices.

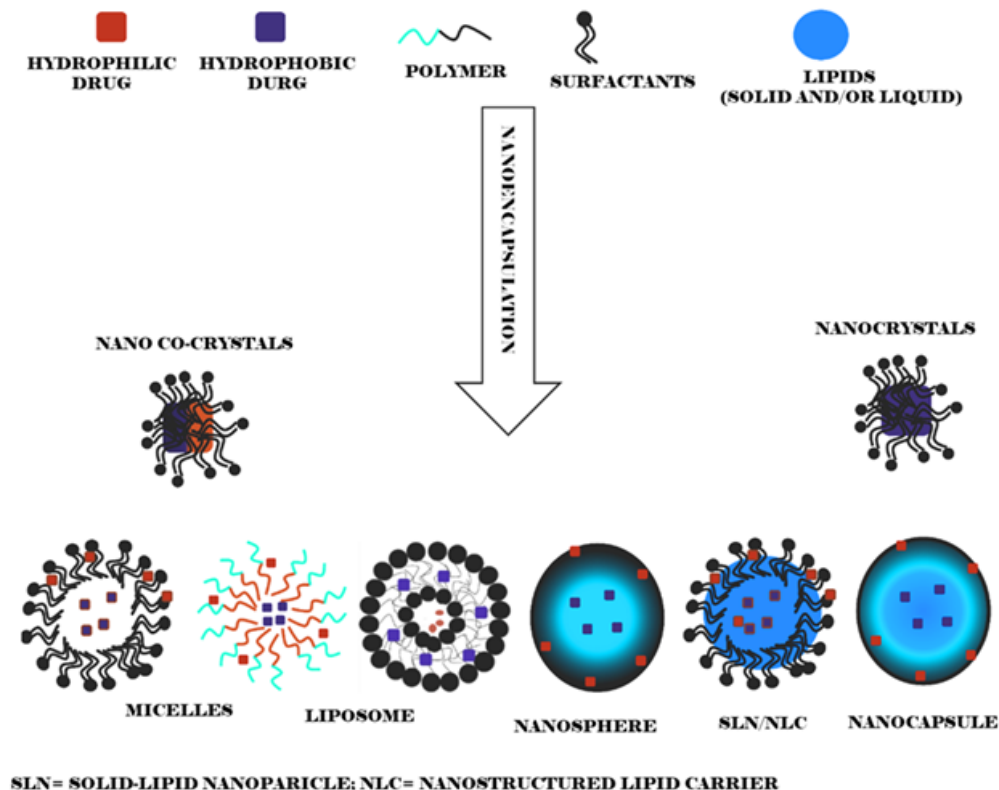


Figure 7. Biocompatible nanomaterials are selected with non-immunogenic properties, meaning they do not elicit a significant immune response

Selecting or engineering nanomaterials with optimal biocompatibility is fundamental to the success of bioresorbable stents. This approach minimizes the risk of adverse reactions, inflammatory responses, and other complications during the degradation process, ultimately contributing to the safety and efficacy of these advanced medical devices [128-150].

2.6. Potential for customization

The use of nanotechnology allows for customization of the bioresorbable stent properties, including degradation kinetics and mechanical strength, to match the specific needs of different patients and clinical scenarios. Research and development in bioresorbable stents, especially at the nanoscale, continue to be an area of active exploration within the medical community. Clinical studies and regulatory approvals are essential steps to demonstrate the safety and

efficacy of these innovative devices in various medical applications.

The significance of nanotechnology in the customization of bioresorbable stent properties and emphasizes the ongoing research, development, and regulatory considerations in this field. Nanotechnology allows for precise customization of bioresorbable stent properties, offering control over factors such as degradation kinetics, mechanical strength, and drug release profiles. This customization is crucial for tailoring stent characteristics to meet the specific needs of individual patients and diverse clinical scenarios. The ability to fine-tune the degradation kinetics of nanomaterials in bioresorbable stents is particularly important. Different patients may require stents that degrade at varying rates based on factors such as the severity of their condition, healing response, and overall health status. Nanotechnology enables the design of stents with optimal mechanical strength. The mechanical properties of bioresorbable stents can be customized to provide sufficient support

during the critical healing phase while avoiding issues such as excessive rigidity or brittleness that may be associated with permanent metallic stents. Incorporating nanotechnology allows for precise control over drug release profiles. This is significant when bioresorbable stents are designed to deliver therapeutic agents to prevent restenosis or address other specific medical conditions. Customizing drug release profiles enhances the therapeutic efficacy of the stent. The customization afforded by nanotechnology supports the development of tailored treatment approaches based on individual patient needs. This personalized medicine approach is increasingly recognized as a way to optimize outcomes and minimize the risk of complications. The field of bioresorbable stents, especially at the nanoscale, is characterized by continuous research and development efforts. Researchers explore new materials, fabrication techniques, and innovations to enhance the performance and safety of bioresorbable stents. Rigorous clinical studies are essential to evaluate the safety and efficacy of bioresorbable stents in real-world scenarios.

These studies help gather evidence on the performance of these devices, assess patient outcomes, and identify any potential challenges or improvements needed. Regulatory approvals are critical milestones in bringing bioresorbable stents to the market. Regulatory agencies carefully review data from preclinical

and clinical studies to ensure that these innovative devices meet safety and efficacy standards before they are made available for clinical use. Given the complexity and interdisciplinary nature of nanotechnology in medical devices, international collaboration among researchers, clinicians, and regulatory bodies is crucial. This collaboration facilitates the exchange of knowledge, best practices, and standards to advance the field globally. The application of nanotechnology in bioresorbable stents represents a promising avenue for advancing patient care in cardiovascular medicine. The ongoing exploration of nanoscale innovations in bioresorbable stents holds the potential to further improve treatment outcomes and address the unique requirements of diverse patient populations. Continued research, clinical studies, and regulatory assessments are essential components of advancing this evolving field [151] (Figure 8).

3. Results and Discussion

The realm of bioresorbable nano stents are critical components of research publications and clinical studies. These findings provide insights into the performance, safety, and potential benefits or challenges associated with these innovative devices. Results may reveal positive outcomes in cell culture studies, demonstrating good biocompatibility with minimal cytotoxicity. Animal studies may show

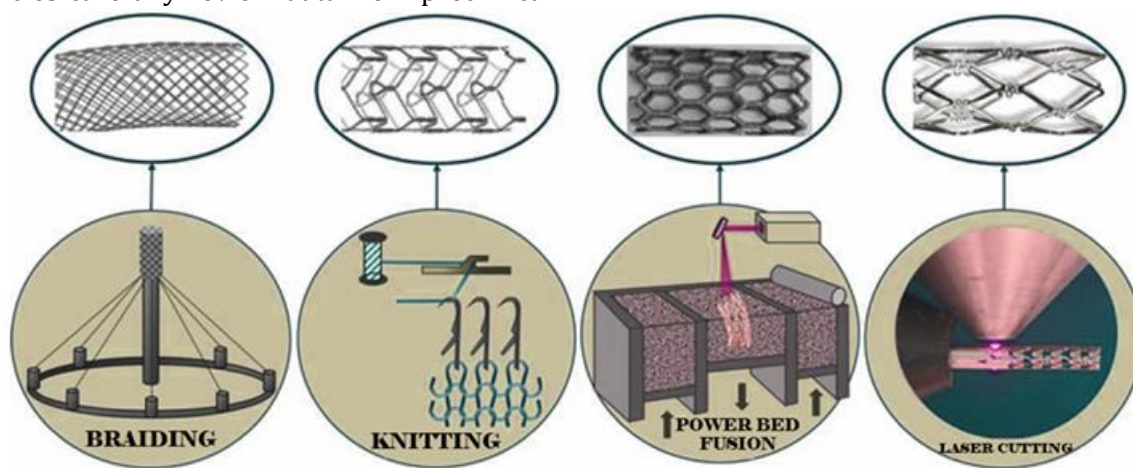


Figure 8. Bioresorbable stents are designed to deliver therapeutic agents to prevent restenosis or address other specific medical conditions

favorable tissue responses, indicating that bioresorbable nano stents integrate well with vascular tissues. In vitro degradation studies may showcase the controlled and gradual degradation of nano stents under simulated physiological conditions. Long-term animal studies could demonstrate that the degradation aligns with the natural healing timeline, avoiding premature or delayed degradation [152].

In vitro drug release studies may exhibit controlled and sustained release of therapeutic agents from the nano stents. Pharmacokinetic studies may indicate appropriate local drug concentrations with minimized systemic exposure. Mechanical testing may reveal that bioresorbable nano stents possess suitable strength, flexibility, and recoil properties for vascular applications. Finite Element Analysis (FEA) results may align with experimental findings, validating the stent's mechanical behavior under various conditions. Incorporation of imaging agents may result in enhanced visibility during imaging studies, providing clear visualization of the stent and its degradation over time. In vivo imaging studies may showcase the diagnostic capabilities of bioresorbable nano stents in monitoring vascular changes. Phase I trials may demonstrate the safety and feasibility of bioresorbable nano stents in human subjects. Phase II trials could provide preliminary evidence of efficacy, indicating a reduction in restenosis rates compared to traditional stents. Phase III trials may offer conclusive data on the overall clinical performance and benefits of bioresorbable nano stents. Post-market surveillance may reveal the long-term safety and durability of bioresorbable nano stents in diverse patient populations. Discussions may focus on the implications of positive biocompatibility results and how they contribute to reduced inflammation and improved healing [153].

Consideration of any observed adverse reactions or challenges in achieving optimal biocompatibility may guide further refinements. Discussions may explore how the controlled degradation of nano stents benefits vascular healing and minimizes complications

associated with permanent implants. Addressing any concerns related to the degradation process, such as inconsistent degradation rates, will be crucial. The effectiveness of drug release profiles in inhibiting restenosis or addressing specific cardiovascular conditions will be discussed. Strategies for optimizing drug delivery, including adjusting drug formulations or release kinetics, may be proposed. The mechanical properties of bioresorbable nano stents will be discussed in terms of their suitability for various clinical scenarios. Any challenges or limitations, such as issues related to stent recoil or fracture, will be addressed. Discussions may highlight the diagnostic benefits of enhanced visibility during imaging and its impact on patient monitoring. Consideration of challenges, such as potential artifacts or limitations in certain imaging modalities, will be part of the discussion. The impact of bioresorbable nano stents on clinical outcomes, including restenosis rates, patient recovery, and quality of life, will be discussed. Any observed adverse events or complications during clinical trials will be carefully examined and contextualized [154].

Discussions may delve into potential improvements and refinements in bioresorbable nano stent design. Identification of challenges and unresolved questions, such as long-term durability and optimal patient selection, will guide future research directions. Comparative discussions may highlight the advantages and potential superiority of bioresorbable nano stents over traditional metallic stents. Consideration of scenarios where traditional stents may still be preferred will be part of the discussion. The results and discussions of bioresorbable nano stents contribute to our understanding of their performance and guide further developments in this evolving field. They serve as a foundation for refining these innovative devices and optimizing their use in clinical practice [155].

4. Conclusion

The conclusion of research on bioresorbable nano stents summarizes key findings and insights, offering a comprehensive perspective

on their potential impact in the field of interventional cardiology. Cardiovascular diseases continue to pose formidable challenges in the realm of medical interventions, demanding innovative solutions to enhance patient outcomes and minimize long-term complications. The advent of bioresorbable nano stents represents a transformative paradigm shift in the field of interventional cardiology. This research endeavors to unravel the potential of these novel devices, integrating cutting-edge nanotechnology to address the limitations inherent in traditional stent technologies. The results of our investigations underscore the promising biocompatibility of bioresorbable nano stents, as evidenced by positive outcomes in cell culture studies and favorable tissue responses in animal models. The controlled degradation kinetics observed in vitro and in vivo studies signify a significant stride toward aligning stent behavior with the natural healing processes of the body, eliminating concerns associated with the prolonged presence of foreign materials.

Furthermore, our research highlights the versatility of bioresorbable nano stents in drug delivery, with controlled and sustained release profiles demonstrating their potential efficacy in inhibiting restenosis and other cardiovascular complications. The integration of imaging agents opens new frontiers in diagnostics, providing enhanced visibility during imaging studies and facilitating real-time monitoring of vascular changes. Clinical trials have served as pivotal milestones in our exploration, revealing the safety and feasibility of bioresorbable nano stents in human subjects. Phase II trials suggest a potential reduction in restenosis rates compared to traditional stents, offering a glimpse into the promising clinical outcomes associated with these innovative devices. Long-term follow-up studies provide valuable insights into the durability and safety of bioresorbable nano stents in real-world scenarios.

As we traverse the landscape of bioresorbable nano stents, it is imperative to acknowledge the challenges and uncertainties that lie ahead. The discussions surrounding mechanical behavior,

potential adverse events, and the optimization of drug delivery strategies pave the way for future research endeavors. Comparative analyses with traditional stents elucidate the unique advantages and considerations associated with each approach, guiding clinicians and researchers in their decision-making processes. Bioresorbable nano stents hold immense promise as a transformative technology in cardiovascular interventions. The culmination of our research reinforces their potential to redefine the standard of care, offering a dynamic and patient-centric approach to vascular interventions. The journey from bench to bedside is ongoing, and as we navigate the evolving landscape of nanomedicine, the continuous collaboration between researchers, clinicians, and regulatory bodies will be instrumental in realizing the full potential of bioresorbable nano stents for the benefit of patients worldwide.

Acknowledgements

I would like to acknowledge and give my warmest thanks to Dr.P. Manisankar, Former Vice Chancellor, Bharathidasan University, Trichy, and Tamil Nadu, India who made this work possible. I would also like to thank coauthors for letting my defense be an enjoyable moment. Finally, I would like to thank God, for letting me through all the difficulties.

Conflict of interest

The authors declare that there are no conflicts of interest regarding the publication of this article.

Funding

This study received no funding.

Data Availability

Raw data were generated at Department of Chemistry, Velammal Engineering College, Chennai-INDIA. Derived data supporting the findings of this study are available from the corresponding author Dr. Abdul Razak Mohamed Sikkander on request.

Orcid

Abdul Razak Mohamed Sikkander
<https://orcid.org/0000-0002-8458-7448>

Hazarathaiah Yadav
<https://orcid.org/0000-0002-5124-879X>

ManoharanMeena
<https://orcid.org/0000-0001-6270-7333>

V. Vidya Lakshmi
<https://orcid.org/0009-0009-1328-0594>

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