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NANOPLASTY AND NANOTECHNOLOGY IN STENTING OF THE HEART A NARRATIVE REVIEW OF ADVANCES IN CORONARY INTERVENTIONS

Dr. AMAN KHANDELWAL

Assistant Teacher, Samarkand state medical university, Uzbekistan

Aman3238@gmail.com

Danish Abdullah

Medical Student, Samarkand state medical university, Uzbekistan
abdullahdanishkne@gmail.com

Nayaab Shamim

Medical Student, Samarkand state medical university, Uzbekistan

nayaabshamim64@gmail.com

Anshika Pandey

Medical Student, Samarkand state medical university, Uzbekistan

anshika21517@gmail.com

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Abstract and Keywords

Coronary artery disease remains the leading cause of mortality worldwide, and percutaneous coronary intervention with stent implantation has revolutionized its management. Despite significant advancements from bare metal stents to drug-eluting stents, challenges such as in-stent restenosis, delayed endothelialization, and late stent thrombosis persist. Nanotechnology offers promising solutions through nanoparticle-based drug delivery systems, nanocoatings, and molecular targeting strategies that may achieve restenosis prevention while preserving endothelial healing. This narrative review examines the evolution of coronary stent technology, the pathophysiology of in-stent restenosis, and the application of nanotechnology in contemporary stent design. We discuss various nanoparticle platforms including liposomes, polymeric nanoparticles, and magnetic nanoparticles, along with their mechanisms of targeted drug delivery to the vascular wall. Furthermore, we review preclinical studies and early clinical trials of nanoparticle-enhanced stents, analyze current challenges in clinical translation, and outline future directions for this rapidly evolving field.

Keywords: Nanoplasty; Nanotechnology; Coronary stent; Drug-eluting stent; In-stent restenosis; Nanoparticle; Molecular targeting; Cardiovascular disease; Percutaneous coronary intervention; Endothelialization

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1. Introduction

Cardiovascular diseases account for approximately 17.9 million deaths annually, representing 32 percent of all global mortality. Coronary artery disease, characterized by atherosclerotic plaque buildup within the coronary arteries, remains the predominant contributor to this burden. Since Andreas Gruentzig performed the first percutaneous transluminal coronary angioplasty in 1977, interventional cardiology has undergone remarkable transformation. The introduction of coronary stents in the 1980s marked a pivotal advancement, addressing the limitations of balloon angioplasty including acute vessel recoil and dissection.

Contemporary stent technology has evolved through multiple generations, from bare metal stents to first-generation and second-generation drug-eluting stents. Each iteration has sought to reduce the incidence of in-stent restenosis, the pathological renarrowing of the treated vessel segment that plagued early interventions. However, even modern drug-eluting stents present significant shortcomings, including delayed endothelial healing, hypersensitivity reactions to polymeric carriers, and the risk of late and very late stent thrombosis requiring prolonged dual antiplatelet therapy.

Nanotechnology, defined as the manipulation of matter at the atomic and molecular scale ranging from 1 to 100 nanometers, has emerged as a transformative approach in cardiovascular medicine. The application of nanotechnology to stent design encompasses nanoparticle-based drug delivery, nanostructured surface coatings, and molecularly targeted therapeutic strategies. These innovations hold the potential to achieve controlled, sustained release of antiproliferative agents while simultaneously promoting rapid endothelialization, thereby addressing the fundamental limitations of current stent platforms.

This narrative review provides a comprehensive examination of the role of nanoplasty and nanotechnology in coronary stenting. We trace the historical evolution of stent technology, elucidate the pathophysiological mechanisms underlying in-stent restenosis, and critically evaluate the application of nanotechnology in contemporary and next-generation stent designs. Furthermore, we discuss the various nanoparticle platforms employed for cardiovascular applications, molecular targeting strategies, clinical outcomes from preclinical and early clinical studies, and the challenges that must be overcome for successful clinical translation.

2. Historical Evolution of Coronary Stents

The development of coronary stents represents one of the most significant achievements in interventional cardiology. Understanding this evolution provides essential context for appreciating how nanotechnology may address persistent clinical challenges. The progression from bare metal platforms to sophisticated drug delivery systems reflects the continuous effort to balance prevention of restenosis with promotion of vascular healing.

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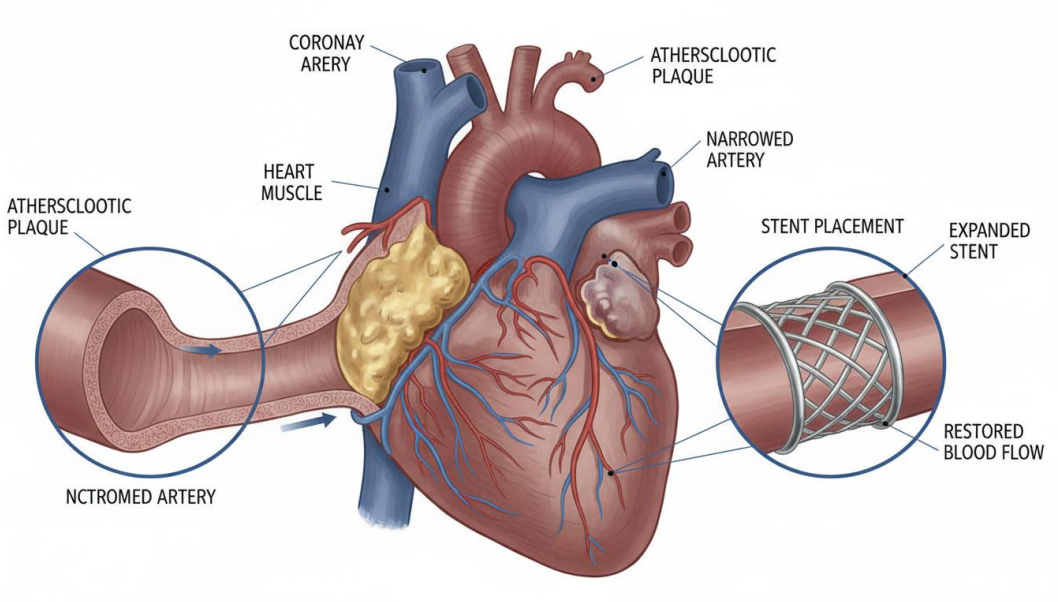

Figure 1. Coronary artery disease and stent placement. The illustration depicts atherosclerotic plaque buildup causing arterial narrowing and the deployment of a metallic stent to restore vascular patency and normal blood flow.

2.1 Bare Metal Stents

The first coronary stents were introduced in the late 1980s as metallic scaffolds designed to prevent acute vessel closure following balloon angioplasty. Constructed primarily from 316L stainless steel, these bare metal stents provided structural support against elastic recoil and effectively sealed dissections. The landmark BENESTENT and STRESS trials demonstrated superior angiographic and clinical outcomes compared to balloon angioplasty alone, establishing stenting as the standard of care for percutaneous coronary intervention.

However, bare metal stents introduced a new challenge: in-stent restenosis occurred in 20 to 30 percent of cases within six to twelve months following implantation. This renarrowing resulted primarily from neointimal hyperplasia, the exuberant proliferation and migration of vascular smooth muscle cells in response to mechanical injury and the presence of a foreign metallic body. The pathological process involved platelet activation, inflammatory cell recruitment, smooth muscle cell phenotypic switching from contractile to synthetic state, and excessive extracellular matrix deposition, ultimately compromising the vessel lumen.

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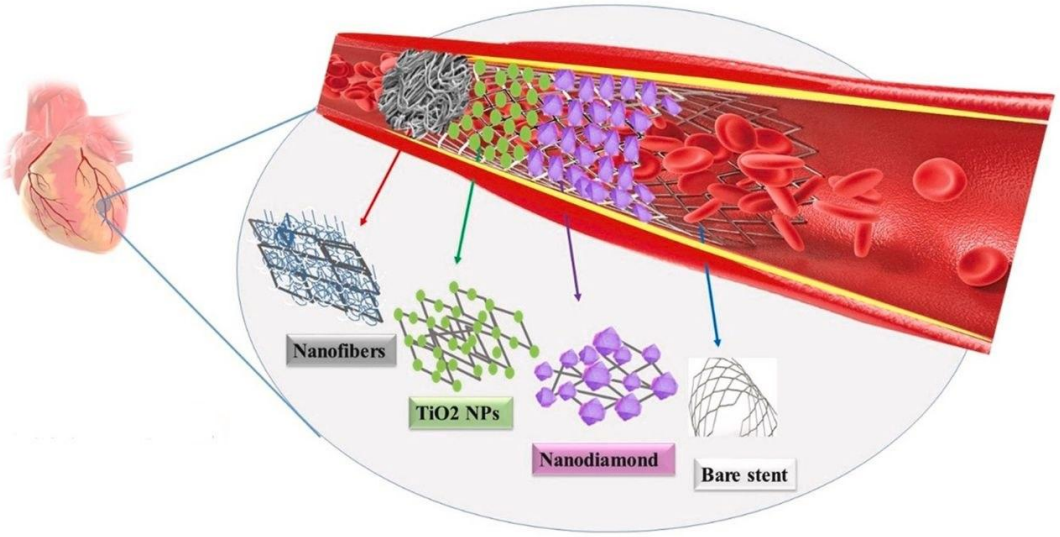

2.2 Drug-Eluting Stents

The recognition that in-stent restenosis represented a localized proliferative disorder prompted the development of drug-eluting stents capable of delivering antiproliferative agents directly to the site of vascular injury. First-generation drug-eluting stents, exemplified by the sirolimus-eluting Cypher stent and the paclitaxel-eluting Taxus stent, incorporated therapeutic agents into non-degradable polymeric coatings. The Cypher stent received CE mark approval in 2002 and FDA approval in 2003, while the Taxus stent followed in 2004. Clinical trials demonstrated dramatic reductions in in-stent restenosis rates from approximately 25 percent with bare metal stents to less than 10 percent with drug-eluting stents.

Despite these favorable outcomes, first-generation drug-eluting stents exhibited significant limitations. The non-degradable polymer coatings induced chronic inflammatory reactions and hypersensitivity responses in some patients. More critically, the antiproliferative drugs, while effectively suppressing smooth muscle cell proliferation, also inhibited endothelial cell growth and migration, leading to delayed re-endothelialization. This incomplete endothelial coverage increased the risk of late and very late stent thrombosis, necessitating prolonged dual antiplatelet therapy for at least twelve months following implantation.

Second-generation drug-eluting stents addressed several of these concerns through the use of biodegradable polymers, thinner stent struts constructed from cobalt-chromium or platinum-chromium alloys, and improved drug delivery kinetics. The everolimus-eluting Xience stent and the zotarolimus-eluting Endeavor stent demonstrated improved safety profiles with reduced rates of stent thrombosis compared to first-generation devices. The biodegradable polymer coating allowed for complete drug release followed by polymer resorption, leaving behind a bare metal surface that could endothelialize more completely.

2.3 Bioabsorbable Vascular Scaffolds

The concept of a temporary scaffold that provides mechanical support during the vessel healing period before completely resorbing has driven the development of bioabsorbable vascular scaffolds. The Absorb bioresorbable vascular scaffold, constructed from poly-L-lactide, represented the first widely investigated fully bioabsorbable stent platform. The rationale underlying this approach was compelling: once the scaffold resorbed, the vessel would be free of

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permanent metallic foreign material, potentially restoring vasomotor function and allowing future bypass grafting at the site if needed.

Early trials of the Absorb scaffold demonstrated acceptable safety and efficacy, but longer-term follow-up revealed concerning rates of scaffold thrombosis, attributed partly to thicker strut profiles and suboptimal mechanical properties compared to metallic platforms. The ABSORB IV trial ultimately demonstrated inferior outcomes compared to metallic drug-eluting stents, leading to withdrawal of the device from the market. Nevertheless, the concept of bioabsorbable scaffolds remains actively pursued, with newer iterations incorporating improved polymer formulations, thinner struts, and enhanced deliverability. The integration of nanotechnology with bioabsorbable platforms represents a particularly promising avenue for next-generation scaffold development.

3. Understanding In-Stent Restenosis

In-stent restenosis represents the pathological renarrowing of a stented coronary artery segment following percutaneous intervention. Despite progressive refinements in stent technology and implantation techniques, restenosis remains a clinically significant cause of recurrent ischemia and the need for repeat revascularization. Contemporary data indicate that while target lesion revascularization rates have declined substantially from the bare metal stent era to modern drug-eluting stent platforms, in-stent restenosis continues to accumulate over long-term follow-up and is associated with worse outcomes than intervention for de novo lesions.

The pathophysiology of in-stent restenosis involves a complex cascade of interrelated biological processes initiated by mechanical injury during stent deployment. The deployment of a stent causes deep injury to the vessel wall, disrupting the endothelial lining and exposing the thrombogenic subendothelial matrix. This injury triggers a series of pathological responses including endothelial dysfunction, platelet activation and thrombus formation, leukocyte recruitment, and vascular smooth muscle cell migration and proliferation. The final outcome is the formation of a neointima composed primarily of smooth muscle cells and extracellular matrix that progressively encroaches upon the vessel lumen.

Vascular smooth muscle cells play a central role in restenosis pathophysiology. In the normal vessel wall, these cells exist in a quiescent contractile phenotype characterized by low proliferative activity and expression of contractile proteins. Following vascular injury, smooth muscle cells undergo phenotypic switching to a synthetic state, acquiring proliferative, migratory, and secretory capabilities. This transition is regulated by numerous factors including platelet-derived growth factor, transforming growth factor beta, and various cytokines and chemokines released by activated platelets and inflammatory cells.

Inflammation constitutes another critical component of the restenosis response. The stent implantation procedure triggers an acute inflammatory reaction characterized by neutrophil and monocyte recruitment to the injured vessel wall. Monocytes differentiate into macrophages within the subintimal space, where they produce inflammatory cytokines, reactive oxygen species, and matrix metalloproteinases that promote smooth muscle cell migration and extracellular matrix remodeling. The persistence of inflammation, particularly in response to polymeric coatings or metallic ions, can exacerbate the restenosis response and predispose to late complications including neoatherosclerosis.

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4. Nanotechnology in Stent Design

Nanotechnology encompasses the manipulation of materials at the nanometer scale to create structures with novel physical, chemical, and biological properties. In the context of cardiovascular stenting, nanotechnology offers multiple avenues for improving clinical outcomes: nanostructured surfaces that enhance biocompatibility and endothelialization, nanoparticle-based drug delivery systems that achieve controlled therapeutic release, and molecular targeting strategies that direct drugs to specific cell types or extracellular components within the injured vascular wall.

4.1 Nanocoatings and Surface Modifications

Nanocoatings represent ultra-thin layered structures applied to stent surfaces to modify their biological interactions. Unlike conventional polymeric coatings that can be tens of microns thick, nanocoatings typically range from several nanometers to a few hundred nanometers in thickness. This reduced dimension minimizes the foreign body response while enabling precise control over surface properties. Various nanocoating approaches have been investigated, including nanotextured ceramic coatings, self-assembled monolayers, and peptide-based nanomatrix coatings.

A particularly innovative approach involves peptide amphiphile-based nanomatrix coatings. These coatings consist of peptide amphiphile molecules that self-assemble into nanofibers, depositing in layered configurations that mimic the native endothelial basement membrane. Research has demonstrated that such nanomatrix coatings can simultaneously enhance endothelial cell migration and adhesion, discourage smooth muscle cell proliferation, reduce platelet activation and adhesion, and attenuate inflammatory monocyte recruitment. The multifunctional nature of these coatings addresses the key challenges facing current stent technology in a single integrated platform.

Titanium dioxide nanoparticle coatings have also shown considerable promise. Studies have demonstrated that coating bare metal stents with titanium dioxide nanoparticles effectively reduces the release of metallic ions such as nickel, thereby minimizing the inflammatory response associated with metal corrosion. Furthermore, titanium dioxide nanocoatings have been shown to promote intimal re-endothelialization without requiring drugs or polymeric carriers, offering a purely biocompatibility-based approach to improving stent performance.

4.2 Nanoparticle Drug Delivery Systems

Nanoparticle-based drug delivery systems offer fundamental advantages over conventional polymeric stent coatings. The decoupling of drug carriers from the stent structure enables spatiotemporal control of therapeutic delivery, potentially maximizing antiproliferative effects at the target site while minimizing systemic drug exposure and toxicity. Nanoparticles can be designed for local infusion using specialized delivery catheters, incorporation into stent coatings, or systemic administration with targeted localization to the injured vessel wall.

The development of nanoparticle drug delivery systems for cardiovascular applications draws upon extensive experience from oncology, where several nanoparticle-based drug formulations have achieved clinical approval. Doxil, a liposomal formulation of doxorubicin, and Abraxane, an albumin-bound nanoparticle formulation of paclitaxel, demonstrated the feasibility of nanoparticle-based drug delivery in clinical practice. These successes have

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provided valuable insights for adapting nanoparticle platforms for cardiovascular therapeutic applications.

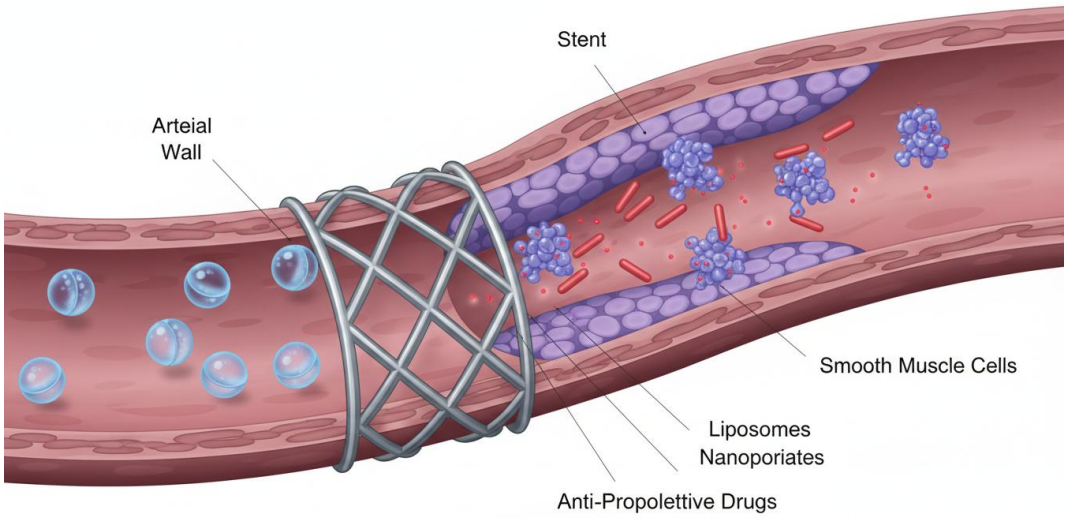

Figure 2. Nanoparticle drug delivery to a stented coronary artery. Various nanoparticle platforms including liposomes and polymeric nanoparticles deliver anti-proliferative drugs to smooth muscle cells while promoting endothelial healing.

5. Types of Nanoparticles for Cardiovascular Applications

Multiple nanoparticle platforms have been investigated for cardiovascular drug delivery, each offering distinct advantages in terms of drug loading capacity, release kinetics, biocompatibility, and targeting capabilities. The selection of an appropriate nanoparticle system depends on the specific therapeutic objectives, the physicochemical properties of the drug to be delivered, and the desired duration and pattern of drug release.

Nanoparticle Type	Composition	Advantages	Drug Examples
Liposomes	Phospholipid bilayers	Biocompatible, versatile loading	Alendronate, Prednisolone
Polymeric NPs	PLGA, PCL	Controlled release, biodegradable	Paclitaxel, Sirolimus
Magnetic NPs	Iron oxide core	External targeting, imaging	Paclitaxel
Albumin NPs	Human serum albumin	Long circulation, natural carrier	Paclitaxel

Table 1. Comparison of Nanoparticle Platforms for Cardiovascular Drug Delivery

Liposomal nanoparticles represent one of the most extensively investigated platforms for cardiovascular drug delivery. These spherical vesicles consist of phospholipid bilayers enclosing an aqueous core, enabling encapsulation of both hydrophilic and hydrophobic therapeutic agents. Liposomal formulations of alendronate, a potent bisphosphonate that inhibits monocyte and

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macrophage activity, have demonstrated significant reductions in neointimal formation in preclinical models. Liposomal alendronate is currently being evaluated in phase II clinical trials for the prevention of in-stent restenosis.

Polymeric nanoparticles, typically fabricated from biodegradable polymers such as poly-lactic-co-glycolic acid and polycaprolactone, offer excellent versatility in drug loading and release characteristics. These particles can be engineered with precise size distributions, surface charge properties, and drug loading capacities. Paclitaxel-encapsulated polymeric nanoparticles targeted to collagen IV, designated nanoburrs, have demonstrated preferential accumulation at sites of vascular injury and significant improvements in arterial patency in rat carotid injury models.

Magnetic nanoparticles, typically composed of iron oxide cores coated with biocompatible polymers, enable an innovative approach to targeted drug delivery through the application of external magnetic fields. Magnetic nanoparticles loaded with therapeutic agents can be attracted to stent struts and adjacent arterial tissues using properly positioned magnetic field sources, facilitating precise localization of drug delivery. Preclinical studies have demonstrated that magnetic targeting of paclitaxel-loaded nanoparticles achieves effective inhibition of in-stent restenosis with substantially lower drug doses than systemic administration.

Albumin-based nanoparticles leverage the natural biocompatibility and long circulating half-life of albumin to achieve sustained drug delivery. Nab-paclitaxel, an albumin-bound nanoparticle formulation of paclitaxel originally developed for oncology applications, has been investigated for cardiovascular applications. Preclinical studies demonstrated dose-dependent reduction in stent restenosis following infusion of nab-paclitaxel, and early phase clinical trials confirmed that systemic delivery was well tolerated without significant toxicity.

6. Molecular Targeting Strategies

Molecularly targeted nanoparticle delivery represents a paradigm shift in the approach to preventing in-stent restenosis. Rather than relying on passive drug release from stent coatings, targeted delivery systems actively seek specific molecular epitopes present in the injured vascular wall. This strategy enables preferential drug accumulation at the sites requiring therapy while minimizing exposure to healthy tissues. Importantly, by targeting specific cell populations or extracellular matrix components, molecular targeting may achieve restenosis prevention without the delayed endothelialization that characterizes conventional drug-eluting stents.

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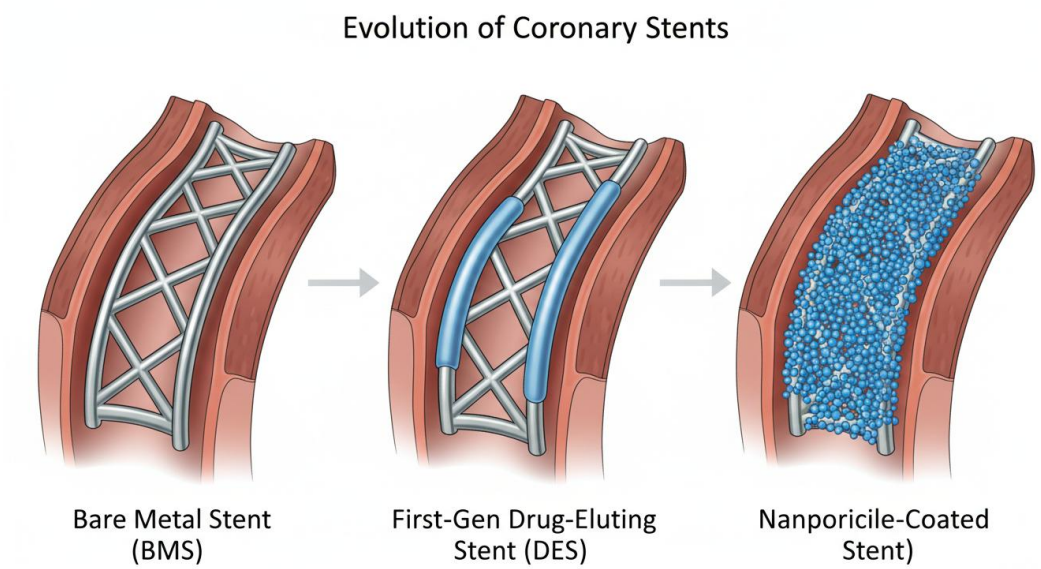

Figure 3. Evolution of coronary stent technology from bare metal stents (BMS) through first-generation drug-eluting stents (DES) to advanced nanoparticle-coated stent platforms.

Several molecular targets have been identified for targeted nanoparticle delivery in the context of vascular injury. Alpha-v beta-3 integrin, a cell adhesion molecule highly expressed on activated endothelial cells, smooth muscle cells, and platelets at sites of vascular injury, represents a particularly attractive target. Nanoparticles functionalized with integrin-targeting ligands have demonstrated selective binding to injured vascular segments, achieving high local drug concentrations while sparing quiescent vessel wall regions.

Chondroitin sulfate proteoglycans represent another important target. These extracellular matrix components are exposed and upregulated following vascular injury and stent deployment. Prednisolone-encapsulated liposomal formulations targeted to chondroitin sulfate proteoglycans have demonstrated preferential localization to sites of stent-induced injury and subsequent reduction in restenosis in atherosclerotic rabbit models. Similarly, collagen IV-targeted nanoparticles have shown promise in preclinical studies.

Tissue factor, a transmembrane glycoprotein that is overexpressed following vascular injury, has also been exploited as a molecular target. Paclitaxel-loaded nanoparticles directed against tissue factor have demonstrated anti-restenotic effects comparable to conventional drug-eluting stents in preclinical models. The dual role of tissue factor in both thrombosis and restenosis pathogenesis makes it an appealing target for therapeutic intervention.

An alternative targeting strategy involves using the stent itself as the target for nanoparticle-assisted drug delivery. Magnetic nanoparticles can be attracted to stent struts using external magnetic fields, effectively converting the stent into a target for therapeutic delivery. This approach offers the practical advantage of not requiring specific molecular epitopes for targeting, relying instead on physical forces to achieve drug localization.

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7. Clinical Outcomes and Trials

While nanoparticle-based stent technologies remain predominantly in the preclinical development phase, several important studies have provided proof-of-concept for clinical translation. Early-phase clinical trials have evaluated the safety and feasibility of nanoparticle-enhanced stent systems, with promising results that support continued development.

Drug	Nanocarrier	Key Findings	Reference
Imatinib	Polymeric NP-eluting stent	50% reduction in in-stent neointima in pig model	Masuda et al.
Paclitaxel	Carbon-carbon coated CoCr stent	Safe, effective endothelialization	Bhargava et al.
Paclitaxel	Magnetic NPs	ISR inhibition at low dose in rat model	Chorny et al.
Pitavastatin	Polymeric NP-eluting stent	Comparable to sirolimus-eluting stent	Tsukie et al.
VEGF/Paclitaxel	Bi-layered PLGA NPs	Complete re-endothelialization, reduced ISR	Yang et al.

Table 2. Key Preclinical and Early Clinical Studies of Nanoparticle-Based Stent Systems

The evaluation of carbon-carbon coated, nonpolymeric cobalt-chromium stents with low and medium doses of paclitaxel in porcine coronary arteries represents one of the most comprehensive preclinical assessments of nanoparticle stent technology. Histomorphometric analysis at six weeks demonstrated acceptable performance characteristics with respect to endothelialization, neointimal hyperplasia, percentage diameter stenosis, inflammatory response, and fibrin deposition. Notably, these nanoparticle-coated stents outperformed stents coated with biodegradable polymers loaded with equivalent paclitaxel doses, suggesting that the nanoparticle delivery platform itself may contribute favorably to vascular healing.

The systemic delivery of nab-paclitaxel in patients undergoing bare metal stent placement was evaluated in early phase clinical trials to determine safety and optimal dosing. Results indicated that nab-paclitaxel was well tolerated at doses that achieved meaningful antiproliferative effects, without the significant systemic toxicity that has limited systemic administration of conventional paclitaxel formulations. These findings support the continued investigation of albumin-based nanoparticle formulations for cardiovascular applications.

Dual-drug nanoparticle-eluting stents represent another frontier in clinical development. Stents coated with bi-layered poly-lactic-co-glycolic acid nanoparticles containing vascular endothelial growth factor DNA plasmid in the outer layer and paclitaxel in the inner core have demonstrated sequential drug release in preclinical models. The early release of vascular endothelial growth factor promotes re-endothelialization while the slower release of paclitaxel suppresses smooth muscle cell proliferation. Mini-swine studies demonstrated complete re-endothelialization and significantly suppressed in-stent restenosis after one month compared to commercial drug-eluting stents.

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8. Challenges and Future Directions

Despite the considerable promise of nanotechnology in coronary stenting, multiple challenges must be addressed before these innovations can achieve widespread clinical adoption. The translation of nanoparticle-based therapies from preclinical models to human clinical practice requires navigating complex regulatory pathways, establishing robust manufacturing processes, and demonstrating clear clinical benefits over existing technologies.

Regulatory considerations represent a significant challenge for nanoparticle-based medical devices. Current regulatory frameworks were developed primarily for conventional pharmaceuticals and medical devices, and may not adequately address the unique characteristics of nanotechnology-enhanced products. The complex structure of nanoparticles, their unclear interactions with human tissues, and the multifunctional nature of some formulations necessitate the development of standardized testing protocols and evaluation criteria specifically designed for nanomedicine applications. Regulatory agencies must strike a balance between ensuring patient safety and avoiding overly burdensome requirements that could stifle innovation.

Scalability and manufacturing reproducibility constitute additional critical challenges. Many nanoparticle platforms that perform well in laboratory settings prove difficult to manufacture at clinical scale with consistent properties. Batch-to-batch variability in nanoparticle size, drug loading, surface characteristics, and stability can significantly impact therapeutic efficacy and safety. The development of scalable manufacturing processes with robust quality control measures is essential for clinical translation.

Biocompatibility and long-term safety of nanoparticles within the cardiovascular system require careful evaluation. While short-term studies have demonstrated acceptable safety profiles, the long-term fate of nanoparticles within the vascular wall and potential for systemic distribution remain incompletely characterized. Understanding the degradation kinetics, clearance pathways, and potential for chronic inflammatory responses is essential for establishing the safety of nanoparticle-based stent systems.

Future directions in this field include the development of personalized nanomedicine approaches using patient-derived biological materials, integration of theranostic capabilities that combine therapeutic delivery with diagnostic imaging, and the application of artificial intelligence to optimize stent design and patient selection. Exosome-mimetic nanovesicle coatings represent a particularly exciting frontier, as these bioinspired particles can mimic the natural functions of endogenous exosomes in promoting vascular healing and modulating inflammatory responses.

9. Conclusion

The application of nanoplasty and nanotechnology in coronary stenting represents a transformative approach to addressing the persistent challenges of in-stent restenosis, delayed endothelialization, and stent thrombosis. From the early development of bare metal stents through the successive generations of drug-eluting stents, the evolution of interventional cardiology has been driven by the search for an optimal balance between preventing restenosis and promoting vascular healing. Nanotechnology offers the potential to achieve this balance through precisely controlled drug delivery, molecular targeting, and biocompatible surface engineering.

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The diverse array of nanoparticle platforms under investigation, including liposomes, polymeric nanoparticles, magnetic nanoparticles, and albumin-based carriers, each offers unique advantages for cardiovascular therapeutic delivery. Molecular targeting strategies that direct drugs to specific epitopes within the injured vascular wall may enable restenosis prevention without the delayed endothelial healing that characterizes conventional drug-eluting stents. Preclinical studies have consistently demonstrated the feasibility and efficacy of nanoparticle-based approaches, while early clinical trials have established acceptable safety profiles.

However, significant challenges remain before nanoparticle-enhanced stents can achieve widespread clinical adoption. Regulatory pathways must be clarified, manufacturing processes scaled, and long-term safety established through rigorous clinical trials. The convergence of nanotechnology, molecular biology, and interventional cardiology continues to accelerate, and it is anticipated that in the coming years, nanoparticle-based stent systems will enter larger-scale clinical trials, potentially establishing a new paradigm for percutaneous coronary intervention. The future of coronary stenting lies not merely in incremental improvements to existing technology, but in the fundamental reimagining of how therapeutic agents are delivered to the vascular wall, and nanotechnology stands at the forefront of this transformation.

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