INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

Review Paper

Biomedical Stents: Design Strategies, Manufacturing Approaches, And Emerging Innovations

Athira K*, Anju G. A., Roma Mathew

Department Of Pharmaceutics, College of Pharmaceutical Sciences, Govt Medical College, Trivandrum, Kerala, India.

ARTICLE INFO

Published: 09 May 2026

Keywords:

Biomedical stents, Drug-eluting stents, Bioresorbable stents, Additive manufacturing, Surface modification, Smart stents, Controlled drug delivery, Personalized medicine.

DOI:

10.5281/zenodo.20095068

ABSTRACT

Biomedical stents have revolutionized the management of obstructive disorders in multiple clinical disciplines, including cardiology, gastroenterology, pulmonology, and urology. These implantable devices provide mechanical support to restore luminal patency, improve organ function and enhance patient outcomes. Over the past few decades, stent technology has evolved remarkably, from bare-metal platforms to sophisticated drug-eluting, bioresorbable, and smart stent systems. Recent advances in biomaterials, computational design, additive manufacturing, and surface engineering have significantly expanded their therapeutic potentials. The integration of controlled drug delivery, biodegradable polymers, and patient-specific fabrication has accelerated innovation in this field. This review comprehensively discusses the classification, materials, design principles, manufacturing approaches, and evaluation methods of stents. Emerging technologies, including three-dimensional printing, nanotechnology, biodegradable materials, and stimuli-responsive systems are also highlighted. Furthermore, current challenges and future perspectives are critically examined to provide insights into the next generation of stent platforms. This review aims to serve as a valuable resource for researchers, clinicians, and biomedical engineers engaged in developing advanced stent technologies.

INTRODUCTION

Biomedical stents are implantable tubular scaffolds designed to restore, maintain, or improve the patency of anatomical lumens that are compromised by disease, trauma, or congenital abnormalities. They have become indispensable in modern interventional medicine, particularly in the management of cardiovascular diseases,

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***Corresponding Author:** Athira K.

Address: *Department Of Pharmaceutics, College of Pharmaceutical Sciences, Govt Medical College, Trivandrum, Kerala, India*

Email : athirajmohan123@gmail.com

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

gastrointestinal strictures, airway obstruction, and urological disorders. [1]

Cardiovascular diseases remain the leading cause of mortality worldwide, with coronary artery disease accounting for a substantial proportion of deaths. The advent of percutaneous transluminal angioplasty, followed by stent implantation, has revolutionized coronary revascularization. Beyond vascular applications, stents are increasingly used in esophageal, biliary, colonic, tracheobronchial, and ureteral interventions.[2]

An ideal stent should provide adequate radial support while minimizing vessel trauma, inflammation, thrombosis, and restenosis. Achieving this balance requires careful integration of the material properties, structural design, manufacturing precision, and biological performance.[3]

Recent advancements in computational modeling, nanotechnology, biomaterials, and additive manufacturing have propelled stent technology into a new era of personalized and multifunctional therapeutic platforms. This review presents a detailed overview of the fundamental principles, manufacturing strategies, clinical applications, and future prospects of stents.[17]

2. Classification of Biomedical Stents

2.1 Based on Anatomical Application

- Coronary stents
- Peripheral vascular stents
- Gastrointestinal stents
- Tracheobronchial stents
- Ureteral stents
- Neurovascular stents

2.2 Based on Material

1. Metallic stents
2. Polymeric stents
3. Composite stents
4. Biodegradable stents

2.3 Based on Functional Properties

- Bare-metal stents
- Drug-eluting stents
- Covered stents
- Bioresorbable stents
- Smart stents

3. Materials Used in Stent Fabrication

3.1 Metallic Materials

Stainless Steel (316L)

[1] It has excellent mechanical strength.
[2] It has a high corrosion resistance.
[3] Cost-effective.

Cobalt-Chromium Alloys

- It has a superior strength-to-weight ratio.
- Enhanced radiopacity.
- Allows thinner struts.

Nitinol

- Shape memory and super-elasticity .
- This is ideal for self-expanding stents.

Magnesium Alloys

- Biodegradable.
- Favorable mechanical properties of the material It is promising for temporary scaffolding.

3.2 Polymeric Materials

- Poly(L-lactic acid) (PLLA)
- Polycaprolactone (PCL)
- Poly(lactic-co-glycolic acid) (PLGA)
- Polyurethane
- Silicone

3.3 Composite Materials

Hybrid combinations of metals, polymers, ceramics, and nanomaterials provide enhanced multifunctionality of the resulting composites.[15]

4. Design Principles of Biomedical Stents

The primary objectives of stent design include the following:

- Restoration and maintenance of luminal patency.
- Prevention of elastic recoil and vessel collapse.
- Minimization of vessel trauma during deployment.
- Reduction of neointimal hyperplasia and restenosis.
- Enhancement of long-term biocompatibility.
- Facilitation of easy delivery through tortuous anatomies.

An ideal stent should combine high radial strength, excellent flexibility, minimal recoil, and superior fatigue resistance.[16]

4.1 Mechanical Design Requirements

Radial Strength

Radial strength refers to the ability of a stent to resist external compressive forces and maintain vessel patency after deployment. It is essential for preventing vessel recoil and is directly influenced by strut thickness, material modulus, and cell geometry. It is of great importance in calcified or highly stenotic lesions. [19]

Higher radial strength generally improves scaffolding but may reduce its flexibility.

Flexibility

Flexibility enables the stent delivery system to navigate tortuous vascular pathways. This is critical for coronary, neurovascular, and peripheral applications. It is highly influenced by the connector design, cell geometry, and strut arrangement. Open-cell designs generally offer superior flexibility compared to closed-cell designs. [20]

Reoil Resistance

After balloon deflation, the stent should retain its expanded diameter. A low recoil ensures optimal lumen gain. Metallic alloys, such as cobalt-chromium, exhibit excellent recoil resistance. [20]

Fatigue Resistance

Stents undergo millions of cyclic loading events owing to pulsatile blood flow. Poor fatigue resistance can lead to fractures. This is important for long-term implantation. These were evaluated using accelerated durability testing.[20]

Crush Resistance

Crush resistance is the ability to withstand external compressions. Self-expanding nitinol stents excel in this property and are essential for esophageal, tracheal, and colonic stents. [20]

4.2 Geometrical Design Parameters

Strut Thickness

Strut thickness is one of the most critical design variables. Thin struts improve deliverability and endothelialization of the stent. Thick struts enhance the radial strength. Excessively thick struts may increase thrombogenicity.

Typical range:

- Coronary stents: 60–120 µm
- Peripheral stents: 150–250 µm[10.19]

Strut Width

It influences scaffolding efficiency and affects the drug-loading capacity of drug-eluting stents. Wider struts may impair the blood flow.

Cell Design

Cell architecture determines the expansion characteristics and vessel coverage.

Open-Cell Design

- Better flexibility.
- Improved side branch access.
- The scaffolding was less uniform.

Closed-Cell Design

- Greater radial support.
- More uniform lesion coverage was observed.

- Reduced conformability. [6,7]

Connector Configuration

Connectors join the adjacent rings. Fewer connectors increase the flexibility. More connectors enhance the longitudinal stability. Common configurations include the following:

- Straight connectors
- S-shaped connectors
- Helical connectors [9]

4.3 Material Selection Considerations

The material properties strongly influence the stent performance. They can be metallic or polymeric. Important properties that should be considered include the elastic modulus, yield strength, corrosion resistance, and biocompatibility. [15]

4.5 Hemodynamic Considerations

The stent geometry affects the local blood flow. Disturbed blood flow can promote thrombosis. Streamlined strut profiles reduce the flow separation. Computational fluid dynamics (CFD) is commonly employed to optimize the blood flow patterns.[16]

4.6 Computational Design and Optimization

Finite Element Analysis (FEA) plays a central role in modern stent design. This is widely employed to predict stress distribution, expansion behavior, fatigue life, and vessel interaction.

5. Manufacturing Technologies of Biomedical Stents

5.1 Laser Cutting: Most commonly used method for manufacturing metallic stents. In this technique, a high-energy laser precisely cuts the desired stent pattern from a thin metal tube based on a computer-generated design of the stent. It offers excellent dimensional accuracy, allows the fabrication of complex geometries, and is highly reproducible. After cutting, the stent undergoes post-processing steps, such as electropolishing and heat treatment, to improve its surface finish and mechanical properties. This method is widely used for coronary, peripheral, and neurovascular stenting.[16]

5.2 Braiding and Weaving

Braiding involves the interlacing of multiple metallic or polymeric wires to form a tubular mesh structure. Nitinol is commonly used because of its excellent flexibility and shape memory properties. Braided stents exhibit superior flexibility, crush resistance, and conformability, making them ideal for gastrointestinal, biliary, and airway applications in the human body. The braid angle and wire diameter significantly influenced the radial force and expansion characteristics. Heat treatment is usually performed to set the final shape of stents.[18]

5.3 Photochemical Etching

Photochemical etching is a non-thermal manufacturing process mainly used for prototype development. A metal sheet is coated with a photoresist, exposed to ultraviolet light through a patterned mask, and chemically etched to remove unwanted areas. The flat patterned sheet was rolled into a tubular structure and welded. This technique avoids the thermal damage and residual stresses associated with laser cutting. However, it is less precise and less suitable for large-scale productions.[16]

5.4 Wire Coiling

Wire coiling is one of the earliest methods used for fabricating stents. In this technique, a continuous wire is wound helically around a mandrel to form a tubular scaffold. It is simple, cost-effective, and suitable for temporary stents, such as ureteral and tracheal stents. Although wire-coiled stents offer good flexibility, they generally have lower radial strengths than modern designs. However, their current use is limited to specialized applications.[16]

ADDITIVE MANUFACTURING METHODS

5.5 Fused Deposition Modeling (FDM): FDM is a widely used 3D-printing technique for biodegradable polymeric stents. A thermoplastic filament, such as PCL or PLA, is melted and extruded layer-by-layer to form the stent. It is cost-effective, easy to operate, and allows for customization according to patient anatomy. FDM is particularly useful for drug-eluting gastrointestinal and airway stents. However, its resolution is lower than that of other additive manufacturing methods.

5.6 Stereolithography (SLA): SLA uses ultraviolet light to selectively cure a liquid photopolymer resin layer by layer. This technique provides excellent resolution, a smooth surface finish, and precise geometries. This is particularly useful for producing intricate stent prototypes and research models. SLA enables rapid fabrication and design optimization of parts. However, the availability of biocompatible resins is limited.

5.7 Selective Laser Melting (SLM): SLM is an advanced additive manufacturing technique used for metallic stents. A high-power laser selectively melts the metal powder layer-by-layer to build the stent. This enables the fabrication of highly complex, patient-specific metallic structures with excellent mechanical properties. SLM is particularly promising for customized vascular and airway stent applications. Post-processing is often required to improve the surface finish and dimensional accuracy.[20]

6. EVALUATION OF BIOMEDICAL STENTS

6.1 Dimensional Analysis

Dimensional analysis confirmed that the fabricated stent met the intended design specifications, including diameter, length, strut thickness, and connector dimensions.

6.2 Surface morphology

The surface morphology was evaluated to assess the uniformity, smoothness, and structural integrity of the stent surface. Scanning electron microscopy is widely used to visualize surface topography, coating homogeneity, and the presence of defects, such as cracks or pores.

6.3 Mechanical testing

It involves testing mechanical properties, such as radial compression, flexibility, fatigue analysis, and crush resistance.

6.4 Biological evaluation

It involves evaluating the compatibility, cell adhesion properties, protein adsorption, hemocompatibility, and cytotoxicity.

6.5 In vitro drug release studies

The release kinetics of the incorporated therapeutic agent were evaluated under simulated physiological conditions. The stent was immersed in an appropriate dissolution medium, and the drug concentrations were measured at predetermined intervals.[9]

6.6 In vivo studies

Animal studies provide a comprehensive evaluation of stent safety, efficacy, endothelialization, and tissue response under physiological conditions. Histopathological examination was performed to assess inflammation, neointimal formation, and thrombosis.[20]

7. CLINICAL APPLICATIONS

- Treatment of coronary artery disease and peripheral arterial disease.

- Management of malignant and gastrointestinal strictures.
- It is used for airway stenosis and tracheobronchial collapse.
- It is used for ureteral obstruction.
- Treatment of intracranial aneurysms[11]

8. EMERGING INNOVATIONS

8.1 Bioresorbable Stents

Bioresorbable stents provide temporary mechanical support and gradually degrade after tissue repair. They eliminate the long-term complications associated with permanent metallic implants. Common materials include poly L-lactic acid, magnesium alloys, and zinc alloys.

8.2 Drug-Eluting and Multi-Drug Stents

These stents release one or more therapeutic agents to prevent restenosis, thrombosis, and inflammation of the arteries. Advanced coatings enable controlled and sequential drug release over prolonged periods of time. Multidrug systems improve vascular healing and long-term clinical outcomes.

8.3 Three-Dimensional Printed Stents

Three-dimensional printing enables the fabrication of customized stents tailored to patient-specific anatomies. This allows the production of complex geometries using metals, polymers, or composite materials. This technology enhances precision, personalization, and rapid prototyping of dental restorations.

8.4. Shape-Memory Stents

Shape-memory stents are fabricated from smart materials that recover their original shape upon exposure to body temperature. Nitinol is widely used because of its excellent super elasticity and biocompatibility properties. These stents allow for minimally invasive delivery and reliable self-expansion.

8.5 Nanotechnology-Based Stents

Nanotechnology improves stent performance by enhancing surface properties and controlling drug delivery. Nanostructured coatings promote endothelialization and reduce thrombosis and bacterial adhesion. Nanoparticles also enable targeted and sustained therapeutic releases.

8.6 Smart and Biosensing Stents

Smart stents incorporate sensors that continuously monitor physiological parameters, such as blood flow and pressure. They wirelessly transmit real-time data to healthcare providers for remote monitoring purposes. This facilitates the early detection of restenosis and other complications.[17]

8.7 Surface Functionalization and Bioactive Coatings

Bioactive coatings enhance stent biocompatibility by promoting endothelial healing and reducing thrombosis risk. These may contain heparin, nitric oxide donors, antibodies, or growth factors. These modifications significantly improve the long-term performance of the implants.

8.8 Hybrid Composite Stents

Hybrid stents combine metals, polymers, and nanomaterials to optimize their mechanical and biological properties. They offer improved radial strength, flexibility, and controlled drug release properties. This approach overcomes the limitations of single-material stents.

8.9 Artificial Intelligence-Assisted Stent Design

Artificial intelligence helps optimize stent geometry, deployment, and clinical performance. Machine learning algorithms analyze large datasets to predict outcomes and personalize therapies. This accelerates stent development and improves the precision of treatment.

8.10 Wireless and Magnetically Controlled Stents

Wireless stents enable continuous monitoring without the need for invasive follow-up procedures. Magnetically controlled stents allow for precise navigation and targeted positioning during implantation. These technologies improve procedural accuracy and therapeutic control.

9. CHALLENGES AND LIMITATIONS

- In-stent restenosis
- Late stent thrombosis
- Mechanical fatigue
- Incomplete biodegradation
- Regulatory hurdles
- Manufacturing scalability

CONCLUSION

Biomedical stents have evolved from simple mechanical scaffolds into sophisticated, multifunctional therapeutic devices. Advances in materials science, computational modeling, manufacturing technologies, and surface engineering have substantially improved their clinical performance. Emerging technologies, such as additive manufacturing, smart sensing, and biodegradable materials, promise to further enhance efficacy, safety, and patient-specific treatment. Despite ongoing challenges, the convergence of engineering, medicine, and digital technology is poised to transform the future landscape of stent therapy. Continued interdisciplinary research is essential for translating these innovations into routine clinical practice.

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HOW TO CITE: Athira K., Anju G. A., Roma Mathew, Biomedical Stents: Design Strategies, Manufacturing Approaches, And Emerging Innovations, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 5, 1958-1965, https://doi.org/10.5281/zenodo.20095068