Review paper

Application and clinical significance of biomaterials in vascular prostheses, stents, and artificial heart valves

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Abstract

Progress in cardiology, cardiac surgery, and vascular surgery focuses on improving biomaterials used in stents, vascular prostheses, and heart valves. Material selection determines durability, biocompatibility, and the risk of complications. Newer generations of drug-eluting stents (DES) with thinner struts and improved polymers show greater safety than bare-metal stents (BMS) and early DES. Stent-grafts, combining a stent with a vascular prosthesis, are used for aneurysms and other vessel diseases. Vascular prostheses of expanded polytetrafluoroethylene (ePTFE) and Dacron remain standard, while surface modifications and tissue engineering aim to enhance haemocompatibility and limit infections. Mechanical valves offer durability but require lifelong anticoagulation, whereas biological valves provide better compatibility at the cost of shorter longevity. Transcatheter aortic valve implantation (TAVI) offers a less invasive option for high-risk patients. Emerging polymers, such as polyether-ether-ketone (PEEK), together with tissue-engineering approaches, open perspectives for more durable implants, fewer complications, and improved quality of life.

Introduction

Biomaterials interact with biological systems to treat, diagnose, or replace tissues and organs. In cardiology, and in cardiac and vascular surgery, they are essential for vascular prostheses, heart valves, and stents. The choice of biomaterial impacts therapy effectiveness, implant durability, and complication risks [1].

An ideal biomaterial should have high biocompatibility, optimal mechanical properties, and resistance to biodegradation. Biocompatibility prevents inflammation and rejection, while mechanical strength ensures long-term functionality. Minimising thrombosis and infections is also crucial [2]. With advancements in treating valvular defects and vascular diseases, the demand for durable biomedical materials is rising. Traditional biomaterials include synthetic materials like polytetrafluoroethylene (PTFE) and polyurethane, as well as biological tissues from animal or allogeneic sources [3]. Choosing between biological and mechanical heart valves is a key clinical decision. Biological valves (e.g. bovine pericardium, porcine tissue) have lower thromboembolic risk but limited durability. Mechanical valves last longer but require lifelong anticoagulation, increasing bleeding risk. Selection depends on patient age, comorbidities, and lifespan [4]. Research is advancing biodegradable polymers, anticoagulant coatings, and tissue-engineered materials to reduce reoperations and improve outcomes [4, 5]. Innovative tissue-engineered valves may regenerate and adapt, particularly benefiting younger patients [6].

This study compares treatment outcomes of biomaterials and synthetic materials regarding therapy effectiveness, reoperation rates, and patient survival. It also explores future directions in biomaterial development to enhance treatment outcomes and reduce complications.

Materials used in percutaneous coronary angioplasty

Percutaneous coronary intervention (PCI) with the use of a vascular stent is the most commonly applied method for revascularisation treatment [7]. The currently used types of stents include the following [8]: bare-metal stents (BMS), drug-eluting stents (DES), bioresorbable vascular scaffolds (BVS), dual-therapy stents (DTS).

BMS are the oldest type and have the highest risk of thrombosis [9]. They are no longer as widely used in developed countries, although they may still represent a therapeutic alternative for patients in regions with lower standards of care, where newer types of stents are not available. Moreover, many patients who were initially treated with BMS later underwent

Table 1. Comparison of different types of coronary stents in terms of mortality and risk of myocardial infarction [26–28]

Study	Type of stent	Number of patients	Overall mortality (4-year period)	Risk of myocardial infarction
Kerkmeijer *et al*. [26]	DTS COMBO	1000	7.5%	4.4%
Qian *et al*. [27]	DES (2nd generation, EES)	18522	11.3%	5.9%
Qian *et al*. [27]	BMS	11837	18.4%	7.8%
Chevalierd *et al*. [28]	BVS	335	3.2%	8.6%

procedures with DES implantation. The risk of complete occlusion of the vessel within the bare-metal stent has been reported to be 1.5% within 3 years after the procedure [10]. The first type of stent used for coronary artery stenting was a stainless steel stent [11]. The most commonly used materials for stent construction are Cr-Ni-Mo or Co-Cr alloys. Shape-memory alloys, such as Nitinol, are used to manufacture self-expanding stents, which expand in response to body temperature [12].

DES were introduced into widespread use in 2002. Currently, there are three generations of DES. The first-generation DES includes sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES). The second generation includes everolimus-eluting stents (EES) and zotarolimus-eluting stents (ZES). They are made from thinner struts and improved polymer. Also, antiproliferative drugs used in second-generation DES are less toxic than those used in first-generation DES, and the polymer coating is more biocompatible [13]. Studies indicate that the second generation of drug-eluting stents has a lower risk of major adverse cardiovascular events and target lesion revascularisation compared to the first generation [14]. Among patients undergoing treatment with second-generation drug-eluting stents, overall mortality was lower (2.4% vs. 2.9%), the risk of myocardial infarction was reduced (2.1% vs. 2.9%), and the risk of target lesion revascularisation was also lower (3.5% vs. 8.6%) [13]. Moreover, drug-eluting stents are a safer alternative for patients with a high risk of bleeding due to the necessity of dual antiplatelet therapy [15, 16]. Third-generation DESs are represented by the newest devices made from platinum–chromium or cobalt–chromium platforms [17]. They are also characterised by thinner strut thickness compared with second-generation DESs and are coated with a bioabsorbable polymer, the use of which is intended to reduce the incidence of late stent thrombosis [18]. According to meta-analyses, the use of third-generation DESs has led to a reduction in the frequency of late stent thrombosis and late lumen loss [19]; however, their use did not affect hard endpoints, including all-cause mortality, compared with second-generation stents. An additional advantage of third-generation DESs is the use of newer sirolimus analogues, such as novolimus and biolimus A9, which has helped to limit neointimal hyperplasia, in-stent thrombosis, and in-stent restenosis [20, 21].

The introduction of BVS was initially expected to reduce the risk of restenosis and restore normal endothelial function after treatment. Despite these theoretical benefits, studies have not demonstrated a significant advantage of BVS over everolimus-eluting stents [22]. Improper implantation technique was considered a potential reason for poor results; however, further studies incorporating improved implantation techniques did not show better outcomes compared to everolimus-eluting stents [23]. Although their use appears limited, bioresorbable stents may still serve as an alternative treatment, particularly for patients who cannot undergo dual antiplatelet therapy, especially those with a high risk of bleeding [24].

The latest group of stents includes DTS. COMBO stents contain a coating that includes anti-CD34 antibodies and sirolimus. The drug release reduces the risk of restenosis, while the anti-CD34 antibodies capture circulating endothelial progenitor cells, which accelerate stent endothelialisation, improve healing, and reduce restenosis risk. However, a meta-analysis of patients treated with DTSs did not demonstrate any benefit compared with DESs, and additionally, in patients treated with DTSs, one-year target lesion revascularisation was significantly higher [25]. Table 1 compares different types of coronary stents in terms of overall mortality and the risk of coronary events [26–28].

Stent-grafts

A stent-graft is a combination of a stent, which serves as a structural scaffold, and a vascular prosthesis. The stent, typically made of materials such as nitinol, provides the implant with a specific length and diameter [29]. The stent is covered with a material characteristic of artificial blood vessels, such as polytetrafluoroethylene (PTFE) or Dacron, forming a stent-graft. The type of covering material determines the structure of the stent-graft walls, which can be either ribbed (textured) or smooth [30].

Stent-grafts are classified into straight (simple) stent-grafts and branched stent-grafts. Their primary application includes the treatment of aortic aneurysms and other vascular pathologies, where mechan-

ical support of the vessel wall is required while maintaining blood flow patency. Clinical studies indicate that the integration time of a stent-graft with tissues is slightly shorter than that of traditional stents and significantly shorter compared to synthetic vascular prostheses [31]. Current advancements in stent-graft development focus on coating their surface with therapeutic substances to improve functionality and biocompatibility, thereby reducing the risk of complications and enhancing long-term performance [30, 32].

Biomaterials in vascular prostheses

Vascular prostheses are essential in cardiac and vascular surgery for treating aneurysms, arterial stenosis, and providing vascular access for haemodialysis patients. Common aneurysms include abdominal and ascending aortic aneurysms, with improved treatment methods significantly reducing mortality from ruptures [33].

Vascular prostheses can be autologous, homografts, synthetic, or tissue-engineered. Autologous grafts use the patient's own tissue but are not always viable. Homografts, harvested from brain-dead donors, are stored at 4°C, affecting durability and endothelial integrity [34]. Synthetic vascular prostheses, made from PET, PTFE, PMMA, or PU, replace blood vessel segments. They can be straight or Y-shaped and have smooth or textured walls. Thrombogenic resistance is a key requirement, leading to research on surface modifications, antibiotic immobilisation, and silver salt coatings. Natural polymers like heparin and gelatin help seal prostheses and prevent blood leakage, while albumin inhibits platelet adhesion [35]. Polyurethane surface modifications improve haemocompatibility, but their effectiveness decreases over time. Phospholipid coatings aim to mimic cell membranes, preventing coagulation activation. Early studies on phospholipid-modified polyurethane have shown promising haemocompatibility [36]. Another approach involves coating prostheses with human endothelial cells using integrins to enhance cell adhesion and proliferation [37]. Surface antibiotic modifications enable localised drug release, with drug choice depending on biomaterial stability. Silver salt coatings have shown promising results, reducing infection rates to 1.1% [38]. Tissue-engineered vascular grafts (TEVG) mimic natural blood vessels. Their synthetic scaffolds must be biodegradable and temporarily resistant to blood pressure, degrading as cells populate and proliferate [39]. Despite advancements, synthetic materials like Dacron and ePTFE remain the most widely used in vascular prostheses. ePTFE is preferred for its superior biocompatibility, lower friction, and UV resistance [40]. Comparing Dacron to bovine pericardium-derived biological prostheses, both show similar adverse event rates, including restenosis and transient ischaemic attacks. However, biological prostheses have a significantly lower risk of postoperative bleeding [41].

Biomaterials in heart valves

Artificial heart valves are classified into mechanical, biological, and transcatheter aortic valve implantation (TAVI) valves. Mechanical valves include bileaflet and monoleaflet models, composed of a titanium or stainless steel ring coated with pyrolytic carbon for durability, movable pyrolytic carbon or polymer leaflets, struts ensuring stability, and a PTFE or PET sewing cuff for attachment [42].

Biological valves are categorised into stented and stentless types and classified by origin as xenografts (animal-derived) or allografts (human-derived). Allografts include autografts, used in the Ross procedure, and homografts, harvested from deceased donors and preserved at 4°C or by deep freezing to maintain biological properties [42, 43]. Xenografts, derived from porcine, equine, or bovine tissue, undergo chemical fixation and cross-linking (e.g. with genipin) to enhance durability and prevent calcification. Stentless valves, lacking a rigid frame, reduce mechanical stress, slowing calcification and increasing longevity compared to stented models [42, 44].

TAVI valves, made of bovine or porcine pericardium, are mounted on a self-expanding nitinol frame with three sections: one expanding the calcified native valve for blood flow, one preventing coronary ostia obstruction, and one stabilising in the ascending aorta. The 50 mm frame allows implantation via transfemoral (most common), direct transaortic, or subclavian access. TAVI is preferred for high-risk surgical patients as a less invasive alternative to conventional aortic valve replacement [45].

Artificial valves in the treatment of aortic valve disease

Most aortic valve implants are made of metals, ceramics, or polymers. Stainless steel and titanium were the first materials used in mechanical valves, and due to their durability and resistance to thrombosis, they remain widely used [46]. Introduced in the 1950s, mechanical valves have since been improved for better biocompatibility, reduced anticoagulant use, and fewer reoperations [47]. While they have a lower reoperation risk than biological valves, they pose a higher risk of thromboembolic complications [48]. They are preferred for patients aged 50–70 years due to their longevity, although autografts may be an option for younger patients [49]. Mechanical valves require lifelong anticoagulation, increasing bleeding risk, and proper INR management (2.0–3.5) is essential because NOACs are not suitable [50–52].

Biological valves, made from bovine pericardium or human allografts, are the preferred option for elderly patients and account for about 60% of aortic valve replacements [53]. Their use in patients aged 55–70 years is increasing, especially for those with shorter life expectancy or higher bleeding risk. Euro-

Table 2. Comparison of 10-year outcomes for patients over 70 years old with biological and mechanical heart valves (based on: Kytö *et al.* [54])

Study	Valve type	Number of patients	Patient age	10-year survival rate	10-year risk of major bleeding	10-year risk of reoperation	10-year risk of ischemic stroke
Kytö *et al.* [54]	Biological	3931	> 70	57.8%	18.8%	2.8%	16.9%
Kytö *et al.*	Mechanical	296	> 70	46.1%	37.0%	0.8%	18.9%

pean Society of Cardiology guidelines classify these indications as Class I recommendations [52].

The study by Kytö *et al.* [54] illustrates the advantages and disadvantages of different types of valves and explains the growing trend of choosing biological valves for the treatment of older patients (Table 2).

Artificial valves in the treatment of mitral valve disease

Mitral regurgitation is the third most common valvular heart disease, affecting approximately 24.2 million people worldwide [55]. Standard treatment involves valve replacement with either a biological or mechanical prosthesis, with the use of biological valves increasing in recent years [56]. Complications are similar to those seen with mechanical aortic valves. According to Yu *et al.* [57], mortality is lower in patients with mechanical mitral valves compared to biological ones, and mechanical valves have a lower risk of reoperation. However, they are associated with a higher risk of bleeding, strokes, and embolic events. The role of biological valves in mitral valve disease has grown, with their use rising from 17% of replacements in 1996 to nearly 54% in 2013 [58]. These valves, made from bovine pericardium or porcine tissue, show similar treatment outcomes, though bovine pericardial valves have a larger effective orifice area and lower pressure gradients postoperatively [59].

Challenges and future directions

The increasing demand for vascular prostheses and heart valves is driven by rising cardiovascular diseases and longer life expectancy, leading to more reoperations, especially in younger patients with biological prostheses. Reducing material biodegradation could enhance durability and reduce repeat surgeries [60]. Polymers like polyether ether ketone (PEEK) offer durability and flexibility for cardiovascular prostheses, with lower platelet adhesion improving haemocompatibility [61]. LifePolymer by Foldax, in clinical trials, promises enhanced durability and resistance to mineralisation, eliminating the need for chemical crosslinking and reducing immune response risks [62].

Conclusions

The evolution of biomaterials has transformed cardiovascular medicine, improving the safety and effectiveness of stents, vascular prostheses, and heart valves. While current devices such as drug-eluting stents, ePTFE and Dacron grafts, or transcatheter aortic valve implantation provide reliable clinical outcomes, they still face limitations related to thrombosis, restenosis, infection, and implant longevity. Mechanical and biological valves, as well as vascular grafts, remain essential, but none of the available options is free from drawbacks. Future progress will depend on the development of novel polymers, surface modifications, and tissue-engineering strategies, aiming not only to extend implant durability but also to enhance long-term biocompatibility. Continuous innovation in this field is crucial to reduce reinterventions and to further improve survival and quality of life in patients with cardiovascular diseases.

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Conflict of interest

The authors declare no conflict of interest.

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