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Bio-resorbable polymer stents: a review of material progress and prospects

Sean McMahon[a,d,1], Nicky Bertollo[b,1], Eoin D. O' Cearbhaill[c], Jochen Salber[f], Luca Pierucci[d], Patrick Duffy[a,d], Thomas Dürig[e], Vivian Bi[e], Wenxin Wang[a,*]

[a] The Charles Institute of Dermatology, School of Medicine, University College Dublin, Belfield, Dublin, Ireland
[b] School of Medicine, UCD Centre for Biomedical Engineering, University College Dublin, Belfield, Dublin, Ireland
[c] School of Mechanical and Materials Engineering, UCD Centre for Biomedical Engineering, UCD Conway Institute of Biomolecular and Biomedical Research, University College Dublin, Belfield, Dublin, Ireland
[d] Ashland Specialties Ireland Ltd., Laboratory A, Synergy Centre, Tallaght, Dublin, Ireland
[e] Ashland Specialty Ingredients, Global Pharma R&D, Wilmington, USA
[f] Zentrum für klinische Forschung, Ruhr-Universität Bochum and Universitätsklinikum Knappschaftskrankenhaus, Bochum, Germany

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ABSTRACT

Coronary Artery Disease (CAD) remains the leading cause of death in the developed world. The advent of drug-eluting Bio-resorbable Stents (BRSs) heralded a significant development in the field of CAD, representing a step-change in the treatment paradigm and offering significant improvements in patient outcome. But, as noted by a Task Force sanctioned by the European Commission in 2017, their widespread clinical deployment has primarily been hampered by a lack of randomised clinical trial data demonstrating improved efficacy over traditional permanent drug-eluting stents (DESs). To date, only the Abbott BVS, voluntarily withdrawn from sale in 2017, has undergone such rigorous evaluation, and which showed inferior outcomes at 2–3 years. This timely review paper addresses leading BRS polymer stent technologies to highlight the trends in design strategies and current technological advancements aimed at overcoming such performance limitations. This review examines the leading BRS technologies to gauge the progression of polymer materials technology and strategies in this field. To highlight emerging trends with respect to constituent materials, the developmental history of each stent is discussed briefly, providing context to progress. Many stent features that relate to material selection including material types, material combinations, drugs, architecture features, strut thickness, processing techniques and radiopacity are considered and compared. Following detailed review of these stents, materials and related features are summarised and discussed to highlight the changing clinical needs, current targets and challenges ahead.

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Contents

Abbreviations: PAE, poly(anhydride ester); PDLA, poly(D-lactide); PLLA, poly(L-lactide); PDLLA, poly(D,L-lactide); PGA, poly(glycolide); PLGA, poly(D,L-lactide-co-glycolide); PCL, poly(ε-caprolactone); PLCL, poly(L-lactide-co-ε-caprolactone); PTD-PC, desaminotyrosine polycarbonate polymer; SA/AA, salicylic acid/adipic acid.

* Corresponding author at: The Charles Institute of Dermatology, School of Medicine, University College Dublin, Ireland.
E-mail address: wenxin.wang@ucd.ie (W. Wang).

[1] These authors contributed equally to this work.

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1. Introduction

Coronary Artery Disease (CAD) is a condition characterised by a plaque-mediated narrowing of the vessels providing oxygenated blood to the cardiac muscles, and is the leading cause of death in the developed world [1]. Coronary stents are structural scaffolds designed primarily to prevent elastic recoil and intimal hyperplasia associated with percutaneous transluminal coronary angioplasty (PTCA) [2]. As a wound healing event, arterial patency is typically recovered within the first six months [3,4] following the procedure, which coincides with the timeframe for potential onset of in-stent restenosis. There is a general consensus within the clinical community that the presence of a permanent stent beyond the point of mechanical support for arterial remodelling and drug release presents long-term disadvantages [5,6] while there are no significantly supported advantages to long-term continued presence of a stent [7].

While the advent of bare metallic stents (BMSs) heralded a significant advance in the treatment of CAD, the rate of clinically indicated target lesion repeat revascularisation resulting from in-stent restenosis and neointimal tissue growth remained high [8]. Drug eluting stents (DESs) have been successful in reducing the rate

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