

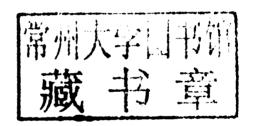
Coatings for biomedical applications

Edited by Mike Driver



Coatings for biomedical applications

Edited by Mike Driver





Oxford Cambridge

Philadelphia

New Delhi

Published by Woodhead Publishing Limited, 80 High Street, Sawston, Cambridge CB22 3HJ, UK www.woodheadpublishing.com www.woodheadpublishingonline.com

Woodhead Publishing, 1518 Walnut Street, Suite 1100, Philadelphia, PA 19102-3406. USA

Woodhead Publishing India Private Limited, G-2, Vardaan House, 7/28 Ansari Road, Daryaganj, New Delhi – 110002, India www.woodheadpublishingindia.com

First published 2012, Woodhead Publishing Limited © Woodhead Publishing Limited, 2012; except Chapter 9 © Expert Reviews Ltd, 2012 The authors have asserted their moral rights.

This book contains information obtained from authentic and highly regarded sources. Reprinted material is quoted with permission, and sources are indicated. Reasonable efforts have been made to publish reliable data and information, but the authors and the publisher cannot assume responsibility for the validity of all materials. Neither the authors nor the publisher, nor anyone else associated with this publication, shall be liable for any loss, damage or liability directly or indirectly caused or alleged to be caused by this book.

Neither this book nor any part may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, microfilming and recording, or by any information storage or retrieval system, without permission in writing from Woodhead Publishing Limited.

The consent of Woodhead Publishing Limited does not extend to copying for general distribution, for promotion, for creating new works, or for resale. Specific permission must be obtained in writing from Woodhead Publishing Limited for such copying.

Trademark notice: Product or corporate names may be trademarks or registered trademarks, and are used only for identification and explanation, without intent to infringe.

British Library Cataloguing in Publication Data A catalogue record for this book is available from the British Library.

Library of Congress Control Number: 2011942775

ISBN 978-1-84569-568-2 (print) ISBN 978-0-85709-367-7 (online)

The publisher's policy is to use permanent paper from mills that operate a sustainable forestry policy, and which has been manufactured from pulp which is processed using acid-free and elemental chlorine-free practices. Furthermore, the publisher ensures that the text paper and cover board used have met acceptable environmental accreditation standards.

Typeset by Toppan Best-set Premedia Limited Printed by TJI Digital, Padstow, Cornwall, UK

Coatings for biomedical applications

Related titles:

Surfaces and interfaces for biomaterials (ISBN 978-1-85573-930-7)

Given such problems as rejection, the interface between an implant and its human host is a critical area in biomaterials. Surfaces and interfaces for biomaterials summarises the wealth of research on understanding the surface properties of biomaterials and the way they interact with human tissue. The first part of the book reviews the way biomaterial surfaces form. Part II discusses ways of monitoring and characterising surface structure and behaviour. The final two parts of the book look at a range of in vitro and in vivo studies of the complex interactions between biomaterials and the body. Surfaces and interfaces for biomaterials is a standard work on how to understand and control surface processes in ensuring biomaterials are used successfully in medicine.

Cellular response to biomaterials (ISBN 978-1-84569-358-9)

The response of cells to biomaterials is critical in medical devices. Specific cell responses may be beneficial – encouraging adhesion, healing or cell multiplication. *Cellular response to biomaterials* examines the response of cells with a wide range of materials, targeted at specific medical applications. Chapters in the first section review cellular response to polymers and ceramics. A second group of chapters discuss cell responses and regenerative medicine for nerves, muscles and orthopaedic materials. The final set of chapters analyse the effect of surface chemistry and how it can be manipulated to provoke a useful cell response.

Biointegration of medical implant materials (ISBN 978-1-84569-509-5)

Biointegration is essential for the successful performance of implanted materials and devices within the human body. With an increasing number and wide range of implant procedures being performed, it is critical that materials scientists and engineers effectively design implant materials which will create a positive biological and mechanical response with the host tissue. Biointegration of medical implant materials provides a unique and comprehensive review of the most recent research into material and tissue interaction and integration.

Details of these and other Woodhead Publishing materials books can be obtained by:

- visiting our web site at www.woodheadpublishing.com
- contacting Customer Services (e-mail: sales@woodheadpublishing.com; fax: +44

 (0) 1223 832819; tel.: +44 (0) 1223 499140 ext. 130; address: Woodhead Publishing
 Limited, 80 High Street, Sawston, Cambridge CB22 3HJ, UK)
- in North America, contacting our US office (e-mail: usmarketing@woodheadpublishing.com; tel.: (215) 928 9112; address: Woodhead Publishing, 1518 Walnut Street, Suite 1100, Philadelphia, PA 19102-3406, USA)

If you would like e-versions of our content, please visit our online platform: www. woodheadpublishingonline.com. Please recommend it to your librarian so that everyone in your institution can benefit from the wealth of content on the site.

Contributor contact details

(* = main contact)

Editor and Chapter 7

M. Driver Vertellus Specialties UK Ltd Unit 3, The Bullpens Manor Court Herriard, Basingstoke Hampshire RG25 2PH UK

Email: mdriver@Vertellus.com

Chapter 1

P. Wyman
DSM Biomedical Materials
PO Box 18
6160 MD Geleen
the Netherlands
Email: paul.wyman@dsm.com

Chapter 2

S. M. Best
Department of Materials Science
and Metallurgy
University of Cambridge
Pembroke Street
Cambridge
CB2 3QZ
UK
Email: smb51@cam.ac.uk

Chapter 3

M. Hassler
Tornier SAS – Bioprofile
161 Rue Lavoisier
Montbonnot
38334 Saint-Ismier CEDEX
France
Email: michel.hassler@tornier.fr

Chapter 4

L. De Nardo*, L. Altomare, B. Del Curto, A. Cigada and L. Draghi Dipartimento di Chimica, Materiali e Ingegneria Chimica 'Giulio Natta' Politecnico di Milano Piazza L. da Vinci 32 20133 Milano Italy Email: luigi.denardo@polimi.it

Chapter 5

J. H. Wang
Vertellus Specialties UK Ltd
Unit 3, The Bullpens
Manor Court
Herriard, Basingstoke
Hampshire
RG25 2PH
UK
Email: jhwang@Vertellus.com

Chapter 6

M. Yaseen*, B. J. Cowsill and J. R. Lu Biological Physics Group School of Physics and Astronomy University of Manchester Schuster Building, Brunswick Street Manchester M13 9PL

UK

Email: Mohammed.

Yaseen@manchester.ac.uk; ben.cowsill@postgrad. manchester.ac.uk; j.lu@manchester.ac.uk

Chapter 8

L. K. von Segesser
Department of Cardio-vascular
Surgery
CHUV, CCV, BH 10-275
Rue du Bugnon 46
1011 Lausanne
Switzerland
Email: Ludwig.von-segesser@chuv.
ch

Chapter 9

D. C. Sin*
Materials Engineering
Room 115, Building 69
Monash University
Clayton
Victoria 3800
Australia
Email: daniel.sin@monash.edu

Kuang-Chi Institute of Advanced Technology Software Building No. 9 Gaoxin Zhong 1st Road High-Tech Industrial Estate Shenzhen Guangdong

P. R. China

X. Miao

H. L. Kei
Formerly at:
School of Engineering Systems
Queensland University of
Technology
Brisbane
Queensland 4059
Australia

Chapter 10

I. G. Turner
Centre for Orthopaedic
Biomechanics
Department of Mechanical
Engineering
University of Bath
Bath
BA2 7AY
UK
Email: L.G.Turner@bath.ac.uk

Chapter 11

D. J. Stickler
Cardiff School of Biosciences
Cardiff University
Cardiff
CF10 3TL
UK
Email: Stickler@cardiff.ac.uk

Chapter 12

H. Sheardown* and L. Subbaraman Department of Chemical Engineering McMaster University 1280 Main St West Hamilton Ontario L8S 4L7 Canada

Email: sheardow@mcmaster.ca

Coatings are used in a multitude of applications, and invariably when a substrate material does not provide all of the required properties in a particular application. The coating may provide an obvious decorative or protective function, as in many household and industrial applications, or it may provide a much more fundamental change in performance or function by, for example, improving the clinical performance of a medical device. The purpose of this book is to explore some of the types of coating and other surface modification technologies developed for use in biomedical applications and how they have been used to improve performance characteristics.

The book is divided into two parts; the first is focused on different types of coatings and their general applications and the second presents case studies, with a more in-depth look at specific application areas.

Part I starts with a detailed look at hydrophilic coatings, giving consideration to the types of polymers used to make the coatings, including polyethylene glycol (PEG), polyvinyl pyrrolidone (PVP), hyaluronic acid and phosphorylcholine-containing materials, their attachment to surfaces and their properties. An important point is made; hydrophilicity per se must not be regarded as the only major consideration when designing an effective biocompatible coating. Chapter 2 looks at mineral coatings developed for use in orthopaedic applications, methods of making and applying them, and their clinical performance. Chapter 3 is focused on the uses of pyrolytic carbon coatings, particularly in orthopaedic and cardiovascular applications. The electrochemical surface modification of titanium is the subject of chapter 4, providing details of the various processes that may be used to modify surfaces with complex inorganic species and more recent research directed towards the development of hybrid organic-inorganic surface treatments. Chapter 5 looks at the methods used to prepare a surface (cleaning, polishing, etching and priming) prior to further treatment, while chapter 6 describes some of the methods employed for characterising surfaces and coatings.

Part II of the book looks in more detail at specific application areas where the use of surface treatments has resulted in medical devices with better performance characteristics. Chapter 7 focuses on the development of coronary stents incorporating drug-eluting coatings and how this approach has dramatically improved clinical outcomes. Chapter 8 looks at the use of coatings to improve the blood compatibility of extracorporeal circuits that are used during open-heart surgical procedures such as cardiopulmonary bypass. In a similar vein, chapter 9 discusses surface modifications designed to reduce complications resulting from blood activation of ventricular assist devices (VADs). Chapter 10 describes the development of joint-replacement prostheses, in particular total hip replacements, with modified surface composition and topography, intended to integrate better with bone. Biofilm formation and mineral encrustation are two related issues affecting the function of urological devices and chapter 11 reviews the use of coatings, including those incorporating antimicrobial compositions, to combat this. Finally, chapter 12 looks at the development of soft contact lenses and other ocular devices, and the use of performance-enhancing surface treatments.

It is not the aim of this book to provide a comprehensive review of every coating system ever reported, but rather to provide an insight into the process that starts with the identification of an unmet need in the clinic, which then leads to scientists providing design, materials science and engineering input, all of which, after many iterative loops and much evaluation (and the support of marketing and regulatory colleagues), can lead to the development of improved medical devices.

Mike Driver

Contents

	Contributor contact details Preface	ix xiii
Part I	Coating types and applications	1
1	Hydrophilic coatings for biomedical applications	
	in and <i>ex vivo</i>	3
	P. WYMAN, DSM Biomedical Materials, the Netherlands	
1.1	Introduction	3
1.2	Examples of hydrophilic coatings	9
1.3	Applications for hydrophilic coatings in the clinical	
	environment (ex vivo)	20
1.4	Applications for hydrophilic coatings in the clinical	
	environment (in vivo)	23
1.5	Conclusions and future trends	29
1.6	Sources of further information	30
1.7	References	31
1.8	Appendix: list of suppliers of hydrophilic coatings	
	for biomedical devices	40
2	Mineral coatings for orthopaedic applications	43
	S. M. BEST and P. C. MARTI, University of Cambridge, UK	
2.1	Introduction	43
2.2	Important characteristics of mineral coatings	45
2.3	Coating methods	48
2.4	Clinical studies	64
2.5	Future trends	64
2.6	Sources of further information	65
2.7	References	65

7.6	^
VI	Contents

3

	M. Hassler, Tornier – Bioprofile, France	
3.1	Introduction	75
3.2	Carbon solid materials	76
3.3	Carbon film coatings	81
3.4	Pyrolytic carbon coatings	83
3.5	Conclusion	102
3.6	References	103
4	Electrochemical surface modifications of titanium	
	and titanium alloys for biomedical applications	106
	L. DE NARDO, L. ALTOMARE, B. DEL CURTO,	
	A. CIGADA and L. DRAGHI, Politecnico di Milano, Italy	
4.1	Introduction	106
4.2	Electrochemical treatments	112
4.3	Future trends in chemical and electrochemical treatments	132
4.4	Conclusions	136
4.5	Acknowledgements	137
4.6	References	137
4.7	Appendix: list of abbreviations	142
5	Surface preparation techniques for biomedical	
	applications	143
	J. H. Wang, Vertellus Specialties UK Ltd, UK	
5.1	Introduction	143
5.2	Sonication	145
5.3	Mechanical polishing	146
5.4	Electropolishing	150
5.5	Chemical etching	152
5.6	Plasma treatment	155
5.7	Priming	162
5.8	Future trends	164
5.9	Sources of further information	167
5.10	References	168
6	Characterisation of biomedical coatings	176
	M. YASEEN, B. J. COWSILL and J. R. LU,	
	University of Manchester, UK	
6.1	Introduction	176
6.2	Surfaces, concepts and techniques	177
6.3	Contact angle	179
6.4	Analysis of adhesion	182
6.5	Scanning probe microscopy	186

Other commonly used biomedical coatings:

75

pyrolytic carbon coatings

	Contents	VII
5.6	Confocal microscopy	193
5.7	Scanning electron microscopy and transmission	
	electron microscopy	194
5.8	Spectroscopic methods	196
5.9	Optical detection methods	202
5.10	Neutron reflectivity	208
5.11	Other techniques	211
5.12	Future trends	213
6.13	Sources of further information	214
6.14	References	215
Part II	Case studies	221
7	Coatings for cardiovascular devices: coronary stents M. Driver, Vertellus Specialties UK Ltd, UK	223
7.1	Introduction: heart disease and its treatments	223
7.2	Artery structure and mechanism of restenosis	229
7.3	Commercial drug-eluting stent (DES) systems	230
7.4	Increased use of DES and concerns surrounding stent	
	thrombosis	236
7.5	Second generation DES systems	238
7.6	Other approaches and future trends	242
7.7	Conclusions	245
7.8	References	246
8	Coatings for cardiovascular devices:	
	extracorporeal circuits	251
	L. K. von Segesser, Centre Hospitalier Universitaire Vaudois, Switzerland	
8.1	Background of coatings for extracorporeal circulation	251
8.2	Coatings for left-heart bypass	253
8.3	Coatings for cardiopulmonary bypass	254
8.4	Coatings for mechanical circulatory support	257
8.5	Coatings for other devices in cardiothoracic surgery	258
8.6	Conclusions	261
8.7	References	261
9	Surface coatings for ventricular assist devices D. C. Sin, Monash University, Australia, H. L. Kei,	264
	formerly at Queensland University of Technology,	
	Australia and X. Miao, Kuang-Chi Institute of Advanced	
	Technology, P. R. China	
9.1	Introduction	264
9.1	Ventricular assist devices (VADs)	265

viii	Contents	
9.3	Hemocompatible surface coatings for VADs	269
9.4	Future trends	277
9.5	Conclusions	278
9.6	References	279
10	Orthopaedic coatings	284
	I. G. Turner, University of Bath, UK	
10.1	History of joint replacement	284
10.2	Development of joint replacement prostheses	285
10.3	Development of cementless fixation	289
10.4	Thermal spray coating techniques	292
10.5	Coating characteristics	294
10.6	Alternative coating methods	297
10.7	Clinical experience	300
10.8	Acknowledgements	301
10.9	References	302
11	Surface coatings in urology	304
	D. J. STICKLER, Cardiff University, UK	
11.1	Introduction	304
11.2	Indwelling bladder catheters	305
11.3	Biofilm formation on implanted urological devices	309
11.4	Challenges in controlling catheter-associated urinary	
	tract infection	309
11.5	Developments in antimicrobial catheters	310
11.6	The catheter encrustation problem	318
11.7	Ureteric stents	322
11.8	Conclusions	327
11.9	References	328
12	Ophthalmic coatings	336
	H. SHEARDOWN and L. SUBBARAMAN,	
	McMaster University, Canada	
12.1	Introduction	336
12.2	Contact lenses	336
12.3	Artificial cornea	342
12.4	Intraocular lenses	344
12.5	Other ophthalmic devices	345
12.6	Conclusions	345
12.7	References	345
	Index	353

Part I

Coating types and applications

Hydrophilic coatings for biomedical applications in and ex vivo

P. WYMAN, DSM Biomedical Materials, the Netherlands

Abstract: Hydrophilic coatings are applied to a wide range of surfaces of biomaterials. This chapter addresses the need for coatings in both *in-* and *ex-vivo* settings for both blood-contacting and non-blood-contacting applications, with illustrations of the coating chemistry used in each setting. Applications for non-fouling surfaces in diagnostics, lubricious surfaces on cardiovascular devices, and both lubricious and antimicrobial hydrophilic surfaces for urological applications are presented. Processes using both photochemical grafting and addition cure technologies to generate hydrophilic surfaces are outlined, and a selection of polymers commonly employed in commercially available coating systems are considered and discussed in the context of the application area.

Key words: hydrophilic polymer coatings, non-fouling surfaces, medical devices, *in-vitro* diagnostics, blood contact.

1.1 Introduction

Hydrophilic coatings for biomedical application, and more specifically for medical devices, serve numerous purposes. This chapter focuses on applications relevant to medical and medical-related devices, with occasional reference to other applications.

The features and chemistry of common polymers are explored, including covalently and non-covalently bound layers and interpenetrating networks. The relative merits of each approach, along with the advantages and disadvantages of a particular polymer, are illustrated. The chapter covers the application areas relevant to hydrophilic coatings and provides some background and highlights of the favoured chemistries in each of these areas; they are split into *in-vivo* blood contact and non-blood contacting and *ex-vivo*, the division reflecting the regulatory requirements in each application area.

Section 1.2 explores the polymers and chemistries used to generate hydrophilic surfaces and considers the most commonly used materials. Section 1.3 on *ex-vivo* coatings evaluates the use of polyethylene glycol (PEG), and especially PEG functional colloidal particles, for non-fouling