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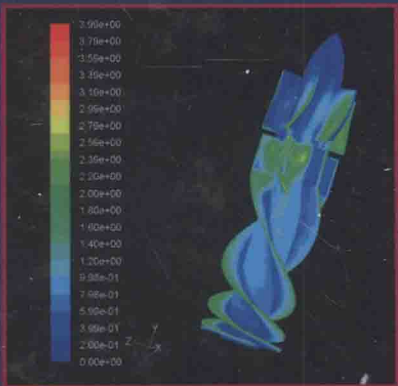

Biomaterials and devices for the circulatory system

Edited by Terence Gourlay and Richard A. Black

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Foreword

Interventions on the heart and major blood vessels were of a very limited scope until the advent in the early 1950s of safe equipment that would allow the function of the heart and lungs to be maintained while the heart or major vessels around the heart were opened and repaired. The heart–lung machine has been the mainstay of cardiovascular surgery ever since. The ability to operate within the heart was rapidly followed by development of artificial heart valves, vascular conduits and pacemakers. Similarly, replacement of diseased arteries elsewhere in the body had to await development of suitable materials for construction of tubes to conduct blood. Today, virtually all interventions for cardiovascular disease require the use of some form of material, device or equipment – all needing to be compatible with the complex biological environment within the body. The spectrum of mechanical complexity ranges from simple sutures and patches that will remain intact within the vascular system without initiating thrombosis, to highly sophisticated, implantable pumps that can take over the function of the heart and maintain normal cardiovascular physiology within the body for prolonged periods.

Use of materials foreign to the body, both as part of a temporary extracorporeal circulation, and as implanted devices such as prosthetic heart valves, soon drew attention to the problems of biocompatibility and biostability, as well as the complex responses of the body to the presence of foreign materials. In responding to these challenges, the discipline of bioengineering was born. The key role of devices in cardiovascular surgery soon spawned a medical devices industry that has ensured high standards of precision and sterility of products and has stimulated the search for improved and novel devices. This multi-billion-dollar industry has become an essential part of the healthcare sector, providing highly reliable medical products of a variety and on a scale that contribute greatly to the success and safety of cardiovascular interventions worldwide.

In the past two or three decades there have been major developments in implantable devices aimed at avoiding some of the more invasive procedures of cardiovascular surgery necessary for their implantation. Percutaneous balloon dilatation of narrowed vessels and, later, maintenance of that dilatation by simultaneous implantation of a stent, have transformed the management of much of coronary artery disease, becoming the commonest method of myocardial revascularisation today. There have been similar developments of stents for management of aneurysms and dissections of the aorta and major arteries, offering an attractive alternative to more invasive, conventional surgery and making interventions feasible in the elderly, frail or critically ill. Remarkably, the implantation of an artificial aortic valve, via percutaneous access to a suitable peripheral artery, has been developed within a decade to the stage of offering a safe and reasonable alternative to conventional heart valve replacement for many who are too old or frail to tolerate major surgery. Minimal access surgery and computer-guided surgery are gradually making inroads into traditional surgical techniques for exposure of the operating site. These developments aim at reducing the injury to the body associated with the exposure of the heart, and they are totally dependent on technologically advanced equipment and devices specifically designed for their role. The heart–lung machine has been challenged in its central role in cardiac surgery by the advent of 'off-pump' surgery for coronary disease – made possible by devices for selectively immobilising parts of the beating heart to allow implantation of bypass grafts to the coronary arteries while the heart continues to maintain the circulation of blood through the body.

It has long been recognised that the materials and structures of the body are extremely well suited to their function. The apparently simple blood vessel is not merely a conduit for conducting blood. Apart from its ability to grow and heal itself, it has muscular and elastic components that allow it to adapt to differing pressures and flow requirements, and its endothelial lining cells have complex metabolic functions that influence the coagulability of the blood within the vessel. Replicating these functions in an implantable vascular conduit is a formidable task, not yet feasible. Few materials can match the mechanical properties of pericardium in cardiovascular applications such as patches or heart valve leaflets. Similarly, the natural heart valve morphology is recognised to disturb the flowing blood and initiate coagulation far less than the mechanical valves designed for their replacement. As a result, ever since the early days of valve replacement there have been two categories of heart valve replacements – the biological valves derived from human or animal sources, that mimic the flow characteristics of the natural valves, and the mechanical valves that employ more conventionally engineered designs. To this day there remain advantages and drawbacks to each category of valve.

Better understanding of the response of the body to foreign materials has resulted in development of improved biomaterials and better design of devices for use in the circulatory system. The ability to implant sensors within the body to monitor, externally and non-invasively, the function of the circulatory system, as well as the function of implanted devices such as conduits and valves, is already nearing clinical application. The ingenuity and imagination of individuals and the resources of the medical devices industry continue to result in new applications to management of cardiovascular disease in ways that would have been considered impossible only a few decades ago.

A future prospect for intervention in the circulatory system lies in the new discipline of tissue engineering – that attempts to utilise living cells to generate new living tissue possessing the form and function, including growth and repair, of parts of the body intended for replacement. Attempts to repopulate areas of heart muscle destroyed by heart attacks, with living myocytes derived from the patient's own stem cells are examples of some of the possibilities for the future. To date, within the cardiovascular field this new approach has shown some promise in the construction of new heart valves using precursor cells of endothelium and connective tissue, though clinical application remains elusive.

Cardiovascular disease is one of the leading causes of premature death and ill health in virtually all countries of the world. Most of its manifestations are nowadays amenable to some form of intervention, whether by percutaneous access or by conventional surgical access. The major remaining field for intervention is heart failure, where devices are beginning to play an important clinical role. Thus, a major clinical need for biomaterials and devices for the circulatory system is assured for the foreseeable future.

Professor Gourlay and Dr Black each have extensive experience and detailed knowledge in the field of cardiovascular bioengineering and the contribution of medical technology to clinical cardiovascular surgery. In this book they have drawn on their knowledge to bring together internationally acknowledged experts covering the range of bioengineering as applied to cardiovascular medicine today. In this fast developing and important discipline, this book brings a welcome review of the state of the art, with new insights and a glimpse of the future. The book will be of value to those working in the bioengineering, medical devices and clinical fields relevant to diseases of the circulatory system.

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Contents

Contributor contact details *xi*

Foreword by Professor David J. Wheatley, University of Glasgow, UK *xv*

Part I Physiological responses to biomaterials **1**

1 Tissue responses to implanted materials **3**

I. DIMARAKIS and S. M. REHMAN, University Hospital of South Manchester, UK and G. ASIMAKOPOULOS, University Hospitals Bristol NHS Foundation Trust, UK

1.1 Introduction 3
1.2 Inflammatory response 5
1.3 Immune response 8
1.4 Hypersensitivity response 12
1.5 Thromboembolic complications 13
1.6 Biofilm 14
1.7 Carcinogenesis 16
1.8 Future trends 17
1.9 References 18

2 Blood interface biomaterials **24**

X. ZHAO, J. M. COURTNEY and H. QIAN, University of Strathclyde, UK

2.1 Introduction 24
2.2 Factors influencing blood compatibility 25
2.3 Factors influencing the blood compatibility of plasticised poly(vinyl chloride) 30
2.4 Molecular design of surfaces for improved blood compatibility 32

2.5 Microdomain structured and bioactive surfaces 41
2.6 Conclusions 44
2.7 References 45

3 Biocompatibility of cardiovascular devices 54
A. A. Ucuzian and H. P. Greisler, Loyola University Medical Center, USA

3.1 Introduction 54
3.2 Blood–biomaterial interfacial events 54
3.3 Specific biocompatibility issues 63
3.4 Strategies to improve device biocompatibility 66
3.5 Conclusions 72
3.6 References 73

Part II Clinical application of biomaterials 87

4 Developments in cardiovascular valve technology 89
A. H. Olivencia-Yurvati, R. T. Mallet and J. Fernandez, University of North Texas Health Science Center, USA

4.1 Introduction: cardiac valvular disease 89
4.2 Historical perspectives 91
4.3 Mechanical prosthetic cardiac valves 92
4.4 Biologic tissue valves 101
4.5 Valve materials 108
4.6 Future trends 113
4.7 Conclusions 115
4.8 References 115

5 Percutaneous cardiovascular valve replacement 123
T. Modine, A. Sudre, T. Gourlay and J. C. Laborde, Centre Hospitalier Régional Universitaire de Lille, France

5.1 Introduction 123
5.2 Material 124
5.3 *In vitro* studies 130
5.4 Cadaver studies 131
5.5 Animal studies 133
5.6 Clinical studies with the CoreValve system 136
5.7 Future trends 140
5.8 References 141

6 Cardiopulmonary bypass technologies **144**
S. GUNAYDIN, University of Kirikkale, Turkey

6.1 Introduction 144
6.2 Historical development of cardiopulmonary bypass 145
6.3 Basic principles of cardiopulmonary bypass 146
6.4 Blood pumps and circuitry 147
6.5 Technologies for moderating inflammatory response to cardiopulmonary bypass 147
6.6 Novel monitoring devices for safety in cardiopulmonary bypass 160
6.7 Controversies and challenges facing cardiopulmonary bypass 164
6.8 Future trends 168
6.9 References 169

7 Cardiovascular stents **173**
A. GUILDFORD, M. SANTIN and G. J. PHILLIPS, University of Brighton, UK

7.1 Introduction 173
7.2 Use of cardiovascular stents 174
7.3 Biomaterials for cardiovascular stents 179
7.4 Surface modifications and coatings 183
7.5 Radioactive stents 193
7.6 Drug eluting stents 194
7.7 Biodegradable stents 201
7.8 Future trends 203
7.9 Sources of further information and advice 204
7.10 References 205

8 Vascular implants for peripheral arterial bypass and aortic aneurysm repair **217**
T. V. HOW, University of Liverpool, UK, R. K. FISHER and S. R. VALLABHANENI, Royal Liverpool and Broadgreen University Hospitals NHS Trust, UK and C. K. CHONG, University of Sheffield, UK

8.1 Introduction 217
8.2 Vascular stents 218
8.3 Bypass grafts 220
8.4 Intimal hyperplasia 224
8.5 Tissue engineering of vascular grafts 229

8.6 Abdominal aortic aneurysm 231
8.7 Endovascular aortic aneurysm repair 232
8.8 Complications of endovascular aneurysm repair 235
8.9 Conclusions 240
8.10 References 241

Part III Future developments 249

9 Nanotechnology and nanomedicine in cardiovascular therapy 251
T. KHAN, R. S. VOHRA and S. HOMER-VANNIASINKAM, Leeds General Infirmary, UK

9.1 Introduction: nanomedicine in cardiovascular therapy 251
9.2 Nanomedicine in cardiovascular imaging 255
9.3 Nanofibres 261
9.4 Future trends 262
9.5 References 263

10 Biomaterials in cardiac restoration therapy 270
D. SELIKTAR and K. SHAPIRA-SCHWEITZER, Technion – Israel Institute of Technology, Israel

10.1 Introduction 270
10.2 Acellular approaches 271
10.3 Cell-based approaches: non-injectable materials 274
10.4 Injectable materials 278
10.5 Conclusions 280
10.6 References 281

11 Biosensor technology in the treatment of cardiovascular disease 286
L. SHEDDEN, University of Strathclyde, UK

11.1 Introduction 286
11.2 Biosensor technology 287
11.3 *Ex vivo* sensors 292
11.4 *In vivo* sensors 297
11.5 *In vitro* sensors 300
11.6 Biosensors in tissue engineering 302
11.7 Biosensors and nanotechnology 302
11.8 Conclusions 303
11.9 References 304

12 Vascular tissue engineering **309**
A. T. Halka, Northern General Hospital, UK, C. Kielty, University of Manchester, UK and M. G. Walker, Alexandra Hospital, UK

12.1 Introduction 309
12.2 Surface modification techniques for synthetic conduits 312
12.3 Tissue engineered arteries: historical and modern perspectives 313
12.4 Approaches to tissue engineered vascular conduits 315
12.5 The inclusion of cells in vascular constructs 329
12.6 Stem cells 332
12.7 Examining the mechanical forces influencing tissue engineered blood vessels 344
12.8 Conclusions 345
12.9 References 346

Index *367*