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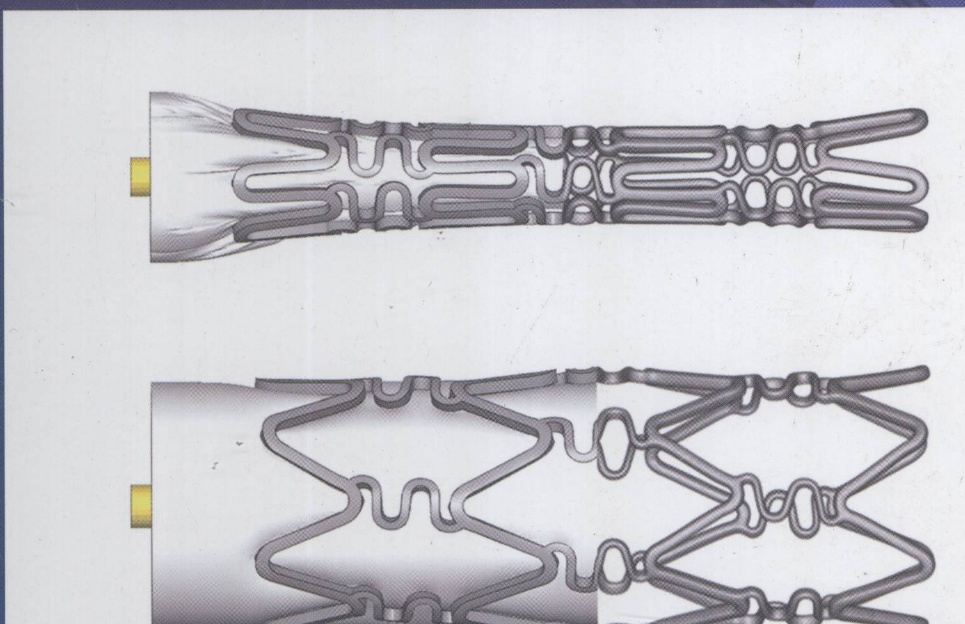
ADVANCES IN BIOMEDICAL ENGINEERING



EDITOR

PASCAL VERDONCK

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Amsterdam • Boston • Heidelberg • London • New York • Oxford
Paris • San Diego • San Francisco • Singapore • Sydney • Tokyo

Elsevier
Radarweg 29, PO Box 211, 1000 AE Amsterdam, The Netherlands
Linacre House, Jordan Hill, Oxford OX2 8DP, UK

First edition 2009

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

Library of Congress Cataloging-in-Publication Data
A catalog record for this book is available from the Library of Congress

ISBN: 978-0-444-53075-2

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Printed and bound in Hungary
08 09 10 10 9 8 7 6 5 4 3 2 1

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Preface

The aim of this book is to bridge the interdisciplinary gap in biomedical engineering education. No single medical device has ever been developed without an extensive interdisciplinary collaboration but, nevertheless, a wide gap still exists between different themes like biomaterials, biomechanics, extracorporeal circulation research, nanotechnology, and safety and regulations.

We have to evitate that, due to the growing complexity, we only gather with and communicate in our own expert groups with their specific research topics. Therefore it is, in my opinion, extremely important that a high quality book is available to cover these interdisciplinary islands by bringing representative research groups together. The aim of this book is a top review of current research advances in biomedical engineering but on an educational level, so it is also useful for teaching master's students, Ph.D. students, and professionals. Each chapter is complementary to reviews in specific scientific journals. The topics range from visualization technology and biosignal and imaging analysis over biomechanics and artificial organs to nanotechnology and biophotonics and cardiovascular medical devices. I thank all authors for their support and I sincerely hope this book will contribute to better engineering for health.

Prof. Pascal Verdonck
December 2007

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CHAPTER 1

Review of Research in Cardiovascular Devices

Zbigniew Nawrat

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Abstract

An explosion in multidisciplinary research, combining mechanical, chemical, and electrical engineering with physiology and medicine, during the 1960s created huge advances in modern health care. In cardiovascular therapy, lifesaving implantable defibrillators, ventricular assist devices, catheter-based ablation devices, vascular stent technology, and cell and tissue engineering technologies have been introduced. The latest and leading technology presents robots intended to keep the surgeon in the most comfortable, dexterous, and ergonomic position during the entire procedure. The branch of the medical and rehabilitation robotics includes the manipulators and robots providing surgery, therapy, prosthetics, and rehabilitation. This chapter provides an overview of research in cardiac surgery devices.

Keywords: Heart prostheses, valve prostheses, blood pumps, stents, training and expert systems, surgical tools, medical robots, biomaterials

Advances in Biomedical Engineering
ISBN 978-0-444-53075-2

1. Introduction

Remarkable advances in biomedical engineering create new possibilities of help for people with heart diseases. This chapter provides an overview of research in cardiac surgery devices. An explosion in multidisciplinary research, combining mechanical, chemical, and electrical engineering with physiology and medicine, during the 1960s created huge advances in modern health care. This decade opened new possibilities in aerospace traveling and in human body organ replacement. *Homo sapiens* after World War II trauma became not only the hero of mind and progress but also the creator of the culture of freedom. Computed tomographic (CT) scanning was developed at EMI Research Laboratories (Hayes, Middlesex, England) funded in part by the success of EMI's Beatles records. Modern medical imaging techniques such as CT, nuclear magnetic resonance (NMR), and ultrasonic imaging enable the surgeon to have a very precise representation of internal anatomy as preoperative scans. It creates possibilities of realizing new intervention methods, for instance, the very popular bypass surgery. It was a revolution in disease diagnosis and generally in medicine. In cardiovascular therapy, lifesaving implantable defibrillators, ventricular assist devices (VADs), catheter-based ablation devices, vascular stent technology, and cell and tissue engineering technologies have been introduced.

Currently, the number of people on Earth is more than 6 billion: increasingly lesser number of living organisms and about million increasingly more "intelligent" robots accompany them.

Robotics, a technical discipline, deals with the synthesis of certain functions of the human using some mechanisms, sensors, actuators, and computers. Among many types of robotics is the medical and rehabilitation robotics – the latest but rapidly developing branch at present, which includes the manipulators and robots providing surgery, therapy, prosthetics, and rehabilitation. They help fight pareses in humans and can also fulfill the role of a patient's assistant. Rehabilitation manipulators can be steered using ergonomic user interfaces – e.g., the head, the chin, and eye movements. The "nurse" robots for patients and physically challenged persons' service are being developed very quickly. Partially or fully robotic devices help in almost all life actions, such as person moving or consuming meals, simple mechanical devices, science education, and entertainment activities. HelpMate, an already existing robot-nurse, moving on the hospital corridors and rooms delivers meals, helps find the right way, etc.

On the one hand, robots are created that resemble the human body in appearance (humanoids), able to direct care; on the other hand, robotic devices are constructed – telemanipulators – controlled by the human tools allowing to improve the precision of human tasks. Robots such as ISAC (Highbrow Soft Arm Control) or HelpMate can replace several functions of the nurse, who will give information, help find the way, bring the medicines and the meal. In case of lack of qualified staff, to provide care for hospice patients at home, these robots will be of irreplaceable help.

Robotic surgery was born out of microsurgery and endoscopic experience. Minimally invasive interventions require a multitude of technical devices: cameras, light sources, special tools (offering the mechanical efficiency and tissue coagulation for preventing bleeding), and insufflations (thanks to advances in computer engineering, electronics, optics, materials, and miniaturization). The mobility of instruments is decreased [from seven, natural for human arm, to four degrees of freedom (DOFs)] due to the invariant point of insertion through the patient's body wall. Across the world, physicians and engineers are working together toward developing increasingly effective instruments to enable surgery using the latest technology. The leading technology presents robots intended to keep the surgeon in the most comfortable, dexterous, and ergonomic position during the entire procedure. The surgery is complex and requires precise control of position and force. The basic advantages of minimally invasive robot-aided surgery are safe, reliable, and repeatable operative results with less patient pain, trauma, and recovery time. Conventional open-heart surgery requires full median sternotomy, which means cracking of sternum, compromising pulmonary function, and considerable loss of blood.

Milestones in the Evolution of Cardiac Devices

1628	William Harvey, St Bartholomew's Hospital, London, presented his theory of the circulatory system. He described the function of the heart, arteries, and veins. It is considered to be one of the greatest advances in medicine.
1812	Julien-Jean Cesar LeGallois, a French physician, proposed the idea of artificial circulation.
1882	German von Schröder introduced the first bubble oxygenator.
1929	Werner Forssmann, a German surgeon, developed the technique of cardiac catheterization, the first to document right heart catheterization in humans using radiographic techniques (won the Nobel Prize in 1956).
1934	Dr Michael DeBakey invented the DeBakey pump (peristaltic).
1937	Artificial heart designed by the Soviet scientist W.P. Demichow was first successfully applied on the dog for 5.5 h.
1949	IBM developed the Gibbon Model I heart–lung machine, delivered to Jefferson Medical College, Philadelphia, PA, USA. It consisted of DeBakey pumps and film oxygenator.
1952	Paul Zoll developed the first cardiac pacemaker.
1952	Charles Hufnagel sewed an artificial valve into a patient's aorta.
1953	Dr John H. Gibbon, Jr, Jefferson Medical College Hospital, Philadelphia, PA, USA, first successfully applied extracorporeal circulation in an 18-year-old female with an atrial septal defect.
1953	Dr Michael DeBakey, Baylor University, Houston, TX, USA, implanted a seamless, knit Dacron tube for surgical repairs and/or replacement of occluded vessels or vascular aneurysms.
1957	Wild et al. reported the use of ultrasound to visualize the heart noninvasively.
1957	Dr C. Walton Lillehei and Earl Bakken, an electronic engineer, developed the first portable pacemaker. Bakken later formed the Medtronics Corporation.
1957	Drs William Kolff and Tetsuzo Akutsu at the Cleveland Clinic implanted the first artificial heart in a dog. The animal survived for 90 min.

1958	Dr Mason Sones, a cardiologist at the Cleveland Clinic Foundation, developed coronary angiography.
1960s	Semm et al. developed laparoscopic instrumentation.
1960	Dr Albert Starr, an Oregon surgeon, developed the Starr–Edwards heart valve. One of the most successful heart valves produced until the late 1970s.
1967	René Favaloro, an Argentine surgeon in the United States, performed the first coronary bypass operation using the patient's native saphenous vein as an autograft.
1967	Christiaan Barnard performed the first heart transplantation.
1968	A. Kantrowitz et al. performed the first clinical trial in a man with intra-aortic balloon pumping.
1969	Dr Denton Cooley, Texas Heart Institute, Houston, TX, USA, implanted a total artificial heart (TAH) designed by Domingo Liotta. The device served as a "bridge" to heart transplantation until a donor heart was found, for 64 h. The heart transplant functioned for an additional 32 h until the patient died of pneumonia.
1971	White – ECMO on newborn babies using veno-venous bypass for up to 9 days.
1975	A. Gruentzing developed the first balloon catheter.
1975	Dr Willem Kolff, University of Utah, designed a nuclear-powered artificial heart (Westinghouse Corporation).
1975	BioMedicus BioPump (Centrifugal) introduced for clinical applications.
1975	Computerized axial tomography, the "CAT scanner", was introduced.
1977	Newer generations of mechanical prostheses included the monoleaflet (Medtronic-Hall) and the bileaflet (St Jude Medical).
1979	The Jarvik TAH was designed using a flexible four-layer diaphragm and a structural design that fits in the human chest. This design was a larger 100 cc version of today's CardioWest TAH–t, which is 70 cc.
1981	Dr Denton Cooley implanted another pneumatically driven artificial heart designed by Dr Akutsu. This artificial heart was used for 27 h as a "bridge" to cardiac transplantation.
1982	Dr William DeVries implanted the Jarvik 7 into Barney Clark, DDS. Dr Clark lived for 112 days.
1984	Baby girl Faye's native heart, Loma Linda Medical Center, was explanted and replaced with a baboon heart. She survived for 3 weeks.
1984	First human implant and successful bridge-to-transplant – a Novacor® LVAS.
1985	The FDA gave approval for Hershey Medical Center to perform six PennState artificial heart implants as bridges to human heart transplantations. This heart is no longer used with human subjects.
1985	At the University of Arizona, Dr Jack Copeland implanted a prototype TAH in a patient who had rejected a recently transplanted heart.
1986	The first atherectomy devices that remove material from the vessel wall were introduced.
1987	Introduction of the first use of coronary stent (by 1997, more than 1 million angioplasties had been performed worldwide).
1990	First LVAS patient discharged home with a Novacor LVAS.
1990–1992	The FDA had withdrawn the Investigational Device Exemption (IDE) from Symbion for the clinical study of the Jarvik TAH. Symbion

	subsequently donated the TAH technology to University Medical Center (UMC), Tucson, AZ, USA, which reincorporated the company and renamed it CardioWest.
1994	First FDA-approved robot for assisting surgery [automated endoscopic system for optimal positioning (AESOP) produced by Computer Motion (CM; Goleta, CA, USA)].
1994	FDA approved the pneumatically driven HeartMate® LVAD (Thoratec Corporation, Burlington, MA, USA) for bridge to transplantation (the first pump with textured blood-contacting surfaces).
1994	HeartMate LVAS has been approved as a bridge to cardiac transplantation.
1996	REMATCH Trial (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart failure, E. Rose principal investigator) initiated with HeartMate® VE (Thoratec Corp.). Results published in 2002 showed mortality reduction of 50% at 1 year as compared to patients receiving optimal medical therapy.
1998	Simultaneous FDA approval of HeartMate VE (Thoratec Corporation, Burlington, MA, USA) and Novacor LVAS (World Heart Corporation, Ontario, Canada), electrically powered, wearable assist systems for bridge to transplantation, utilized in more than 4000 procedures to 2002. Till now, we can estimate 4500 HeartMate XVE, more than 440 IVAD (Implantable Ventricular Assist Device) and more than 1700 Novacor in this kind of blood pump.
1998	First clinical application of next-generation continuous-flow assist devices. DeBakey (MicroMed Inc.) axial-flow pump implanted by R. Hetzer, G. Noon, and M. DeBakey.
1998	Carpentier and Loulmet performed first in the world endoscopic operation of single bypass graft between left internal thoracic artery and left anterior descending (LITA–LAD) and first operation inside the heart – mitral valve plastic and atrial septal defect closure was performed using surgical robot da Vinci (Intuitive Surgical, Sunnyvale, CA, USA).
1998	Mohr and Falk bypass surgery and mitral valve repairs in near endoscopic technique (da Vinci).
1999	First clinical application of a totally implantable circulatory support system. LionHeart LVAS implanted in a 67 year-old male recipient by R. Koerfer and W. Pae.
1999	D. Boyd first totally endoscopic coronary artery bypass graft (E-CABG) using Zeus robot (Computer Motion, CA, USA, currently intuitive surgical, not in the market).
2000	Physicians in Houston US have realised the implantation and have got the first patient in the clinical investigation of the Jarvik 2000 Heart. Jarvik Heart, Inc. and the Texas Heart Institute began developing the Jarvik 2000 Heart in 1988.
2000	THI was granted permission by the Food and Drug Administration to evaluate the Jarvik 2000 Heart as a bridge to transplantation in five patients.
2000	The FDA gave permission to extend the study. Patients have been sustained for more than 400 days with this device. (http://www.texasheartinstitute.org/Research/Devices/j2000.cfm).
2001	The AbioCor was implanted in Robert Tools by cardiac surgeons Laman Gray and Robert Dowling on July 2, 2001, at Jewish Hospital in Louisville, Kentucky. L. Robert Tools aged 59 years with the artificial heart survived 5 months. He died because of the blood clot.

2001	Doctors Laman Gray and Robert Dowling in Louisville (KY, USA) implanted the first autonomic artificial heart – AbioCor (Abiomed, Inc., Danvers, MA, USA). The FDA approved the Abiocor for commercial approval under a Humanitarian Device Exemption in September, 2006. ABIOMED is also working on the next generation implantable replacement heart, the AbioCor II. Incorporating technology both from ABIOMED and Penn State, the AbioCor II is smaller and is being designed with a goal of 5-year reliability. The BVS 5000 was the first extracorporeal, or outside the body, ventricular assist device on the market and is still the most widely used bridge to recovery device with systems located in more than 700 institutions throughout the world. Abiomed also offers the Impella 2.5 – a minimally invasive, percutaneous ventricular assist device that allows the heart to rest and recover (http://www.abiomed.com/products/faqs.cfm).
2001	Drs Laman Gray and Robert Dowling in Louisville (KY, USA) implanted the first autonomic artificial heart – AbioCor (Abiomed Inc., Danvers, MA, USA).
2001	The first transatlantic telesurgery – Lindbergh operation – surgeon from New York operated patients in Strasburg using Zeus® system.
2001	The first full implantable TAH Lion Heart (the Texas Heart Institute in Houston, Abiomed in Danvers, US) was used. The first-ever human implant of the LionHeart™ left ventricular assist system took place October 26, 1999 at the Hearzzentrum NRW in Bad Oeynhausen, Germany. Eight patients have lived with the device for more than 1 year, and four patients have lived with the device for more than 2 years. The Food and Drug Administration approved the first series of US clinical trials for the Arrow LionHeart™ heart assist device in February 2001. Penn State Milton S. Hershey Medical Center implanted the device in the first US patient later that month (http://www.hmc.psu.edu/lionheart/clinical/index.htm).
2001	The first totally implantable TAH LionHeart (the Texas Heart Institute in Houston, TX, USA; Abiomed in Danvers, MA, USA) was used.
2002	FDA approved the HeartMate VE LVAD for permanent use (Thoratec Corp.).
2002	Novacor LVAS became the first implanted heart assist device to support a single patient for longer than 5 years.
2002	The first percutaneous aortic valve replacement was performed by Alain Cribier in April of 2002 [xxxx]. To
2004	The CardioWest TAH-t becomes the world's first and only FDA-approved temporary total artificial heart (TAH-t). The indication for use is as a bridge to transplant in cardiac transplant patients at risk of imminent death from nonreversible biventricular failure. SynCardia Systems, Inc. (Tucson, AZ, USA) is the manufacturer of the CardioWest™ TAH-t. It is the only FDA- and CE-approved TAH-t in the world. It is designed for severely ill patients with end-stage biventricular failure. The TAH-t serves as a bridge to human heart transplant for transplant eligible patients who are within days or even hours of death. A New England Journal of Medicine paper published on August 26, 2004 (NEJM 2004; 351: 859–867), states that in the pivotal clinical study of the TAH-t, the 1-year survival rate for patients receiving the CardioWest TAH-t was 70% versus 31% for control patients who did not receive the device. One-year and 5-year survival rates after transplantation among patients who had received a TAH-t as a bridge to human heart transplant were 86% and 64%. The highest bridge to human heart transplant rate of any heart device is 79%