R. Chiesa, G. Melissano, C. Setacci, A. Argenteri

HISTORY OF AORTIC SURGERY IN THE WORLD

EDIZIONI MINERVA MEDICA

ISBN: 978-88-7711-824-0

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FOREWORD

History is unquestionably important, but is too often forgotten. Little has been published in one place before on the history of aortic surgery. This book, by Roberto Chiesa, Germano Melissano, Carlo Setacci and Angelo Argenteri and its associated to the 6th International Congress on Aortic Surgery and Anesthesia, fills a void in the fascinating field of aortic surgery, an area of explosive development and intense interest throughout the civilized world since 65 years.

Diseases and injuries of the aorta instilled fear and wonder in the minds of physicians and surgeons alike because there was so little that could be done to alter the inexorable demise and suffering of patients. It was only with the advent of modern anesthesia, heparin anticoagulation and prosthetic vascular grafts that vascular surgeons could develop innovative techniques and instruments for treating many of the life- and limb-threatening aortic lesions, including aneurysms and occlusions. This volume chronicles the early exciting development of these techniques and instruments at leading aortic centers around the world with an emphasis on those in Italy.

Despite the dramatic developments, many of the sickest patients could not be treated because of the location and extent of their disease or, more importantly, because the severity of their comorbidities precluded the extensive open surgical procedures required to repair their aortic lesions. The introduction of less invasive endovascular techniques in the late 1980s and early 1990s provided a less morbid approach to treating many of these surgically inoperable patients. The innovation of stents and transluminally placed endovascular stented grafts made it possible to treat even more of these very sick patients. The last 15 years have seen dramatic improvements in these endovascular devices so that almost all patients, even those with complex aortic problems, can be treated. The history of this endovascular revolution in aortic surgery is beautifully chronicled in this outstanding volume to which most of the distinguished pioneers in aortic surgery or their first-generation descendants have contributed.

This volume also summarizes the present state of the art of aortic surgery, both open and endovascular, at leading aortic centers and institutions around the globe. It is richly illustrated and contains a wealth of information not only about the history of aortic surgery but also about the present state of the art in the field. Controversial issues are touched upon as are areas of uncertainty in which future work is needed.

The editors, Professors Chiesa, Melissano, Setacci and Argenteri, are to be lauded for compiling this comprehensive and informative book. It is a must- have for all those with an interest in aortic disease and its treatment, past, present and future.

FRANK J. VEITH

PREFACE

Every time we are in the operating room and we ask for a De Backey forceps or a Fogarty clamp, every time we describe a thoraco-abdominal aortic aneurysm according to Crawford's classification, or reattach an artery with a Carrell patch, we commemorate a little piece of the history of aortic surgery. But do we know the whole story?

Aortic surgery is now a mature discipline. However, this is only thanks to the ingenuity and the pioneering work of many masters of the past. As several once-challenging aortic procedures become routine operations, it is easy to forget the stories of the innovators who made it possible. This book is a tribute to those great surgeons: a trip back in time and across continents to capture their fascinating accounts.

We wish to thank wholeheartedly all the colleagues who contributed to this book. It is a great privilege to have been able to chronicle the origins of endovascular aortic procedures from the pens of the pioneers themselves. Because the origins of open aortic procedures precede our generation, those chapters have been written by the "pupils" of the pioneers, now world-famous surgeons themselves and chiefs of the most important vascular surgery institutions in the world.

We have truly enjoyed these amazing and intriguing stories of men and women ahead of their time who invented the techniques, instruments and devices that have crafted aortic surgery into what it is today. Their tales of innovation not only educate, but reinvigorate our love for this discipline. We hope you will share our enthusiasm, and that this book will have a place on your bookshelf for many years to come.

Roberto Chiesa
Germano Melissano
Carlo Setacci
Angelo Argenteri

Contributors

Giovanni B. Agus Department of Clinical Sciences and Community Health, University of Milan, Milan, Italy

Ottavio Alfieri Department of Cardiac Surgery, Scientific Institute San Raffaele Hospital, "Vita-Salute" University School of Medicine, Milan, Italy

Valeri Arakelyan Bakoulev Scientific Center for Cardiovascular Surgery, RAMS, Moscow, Russia

Eloisa Arbustini Center for Inherited Cardiovascular Diseases, IRCCS Foundation Policlinico San Matteo, Pavia, Italy

Angelo Argenteri Vascular and Endovascular Surgery Unit, School of Medicine University of Pavia - IRCCS Foundation Policlinico S. Matteo, Pavia, Italy

Francesca Ariano Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Ali Azizzadeh Department of Cardiothoracic and Vascular Surgery, University of Texas Medical School at Houston and Memorial Hermann Heart and Vascular Institute, Houston, Texas, USA

Fabrizia Ballabio Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Xavier Barral Department of Vascular Surgery, St. Etienne University Hospital, St. Etienne, France

Cristian Benatti Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Ramon Berguer Department of Vascular Surgery, University of Michigan, Ann Arbor, Michigan, USA

Giorgio M. Biasi Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Leo A. Bockeria Bakoulev Scientific Center for Cardiovascular Surgery, RAMS, Moscow, Russia

Giancarlo Bracale Department of Vascular and Endovascular Surgery, Federico II University of Naples, Naples, Italy

Umberto Marcello Bracale Department of Vascular and Endovascular Surgery, Federico II University of Naples, Naples, Italy

Valter Camesasca Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Piergiorgio Cao Unit of Vascular Surgery, Department of Cardiosciences, Hospital S. Camillo-Forlanini, Rome, Italy

Laura Capoccia Vascular and Endovascular Surgery, Department of Surgery "Paride Stefanini", Sapienza University of Rome, Rome, Italy

Thierry Carrel Inselspital, Berne, Switzerland

Claudio Castagno Division of Vascular Surgery, Department of Surgical Sciences, Città della Salute e della Scienza, Molinette Hospital, University of Turin, Turin, Italy

Renata Castellano Department of Vascular Surgery, Scientific Institute San Raffaele Hospital, "Vita-Salute" University School of Medicine, Milan, Italy

Patrizio M. Castelli Insubria University, Varese, Italy

Alessandro Castiglioni Department of Cardiac Surgery, Scientific Institute San Raffaele Hospital, "Vita-Salute" University School of Medicine, Milan, Italy

Javier G. Castillo Department of Cardiothoracic Surgery, The Icahn School of Medicine at Mount Sinai, New York, USA

Stephen W.K. Cheng Division of Vascular Surgery, Department of Surgery, The University of Hong Kong, Queen Mary Hospital, Hong Kong

Laurent Chiche Unit of Vascular Surgery, Pitié-Salpêtrière University Hospital, Paris, France

Roberto Chiesa Department of Vascular Surgery, Scientific Institute San Raffaele Hospital, "Vita-Salute" University School of Medicine, Milan, Italy

Efrem Civilini Department of Vascular Surgery, Scientific Institute San Raffaele Hospital, "Vita-Salute" University School of Medicine, Milan, Italy

Jeff A. Clark Calgary Foothills Hospital, Calgary, Canada and The Cleveland Clinic Foundation, Cleveland, USA

Jason Constantinou Unit of Vascular Surgery, Department of Surgery, Royal Free Hospital, London

Joseph S. Coselli Baylor College of Medicine, CHI Baylor St. Luke's Medical Center, and the Texas Heart Institute, Houston, Texas, USA

Jacob Cynamon Department of Radiology, Montefiore Medical Center, Bronx, New York, USA

Michael Dake Thelma and Henry Doelger Professor of Cardiovascular Surgery, Stanford University School of Medicine, Stanford, California, USA

Ronald L. Dalman Division of Vascular Surgery, Stanford University, School of Medicine, Stanford, California, USA

Lazar B. Davidović Faculty of Medicine, University of Belgrade and Clinic for Vascular and Endovascular Surgery, Clinical Center of Serbia, Belgrade, Serbia

Meryl Davis Royal Free London NHS Foundation Trust, London, UK

Gianmarco de Donato Department of Medicine, Surgery and Neurological Sciences, Vascular and Endovascular Surgery Unit, School of Medicine, University of Siena, Siena, Italy

Paola De Rango Unit of Vascular and Endovascular Surgery, Hospital S.M. Misericordia, Perugia, Italy

Costantino Del Giudice Department of Diagnostic Imaging, Molecular Imaging, Interventional Radiology, and Radiation Therapy, IRCCS Policlinico di Tor Vergata, Rome, Italy

Gaetano Deleo Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Giovanni Deriu Past Director of the Department of Vascular and Endovascular Surgery University of Padua, Padua, Italy - European Society for Cardiovascular and Endovascular Surgery - ESCVS, Past President

Eliana Disabella Center for Inherited Cardiovascular Diseases, IRCCS Foundation Policlinico San Matteo, Pavia, Italy

Walter Dorigo Department of Vascular Surgery, University of Florence, Florence, Italy

Ionel Droc Unit of Vascular Surgery, Centre des Maladies Cardiovasculaires de l'Armee, Bucarest, Romania

Joseph J. Dubose Department of Cardiothoracic and Vascular Surgery, University of Texas Medical School at Houston and Memorial Hermann Heart and Vascular Institute, Houston, Texas, USA

Ambroise Duprey Department of Vascular Surgery, St. Etienne University Hospital, St. Etienne, France

Csaba Dzsinich Department of Cardiovascular and Thoracic Surgery, State Medical Center of Hungary, Budapest, Hungary

Eric A. Elster F. Edward Hébert School of Medicine, Uniformed Services University of the Health Sciences, Bethesda, Maryland, USA

Gianluca Faggioli Department of Vascular Surgery, University of Bologna, S. Orsola-Malpighi Hospital, Bologna, Italy

Simone Fajer Unit of Vascular and Endovascular Surgery, Meir Medical Center, Kfar Saba, Israel

José Fernandes e Fernandes Department of Vascular Surgery, Santa Maria Hospital, Faculty of Medicine, University of Lisbon, Lisbon, Portugal

Ruy Fernandes e Fernandes Department of Vascular Surgery, Santa Maria Hospital, Faculty of Medicine, University of Lisbon, Lisbon, Portugal

Ciro Ferrer Unit of Vascular Surgery, Department of Cardiosciences, Hospital S. Camillo-Forlanini, Rome, Italy

Marco Fresa Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Antonio Freyrie Department of Vascular Surgery, University of Bologna, S. Orsola-Malpighi Hospital, Bologna, Italy

Alberto Froio Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Armando Fusco Department of Diagnostic Imaging, Molecular Imaging, Interventional Radiology, and Radiation Therapy, IRCCS Policlinico di Tor Vergata, Rome, Italy

Livio Gabrielli Department of Clinical Sciences and Community Health, University of Milan, Milan, Italy

Giuseppe Galzerano Department of Medicine, Surgery and Neurological Sciences, Vascular and Endovascular Surgery Unit, School of Medicine, University of Siena, Siena, Italy

Mauro Gargiulo Department of Vascular Surgery, University of Bologna, S. Orsola-Malpighi Hospital, Bologna, Italy

Paolo Garneri Division of Vascular Surgery, Department of Surgical Sciences, Città della Salute e della Scienza, Molinette Hospital, University of Turin, Turin, Italy

Maria Fabrizia Giannoni Vascular and Endovascular Surgery, Department of Surgery "Paride Stefanini", Sapienza University of Rome, Rome, Italy

Susan Y. Green Baylor College of Medicine, CHI Baylor St. Luke's Medical Center, and the Texas Heart Institute, Houston, Texas, USA

George Hamilton Royal Free London NHS Foundation Trust, London, UK

John P. Harris Department of Vascular Surgery, University of Sydney, Sydney, Australia

David Hartley Medical Imaging Technologist, Perth Western, Australia

Nikola Ilic Faculty of Medicine, University of Belgrade - Clinic for Vascular and Endovascular Surgery, Clinical Center of Serbia, Belgrade, Serbia

Krassi Ivancev Unit of Vascular Surgery, Department of Surgery, Royal Free Hospital, London, UK

Michael J. Jacobs Department of Vascular Surgery at the Maastricht University Medical Center, Maastricht, The Netherlands - University Hospital Aachen, Aachen, Germany

John Kakisis Department of Vascular Surgery, Athens University Medical School, Attikon University Hospital, Athens, Greece

Igor Končar Faculty of Medicine, University of Belgrade and Clinic for Vascular and Endovascular Surgery, Clinical Center of Serbia, Belgrade, Serbia

Thomas Larzon Department of Cardiothoracic and Vascular Surgery, Örebro University Hospital, Örebro, Sweden

George K. Lee Division of Vascular Surgery, Stanford University, School of Medicine, Stanford, California, USA

Scott A. LeMaire Baylor College of Medicine, CHI Baylor St. Luke's Medical Center, and the Texas Heart Institute, Houston, Texas, USA

Christos D. Liapis Department of Vascular Surgery, Athens University Medical School, Attikon University Hospital, Athens, Greece

Miroslav Marković Faculty of Medicine, University of Belgrade and Clinic for Vascular and Endovascular Surgery, Clinical Center of Serbia, Belgrade, Serbia

Enrico M. Marone Department of Vascular Surgery, Scientific Institute San Raffaele Hospital, "Vita-Salute" University School of Medicine, Milan, Italy

Tara M. Mastracci Clinical Lead, Complex Aortic Surgery, The Royal Free London NHS Foundation Trust, London, UK

James May Bosch Professor of Surgery, University of Sydney, Sydney, Australia

Giulia Mazzitelli Department of Medicine, Surgery and Neurological Sciences, Vascular and Endovascular Surgery Unit, School of Medicine, University of Siena, Siena, Italy

Germano Melissano Department of Vascular Surgery, Scientific Institute San Raffaele Hospital, "Vita-Salute" University School of Medicine, Milan, Italy

Randy D. Moore Calgary Foothills Hospital, Calgary, Canada and The Cleveland Clinic Foundation, Cleveland, USA

Konstantinos G. Moulakakis Department of Vascular Surgery, Athens University Medical School, Attikon University Hospital, Athens, Greece

Spyridon N. Mylonas Department of Vascular Surgery, Athens University Medical School, Attikon University Hospital, Athens, Greece

Petr Nemec Center of Cardiovascular Surgery and Transplantations, Brno, Czech Republic

Ângelo Nobre Cardiothoracic Surgery, Santa Maria Hospital, Faculty of Medicine, University of Lisbon, Lisbon, Portugal

Juan C. Parodi Department of Surgery, University of Buenos Aires, Buenos Aires, Argentina

Savino Pasquadibisceglie Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Luís Mendes Pedro Department of Vascular Surgery, Santa Maria Hospital, Faculty of Medicine, University of Lisbon, Lisbon, Portugal

Flavio Peinetti Department of Vascular Surgery, Umberto Parini Hospital, Aosta, Italy - Italian Society of Vascular EndoVascular Surgery - SICVE, President 2013-2014

Maria Rosa Piglionica Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Massimo Porcellini Department of Vascular and Endovascular Surgery, University of Salerno, Salerno, Italy

Alberto Pozzoli Department of Cardiac Surgery, Scientific Institute San Raffaele Hospital, "Vita-Salute" University School of Medicine, Milan, Italy

Carlo Pratesi Department of Vascular Surgery, University of Florence, Florence, Italy

Calogero Presti Vascular and Endovascular Surgery, Clinics Hospital, University of São Paulo, São Paulo, Brazil

Raffaele Pulli Department of Vascular Surgery, University of Florence, Florence, Italy

Kumud Rai Max Heart and Vascular Institute, New Delhi, India

Vincenzo Rampoldi Unit of Vascular Surgery II, Policlinico San Donato IRCCS, University of Milan, Milan, Italy

Todd E. Rasmussen F. Edward Hébert School of Medicine, Uniformed Services University of the Health Sciences, Bethesda, Maryland, USA

Vincent Riambau Vascular Surgery Division, Thorax Institute, Hospital Clinic, University of Barcelona, Barcelona, Spain

Norman M. Rich F. Edward Hébert School of Medicine, Uniformed Services University of the Health Sciences, Bethesda, Maryland, USA

Pietro Rispoli Division of Vascular Surgery, Department of Surgical Sciences, Città della Salute e della Scienza, Molinette Hospital, University of Turin, Turin, Italy

Blayne Roeder Product Development, Aortic Intervention, COOK Medical, Perth Western, Australia

Luca Rossi Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Umberto Ruzzi Department of Medicine, Surgery and Neurological Sciences, Vascular and Endovascular Surgery Unit, School of Medicine, University of Siena, Siena, Italy

Hazim J. Safi Department of Cardiothoracic and Vascular Surgery, University of Texas Medical School at Houston and Memorial Hermann Heart and Vascular Institute, Houston, Texas

Wilhelm Sandmann Hospital Ev. Klinikum Niederrhein, Duisburg, Germany - Department of Vascular Surgery and Kidney Transplantation, Heinrich-Heine-University Hospital, Dusseldorf, Germany

Enrico Sbarigia Vascular and Endovascular Surgery, Department of Surgery "Paride Stefanini", Sapienza University of Rome, Rome, Italy

Claudio J. Schonholz Department of Radiology, Medical University of South Carolina, Charleston, South Carolina, USA

Vittorio Segramora Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Carlo Setacci Department of Medicine, Surgery and Neurological Sciences, Vascular and Endovascular Surgery Unit, School of Medicine, University of Siena, Siena, Italy

Francesco Setacci Department of Surgery "P. Valdoni", School of Medicine, Sapienza University of Rome, Rome, Italy

George Sfyroeras Department of Vascular Surgery, Athens University Medical School, Attikon University Hospital, Athens, Greece

George Silvay Department of Anesthesiology, The Icahn School of Medicine at Mount Sinai, New York, USA

Giovanni Simonetti Department of Diagnostic Imaging, Molecular Imaging, Interventional Radiology, and Radiation Therapy, IRCCS Policlinico di Tor Vergata, Rome, Italy

Francesco Speziale Vascular and Endovascular Surgery, Department of Surgery "Paride Stefanini", Sapienza University of Rome, Rome, Italy

Robert Staffa 2nd Department of Surgery, Center for Vascular Diseases St. Anne's University Hospital, Brno, Czech Republic

Andrea Stella Department of Vascular Surgery, University of Bologna, S. Orsola-Malpighi Hospital, Bologna, Italy

Zeljko Sutlic Department of Cardiac and Transplant Surgery, Dubrava University Hospital, Zagreb, Croatia

Ugo Filippo Tesler Scientific Director Cardiac Surgery Department, Policlinico di Monza Hospital Group, Monza, Italy

Ramesh K. Tripathi Narayana Institute of Vascular Sceinces, Bangalore, India

Yamume Tshomba Department of Vascular Surgery, Scientific Institute San Raffaele Hospital, "Vita-Salute" University School of Medicine, Milan, Italy

Marko Turina University Hospital, Zurich, Switzerland

Malcolm J. Underwood Division of Cardiothoracic Surgery, Department of Surgery, The Chinese University of Hong Kong, Prince of Wales Hospital, Hong Kong

S. Rao Vallabhaneni Royal Liverpool University Hospital, Liverpool, UK

Andre Van Rij Ralph Barnett Professor of Surgery, Dunedin School of Medicine, University of Otago, New Zealand

Gianfranco Varetto Division of Vascular Surgery, Department of Surgical Sciences, Città della Salute e della Scienza, Molinette Hospital, University of Turin, Turin, Italy

Josip Varvodic Department of Cardiac and Transplant Surgery, Dubrava University Hospital, Zagreb, Croatia

Frank J. Veith Division of Vascular Surgery, Department of Surgery, New York University and The Cleveland Clinic, New York, USA

Himanshu Verma Narayana Institute of Vascular Sceinces, Bangalore, India

Pierfrancesco Veroux Vascular Surgery and Organ Transplant Unit, Department of Surgery, Transplantation and Advanced Technologies, University Hospital of Catania, Catania, Italy

Vittorio Villa Department of Surgery and Translational Medicine, University of Milano Bicocca, Milan, Italy

Nikolay L. Volodos Centre of Cardiovascular Surgery, Kharkov, Ukraine

Randolph H.L. Wong Division of Cardiothoracic Surgery, Department of Surgery, The Chinese University of Hong Kong, Prince of Wales Hospital, Hong Kong

Sanford Zeigler Stanford Hospital and Clinics Department of Cardiothoracic Surgery, Stanford, California, USA

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Section I

Specific Issues

THE ORIGIN OF TEVAR

N.L. Volodos

On March 24, 1987 we performed the first stent-grafting procedure of the thoracic aorta aneurysm. Luckily, it was successful, without complications. The operation was neither spontaneous nor unexpected. It had been preceded by a period of intensive searching for a low-traumatic method of aorta prosthetic repair. Our main motivation was the unacceptably high mortality of patients with aorta aneurysm ruptures and aorta dissection, and our helplessness in treating them.

Those patients came to us to be treated and hoped to survive and live, but almost all died after our surgical attempts to save them. It was obvious that something must be radically changed, that we should look for completely new solutions.

While we were looking for a low-traumatic method to use with prosthetics of the aorta we were influenced by the experimental work of Charles Dotter.[1] At the beginning of the 1980s we were obsessed with the idea of creating a self-fixing synthetic prosthesis which could be delivered remotely and could be self-fixed in the vessel.

We believed that the prosthesis had to have two main properties: autonomous self-fixation and the ability to change its diameter while being delivered along the vessel and at the moment of placing it in the predetermined segment of the aorta. We considered that designing a structure which would give the prosthesis a self-fixing quality was the key to this problem, and for that purpose we designed and made a Z-shape cylindrical radial spring (Fig. 1).

The spring was protected by a USSR patent dated May 15, 1984 (Fig. 2), which was five months earlier than the date of the patent for a similar structure - a Gianturco stent.

In collaboration with technical scientific-research institutions in Kharkov, the properties of the fundamentally new geometric structure were studied, and special devices for measuring the value of radial forces of the spring were designed and constructed.

The invention of a Z-shaped spring became a precondition for the creation of a self-fixing endoprosthesis for clinical use (Fig. 3).

In experiments with segments of a cadaver aorta, in which a pulsating flow of preserved blood was created with the help of a bypass machine, the behavior of the self-fixing synthetic endoprosthesis was studied, as well as the value of the optimal radial force necessary for its fixation.[2]

Our next goals were to develop a method of prosthetic repair with the help of the endoprosthesis we had made, to develop the technology of that method, and to design and make the necessary tools for applying the method.

The technology of the new method was developed on glass and synthetic models of the vascular bed which was a single unit that included all segments of the thoracic aorta, abdominal aorta, iliac and common femoral arteries.[3, 4]

In our country we originally called this method "a remote endoprosthetic repair". The generally accepted term is now stent-grafting, and we shall use this term throughout this chapter.

The delivery system (Fig. 4) and its components were designed and made.

At that time our domestic medical industry didn't produce the items required to carry out such operations. We were forced to design and make the necessary tools and instruments ourselves, including

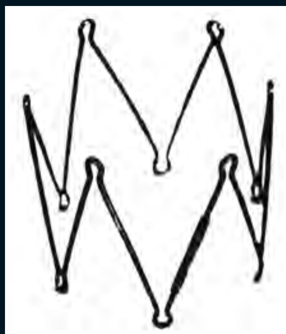


Figure 1 Z-shape radial cylindrical spring as a fixing element of self-fixating synthetic prosthesis.

СОЮЗ СОВЕТСКИХ СОЦИАЛИСТИЧЕСКИХ РЕСПУБЛИК

ГОСУДАРСТВЕННЫЙ КОМИТЕТ СССР
ПО ДЕЛАМ ИЗОБРЕТЕНИЙ И ОТКРЫТИЙ

АВТОРСКОЕ СВИДЕТЕЛЬСТВО

№ 1217402

На основании полномочий, предоставленных Правительством СССР, Государственный комитет СССР по делам изобретений и открытий выдал настоящее авторское свидетельство на изобретение:
"Протез кровеносного сосуда"

Автор (авторы): Володось Николай Леонтьевич, Шеханин Василий Егорович и Карлович Иван Павлович

Заявитель: ХАРЬКОВСКИЙ НАУЧНО-ИССЛЕДОВАТЕЛЬСКИЙ ИНСТИТУТ ОБЩЕЙ И НЕОТЛОЖНОЙ ХИРУРГИИ И ХАРЬКОВСКИЙ ОРДЕНА ЛЕНИНА, ОРДЕНА ОКТЯБРЬСКОЙ РЕВОЛЮЦИИ И ОРДЕНА ТРУДОВОГО КРАСНОГО ЗНАМЕНИ МОТОРОСТРОИТЕЛЬНЫЙ ЗАВОД "СЕРП И МОЛОТ"

Заявка № 3744158 Приоритет изобретения 22 мая 1984г.

Зарегистрировано в Государственном реестре изобретений СССР

15 ноября 1985г.

Действие авторского свидетельства распространяется на всю территорию Союза ССР.

Председатель Комитета

Начальник отдела

МПФ Гознака. 1979. Зак. 79-3083.

Figure 2 USSR patent 22 May, 1984 for spring and prosthesis.

Figure 3 One of the first versions of stent-graft.

Figure 4 The first delivery system for clinical use to perform stent-grafting of thoracic aorta.

such devices as tubing lines for the delivery system with hemovalves, dilatation balloon catheters with a predetermined diameter (Fig. 5), and catheters for measuring the diameter of the aorta (at that time we didn't have access to ultrasound machines or CT scans).

Once we had studied the behavior of the self-fixating synthetic endoprosthesis (stent-graft) in the pulsating blood flow and designed and made the delivery system and its components, the stent-grafting method was researched in acute and chronic experiments on large dogs (over 30 kg).[4] The positive results of that experimental research allowed us to start using the stent-grafting method in clinic.

We felt that the first clinical application had to start with the simplest version, and we believed that the most acceptable, safe method, which could be easily fixed by open surgery in case of complications, was stent-grafting of the iliac arteries.

On May 4, 1985 the first stent-grafting procedure of iliac artery stenosis was performed. It was carried out in combination with a femoral-tibial bypass, which now would be called a hybrid operation.[2, 3] Later, 19 such procedures were performed.

By 1987 we had certain experience in using the stent-grafting method in clinic and considered it possible to take the next step when we had care of a patient with an aneurysm of the descending segment of the thoracic aorta.[5]

Our first patient was B., a 53 year old, male who had been diagnosed in another hospital during open surgery. The patient underwent a left-side thoracotomy to remove a supposed tumor of the posterior mediastinum.

The patient told us that 28 years before that, when he was 25 years old, he had been in a serious car accident and his chest seriously injured, the XII vertebra was fractured by compression and he was paraplegic for some time.

The thoracic aortography detected an aneurysm in the distal part of the descending aorta (Fig. 6). Its diameter was 6.5 cm. There was also stenosis of the aorta segment directly above the aneurysm. The smallest diameter of the stenosis was 11 mm. Below the aneurysm, the aorta diameter was 20 mm.

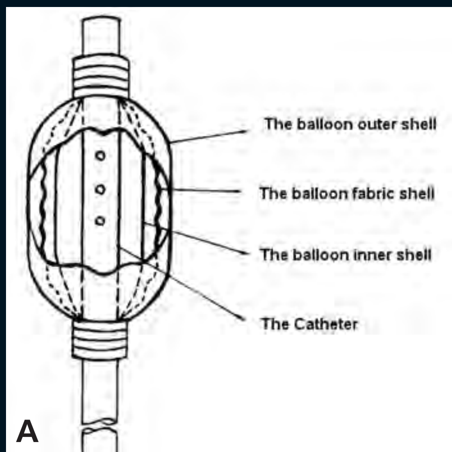
On March 24, 1987 our first stent-grafting of the thoracic aorta aneurysm was performed. The scheme of the procedure is shown in figure 7.

In the angiography room under general anesthesia open access to the right common femoral artery was attained. At first, the narrowed segment of the aorta was dilated with the help of an 18mm diameter balloon catheter we made ourselves. A homemade stent-graft of diameter 22 mm was delivered to the predetermined segment of the aorta with the help of a delivery system, also made by ourselves, under X-ray control (Fig. 7 A). The final placing of the stent-graft (Fig.7 B) was performed with the help of a dilatation balloon catheter with a balloon of diameter 24 mm (Fig.7 C). Angiography conducted to check the position of the stent-graft showed that it was positioned in the predetermined position (Fig. 8). There was no endoleak, no neurological disorders. The aneurysm was completely excluded from the bloodflow.

Subsequent follow-up showed that the position of the stent-graft was stable.[6] Ten years later we had the opportunity to obtain CT scans (Fig. 9).

No complications connected with the stent-graft in the aorta were found in the entire follow-up period. The patient lived for 18 years and 3 months after the surgery and died of an acute heart attack (myocardial infarction).

The next case we consider an important stage in the evolution of our own experience in prosthetic repair of the aorta. It was a combined endovascular-surgical prosthetic repair in the case of a complicated aortic arch aneurysm with aorta debranching (hybrid procedure).[7] Patient K., a 41 year-old female, had a complicated aneurysm of the aortic arch and proximal portion of the descending aorta. When she was 23 years old she had undergone surgery for the prosthetic repair of a segment of the thoracic



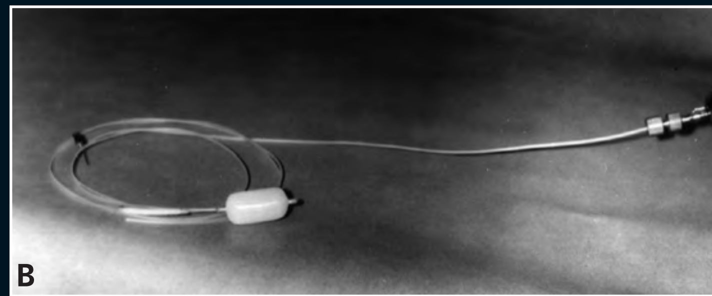


Figure 5 Balloon dilatation catheter with balloon of a predetermined diameter of our own design. A) Structure. B) Photo.

Figure 6 Angiogram of Patient B before surgery.

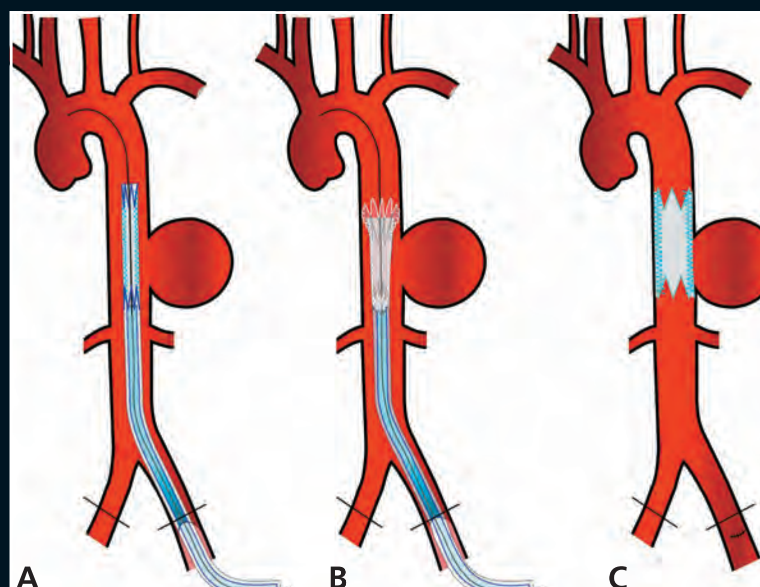


Figure 7 Scheme of the first stent-grafting of thoracic aorta of Patient B. A) Transfemoral introducing of theivery system. B) Placing stent-graft in Patient B. C) Final position of stent-graft in Patient B.

Figure 8 Angiogram of patient B. after stent-grafting.

Figure 9 CT scan of Patient B ten years after stent-grafting.

aorta with a tubular Dacron graft for coarctation. Angiography 17 years later (Fig. 10) detected large aneurysms (over 6 cm) of both anastomoses involving the distal section of the aorta arch including the ostium of the left common carotid and left subclavian arteries and proximal segment of the descending aorta.

As a repeated repair using the direct approach would be very dangerous, it was decided to make a prosthetic repair using a combined endovascular-surgical method. The operation was performed on June 14, 1991. The steps of the procedure were as follows (Fig. 11).

An angiographic catheter was inserted through the left open femoral artery into the ascending aorta. (Fig. 11 A). The middle sternotomy was performed. A tubular graft of a 14 mm diameter was sewn-in end-to-side into the ascending aorta. (Fig.11 A). Replantation of the left common carotid artery into the brachiocephalic trunk was performed (Fig.11 A), And then an autovenous shunt (v. saphena magna) was sewn-in between the left carotid artery and the left subclavian artery (Fig. 11 A). The angiographic catheter, which had been inserted into the ascending aorta earlier, was removed through the synthetic graft that had been sewn-in into it earlier. In this way the ascending aorta and the left femoral artery were connected with the help of a catheter and both ends of the catheter were available for manipulative actions. The upper end of the catheter was connected to the end of the delivery system (Fig. 11 A). This system was created specifically for this operative procedure (Fig. 12). A homemade stent-graft was located inside this system.

The delivery system was a fluoroplastic tubular line with a removable cone-shaped tip turning into a very long catheter, the end of which was pulled out through the open left femoral artery (Fig. 12). The delivery system was a single trail unit. It was inserted into the aorta arch through the sewn-in synthetic graft (Fig. 11 B). That single trail unit was moved in the aorta arch and the descending aorta by traction from the lower bottom part and pushing from the upper part (Fig. 11 B). All movements were performed under X-ray control.

The system structure in this kind of a trail unit made it possible to control the stent-graft from both the upper and lower ends, which secured its stable position and was very important for calculation and correction of the stent-graft position in the aorta segment. The proximal end of the stent-graft was put in the aorta arch and behind the brachiocephalic trunk. The aorta segment near the proximal end of the stent-graft was strengthened by a sleeve of the tubular synthetic prosthesis cut lengthwise: the zone of stent-graft fixation (load zone) was strengthened (Fig. 11). The distal end of the stent-graft was placed in the middle section of the descending aorta. The aneurysm was excluded from the blood flow.[7, 8] The condition of the stent-graft and its position during the whole period of follow-up were stable, there were no signs of endoleak or dissection of the aorta wall. The aneurysm now presented as a narrowing strip scar interspersed with calcium. The results of computer tomography 23 years after procedure are shown in figure 13.

In our opinion, it is also interesting to see the function of the new artificial structure of the vascular bed in the long-term (23 years) result of the debranching of the left carotid artery and subclavian artery. On the whole, it should be noted that there were no clinical signs of blood supply deficiency to the brain or the left upper extremity. The system of blood flow created in the resultant debranching thus provides normal blood flow to the brain and the upper body in the long term. The patient is still alive. Her condition is good.

The next patient also was an important stage in the evolution of our experience. Patient V, a 41 year-old male, was admitted in critical condition with profuse pulmonary hemorrhage. The patient had undergone surgery of the thoracic aorta plastic repair due to aorta coarctation 26 years earlier. Isthmoplastic repair with the sewing-in of a synthetic patch had been performed.

Using thoracic aortography, an aorta-bronchial fistula was detected (Fig. 14). There was an infiltration in the tissue of the left lung in a zone close to the damaged aorta segment.

Figure 10 Angiogram of Patient K. before stent-grafting.

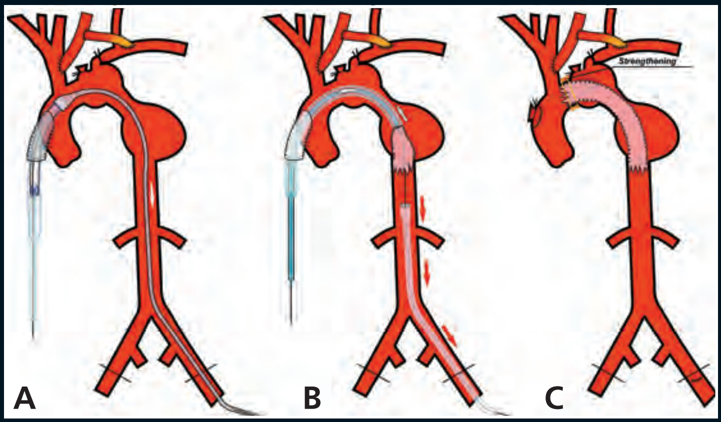


Figure 11 Scheme of combined (hybrid) endovascular-surgical prosthetic repair of aorta arch of patient K. A) Tubular prosthesis of 14 mm diameter is sewn-in in the ascending aorta "end-to-side". Replantation of left carotid artery in brachiocephal trunk; autovenous shunt between left carotid and left subclavian arteries is sewn-in; catheter from femoral artery to ascending aorta is inserted and pulled out through sewn-in prosthesis; end of inserted catheter is connected to delivery system. B) Inserting the delivery system into aortic arch and descending aorta. C) Strengthening of proximal segment of the stent-graft. Final positioning of the stent-graft.

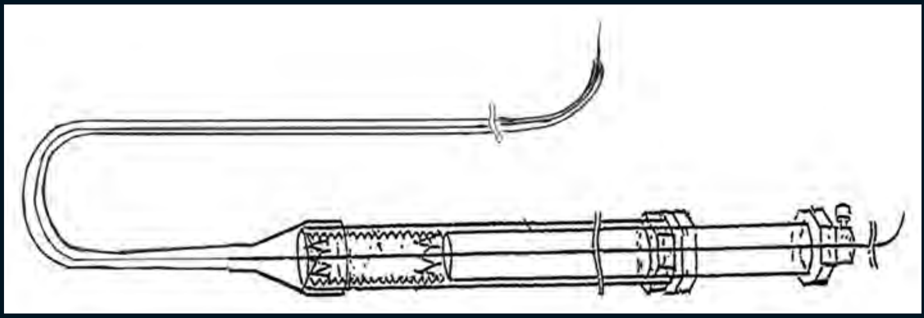


Figure 12 Delivery system for stent-grafting of aorta arch aneurysm, which consists of two parts: a cone tip removed through femoral access and main tubing line with pusher.

Figure 13 CT scan of patient K. 23 years after hybrid procedure.

Figure 14 Angiogram of Patient V. before procedure.

On 19 August, 1993 as an emergency, the aorta segment was repaired by placing a homemade stent-graft in the segment of aorta where the isthmoplastic repair had been done, including the ostium of the aorta-bronchial fistula (Fig. 15).

Endoprosthetic repair was performed in the angiography room under general anesthesia. We used an endotracheal tube for separate intubation of bronchi. The left common iliac and the left axillary arteries were accessed. We used our original delivery system for two accesses which were inserted through the femoral artery, abdominal aorta and thoracic aorta, not reaching the mouth of the left axillary artery (Fig. 15 A). The cone from the proximal end of the system was pulled in the axillary artery. We then positioned the stent-graft by holding it by the upper part of the stent-graft from upper access (Fig. 15 B). We managed to put the stent-graft in the predetermined place without any technical difficulties. The ostium of the aorta-bronchial fistula was closed (Fig. 15 C). No endoleak was found (Fig. 16).

Immediately after the surgery pulmonary hemorrhage stopped. During the period directly after the surgery there were no complications in the zone where the stent-graft was placed, as far as the aorta and the left lung were concerned. There were also no signs of stent-graft infection despite the presence of an inflammatory infiltrate in the tissue of the left lung in the stent-graft location zone. The inflammatory infiltrate in the lung tissue resolved without signs of abscess formation.[9] The patient lived for 18 years after the endoprosthetic surgery. Follow-up examination in the long term showed the stable position of the stent-graft (Fig. 17).

The patient had a bicuspid aortic valve and subsequently he developed stenosis of the valve. The patient refused to undergo prosthetic repair of the aortic valve. Seemingly healthy after endoprosthetic repair, the patient died suddenly when abruptly attempting hard physical work.

During our early period of experience we performed one more successful endoprosthetic repair of a non-complicated traumatic aneurysm of the proximal segment of the thoracic aorta using a delivery system for two accesses on a 43-year-old female. Altogether, during that early stage, we performed 94 operations of endoprosthetic repair of various segments of the aorta and iliac arteries. According to F. Criado, at that point we had the greatest experience in developing and applying that technology.[10]

Information about our early experience in remote endovascular repair of the thoracic aorta is given in our early articles, and was also presented at international congresses.[2-9]

In evaluating the initial stage of our work, when we performed our first stent-grafting procedures of the thoracic aorta, from the point of view of the present and what we went through while establishing this method of prosthetic repair, I think it is necessary to mention several issues.

First, fate looked with favor upon us, enabling us and giving us opportunities to treat patients with various kinds of aorta defects, which was a stimulus to performing new means of endoprosthetic repair of the thoracic aorta. I would like to emphasize that our patients were our main customers and teachers. It was their cases that were our "orders" and forced us to develop and perform the above-mentioned ways of endoprosthetic repair of the thoracic aorta.

Second, we are pleased that, practically starting from scratch, so to speak, we managed to realize the project, moving from the idea itself to its practical realization, including the clinical use of the main kinds of operations. We had to design and make everything required for this method by ourselves (a Z-shape spring, stent-graft, balloon catheter, measuring catheter, tubing lines with haemovalves etc.). This was possible thanks to the enthusiasm of our department workers and also the designers and engineers of many technical scientific-research institutions in Kharkov. We wouldn't have been able to achieve what we achieved without them.

Finally, we are happy that our fate allowed us to be among the first of those who were at very beginning of the method that was totally revolutionary in the treatment of patients with diseases of the aorta and vessels, changed the scheme of treatment for many diseases (of vessel dissections, ruptured aneurysms and others) and made it possible to save otherwise doomed patients.

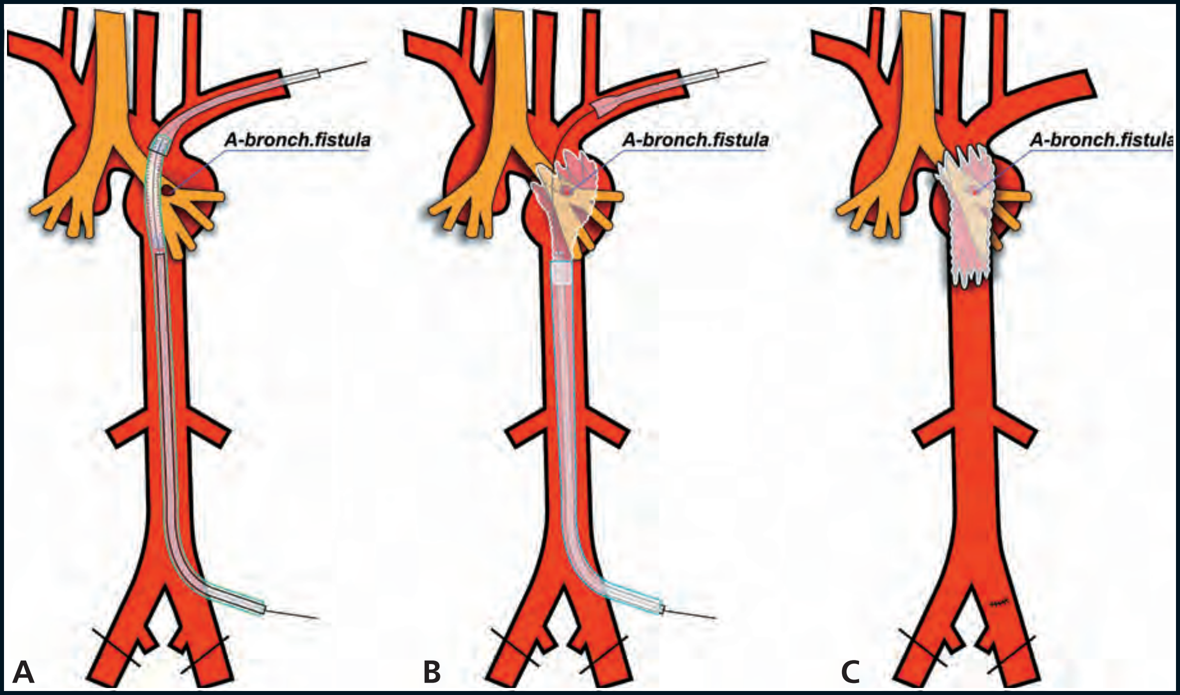


Figure 15 Scheme of procedure of Patient V. A) Inserting of special delivery system with a cone tip for two accesses through common left ileac and left axillary arteries into thoracic aorta. B) Placing stent-graft by holding it by the upper part of stent-graft from upper access. C) Final position of stent-graft.

Figure 16 Angiogram of Patient V. after procedure.

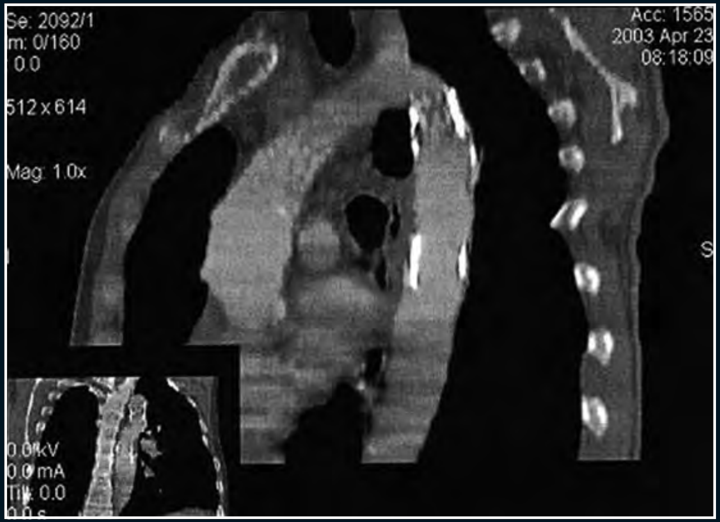


Figure 17 CT scan of Patient V. 10 years after procedure.

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