Gerhard Ziemer Axel Haverich Editors

# Cardiac Surgery

Operations on the Heart and Great Vessels in Adults and Children



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Operations on the Heart and Great Vessels in Adults and Children



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#### **Preface**

The majority of the various comprehensive textbooks available cover either cardiac surgery in adults, mostly synonymous for acquired heart disease, or pediatric cardiac surgery, synonymous for congenital heart defects. This separation of the spectrum of cardiac surgery is not appropriate anymore, especially as the majority of children operated for congenital heart disease reach adulthood, potentially needing further surgical attention. On the other hand, although a rare phenomenon in the Western world, cardiac surgeons have to deal with acquired heart disease in children as well.

Surgery and catheter interventions, competing therapeutic strategies in the beginning, have become complementary: interventional valve implantation may be performed by cardiac surgeons, and aortic stent implantation is well established in the thoracic domain. This development also blurred the boundaries of involved specialties, necessitating close cooperation not only between cardiologists and cardiac surgeons, but also involving vascular surgeons, radiologists, and others. Furthermore, hybrid procedures performed in parallel or in sequence with open surgery and catheter intervention in the same setting by different groups of specialists (e.g., surgeons and catheter interventionalists) have changed the traditional field of surgery.

Only a few textbooks cover such a broad spectrum of cardiac surgery. Our predecessors as editors, Hans Georg Borst, Werner Klinner, and Åke Senning, started this endeavor, when they published the first and only German textbook on cardiac surgery, "Herz + herznahe Gefäße" 1978 [1], the year, in which both of us (G.Z. and A.H.) just finished medical school.

For the second edition, published in 1991, now named "Herzchirurgie" [2], edited by Hans Borst, Werner Klinner, and Hellmut Oelert, we could contribute as junior faculty in our primary fields of interest. This led us to become editors of

the third and latest edition of this German textbook in 2010 [3].

In the spirit of our German teacher Hans Borst's honored guest's address at the 65th Annual Meeting of the American Association for Thoracic Surgery in New Orleans 1985: *Hands across the ocean, German-American relations in thoracic surgery* [4], we expanded the project of our German textbook and planned for an updated English language edition.

Among the authors and co-authors contributing to the latest German edition (mainly from Germany, Austria, and Switzerland), many had received at least part of their specialty and subspecialty training in clinical cardiac surgery or research in English-speaking countries, most of them in North America, but also in the United Kingdom, Australia, and South Africa.

This our first English language edition entitled Cardiac Surgery: Operations on the Heart and Great Vessels in Adults and Children comprises the view of 71 authors not only from 30 German, Austrian, Swiss, French, and Luxembourgian Cardiac Units, but also from Boston, MA; Chicago, IL; Greenville, NC; Houston, TX; Los Angeles, CA; Miami, FL; Milwaukee, WI; St. Petersburg, FL; Toronto, ON; and Washington, DC.

Starting rather traditionally, with a chapter on the history of cardiac surgery, we continue with risk scores and principles of quality assurance, followed by quality control in cardiac surgery in the United States, and an overview of databases in cardiac surgery.

This introduction is completed with a section of chapters on technical prerequisites for cardiac surgery in which we focus separately on postoperative critical care for adults and children. There also is a chapter on tissue engineering in cardiac surgery.

The major part of this book is divided into sections on congenital anomalies and those for acquired diseases, also addressing minimally invasive cardiac surgery as well as endovascular treatment of aortic diseases.

The publication of this book was significantly delayed due to the sudden death of our highly valued German Illustrator Reinhold Henkel, who had been responsible for our anatomical figures before. In memory of him and his longstanding contribution, we had to complete this edition without being able to use his artwork throughout.

We thank Claus-Dieter Bachem for serving as our project coordinator and Ellen Blasig and Gabriele Schroeder from Springer as publishing editors.

At the University of Chicago, we had native speaker editing support from Liz Johnson, Grace Macek, and Melanie Sojka.

Our hope is that this comprehensive but still concise textbook is suitable not only for cardiac surgical residents in training, but may also serve as reference for all surgeons, physicians, nurses, and technicians caring for patients with heart disease of any type, at any age.

Gerhard Ziemer Chicago, IL, USA Axel Haverich Hannover, Germany

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# The History of Cardiac Surgery

Knut H. Leitz and Gerhard Ziemer

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#### 1.1 From the Beginning

September 9, 1896, is generally agreed upon as the date of birth for clinical cardiac surgery. This was the day when in Frankfurt/Main, Germany, Ludwig Rehn (1849-1930) decided to operate on a 22-year-old gardener who suffered from a stab wound to his chest. He had been treated for 1 day conservatively with icepacks and camphor injections. When the patient's clinical condition rapidly deteriorated, Rehn performed a left thoracotomy and opened the pericardium. He found a 1.5 cm stab wound in the right ventricle, which he closed with three single stitches. The postoperative course was complicated by fever and frank pus draining from the thoracotomy wound; however, the patient eventually recovered and was discharged from hospital. When Rehn presented this case at the 26th Meeting of the German Society for Surgery in 1897, he concluded: «From now on, there should not be any more doubt about the feasibility of a heart suture.» He hoped his successful case would encourage others to continue the work in the field of heart surgery (Rehn 1897).

Rehn's pioneering effort was not an ingenious, spontaneous flash of inspiration. In 1868 Georg Fisher from Hannover, Germany, had published an analysis of medical discharge summaries of 452 patients with heart wounds (Fisher 1868). He found the recovery rate to be 10%. This meant not all patients died immediately from wound to the heart, which at least for some should allow for surgical intervention. Reports on successful experimental and unsuccessful clinical cases of stab wounds to the heart had been presented by Block from Gdansk (then Germany) and also by Norwegian and Italian surgeons (Bircks 2002; Block 1882).

The first surgery for a stab wound to the heart in the United States was performed in Montgomery, Alabama, by Luther Hill on September 14, 1902, on a 13-year-old boy, who had suffered numerous stab wounds to his chest. Surgery was performed under chloroform anesthesia. One single stitch had to be done on the myocardium, and the patient survived surgery without complications (Westaby 1997). In 1903, Ricketts from Cincinnati, Ohio, reported on 56 cases of cardiac sutures, with success in 20 (Ricketts 1903).

There has been controversy about a notion attributed to Theodor Billroth (1829–1894), «The surgeon who will try to suture a wound of the

heart can be sure to be definitively discredited by his colleagues.» This quotation is found in K.H. Bauer's *Aphorismen und Zitate in der Chirurgie* [*Aphorisms and Citations in Surgery*] (Bauer 1972). Karl-Ludwig Schober, in his work on early history of surgery of the thorax and its organs, has his doubts about this being a proper citation of what Billroth actually said. He rather thinks that this notion is a misquotation, originating from hearsay or from primary mistakes in citation (Schober 1981, 1993).

Among crucial points for the early years of cardiac surgery, Rehn's experience (Rehn 1913) is repeatedly quoted by Herrmann Küttner, who wrote the chapter «Cardiac Surgery» for the first 6 editions of the *Textbook of Surgery* edited by Bier, Braun, and Kümmel, first edition 1912 (Schober 1993):

It is important not to take shallow bites on both wound edges, as the sutures need to be tied without cutting through the fragile tissue of the heart muscle.

Referring to the issue of continuous versus interrupted single sutures, Rehn clearly pleaded for interrupted single sutures.

If the heart shows signs of fatigue and starts working in an irregular fashion while the suturing is performed, give it a rest to recover. Therefore one should put the heart back into its original, normal position and refrain from any manipulation for some time.

Most of this advice is still up to date!

Ludwig Rehn was a self-made man who had not been trained at any of the leading centers for surgery at that time. However, he was a thoroughbred surgeon who caught the momentum and acted accordingly. He became not only the first to successfully perform cardiac surgery, he also was the first cardiac surgeon, who developed and controlled his surgical techniques in animal experiments. This made him the founder of academic cardiac surgery (Mueller 2007; Schmieden 1931).

Three other surgeons became the leaders of experimental cardiac surgery before World War I and provided the base for its further clinical application (Schober 1993; Vaubel 1980; Westaby 1997):

- Alexis Carrel (1873–1944)
- Ernst Jeger (1884–1915)
- Rudolf Haecker (1878–1957)

Alexis Carrel was born in Lyons, France. After graduating in medicine from the University of Lyons, he left France for Montreal, Canada, but joined shortly afterward the Department of Physiology at the University of Chicago, where he mainly worked with Charles Guthrie (1880–1963). They perfected the technique of vascular anastomosis. The triangle method for vascular anastomosis developed by Carrel in 1902 is still a standard today. They also reimplanted limbs and performed autotransplantations of kidneys, ovaries, and thyroid glands.

In 1906 they separated; Charles Guthrie went to Washington University in St. Louis, Missouri, and Alexis Carrel joined the Department of Experimental Surgery at the Rockefeller Institute in New York City. There he replaced segments of the descending thoracic aorta with caval vein grafts, being already aware of the risk of paraplegia in this type of surgery. He did experiments on techniques of mitral commissurotomy and cardiac aneurysmectomy, and he also did research on coronary artery bypass surgery.

Another one of his areas of interest was heart transplantations. He transplanted hearts from little animals to the neck vessels of bigger animals (Carrel and Guthrie 1905). In 1912 Carrel was named the Nobel Laureate for Physiology and Medicine. After the World War I, he continued his research on organ preservation and worked with Charles Lindbergh on a mechanical pump which should support the circulation when the heart needed to be stopped for surgical procedures (Edwards and Edwards 1974; Westaby 1997).

Ernst Jeger (1884-1915) was born in Vienna, Austria. There he received his training in surgery Professor Eiselsberg and from Professor Zuckerkandl. A short time after that, he went to the Physiological Institute in London, England, and then to Berlin, Germany, to Professor Bickel in the Department of Experimental Biology at the Charité. In between, he spent 6 months studying with Carrel in New York City. In June 1913 he started working as a volunteer in the Department of Surgery at the University of Breslau with Hermann Küttner. Being a foreigner from Austria, taking this unpaid position was his only chance to work there without having to pass a new medical examination for the German Reich. When World War I began, he had to join the Austrian army and had to defend the Przemysl fortress against the Russians (Schober 1993). Just before he could publish his overview «The Current State of Blood Vessel Surgery» (Jeger 1914b), Jeger died in 1915 of typhus as a prisoner of war in Russia (Schober 1993).

Ernst Jeger's main interest was experimental cardiovascular surgery. In 1913 he reported on reimplantation of the renal vein into the inferior vena cava (Jeger and Israel 1913). In Breslau he succeeded in bridging resected aortal segments by end-to-side anastomoses of vein grafts (Jeger 1913). For treatment of portal hypertension, he proposed the mesenteric-caval shunt (Jeger 1914a). While in war, he took care of vascular injuries and was successful in six out of eight cases (Jeger 1914b).

In 1913, as part of a lecture at the 42nd Congress of the German Society of Surgery, he anticipated the later Blalock-Taussig shunt as a way to arterialize the pulmonary circulation, without having any idea about the clinical significance at that time (Jeger 1914a). Ernst Jeger's early death was not only a personal tragedy but also a step back for the development of the European cardiac surgery.

Rudolf Haecker is the third surgeon who has to be mentioned here. As an assistant to Paul Leopold Friedrich in the Department of Surgery at the University in Greifswald, Germany, he published on experimental cardiac pathology and surgery (Haecker 1907). His experiments on caval inflow occlusion in normothermia showed that dogs survived this for no more than 3 min without cerebral damage. Therefore, normothermic caval inflow occlusion was defined as a method to be used only for a very short period of time when treating wounds of the heart. This was confirmed by Ferdinand Sauerbruch and Ludwig Rehn (Rehn 1913; Sauerbruch 1907).

The next steps in the development of cardiac surgery included success in closed-heart surgery; the heart was operated from the outer surface, «trying not to disturb and certainly not interrupt the heart's pump function».

#### 1.2 Operations on the Pericardium

At the beginning of the twentieth century, it was not possible to treat inflammatory pericardial disease in the state of purulent, especially tuberculous pericarditis; the consequence often was a severely contracting pericarditis leading to the end stage of *constrictive pericarditis*. In 1902 Ludolf Brauer inaugurated what he called cardiolysis: resection of the ventral parts of the calcified

pericardium together with segments of the thoracic wall (Brauer 1903). The heart was indirectly unwrapped. The first successful pericardectomies were performed in 1912, again by Ludwig Rehn in Frankfurt/Main, and in 1913, by Ferdinand Sauerbruch in Zurich, Switzerland. Later, the technique of pericardectomy was mastered by Viktor Schmieden (1874-1945) in Halle/Saale and later in Frankfurt/Main, where he had become Rehn's successor in 1919. There he later continued to work with the internist Franz Volhard (1872-1950), who came to Frankfurt in 1927 after having been professor in Halle/Saale (Bircks 2002; Schober 1993). The first pericardectomy in the United States was performed in 1928 by Edward D. Churchill in Boston on an 18-year-old girl (Churchill 1929). In Cleveland, Ohio, Claude Beck worked experimentally on the clinical symptoms and the surgical therapy of constrictive pericarditis (Westaby 1997).

#### 1.3 Trendelenburg's Pulmonary Thromboembolectomy

In his classical work about surgical pulmonary artery thromboembolectomy in 1908, Friedrich Trendelenburg (1844-1924), surgeon-in-chief at the University of Leipzig, Germany, precisely described and meticulously specified his technique of surgery (Trendelenburg 1908). With forceps and a suction cannula, the trombembolic material was extracted from the pulmonary arteries after the pulmonary trunk was opened with a transverse incision. He argued that patients often survived 10-15 min even after fulminant lung embolism. Therefore, a well-trained team should succeed in saving a patient with an intervention, which in those days only meant surgery. External cardiac massage would also help. Unfortunately, Trendelenburg had no successful clinical cases of his own in Leipzig. In Jena, Germany, F. Krüger (1878-1954) had a patient who, in 1909, survived the Trendelenburg operation for 5 days (Krüger 1909; Schober 1993). Dagobert Schumacher, chief resident with Ferdinand Sauerbruch in Zurich, Switzerland, summarized nine unsuccessful pulmonary embolectomies from the literature and added three new unsuccessful cases from their group (Schumacher 1913). It was not until 1924 that the first successful embolectomy was performed by Martin Kirschner (1879-1942) in: Königsberg,

East Prussia/Germany (Kirschner 1924). Thereafter, successful Trendelenburg operations were reported by Arthur W. Meyer (1885–1933) from Berlin, Germany (Meyer 1928, 1931) and by Clarence Crafoord and G. Nystrom from Sweden (Crafoord 1929; Nystrom 1930).

#### 1.4 Resection of a Right Ventricular Aneurysm by Sauerbruch (1931)

With the diagnosis of a mediastinal tumor, the big mass was punctured intraoperatively. When bleeding occurred, the tissue had to be clamped; however, it continued tearing and bleeding even more. It eventually could be controlled by compression with a finger. Sutures were laid over the compressing finger in situ and tied. Histopathology revealed an aneurysm of the wall of the right ventricle (Sauerbruch 1931).

# The First Successful Ligatures of a Patent Arterial Duct by Robert Edward Gross (1905–1988) in the United States and by Emil Karl Frey (1888–1977) in Germany

Frey was working at the University of Duesseldorf, Germany, before World War II (Bircks 2002; Frey 1978). In his book *Rueckschau und Umschau* (retrospective look around), he writes:

>> In 1939 Edens, the internist in Duesseldorf sent a 14 year old boy to us, in whom loud sibilating sounds were heard through the chest, that made me think of an arteriovenous aneurysm. In surgery, we found a patent ductus Botalli. The loud sound immediately disappeared, when I compressed the small communication between pulmonary artery and aorta. As this did not show unfavorable sequelae, I ligated the short passage twice with the assistance of Karl Vossschulte. I did not report this operation immediately, as we hoped we could soon treat another patient in the same way, so that more accurate data from preoperative examinations and exact reports about changes after surgery could be presented. This did not happen,

World War II came. I was told somewhat later, that Gross in the United States already had written about the ligation of a patent ductus Botalli. He had the primacy of this surgery (Frey 1978).

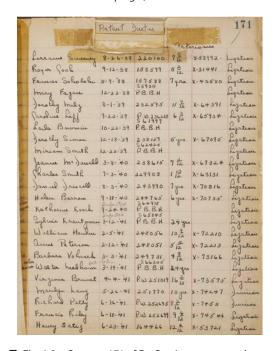
In fact, Robert Gross had already ligated an open ductus Botalli on August 26, 1938 at Boston Children's Hospital (■ Fig. 1.1). With this, he started the era of pediatric cardiac surgery (Gross and Hubbard 1939). While Frey described his surgery as rather unplanned, Gross had planned to perform a ductus closure well ahead by working out a surgical approach with his pediatrician partner John Hubbard in the laboratory and autopsy room (Moore and Folkman 1995). The first suitable patient, a 7-year-old girl showed up when Gross was still chief resident, and his chief William Ladd like many Bostonians was out of town taking summer vacation. With the permission of the acting chief, Thomas Lanman, he went ahead. Apparently, so the story goes, Ladd encountered Gross shortly after the successful operation at some sporting event. When asked how things were at the hospital, the laconic answer of Gross was that nothing unusual had happened (Castaneda 1981).

Doubts about Gross's primacy in successfully closing a persistent ductus arteriosus are not substantiated, although published peer reviewed (Kaemmerer et al. 2004).

In his biographical memoir (Moore and Folkman 1995) Dr. Gross is cited to never again have ligated a ductus after the 12th pediatric patient, a 14-year-old girl, died while dancing with her friends at a party for her 2 weeks after surgery. Autopsy showed a cut through ligature permitting massive hemorrhage. According to Dr. Gross's original surgery case logbook 1937-1972 (provided by Bob Replogle, see ■ Fig. 1.1), this must have been his 14th pediatric ligation patient (of total 20), a 16 year old girl (■ Fig. 1.2). Thereafter he performed two ductus divisions before he returned to ligation only for another 14 months up to patient number 42. Thereafter ductus ligation became a rarity in his and his associates' practice ( Fig. 1.3). Almost all further ductus patients until his last one, number 1610, in March 1972, underwent ductus division with suture closure of the ends (Moore and Folkman 1995).

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7/11/88	Daby Day Keels	225 498	Muster volveles of item, lotred
1 1			anastomis; eascostomy
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7/13/58	Dany Gordon	1776Yo	Procession to drainage at leg
7/4/38	Daby Girl Tichurst	225018	and Egal with forzing fedhisma
× 1/15/38	-1 · m:	2.4	of granum dilatation of glunum
1/20/38	Edwin Miner	C.H.	Biduction - intersusception Excession cystic Bygnessa
7/22/38	Manjorie Cousins		Sutraine tendon left hand
8/11/28	Baby Goll Riceons	224800	Foreing adhesions - duodeso jajunostory
4/16/58	Lauce Steem	221827	Prodoscopey
8/11/38	Dury Gordon	137646	gas doessing
8/18/38	James Strom	221827	Proclemopay is undertisting to polype
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, 9/12/58	Helan Chass.	225279	Prochecopy excession of golyps
1	Roger Cook	158579	digation - patent duction andrisons.

■ Fig. 1.1 First ductus ligation: According to Dr. Goss's surgery case logbook #1 page 7, on 8/26/38 his only case was «Ligation patent ductus arteriosus». (Courtesy Dr. Robert and Carol Replogle)



■ Fig. 1.2 On page 171 of Dr. Goss's surgery case logbook #1 he started his special list «Patent Ductus». Adult patients where operated at Peter Bent Brigham Hospital (P.B.B.H.). His 14th pediatric patient receiving ductus ligation was a 16 yo girl operated on 4-4-41. Following her lethal ductus rupture, the next two patients received ductus division followed by patients most frequently receiving ligations for another 14 months (Courtesy Dr. Robert and Carol Replogle)

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74.	Beverly albrecht				Junion	96	Barbara Shaffer 6-7-45			Jevien
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74	Sand Willie Smith				Junion	98.	Jannie Jullon 6-12-45		1	Livinan'
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■ Fig. 1.3 After September 1942, ductus ligation became a rarity, almost exclusively replaced by ductus division (Dr. Goss's surgery case logbook #1, «Patent Ductus» list, pp.174/5, Sept. 1944 – Oct. 1945) (Courtesy Dr. Robert and Carol Replogle)

## 1.6 Blocked Developments and Missed Opportunities

#### 1.6.1 Endotracheal Intubation

Friedrich Trendelenburg (1844–1924), at that time still at the University of Rostock, Germany, used tracheal intubation in a patient for the first time in 1869. The rationale was to avoid aspiration of blood and secretions during oral surgery (Trendelenburg 1871). At the end of the nineteenth century, other surgeons reported successful narcosis employing tracheal intubation, like Karel Maydl (1853–1903) in Prague, Bohemia (Maydl 1892); Viktor Eisenmenger (1864–1932) in Vienna, Austria (Eisenmenger 1893); and Theodore Tuffier in Paris, France (Schober 1993). A cuffed rubber tube, which also had a pilot balloon, was already used by Eisenmenger in 1893 (Goerig and Schulte am Eich 2003).

Franz Kuhn (1866–1929), working as a general surgeon in Kassel, Germany, was a proponent of tracheal intubation (Kuhn 1901). He employed flexible metal pipes. In March of 1905, he described his experiments on dogs as follows: «In deep narcosis the right thorax is entered. Due to

the pressure ventilation, the lung is expanded and breathes very calmly and regularly. When the pressure pipe is disconnected from the endotracheal tube, the lung collapses.» Kuhn saw the advantages of this method for an undisturbed gas exchange and superior kinetics of the inhaled narcotic agents, which lead to a better control of narcosis. In describing his experiments, he obviously saw also the advantage of avoiding pneumothorax during his open chest experiments; however, he was not a thoracic surgeon (Schober 1993).

At almost the same time, Franz Kuhn was performing his endotracheal intubation experiments, in 1904 Ferdinand Sauerbruch (1875–1951), assistant to Johannes (born: Jan) von Mikulicz-Radecki (1850–1905) in Breslau, Germany, performed open chest surgery on a lung in a low-pressure chamber developed and constructed by himself (Sauerbruch 1904b, c). To avoid pneumothorax, he employed a low-pressure technique he developed, in which the patient's head was exposed to normal atmospheric pressure outside the box, while the other parts of the body were in subatmospheric pressure within the low-pressure chamber. When opening the chest in the low-pressure chamber (in which, in addition to the

patient, the whole surgical team had to fit), the lung did not collapse, and the patient could breathe spontaneously. Sauerbruch, who got worldwide attention for this discovery, rejected the endotracheal positive pressure ventilation as suggested by Kuhn, which he viewed to be unphysiological (Sauerbruch 1904a, b, and c; Schober 1993). In his mind, positive pressure ventilation represented a permanent Valsalva maneuver, potentially leading to circulatory disturbance. On another occasion he wrote, «The low pressure procedure creates the pressure difference (necessary to keep the lung expanded) by thinning the air on the lung surface, while the positive pressure procedure increases the air pressure in the lung» (Schober 1993). After a visit in New York City in 1908, bringing over his low-pressure chamber from Germany for demonstration, Sauerbruch left it with Willy Meyer (1858-1922) at Lennox Hill Hospital. He may not have liked when Willy Meyer and his brother, who was an engineer, later tried to reverse the low pressure into a highpressure chamber («universal chamber») with having the patient's head inside and the surgical team operating on the patient's chest outside under normal pressure.

The air insufflation method, developed by John Auer (1875-1948) and his father-in-law James Meltzer (1851-1920) in New York City, also was rejected by Sauerbruch (Meltzer 1910; Schober1993). Oxygenation was achieved by a continuous flow of air via a small pipe introduced into the patient's upper airway. In animal experiments the depth of insertion of that pipe into the trachea correlated with the length of survival. In 1910, the neurosurgeon Charles Elsberg (1872–1948) employed the Meltzer/Auer method successfully in a patient at Mount Sinai Hospital in New York City (Schober 1993). Not surprisingly, Sauerbruch also rejected the concept of high-pressure respiration, as suggested by the internist Ludolf Brauer (1885-1951) in Marburg, Germany (Brauer 1904). In high-pressure respiration, the patient had to exhale against a high airway pressure delivered by an airtight face mask. With the overwhelming authority of Sauerbruch in opposition, endotracheal ventilation and endotracheal anesthesia had no chance to develop in Germany at that time. Interestingly, both Ferdinand Sauerbruch's and Ludolf Brauer's papers were published in the same journal, both receiving editorial comments by von Mikulicz-Radecki, the authoritative contemporary thoracic surgeon in Germany. In his comments he did not favor one technique over the other (Goerig and Schulte am Eich 2003; Schober 1993).

High-pressure and low-pressure techniques, as well as the insufflation techniques, illustrate the struggle of the different schools for the best method to avoid pneumothorax and at the same time provide the best gas exchange during thoracic surgery. The superior solution that was ultimately accepted, however, had already been published in 1886 by the French surgeon Théodore Tuffier (1857–1929). Employing a snugly fit endotracheal tube, he intermittently delivered high-pressure air. This optimal French solution was only reluctantly accepted in Germany (Goerig and Schulte am Eich 2003; Schober 1993).

At this point we like to briefly focus on Ferdinand Sauerbruch and his professional career. After medical school education at the universities of Marburg, Greifswald, Jena, and Leipzig, he took his first resident position in Breslau 1903. Six days after he finished his PhD thesis on experimental thoracic esophageal surgery, he had to attend the funeral of his teacher, von Mikulicz in 1905. He went to work with Paul Leopold Friedrich (1864-1905) in Greifswald. Friedrich was already a respected thoracic surgeon at that time (Cherian et al. 2001; Dewey et al. 2006; Schober 1993). When he took a university chair in Marburg in 1907, Sauerbruch went with him and was appointed Professor in Marburg. In 1910 his reputation in lung surgery made him chairman and Professor of Surgery at the University of Zurich, Switzerland, the country of tuberculosis hospitals and spas. He published the standard text book Techniques of Thoracic Surgery in 1911 (Sauerbruch and Schumacher 1911). In 1918 Ferdinand Sauerbruch went to become Professor in Munich, Germany, just in time to receive the title of Geheimer Hofrat (privy councillor) from the last Bavarian King (Cherian et al. 2001; Dewey et al. 2006). There he founded what was called the Sauerbruch school, which later peaked at the Charité in Berlin (1928-1949).

Nobody could overrule his judgement. In Sauerbruch's defense, Rudolf Nissen stated in his book *Real-life in Thoracic Surgery (Erlebtes aus der Thoraxchirurgie)*:

Sauerbruch's rejection of the endotracheal intubation today seems unbelievable to us. However, it was only in a small portion related to stubbornness. The main reason

was a lack of an organized management for anaethesia. Sauerbruch opposed the establishment of anaesthesia as a specialized discipline. He saw it as a step forward to the decomposition of the discipline of surgery into different subspecialties. (Nissen 1955)

#### 1.6.2 Cardiac Catheterization

Similarly, cardiac catheterization was not recognized as diagnostic tool. There was a lack of clinical questions and therapeutic options. Werner Forssmann (1904–1979) was a young resident in the hospital of Eberswalde, a small town near Berlin. Motivated by a picture he saw in a textbook of physiology, in 1929 he pushed a thin, well-lubricated urine catheter through a cubital vein directly into his heart (Lichtlen 2002). He went to radiology to document this experiment on himself by x-ray. His idea was to later inject drugs directly into the heart and immediately study the response (Forssman 1929). In 1931 he published an article about contrast images of heart cavities with the same experimental setup (Forssmann 1931). The importance of Forssmann's experiments was recognized by his chief, Dr. Schneider. He advised Forssmann to go to the most authoritative surgeon in Germany, who happened to work in the close-by Charité. Sauerbruch had not the slightest recognition of the potential of Forssmann's work, and he dismissed the young colleague with the words, «With this you cannot do anything at all in surgery.... for such tricks you may receive your PhD in a circus but not at a respectable German medical department» (Forssmann 1972). In 1956 Forssman and the Americans André F. Cournand (1896-1988) and Dickinson Richards (1895–1973), both working at the Bellevue Hospital in New York City, became Nobel Laureates in Medicine for their pioneering work in cardiac catheterization (Bircks 2002; Lichten 2002).

#### 1.6.3 Decline of German Surgery Pre-World War II

It became evident that after the stunning developments up to the beginning of World War I in 1914—a period during which the names of Ernst von Bergmann, Curt Schimmelbusch, Robert Koch, August Bier, Rudolf Virchow, Konrad Röntgen, and Karl Landsteiner can be mentioned—

an inactivity in progress in German medicine occurred. This cannot be explained with the war and its consequences alone (Schober 1993; Wachsmuth 1985b). German medicine and surgery fell below the level of the leading nations. The North American, British, and Scandinavian proponents of thoracic surgery took over the field (Schober 1993).

Looking through the congress communications of the German Society of Surgery after 1920, the successful Trendelenburg operation in 1924 performed by Martin Kirschner and the aneurysmectomy done by Ferdinand Sauerbruch in 1931 were the only highlights. Several reasons are named and discussed; others may be added; many of them may be interdependent (Sauerbruch 1924; Schober 1993):

- Fear of splitting the field of surgery into independent subspecialties: The best will only become master in a subspecialty (Nissen 1955).
- Lack of diagnostic options (only very few internists were willing to expose their patients to risky therapies).
- Exclusion of the German Society of Surgery from the Societé Internationale de Chirurgie after World War I.
- Lack of cooperation within Germany, especially as compared to the situation in the United States.
- Both World wars with tremendous human sacrifice and waste of material resources and wealth.
- The hierarchical structure of the German society, in which only a few opinion leaders had the say (Forssmann 1972).
- Decline of the German language as the scientific language. Most scientific publications were now in English, a language only very few of the German opinion leaders spoke (Leitz 2005).
- The therefore difficult information transfer as compared to today (e.g., when the German surgeon Werner Wachsmuth was prisoner of war in England after 1945, he was asked whether the Germans used penicillin: He had never heard about it before, even though Alexander Fleming had already discovered penicillin in 1928, and the Allied Troops used it since 1940 routinely (Wachsmuth 1985a).
- The exodus and murder of a vast number of scientists with Jewish background due to the Nazi racial discrimination politics, which had been sharpened with the law launched April 7, 1933, to restore the civil servants career with the Arian paragraph (Nissen 1969).

# 1.7 Heart Valve Surgery in the Time Before Extracorporeal Circulation

The first operation on a heart valve is attributed to Theodore Tuffier (1857–1929). On July 13, 1912, he operated a patient with aortic valve stenosis. After consulting Carrel, who was present at the operation in Paris, France, he did not incise the aortic wall but tore the aortic valve as he invaginated the aortic wall with the index finger, tearing the valve open in this way (Tuffier 1914). The idea of bursting stenotic valves dominated the surgical circles of that time. Valvulotomes and cardioscopes were constructed, e.g., by E. Cutler, S. Levine, and C. Beck but also by others (Westaby 1997). But cardioscopes were never successful due to the bad viewing conditions.

Encouraged by his experimental experience with animals, in 1923 Elliot Cutler (1888–1947) operated a 12-year-old girl with hemoptysis at Peter Bent Brigham Hospital in Boston, Massachusetts. Via a modified sternotomy, he exposed the heart without opening the pleurae and drove a valvulotome from the apex of the left ventricle through the mitral valve and burst it open. The girl survived for four and a half years, the hemoptysis diminished (Cutler and Levine 1923). Cutler abandoned this type of surgery after further clinical treatments failed.

Sir Henry Souttar (1875–1964), a surgeon from London, England, operated in 1925 on a 19-year-old woman with rheumatic mitral stenosis through a left thoracotomy. Employing positive pressure ventilation and ether anesthesia, he dissected the heart and inserted his index finger into the left atrium. In this way he divided the leaflets of the mitral valve; however, this caused regurgitation (Souttar 1925). The women was hospitalized again in 1930 but died of multiple cerebral embolisms and heart failure.

Souttar performed mitral valvulotomy only once, and when asked why, he explained his decision in a letter to Harken: «. . . The physicians declared that it was all nonsense and in fact that the operation was unjustifiable. In fact it is of no use to be ahead of time. . . .» (Harken and Curtis 1967; Westaby 1997).

In summary, it may be concluded that the first attempts to divide heart valves were not very successful. But these attempts established sternotomy as the access to the heart and the left auricle as the entry for the digital disruption of the mitral valve.

After World War II, it was Russell Brock (1903-1980) in London who tried to treat aortic valve stenoses. Coming either from the brachiocephalic trunk, the subclavian artery, or through the left ventricular apex, he inserted valvulotomes through stenotic aortic valves to relieve stenotic aortic valves. The results, however, were bad (Brock 1950). Horace Smithy (1914-1948) in Charleston, South Carolina, had similar experiences. He tried to perforate the mitral valve with a punch, which rarely went smoothly. However, five out of his seven patients with mitral stenosis survived. Smithy himself died of rheumatic aortic valve stenosis. His paper on his surgical achievements was published shortly thereafter (Smithy et al. 1950). Just before he died, he had visited Alfred Blalock in Baltimore, who offered to operate on him after he would have assisted Dr. Smithy operating on a few patients there. The first patient fibrillated after thoracotomy and died, and Blalock refrained from further operations like this (Crawford 2010).

Hahnemann Hospital, Philadelphia, Pennsylvania, Charles Bailey (1910-1993) took his chance. After numerous animal experiments, he operated on five patients with mitral stenosis, but only one patient survived (Bailey 1949). For disrupting the mitral valve, Bailey utilized little knives mounted to his index finger. Due to his failure, he was referred to as the «butcher of Hahnemann Hospital» and was prohibited by the administration of his hospital from operating on any other patients for mitral stenosis (Stephenson 1997). Therefore, he in part started operating in other hospitals. At the meeting of the American College of Chest Physicians in Chicago, 1948, he presented his only successful mitral commissurotomy case, a young woman (Stephenson 1997).

Shortly after Bailey's success with his first case, Dwight Harken (1910–1993) in Boston, Massachusetts, was also successful with his first mitral commissurotomy. When his next six consecutive patients died, Harken decided to quit cardiac surgery; however, colleagues persuaded him to continue. In England, Russell Brock reported in 1950 on six successful closed mitral commissurotomies (Baker et al. 1950).

1948 was the year of the closed mitral commissurotomies (Westaby 1997) (see ■ Table 1.1).

It was Brock, DuBost (1914–1991), and Tubbs (1908–1993) who earned the credit to have

■ Table 1.1	Closed mitral commissurotomies
of 1948	

Date	Surgeon	Location	
January 30, 1948	Smithy	Charleston, SC, USA	
June 10, 1948	Bailey	Philadelphia, PA, USA	
June 16, 1948	Harken	Boston, MA, USA	
September 16, 1948	Brock	London, England	

decisively improved valvulotomies. They developed parachute-like instruments, which could be transformed into two or three jawed instruments, depending on the type of valve. In addition, the effective width of the instrument could be modified by an adjusting screw. It became standard to introduce the dilatation instrument through the apex of the left ventricle. Lead by the index finger introduced through the left atrial appendage, it was placed within the stenotic valve to perform the disruption. The initially high mortality decreased, and the degree of resulting mitral regurgitation progressively diminished. From there, the closed mitral commissurotomy started its triumph until it was replaced on a larger scale by the open commissurotomy about 30 years later (Westaby 1997).

Bursting procedures for aortic valve stenosis, as well as the treatment of mitral insufficiency, were attempted in the era before extracorporeal circulation was in clinical use, but they were more or less unsuccessful.

The efforts to surgically treat aortic insufficiency were more promising. Charles Hufnagel (1917-1989) in Washington, D.C., had the idea to implant a to-and-fro moving nylon ball, enclosed in a cage made of firm synthetic material (Plexiglass) into the descending aorta. The original idea to design a caged ball valve prosthesis (ball in cage) traces back to US patent No.19323 for a bottle closer (Matthews 1998). Hufnagel performed his first clinical implantation on September 11, 1952. The ball, initially made of nylon, was too noisy for the patients. Therefore, future models contained a silicon-coated caged ball. The first series published reported on 23 patients with a mortality of 26%. The surviving patients showed marked clinical improvements with a shrinking heart size as seen on x-ray (Hufnagel 1951, 1954).

### 1.8 History of Extracorporeal Circulation

Physiologists and pharmacologists were the first to be interested in organ perfusion. They perfused selected organs to study their function and also their reaction to certain drugs. The first device constructed for a whole-body perfusion was the «respiration apparatus» developed in 1885 by Frey and Gruber in Leipzig, Germany, which is regarded as the predecessor of the modern heartlung machine for extracorporeal circulation (Frey and Gruber 1885). Ten years later Jakoby in Tuebingen, Germany, experimented with isolated lungs of animals to be used as an oxygenator (Jakoby 1895). In 1926 it was the Russian S.S. Brunkhonenko who developed a heart-lung machine which he called «Autojektor.» His experimental device comprised two pumps, one pump to propel the venous blood through an isolated lung and another pump for the systemic circulation of their experimental animals (Brunkhonenko 1928; Rukosujew et al. 2007). Alexis Carrel and Charles Lindbergh also built perfusion devices in the 1930s, first for isolated organs only, later they also looked into human total body perfusion (Edwards and Edwards 1974). An in-depth overview about the evolution of extracorporeal circulation can be found in Galletti and Brecher (1962), Galletti (1993), and Lillehei (1993).

It was around 1950 when all closed surgical interventions to treat congenital and acquired heart defects seemed to have reached a limit. To introduce instruments blindly into the heart cavities did not directly address the problem, and very often did not solve it. It was every surgeon's desire to perform his work under direct vision and therefore perform it precisely. If this should not be accomplished, cardiac surgery would have to play an inferior role within the surgical specialties (Kirklin 1989).

Three experimental ways, partly underway already since the 1930s, were further pursued:

- Hypothermia by Wilfred Gordon Bigelow (1913–2005), Toronto, ON, Canada
- Controlled cross circulation by C. Walton Lillehei (1918–1999), Minneapolis, MN, USA
- Heart-lung machine by John H. Gibbon (1903–1973), Philadelphia, PA, USA

Bigelow's approach was simple. Cooling down an organism would reduce its oxygen consumption,

allowing interruption of the circulation for some time to have a direct look into the heart and eventually perform a procedure. Animal experiments showed that oxygen consumption could be only reduced linearly with body temperature, when muscle shivering was suppressed (Bigelow et al. 1950a). Bigelow also learned that an adult laboratory animal can be cooled down without risk of adverse sequelae to 20 °C body temperature. At 20 °C body temperature, oxygen consumption was only 20 % as compared to 37 °C; 20 min would be allowed to perform controlled heart surgery under direct vision (Bigelow et al. 1950b, 1969).

In Bigelow's experiments the anesthetized and ventilated animals were placed on cooling blankets and cooled down to 20 °C. After thoracotomy, caval inflow occlusion was initiated, and the right atrium was opened. It was closed again after 15 min. Survival was 50% in these laboratory animals (Bigelow 1950a). Bigelow presented his experimental results in 1950 at the annual meeting of the American Surgical Association (Westaby 1997).

F.J. Lewis and M. Taufic at the University of Minnesota in Minneapolis were the first to clinically apply hypothermia and caval inflow occlusion after having done numerous experiments themselves. On September 2, 1952, they operated on a 5-year-old girl after cooling her down to 28 °C rectal temperature. The atrial septum defect they found measured 2 cm and has been closed directly. After five and a half minutes, the inflow to the heart was opened again; the heart started beating (Lewis and Taufic 1953). Shortly thereafter, Henry Swan from Denver, Colorado, reported on 13 patients he had operated upon in the same way (Swan et al. 1953). See also ▶ Chapter «Surgery for Congenital Heart Defects: A Historical Perspective», Sect. 11.2.

Ernst Derra (1901–1979), University of Düsseldorf, Germany, was the first in Europe to perform open-heart surgery employing surface hypothermia; when in 1955, he closed a secundum atrial septum defect (Derra et al. 1965; Bircks 2002). Without any doubt, Derra and his group have set the standard in employing surface hypothermia for open-heart surgery in atrial septum defect and pulmonary stenosis. Ranging well into the 1960s, Derra's group performed the largest single hospital series of surface hypothermia in the world, comprising 1851 patients (Schulte 2001).

At the University of Minnesota in Minneapolis, C. Walton Lillehei (1918–1999) developed the so-called «controlled cross circulation» (Lillehei et al.

1955a; Lillehei et al. 1955b). Usually an adult served as the «circulation donor» who continuously supported with part of his arterial blood the perfusion of the arterial system of a usually much smaller patient. The blood flow was controlled by a pump. The venous blood of the patient was pumped back to the donor's venous system. The donor only required his groin vessels to be cannulated. With adequate cannulation of the patient, the heart was taken out of the circulation, and the cardiac cavities could be opened for direct vision heart defect repair (Lillehei et al. 1955a; Lillehei et al. 1955b) (see also ▶ Chapter «Surgery for Congenital Heart Defects: A Historical Perspective», Sect. 11.2).

With this approach, Lillehei and his team set the following milestones in surgical repair of congenital heart disease (Lillehei et al. 1955a; Lillehei et al. 1955b):

- Ventricular septal defect (1953)
- Complete atrioventricular canal (1954)
- Tetralogy of Fallot (1954)

Lillehei endured almost hostile opposition. Critics talked about the potential of a 200 % mortality, as two persons were operated upon for only one patient to be treated. But the head of the Department of Surgery in Minneapolis, Owen H. Wangensteen, always protected him and greatly supported his intellectual and surgical enthusiasm (see ► Chapter «Surgery for Congenital Heart Defects: A Historical Perspective», Sect. 11.2).

Hypothermia and cross circulation had opened the window of direct vision-controlled heart surgery. The real breakthrough, however, only came when finally the heart-lung machine became available for support of extracorporeal circulation. It was John Gibbon (1903-1973) who worked his whole professional life, together with his wife Mary, on the development of a machine to support extracorporeal circulation. As early as 1937 he could demonstrate that heart and lung would, in principle, resume their full function after their work had been temporarily taken over by an artificial pump and oxygenator. However, only a few animals survived and those only for a few hours (Gibbon 1939). Gibbon became more successful when, after World War II, he met Thomas Watson, Chairman of IBM, who was fascinated by Gibbon's ideas and promised to help him. A heart-lung machine was built with modified DeBakey roller pumps and with a grid oxygenator (Stephenson 1997). Employing this new Gibbon-IBM heart-lung

machine, he successfully closed an ostium secundum atrial septal defect in an 18-year-old girl on May 6, 1953 (Gibbon 1954). When his next two patients died, he retired to investigate the potential causes of the failure of his heart-lung machine. Later he retired completely from cardiac surgery and exclusively worked on issues in thoracic surgery (Stephenson 1997).

As other groups also worked on the development of a heart-lung machine, so did C. Dennis (1902–2005) in Minneapolis; he, however, was unsuccessful with his first clinical case (Dennis et al. 1951). F. Dodrill (1902–1997) in Detroit, who had built a heart-lung machine with the support of General Motors, successfully used it as a left heart bypass in a mitral valve operation (Dodrill et al. 1952). Shortly thereafter he also used it as a right heart bypass in pulmonary valve surgery (Dodrill et al. 1953).

In Europe, among others, Clarence Crafoord (1899–1984), Viking Björk (1918–2009), and Ake Senning (1915–2000) in Sweden (Andersen and Senning 1946; Björk 1948), J. Jongbloed in Holland (Jongbloed 1949), and AM Dogliotti in Italy (Dogliotti 1951) experimented with extracorporeal circulation. The world's second successful operation with a heart-lung machine was the excision of a left atrial myxoma in Stockholm, Sweden (Senning 1954).

The final breakthrough in using the heart-lung machine as a routine tool in open-heart surgery was accomplished by John W. Kirklin (1917–2004) in the Mayo Clinic. After having visited Gibbon and Dodrill, the Mayo group decided to build their own oxygenator-pump, based on the work they were shown. During the winter of 1954/1955, nine of ten experiments in dogs employing the new Mayo-Gibbon heart-lung machine were successful. The group decided to choose eight patients to be operated upon. All of these patients would be operated, even if the first seven surgeries had a fatal outcome. Four patients survived, and with this the success story of cardiac surgery began (Kirklin et al. 1955; Kirklin 1989).

The Mayo-Gibbon oxygenator represented a stationary grid oxygenator, in which the blood passes along stiff narrowly spaced grids. Another principle is that of a cylinder oxygenator described in 1953 by Denis Melrose (1953) or the rotating disk oxygenator described in 1956 by E. Kay and FS Cross (Cross et al. 1956; Kay et al. 1956). In both types of oxygenators, rotation produces a

thin blood film which provides a rapid gas exchange. The disadvantage of both film oxygenators is the complicated maintenance and assembly, which requires a lot of time and personnel.

Extracorporeal circulation was simplified when a new, less complex and therefore easier to set up oxygenator, the bubble oxygenator, was finally developed by DeWall and Lillehei in 1955 (Lillehei et al. 1956; DeWall and Lillehei 1958). This development was made possible by LC Clark's findings published 1950, who had demonstrated that excess gas bubbles could be eliminated from blood by adding silicone components to the oxygenator setup (Clark et al. 1950). The previous inability to get rid of these bubbles, to defoam the oxygenated extracorporeal blood, had delayed the development of this type of oxygenator significantly.

When Vincent Gott succeeded in building a one-way bubble oxygenator and have it produced, it made preparation for cardiac operations much easier and significantly less time consuming (Gott et al. 1957). From then on, the DeWall-Lillehei oxygenator became a standard element in the setup for extracorporeal circulation until the late 1970s. IH Rygg in Denmark succeeded in constructing a similar device (Rygg and Kyvsgaard 1958). WJ Kolff and SA Clowes developed the first membrane oxygenators (Clowes et al. 1956; Kolff et al. 1956). They came into practical use once appropriate membranes could be produced successfully with the reliability required. AJ Lande described the first commercially available one-way membrane oxygenators for routine clinical use (Lande et al. 1967). Frank Gerbode and his group later reported success with other types of membrane oxygenators (Gerbode et al. 1967; Hill et al. 1972; Zapol et al. 1979). See also ▶ Chapter «Advances in Cardiopulmonary Bypass for the Neonate and Infant», Sect. 7.2.1 and chapter «Surgery for Congenital Heart Defects: A Historical Perspective», Sect. 11.2).

Further innovations in extracorporeal circulation comprised hemodilution, respectively, non-blood prime, when 5 % glucose or dextran was used as reported by Zuhdi, Long, Cooley, and Neville in the early 1960s (Westaby 1997). Another new feature was the integration of a heat exchanger into the arterial side of the circuit (Sealey et al. 1958, 1959). With this, the advantages of hypothermia could be integrated into the concept of extracorporeal circulation. The combination of deep hypothermia and

extracorporeal circulation was developed by Hans Borst in Germany for aortic arch surgery (Borst 1959; Borst et al. 1964) and by Y Hikasa in Japan and Brian G Barratt-Boyes in New Zealand for surgical correction of congenital heart defects (Hikasa et al. 1967; Barratt-Boyes et al. 1972).

A prerequisite for extracorporeal circulation and whole-body perfusion had been the discovery of heparin by J McLean in 1916 (McLean 1916) and protamine by E Chargaff and KB Olson in 1937 (Chargraff and Olson 1937).

In order to limit the ischemic time of heart on one side, and still having sufficient time to operate on the immobilized heart, various methods were developed. Ake Senning (1952) very early on used electrically induced ventricular fibrillation. For aortic valve replacement, Dwight McGoon (1925–1999) utilized selective coronary perfusion employing special cannulas (McGoon 1976). In the beginning many groups used intermittent interruption coronary of circulation intermittent aortic cross clamping. The time intervals provided by this way were 15-20 min, which seemed to be sufficient for some (Cooley et al. 1958a). But Denton Cooley also described the «stone heart» (Cooley et al. 1972). Further tolerance to ischemia was achieved by topical cooling as suggested by the Stanford group (Shumway et al. 1959). Simple cardioplegia solutions were ready for clinical use as early as 1955, like the potassium citrate cardioplegia of Melrose (Melrose et al. 1955), the magnesium cardioplegia of Kirsch (Kirsch et al. 1972), or the sodium extraction car-1980). dioplegia of Bretschneider (1964,Bretschneider's solution was clinically tested by Sondergaard (Sondergaard and Senn 1967). From 1975 on, experimentally proven solutions were commonly available, like the crystalloid HTK solutions after Bretschneider (1980) and the St. Thomas solution (Hearse et al. 1978) or blood cardioplegia after Buckberg (1982), which later was modified by Calafiore (Calafiore et al. 1994).

Although extracorporeal circulation was and is an integral part of the success story of cardiac surgery, it had to be learned that through temporary whole-body perfusion with extracorporeal devices, harm can also be produced (Blackstone et al. 1982; Kirklin et al. 1986; Kirklin and Barratt-Boyes 1993; Edmunds 1997). The contact of blood with artificial extracorporeal surfaces activates about five plasma proteins and five cell systems, which through a cascade-type activation can to

different degrees lead to bleeding tendency, thromboembolism, fluid retention, and primary or secondary organ damage (Edmunds 1998). See also ► Chapter «Extracorporeal Circulation and Myocardial Protection in Adult Cardiac Surgery», Sect. 6.1.4.

#### 1.9 Development of Heart Valve Surgery in the Era of Extracorporeal Circulation

The first aortic valve replacement with an artificially manufactured valve was accomplished in 1960 by Dwight E. Harken (1910-1993) in Boston, Massachusetts. He implanted a prosthesis consisting of a ball in a steel cage. It was implanted with single interrupted sutures into the aortic anulus. As he thought that the aortic wall could interfere with the ball in the cage and thus be affected, his valve had a double cage (Harken 1989). For the implantation, he used extracorporeal circulation at a temperature of 26 °C (Harken et al. 1960). Albert Starr (born 1926) in Portland, Oregon, constructed a similar prosthesis for the mitral position in cooperation with the retired engineer Lowell Edwards (1898-1982). Their cooperation started in 1958. As did so many others, they started out to develop a bileaflet valve, which, in most cases, completely thrombosed within 2-3 days in their dog experiments. Therefore, they had to go back to the conception of the caged ball valve, the concept used already in Hufnagel's first off-pump descending aortic valve implantation in 1952 (see ► Sect. 1.7, «Heart Valve Surgery in the Time Before Extracorporeal Circulation»).

Ball valves absolutely did not resemble a natural valve, but flawless function was more important than the shape and design. An advantage of the ball valve concept was the fact that the ball was not fixed to the ring, and in this way thrombus formation beyond the ring, especially in mitral position, was completely eliminated. In addition, the constant toand-fro oscillation of the ball had a cleansing effect on the ring. Furthermore, dogs with ball valve implants in the mitral position showed clearly less problems, and many of them became long-time survivors (Matthews 1998). The model chosen for human use consisted of a cage of steel, a silastic ball, and a Teflon sewing ring. After the first patient died 10 h postoperatively caused by an air embolism, Albert Starr successfully implanted this type of ball valve in mitral position in the eight following patients between July 1960 and February 1961.

With the support of extracorporeal circulation, he operated through a right thoracotomy. Six patients became long-term survivors, with two even going back to work (Starr and Edwards 1961; Pluth 1991; Matthews 1998). The original model of the Starr-Edwards valve has been modified several times. Sheathing the brackets of the cage with Teflon cloth in order to reduce the incidence of thromboembolism did not prove successful. Only model 1260 and model 6120 received subsequent FDA approval (Akins 1991), which entered the medical manufacturing environment in 1976 (Siposs 1989). Another caged ball valve model is the Smeloff-Cutter valve, which was introduced on the market in 1966. Remarkable is its double-cage construction; the smaller dimensions of the cage were favorable, especially for implantation in the mitral position, as this caused left ventricular outflow tract obstruction less often and to a lesser degree (Smeloff 1989). Numerous artificial heart valves were developed, but did not find widespread acceptance or had been implanted only by a few, like the Barnard-Goosen valve or the Gott-Daggett valve (Westaby 1997).

Progress came with the development of the tilting disk heart valve prosthesis. Its design concept, a mobile disk occluder contained in a ring, was developed by Juro Wada (1922-2011) from Sapporo Medical College, Japan, in 1966. The Wada-Cutter valve was characterized by a very low profile, in addition it had a significantly lower-pressure gradient compared to all other artificial heart valve models available at that time, as the central blood stream was not obstructed (Wada et al. 1989). Viking Björk (1918-2009) in Stockholm, Sweden, visited Wada in Japan and immediately started implanting the Wada-Cutter valve. He compared its performance with the Kaye-Shiley valve, which revealed a significantly higher-pressure gradient (Westaby 1997). Therefore, Björk convinced Don Shiley to design and build a prosthesis according to Wada's conception. Shiley was a former Edwards Laboratories engineer, who later worked independently. The result was the Björk-Shiley valve, which was implanted for the first time on January 16, 1969, in Stockholm by Björk himself (Björk 1969, 1984; Westaby 1997). The original model consisted of a ring with two brackets which lay within the ring plane, in between which the disk moved. The opening angle originally was 60°. The disk underwent various modifications, and from 1976 it became a convex-concave shape (Björk 1978). After a significant number of fatal bracket fractures, which for the first time were reported in 1978, the convex-concave valve was taken off the market in 1986 (Lindblom et al. 1986; Ostermeyer et al. 1987). A follow-up model, the so-called monostrut valve (Björk and Lindblom 1985), which was manufactured out of one block of metal, therefore not requiring weld joints anymore, was introduced in response to the failures. Success was limited; when due to the worldwide problems with the old valve and the consecutive law suits, Shiley's company finally collapsed after a settlement (Westaby 1997).

Walt Lillehei also participated in the development of tilting disk valve prostheses. In 1966 the Lillehei-Nakib toroidal discoid prosthesis was described, and it was followed in 1967 by the improved Lillehei-Kaster pivoting disk valve (Lillehei et al. 1974, 1977, 1989). Almost a crossbreed between the Björk-Shiley and the Lillehei-Kaster valve is the Medtronic-Hall tilting disk prosthesis, inserted for the first time in a patient in June 1977. It was developed by the Norwegian Karl Victor Hall (1992, 1989) and received worldwide recognition (Akins 1995).

It also was in Lillehei's laboratories where the design of the first artificial double leaflet valve, the St. Jude valve, was thought of. In these models the suture ring as well as the leaflets were made of synthetic nonthrombogenic pyrolytic carbon. The leaflets, which are mounted into articular caves in the valve prosthesis ring, open up to 85° and allowed for almost laminar blood flow. The first clinical implantation was on October 3, 1977, by DM Nicoloff in Minneapolis, Minnesota (Emery et al. 1978; Lillehei et al. 1989).

Only a few of the 32 mechanical heart valve prostheses that were developed from the mid-1960s to the end of the 1980s received FDA approval and survived (Akins 1991). These are the Starr-Edwards valve, the Medtronic-Hall valve, the St. Jude Medical valve, and the Omniscience valve (Akins 1991). In 1993 the Carbomedics valve was approved as the second bileaflet valve in the United States (Akins 1995).

The era of homografts (postmortem-harvested human heart valves) began in 1962 with the implantation of homografts by the Toronto group (Heimbecker et al. 1962). Donald Ross (1922–2014) in London, England, on July 24, 1962, and independently Brian Barratt-Boyes in Auckland, New Zealand, on August 23, 1962, performed the first aortic valve replacements with aortic homografts (Ross 1962; Barratt-Boyes 1965).

Experimentally Alfred Gunning (1918-2011) and Carlos Duran in Oxford, England (Binet et al. 1971) worked on the extraction, conservation, and implantation of homografts but also of heterografts (Duran and Gunning 1962). They suggested the technique Ross employed in his first successful clinical case (Ross 1962). As the implantation of homografts was technically considerably complex, Angell mounted homografts to a stent which made a mitral valve replacement possible (Binet et al. 1971). Instead of homografts, Ake Senning in Zürich and Marion Ionescu in Leeds, U.K., used valves constructed out of autologous fascia lata and mounted them on a stent (Senning 1967; Ionescu et al. 1970). These fascia lata valves, however, had a high failure rate and were soon abandoned (Thiede et al. 1971). Donald Ross in 1967 for the first time used the pulmonary artery valve of a patient as an aortic valve replacement and restored the continuity between the right ventricle and the pulmonary artery with an aortic or a pulmonary homograft (Ross operation) (Ross 1967). The first successful Ross operation in a neonate, employing the autograft's growth potential, was performed by Gerhard Ziemer in 1989 in Hannover, Germany in a 2.7 kg baby (Ziemer 1992). After root remodeling surgery at 13 years, the autograft got finally replaced at 26 years of age with a mechanical valve.

In 1964 Duran and Gunning in Oxford clinically implanted for the first time a porcine valve prosthesis mounted on a stent (Binet et al. 1971). In Paris Binet and Carpentier implanted heterografts/ xenografts mounted on a stent including the first stented mitral heterograft prosthesis in 1967 (Carpentier 1972). Originally, the animal valves used, mainly porcine valves, were preserved in organic mercurial salt solution or 4 % formaldehyde, from 1968 on in glutaraldehyde. Glutaraldehyde was introduced by Alain Carpentier. As an associate Professor of Surgery, he interrupted his surgical activity 2 days a week to study chemistry and discovered glutaraldehyde (Spencer 1983; Carpentier 1989). Glutaraldehyde diminishes antigenicity and avoids denaturation of collagen fibers, strengthening the tissue by intense collagen crosslinking at the same time. Carpentier summarized: «The valve substitute obtained on this way is a bioprosthesis rather than a heterograft» (Binet 1989; Carpentier 1989; Stephenson 1997). These experimental and first clinical experiences lead to the first commercially available bioprostheses: IonescuShiley and Carpentier-Edwards biological heart valves (Carpentier 1972). Warren Hancock, employed at Edwards Laboratories until 1967, developed a porcine valve, which was implanted clinically by Robert Litwak (Kaiser et al. 1969). Later models incorporated flexible stents (Westaby 1997). Because of transvalvular obstruction, especially in the smaller porcine bioprosthesis, a technique was devised to remove the native right coronary cusp, which contains in pigs a bar of ventricular muscle. The removed cusp was substituted by a cusp of a second animal. The first Hancock modified orifice valve was used clinically in 1976 (Cohn et al. 1989).

During the 1980s, the early enthusiasm to use glutaraldehyde-treated bioprostheses cooled down since bioprostheses calcified with time and the decreased durability became an established fact (Carpentier et al. 1984). This opened up the development and use of stentless bioprotheses experimentally and in humans (David et al. 1992).

To preserve the mitral valve in clinical mitral insufficiency had already been suggested by Walt Lillehei (Lillehei et al. 1957) and later on by GH Wooler (Wooler et al. 1962), GE Reed (Reed et al. 1965), and JH Kay (Kay et. 1978). But it is Alain Carpentier who is entitled to the leadership of reconstructive mitral valve surgery. Since 1971, he concentrated his work on the anatomical changes in mitral regurgitation and published a classification based on the involved segment of the valve. It dates back to him developing the understanding that mitral valve anulus dilatation primarily relates to the posterior portion of the anulus. He was the first to suggest a rigid ring for stabilizing the mitral valve anulus and developed various technical details for reconstructive mitral valve surgery. He summarized his experience in the famous paper published in 1983: Cardiac Valve Surgery-The French Correction (Carpentier 1983).

#### 1.10 Development of Coronary Surgery

The first surgical attempts to treat coronary heart disease were sympathectomy of cervical ganglia to achieve analgesia and thyroidectomy to lower metabolism and, in this way, cardiac oxygen consumption (Parsons and Purks 1937; Mueller et al. 1997). Claude Beck, professor at the Western Reserve University in Cleveland, Ohio, went a step

further following the idea of creating collateral vessels to increase myocardial blood flow (Beck and Tichy 1934; Beck 1935). He employed mechanical irritation to create adhesions between the pericardium and epicardium. He also interposed pectoral muscle or omentum to induce neovascularization (Beck 1935). Similar procedures were reported by O'Shaughnessy in London, England, and by A. Lezius in Hamburg, Germany (O'Shaughnessy 1936; Lezius 1938). To achieve the same result, Lezius also sewed the lung to the epicardium, a procedure he called cardiopneumopexy (Lezius 1951).

Arthur Vineberg (1903-1988) from Montreal, Canada, went a step further when, in an experimental setting in 1947, he implanted the mammary artery into a tunnel made into the left ventricular myocardium. To his surprise, there was no hematoma formation, as he had seen after implantation of an artery into a skeletal muscle in the same way. So the myocardium seemed to have properties like a sponge. He explained this with sinusoids known from embryology. In cases of ischemia caused by coronary disease, the sinusoids were supposed to open up. He proved the existence of the assumed connections by stain injections. Clinically he performed this procedure in 1950 for the first time and reported his 140 operations 1964 with a final mortality of 2% (Vineberg 1946, 1958; Vineberg and Buller 1955; Westaby 1997). Vineberg had his late satisfaction through Mason Sones, who proved by angiography that most internal mammary artery implants remained open and even developed anastomoses to the native coronary arteries in 70-80% of the patients (Effler et al. 1963).

The evolution from the indirect to direct procedures in coronary surgery would not have been possible without the development of coronary angiography by Mason Sones (1918-1985) at the Cleveland Clinic in Cleveland, Ohio. Before 1959 coronary arteries were visualized only nonselectively by injecting contrast through a catheter positioned in the aortic root. On October 30, 1958, the catheter migrated unnoticed into the right coronary artery during contrast injection and an image was taken; the error was only noticed after the angiography film was developed and ready to be inspected. The patient went through the nonvoluntary maneuver without subjective or even objective harm (Westaby 1997). After repetition of direct coronary angiography on 1,020 patients, Sones stated correctly that now the era of selective coronary angiography had begun. Not only new diagnostic means to detect the pathology of coronary artery disease were created, but also the efficacy of the utilized surgical treatment modalities could be directly evaluated (Sones and Shirey 1962; Lichtlen 2002).

Lillehei (Absolon et al. 1956) and Bailey (Bailey et al. 1957) were the first to envision direct coronary artery surgery with their experimental open and closed coronary thromboendarterectomy. Longmire in Los Angeles, California (Longmire et al. 1958), and Ake Senning in Stockholm, Sweden (Senning 1959), were the first who applied these techniques in clinical cases. Rene Favaloro (1923-2000) from the Cleveland Clinic reported about 163 patients who underwent open coronary thromboendarterectomy and vein or pericardial patch plasty between January 1962 and May 1967. These procedures were performed on a fibrillating heart with extracorporeal circulation at a temperature of 30 ° C. It was primarily the right coronary artery which was treated. Twenty-eight patients died during hospital stay (17%). Of 94 patients who underwent postoperative angiography, the result was considered good in 53 (Favaloro 1970).

As these results were not satisfying, Favaloro proceeded with direct coronary bypass surgery. On May 9, 1967, he implanted an aortocoronary venous bypass in a 51-year-old female patient who had proximal obstruction of the right coronary artery on angiography. The left coronary artery was unobstructed and fed via collateral vessels the peripheral right coronary artery which had no further artheriosclerotic changes. On this healthy periphery, Favaloro anastomosed the bypass vein. Twenty days later, the patient underwent postoperative coronary angiography. The aortocoronary artery venous bypass was open (Favaloro 1968, 1970). Between May 1967 and December 1968, 171 coronary artery venous bypass surgeries were performed. From this point on, the success story of coronary artery bypass surgery took off. Favaloro summarized the advantages of the bypass graft technique as follows:

- Low mortality
- Accessibility of all regions of the coronary artery system and hence
- Enlarging the indication for coronary surgery

Next to Favaloro, it is Dudley Johnson from Milwaukee, Wisconsin, who was part of the inauguration of routine coronary surgery. In 1969 he reported on 301 coronary patients whom he had operated upon since February 1967 and who in most cases received a vein graft (Johnson et al. 1969). His conclusions were similar to Favaloro's. Johnson noted that there have been others who reported on sporadic cases of coronary artery bypass surgery between 1962 and 1967. But none of these publications had any influence on further development. Among those, for example, was a venous bypass to the left anterior descending coronary artery in 1964, which, however, was reported only much later (Garret et al. 1973).

Originally, coronary bypass surgery favored vein grafts. Years later, Loop and Lytle, also from the Cleveland Clinic, demonstrated the superiority of arterial grafts. Consequently, this made arterial revascularization the technique of choice, especially in young patients (Loop et al. 1986; Lytle et al. 2004). The use of the internal mammary artery as a bypass graft was reported as early as 1967 by Vasilii Kolesov from St. Petersburg, Russia. He operated through a left thoracotomy on the beating heart without extracorporeal circulation. Donald Effler (1915-2004), cardiac surgeon-in-chief at Cleveland Clinic, discussed this technique and suggested a pre- and postoperative angiographic control (Kolessov 1967). In the United States, Goetz, Bailey, and Green worked using the mammary artery (Borst and Mohr 2001). But its widespread use started only after the convincing publication out of the Cleveland Clinic. The radial artery as a bypass graft was brought into discussion by Carpentier in 1973 (Carpentier and Guernonprez 1973). Because of frequently seen graft spasms, the radial artery did not gain acceptance at the beginning, but rather experienced a renaissance in recent years.

Following Dudley Johnson's dictum: «anastomoses on small vessels can't be performed on a moving object» (Johnson et al. 1969), it was through the late 1990s that employing extracorporeal circulation in coronary surgery seemed to be mandatory. Nevertheless, there were already large off-pump coronary surgery series reported showing acceptable results (Buffolo et al. 1985). SIRS (systemic inflammatory response syndrome) frequently is a response of the immune system to blood contact with artificial surfaces. In order to avoid SIRS whenever possible, many groups almost exclusively embarked on off-pump coronary surgery (Calafiore et al. 1996; Subramanian 1997; Borst and Mohr 2001).

Off-pump resections of ventricular aneurysms by simply applying big clamps between aneurysmal sac and left ventricle were described by Likoff and Bailey (1955). It was Denton Cooley in 1957 who for the first time employed extracorporeal circulation to resect a ventricular aneurysm (Cooley et al. 1958b). A further development in cardiac aneurysm surgery came from Vincent Dor, Monte Carlo, Monaco, who suggested an endocardial patch plasty to maintain and receive a better remodeling of the heart leading to improved function (Dor et al. 1989).

The first closure of a postinfarction ventricular septal defect was performed by Cooley in 1957 (Cooley et al. 1957). The early operations were performed only on hemodynamically stable patients through an incision in the right ventricle. Later on, emergency patients with huge left to right shunts were also operated on. Heimbecker et al. (1968), Dagett et al. (1970, Dagett (1990), Kitamura et al. (1971), and David et al. (1972) are among those who developed the techniques currently used with incision through the infarcted area and application of synthetic patch material.

## 1.11 Pacemaker, Defibrillators, and Arrhythmia Surgery

P.M. Zoll opened the modern era of pacemaker therapy in 1951, when he treated Adam-Stokes syndrome with externally applied stimulation (Zoll 1952). He fixed electrodes precardially to the skin and stimulated the heart with intermittent electrical impulses. Skin changes were caused and patients complained about bad pain.

An important push to the development of pacemarkers came from Lillehei's group in Minneapolis. Following VSD surgery, they repeatedly had to deal with the problem of complete AV block. In experiments on dogs, they created complete heart block and applied low voltage current. This leads to continuous heart beats again and reestablished normal blood pressure.

Lillehei immediately put this laboratory experience into clinical practice. He must have been the first to implant temporary pacemaker wires on the right ventricle. They could be removed by simply pulling them once postoperatively the patient's heart rhythm was stabilized. Lillehei also realized that wires could be introduced through cannulas into the closed chest and placed on the

right ventricle, so that patients with Adam-Stokes syndrome could be helped without further surgical interventions (Westaby 1997). Together with Earl Bakken, he built a pacemaker generator as big as a cigarette box, which could be carried around outside the body. Attached to suspenders, it hung over the shoulder. The steel wires being connected to the right ventricle and transmitting the impulse were isolated with Teflon (Lillehei et al. 1960). In this way pain and skin changes which annoyed Zoll's patients were eliminated.

The first totally implantable pacemaker was inserted by Senning and Elmquist in 1958 in Stockholm, Sweden (Elmquist and Senning 1959). The electrical switch had been embedded in epoxy resin. The patient had a total AV block with frequent Adam-Stokes attacks. As the quicksilver batteries used at that time had a short life span, a patient might have to experience quite a lot of battery changes. In the United States, it was William Chardack in 1960 who implanted the first pacemaker in Buffalo, NY (Chardack et al. 1960). He worked together with Wilson Greatbatch, an electrical engineer. Other types of implantable pacemakers were developed by Zoll in 1960 (Zoll and Linenthal 1960). A further milestone in pacemaker therapy was the development of tranvenous electrodes, which avoided surgery to expose the right ventricle. Both in 1962 it was Parsonnet in the United States (Parsonnet et al. 1962) and Ekestrom and Lagergren in Sweden (Ekestrom et al. 1962) who were the first to implant transvenous electrodes. Not only the demand function in 1964 but also the principle of bifocal, AVsequential stimulation in 1969, was developed by Castellanos et al. (1964) and Berkovitz et al. (1969).

The cumbersome short life spans of pacemaker generators could be significantly prolonged when W Greatbatch developed lithium batteries, which have a life span five to ten times longer than quicksilver batteries (Greatbatch et al. 1978).

The first implantable defibrillator (automatic internal cardioverter/defibrillator: AICD) was implanted by M Mirowsky at Johns Hopkins Hospital in Baltimore, Maryland (Mirowsky et al. 1980). The first systems required a thoracotomy to implant patch electrodes on the heart; however, from 1991 on the transvenous implantation became possible (Moore et al. 1991).

As a result of the rapid development in pacemaker and defibrillator technology, including less invasive catheter methods, many of the techniques designed for the surgical therapy of arrhythmias became obsolete. The complex surgical procedures for atrial fibrillation, developed by Gerard Guiraudon in France and by James Cox in St. Louis, Missouri, the so-called Maze procedure, underwent multiple variations following the development of various ablation devices (see ► Chapter «Surgical Therapy of Atrial Fibrillation», Sect. 29.6).

## 1.12 Thoracic Organ Transplantations

After initial experimental work by Carrel and Guthrie (1905), Demichov (1962), and Mann et al. (1933), Richard Lower (1930-2008) and Norman Shumway (1923–2006) at Stanford University in California developed the experimental foundation for clinical heart transplantation (Lower and Shumway 1960; Lower et al. 1962). Starting from the experiments on surface cooling for myocardial protection, they perfected the surgical technique of orthotopic heart transplantation. With the recipient animal being on extracorporeal circulation in mild hypothermia for excision of the «sick» heart, they developed the technique of leaving portions of the posterior wall of the left and right atrium as a cuff to be anastomosed to the donor heart. Thereafter, aorta and pulmonary artery were anastomosed. Some of their experiments were autotransplantations; others were heterotopic transplantations in dogs. When in 1967 they got the first dogs to survive more than 250 days with the aid of immunosuppressive drugs (azathioprine, cortisone), they thought to be ready for the first clinical heart transplantation (Lower et al. 1965).

The first homologous human heart transplantation in the world took place on December 3, 1967; however, it was not performed at Stanford University, California, but at Groote Schuur Hospital in Cape Town, South Africa. The donor was a young woman who died from a car accident, the recipient was a 54-year-old grocer named Louis Washkansky, who had end-stage ischemic cardiomyopathy after multiple myocardial infarctions, being considered inoperable by various authorities. He was in irreversible heart failure. After donor brain death was confirmed, the transplantation process started, in which a team of 30 people under the leadership of Christiaan Barnard (1922-2001) participated. Before this, Barnard had visited Richard Lower's laboratory to get firsthand information about the transplantation technique developed by Shumway and Lower, the technique he employed (Barnard 1967).

After the donor heart was cooled to 16 °C, it was put in 10° cold saline and transported to the next door recipient operating room, where it was perfused with blood. The ischemic time was 4 min. Barnard described the moment after he had excised the diseased recipient's heart that for the first time in his life he looked into an empty chest (Schmid et al. 2003). Louis Washkansky died on December 21, 1967, of pneumonia.

The second heart transplantation in the world was performed 3 days later, on December 6, 1967, by A. Kantrovitz at Maimonides Hospital in Brooklyn, New York. But the recipient, a 2-day-old baby, died immediately after the operation (Schmid et al. 2003).

On January 2, 1968, Barnard transplanted the heart of an organ donor who died of subarachnoid bleeding to the 58-year-old dentist Philip Blaiberg. Blaiberg survived for 18 months. He finally died of chronic rejection (Westaby 1997).

Soon thereafter, other heart surgeons followed with their first clinical heart transplantations: Shumway in Stanford; again Kantrovitz in Brooklyn; Sen in Bombay, India; Cabrol in Paris, France; Ross in London, England; and independently Cooley as well as DeBakey, both in Houston, Texas. The results of the more than 100 patients transplanted within a year after Barnard's first operation were very poor. More than 60 patients died within the first postoperative week; average survival for the remaining patients was less than 30 days (Westaby 1997). The problems of indications, definition of brain death, myocardial protection, as well as rejection and its diagnosis diminished the initial enthusiasm. Most of these problems were solved in the following years, mainly by the Stanford group:

- Exclusion criteria for heart transplantation were specified (Jamieson et al. 1982).
- Transvenous biopsy was introduced for rejection diagnosis (Caves et al. 1973).
- New concepts for myocardial protection made long-distance organ procurement possible.
   Ischemia of up to 4 h could be accepted (Thomas et al. 1978).
- Improvement of immunosuppressive medication, first by human antithymocyte globulin with introduction of T-cell monitoring (Bieber et al. 1976), thereafter by introduction of cyclo-

- sporin A, which was available to the Stanford group in 1980 (Oyer et al. 1983).
- The concept of retransplantation for acute and chronic rejection was established (Copeland et al. 1977).

Due to the new facilitating supportive features, the number of heart transplantations rose up to almost 4,500 worldwide cases in 1995. By that time, heart transplantation had become an established surgical treatment for end-stage cardiac failure (see ► Chapter «Heart and Heart-Lung Transplantation», Sect. 37.1.1).

The first attempts of combined heart and lung transplantation were undertaken 1968 by Cooley, 1969 by Lillehei, and 1981 by Barnard. They all were not successful (Westaby 1997). It was Bruce Reitz in Stanford, California, who, after exhaustive animal experiments on monkeys (Reitz et al. 1980) based on Castañedas heart-lung autotransplantation experiments in baboons (Castañeda et al. 1972), succeeded in applying this surgery on a 45-year-old woman with primary pulmonary hypertension on March 9, 1981. The woman was extubated 48 h after surgery and survived for more than 5 years. Reitz's second patient, who had Eisenmenger's syndrome caused by a VSD, was a long-term success, also (Reitz et al. 1982).

The first isolated lung transplantation was performed by James Hardy in 1963. His patient died 7 days after surgery (Hardy et al. 1963). More success had Fritz Dermon (Dermon et al. 1971) from Belgium, whose patient survived for 10 months. The final scientific and clinical breakthrough in lung transplantation surgery was achieved by Joel Cooper's group in Toronto, Canada. They reported on two patients who had returned to normal life activities after surgery and survived lung transplantation 14 and 26 months (Cooper et al. 1986). Since then, the number of lung transplantations performed yearly has progressively risen all over the world. In 2013, lung transplantation was performed in more than 4000 patients (see ▶ Chapter «Lung Transplantation», Sect. 36.1, 
Table 36.1).

#### 1.13 Circulatory Assist Devices

The idea of mechanical circulatory assist devices is old. Different approaches were followed. The concept of diastolic augmentation to improve coronary perfusion was developed in experimental animal

studies by the brothers Kantrowitz (1953) and Kantrowitz and Kinnen (1958). Internal counterpulsation was employed by Claus and coworkers (1961). Thereby the blood was aspirated from the aorta during systole and injected back during diastole. With modifications and, most importantly, the availability of inflatable latex balloons, Moulopoulos and coworkers succeeded in 1962 in the development of the intra-aortic balloon pump (IABP) (Moulopoulos et al. 1962). Inflating and deflating of gases, at first C02, later helium, were ECG triggered. The first clinical successes were reported by Kantrowitz in 1968 (Kantrowitz et al. 1968). Since 1979, the Seldinger technique allowed insertion of the IABP balloon pump from the periphery through the femoral artery (Bregman and Cassarella 1980). The intra-aortic balloon pump, in addition to increasing coronary perfusion in diastole, also causes systolic afterload reduction.

Extracorporeal membrane oxygenation (ECMO), developed by Hill et al. (1972) and Zapol et al. (1979) and modified by Gattinoni (Pesenti et al. 1993), is another principle for treating post-cardiotomy heart failure. The ECMO principle is a long-term extracorporeal circulatory and respiratory support, derived from its use during cardiac surgery. As left ventricular afterload cannot be reduced with the ECMO system alone, the combination of both support systems, ECMO and IABP, has been suggested (Bavaria et al. 1990).

The first realistic attempts to replace the heart with an artificial implant are attributed to Willem Kolff and his coworkers T. Akutsu and Y. Nose at the Cleveland Clinic. They implanted in the mid-1960s four-chambered air-driven artificial hearts into calves in an orthotopic position. The animals could be kept alive for more than 24 h. In 1967 Kolff became head of the Division of Artificial Organs and Institute for Biomedical Engineering at the University of Utah. He worked with Kwan-Gett and Robert Jarvik on the design of a completely implantable artificial heart (Westaby 1997).

In Houston, Texas, Domingo Liotta (born 1924) designed artificial ventricles, planned to be used as pumps for extracorporeal circulation or as an artificial heart. Already in 1966 Michael DeBakey (1908–2008) successfully employed an artificial Liotta ventricle as part of a left heart bypass in a 37-year-old woman for postcardiotomy heart failure. After 10 days, she was weaned off bypass and became a long-term survivor (DeBakey 1971). DeBakey was successful with

two more patients (Campbell et al. 1988). PE Oyer in Stanford did the first successful «bridge to transplant», when he successfully transplanted a heart after having implanted a Novacor left heart assist system before (Portner et al. 1985), see also ► Chapter «Cardiac Assist Devices and Total Artificial Heart», Sect. 38.2.

The patient Barney Clark was the first to undergo a complete artificial orthotopic heart replacement. In December 1982, a Jarvik Type 7 total artificial heart was implanted in the University of Utah by William DeVries. The patient was extubated on the second postoperative day, but he died on the 112th postoperative day after multiple, mostly thromboembolic, complications (De Vries et al. 1984; Westaby 1997).

The idea of using peripheral muscles to augment cardiac performance came from Kantrowitz and MiKinnen (1958). But the idea could only be realized once the fatigability of peripheral muscles was understood and managed (Macoviak et al. 1982). Of same importance was the knowledge to muscle correctly stimulate the skeletal (Drinkwater et al. 1980). The first one to apply the cardiomyoplasty clinically was Carpentier in 1985 with a transformed latissimus dorsi muscle wrapped around the heart (Carpentier and Chachques 1985). See also ▶ Chapter «Left Ventricular Reconstruction and Conventional Surgery for Cardiac Failure», Sect. 23.3.4.

# 1.14 The History of (Thoracic) Aortic Surgery

The first surgeons who concentrated their efforts on the thoracic aorta and its branches were HB Shumacker (1947), Henry Swan et al. (1950), Henry Bahnson (1953), as well as Michael DeBakey and Denton Cooley (1953). The first infrarenal aortic aneurysm was resected by Charles DuBost in 1951 (DuBost et al. 1952). They all replaced the aortic segments resected with aortic tube homografts.

The first synthetic tube graft, made from Vinyon-N, was implanted in 1952 by Arthur Voorhees (1921–1991) at Columbia University in New York, NY (Voorhees et al. 1952). They had found that synthetic grafts were accepted by the body as a vessel substitute, when the material used had a rather porous structure and was biologically indifferent. Around the same time, DeBakey started using Dacron, with the first grafts being manufactured

on a household sewing machine (DeBakey et al. 1958; Spencer 1983; Stephenson 1997).

The first replacement of the ascending aorta with a graft, employing extracorporeal circulation, was carried out by Cooley and DeBakey in 1956 (Cooley and DeBakey 1956). Albert Starr reported substitution of the supracoronary aorta with a synthetic prosthesis concomitant with an aortic valve replacement (Starr et al. 1963). A more radical procedure, requiring reimplantation of the coronary arteries, was described by Wheat replacing aortic valve and ascending aorta separately (Wheat et al. 1964) and by Bentall and De Bono as the combined aortic valve and ascending aortic replacement with a valve carrying tube prosthesis (Bentall and De Bono 1968). For many years, a graft inclusion technique, wrapping the aneurysm wall around the implanted prosthesis, was used. In case of persistent significant bleeding from any prosthetic anastomose inside the wrapped space, not amenable to direct suture, Christian Cabrol suggested implantation of a prosthetic shunt between the periprosthetic wrapped space and the right atrium (Cabrol et al. 1981). Today the inclusion technique has been abandoned in favor of a freestanding open technique with total resection of the diseased aorta, as a consequence of reported pseudoaneurysm formation at coronary and aortic anastomotic sites with the inclusion technique (Kouchoukos et al. 1986).

In 1957 the Houston group with DeBakey, Crawford and Cooley replaced an aortic arch on extracorporeal circulation (DeBakey et al. 1957). After Hans Borst was the first to successfully employ deep hypothermia for aortic arch surgery (Borst et al. 1964), the later publications of Randall Griepp et al. (1975), DA Ott et al. (1978), and ES Crawford (Crawford and Saleh 1981; Crawford et al. 1987) lead to the technique of aortic arch replacement performed in deep hypothermia with the shortest possible circulatory interruption. In those cases in which the hypothermic circulatory arrest takes a relatively long time, Jean Bachet in France and Teruhisa Kazui in Japan established antegrade selected cerebral perfusion as a method of cerebral protection (Bachet et al. 1991; Kazui et al. 1994).

For the further development of aortic surgery, especially with reference to interventional and hybrid procedures, please refer to 
Chaps. 27 and 28.

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# Risk Scores in Cardiac Surgery

Dietmar Boethig and Jeffrey Phillip Jacobs

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### 2.1 What Is a Score?

Scores can influence the ultimate survival of patients. For example, the urgency of need for hepatic transplantation is determined by scores (Asrani and Kim 2010). Scores also can influence survival of hospitals or departments. If the scores of performance of a hospital or department are considered too low, they are at risk for closure. Therefore, scores can be rather important. The term «score,» however, can have multiple meanings. The following chapter tries to define the appropriate interpretation of the word «score,» explains various ways of constructing scores, and provides orientation about scores currently used in the field of cardiothoracic surgery.

Generally speaking, «score» means a simplified method of counting. The Old English word «scoru» is derived from Norwegian and means «twenty» (> www.etymonline.com). Later on, a notch in a stick, made as a mark to remember a certain number of counted items, e.g., 20 sheep, was called a score. Today, the word «score» has a wide variety of meanings. The multiple interpretations today comprise such different domains as the instructions for playing a piece of music, a vote in sporting competitions, a container of fruit, or the sum of points achieved points in a game on a computer. Of specific relevance to this chapter, probabilities for mortality (Abel 1993) and other classifications of humans are summarized or characterized by scores, which can be used to simplify more extensive descriptions (Lee et al. 2006, Harrell 2001, Hosmer and Limeshow 2000, Tischendorf et al. 2007).

In cardiac surgery, scores mainly classify patients according to certain symptoms, laboratory values, or other properties and aim to estimate the risk for an adverse event such as mortality, renal failure, or complicated wound healing (Overman et al. 2013). Scores can be used to group patients according to a comparable risk for events (Budoff et al. 2007, Higgins et al. 1992, Tu et al. 1995). A good score predicts results reliably (good calibration) and differentiates well between patients with higher and lower risk (good discrimination). Clinicians like scores that are easy to calculate, easy to interpret, and are both applicable and relevant for many patients.

Propensity scores are a statistical method originally introduced by Rosenbaum and Rubin (1983) and re-presented to the community of cardiac surgeons by Blackstone (2002): calculating

propensity scores applying Cox' regression (Cox 1972) with treatment as endpoint permits within certain limits a kind of «retrograde randomization». Meanwhile the number of citations for «propensity score» AND «cardiac surgery» in PubMed exceeds 500.

Scores are the subject of the following chapter. This chapter describes six widely used scores, three for patients with acquired cardiac disease and three for patients with congenital cardiac disease. Several other risk stratification models have been applied in cardiac surgery (Nilsson et al. 2006 and Parsonnet 1995). Some remarks are provided about the appropriate use of scores and some of the potential limitations of these scores.

### 2.2 Prominent Risk Scores in Cardiac Surgery

### 2.2.1 Society of Thoracic Surgeons Score

The Society of Thoracic Surgeons (STS) database is one of the largest cardiac surgical databases in the world and receives data from over 90 % of the units performing cardiac surgery in the USA. The total number of included operations amounts to more than 5.3 million. Around 250,000 cardiac surgery procedures are added each year. STS uses one of the largest surgical audit programs in the world to assure accuracy and completeness of data in the STS databases.

After entering the data (risk factors) from a specific patient, the risk calculator of the STS website (▶ http://riskcalc.sts.org/STSWebRiskCalc273/de.aspx) will calculate the risk for mortality and a series of complications for patients receiving coronary artery bypass grafts and/ or aortic or mitral valve replacement or repair.

The following probabilities are calculated from STS database entries:

- Mortality
- Morbidity or mortality
- Length of stay more than 14 days
- Length of stay less than 14 days
- Permanent stroke
- Prolonged ventilation time
- Deep sternal wound infection
- Renal failure
- Reoperation

Risk determination is accomplished via logistic regression models that base on roughly 500,000 STS data sets entered between 1/2002 and 12/2006.

The STS risk calculator has by far the largest underlying database for its risk models. Some of the specific prediction—at least for mitral valve operations—cannot to be obtained elsewhere.

With a limited effort of entry of data, the internet-based STS risk calculator is suitable to obtain reliable predictions for individual cardiac surgical patients for the most frequent operations. Immediately after data entry, the calculated probabilities for mortality of a variety of potential morbidities are provided.

#### 2.2.2 EuroSCORE

The EuroSCORE (European System for Cardiac Operative Risk Evaluation; Nashef et al. 1999; ► http://www.euroscore.org/calc.html) predicts the in-hospital mortality risk after cardiac surgery. The score was constructed to be applicable on a large fraction of cardiac surgery patients, such as:

- CABG
- Valve repair or replacement
- Replacement of part of the aorta
- Repair of a structural defect
- Maze procedure
- Resection of a cardiac tumor

Originally derived from 19,030 data sets of numerous European clinics in 1995, the EuroSCORE database was updated in October 2011 (22,000 data sets). It is a robust, simple-to-use, and reliable tool to estimate mortality after cardiac and intrathoracic aortic surgery. Eighteen well defined and easily available factors are entered. The resulting risk is returned either by addition of risk points (additive model, old version) or by inclusion of the factors in a regression model (regression model, new model). The latter can be programmed on the user's computer (for larger data sets), because the complete model is published. Alternatively, the EuroSCORE risk of

mortality risk can be requested interactively on the website ( http://www.euroscore.org/calc.html).

The revised version no longer recommends the use of an additive model. A continuous prospective data harvesting of the EuroSCORE study group at selected centers has finished recently a recalibration. A sentinel group of hospitals is continuously observed and will trigger the next recalibration if their mortality rates diverge too far from the currently observed ones. The calculator website mentioned above is followed by a one-page section of definitions section that contains:

- 1. Short definitions of various items.
- 2. A listing of the choices for some items with multiple answers.
- 3. A calculator for estimation of creatinine clearance from the level serum creatinine, age, height, and weight (according to Cockroft-Gault). (If present, the user can enter the creatinine clearance directly.)

A detailed description of how to calculate the score is given in the paper of Nashef et al. (2012) This paper provides:

- 1. The factor weights for a total of 29 status descriptions
- 2. The constant of the final regression model
- A detailed calculation instruction

The EuroSCORE II is useful if one intends to estimate mortality of a broad range of cardiac surgery patients, especially if the patient group is large and thus manual data entry into a website is challenging. Another advantage is its recent recalibration to current results of surgery and the continuous surveillance for the necessity of future recalibration.

### 2.2.3 German Quality Assurance: Aortic Valve Replacement and Coronary Artery Bypass Scores (KCH-SCORE 3.0)

The section for cross-sectoral quality assurance in health care, SQG, of the AQUA-Institut (Göttingen, Germany) regularly evaluates a virtually complete data set (98.8%) of all German isolated coronary artery bypass grafting procedures,

isolated aortic valve replacements, and the combination of both (n=66,365 in 2011), as well as transplantations of the heart, lungs, and both. The institution uses a set of well-defined risk factors. A random validation of source data was performed and did not reveal any evidence of purposeful manipulation of entry of data. The most recent data set used to develop regression models for in-hospital mortality is based on patients operated on in 2010. The regression coefficients and the constant of the models derived from this huge data set can be downloaded from the following website hyperlinks:

- ► http://www.sqg.de/ergebnisse/leistungsbereiche/ koronarchirurgie-isoliert.html
- http://www.sqg.de/ergebnisse/leistungsbereiche/ aortenklappenchirurgie-konventionell.html
- http://www.sqg.de/ergebnisse/leistungsbereiche/kombinierte-koronarundaortenklappenchirurgie.html

■ Table 2.1 gives the 2011 results for isolated cardiac surgery based on data of 40,353 such operations.

Unlike for the EuroSCORE, data for this KCH-SCORE 3.0 model are specific for the described procedures and come from German centers only, so they should me more specific for comparisons with or within Germany. The AQUA-Institut updates the regression models in short intervals, making current factor weights available. When using these models outside Germany, it is advisable to consider the usual postoperative length of hospital stay in German hospitals (isolated aortic valve replacement: 5% up to 7 days, 56.5 % 8-14 days, 22.2 % 15-21 days, 15.8% >21 days; isolated CABG: 9.5% up to 7 days, 61.7% 8-14 days, 17.6% 15-21 days, 11.2 % >21 days; CABG plus aortic valve replacement: 6.0 % up to 7 days, 48.2 % 8-14 days, 25.2 % 15-21 days, 20.5 % >21 days).

The KCH-SCORE 3.0 is very useful to compare results of isolated coronary artery surgery, aortic valve replacement, or both of them to actual expectations in Germany. The KCH-SCORE 3.0 is best used to compare outcomes with or within Germany.

# 2.2.4 Risk Adjustment in Congenital Heart Surgery, 1st Version (RACHS-1)

RACHS-1 (Jenkins et al. 2002, 2004) is a score that groups most of the procedures performed in patients with congenital cardiac malformations according to their risk of postoperative in-hospital mortality. The developers of RACHS-1 wanted to keep the score relatively as simple, with minimal entry of data that could all be obtained from the usual hospital discharge data sets. The developers of RACHS-1 used a data set of 3,709 surgical procedures performed in 1996, including patients from 32 institutions. The procedures were first classified by their estimated mortality risk, and then the group assignment was adapted to reality. Finally, a validation using 3,419 discharge data sets was performed and confirmed good calibration and discrimination. For 5 of the 79 procedures (■ Table 2.2), an age split was introduced. The 79 procedures are divided into six categories. The applicability of this simple scoring system for dividing patient populations into groups with significantly differing operative risk has been shown repeatedly in various countries ( Table 2.3)

RACHS-2, an updated version of RACHS-1, has not yet been published. In the future, increasing availability of computer power and larger data sets may lead to the development of procedurespecific mortality prediction models based on the primary procedure of the index operation carried out during a hospital stay. Such a procedurespecific mortality prediction model may be applicable for common operations but will likely not obviate the need for a grouping process such as RACHS-1 to deal with the multiple rarer operations. The large databases for congenital heart surgery (STS Congenital Heart Surgery Database and European Association for Cardio-Thoracic Surgery [EACTS] Congenital Heart Surgery Database) can provide the large numbers required for both procedure-specific mortality prediction model and complexity stratified models.

RACHS-1 is suited to group pediatric cardiac surgery patients according to their risk of mortality after cardiac surgery.

<sub>37</sub> **2** 

■ Table 2.1 Risk-adjusted in-hospital	mortality according	to the log.	(KCH-SCORE 3.0)
---------------------------------------	---------------------	-------------	-----------------

Risk factor	Definition	Regression coefficient
(Constant)	-	$-5.7503853602647300 = \beta_0$
Age	66–70 years	$0.3997704422494380 = \beta_1$
	71–75 years	$0.6471051658100260 = \beta_2$
	76–80 years	0.8592868665625700
	80–85 years	1.2456627767548900
	86 years or more	1.7534572132889400
Gender	Female	$0.2409740617585420 = \beta_3$
Body mass index	<22	$-0.0747372660361782 = \beta_4$
	>35	$0.4181980662086110 = \beta_5$
NYHA state IV	Angina at rest	$0.4844037233502880 = \beta_6$
Myocardial infarction within the last 21 days		$0.4257073497896120 = \beta_7$
Critical preoperative state		$0.9021816586032620 = \beta_8$
Pulmonary hypertension		$0.6773151306260310 = \beta_9$
Atrial flutter or other dysrhythmias		$0.4537995728069390 = \beta_{10}$
Left ventricular ejection fraction	<30%	$1.2141884842788300 = \beta_{11}$
	30-50%	$0.5526803957590370 = \beta_{12}$
3-vessel coronary artery disease		$0.1599987092081420 = \beta_{13}$
Reoperation heart/ aorta		$0.9656245650921850 = \beta_{14}$
Insulin-dependent diabetes mellitus		$0.2805516494146400 = \beta_{15}$
Peripheral arterial disease		$0.5589691496985530 = \beta_{16}$
Chronic obstructive pulmonary disease		$0.4369515198143070 = \beta_{17}$
Other lung diseases		$0.4186316551698350 = \beta_{18}$
Neurologic dysfunction		$0.1342343822193820\ 0.245 = \beta_{19}$
Preoperative renal replacement therapy or preoperative serum creatinine >2.3 mg/dl		$1.0294845545444300\ 0.829 = \beta_{20}$
Emergency		$0.6794065906504790\ 0.600 = \beta_{201}$

How to calculate the mortality risk:

Mark all applying risk factors

Add their regression coefficients

Add the constant (in this case: -5.7503853602647300), name the result «R,» and replace «R» with the result in the following formula:

2.718259<sup>R</sup>/ (1+2.718259<sup>R</sup>)

The result of this calculation multiplied by 100 is the mortality risk in %

## ■ Table 2.2 Risk classes of the score «Risk Adjustment in Congenital Heart Surgery, 1st version» (RACHS-1)

VCISIOI	I» (KACH3-1)
Risk class	Procedure
1	Atrial septal defect surgery (including secundum atrial septal defect, sinus venosus atrial septal defect, patent foramen ovale closure)
	Aortopexy
	Patent ductus arteriosus surgery at age >30 days
	Coarctation repair at age >30 days
	Partially anomalous pulmonary venous connection surgery
2	Aortic valvotomy or valvuloplasty at age >30 days
	Subaortic stenosis resection
	Pulmonary valvotomy or valvuloplasty
	Pulmonary valve replacement
	Right ventricular infundibulectomy
	Pulmonary outflow tract augmentation
	Repair of coronary artery fistula
	Atrial septal defect and ventricular septal defect repair
	Primum atrial septal defect repair
	Ventricular septal defect repair
	Ventricular septal defect closure and pulmonary valvotomy or infundibular resection
	Ventricular septal defect closure and pulmonary artery band removal
	Repair of unspecified septal defect
	Total repair of tetralogy of Fallot
	Repair of total anomalous pulmonary venous at age >30 days
	Glenn shunt
	Vascular ring surgery
	Repair of aortopulmonary window
	Coarctation repair at age ≤30 days
	Repair of pulmonary artery stenosis
	Transection of pulmonary artery
	Common atrium closure
	Left ventricular to right atrial shunt repair

Risk class	Procedure
3	Aortic valve replacement
3	Ross procedure
	Left ventricular outflow tract patch
	Ventriculomyotomy
	Aortoplasty
	Mitral valvotomy or valvuloplasty
	Mitral valve replacement
	Valvectomy of tricuspid valve
	Tricuspid valvotomy or valvuloplasty
	Tricuspid valve replacement
	Tricuspid valve replacement repositioning for Ebstein anomaly at age >30 days
	Repair of anomalous coronary artery without intrapulmonary tunnel
	Repair of anomalous coronary artery with intrapulmonary tunnel (Takeuchi)
	Closure of semilunar valve, aortic or pulmonary
	Right ventricular to pulmonary artery conduit
	Left ventricular to pulmonary artery conduit
	Repair of double-outlet right ventricle with or without repair of right ventricular obstruction
	Fontan procedure
	Repair of transitional or complete atrioventricular canal with or without valve replacement
	Pulmonary artery banding
	Repair of tetralogy of Fallot with pulmonary atresia
	Repair of cor triatriatum
	Systemic to pulmonary artery shunt
	Atrial switch operation
	Reimplantation of anomalous pulmonary artery
	Anuloplasty
	Repair of coarctation and ventricular septal defect closure
	Excision of intracardiac tumor

#### ■ Table 2.2 (continued)

_		iz (continued)
	Risk class	Procedure
	4	Aortic valvotomy or valvuloplasty at age ≤30 days
		Konno procedure
		Repair of complex anomaly (single ventricle) by ventricular septal defect enlargement
		Repair of total anomalous pulmonary veins at age ≤30 days
		Atrial septectomy
		Repair of transposition, ventricular septal defect, and subpulmonary stenosis (Rastelli)
		Atrial switch operation with ventricular septal defect closure
		Atrial switch operation with repair of subpulmonary stenosis
		Arterial switch operation with pulmonary artery band removal
		Arterial switch operation with ventricular septal defect closure
		Arterial switch operation with repair of subpulmonary stenosis
		Repair of truncus arteriosus
		Repair of hypoplastic or interrupted aortic arch without ventricular septal defect closure
		Repair of hypoplastic or interrupted aortic arch with ventricular septal defect closure
		Transverse arch graft
		Unifocalization for tetralogy of Fallot and pulmonary atresia
		Double switch
	5	Tricuspid valve repositioning for neonatal Ebstein anomaly at age ≤30 days
		Repair of truncus arteriosus and interrupted arch
	6	Stage 1 repair of hypoplastic left heart syndrome conditions
		Damus-Kaye-Stansel procedure
	referer	pwise mortality comparison based on these nce values is achieved by comparing red and expected mortality:
	followi perfori	ed mortality. For each RACHS-1 group, the ng product is calculated: number of med operations pertaining to the designated by mortality in the comparison group

clas	-	Procedure
	•	oducts are added, and their sum indicates ther of expected deaths. This number can then

The products are added, and their sum indicates the number of expected deaths. This number can then be expressed as percentage of the entire group of operated patients: the mortality rate expected if mortalities were equal in the observed and the reference population

Comparison: The quotient of observed and expected mortality rates (in %) shows the relationship of observed and expected mortality. Another intuitive measure of comparison is to indicate the mortality rate difference: it shows how many lives per 100 were saved (or lost) in one group (hospital, country) in respect to the reference group

(From Jenkins et al. (2002), Jenkins (2004); used with permission)

### 2.2.5 The Aristotle Score

In 1999, under the leadership of Dr. Francois Lacour-Gayet, the Aristotle Committee was created to address the issue of stratification of complexity in surgery for congenital cardiac diseases (Lacour-Gayet 2002, 2004a, and 2004b; Mavroudis and Jacobs 2000). The developers of this tool recognized that standard methods of benchmarking in quality of care assessment were based on stratification of risk, with nearly exclusive emphasis on the measurement of the outcome of operative mortality. They believed that to assess outcomes, including comparison of outcomes between centers, and to establish a platform for continuous improvement in quality, stratification based on the risk for mortality alone is insufficient. The fundamental principle of the Aristotle Complexity Score is to define complexity as a constant for the challenge presented by a given surgical procedure. The Aristotle Committee postulated that the complexity of a given procedure in surgery for congenital cardiac diseases is the sum of three factors or indices: (1) the potential for operative mortality, (2) the potential for operative morbidity, and (3) the technical difficulty of the operation (Jacobs et al. 2006a).

Lacour-Gayet and the Aristotle Committee created a tool for stratification of complexity and called it the Aristotle Complexity Score, following Aristotle's belief in the importance of current opinion. In the

■ Table 2.3 Various published mortality rates with RACHS-1 stratified RACHS-1 groups

	Treatment period	Operations	Mortality [	Mortality [%] in the different RACHS-1 categories	ent RACHS-1 ca	ategories		
			-	2	es.	4	rV.	9
	1996	4370	0.4	3.8	8.5	19.4	ı	47.7
	1994–1996	3646	0.3	3.3	9.5	19.2	ı	47.0
Bad Oeynhausen, Germany	1996–2002	2386	0.3	4.0	5.6	6.6	50.0	40.1
Aarhus, Denmark	1996–2002	957	1:1	3.1	8.5	17.0	ı	57.0
London, England	200-2003	866	0	1.3	5.0	11.1	ı	36.5
CHSS members	2001–2004	12.672	0.7	6:0	2.7	7.7	ı	17.2
Toronto, Canada	1999–2004	2397	0	1.0	4.0	7.0	17.0ª	17.0ª
Maranhao, Brazil	2001–2004	145	3.8	26.0	0.09	1	ı	ı
Guatemala City, Guatemala	2003–2004	537	0.5	7.4	23.3	25.0	ı	ı
Nairobi, Kenya	2002–2006	313	2.5	16.9	29.4	50		
Helsinki, Finland	2000–2004	1001	0	2.1	3.2	6.7	1	14.3
Sydney, Australia	2005–2010	1745	0	1.1	1.6	6.2	0	25.8
38 USA centers	2003–2008	46.730	8.0	1.3	2.7	7.0	17.1ª	17.1ª
Bangkok, Thailand	2005	230	0	1.7	11.1	25	100	100
Paris, France	2007–2009	1384	0	1.7	3.0	7.1	100	57.9
Buenos Aires, Argentina	2004–2009	2942	0.4	2.4	7.1	14.0	34	34

CHSS Congenital Heart Surgeons Society, HDD Hospital Discharge Data Sets, PCCC Pediatric Cardiac Care Consortium, RACHS-1 Risk Adjustment in Congenital Heart Surgery, 1st version aRACHS-1 categories 5 and 6 were combined to calculate the mortality rate

year 350 BCE, in Rhetoric, Book 1, Aristotle stated, «When there is no scientific answer available, the opinion (Doxa) perceived and admitted by the majority has the value of truth.»

Lacour-Gayet and the Aristotle Committee have differentiated the concepts of complexity and risk and have stated, «Complexity is a constant precise value for a given patient at a given point in time; performance varies between centers and surgeons. In other words, in the same exact patient with the same exact pathology, complexity is a constant precise value for that given patient at a given point in time. The risk for that patient will vary between centers and surgeons because performance varies between centers and surgeons.»

Under the leadership of Lacour-Gayet and the Aristotle Committee, the Aristotle Basic Complexity Score was developed by a panel of experts, made up of 50 surgeons who repair congenital cardiac defects in 23 countries and represent several major societies. The Aristotle professional Basic Complexity Score allocates a basic score to each operation, varying from 1.5 to 15, with 15 being the most complex, based on the primary procedure of a given operation. The Aristotle Basic Complexity Score represents the sum or aggregate of scores assigned to a given procedure for the three components of complexity-potential for mortality, potential for morbidity, and technical difficultyeach of which varies from 0.5 to 5. To facilitate analysis across large populations of patients, each procedure is then assigned an Aristotle Basic Complexity Level, which is an integer ranging from 1 to 4 based on the Aristotle Basic Complexity Score (■ Table 2.4) (O'Brien et al. 2007).

The Aristotle Comprehensive Complexity Score adds further discrimination to the Basic Score by incorporating two sorts of patient-specific complexity modifiers: (1) procedure-dependent factors, including anatomic factors, associated procedures, and age at procedure, and (2) procedure-independent factors, including general factors such as weight and prematurity, clinical factors such as preoperative sepsis or renal failure, extracardiac factors such as duodenal atresia and imperforate anus, and surgical factors such as reoperative sternotomy. Additional points, up to a maximum of 10, are added to the Basic Score to account for the added complexity and challenge imputed by these modifying factors. The Aristotle Comprehensive Complexity Score has been used by numerous investigators to analyze the outcomes from complex procedures, such as Sinzobahamvya et al. (2006), Miyamoto et al. (2005), Artrip et al. (2006), and Derby et al. (2007).

The Aristotle Score is suited to group pediatric cardiac surgery patients according to their risk of mortality after cardiac surgery.

### 2.2.6 The STS-EACTS Congenital Heart Surgery Mortality Score (STAT Mortality Score)

First published in 2009 by O'Brien et al., the STS-EACTS Mortality Score (later abbreviated as STAT Mortality Score: Society of Thoracic Surgeons – European Association for Cardio-Thoracic Surgery Congenital Heart Surgery Mortality Score) was derived from 77,294 congenital heart surgery data sets. They were pooled from the databases of STS and EACTS, collected between 2002 and 2007, and describe outcomes of 148 different operations. Similar to RACHS-1, only the most complex component procedure of a given operation is considered (Jacobs et al. 2009b).

To create the STAT Mortality Score, at first the observed hospital discharge mortality rates were adjusted by approaching the mortality rates of rarely encountered procedures to the average mortality, in order to limit over- or underestimation by chance. The applied Bayesian algorithm modified the observed rates stronger if the total case number was lower. Then, the adjusted mortality rates were transformed by shifting and rescaling, in order to fit into a scale ranging from 0.1 to 5. The result is the «STS–EACTS Congenital Heart Surgery Mortality Score (O'Brien et al. 2009).»

In a further step, these score values were grouped into the five «STS–EACTS Congenital Heart Surgery Mortality Categories (STAT Mortality Categories).» The comparative validation on 25,106 data sets collected (2007–2008) from the same database showed optimal discrimination of the STAT Mortality Score for the procedure-specific mortality rates (C-index=0.787), followed by the STAT Mortality Categories (C-index=0.778), then the RACHS-1 categories (C-index=0.745), and then the Aristotle Basic Score (C-index=0.687). Addition of patient-specific variables improved the C-indexes to 0.816, 0.812, 0.802, and 0.795, respectively.

■ Table 2.4 The Aristotle basic complexity score (ABC score) and the Aristotle basic complexity levels (ABC levels) (January 1, 2010)

Score	Mortality	Morbidity	Difficulty
1 pt	<1 %	ICU 0-24H	elementary
2 pt	1-5 %	ICU 1D-3D	simple
3 pt	5-10 %	ICU 4D-7D	average
4 pt	10-20 %	ICU 1W-2W	important
5 pt	> 20 %	ICU > 2W	major

Complexity

1.5–5.9

6.0–7.9

8.0–9.9

3

10.0–15.0

4

	Total	Complexity			
Procedures	(Basic score)	(Basic level)	Mortality	Morbidity	Difficulty
Pleural drainage procedure	1.5	1	0.5	0.5	0.5
Bronchoscopy	1.5	1	0.5	0.5	0.5
Delayed sternal closure	1.5	1	0.5	0.5	0.5
Mediastinal exploration		1	0.5	0.5	0.5
Sternotomy wound drainage	1.5	1	0.5	0.5	0.5
Intra-aortic balloon pump (IABP) insertion	2.0	1	0.5	1.0	0.5
Explantation of pacing system	2.5	1	1.0	1.0	0.5
PFO, primary closure	3.0	1	1.0	1.0	1.0
ASD repair, primary closure	3.0	1	1.0	1.0	1.0
ASD repair, patch	3.0	1	1.0	1.0	1.0
ASD partial closure	3.0	1	1.0	1.0	1.0
Atrial fenestration closure	3.0	1	1.0	1.0	1.0
Pericardial drainage procedure	3.0	1	1.0	1.0	1.0
PDA closure, surgical	3.0	1	1.0	1.0	1.0
Pacemaker implantation, permanent	3.0	1	1.0	1.0	1.0
Pacemaker procedure	3.0	1	1.0	1.0	1.0
Shunt, ligation and takedown	3.5	1	1.5	1.0	1.0
ASD, common atrium (single atrium), Septation	3.8	1	1.0	1.0	1.8
AVC (AVSD) repair, partial (incomplete) (PAVSD)	4.0	1	1.0	1.0	2.0

### ■ Table 2.4 (continued)

	Total	Complexity			
Procedures	(Basic score)	(Basic level)	Mortality	Morbidity	Difficulty
Coronary artery fistula ligation	4.0	1	1.0	2.0	1.0
Aortopexy	4.0	1	1.5	1.5	1.0
ICD (AICD) implantation	4.0	1	1.5	1.0	1.5
ICD (AICD) (automatic implantable cardioverter defibrillator) procedure	4.0	1	1.5	1.0	1.5
Ligation, thoracic duct	4.0	1	1.0	2.0	1.0
Diaphragm plication	4.0	1	1.0	2.0	1.0
ECMO decannulation	4.0	1	2.0	1.0	1.0
ASD creation/enlargement	5.0	1	2.0	2.0	1.0
Atrial septal fenestration	5.0	1	2.0	2.0	1.0
AVC (AVSD) repair, intermediate (transitional)	5.0	1	1.5	1.5	2.0
PAPVC repair	5.0	1	2.0	1.0	2.0
Lung biopsy	5.0	1	1.5	2.0	1.5
Ligation, pulmonary artery	5.0	1	1.5	2.0	1.5
Decortication	5.0	1	1.0	1.0	3.0
ASD repair, patch + PAPVC repair	5.0	1	2.0	1.0	2.0
PAPVC repair, baffle redirection to the left atrium with systemic vein translocation (Warden) (SVC sewn to the right atrial appendage)	5.0	1	1.0	2.0	2.0
ECMO cannulation	5.0	1	2.0	1.0	2.0
Pectus repair	5.3	1	2.0	1.0	2.3
Aortic stenosis, supravalvar, repair	5.5	1	1.5	2.0	2.0
Valvuloplasty, pulmonic	5.6	1	1.8	1.8	2.0
VSD repair, primary closure	6.0	2	2.0	2.0	2.0
VSD repair, patch	6.0	2	2.0	2.0	2.0
AP window repair	6.0	2	2.0	2.0	2.0
Valve replacement, truncal valve	6.0	2	2.0	2.0	2.0
Cor triatriatum repair	6.0	2	2.0	2.0	2.0
Valve excision, tricuspid (without replacement)	6.0	2	2.0	2.0	2.0
PA, reconstruction (plasty), main (trunk)	6.0	2	2.0	2.0	2.0
Pericardiectomy	6.0	2	2.0	2.0	2.0
Coarctation repair, end to end	6.0	2	2.0	2.0	2.0
Coarctation repair, subclavian flap	6.0	2	2.0	2.0	2.0
Coarctation repair, patch aortoplasty	6.0	2	2.0	2.0	2.0
Vascular ring repair	6.0	2	2.0	2.0	2.0

### ■ Table 2.4 (continued)

	Total	Complexity			
Procedures	(Basic score)	(Basic level)	Mortality	Morbidity	Difficulty
PA banding (PAB)	6.0	2	2.0	2.0	2.0
PA debanding	6.0	2	2.0	2.0	2.0
ECMO procedure	6.0	2	2.0	3.0	1.0
Aortic stenosis, subvalvar, repair	6.3	2	2.0	1.8	2.5
Shunt, systemic to pulmonary, modified Blalock–Taussig shunt (MBTS)	6.3	2	2.0	2.0	2.3
RVOT procedure	6.5	2	2.0	2.0	2.5
Valve replacement, pulmonic (PVR)	6.5	2	2.0	2.0	2.5
Shunt, systemic to pulmonary, central (From the aorta or to the main pulmonary artery)	6.8	2	2.0	2.0	2.8
Valvuloplasty, truncal valve	7.0	2	2.0	2.0	3.0
Anomalous systemic venous connection repair	7.0	2	2.0	2.0	3.0
Occlusion MAPCA(s)	7.0	2	2.0	2.0	3.0
Valvuloplasty, tricuspid	7.0	2	2.0	2.0	3.0
DCRV repair	7.0	2	2.0	2.0	3.0
Valve replacement, aortic (AVR), mechanical	7.0	2	2.0	2.0	3.0
Valve replacement, aortic (AVR), bioprosthetic	7.0	2	2.0	2.0	3.0
Atrial baffle procedure, Mustard or Senning revision	7.0	2	2.0	2.0	3.0
Aortic arch repair	7.0	2	2.0	2.0	3.0
Bidirectional cavopulmonary anastomosis (BDCPA) (bidirectional Glenn)	7.0	2	2.5	2.0	2.5
Glenn (unidirectional cavopulmonary anastomosis) (unidirectional Glenn)	7.0	2	2.5	2.0	2.5
Right/left heart assist device procedure	7.0	2	2.0	3.0	2.0
Hybrid approach "Stage 1," stent placement in arterial duct (PDA)	7.0	2	1.5	1.5	4.0
VAD implantation	7.0	2	2.0	3.0	2.0
VAD explantation	7.0	2	2.0	3.0	2.0
Ventricular septal fenestration	7.5	2	3.0	2.0	2.5
TOF repair, ventriculotomy, non-transanular patch	7.5	2	2.5	2.0	3.0
Valve replacement, Tricuspid (TVR)	7.5	2	2.5	2.0	3.0