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Ann Thorac Surg 2003;76:2230-2239

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Mechanical Heart Valves: 50 Years of Evolution

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The past 50 years have witnessed remarkable progress in the development of safe, hemodynamically favorable mechanical heart valves. Starr-Edwards aortic and mitral ball valves introduced in the mid-1960s, continue to be used successfully worldwide. More than 100,000 Omniscience and Omnicarbon tilting-disc valves have been implanted since 1978 with essentially no mechanical failure; similar results have been obtained with more than 300,000 Hall-Kaster and Medtronic-Hall tilting-disc valves over the past 25 years. Pyrolytic carbon, originally used to encapsulate nuclear fuel rods, has been adapted for the fabrication of discs, leaflets and the housings for more than 2 million mechanical valves. The St. Jude bileaflet valves, totally fabricated from pyrolytic carbon, have remained virtually unchanged in design since their introduction in 1977. More than 1.3 million of these valves have been implanted worldwide with virtually no reported failures of the carbon leaflets or housings. Similarly, pyrolytic carbon bileaflet Carbomedics valves have been implanted in more than 500,000 patients since 1986. Now, 50 years after Dr Gibbon’s seminal achievement, patients with debilitating valve disease can have elective valve replacement (mechanical or tissue) with an operative mortality approaching 1% to 2% and a low lifetime complication rate.

(Ann Thorac Surg 2003;76:S2230–9)
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When Dr John Gibbon, Jr, performed the first successful closure of an intracardiac defect on May 6, 1953 with his heart-lung machine, he could not have imagined the remarkable achievements that would occur in the specialty of cardiac surgery over the next 50 years. This symposium documents many of those achievements in the area of cardiopulmonary bypass, congenital heart disease, coronary artery disease, and the development of mechanical heart valves. In 1952, just 1 year before Dr Gibbon’s successful closure of an atrial septal defect, Dr Charles Hufnagel implanted a caged ball valve in the descending thoracic aorta in a patient with aortic valve disease. A valve placed in this location would, of course, provide no benefit to a patient with aortic stenosis and only minimal benefit to patients with aortic insufficiency. Remarkably, within 7 years after Dr Gibbon’s first successful case, Dr Dwight Harken was able to implant a caged ball valve in the subcoronary position in a patient with aortic stenosis. Since Dr Harken’s first successful valve implantation in 1960, there have been more than 70 different types of prosthetic valves and a number of different tissue valves implanted in hundreds of thousands of patients throughout the world. In the early days of mechanical valve implantation, the operative mortality reached as high as 15% to 20%. Today, on the 50th anniversary of Dr Gibbon’s seminal achievement, operative risk for valve replacement in most heart centers of the world is less than 2%, and the complication rates of thromboembolism and endocarditis are extremely low.

Caged Ball Valves

Hufnagel Ball Valve

In 1952, Dr Charles Hufnagel, Professor of Experimental Surgery at Georgetown Medical Center in Washington, DC, implanted the ball valve depicted in Figure 1 and briefly described in Table 1a. In the late 1940s, Dr Hufnagel experimented in an animal preparation with methacrylate tubes for arterial replacement; this led to animal implants with a ball valve similar to that depicted in Figure 1 [4]. The methacrylate chamber containing the methacrylate ball could be inserted in the descending
Harken-Soroff Ball Valve

Doctor Hufnagel had worked in Dr Dwight Harken’s laboratory at the Peter Brigham Hospital on his chambered ball valve. With the development of the heart-lung machine and the opportunity to work within the open heart, Dr Harken working with Mr W. C. Birtwell at Davol, Inc, developed a ball valve with a double cage fabricated of stainless steel (Fig 1). Doctor Harken was concerned that the ball could impinge on the aortic wall and therefore he designed his valve with a second outer concentric cage. Remarkably, there were two survivors among the first seven patients, one of whom had an operation on March 10, 1960, and the other on June 6, 1960. Both required subsequent valve replacement, one at 3 years for a perivalvular leak and one at 22 years for bacterial endocarditis. Even though the silicone balls in these early Harken valves did not have the benefit of the “heat curing process” that would be developed in the mid 1960s, the silicone ball in the valve removed after 22 years appeared to have essentially no deterioration.

Starr-Edwards Ball Valve

It was a fortuitous meeting in the late 1950s when a retired pump engineer, M. Lowell Edwards, presented his idea for a new heart valve to a young cardiac surgeon at the University of Oregon, Dr Albert Starr. The valve concept was a simple one: a design based on an 1858 wine bottle stopper. In early 1960, Mr Edwards fabricated a bulky valve with a Lucite cage (methacrylate) and a silicone elastomer rubber ball, which was implanted in a 52-year-old human with calcific mitral stenosis on September 21, 1960 [6]. This patient did well for 10 years, but unfortunately died in a fall from a ladder while painting his house. A total of three of these early Lucite valves were implanted in 1960; the Lucite cage design was replaced later that same year with a stellite metal cage.

The next 12 years witnessed the development of a remarkable series of ball valves from the Edwards Laboratories, culminating with the SE#1260 aortic valve and SE#6120 mitral valve, depicted in Figure 1 and further described in Table 1a. The evolution of the Starr-Edwards ball valves can be succinctly summarized by the four valves in Figure 2 [6]. This series of aortic valves commences with the aortic model #1000, introduced as the “pre-1000” model in 1961. With the SE#1200, the heavy stellite cage was streamlined and the Teflon fabric on the annular apron was extended to the valve orifice. Because the early silicone rubber balls tended to absorb lipids, which disposed them to early deterioration and variance, the SE#1250 valve was developed with a hollow stellite ball. This valve generated considerable noise and so the SE#2300 was introduced in 1967 with a total cloth covering of the struts. It soon became apparent that the stellite ball damaged the fabric on the struts. Consequently, in 1972, the so-called aortic “track valve” (SE#2400) was introduced; although this valve eliminated strut fabric wear, it was discontinued in 1980 and replaced by SE#1260, a modified version of SE1200 shown in Figure 2. By the time the aortic #1260 was introduced in 1968, the problem of silicone ball variance had been eliminated by heat curing the balls (after molding) at a relative high temperature for several hours. The SE#1260 with a heat-cured silicone elastomer ball has remained the primary Starr-Edwards aortic valve to the present time [7].

The Starr-Edwards mitral ball valves, commencing with #6000 (Table 1a), evolved in a similar manner as the aortic valves. The SE#6120 introduced in 1966 is still in production. To date, more than 250,000 Starr-Edwards valves of all types have been implanted worldwide with essentially no valve malfunction since the introduction of the postmold silicone rubber heat cure process in the mid 1960s.

It is true that the tilting disc valves and the bileaflet valves that appeared in the 1970s offered hemodynamically superior aortic valve function when compared with the Starr-Edwards prosthesis, but the extremely durable SE#6120 mitral valve still provides quite satisfactory hemodynamic function and continues to be used, particularly in third world countries because of its reasonable cost.

Magovern-Cromie Ball Valve

In the early 1960s, Dr George Magovern, Sr, Chief of Cardiothoracic Surgery at the University of Pittsburgh Medical Center, working with an engineer, Mr Harry Cromie, developed a ball valve that incorporated a unique method of sutureless fixation (Fig 1, Table 1b). This valve was inserted by rotating an implantation tool to engage the multiple vertical pins in the aortic annulus and was particularly suited for aortic implantation. In the early 1960s, when cardiopulmonary bypass was not as safe as it is today, the Magovern-Cromie valve had the
### Table 1a – Caged Ball Valves

<table>
<thead>
<tr>
<th>Valve and Date of First Implant</th>
<th>Valve Description</th>
<th>Date Production Ceased</th>
<th>Total Implants^1</th>
<th>Miscellaneous</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Housing – Ball</td>
<td>Ball Modified</td>
<td>A – Aortic</td>
<td>M – Mitral</td>
</tr>
<tr>
<td></td>
<td>Unique Design</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hufnagel 1952</td>
<td>Methacrylate – Silicone r.(^2) Sutureless fixation for cylindrical chamber</td>
<td>—</td>
<td>1956</td>
<td>A &gt; 200</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Placement in descending thoracic aorta</td>
</tr>
<tr>
<td>Harken-Soroff 1960</td>
<td>Stainless steel – Silicone r.(^3) Two concentric cages</td>
<td>—</td>
<td>1962</td>
<td>A &lt; 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>First clinical aortic ball valve (March 1960)</td>
</tr>
<tr>
<td>Starr-Edwards</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>First clinical mitral ball valve had Lucite cage and silicone rubber ball (September 1960)</td>
</tr>
<tr>
<td>A - #1260 (1968) M - #6120 (1966)</td>
<td>Bare metal cage</td>
<td></td>
<td></td>
<td>A ~ 80,000 M ~ 100,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Still in production</td>
</tr>
</tbody>
</table>

^1 All implant data are approximate.
^2 Hollow nylon ball coated with silicone rubber.
^3 Solid silicone rubber ball.
^4 Stellite is an alloy of cobalt, chromium, molybdenum and nickel.
^5 Silastic is Dow Corning’s proprietary silicone rubber.
^6 The heat cure technique was used for all silicone rubber poppets after 1965 to minimize poppet wear.

### Table 1b – Caged Ball Valves – cont.

<table>
<thead>
<tr>
<th>Valve and Date of First Implant</th>
<th>Valve Description</th>
<th>Date Production Ceased</th>
<th>Total Implants^1</th>
<th>Miscellaneous</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Housing – Ball</td>
<td>Ball Modified</td>
<td>A – Aortic</td>
<td>M – Mitral</td>
</tr>
<tr>
<td></td>
<td>Unique Design</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magovern-Cromie 1962</td>
<td>Titanium – Silicone rubber Sutureless mechanical fixation</td>
<td>Post-mold heat cure</td>
<td>1980</td>
<td>A ~ 7300 M &lt; 200</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Very durable valve after 1965 with heat cured silicone ball</td>
</tr>
<tr>
<td>Smeloff-Cutter 1966</td>
<td>Titanium – Silastic Double cage with equator-seating ball</td>
<td>Post-mold heat cure</td>
<td>1988</td>
<td>A ~ 72,000 M</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Double cage permits “full-flow” orifice</td>
</tr>
<tr>
<td>DeBakey-Surgitool 1967</td>
<td>Titanium – HMWP(^2) First valve to have pyrolyte poppet</td>
<td>Pyrolyte 1969</td>
<td>1984</td>
<td>A ~ 1200</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DC’d because pyrolyte ball eroded titanium struts</td>
</tr>
<tr>
<td>Braunwald-Cutter 1968</td>
<td>Titanium – Silicone rubber Cage and annulus covered with Dacron fabric</td>
<td>Post-mold heat cure</td>
<td>1979</td>
<td>A ~ 5,000 M</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>DC’d because of significant ball and strut-fabric wear</td>
</tr>
</tbody>
</table>

^1 All implant data are approximate.
^2 High molecular weight polyethylene.
distinct advantage of permitting rapid placement into the aortic annulus.

In 1989, Dr Magovern reported on his 25-year experience with the Magovern-Cromie aortic valve [8]. His valve was implanted in 728 patients between 1962 and 1988; ball variance occurred in 14 patients (2%), and necessitated 12 reoperations with two deaths. Just as with the Starr-Edwards valves, ball variance was virtually eliminated in the mid 1960s with the postmold heat cure process.

Production of the Magovern-Cromie ball valves ceased in 1980, although Dr Magovern continued to implant this valve for several more years.

**Smeloff-Cutter Ball Valve**

This ball valve was the first prosthetic valve to employ the “full-flow” orifice concept. This was achieved by a double set of cages permitting the silicone elastomer ball to rest on the smaller inflow cage during valve closure. Development of this valve commenced in 1963 as a joint effort between Drs Edward Smeloff and two professors of mechanical engineering at California State University in Sacramento. After the implantation of a few of these Smeloff valves, commercial manufacture and sales were transferred to Cutter Laboratories in Berkeley, California, in 1966. Doctor Smeloff summarized the worldwide experience with his valve at the 1989 World Congress on Valve Replacement in San Diego in 1989 [9]; in this paper, he reported that more than 50,000 Smeloff-Cutter valves had been implanted worldwide and there had been no structural failures during 22 years of use.

**DeBakey-Surgitool Ball Valve**

This valve was developed by Dr Michael DeBakey and Harry Cromie of Surgitool and was introduced in 1967. In 1969, the polyethylene poppet was replaced with a hollow pyrolytic carbon poppet. This was the first use of a new carbon material developed by Dr Jack Bokros at the General Atomic Company in La Jolla, California. The pyrolyte ball was intended to limit ball variance; unfortunately the relatively hard ball and soft titanium cage led to strut wear and some instances of strut fracture [10].

**Braunwald-Cutter Ball Valve**

After completing her general surgery training at New York Bellevue Hospital, Dr Nina Braunwald worked as a surgical fellow in Charles Hufnagel’s laboratory at Georgetown Medical Center. At the completion of her surgical residency, Dr Braunwald joined the cardiothoracic surgery staff at the National Heart Institute in Washington, DC, where she and Dr Andrew Morrow developed a flexible polyurethane-Dacron fabric mitral valve prosthesis with attached Teflon-tape chordae tendineae [11]. This valve was first used clinically on March 11, 1960. Doctor Braunwald noted that the fabric was infiltrated by fibrous connective tissue and she speculated that applying fabric to the metal cage of a ball valve might reduce thrombus formation.

Doctor Braunwald worked jointly with the Cutter Laboratories to develop a cloth covered caged ball valve (Fig 1). The struts were covered with a knit Dacron tubing and the inflow ring with an ultrathin polypropylene mesh fabric. Clinical use of this prosthesis commenced in 1968 and initial results were very good with a low incidence of valve-related problems. However, in 1977, after several years of clinical use, there were literature reports of fabric wear and silicone poppet abrasion in aortic valves leading to poppet escape [12]. Production of the Braunwald-Cutter valve ceased in 1979.

**Pyrolytic Carbon for the Fabrication of Prosthetic Heart Valves**

The fabrication of a hollow ball of pyrolytic carbon (pyrolyte) for the DeBakey-Surgitool valve in 1969 by the materials engineer Dr Jack Bokros was a landmark in mechanical valve development [13]. Bokros’ pyrolytic carbon, originally developed for the encapsulation of nuclear fuel rods, would become over the next decade, the principal biomaterial for virtually all new mechanical valves [14].

The senior author (VLG) and Ronald Daggett, Professor of Polymer Engineering at the University of Wisconsin, developed the Gott-Daggett bileaflet valve (see Fig 5 and Table 4) with a heparinized carbon coating [15]. This graphite-benzalkonium-heparin (GBH) coating was developed somewhat serendipitously and was first described in 1963 [16, 17]. Doctor Bokros, who was carrying out his carbon research at General Atomic, read our paper and contacted the senior author about the possibility of our binding heparin to his pyrolytic carbon. We
found that Dr Bokros’ highly polished pyrolytic carbon
would not bond heparin, but in our canine in vivo
screening test, the Bokros material proved to be the most
thromboresistant, nonheparinized material we had eval-
uated. Encouraged by our findings, Bokros subsequently
developed the ball poppet for the DeBakey-Surgitool
valve and the discs and leaflets for virtually all mechan-
ical valves developed over the next 30 years.

Non-Tilting Disc Valves

Kay-Shiley Disc Valve

The Kay-Shiley disc valve was the result of a productive
 collaboration between Dr Jerome Kay, Professor of Car-
diac Surgery at the University of Southern California
Medical Center, and a valve engineer, Mr Donald Shiley
(Table 2). Together, they designed the first disc valve that
achieved worldwide use beginning in 1965 (Fig 3). This
was a reliable mitral prosthesis that utilized a stellite
housing and a flat silicone elastomer disc [18]. Unfortu-
nately, there were problems with wear of the silicone
elastomer disc and it was replaced with a Delrin polymer
disc in 1975. Valve durability was markedly improved
with the Delrin disc and approximately 12,000 of these
Kay-Shiley valves were implanted worldwide in the
mitral and tricuspid areas.

It should be pointed out that Dr Kay modified the
standard Kay-Shiley valve by adding a muscle-guard to
prevent disc impingement by the left ventricular wall.
The Kay-Shiley valves with the muscle-guard was used
primarily by Dr Kay and was not widely used by other
surgeons.

Beall-Surgitool Disc Valve

In the mid-1960s, Dr Arthur Beall of the Baylor College of
Medicine in Houston, collaborated with Mr Howard
Cromie of Surgitool to develop a Teflon disc valve.
During the first 10 years of this valve’s clinical existence,
there were five design changes [19]. Initially, the annular
apron was covered with a velour fabric; however, the
Teflon disc tended to notch on the parallel struts, so a
pyrolyte disc was substituted in 1971. Almost 5,000 of
these mitral valves were implanted, but production was
discontinued in 1985 because of fabric wear on the
annular apron.

Cooley-Cutter Biconical Disc Valve

In the late 1960s, Dr Denton Cooley, Surgeon-in-Chief at
the Texas Heart Institute, in collaboration with valve
engineers at Cutter Laboratories, developed a nontilting
disc valve with a biconical silicone rubber poppet. Based
on the success of the earlier Smeloff-Cutter ball valve
with a double set of struts and “full-flow orifice,” the
Cooley-Cutter valve was designed with a double set of
struts and an equator-seating disc [20]. The silicone disc
was replaced with a pyrolyte disc in 1973 (Fig 3) and

Table 2 – Non-Tilting Disc Valves

<table>
<thead>
<tr>
<th>Valve and Date of First Implant</th>
<th>Valve Description</th>
<th>Date Production Ceased</th>
<th>Total Implants</th>
<th>Miscellaneous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kay – Shiley 1965</td>
<td>Stellite – Silastic Housing also made with muscle-guard</td>
<td>Delrin 1975</td>
<td>M ~ 12,000</td>
<td>One of most widely used mitral valves (1965 – 1980)</td>
</tr>
<tr>
<td>Beall – Surgitool 1967</td>
<td>Titanium – Teflon Flat-disc valve with fabric on disc-apron</td>
<td>Pyrolyte 1971</td>
<td>M ~ 4800</td>
<td>DC’d because of fabric wear on disc-apron</td>
</tr>
</tbody>
</table>

1 All implant data are approximate.
2 Muscle-guard designed as barrier between valve disc and ventricular wall.
3 Biconical pyrolyte poppet replaced silicone rubber poppet.

Fig 3. Three landmark non-tilting disc valves.
approximately 3000 of these valves were implanted through the late 1970s.

Tilting Disc Valves

Bjork-Shiley Flat Disc Valve

In the late 1960s, Dr. Viking Bjork, Chairman of the Department of Surgery at the Karolinska Institute in Stockholm, commenced collaboration with Donald Shiley in the development of a tilting disc valve (Table 3). Initially, the disc was constructed of Delrin polymer; it was later determined that Delrin absorbs water, which changes the configuration of the disc. The Delrin disc was therefore replaced with a pyrolyte disc in 1971 (Fig 4). This so-called flat-disc Bjork-Shiley valve (also designated as standard or spherical disc valve) was extremely successful worldwide, with nearly 300,000 aortic and mitral prostheses implanted between 1969 and 1986 [21].

Bjork-Shiley Convexo-Concave Tilting Disc Valve

In an effort to provide a larger flow-through orifice on the backside of the open disc, it was elected to reconfigure both the stellite housing and the pyrolyte disc. By making a concave pyrolyte disc and modifying the inlet and outlet struts, the disc could slide forward and down about 2 mm, thus achieving the desired enlargement of the lesser valve orifice.

The first Bjork-Shiley valve with a convexo-concave tilting disc (BSCC) was implanted in 1975 but within a few years there were reports of an inordinate number of fractures at the weld site of the small C-shaped outfl

Table 3 – Tilting Disc Valves

<table>
<thead>
<tr>
<th>Valve and Date of First Implant</th>
<th>Valve Description</th>
<th>Date Production Ceased</th>
<th>Total Implants</th>
<th>Miscellaneous</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bjork-Shiley (Flat-disc) 1969</td>
<td>Stellite – Delrin</td>
<td>1971</td>
<td>A ~ 157,000</td>
<td>Excellent performance and durability</td>
</tr>
<tr>
<td>(Convexo-concave disc) 1975</td>
<td>Stellite – Pyrolyte</td>
<td>1975</td>
<td>A ~ 46,000</td>
<td>DC’d because of strut fracture in &lt;2% of pts</td>
</tr>
<tr>
<td>Lillehei-Kaster 1970</td>
<td>Titanium – Pyrolyte</td>
<td>1970</td>
<td>A ~ 29,000</td>
<td>One of first valves with pyrolyte poppet</td>
</tr>
<tr>
<td>Omni-Science 1978</td>
<td>Titanium – Pyrolyte</td>
<td>1978</td>
<td>A ~ 72,000</td>
<td>Curvilinear pyrolyte disc</td>
</tr>
<tr>
<td>Omni-Carbon 1984</td>
<td>Pyrolyte – Pyrolyte</td>
<td>1984</td>
<td>A ~ 17,000</td>
<td>All pyrolyte valve</td>
</tr>
</tbody>
</table>

1 All implant data are approximate.
strut. In 1989, Bjork and colleagues published a paper [22] stating that the early-production models of their 29-, 31-, and 33-mm BSCC heart valves constituted a subgroup with a higher risk of outlet strut fracture. They determined that the 7-year actuarial incidence of mechanical failure among these valves was 12%; they suggested that patients with these larger valves be considered for prophylactic replacement. Because of this problem, production of both the flat-disc and the convexo-concave disc Bjork-Shiley valves ceased in 1986; by then approximately 86,000 of these valves had been implanted.

As of December 2002, outlet strut failure had been reported in approximately 640 patients with BSCC valves worldwide. It is estimated that approximately 30% of these patients are alive after urgent valve replacement (personal communication with the Bowling Supervisory Panel for Bjork-Shiley convexo-concave disc valves, April 2003). As a result of a 1992 class-action settlement, patients with large (29- to 33-mm) BSCC valves who are at high risk for outlet strut rupture (male, age greater than 50 years, mitral location, and specific valve weld dates) may qualify for financial reimbursement for valve replacement surgery. To date, approximately 130 patients have received financial compensation under this settlement agreement.

Although it was initially thought that the problem with outlet strut rupture was related only to faulty welding of the outlet strut, a careful engineering analysis has shown that with the large-diameter BSCC valves there can be inappropriate “leverage loading” on the center of the small outlet strut during leaflet closure.

It was unfortunate that a minor design change to improve ejected blood flow through the “lesser orifice” behind the disc led to a higher rate of mechanical failure. Ironically, a monostrut tilting-disc Bjork-Shiley valve with no welded struts introduced in 1983 and only sold overseas, had no reported structural failures in more than 100,000 patients [23].

Lillehei-Kaster Tilting Disc Valve
Robert Kaster received an electrical engineering degree at the University of Minnesota in 1951 and became interested in prosthetic valve development while working in Dr C. Walton Lillehei’s laboratory. He designed the tilting disc valve shown in Figure 4, which has a distinctly different disc-containment configuration than earlier tilting disc valves. The flat disc of the Lillehei-Kaster valve is retained during valve opening by two prominent side-prongs. Mr Kaster believed that the ideal disc material was pyrolyte carbon and worked with Jack Bokros on the fabrication of a flat disc for his valve. Approximately 55,000 Lillehei-Kaster valves were commercially produced by Medical Incorporated in Minneapolis and implanted through 1987 [24]. In December 1987, Medical Incorporated ceased distribution of the Lillehei-Kaster valve because the Food and Drug Administration required that prosthetic valves marketed before the 1976 Medical Device Amendment undergo the regulatory approval process. By this time Medical Incorporated already had approval to market the Omniscience valve and to export the Omnicarbon valve described below.

Omniscience Tilting Disc Valve
Robert Kaster further modified the Lillehei-Kaster valve by markedly reducing the profile of the prominent prongs on the valve housing. Also, the flat disc of the Lillehei-Kaster valve was given a slight curvilinear profile in the Omniscience valve. The Omniscience valve is still in production and has nearly 100,000 implants [25].

Omnicarbon Tilting Disc Valve
The Omnicarbon valve manufactured and distributed by Medical CV, Inc, is nearly identical to the Omniscience valve, but has a pyrolyte housing rather than the titanium housing of the earlier valve [26]. Both the Omniscience and Omnicarbon valves have demonstrated remarkable durability with essentially no valve failures.

Hall-Kaster and Medtronic-Hall Tilting Disc Valves
The Hall-Kaster valve was first implanted in 1977 and was jointly developed by Dr Karl Victor Hall, Chairman of the Department of Surgery at the Rikshospitalet in Oslo, Norway, and Robert Kaster. This valve utilized a unique tilting pyrolyte disc with a small central perforation for a thin metal strut that guides the disc during opening and closing (Fig 4). The Hall-Kaster valve was widely used throughout the world. In 1987, after minimal engineering modification, the valve manufacture and distribution was assumed by Medtronic, hence the name change [27]. To date, more than 300,000 Hall-Kaster and Medtronic-Hall valves have been implanted worldwide with no reports of structural failure.

Bileaflet Valves

Gott-Daggett Bileaflet Valve
The Gott-Daggett bileaflet valve (Table 4) was described earlier in the section on the development of pyrolytic carbon. It was implanted in approximately 500 patients in both mitral and aortic positions with relatively good clinical results. The main purpose of the bileaflet design (Fig 5) was to provide a lower profile than the bulky caged-ball valves that were available in the early 1960s. The valve had one disadvantage: there was relatively stagnant blood flow in the area of the superstrut used to capture the flexible leaflets. This area was occasionally the site of thrombus; however, we are not aware of any clinical episodes of thromboembolism. For this reason, we took this valve off the market in 1966; a number of patients with this valve were followed for more than 25 years and deterioration of the flexible silicone-coated Teflon leaflets was not observed [28].

Kalke-Lillehei Bileaflet Valve
Doctor Bhagabant Kalke came from India to work in Dr Lillehei’s laboratory in 1964. Doctor Kalke had grown up on the west coast of India and was familiar with the
passive tidal floodgates that opened with the outgoing tide and closed with the incoming tide to protect shoreline crops. Doctor Kalke fabricated a polymer valve in Dr Lillehei’s laboratory based on the configuration of the Indian tidal floodgates with peripheral hinging leaflets and a central opening. As this configuration did not work well, he placed the pivot sites for the two rigid leaflets at the equator of the annular ring. The initial Kalke valve was designed with an overriding semicircular strut to prevent leaflet migration. Robert Kaster was also working in Dr Lillehei’s laboratory at that time, and he was able to design a pivot mechanism for the two leaflets so that the overriding strut could be removed. Only a few of these Kalke-Lillehei valves were fabricated by Harry Cromie (Surgitool Company, Pittsburgh, PA). One of the Kalke-Lillehei valves was implanted on May 20, 1968, in a woman with advanced rheumatic mitral disease [29]. Postoperatively, her condition was initially satisfactory for 24 hours but she developed low cardiac output and died 48 hours postoperatively. At autopsy, it was not possible to determine the cause of death. Mr Kaster has indicated that no further Kalke-Lillehei valves were implanted because he and Mr Cromie, along with Drs Lillehei and Kalke, believed that they did not have suitable biomaterials for fabrication of further valves (personal communication with Mr Robert Kaster).

**St. Jude Medical Bileaflet Valve**

Although the original St. Jude Medical bileaflet valve implanted in 1977 looks very similar to the Kalke-Lillehei valve, it was not a “direct descendant” of the Kalke valve...
(personal communication with Mr Manny Villafana). The primary facilitator of the development of the St. Jude Medical valve was Mr Manny Villafana, founder of Cardiac Pacemakers, Inc. In 1976, Xinon (Chris) Posis, an industrial engineer, designed a prototype of a bileaflet valve with the pivots near the periphery and a central opening. Mr Posis obtained additional suggestions for his design from Dr Demetre Nicoloff, a cardiovascular surgeon at the University of Minnesota. Posis and Nicoloff showed their prototype valve to Manny Villafana who felt the peripheral hinges would not be suitable. Subsequently, Mr Posis along with another engineer, Donald Hanson, redesigned the valve with the hinge mechanism located near the central axis of the housing. It was Mr Villafana’s idea that the entire valve be fabricated of Jack Bokros’ pyrolytic carbon, which had been widely adapted for most monoleaet valves in the 1970s. Working with Jack Bokros, the engineers Posis and Hanson modified the initial pivot mechanism and came up with the concept of a lealet-tab rotating in a “butterfly recess” in the inner wall of the housing. Doctor Nicoloff implanted the first St. Jude valve on October 3, 1977. Doctor Nicoloff was invited to become the medical director of the new St. Jude Medical valve company, but because of the demands of his clinical practice he declined this position. He suggested that Dr C. Walton Lillehei become the medical director, a position Dr Lillehei held until his death in 1999. Remarkably, the original design of the St. Jude valve implanted in 1977 has remained virtually unchanged over the past 26 years. There have been changes in the sewing ring over the years, and the Regent valve introduced in 1999 incorporates a housing design that significantly improves the orifice size of smaller aortic prostheses. With more than 1.3 million St. Jude valves implanted, it is the most widely used prosthetic valve in the world [30].

Carbomedics Bileaflet Valve

As mentioned in the section on the development of pyrolytic carbon, Jack Bokros fabricated most of the monoleaets for valves developed in the 1970s; he also helped to design and did fabricate the first St. Jude valves. In 1979, Dr Bokros organized the Carbomedics Company in LaJolla, California, which he subsequently moved to Austin, Texas. Over the ensuing years, Carbomedics fabricated pyrolytic components (partial and complete) for more than 2 million valves manufactured by 14 valve companies worldwide. By 1993, St. Jude Medical fabricated all carbon parts for their valves.

In 1986, Dr Bokros created the Carbomedics bileaflet valve, which was similar to the St. Jude valve, but its housing could be rotated within the sewing ring. Also in 1993, Carbomedics commenced distribution of its Top Hat supraannular aortic valve with a design particularly suitable for the small aortic root [31]. To date, more than 500,000 Carbomedics valves have been implanted.

Doctor Bokros and Mr Villafana would go on to develop new valve companies and new bileaflet, pyrolyte valves (On-X and ATS respectively). Unfortunately, space does not permit discussion of these two new valves.

Conclusion

Remarkable progress has been made over the last 50 years in the development of mechanical heart valves. Much of that progress has come about by simple trial and error and certainly some has resulted from unexpected fortuitous events. It is remarkable that two of the six mechanical heart valves currently available for implantation in the United States (the Starr-Edwards ball valve and the St. Jude Medical bileaflet valve) are virtually unchanged from the original models implanted in 1965 and 1977, respectively. Four other mechanical valves approved for implantation in the United States (Omniscience, Omnicarbon, Medtronic-Hall, and Carbomedics valves) have been in use for more than 16 years with essentially no mechanical failures. Pyrolytic carbon, a compatible and virtually indestructible biomaterial that has been adapted from the nuclear fuel industry, has enabled much of the progress. There will always be room for improvement in mechanical valves. Eventually, with the right valve design and the right valve material, it is conceivable that we may someday have a mechanical valve that does not require lifelong anticoagulation therapy.

This study was supported by the Dana and Albert “Cubby” Broccoli Center for Aortic Diseases at The Johns Hopkins Medical Institutions and by the Mildred and Carmont Blizt Cardiac Research Fund. We wish to thank Ms Eileen Wright and Ms Barbara Dobbs for their assistance in preparing our manuscript. We would like to thank the following surgeons, engineers, and valve production individuals for providing much of the historical information and implant data for the mechanical valves described in this paper. These persons are listed with the specific mechanical valves with which they are associated. Starr-Edwards valves (Edwards Lifesciences): Dr Albert Starr, Ms Laura Brooks, and Ms Cindy Fessler. Magovern-Cromie valves, DeBakey-Surgitool valves, Beall-Surgitool valves, Kalke-Lillehei valves (Surgitool, Inc): Dr George Magovern, Sr, Mr Harry Cromie, and Mr Robert Kaster. Smeloff-Cutter valves, Braunwald-Cutter valves, Cooley-Cutter valves (Cutter Labs, Inc): Drs Edward Smeloff and Denton Cooley. Kay-Shiley valves, Bjork-Shiley valves (Pfizer-Shiley Labs, Inc): Dr Jerome Kay, Mr Donald Shiley, Mr Bruce Fettel, and Dr Roger Sachs. Lillehei-Kaster valves, Omniscience valves, Omnicarbon valves (Medical Incorporated; Medical CV, Inc): Mr Robert Kaster and Ms Shelly Johnson. Hall-Kaster valves, Medtronic-Hall valves (Medtronic): Mr Robert Kaster. Gott-Daggett valves (Daggett Engineering, Inc): Mr Ronald Daggett. St. Jude Medical valves (St. Jude Medical): Dr Demetre Nicoloff, Mr Manny Villafana, Mr Terry Shepard, and Ms Mary Kay Keers. Carbomedics valves and all valves with pyrolytic carbon components (Carbomedics): Dr Jack Bokros and Mr R. E. Phillips.

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