Class: Four
Subject: Mechanics of Artificial Organs 2
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Lecture # 6

The Design of Heart Valves / Part 2

1. Valve Descriptions

A heart valve functions as a check valve, opening to permit forward blood flow and closing to prevent retrograde flow, about 40 million times per year. Heart valve prostheses consist of an orifice, through which blood flows, and an occluding mechanism that closes and opens the orifice. There are two fundamental approaches to valve design: mechanical prostheses with rigid manufactured occluders, and biological prostheses (also called tissue valves) with flexible leaflet occluders of animal origin. The latter category includes replacement valves of human origin.

2. Mechanical Valves

The type of a mechanical valve is designated by its occluder: a ball, a circular disk, or two semicircular leaflets (bileaflet). For ball and disk valves, the occluder is guided and retained by structural members call struts attached to the orifice. The combination of orifice and struts is referred to as the valve housing. For bileaflet valves, the leaflets are retained and guided by a hinge or pivot mechanism: Projections of the leaflets fit into indentations or sockets in the housing, which serve to retain the leaflets and define their limits of travel.

It will not be out of place to quickly look into the materials that were used over the years in different heart valve designs (Table 1).

Table 1: Summary of the material composition of nine key designs of mechanical valves developed over the course of 30 years

Year	Name	Type	Poppet	Material
1959	Hufnagel	Ball	Polypropylene	Methacrylate
1964	Starr–Edwards 1000	Ball	Silastic	Stellite
1968	Wada–Cutter	Tilting disk	Teflon	Titanium
1969	Bjork–Shiley	Tilting disk	Delrin	Stellite
1970	Lillehei–Kaster	Tilting disk	Pyrolitic carbon	Titanium
1971	Bjork–Shiley	Tilting disk	Pyrolitic carbon	Stellite
1977	Medtronic–Hall	Tilting disk	Pyrolitic carbon	Titanium
1977	St Jude Medical	Bileaflet	Pyrolitic carbon	Pyrolitic carbon
1991	Jyros	Bileaflet	Vitreous carbon	Vitreous carbon

The most commonly used materials include

Stainless steel alloys (316L SMo)—for cage

Molybdenum alloys (Co-Cr-Mo)—for cage

Pyrolitic carbon for the valve housings and leaflets

Silicone, Teflon®

Polyester (Dacron®) for sewing rings.

3. Caged Ball Valve

The first clinically successful heart valve was the Starr–Edwards caged ball valve introduced in 1960. The valve underwent several slight design modifications for five years, resulting in the model currently used. The ball is a silicone rubber polymer impregnated with barium sulfate for radio-opacity. The cobalt-chromium alloy struts are joined at the apex to form a cage (Fig. 1). When the ball opens by moving to the end of its cage, it creates a circular primary orifice and a ring-shaped secondary orifice between the ball and the

housing. In the aortic position, there is a tertiary orifice between the equator of the ball and the aorta (Fig. 1).

Figure 1: Starr–Edwards mitral caged ball valve (courtesy of Baxter Edwards CVS)

4. Tilting Disk Valve

Tilting disk valves have separate projections into the orifice, either single arms or closed loops to retain and guide the disk-shaped occluder. Among the metals used for the housing are stainless steel and titanium. The disks are graphite with a coating of pyrolitic carbon. When the disk pivots to the open position, the primary orifice is separated into two areas, called the major and minor orifices (Fig. 2).

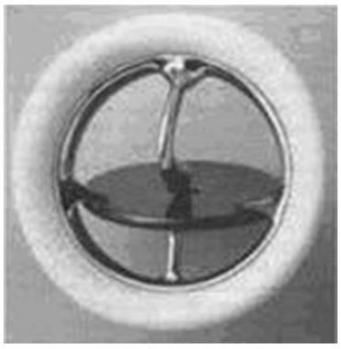

Figure 2: Medtronic Hall tilting disk valve (courtesy of Medtronic Heart Valve Division)

The Bjork–Shiley valve was the first successful tilting valve. It became available in 1971 with a carbon-coated disk and both struts (inflow and outflow) welded to the chromium alloy orifice. The Convexo-Concave model introduced in 1979 had an integral inflow strut to eliminate the few inflow strut fractures that had occurred with previous models. Sorin manufactured a tilting disk valve patterned after the Shiley valve disk, but with both struts integral to the housing to avoid the possibility of strut fracture. It is currently available with a pyrolitic carbon-coated sewing ring and entire housing.

The Medtronic Hall valve has a titanium housing machined from a solid cylinder and a thin carbon-coated disk with flat parallel sides (Fig. 2). The disk opens to 75° in the aortic model and 70° in the mitral. The disk is retained and guided by an S-shaped guide strut that protrudes through a central hole in the disk. Four structural elements project perpendicularly from the annulus into to the orifice: a guide strut and three pivot struts (one inflow, two outflow). The two inflow pivot struts starts from near the top (inflow) edge of the orifice toward each other; the disk sits on the flat triangular bottom surfaces of these struts. The Omniscience valve (Fig. 3) is a streamlined, elegant-looking valve. It has a curved pyrolitic carbon disk with no indentations, a one- piece titanium cage, and a seamless polyester knit sewing ring. The disk opens to 80° and closes at an angle of 12° to the plane of the orifice. It has been in use since 1978 but underwent a design change in 1981–1982 involving a significant modification of the sewing ring.

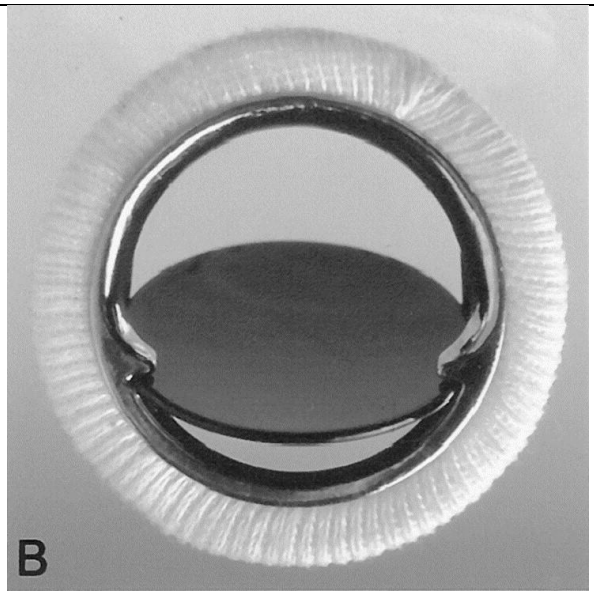

Figure 3: The Omniscience valve

5. Bileaflet Valves

The currently available bileaflet valves vary with regard to several design features. Although the features of the valves manufactured by St. Jude, Baxter, Carbomedics, Soren, ATS, and Medtronic are described here, clinical performance information is included only for the St. Jude valve, for which a large amount of long-term information is available. The two leaflets of a bileaflet valve swing apart during opening, resulting in three separate flow areas. The bileaflet valve housings are solid pyrolytic carbon over a graphite (titanium in the Sorin valve) substrate. All except the St. Jude and Sorin valves have stiffener rings to strengthen the housing, shield it from needles during implantation, and improve radiographic visualization (the Sorin valve has a titanium substrate, rather than graphite, which may confer some benefit). Since its first implant in 1977, the St. Jude bileaflet valve has been used half a million times. Previous bileaflet valves were unsuccessful, but the results with this

design, with pyrolitic carbon-coated housing and leaflets, introduced a new generation of mechanical prostheses. The housing of the valve included two rounded tabs, called pivot guards, that project out from the inflow side. The inside surfaces of these tabs contain the butterfly-shaped indentations that serve to retain the leaflets. The tabs containing the hinge sockets extend above the housing, whereas with the other bileaflet valves, the cavities in the housing containing the pivot recesses are located within the main body of the housing, approximately at the plane of the annulus. The leaflets open to 85° and swing through an arc of 55–60°, depending on the valve size, from fully closed to fully open (travel arc) (Fig. 4).

Figure 4: St. Jude bileaflet valve (courtesy of St. Jude Medical, Inc.)

The TEKNA valve (Baxter Edwards), originally called Duromedics, introduced several modifications to the bileaflet configuration. The leaflets are curved and translate slightly in the direction of flow as they open. Unlike other bileaflet valves, the leaflets sit on a lip or shelf molded into the housing. This seating design may reduce regurgitation and the possibility for suture entrapment but do so at the expense of an increase gradient and higher closing impact. In the

aortic model, the leaflets open to 77°, with a travel arc of 62°; these dimensions in the mitral model are 73° and 58°, respectively. The original Duromedics valve experienced some fractures of leaflets and housing; it was withdrawn from the market in 1988, reintroduced in 1990 as Carbomedics, the company that made pyrolitic carbon components, and in 1993 received the third marketing approval for a bileaflet valve in the United States. The Carbomedics bileaflet valve has flat leaflets that open 78–80°, with the resultant travel arc of 53–55°; it has a carbon-coated blood-contacting surface on the sewing ring.

6. Materials of Construction and Manufacture

Most artificial valves are made of titanium, graphite, pyrolytic carbon, and polyester. The titanium is used for the housing or outer ring graphite-coated with pyrolytic carbon is used for the bileaflets, and 100% pyrolytic carbon is used for the inner ring. The pyrolytic carbon is sometimes impregnated with tungsten so that the valve can easily be seen following implantation. The sewing cuff, used to attach the valve to the heart, is made out of double-velour polyester.

Titanium is used for its strength, low density, and biocompatibility. The outer rings are made from machined bar stock. Lock rings and wire, used to hold the cuff in place, are also made from titanium. The polyester comes in the form of tubes. The inner rings are made from 100% pyrolytic carbon using a fluidized bed process at another manufacturer. This material's atomic microstructure helps resist cracking, making it ductile. However, the processing method can still introduce micro cracks that must be detected.

The polyester cuffs are made by a sewing process that includes various looping, folding, and stitching steps. The manufacturing process therefore consists mainly of various assembly and inspection steps.

7. Assembly

The assembly of parts takes place in a clean room to avoid contamination. The leaflets are attached to the inner rings, which are then placed in the housing or outer ring. While this is being done, the sewing cuffs are being made. A special pressurized heating process is then used to form the cuffs around the valve, which is done at several hundred degrees.

8. Sterilization and Packaging

After the valves are assembled and tested, they are sterilized in a double-plastic container. Steam sterilization is used, which involves temperatures up to 132 °C (270 °F) for 15 min or more. To make sure the sterilization process is in order, a biological indicator is placed inside. If the indicator shows no growth of bacteria or other viable organisms, the valves and its packaging have been properly sterilized. Each plastic-encased valve is then packaged in a box for shipping.

9. Quality Control

Usually, all components are inspected visually, dimensionally, and functionally prior to assembly to make sure they meet specifications. The diameter of each ring is measured and assigned a size, which is then matched to the appropriate bileaflet to make sure they will fit together. High-power microscopic analysis is used to check components for scratches. In total, up to 50 inspections are made

during the assembly process. Proof testing is used to determine the structural quality of potentially flawed heart valves. In this method, a valve is loaded to a certain stress level using a special pressurization fixture to see if it will fail at this stress. During the stress test, acoustic emission technology is used to detect minute cracks that might go undetected so that these valves can be rejected. Then the valves are sterilized and packaged.

10. The Future

Blood clotting is still a problem with mechanical valves, and manufacturers continue to improve designs, sometimes using super-computing modeling tools, as well as surgical procedures. The shape of the orifice is being improved to reduce pressure losses, turbulence, and shear stresses. The flow area is maximized by using stronger materials, which minimizes the wall thickness. Tapering the sides of the valve pumps blood more efficiently. Operations are also being developed that only require an 8–10-cm (3–4-in.) incision instead of 12 in. (30 cm). Manufacturing efficiencies will continue to improve. Researchers are looking at making heart valves out of plastic material that are flexible and strong enough to perform satisfactorily over a long time.