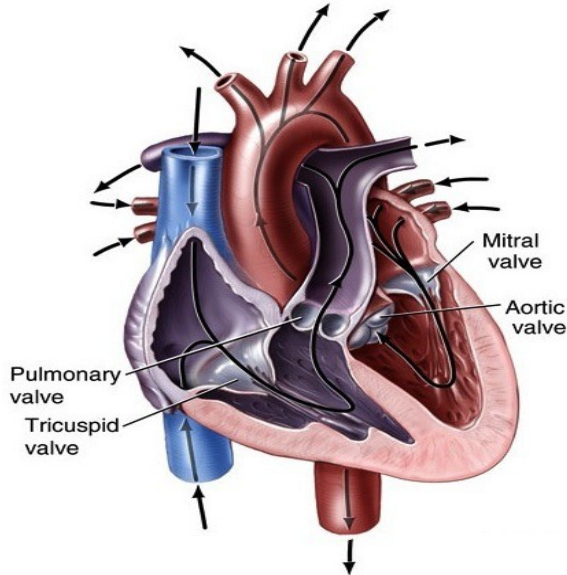


The Incident of the Bjork-Shiley Heart Valve

BME 462 Biomedical Instrumentation – Lecture Notes, by Ying Sun, 2012

Anatomy

The heart has four valves: the aortic valve and the mitral valve on the left side; the pulmonary valve and the tricuspid valve on the right side.



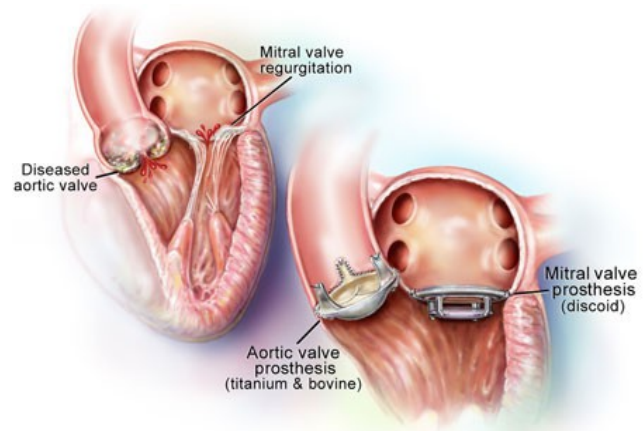
Valvular Diseases

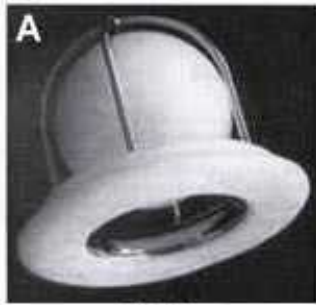
The valvular disease usually involves two conditions: valvular stenosis and valvular insufficiency. Valvular stenosis occurs when a valve opening is smaller than normal due to stiff or fused leaflets. The narrowed opening may make the heart work very hard to pump blood through it. This can lead to heart failure. All four valves can be stenotic (hardened, restricting blood flow); the conditions are called tricuspid stenosis, pulmonic stenosis, mitral stenosis or aortic stenosis. Valvular insufficiency, also called regurgitation, or incompetence, occurs when a valve does not close tightly. If the valves do not seal, some blood will leak backwards across the valve. As the leak worsens, the heart has to work harder to make up for the leaky valve, and less blood may flow to the rest of the body. Depending on which valve is affected, the condition is called tricuspid regurgitation, pulmonary regurgitation, mitral regurgitation or aortic regurgitation.

Causes of Valvular Diseases

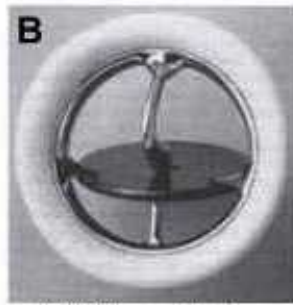
Valve disease can develop before birth (congenital) or can be acquired sometime during one's lifetime. Sometimes the cause of valve disease is unknown. Congenital valve disease most often affects the aortic or pulmonic valve. Valves may be the wrong size, have malformed leaflets, or have leaflets that are

not attached to the annulus correctly. Rheumatic fever is caused by an untreated bacterial infection (usually strep. throat). Luckily, the introduction of antibiotics to treat this infection has dramatically reduced the numbers of this infection. The initial infection usually occurs in children, but the heart problems associated with the infection may not be seen until 20-40 years later. At that time, the heart valves become inflamed, the leaflets stick together and become scarred, rigid, thickened and shortened. This leads to mitral regurgitation. Endocarditis occurs when germs, especially bacteria, enter the bloodstream and attack the heart valves, causing growths and holes in the valves and scarring. This can lead to leaky valves. The germs that cause endocarditis enter the blood during dental procedures, surgery, IV drug use, or with severe infections. People with valve disease (except mitral valve prolapse without thickening or regurgitation) are at increased risk for developing this life-threatening infection. There are many changes that can occur to the valves of the heart. The chordae tendineae or papillary muscles can stretch or tear; the annulus of the valve can dilate (become wide); or the valve leaflets can become fibrotic (stiff) and calcified. Mitral valve prolapse (MVP) is a very common condition, affecting 1 to 2 percent of the population. MVP causes the leaflets of the mitral valve to flop back into the left atrium during the heart's contraction. MVP also causes the tissues of the valve to become abnormal and stretchy, causing the valve to leak. The condition rarely causes symptoms and usually doesn't require treatment. Other causes of valve disease include: coronary artery disease, heart attack, cardiomyopathy (heart muscle disease), syphilis (a sexually transmitted disease), hypertension, aortic aneurysms, and connective tissue diseases. Less common causes of valve disease include tumors, some types of drugs and radiation.

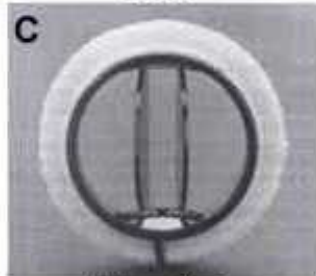




Ball



Tilting disk



Bileaflet



Porcine valve



Bovine valve

**Currently
Used Artificial
Heart Valves**

Currently there are at least five types of prosthetic heart valves used clinically:

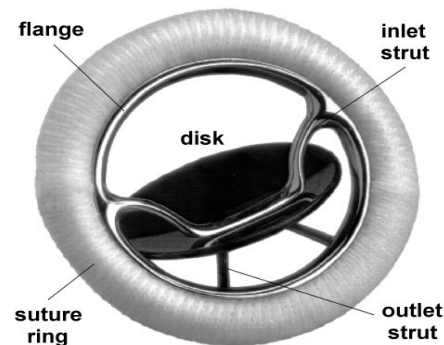
- A) Mechanical ball valves, such as the Starr-Edwards mitral caged ball valve.
- B) Mechanical tilting disk valves, such as the Medtronic Hall tilting disk valve.
- C) Mechanical bileaflet valves, such as the St. Jude bileaflet valve.
- D) Bioprosthetic valves from the pig, such as the D. Hancock porcine valve.
- E) Bioprosthetic valves from the ox or cow, such as the E. Carpentier-Edwards bovine pericardial valve.

The Bjork–Shiley Valve

The Bjork–Shiley valve is a mechanical heart valve prosthesis. Beginning in 1971, it has been used to replace the aortic or mitral valves. It marks the first example of a successfully used tilting-disc valve. It was manufactured first by Shiley Inc., then later by Pfizer after that company purchased Shiley. The Bjork valve consists of a single carbon-coated disc in a tantalum housing. The discs are held in place by two metal

struts, an inflow and an outflow strut. The standard design Bjork–Shiley valve is a very durable valve and was widely used in the 1970s. The housing is an alloy called Haynes 25 which is a chromium cobalt alloy. The Bjork-Shiley heart valve was the first successful example of a mechanical prosthesis with a tilting disk design. However, its plano-convex design was prone to thrombosis, so it was updated with an improved convexo-concave (CC) design that reduced the possibility of thrombus formation and sped up manufacturing. The CC valve was composed of a single carbon-coated disk, held in place by two metal struts, an inflow and an outflow, in a metal housing. The inlet strut was flush with the metal flange, but each end of the outlet strut was welded to it separately. It had an option of several flange sizes ranging from 21 mm- 33 mm and of an opening angle of 60 degrees or 70 degrees. The design was approved to market in 1979, but soon after, fractures of the outlet strut due to problems with welding began to be reported to the Food and Drug Administration (FDA). The model was subsequently withdrawn from the market in 1986.

Bjork-Shiley Convexo-Concave Valve



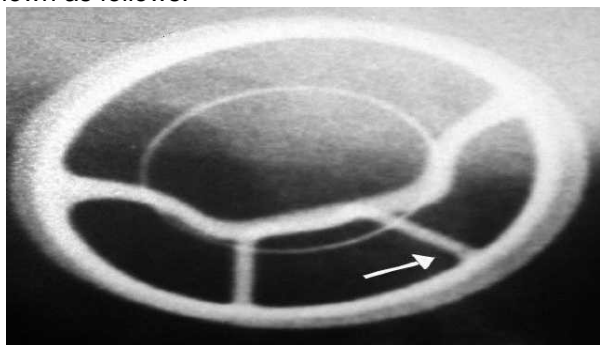
The BSCC valve was used to replace either the aortic or mitral valves. Changes in pressure up and down stream of the valve open and close the disk to regulate blood flow. The struts constrain the range of movement of the disc, allowing the disc to open to an angle of 60 or 70 degrees. The suture ring, made of Teflon, was sewn to the cardiac tissue to hold the valve in place. Though many of the BSCC heart valves fractured during trials, it was determined to be very effective for valve replacement, and was thus approved for market applications.

Device Failure

The cause of failure of these valves was determined to be fractures in the outflow strut, known as outlet strut fracture (OSF). One end of the strut would fracture first, followed generally within a few months by a fracture of the other end. Fracture occurred from brief impacts on the outlet strut

connections due to over-rotation of the disc closing with almost ten times the force of the disc opening. This created bending stresses beyond the strut's fatigue endurance limit that eventually caused fatigue-induced fracture after many occurrences of outlet tip overloading. Valve failure caused the disk to become free from the valve, so blood flow could no longer be regulated, leading to cardiac death if it was not detected in time. These fractures occurred during premarket trials and were assumed to be due to the strut welding. However, Shiley assured the FDA that these failures were flukes and that the lower risk of thrombus in the new design was much more significant than what was thought to be a small chance of OSF.

Even though the actual failure mechanism was still unknown, the FDA approved the device, relying on an "Honor System" and trusting the company to report any problems with the valves. As lawsuits began to be filed, Pfizer, the company that bought Shiley in 1979, insisted on secrecy agreements that restricted the release of important information to the FDA and doctors. Therefore, many patients continued to receive faulty valves even after the company was aware of the defects. An X-ray image of a valve with a complete fracture of the base of the outlet strut is shown as follows:



Another chest x-ray of a heart valve shows complete outlet strut fracture where the outlet strut has completely broken away from the flange and the disc is missing from the valve.



Recall

The BSCC valve was implanted in patients from April 1st, 1979 to November 1, 1986 when the FDA removed it from the market. Approximately 82,000 valves were implanted worldwide, with about 25,000 in the United States. There have been about 500 cases of fracture reported and about two-thirds of those have resulted in death.

Recall factors

After lawyers began taking depositions of Shiley employees in 1987, it was learned that paperwork was falsely filed during manufacturing. After searching through company documents, it was found that many valves were "rewelded" by a "phantom" employee # 2832. These were likely to have had cracks that were polished over by a worker during manufacturing, instead of being rewelded or discarded entirely.

In addition to specifics of manufacturing, the risk of OSF has been proven to be significantly greater in valves with certain specifications. Multiple studies have been done on patients with BSCC valves to determine which risk factors lead to the most failure events. From a study done in Europe in 1992 published in the British medical journal, the Lancet, the hazard ratio for mitral valves was found to be almost three times greater than that of aortic valves. A valve with an opening angle of 70 degrees is six times more likely to fracture than 60 degree valves. Large valves, of flange size greater than 29 mm, are nearly four times more likely to fracture than small valves that are less than 29 mm. Finally, the age of the patient at implantation had a significant effect on the possibility of fracture. Patients that were younger than 50 years old at the time of implantation have a hazard ratio that is two times that of patients who were older than 50 when they received a valve. This could be due to the higher cardiac performance and increased deceleration forces during closure in younger patients. In addition, younger patients will have the valve implanted for a longer period of time and thus have a greater cumulative risk of fracture over the course of their lifetime.

Failure symptoms

Fracture can still occur in any BSCC valve, therefore all patients with one or more of these valves should be familiar with the symptoms of a heart valve that is not functioning properly. If there is a fracture of the outlet strut, the normal clicking sound that occurs when the disc opens and closes will cease. Other symptoms are a sudden, sharp chest pain or a feeling of tight pressure that persists for more than a few minutes; sudden loss of consciousness, even if it is regained soon after; sudden, severe shortness of breath during normal activity; and a sudden, irregular

or rapid heart beat. If any of these symptoms are experienced, the patient is suggested to immediately consult a doctor where chest X-rays might be needed to view the state of the valve.

Diagnosics

When one end of the strut fractures first, it rubs against the housing of the valve and becomes smooth. There is then a short amount of time when fracture can be detected before the other end fractures. Failure then occurs, with one end of the loose outlet strut smooth and the other end jagged. It has been found that computer analysis of high resolution X-rays of the valve can be used to determine if one end of the strut has fractured, though this is an expensive technique that is not practical for use on the thousands of patients that still have these valves implanted. Shiley and Pfizer have created a group of scientists to better understand the mechanisms of OSF so that it can be detected in patients that still have the valve. They are working to discover and test acoustic and imaging methods to identify patients at risk of OSF, and to identify device, manufacturing, and, to a limited extent, patient factors that increase the likelihood of OSF. Finally, they are evaluating the clinical epidemiological risks versus benefits of removing the valve.

Deceit and Deception

In 1990 the FDA became aware of occurrences of fracture and requested that Shiley notify all patients who received CC valves of the problems. Shiley did not recommend surgery to replace the valve because the reoperative risk of replacing it was thought to be greater than that of fracture of the intact valve. After results from the study done in Europe were published, the FDA required Shiley to again notify all patients with CC valves, this time informing them of an increased risk of fracture depending on patient and valve specifications. Patients were advised to speak to their doctors, who were also notified of the new fracture figures, about valve replacement. Those who had smaller valves or were older were assured that the new data did not affect them.

In 1992, Pfizer Inc. and Shiley Incorporated negotiated a settlement with members of the Bowling class in the case called Arthur Ray Bowling, et al. v. Pfizer Inc., et al. Members of the Bowling class were defined as anyone who had received a BSCC valve. Guidelines were developed to determine whether someone qualified for monetary benefits from the Bowling Patient Benefit Fund for elective prophylactic valve replacement. They have been revised several times, with the most recent update in 2003. Patient-specific annual fracture rates must be estimated based on valve size, valve implant position, weld date, welder identity, valve shop order, and current patient age.

Operative mortality calculations are found based on actual BSCC reoperations and from similar studies of elective valve explanations. Open heart surgery has an average mortality rate of 5% in healthy patients. If the risk of fracture exceeds that of the risk of reoperation, the patient qualifies for monetary compensation for the surgery. This includes a lump sum payment of \$38,000 to cover out-of-pocket medical expenses plus reimbursement for lost income. Government claims with Shiley were resolved in a settlement in 1994, and the company paid \$10.75 million in fines and reimbursements for payments the government made for the BSCC valves. Shiley also agreed to pay up to \$10 million more for medical costs that the government incurred or would in the future due to fracture or elective replacement of valves. This agreement was made under the False Claims Act where Shiley made the following grievances:

- ⤴ falsely asserted that the CC valve caused fewer thrombosis events than other models;
- ⤴ falsely asserted that a series of manufacturing changes had corrected a serious design defect;
- ⤴ did not provide the FDA with all of the data it had concerning fractures during laboratory testing;
- ⤴ rebuilt scrap valves, rewelded valves an excessive amount of times, and polished cracked valve struts instead of rewelding them;
- ⤴ falsified employee identification numbers on over 3,000 reworked valves;
- ⤴ argued to keep the valve on the market even after fracture was noticed, claiming that the risk of fracture was outweighed by the decreased risk of blood-clotting.

The extent of the deceit that occurred is exemplified by the fact that Dr. Viking Bjork wrote to Pfizer demanding corrective action and threatened to publish cases of valve failures. A document found in 1980 revealed the response of a Pfizer executive: "Attn Prof. Bjork. We would prefer that you did not publish the data relative to strut fracture. We expect a few more."

Shiley allowed thousands of faulty valves to be implanted in patients worldwide who now must live every day wondering if their valve, or valves in the cases where patients had more than one implanted, will suddenly fracture inside them possibly causing death.

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