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Wear of Heart Valve Prosthesis

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1. INTRODUCTION

A variety of durability tests have been conducted for the heart valve prosthesis [1-3]. Several researchers [1, 4-11] have reported on its wear. The wear of the heart valve prosthesis is wear that occurs while using blood as a lubricant. The mechanical condition of the frictioning parts of the heart prosthesis vary appreciably depending on the valve constitution. The patterns of their movements are rather complicated. Thus, the analysis of the wear mechanisms of a heart valve prosthesis is not a simple task.

2. STRUCTURES OF HUMAN HEART VALVES

In the blood circulation loop of the human body, there are several valves whose job is to allow only one direction of blood flow; they inhibit a reverse flow. Among the valves possessing this function, the most important are those in the heart, whose major function is to circulate blood through the body by pumping. When the heart valve function is lost, it must be replaced by either a transplant or prosthesis. There are four valves in the human heart; the tricuspid valve (entry to right heart chamber), the pulmonary valve (exit of right heart chamber), mitral valve (entry to left heart chamber) and aortic valve (exit of left heart chamber). Each valve is composed of two to three pieces of cusp. One end of the cusp is attached to the wall of blood vessel. The free ends of the set of cusps that create a valve that meets at the center of the blood vessel to close the vessel. In the valve opening period, the free ends of the cusps separate. The vessel diameter of the valve also expands to ensure an efficient blood flow. The flow resistance at the valve during the opening period is very small. The free ends of the entry valves (tricuspid and mitral) are attached with chorda tendinea and papillary muscle to the inner heart wall on the downstream side. This inhibits the undesired bending of the free ends of the cusps toward the up-stream during the opening period. (Fig. 1).

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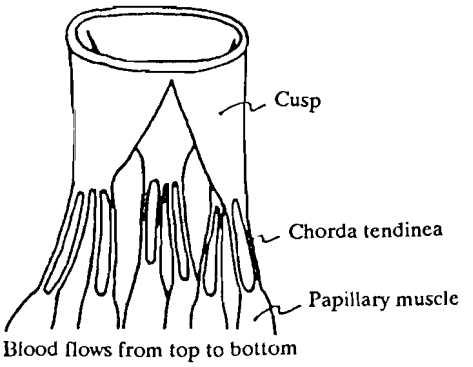

Fig. 1
Structure of tricuspid valve of human heart

3. MECHANICAL ENVIRONMENTS AROUND HUMAN HEART VALVES [12-14]

The average mechanical environment of the heart valves in an adult weighing 60 kg can be described as follows: the valve inside has a diameter = 2.5 cm at entry and 2.3 cm at exit, the blood flow = 5.5 *l*/min average with a cyclic fluctuation around 0.8 s due to the heart beat. The divisions of the 0.8 s period of heart movement are; 400 ms entry and 300 ms exit for the right heart chamber and 460 ms entry and 240 ms exit for the left heart chamber. These periods respectively correspond to the opening periods for the tricuspid, pulmonary, mitral and aortic valves. The rest of the heart beat period involves the total valve closure (constant-volume contraction and relaxation periods). The aortic valve has the shortest opening period of all the heart valves. The maximum instantaneous blood flow rate can reach as high as 30 *l*/min there. With a 0.8 s period cyclic movement, each heart valve repeats as many as 4×10^8 opening/closing motions in 10 years. With this in mind, it is easy to imagine how heavy the load is for human heart valves during a lifetime. The pumping pressure levels of the human heart are as follows; 3 ~ 7 mmHg for entry and 10 ~ 25 mmHg for exit in the right heart chamber, and 2 ~ 10 mmHg for entry and 70 ~ 120 mmHg for exit in the left heart chamber. Obviously, the pumping pressure is greater for the left heart chamber than that for the right chamber. Therefore, the reversal flow inhibiting function is more critical for valves in the left chamber than for those in the right chamber. Heart valve prosthesis cases deal almost exclusively with left heart chambers. Malfunctions of valves in the right heart chamber cause a certain extent of blood entry pressure rise but do not lead to detrimental blood circulation problems.

4. PROPERTIES OF BLOOD

Blood passing through the heart valves have pH = 7.40 at 37 °C and contain particles such as red and white blood-cells and blood pletelets, organic substances such as proteins (fiblinogen, albumine, globuline), inorganic ions of Na^+, K^+, Ca^{++}, Mg^{++}, Cl^-,and HCO_3^- and water. About 45% of the blood volume is composed of particles whose major component is red blood-cells of a bicooncaave disk 8 μm diameter. Protein molecules possess different shapes; 70 × 5 nm ellipsoid for fiblinogen and 20 nm diameter sphere for β-lipo protein [15]. The density of the blood is 1.06 g/cm^3 and it has a viscosity coefficient of 6 cP (a value at shear rate greater than 50 s^{-1}; note that blood is a non-

Newtonian fluid). Taking into account the blood flow rates of the human heart summarized in the preceding chapter, the Reynolds number for blood around the valves in the human heart can be estimated to average 400 and have an instantaneous maximum of 2000. After passing through the lung, the arterial blood flows to the left heart chamber and the venous blood, which returns after circulating through the body, flows to the right heart chamber. The oxygen partial pressure in the left heart chamber is 95 mmHg and that in the right chamber is 40 mmHg. The CO_2 partial pressure in the left chamber is 40 mmHg and that in the right chamber is 45 mmHg.

5. HISTORICAL DEVELOPMENT OF TYPES AND MATERIALS OF HUMAN HEART VALVE PROSTHESIS [13]

Surgical human heart valve replacements were initiated in 1950s. A variety of valve types and materials have been tried. Some involve a prosthetic valve using cusps possessing a similar geometry to the natural ones, the transplant of chemically treated human aortic valve, animal (cow or pig) heart valves, the transplant of artificial cusps formed by using a bio-membrane, such as dura mater or pericardial membrane or polymeric material with sufficient deformability. Other types of prosthetic valves simulate the mechanical pumping function of heart. Fig. 2 depicts the structures of representative types of mechanical prosthetic heart valves and their typical failures. Table 1 summarizes the structural materials used for these mechanical prosthetic valves. The number of heart valve replacement operations in Japan in the past few years exceeds 1000 per year, worldwide they exceed 200,000 [16].

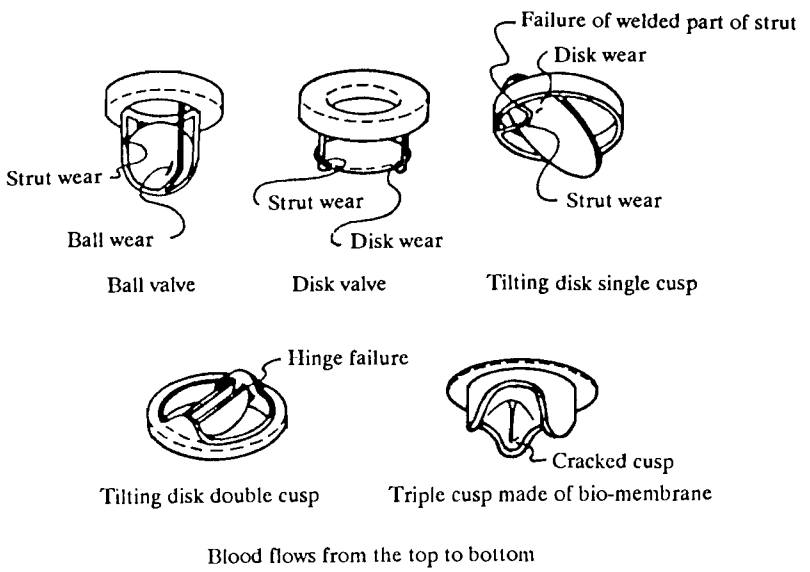

Fig. 2
Structures of representative mechanical prosthetic heart valves and their typical failures

Table 1
Typical materials used for mechanical prosthetic heart valves

Component	Materials
Ball	Nylon, silicon, hollow titanium, pyrolytic carbon
Disk	Silicon, poly 4-fluoro ethylene (TEFLON), poly acetal resin (DELRIN), graphite, pyrolytic carbon
Strut(Cage) and valve seat	Poly 4-fluoro ethylene, Co-Cr alloy, Co-Ni alloy, Re-Mo alloy, stainless steel, Ti alloy, pyrolytic carbon and these materials coated with polypropyrene
Sewing ring to the blood vessel	Poly 4-fluoro ethylene, polyester fiber

6. WEAR CASES REPORTED FOR PROSTHETIC HEART VALVES

The parameter values summarized in Table 2 are calculated on the basis of geometrical factors given in reports [1, 4-10] where wear cases of prosthetic heart valves were described in detail. The normal load on the frictioning surface was estimated from the pressure difference between the up-stream and down-stream sides of the valve [17] or from the maximum load on the strut of Björk-Shiley valve [18] measured by an in vitro simulating test. A specific wear range of $10^{-14} \sim 10^{-15} m^2/N$ is sufficient to cause wear problems for prosthetic heart valves. Table 2 cites wear test results for alumine ceramics using +-shape crossing rotating cylinder arrangement in a glycerine solution as the reference[11]. Those materials were used in double-cusp valve models. Porous ceramics (surface roughness = 70 μm) are expected to exhibit a compatibility with blood but the wear performance appears to be far from satisfactory. It must be remembered that the sliding motion of the frictioning surface in prosthetic heart valve components is not one-way but reciprocative. The frictioning distance values cited in Table 2 refer to the total distance of sliding in opposite directions except for the in vitro wear test for the ceramic rods. When the wear volume exceeded 1 mm^3, the desired function of the valve appeared to be lost. No problems caused by wear powders were reported. Probably the total volume of wear is too small to yield enough powder to cause this problem. Other reported cases of prosthetic heart valve problems include cloth wear due to frictioning between the titanium ball and valve seat and the strut coated with synthetic fiber [2], failure of the welded part between the seat and strut of the valve [19], and ball variance [4] and cracking [20] due to the penetration of fatty components of blood into the silicon ball. According to the survey for the Björk-Shiley valve [19], there have been 9 reported problems among 2102 aortic valves, 10 among 1140 mitral valves, 0 among 87 tricuspid valves and 0 among 5 pulmonary valves. Apparently, the prosthetic valves in the right heart chamber are trouble-free. As described earlier in Chapter 3, the extent of the pressure fluctuation in the right heart chamber is far smaller than that in the left chamber. This is why there is practically no wear trouble for prosthetic right chamber valves. There has been no significant reduction in the material strength due to low oxygen partial pressure in the blood.

Table 2
Analyzed cases of prosthetic heart valve wear

Name of valve	Type of valve	Wear part	Frictioning surface material	Duration in situ	Frictioning distance, m	Frictioning speed, m/s	Load, N	Wear volume, m^3	Specific wear, m^3/N	Observed failure	Reference
M Starr-Edwards	Ball valve	Ball	Si (ball)/Co-Cr alloy (strut)	4 years	2×10^6	6×10^{-2}	0.2	2×10^{-9}	10^{-14}	Malfunction	[4]
A DeBakey	Ball valve	Strut	Pyrolytic carbon (ball)/Ti (strut)	4 years	4×10^6	6×10^{-2}	0.3	10^{-9}	10^{-15}	Malfunction	[5]
M Beall	Disk valve	Disk & Strut	TEFLON (disk)/TEFLON (strut)	5 years	2×10^6	4×10^{-2}	7×10^{-2}	10^{-9}	10^{-14}	Malfunction	[6]
M Beall	Disk valve	Strut	Pyrolytic carbon (disk)/pyrolytic carbon (strut)	11 months	3×10^5	4×10^{-2}	0.5	Not known	Not known	Broken strut	[7]
M Wada-Cutter	Tilting disk single cusp valve	Disk	TEFLON (disk)/Ti (strut)	5 years	6×10^5	2×10^{-2}	8 [18]	3×10^{-9}	10^{-15}	Reversal blood flow on valve closure period	[8]
A Björk-Shiley	Tilting disk single cusp valve	Disk	DELRIN (disk)/Co-Ni alloy (strut)	7 months	9×10^3	2×10^{-3}	2 [18]	2×10^{-11}	10^{-15}		[1]
A Björk-Shiley	Tilting disk single cusp valve	Strut	DELRIN (disk)/Co-Ni alloy (strut)	5 months	3×10^4	8×10^{-3}	8 [18]	2×10^{-12}	10^{-17}		[1]
M St. Jude Medical	Tilting disk double cuspsvalve	Disk & Hinge	Pyrolytic carbon (disk)/ pyrolytic carbon (hinge)	23 months	3×10^5	2×10^{-2}	0.1	Not known	Not known	Escaped cusp Broken hinge	[9]
M Ionescu-Shiley	Triple cusp valve	Cusp	Pericardial membrane of cow (cusp)/pericardial membrane of cow (cusps)	3 years	5×10^5	2×10^{-2}	1	Not known	Not known	Cracked cusp	[10]
* Ceramic double cusp valve	Tilting disk double cusp valve	Axis	Porous alumina (circular rod)/porous alumina (circular rod)	6 months	9×10^5	6×10^{-2}	1	9×10^{-9}	10^{-14}		[11]

A: Aortic valve; M: Mitral valve; *: +-shape crossing rotating cylinder wear test in glycerine solution

7. CONCLUSION

None of the currently available prosthetic heart valves has a satisfactory durability. The base of this unfortunate situation is due to the insufficient understanding of fatigue and wear mechanisms in vivo and the resultant failure to establish reliable in vitro simulation test standards (current test standard [3] strives to prove the durability of the valve for the least number of cycles corresponding to 5 years service). In the actual service of the prosthetic heart valve, problems such as blood clotting and destruction of the blood cells occur due to electric charge conditions at the surface of materials and shear rate in blood flow. These problems occur prior to mechanical failure occurs [13, 16]. For example, clotted blood inhibits the penetration of blood (considered to be a lubricant) to the frictioning part of the prosthetic valve and, as a consequence, the wear of the prosthetic valve is accelerated. In past research efforts for prosthetic heart valves, the primary focus was on the compatibility between the valve material and blood in order to avoid problems with clotting and cell destruction. In this respect, prosthetic cusps made of human or animal tissues are preferable, but the durability of this type of cusp is poor. The durability of cusps made of deformable polymer is not very impressive either. Coatings with silicon, poly 4-fluoro ethylene and poly-propylene were at one time introduced for prosthetic heart valves because of their favorable compatibility with blood. However, they were soon abandoned due to unsatisfactory durability. The solution to this problem was the employment of a pyrolytic carbon whose specific weight is comparable to that of human blood. Frequent failures which occurred at the welded section between the seat and strut of the Björk-shiley valve led to the development of a valve whose seat and strut were shaped out of a single ingot [18]. It was realized that an undesired thermal deformation occurred to the prosthetic valve during the sterilization process in the autoclave. There was also a mechanical deformation which occurred during the surgical implantation of the prosthetic valve [9]. These deformations greatly contributed to the loss of valve durability, therefore, modifications for the sterilization procedures and valve setting surgical operation equipment were made. Prosthetic heart valve research is now at the stage where efforts can focus on the durability of the system.

REFERENCE

[1] V. O. Björk: *Scand. J. Thorac. Cardiovasc. Surg.*, **5** (1971) 87.
[2] R. E. Clark *et al.*: *Ann. Thorac. Surg.*, **26**, 4 (1978) 323.
[3] Jpn Soc. Medical Equipments *et al.*: *The Janpanese Journal of Artificial*, **10**, 3 (1981) 793.
[4] D. C. Connolly *et al.*: *Mayo Clin. Proc.*, **45** (1970) 20.
[5] B. C. Paton and M. B. Pine: *J. Thorac. Cardiovasc. Surg.*, **72**, 4 (1976) 652.
[6] M. D. Silver and G. J. Wilson: *Circulation*, **56**, 4 (1977) 617.
[7] M. J. Nathan: *Ann. Thorac. Surg.*, **16**, 6 (1973) 610.
[8] B. B. Roe *et al.*: *Ann. Thorac. Surg.*, **20**, 3 (1975) 256.
[9] E. Hjelms: *Thorac. Cardiovasc. Surg.*, **31** (1983) 310.
[10] S. C. Ghosh *et al.*: *J. Thorac. Cardiovasc. Surg.*, **86**, 5 (1983) 784.
[11] C. R. Gentle and H. Juden: *Eng. Med.*, **13**, 2 (1984) 79.
[12] P. L. Altman and D. S. Dittmer: Biology Data Book, 2nd ed., Federation of American Societies for Experimental Biology (1974) 1736.
[13] S. Koshikawa *et al.*: Collected Archives on Prosthetic Organs, Life Science Center, 1976.
[14] C. G. Caro *et al.*: *The Mechanics of the Circulation*, Oxford University Press (1978) 476.
[15] E. W. Salzman: *Interaction of the Blood with Natural and Artificial Surfaces*, Marcel Dekker (1981) 3.

[16] Y. Sakurai: *Introduction to Prosthetic Organs*, Nippon Keizai Shimbun Publ., Tokyo, 1986.
[17] K. Ohta *et al.*: *Fundamentals of Prosthetic Organs and Their Clinical Applications*, Shu-jun-sha Publ., Tokyo, 1980, p.37.
[18] V. O. Björk *et al.*: *Scand. J. Thorac. Cardiovasc. Surg.*, **19** (1985) 13.
[19] D. Lindblom *et al.*: *J. Thorac. Cardiovasc. Surg.*, **92**, 5 (1986) 894.
[20] R. C. Bonnabeau Jr. and C. W. Lillehei: *J. Thorac. Cardivasc. Surg.*, **56**, 2 (1968) 258.
[21] B. J. Messmer *et al.*: *Thorac. Cardiovasc. Surg.*, **65**, 3 (1973) 386.