Analysis of the Principle and State-of-art Artificial Heart Valve Facilities

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Abstract. In recent years, the mechanical artificial hearts are widely used in surgery ought to the medical demands. Although the use of mechanical artificial hearts is widespread worldwide and has been clinically proven for many years, current technology is still not sufficient to permanently preserve the heart. With current technology, reliable recovery after transplantation cannot be achieved and patients must continue to struggle to maintain heart function. Valves are therefore the main cause of artificial heart failure, and the choice of valve type is time-consuming. On this basis, this study will discuss the principle as well as the state-of-art facilities of heart valve. According to the analysis, valves, especially mitral and aortic valves (bioprosthetic and purely mechanical), can be further developed and their advantages and disadvantages are obvious. In addition, the limitations as well as the prospects for the devices are discussed accordingly. Overall, these results shed light on guiding further exploration of artificial heart valve development.

Keywords: Mechanical artificial hearts; mitral; aortic valves; aorta bioprosthetic valve.

1. Introduction

Cardiovascular disease, as a major cause of death worldwide, is expected to claim nearly 20 million lives annually. Cardiovascular disease is a category of heart and vascular diseases, including coronary heart disease, cerebrovascular disease, rheumatic heart disease, and other diseases. More than four fifths of cardiovascular disease deaths are due to heart attacks and strokes, with one-third of deaths occurring in people under the age of 70. Moreover, cardiovascular disease is not only afflicted by people of a specific age group, it encompasses all age groups and is divided into congenital and acquired. The population affected by heart disease is not only the elderly, but also many people who suffer from congenital heart disease and have been troubled by heart disease since childhood. Even though many people have already undergone surgery to alleviate or temporarily overcome their heart disease, there are still many activities that this group of people cannot participate in, such as amusement rides, movies that are extremely scary, or a sports event. They cannot even let their emotions fluctuate too much. Some heart disease patients die after experiencing ventricular fibrillation or cardiac arrest after watching a long awaited concert. With modern medical technology, heart disease is an impossible disease to completely cure. Heart transplantation is the end of heart disease for patients, but a patient who needs a heart transplant often has their life in danger and has to make such a choice. However, the donated hearts are far from sufficient to support the number of patients who need heart transplants, and there are very few hearts that can perfectly match the patients. As a result, people began to invent, research, and manufacture artificial hearts.The aortic valve, one of the four passive heart valves, controls blood flow in the left ventricle and throughout the body. It is situated between the end of the aorta and the left ventricle. The aortic valve closes in order to prevent aortic backflow into the left ventricle, which produces an increase in pressure, leading to an increased risk of pathology.Many people have had to switch to artificial heart valves because their aortic valves no longer work properly due to this pathology [1].

Heart valves are an important anatomical structure of the heart, and for 2000 years mankind has continued to explore and discover heart valves. In 1951, American surgeon Cherles Hufnagel (1916-1989) first implanted a plastic basket valve in the descending aorta to improve the dysfunction caused by insufficient aortic valve closure. In 1960, Hacken first replaced the aortic valve with an artificial mechanical cage valve, creating the first generation of clinical artificial heart valves. After clinical

use, mechanical valves with a spherical sheath showed disadvantages such as wide coverage, high total weight, and little hemodynamic improvement [2]. To address these shortcomings, the second generation of prosthetic heart valves, the disc valve, was introduced in 1964. Although this type of valve is still not clinically satisfactory, this generation of prosthetic heart valves played an important role in the history of prosthetic heart valve development, laying the foundation for the further development of single-angle and double-angle valves. The introduction of the ramp valve represented by the Bjork Hillel valve in 1969 marked the beginning of the third generation of mechanical heart valve research; in the late 1970s, the bicuspid St Judea Medici valve (bicuspid St Judea Medici valve) was introduced. Since then, research and use of artificial heart valves has entered a period of relatively mature and stable development. However, the science is endless and how to make an artificial heart valve function in a manner very similar to a natural heart valve remains a scientific challenge for most bioengineered heart valve researchers, developers, manufacturers and users [3].

2. Basic Descriptions

The inside of the heart is made up of four chambers: the left atrium, left ventricle, right atrium and right ventricle. The left and right atria and ventricles are separated by the atrial and ventricular septum, respectively, while the atrioventricular foramen connects the atria and ventricles on one side. The atria and ventricles are connected by blood vessels: the right atrium is connected to the vena cava and the inferior vena cava, the left atrium to the pulmonary vein, the pulmonary artery to the right ventricle and the aorta to the left ventricle, while the space between the atrioventricular orifice, ventricle and artery contains four valves: mitral valve, tricuspid valve and aortic valve. The valves are the mitral valve, the tricuspid valve, the aorta and the pulmonary artery. The valve between the right atrium and the right ventricle is the tricuspid valve, the valve between the right ventricle and the pulmonary artery is the pulmonary valve, the valve between the left atrium and the left ventricle is the mitral valve and the valve between the left ventricle and the aorta is the aortic valve. These valves are an important part of the heart. Each valve has its own function and structure [4]. For example, the mitral valve is the left ventricular valve of the heart and is formed by an endocardial valve leaflet connected to the left atrioventricular ring. This valve is triangular in shape and its tip faces the left ventricular cavity, also known as the "donut valve. The mitral valve lies between the left atrium and the left ventricle, and the lower ends of the two valves are usually fused together, sometimes with a small subvalve between the two valves. The mitral valve consists of the apex, cricothyrotomy, papillary muscle, and perivalvular structures, and is composed of two valve leaflets, the anterior and posterior leaflets. The anterior apex is located anteroinferiorly and is larger, often referred to as the great valve, and forms the boundary between the inlet and outlet of the left ventricle [4]. The posterior end of the flap is located posteriorly and is smaller, often referred to as the small flap; there may be a small extra valve between the two valves. The tendons of the mitral valve are attached to the anterior and posterior papillary muscles, and its outlet is the aortic orifice, to which the semicircular aortic valve is attached [3]. When open, blood flows from the left atrium to the left ventricle; when the left ventricle contracts, the mitral valve automatically closes, closing the aortic orifice and preventing blood from flowing back into the left atrium.

Artificial hearts have been used in clinical practice for decades, and as medicine has evolved and progressed, there have also been studies using heart valves from animals such as pigs or cows to mimic the human heart. These animal hearts have a higher degree of similarity to a purely mechanical heart and are more in keeping with the characteristics of the original human heart, and as a result people are now choosing to use heart implants with biological valves. Although these artificial hearts can temporarily sustain human life, the biological valves will still age like a machine during a person's lifetime, which could have a significant impact. This would increase the risk of secondary surgery, making the durability of the artificial heart of utmost importance at this point in time. Currently, purely mechanical valves are effective in avoiding this problem, and the probability of a second

surgery is much lower than with biologic valves [5]. This article will focus on the use of prosthetic mechanical heart valves, the benefits and drawbacks of them.

3. Principle

Bioprosthetic artificial heart valves consist of a valve leaflet and a stent, which are usually selected from bovine or porcine pericardium and converted into movable parts that can be opened and closed. However, bovine and porcine pericardium must be chemically treated to convert it into more stable biomolecular composite materials. The flap structures are made of polymeric materials and alloys for structuring, support and transport. It is placed inside the stent frame and consists of a circular or fan-shaped outer suture ring outside the stent frame. If circular, the sewing ring is located inside the path of the support structure; if circular, the sewing ring is located 3 to 5 mm above the path of the support structure. Artificial heart bioprosthetic valves can be stented or stentless. Stentless flaps do not have scaffolds or a base ring to support the flap flaps. Stentless bioprosthetic flaps are sutured using different surgical techniques than stented flaps, such as subcoronary, total or mini root replacement [6]. The stentless technique, on the other hand, is designed to maximize the opening area of the flap to restore the physiological pattern of blood flow and improve hemodynamics [7]. However, several studies have raised doubts about the theoretical and hemodynamic benefits and stable reliability of sutureless techniques for bioartificial heart valves, and the benefits in terms of life expectancy remain controversial [8]. More recently, rapidly implantable sutureless valves have emerged as an option for minimally invasive access and shorter duration of extracorporeal circulation [9]. These valves also seem particularly suitable for patients with small aortic rings to optimize hemodynamics. Rapidly implantable sutureless aortic valves are bio-pericardial prosthetic valves that require only three sutures for attachment to the aortic annulus and do not require manual suturing. Finally, transcatheter valves make up the majority of aortic valves currently being implanted [7].

Mechanical prosthetic hearts can be used for a long time and avoid reoperation, but patients with these devices must take anticoagulants for life. They are 'foreign' to the heart, blood can easily clot in and around them, forming blood clots that interfere with the valve's function. The formation of these clots can lead to a vascular embolism, such as a cerebral embolism, which can cause paralysis in mild cases and life-threatening in severe cases. Improper use of anticoagulants can lead to thrombus formation, valve dysfunction, and vascular embolism. Patients who have had a bioprosthetic valve replacement usually need to continue taking anticoagulants for six months. Patients who have undergone mechanical valve replacement surgery must take anticoagulants for life, and anticoagulants (warfarin) should be taken regularly every day and generally should not be arbitrarily stopped except in exceptional circumstances. Early degeneration associated with prosthetic calcification and connective tissue damage is controlled by a variety of mechanisms. These mechanisms include mechanical stress, lipid infiltration and inflammatory cell infiltration, which promote the activation of immunological cofactors. Despite significant improvements in valve design and surgical techniques, pathology remains a major limiting factor in life expectancy. Selection of the right type and size of valve bioprosthesis, as well as appropriate care and follow-up after valve replacement, is essential for optimal prevention. Identification and treatment of structural valve degeneration. Currently, neoplastic surgery is the most common treatment for structural valve degeneration. However, catheter-based endovascular treatment is an important alternative to surgery for high-risk patients [10].

4. Application

When the heart beats, the heart valves can open with the flow of blood or close against the flow of blood, like a valve, and they open and close tightly to prevent blood from stagnating in the circulation. As the valves open and close regularly, the blood in the atria and ventricles is isolated from each other, ensuring one-way circulation of blood throughout the body [4]. When the left and right atria contract,

the mitral and tricuspid valves open to supply blood to the left and right ventricles; when the left and right ventricles contract, the mitral and tricuspid valves close and the aortic and pulmonary artery valves open to supply blood to the aorta and pulmonary arteries. As this cycle repeats, the heart works normally [11]. Each valve can be viewed as a complex set of "devices," each of which has its own role and works in concert with the others. The functions of the various valves are similar in many respects, but take the mitral valve as an example: as the body's oxygen demand increases, so does the volume of blood expelled from the heart, and in response the left ventricular sphincter at the bottom of the heart opens during diastole, making the hole in the mitral valve 40% wider than when stable, allowing more blood to flow through the hole more blood can flow through the hole. This dynamic change is due to the presence of a gap in the posterior valve, the depth of which is approximately 30% of the height of the posterior valve, and in mitral regurgitation the gap may extend to the ring. Simultaneous dilatation of the ventricular muscular layer leads to opening of the mitral valve and initiation of ventricular filling, which can be divided into active and passive filling [3]. During ventricular diastole, when the myocardium expands, suction actively fills the cone chambers. At the end of diastole, atrial contraction further increases blood flow to the ventricles. These complex, coordinated movements are electromechanical, with the electrical component being the synchronised polarisation and depolarisation of the cardiomyocytes and the mechanical component being the contraction and diastole of the heart. The mitral valve connects the ventricular wall to the base of the heart through its mucosal tip and prevents ventricular overfilling and abnormal rotation and deformation of the ventricular wall. Blood that enters the ventricles at the beginning of diastole reaches the end of the ventricles and then returns along the ventricular wall, creating a vortex under the mitral valve and forcing it to close. The papillary muscles are muscles in the centre of the ventricles, with tendons attached to their surface, that prevent the valve from sticking too tightly to the ventricular wall and staying in its functional position when the mitral valve is open. The tricuspid, pulmonary, and aortic valves work together with the mitral valve during a heartbeat, allowing blood to flow in only one direction [3].

5. Fabrication

Materials used in the manufacture of prosthetic heart valves The materials used in the manufacture of prosthetic heart valves are titanium, titanium alloys, and pyrolytic carbon with surface modifications. The surface properties of biomedical materials inserted into the human body, such as surface roughness, wettability, chemical composition, crystallinity, inhomogeneity, and surface roughness, directly affect their biomobility. When in contact with blood, the negative charge of platelets, blood cells, and proteins, together with the negative charge of the blood vessel wall (-8 to 13 mV), causes protein adsorption on the surface of the negatively charged material to form a passive layer, making the material less toxic to blood and thus more haematological compatible[2]. Requirements for a mechanised heart valve manufacturing process: The production of modern heart valves requires a rapid manufacturing process. The rational and economical development of mechanised heart valve processing technology means that the processing precision, processing quality and cost of the valve are very important. The requirements for external dimensional accuracy, positioning accuracy, and overall surface roughness are very high, especially for valve parts with some heterogeneous structures. Various special equipment is used for precision machining, such as slow feed wire cutting machine, electrical discharge machining machine, light calibration sprayer, etc. It is necessary to develop the use of tools. Detection means, artificial heart valves, from the initial physicochemical analysis of raw materials to the testing of product properties and subsequent inspection of finished products, involves the use of a large number of special equipment, in vitro fatigue test, hydrodynamic test, fatigue tester, rectification tester, backflow tester, pulse flow tester, etc. The accuracy of each equipment, the technical level of the weigher, and the degree of application of artificial intelligence affect the quality of the valve. A sketch of the fabrication is given in Fig. 1.

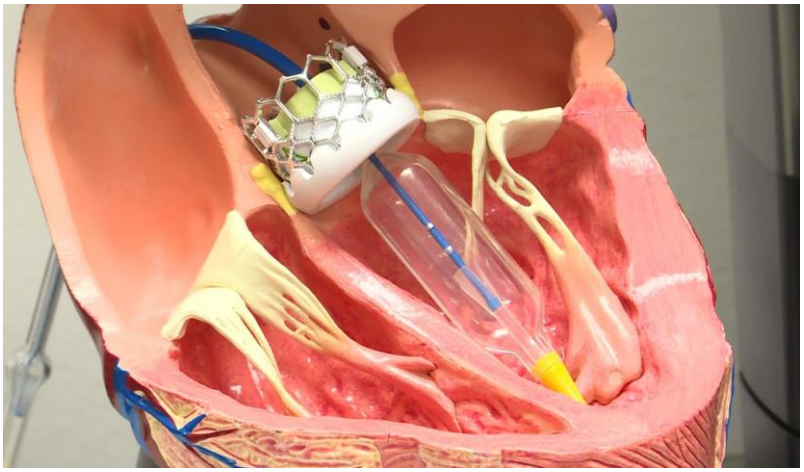


Fig. 1 A sketch of the fabrication for valve.

6. Limitations and Prospects

One of the requirements for the design of mechanical artificial heart valves is to use the dynamics generated by blood flow to find the optimal combination of the three components, the valve disc or valve body, the stent or stem and the ring, to best simulate the natural heart valve. Mechanical artificial heart valves should be designed to have good mechanical properties, good haemodynamic properties and good tissue compatibility [3]. The interposition between the annulus and the valve leaflets forms a potential gap, the size of which affects not only the elasticity of valve motion but also the magnitude of static leakage, and generates a large shear force that destroys blood cells, leading to haemolysis; in addition, the formation of a flow-mixed layer of blood flow and the disruption of blood flow caused by local vortex are important factors in the formation of blood clots. On the other hand, the interruption of blood flow favours the flushing of blood to the valve itself, which may reduce thrombus formation [2]. During opening and closing inside the valve cage, blood flow is retained in the valve flaps, resulting in an abrupt change in flow instability, causing a kind of hydro-shock. The shock effect is a kinetic property associated with the closing mechanism and, in severe cases, can lead to rupture of the valve itself, haemolysis and subsequent bleeding, tissue damage, pulsatile deformation or dysfunction. The amplitude of the throttling effect depends mainly on the peak flow rate of the valve and the propagation velocity of the shock wave, and the magnitude of the flow depends on the configuration of the mechanical prosthetic heart valve and the selected design parameters, such as the position of the articulation axis, the opening angle and clamping direction, the specific gravity and modulus of elasticity of the valve material, and the thickness and curvature of the leaflet [3]. A clear understanding of the valve's haemodynamic characteristics is necessary for the rational optimisation of valve parameters.

Use of mechanical prosthetic heart valves: China is one of the countries with a high prevalence of heart valve disease, and millions of patients with heart valve disease need to undergo valve replacement surgery. Heart valve replacement is an effective way to treat severe valvular heart disease. Currently, there are two main types of prosthetic heart valves in clinical use. They are mechanical valves and biological valves. Despite the obvious advantages of mechanical valves, they also have significant disadvantages that limit their use. Mechanical heart prostheses have the following advantages Good durability, which can last for more than a century in in vitro experiments; in addition, mechanical valves with a small diameter (no more than 19 mm) and a relatively large geometric area of the orifice are suitable for patients with small aortic annulus, and the low height of mechanical valves is suitable for coronary arteries with low orifices when replacing the aortic annulus [2]. Disadvantages of mechanical heart valves: poor compatibility with human tissues, non-physiological eccentric blood flow, the need for lifelong anticoagulation therapy to prevent blood clots from collecting in the valve, significantly increased risk of bleeding in other parts of the body, high incidence of complications from anticoagulation therapy, death or disability of patients due to

complications from anticoagulation therapy certain percentage, difficulty in treatment compliance for other medical problems, and increased risk of additional surgical or invasive procedures [2]; mechanical failure of the prosthetic valve, such as excessive tissue growth around the prosthetic valve that can lead to abnormal opening or closing of the valve leaflet, which affects the function of the prosthetic valve. This can lead to abnormal opening and closing of the valve leaflet and require invasive treatment [2]; mechanical disorders of the prosthetic valve, such as excessive tissue proliferation around the prosthetic valve, which can interfere with valve leaflet function and lead to abnormal opening and closing of the valve leaflet and require revision surgery This can lead to the need for reoperation. Due to the nature of mechanical prosthetic heart valves, patients diagnosed with severe valvular disease, severe obstruction, or severe blood regurgitation problems that require replacement of the prosthetic valve are eligible for this procedure if they are under 60 years of age. The ideal prosthetic heart valve should have the following characteristics Non-toxic, completely sterile during implantation, easily surgically implanted in the normal position of the heart, suitable for the structure of the heart and not vice versa (e.g., the size and shape of the prosthetic valve does not interfere with the normal functioning of the heart). It has the least resistance to blood flow, the pressure reduction caused by blood flow is not more pronounced, the least regurgitation, ensures the closure of the heart valve, prevents insufficient closure of the valve, is resistant to mechanical and structural damage, and maintains normal function over time. It should not interfere with its function. For example, the valve does not deteriorate over time), can minimize the damage to the blood components and epithelial tissue surrounding the valve in the cardiovascular system without the use of anticoagulants, is not prone to thromboembolic syndrome, has low noise and does not interfere with the patient's X-ray vision, and is reasonably priced.

7. Conclusion

Nowadays, it is difficult to compare the "fine" characteristics and performance of different valve prostheses and the evaluation criteria for valve prostheses differ between studies. Long-term follow-up of large groups of patients is required to study the long-term effects of valve prostheses. This phase requires comprehensive development and innovation in many aspects of cardiac valve materials, design and treatment: research, manufacturing and medicine. The age of patients with implanted heart valves and the age of the potential heart valve population are important information for valve selection and life expectancy estimation. Current mechanical and biological prosthetic heart valves are a sensitive issue in the prosthetic heart valve community because, compared with conventional heart valves, they generate relatively high turbulent stresses (which can cause lethal or semi-lethal damage to erythrocytes and platelets) and large pressure gradients and regurgitation volumes. Therefore, the direction of development of artificial mechanical heart valves is to improve the anticoagulant capacity of new artificial materials, to improve the lifetime of new tissue valves, and to improve the hemodynamic properties of heart valves. In particular, it is important to reduce or eliminate the areas of low creep on the valve and vessel surfaces and the surrounding areas of high creep turbulence caused by flow jets or lateral leakage from the valve outlet.

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