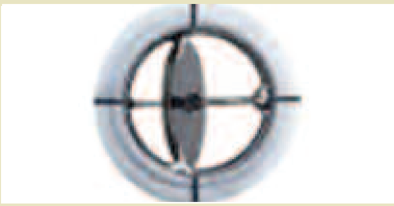
abstract



Prosthetic heart valves (PHVs) are used to replace diseased native valves among patients with valvular stenosis, incompetence, or both. This paper reviews a number of contemporary prosthetic heart valves that are available for implantation in patients for whom valve repair is not possible. There are two major types of PHV: biological and mechanical. Each type of PHV has its own unique benefits and complications, which are outlined in this review. It is important that the practicing physician have some knowledge of contemporary prosthetic heart valves in order to treat patients safely and effectively.

Key words: *prosthetic heart valve, mechanical heart valve, stented bioprosthesis, stentless bioprosthesis*

Prosthetic Heart Valves, Part I: Identification and Potential Complications

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Identification & Potential Complications of Heart Valve Replacement

Introduction

Patients with significant native heart valve disease (HVD) often experience valvular stenosis, incompetence, or both, leading to progressive cardiac changes as well as secondary organ involvement.[1] In cases where native valve repair is not possible, patients must be treated by valve replacement.[1,2] Prosthetic heart valves (PHVs) have been in use for over 50 years[2] and have undergone many changes since their inception. Today, patients with a replacement valve have a better quality of life when compared to those HVD patients with significant disease who are medically managed.[1]

PHVs are broadly categorized as mechanical heart valves (MHVs), composed entirely of synthetic or nonbiological materials, or bioprosthetic heart valves (BHVs), composed of synthetic and biological materials (Figure 1).[2] Bioprostheses are of two kinds: xenografts, which are taken from different species than the recipient, and homografts, which are donor valves taken from the same species as the recipient.[3] Over 250,000 PHVs are implanted worldwide each year, of which 55% are MHV and 45% are BHV (the reverse is true in developed countries).[1,2] Prosthetic valve implantation is increasing at a rate of 5–7% per year, with BHVs gaining favour at a slightly faster pace than MHVs (8–11% increase per year vs. 3–5% increase per year, respectively).[2]

Mechanical valves are divided into two types based on their flow patterns: lateral flow (i.e., ball and cage valves) and central flow (i.e., tilting disc and bileaflet valves).[2] In contrast to MHVs, the most essential component of a BHV is the biological tissue. This tissue is either an intact porcine aortic valve or segments of bovine or equine pericardium fashioned into three valve cusps.[1] These materials are fixed in low concentrations of glutaraldehyde and often treated with antimineralization agents.[1]

BHVs more closely imitate the functional properties of native valves than do MHVs. Namely, BHVs have good thrombo-resistance and hemodynamics.[1] Some stented BHVs have functioned effectively for up to 24 years, and some stentless valves have now been in place for over 10 years with good results.[1] In young patients, MHVs are preferred as the valves are not prone to structural valve deterioration (SVD).[5] However, MHV components are thrombogenic, requiring life-long anticoagulant therapy, which increases a patient's susceptibility to hemorrhage.[2] Patients with a single bioprosthetic heart valve do not require anticoagulant therapy,[1] and bioprostheses are therefore favoured for use in older patients.[5] Although BHVs are prone to SVD at up to 15 years postimplantation, they are suitable for use in older patients as the valves often outlive the patient. Nevertheless, some authors report that there is no advantage in either survival or quality of life for patients 65–75 years of age receiving a bioprosthetic or mechanical valve.[5]

Complications frequently occur in both mechanical and biological heart valves, significantly affecting the postoperative success of a patient (Table 1). Complications are usually prosthesis-related, such as device failure or SVD due to materials and/or design, or host-related factors, such as infection and/or host tissue overgrowth (pannus).[2,6] In BHVs, SVD most commonly manifests as collagen degeneration and mineralization of the cuspal tissue.[1] Mineralization continues to be a problem with all BHVs and is likely related to a number of factors, including the aldehyde fixation process. Ultimately, significant complications necessitate removal and replacement of the prosthesis.[2]

The following sections present information about the most commonly implanted (contemporary) mechanical and bioprosthetic heart valves. The intent is to familiarize the reader with the important features of these valves, including materials, design, and common potential complications.

Table 1: Potential Complications of Prosthetic Heart Valves

Mechanical Valves
Device-related (rare)
Infection
Pannus
Paravalvular leak
Thrombosis
Bleeding
Biological Valves
Structural deterioration
Calcification
Cusp tear
Dehiscence
Infection
Pannus
Paravalvular leak
Stent creep—historic issue
Stent dehiscence
Thrombosis

Mechanical Heart Valves

Single leaflet/tilting disc (Table 2)

The Medtronic-Hall® Prosthesis (Medtronic)

This valve is often used when small-size mechanical prostheses are needed.[2]

Potential Complications

Of the 1,766 valves replaced with this type of valve,[8] valve-related deaths occurred among less than 1% of patients. Primary risk factors for complications include diabetes, age, concurrent coronary artery bypass grafting, and hypertension.[8] The valve shows low thrombogenicity in patients on anticoagulant therapy.[2]

Figure 1 depicts this and other currently marketed prosthetic valves.

The Sorin Allcarbon® tilting disc valve (Sorin)

Potential Complications

Thrombi may form on the struts, the fabric, and on the interface of valve.[10] No mechanical dysfunction has been reported. Valve-related deaths range between 4.5 and 12.1% of implants.[11–13] The valve's overall performance is comparable to other tilting-disc mechanical valves.[11,12,14] Note that this valve is not used in North America today, but is still used in Europe.

Bileaflet

The On-X® (Medical Carbon Research Institute, MCRI)

This is a new valve with good flow characteristics and, thus far, a low thrombosis rate.

Potential Complications

The On-X® is relatively new.[15] Wippermann *et al.*[16] report no paravalvular leaks after 47 implants. McNicholas *et al.*[17] report very low rates of thromboembolism and minimal hemolysis. Some problems with valve sizing due to the elongated housing and the flared inlet have been reported.[18]

The St. Jude Medical (SJM) Standard® bileaflet valve (St. Jude Medical)

This valve is reputedly the "gold standard" against which most mechanical valves are compared. It has been on the market for over 25 years (Table 2).[2,19] The valve housing is made of graphite coated with pyrolytic carbon, as are the leaflets.[2,19] The leaflets are impregnated with tungsten to allow valve visualization during radiography.[2,19] Worldwide, this is the most commonly used MHV.

Potential Complications

Thromboembolism is the most common nonstructural complication of SJM® mechanical valves.[20] Loss of structural integrity has been reported in a small number of cases. One case of postoperative leaflet dislodgment has been reported.[20]

Sulzer CarboMedics® Standard (Sulzer)

The flow and nonflow surface of this valve's sewing cuff is carbon coated in an effort to reduce thrombosis.[21]

Potential Complications

Wu *et al.*[22] report an overall freedom from valve-related events of 74% for aortic valve replacement, 57% for mitral valve replacement, and 66% for double valve replacement during 10 years of follow-up. The operative mortality rate is 5.7%.[22] One of the complications associated with it is thrombosis and leaflet dysfunction.[22]

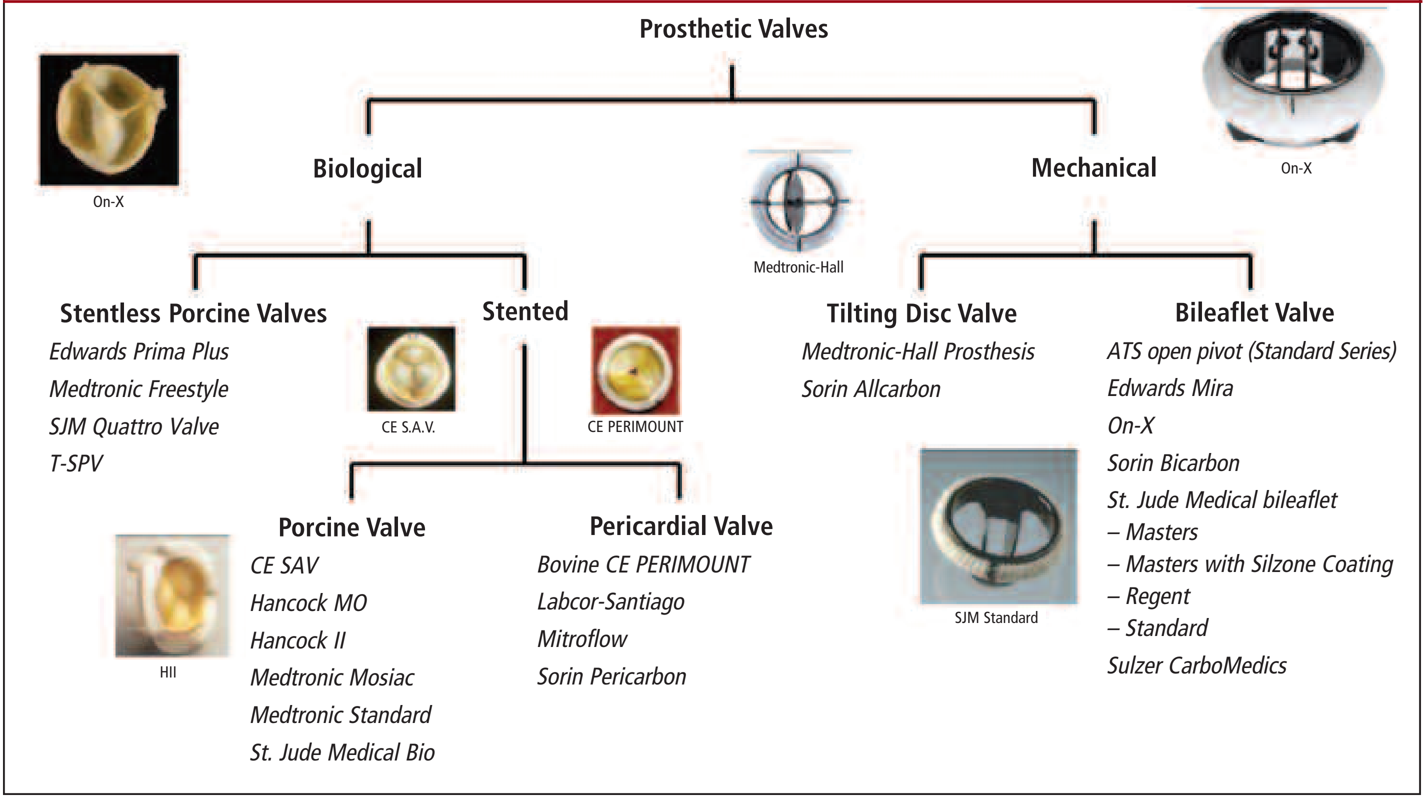
Biological Heart Valves (Table 3)

Stented Porcine Valves

The CE SAV® bioprosthesis (Carpentier Edwards)

The Carpentier-Edwards Supraanular®

Figure 1: Marketed Prosthetic Valves



(CE SAV) bioprosthesis has two models, the 2650 (aortic) and 6650 (mitral). This valve has a long and successful history. The porcine aortic valve used in the CE SAV bioprosthesis is processed using the XenoLogiX treatment to mitigate calcium enucleation in the porcine tissue. The standard model of this valve at times had an unusual mode of failure, with separation of the aortic commissural region at the suture line, leading to cusp prolapse and prosthesis incompetence.[27]

Potential Complications

The CE SAV® has a low incidence of structural valve deterioration and has good clinical performance.[25] At 18 years, CE SAV bioprostheses have maintained an actuarial freedom from structural valve deterioration of 94.6% in patients greater than 70 years of age with a cumulative risk of explant due to structural valve deterioration of only 1.8%.[25] Freedom from valve-related complications at five years has been reported at 84.1% ± 1.3%.[1,26]

Hancock II® (HII) Stented Porcine Bioprosthesis (Medtronic)

The HII® is made of a porcine aortic valve fixed in glutaraldehyde and mounted on a low-profile stent comprised of an acetyl homopolymer (Delrin®). This bioprosthesis has a comparatively lower calcification rate than the above options.[28]

Potential Complications

The HII® bioprosthesis continues to show good long-term results and durability, especially in patients over 65 years of age.[29] The 20-year actual risk of SVD is 18% ± 3% and 23% ± 3% in all aortic and mitral valve replacement patients, respectively.[30,31]

Stented Pericardial Valves

This valve, made of bovine pericardium has excellent hemodynamics and durability. It reportedly compares favourably with the stentless valves.[23,27]

Potential Complications

Jamieson *et al.*[23] report a freedom from valve-related mortality of 84.9% ± 1.7% in 1,430 patients during a 15-year study period. Roselli *et al.*[27] report a structural deterioration rate of 74% after a 19-year follow-up period and cite calcification as the most common reason for valve failure.

Stentless Porcine Valves

Stentless valves have larger effective orifice areas than stented ones primarily due to the absence of the stent and sewing cuff. This larger effective orifice allows more room for blood flow.

Medtronic Freestyle® (Medtronic)

This valve has excellent hemodynamics and is, in fact, a biological valved conduit that is used for aortic root replacement. Recent studies on long-term explants show a cellular reaction to the aortic tissues, suggesting a low-grade cellular rejection-like phenomenon.

Potential Complications and Additional Comments

An eight-year study reports 100% freedom from structural valve deterioration and an overall survival rate of 83%.[34]

Table 2: Physical Properties of Commonly Used Mechanical Heart Valves

Valve	Material	Position	Radiographic Characteristics	FDA Approval
The Medtronic-Hall® Prosthesis	Housing: Titanium Disc: Pyrolytic carbon Sewing Ring: Knitted PTFE, standard	Aortic and Mitral	Housing is radiopaque; disc is radiolucent	2002
The Sorin Allcarbon® tilting disc	Housing: Stellite 25, a chrome alloy Disc: Pyrolytic carbon over a graphite substrate Sewing Ring: Teflon	Aortic and Mitral	Disc has a tantalum wire that is radiopaque	—
ATS open pivot® bileaflet (Standard Series)	Orifice Ring: Pyrolytic carbon Leaflets: Pyrolytic carbon over graphite substrate Sewing Ring: Dacron	Aortic and Mitral	Titanium ring is radiopaque; leaflets are visible due to high tungsten content	2000
Edwards Mira® Valve	Orifice Ring: Pyrolytic carbon Leaflets: Pyrolytic carbon over graphite substrate Sewing Ring: Dacron	Aortic and Mitral	Titanium ring is completely radiopaque; leaflets impregnated with tungsten	—
The MCRI On-X	Orifice Ring: On-X carbon Leaflets: On-X carbon over graphite substrate Sewing Ring: PTFE	Aortic and Mitral	Leaflets impregnated with tungsten	2001 (aortic) 2002 (mitral)
The Sorin Bicarbon® mechanical valve	Housing: Titanium Leaflets: Pyrolytic carbon Sewing Ring: PTFE	Aortic and Mitral	Leaflets and housing are radiopaque	—
The St. Jude Medical (SJM) Standard® bileaflet valve	Housing: Graphite coated with pyrolytic carbon Leaflets: Graphite coated with pyrolytic carbon Sewing Ring: Polyester, PET, or PTFE	Aortic and Mitral	Leaflets impregnated with tungsten	1977
SJM Regent® bileaflet valve	Housing: Graphite coated with pyrolytic carbon Leaflets: Graphite coated with pyrolytic carbon Sewing Ring: Polyester, PET, or PTFE	Aortic and Mitral	Leaflets impregnated with tungsten	2002
SJM Masters® with Silzone coating	Cage Material: Pyrolytic carbon over graphite substrate Leaflets: Pyrolytic carbon with graphite substrate Sewing Ring: PET polyester	Aortic and Mitral	Leaflets impregnated with tungsten	Withdrawn January 2000
Standard Sulzer® Carbomedics Valve	Housing: Pyrolytic carbon Leaflets: Pyrolytic carbon-coated Sewing Ring: Dacron	Aortic and Mitral	The titanium ring surrounding the housing and leaflets is radiopaque	1993

— no information regarding FDA approval

Table 3: Physical Properties of Commonly Used Biological Heart Valves

Valve	Tissue	Material	Location	Radiographic Characteristics	FDA Approval
CE porcine®	Porcine	Sewing ring: molded silicone rubber covered by PTFE cloth Stent material: PTFE cloth Stent: Elgiloy	Aortic or Mitral	Elgiloy® stent is radiopaque	1976
CE SAV®	Porcine	Sewing ring: molded silicone rubber covered by PTFE cloth Stent material: PTFE cloth Stent: Elgiloy	Aortic	Elgiloy® stent is radiopaque	2002
Hancock MO® stented	Porcine	Sewing ring: Dacron Stent: polypropylene	Aortic	Haynes® alloy ring at the annulus	1978
Hancock II® stented porcine	Porcine	Porcine valve Stent: acetyl homopolymer	Aortic, Mitral	Haynes® alloy, scalloped stent, metal ring and eyelets	1999
CE PERIMOUNT®	Bovine Pericardium	Sewing ring: silicone rubber with nonwoven polyester Stent material: woven polyester Stent: Elgiloy	Aortic or Mitral	Elgiloy® stent is radiopaque	1991 (aortic) 2000 (mitral)
Freestyle®	Porcine	Polyester cloth covering a porcine valve	Aortic	—	1997
T-SPV®	Porcine	Polyester cloth covering a porcine valve	Aortic	—-	1997
St. Jude Medical Biocor®	Porcine	Sewing ring: Dacron Stent material: polyester Stent: acetal copolymer	Aortic and Mitral	Contains wire in sewing ring	2005

Matsue *et al.*[35] reported that a small group of patients who had 21 mm valves implanted using the subcoronary technique expressed a suboptimal flow pattern, and therefore recommend extra attention when dealing with such a situation. A recent study by Butany *et al.*[36] on a series of explanted Freestyle® bioprostheses reports that inflammatory cells appear to play a significant role in prosthesis failure.

Toronto Stentless Porcine Valve® (T-SPV) (SJM)

As the first of the stentless valves, the T-SPV® has excellent hemodynamics and results in good left ventricle remodelling, postimplantation.[37,38] Recent studies based on long-term explants show tissue degeneration with calcification at 9–10 years.[38]

Potential Complications

Butany *et al.*[38] reported on a series of 30 valves out of 350 implants, with a mean implant duration of 100.7 ± 27.8 months in which 90% of the valves displayed one or more of the following: tissue degeneration, cusp tears, calcification, or lipid insudation. Butany *et al.*[38] report a calcification rate of 76.7% (seen in 23 of 30 explanted valves from 332 total implants). This is likely due to the absence of antimineralization treatment.

Conclusion

Where valve repair is not possible, valvular heart disease is best treated by valve replacement. Mechanical heart valves are generally more durable but patients must be maintained on lifelong anticoagulant therapy, which increases the risk of hemorrhage and makes patient compliance a critical issue. In comparison, bioprostheses more closely mimic native valves and do not need anticoagulant therapy, but are more prone to structural deterioration. This review focussed on contemporary mechanical and biological valves. Homografts are also effective bioprostheses but are not as widely used due to limited availability. Many other models of mechanical and biological prostheses have been used worldwide, which have been replaced with these newer, more advanced models and are therefore not discussed here. In addition, there are newer trends in bioprosthesis design and application. Some of these will soon be in use and will increase the options available for the patient's benefit. A bioengineered valve made from the host's own tissue, however, is still far away.

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