Cardiac Valve Replacement Surgery: Prostheses and Technological Considerations

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Cardiac valve replacement surgery has advanced considerably over the past 20 years with suitable choices of mechanical prostheses and bioprostheses as valvular substitutes. The extensive developments over the past three decades have been introduced to reduce or eliminate valve related complications, namely thromboembolism, anticoagulant related hemorrhage, and structural failure as well as to optimize hemodynamic performance. The mechanical prostheses have been developed to eliminate structural failure, to facilitate prevention of blood status and thrombus formation, to facilitate intraoperative leaflet positioning and to facilitate radiopacity for evaluation of prosthesis function. The biological valvular prostheses, namely porcine aortic or bovine pericardium, have been developed with tissue preservation, together with stent designs, that contribute to preservation of anatomical characteristics and biomechanical properties of the leaflets. The implantation of the various present generation bioprostheses and

CURRENT MECHANICAL AND BIOLOGICAL PROSTHESES

Bioprostheses	Mechanical Prostheses
Porcine	Starr-Edwards ball valve
Hancock standard	
Carpentier-Edwards standard	Monoleaflet prostheses
Hancock modified orifice	Medtronic-Hall
Hancock 11	Bjork-Shiley Monostrut
Carpentier-Edwards supra-annular	Omnicarbon
Medtronic Intact	
St. Jude Bioimplant	Bileaflet prostheses
Medtronic Mosaic	St. Jude Medical
	Carbomedics
Pericardial	Edwards-Tekna
Carpentier-Edwards	Sorin - Bicarbon
Mitroflow	Medtronic Parallel
Sorin Pericarbon	AST - Mechanical
Bioprostheses - Unstented	
Homografts (Allografts)	
Pulmonary Autograft	
St. Jude Medical - Toronto SAV	
Medtronic Freestyle	
Bravo Stentless	
Edwards Prima	

Table 1. Current Mechanical and Biological Prostheses.

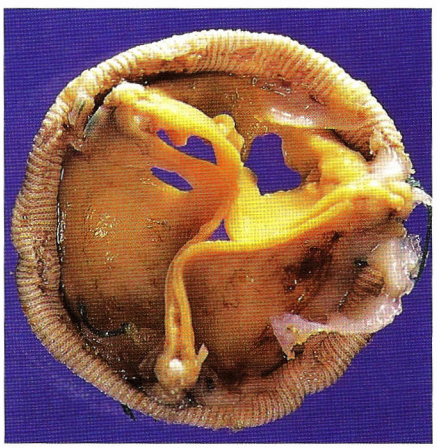

Figure 1. Ionescu-Shiley Pericardial Prosthesis Failed Due to Structural Failure with Tears and Perforations.

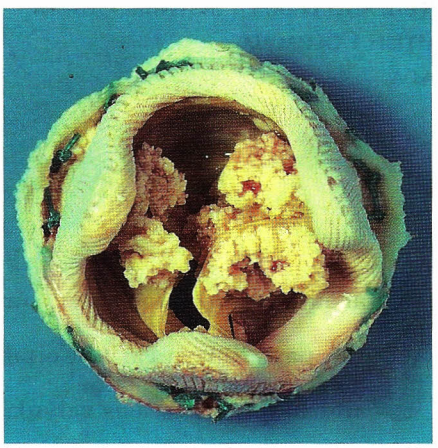

Figure 2. Standard Porcine Bioprostheses with Dystrophic Calcification.

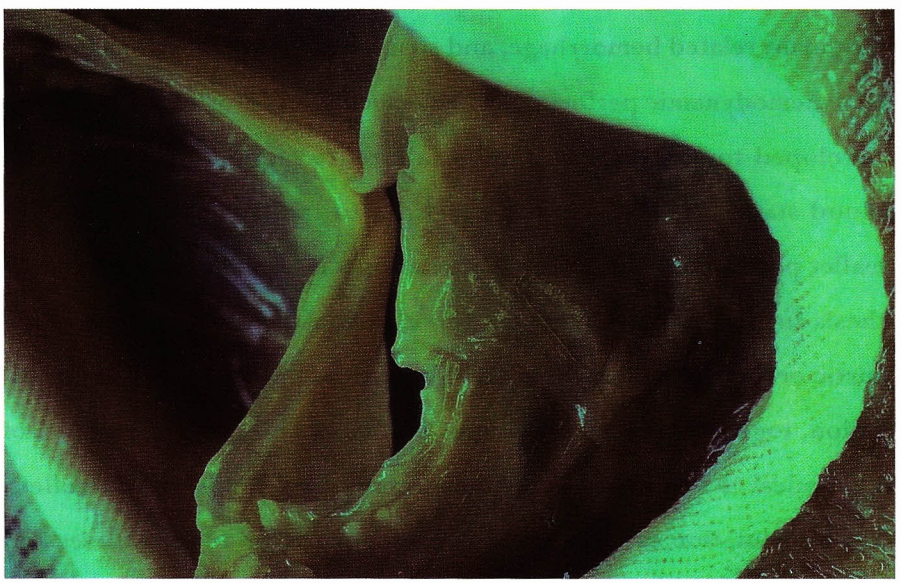

Figure 3. Carpentier-Edwards Supra-Annular Porcine Bioprosthesis with Free Margin Tear.

mechanical prostheses requires special considerations to support ventricular performance and avoid technical complications.

There has been a choice of bioprostheses and mechanical prostheses as valvular substitutes for cardiac valve replacement surgery for over 20 years.[1] The first mechanical prosthesis, the Starr-Edwards ball valve (Baxter Healthcare Corp., Edwards CVS Division) was introduced over 30 years ago, while the first biological prosthesis, the Hancock standard porcine bioprosthesis (Medtronic, Inc., Minneapolis, MN, USA), was introduced over 20 years ago. Since those hallmarks in valvular substitute surgery there have been extensive developments in mechanical and biological prostheses. These developments over the past decades have been introduced to reduce or eliminate valve-related complications, namely thromboembolism and thrombosis, anticoagulant related hemorrhage and structural failure, as well as to optimize hemodynamic performance. The advancements in valvular substitutes have been paralleled by a resurgence in valvular reconstruction, mitral valve predominantly over aortic valve, popularized by Carpentier[2,3] and Duran.[4-6] Mitral valve reconstruction has demonstrated superior results for advanced degenerative disease but not for chronic rheumatic disease, while aortic valve reconstruction is utilized primarily for management of congenital manifestations. The purpose of this communication is to provide an overview of modern cardiac valvular substitutes utilized worldwide, the surgical implantation considerations and the clinical results that influence utilization indications.

The past two decades have seen major advancements in valvular designs and materials for mechanical prostheses and tissue preservation and stent designs for bioprostheses. These advancements in mechanical prostheses have been made to reduce the incidence of thromboembolism and thrombosis, and to eliminate the rare occurrence of failure of structural components. The thromboresistant characteristics of materials and the flow characteristics of the moveable parts and pivot mechanisms have been designed to facilitate reduction of thromboembolism and thrombosis on adequate anticoagulation. The most significant complication

of mechanical prostheses, since structural failure has essentially been eliminated, is prosthesis thrombosis which is a catastrophic complication.

The utilization of heterograft tissue for valvular substitutes, namely porcine aortic valves and bovine pericardium, was made possible following the introduction of glutaraldehyde preservation by Carpentier and colleagues.[7] Biological prostheses were used extensively in the 1970s because of the potential reduction of thromboembolic phenomena and anticoagulant related hemorrhage associated with mechanical prostheses. The durability of biological prostheses has been a significant concern since the mid 1980s because of the presence of dystrophic calcification and stress-related failures, tears and perforations, which are often accompanied by calcification. The 1980s have also brought new biological prostheses with advanced tissue preservation techniques and stent designs to control calcification and stress related fatigue injuries and to optimize hemodynamics. The tissue preservation advancements have included low pressure and pressure-free glutaraldehyde fixation and surfactant antimineralization treatment. The advancement from intra-annular to supra-annular configuration of stent designs has demonstrated superior hemodynamics in small annular sizes.

Cardiovascular surgeons, cardiologists and patients continue to have the choice of bioprostheses and mechanical prostheses as valvular substitutes. The choice of prosthesis for the individual patient has depended on the clinical status of the patient, the confidence of the surgeon in the prosthesis, and the risk of valve-related complications. The mechanical and biological prostheses presently utilized predominantly worldwide, are listed in the accompanying Table I. The description of the structural characteristics of these devices and clinical performance assessment will formulate this documentation.

The majority of the earlier generation mechanical and biological prostheses have been discontinued or have limited clinical utilization. Several of the early mechanical prostheses were discontinued at the time of the 1987 pre-market approval deadline of the Food and Drug Administration of the United States, namely Smeloff-Cutter ball valve, Bjork-Shiley spherical disc, Bjork-Shiley concave-convex disc and Lillehei-Kaster monoleaflet prostheses. Of the early mechanical prostheses only the Starr-Edwards ball valve has survived the test of time with the current design formulated in the early 1960s. Of the biological prostheses, the Hancock pericardial and the Ionescu-Shiley pericardial prostheses were withdrawn in the mid to late 1980s, particularly with pre-market approval, because of structural failure from faulty design features. Of the first generation porcine bioprostheses the high pressure, glutaraldehyde fixed, intra-annular Hancock standard and Carpentier-Edwards standard (Baxter Healthcare Corp.) porcine bioprostheses are utilized essentially only in the United States.

PROSTHETIC FAILURE MODES

There have been several identified modes of failure of valvular prostheses which have been attributed to the structural components of the prostheses. Structural valve deterioration has been the predominant valve-related complication of biological prostheses. The discontinued Ionescu-Shiley pericardial bioprosthesis failed due to structural failure related to stress from the stent post fixation suture and tears and perforations (Figure 1). Porcine bioprostheses fail over extended periods of implantation by dystrophic calcification (Figure 2), primary fatigue-related tears or perforations (Figure 3), or tears secondary to minimal calcification. The failure mode of stent dehiscence, a rare complication, has been identified with the Carpentier-Edwards supraannular (mitral) porcine bioprosthesis.[8] This

Figure 4. Carpentier-Edwards Supra-Annular Porcine Bioprosthesis with Stent Dehiscence.

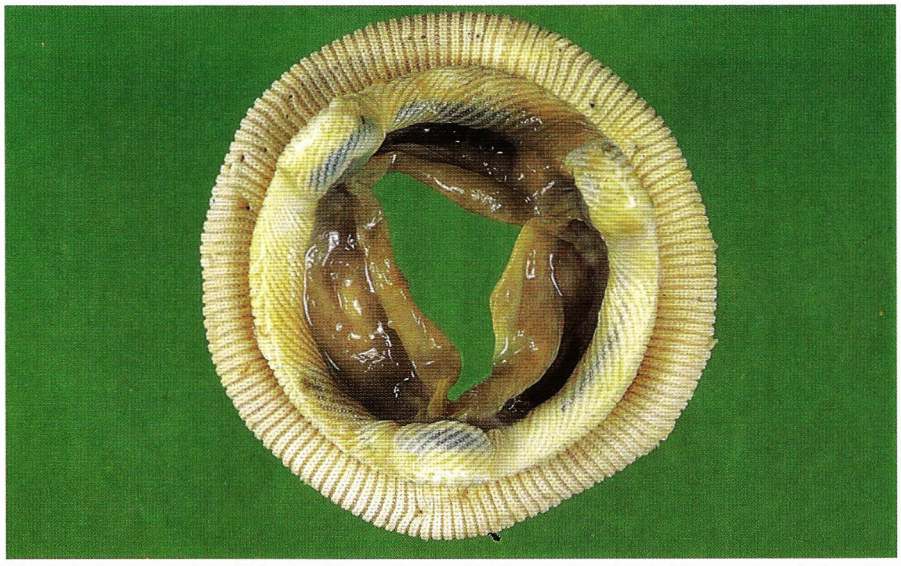

Figure 5. Medtronic Intact Porcine Bioprosthesis with Chronically, Rolled, Thickened Leaflets in the Tricuspid Position.

failure mode was considered to be related to extended trimming of the porcine aortic wall which provided reduced commissural support. The manufacturer has utilized reduced trimming of the aortic wall in large mitral prostheses since 1986 and all mitral and aortic sizes since 1987, and the author's center has had no stent dehiscence failed prostheses in the newly formulated bioprostheses (Figure 4). A further rare complication is the rolled, thickened, chronically open leaflets of a Medtronic Intact porcine bioprosthesis explanted from the tricuspid position (Figure 5).

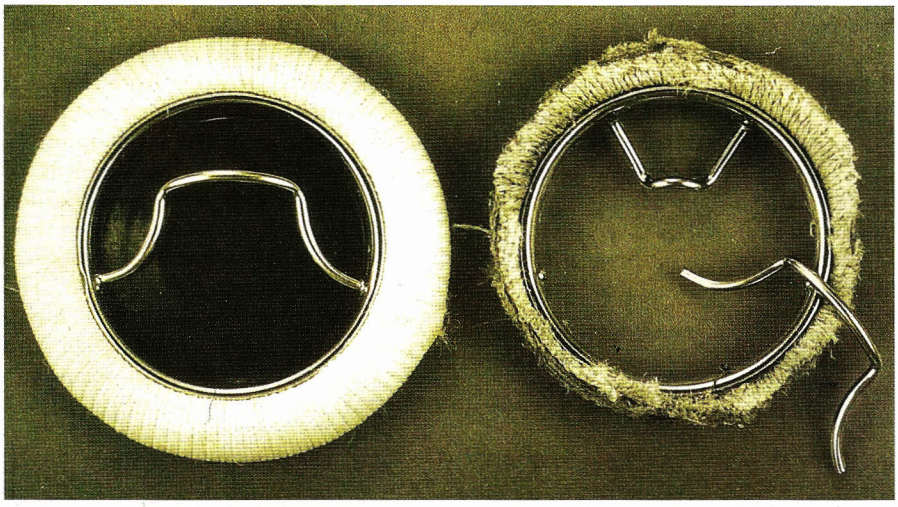

Figure 6. Bjork-Shiley Concave-Convex Prostheses with Outlet Strut Fracture and Disc Embolization.

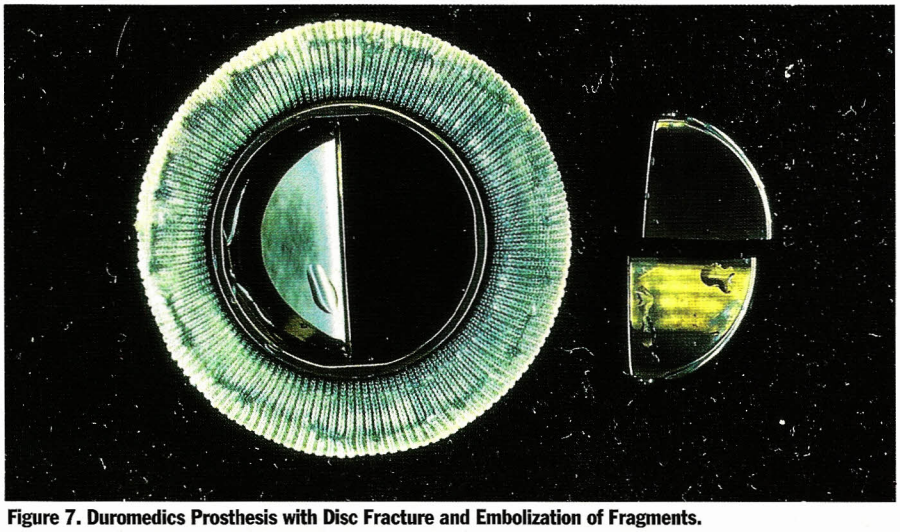

Figure 7. Duromedics Prosthesis with Disc Fracture and Embolization of Fragments.

Figure 8. Bjork-Shiley Monostrut Mechanical Prosthesis.

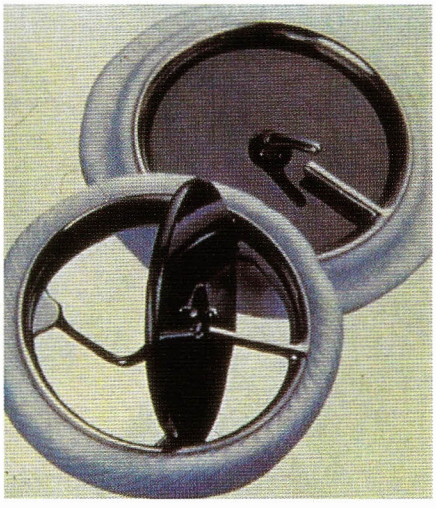

Figure 9. Medtronic-Hall Mechanical Prosthesis.

The structural failure mode of mechanical prostheses has been limited to the Bjork-Shiley concave-convex prosthesis and the Duromedics bileaflet prosthesis. The failure mode of the Bjork-Shiley prostheses is fracture of the welded outlet strut and disc embolization (Figure 6). The mode of failure of the Duromedics is cavitation injury of the disc, housing or pivot ball and resultant fracture and disc embolization (Figure 7). Cavitation phenomena at valve closure has been recognized as a mode of mechanical failure.[9-12] Cavitation is characterized by vaporization of gas and subsequent bubble collapse in regions of high pressure.[13] The impulsion of vapor bubbles results in the generation of pressure waves and fluid jets against adjacent boundary surfaces. The pressure waves and fluid jets result in surface pitting and subsequent potential fracture. The risk of cavitation is elevated in mitral valve closure because of high closing velocities, high dP/dt values, and high acceleration forces. These structural failures can cause catastrophic consequences while the patients in our center with these two failed mechanical prostheses survived emergent surgery.

The structural components of prostheses can contribute to other modes of failure. The disc of a tilting disc orifice-oriented prosthesis (i.e. Bjork-Shiley monostrut) can be entrapped by suture or subvalvular chordae or muscle. Left ventricular outflow tract obstruction can be caused by a Starr-Edwards prosthesis in the mitral position or a strut of a biological prosthesis. These complications result in emergent surgery (disc entrapment) or elective/urgent surgery (outflow tract obstruction). The structural failure complications of biological prostheses, namely tears, perforations and/or calcification, result in the necessity for elective or urgent intervention.

MECHANICAL PROSTHESES

Mechanical prostheses are either monoleaflet or bileaflet prostheses with Pyrolite® pyrolytic carbon leaflets and Pyrolite® or titanium carbon housing. Tungsten is utilized to facilitate radiopacity of the leaflets, as well as metallic band reinforcement if incorporated. The

leaflet(s) is/are rotatable within the housing in most prostheses. Retrograde washing facilitates prevention of blood status and thrombus formation. The monoleaflet prostheses have crossing bars or central guides to control leaflet travel, while bileaflet prostheses have pivot recesses in parallel flat segments of the orifice to control leaflet travel. The leaflets are inserted by orifice or orifice projection deformation.

Monoleaflet Prostheses:

Bjork-Shiley Monostrut Mechanical Prosthesis (Figure 8)

The Bjork-Shiley Monostrut prosthesis (Sorin Biomedica, Saluggia, Italy) is a monoleaflet prosthesis constructed from a single component of cobalt-chromium alloy for the orifice ring and integral struts with a pyrolytic carbon disc with a radiopaque tantalum marker. The opening angle of the prosthesis is 70°. The valve is rotatable within the sewing ring. The leaflet motion is by rotation and translation. The retrograde washing is by relatively low velocity blood flow through controlled backflow between leaflet edge and orifice.

Medtronic Hall Mechanical Prosthesis (Figure 9)

The Medtronic Hall prosthesis is a monoleaflet prosthesis with a central guide for leaflet travel. The housing and central guide is made of titanium and the disc of pyrolytic carbon. The prosthesis is rotatable within the sewing ring. The leaflet motion is by rotation and translation. The opening angle is 70° to 75°. The disc has a tungsten loaded substrate for radiopacity.

Omnicarbon Mechanical Prosthesis (Figure 10)

The Omnicarbon prosthesis (Medical Inc., Grove Heights, MN, USA) is a monoleaflet prosthesis with a titanium orifice ring and a pyrolytic carbon disc. The disc motion is controlled by short struts. The opening angle is 80°.

Bileaflet Prostheses

St. Jude Medical Mechanical Prosthesis (Figure 11)

The St. Jude Medical mechanical prosthesis is a bileaflet prosthesis with pyrolytic carbon over graphite substrate for housing and leaflets. The leaflets are flat and impregnated with tungsten for radiopacity in special three-axis radiographic views. There is no in situ rotation with this prosthesis. The two semicircular leaflets open to 85°, resulting in central, near laminar flow. The leaflets are orifice oriented and closing forces are supported by the pivot system. The pivot guards are raised above the housing, and leaflet motion is by rotation. There are relatively high velocity jets of blood to wash the pivot recesses. There is approximately 10% to 15% regurgitation, which facilitates washing of pivot recesses.

Carbomedics Mechanical Prosthesis (Figure 12)

The Carbomedics (Austin, TX, USA) mechanical prosthesis is a bileaflet prosthesis with solid Pyrolite® housing and flat leaflets of pyrolytic carbon coated over tungsten loaded graphite substrate. The prosthesis has excellent radiopacity with radiopaque titanium stiffening ring and increased tungsten content of leaflet substrate. The opening angle of the leaflet is 78°, which encourages synchronous closure. The leaflet pivot retention mechanism is within the housing without pivot guards, struts, orifice projections. Leaflet motion is by rotation. The leaflets are rotatable within the housing. The pivot recess design reduces potential blood stasis and promotes thorough washout and assures complete leaflet seating. For the small aortic annuli, a special version has modification of the titanium stiffening ring, which minimizes the external valve diameter.

Edwards Tekna Mechanical Prosthesis (Figure 13)

The Edwards-Tekna® mechanical prosthesis (Baxter Healthcare Corp.) is a bileaflet prosthesis with solid pyrolytic housing and curved leaflets of pyrolytic carbon coated over tungsten loaded graphite substrate. Housing stability is increased by a Stellite stiffener ring over solid pyrolytic valve housing. The pivot hinge mechanism is located within the housing, and the leaflet motion is by rotation and translation. The opening angle of the aortic prosthesis is 77 and the mitral prosthesis is 73°. The curved leaflets enhance central flow and rapid closure. The prosthesis is rotatable within both the aortic and mitral designs. The prosthesis, in general, has a low profile housing. The pivot ball and pivot slot mechanism facilitate retrograde washing by relatively high velocity jets. The leaflets close on a circular ledge within the housing and reduce

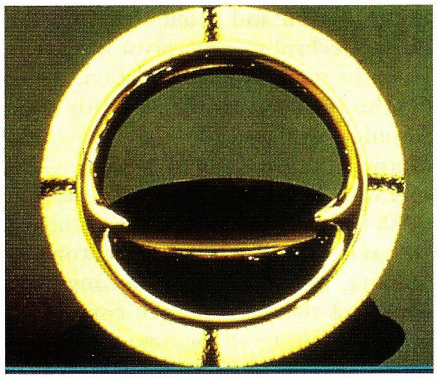

Figure 10. Omnicarbon Mechanical Prosthesis.

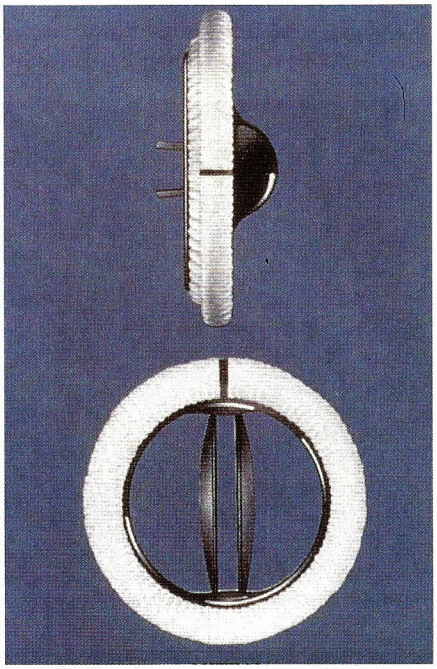

Figure 11. St. Jude Medical Mechanical Prosthesis.

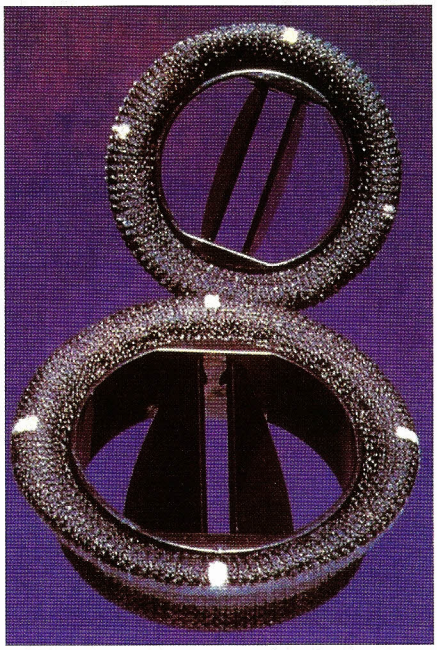

Figure 12. Carbomedics Mechanical Prosthesis.

regurgitation and avoid stress on the hinge mechanism. The pivot ball hinge closes by rotation and translation.

This prosthesis is the currently marketed version of the Edwards Duromedics (previously Hemex) which was withdrawn from the marketplace in 1988 because the prosthesis was subject to cavitation injury and fracture of leaflets, pivot ball, and housing. The causes of the fractures are considered related to clustered microporosity, cavitation erosion and asymmetrical leaflet closure with uneven distribution of the stress load.[9-11] The Edwards-Tekna prosthesis has redefinition of dimensional specifications of the seating lip radius by

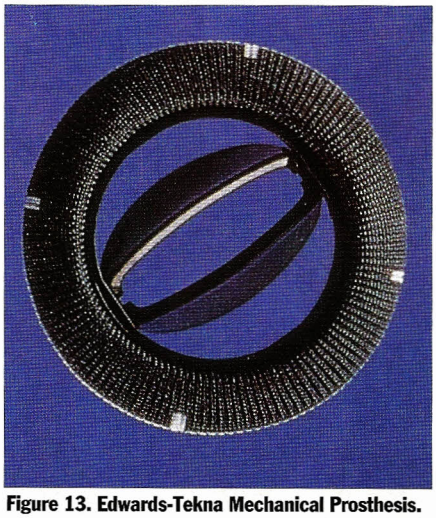

Figure 13. Edwards-Tekna Mechanical Prosthesis.

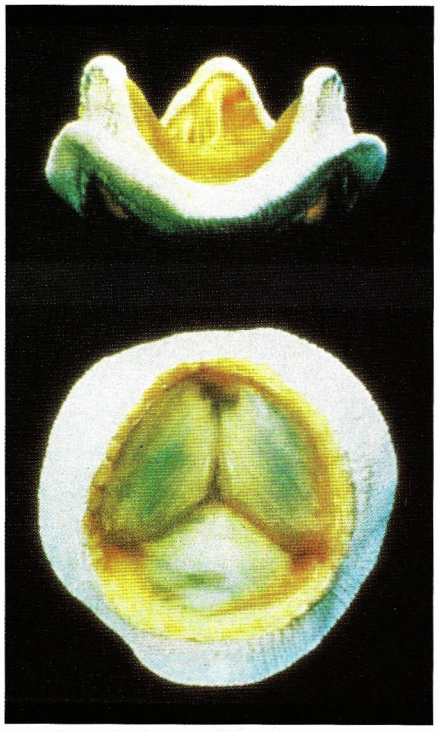

Figure 14. Carpentier-Edwards Supra-Annular Porcine Bioprosthesis.

increasing the contact area, and incorporation of a silicone compliant ring to reduce the leaflet closing impact. The asymmetrical closure was minimized by tighter dimensional specifications of the "flat-to-flat" clearance. The flat-to-flat clearance is the clearance between the flat side portion of the leaflet and flat portion of the valve housing.

Bicarbon Mechanical Prosthesis

The Bicarbon (Sorin Biomedica, Saluggia, Italy) mechanical prosthesis is a bileaflet prosthesis with a titanium alloy housing coated with a thin film of pyrolytic carbon and curved leaflets of pyrolytic carbon coated over a graphite and tungsten substrate. The structural stability of the prosthesis is afforded by the titanium housing and the minimal thickness facilitates an effective orifice. The hinge cavity supports a constantly varying single point of contact between pivot and housing, and two effluent passages for continuous washing even in the closed position. The curved leaflets separate the orifice into three sections with similar resistance to flow, very low pressure gradients and minimal turbulence. The hinge mechanism supports a rolling motion. The opening angle of both the aortic and mitral prosthesis is 70% and both prostheses are rotatable within the housing. The sewing ring is formulated with Dacron and carbon coated Teflon.

ATS (Advance the Standard) Mechanical Prosthesis

The ATS mechanical prosthesis (ATS Medical Inc.,Minneapolis, Minnesota, USA) is a bileaflet prosthesis with a pyrolytic housing and leaflets of pyrolytic carbon with graphite substrate. The prosthesis has a convex hinge mechanism to facilitate retrograde washing. The prosthesis has no protruding struts with this hinge mechanism. The opening angle is 85°. The prosthesis is rotatable within both the aortic and mitral designs.

Medtronic Parallel® Mechanical Prosthesis

The Medtronic Parallel® prosthesis (Medtronic Inc., Minneapolis, Minnesota, USA) is an investigational bileaflet mechanical valve with pyrolytic carbon housing and leaflets with graphite substrate. The housing is fortified by a cobalt chromium alloy ring to facilitate stability. The leaflets are permitted to open to 90° with only a 50% angular excursion. The pivot pocket of the housing and pivot peg on the leaflet encourage washing of the pivot region. The leaflet motion is by translation. The housing protrudes above and below the scalloped sewing ring and should protect the leaflets from tissue ingrowth. The valves of both the aortic and mitral designs are rotatable within the sewing ring.

BIOPROSTHESES

Biological valvular prostheses are formulated from porcine aortic valves or bovine pericardium. The natural aortic valve possesses unique architectural and material characteristics consistent with functional requirements. The current generation porcine bioprostheses have tissue preservation at low pressure or pressure free with glutaraldehyde to preserve bioprosthetic function and durability. The tissue preservation, together with stent designs, contribute to the anatomical characteristics and biomechanical properties of the leaflets. The preservation of the tissue also includes treatment with surfactants as calcium mitigation therapy.

Carpentier-Edwards Supra-Annular Porcine Bioprosthesis (Figure 14)

The Carpentier-Edwards supra-annular porcine bioprosthesis has a supra-annular configuration, mounted on a flexible Elgiloy® wire frame for stress reduction. The prosthesis has a reduced stent profile and the tissue is preserved with glutaraldehyde at low fixation pressure (2 to 4 mmHg). The tissue is treated with the calcium mitigation agent polysorbate 80.

Hancock 11 Porcine Bioprosthesis (Figure 15)

The Hancock II porcine bioprosthesis is a supra-annular prosthesis. The prosthesis has a Delrin® stent, scalloped aortic sewing ring, reduced stent profile, and tissue fixation with glutaraldehyde at low pressure and subsequently for a prolonged period at high pressure. The prosthesis is treated with sodium dodecyl sulfate to retard calcification.

Medtronic Intact® Porcine Bioprosthesis (Figure 16)

The Medtronic Intact porcine bioprosthesis is an intra-annular prosthesis with high stent posts and low stent rails. The prosthesis is designed to retain

leaflet relationships and dimensions, retain maximal area of coaptation, and provide natural stress relief. The tissue is pressure-free fixed with glutaraldehyde and treated with the calcium mitigation agent toluidine blue. The fixation process is considered to conserve leaflet architecture and biomechanics with preservation of the natural collagen crimp pattern to facilitate normal stress-strain relationship. The high profile stent is made of an acetal copolymer resin.

Medtronic Mosaic Porcine Bioprosthesis (Figure 17)

The Medtronic Mosaic® porcine bioprosthesis is a third generation investigational prosthesis. The prosthesis has a supra-annular configuration with a Delrin® stent, scalloped aortic sewing ring and reduced stent profile. The tissue is pressure-free fixed with glutaraldehyde and the aortic wall predilated to reduce deformation of the commissures. The prosthesis is treated with alpha oleic acid to retard calcification.

Hancock-Jaffe Porcine Bioprosthesis

The Hancock-Jaffe porcine bioprosthesis is a third generation prosthesis planned for investigational evaluation. The prosthesis is mounted on a polymer stent with stent-tissue interface to optimize hemodynamics. The valve sizes 25 mm and smaller are composite valves with the right coronary cusp and muscle shelf replaced with a non-coronary leaflet. The porcine tissue is zero pressure fixed with glutaraldehyde and the cellular components removed to remove the nidus sites for calcification.

St. Jude-Bioimplant Porcine Bioprostheses

The St. Jude-Bioimplant (formerly Liotta) porcine bioprosthesis is a third generation prosthesis. The prostheses has a very low profile supra-annular configuration with low pressure glutaraldehyde fixed tissue.

Carpentier-Edwards Perocardial Bioprosthesis

The Carpentier-Edwards pericardial bioprostheses is constructed with an Eligoy® stent for flexibility at the oriface and commissures and pericardium fixed free floating in glutaraldehyde. The leaflets are single and formulated by computer-aided design for optimal leaflet size to stent. The leaflets achieve satisfactory coaptation without stent post sutures.

Mitroflow Pericardial Bioprosthesis (Figure 19)

The Mitroflow pericardial bioprosthesis (Mitroflow International Inc. Richmond, British Columbia, Canada) is formulated with a Delrin® stent for flexibility and pericardium pressure-free fixed with glutaraldehyde. The pericardium is utilized as a single component without critical stent-post sutures. The Dacron® cloth of the prosthesis (current version) has the smooth, rather than ribbed side of the Dacron® in contact with the pericardium.

Pericarbon Pericardial Bioprosthesis

The Pericarbon (Sorin Biomedica, Saluggia, Italy) pericardial bioprosthesis is formulated with two sheets of pressure-free fixed pericardium over a Delrin acetal resin stent, one sheet forming the three cusps with zero stress on the commissures and cylindrical shape in the open position and the other sheet coating the inner surface of the stent. The prosthesis is low profile, has a radiopaque metal wire marker and carbon coated Dacron fabric of the sewing ring.

Stentless Porcine Bioprostheses

Stentless porcine bioprostheses are investigational prostheses fabricated with cloth sewing ring and various configurations of cloth mesh on the aortic wall,

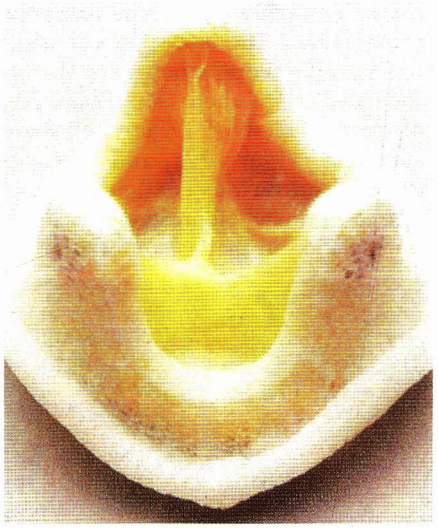

Figure 15. Hancock II Porcine Bioprosthesis.

Figure 16. Medtronic Intact Porcine Bioprosthesis.

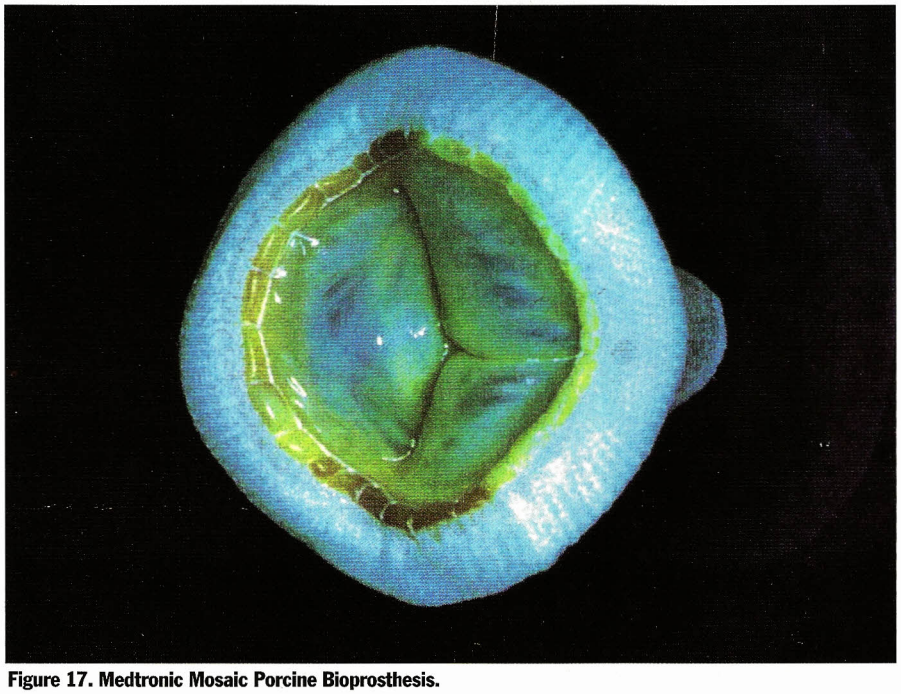

Figure 17. Medtronic Mosaic Porcine Bioprosthesis.

muscular shelf and in some cases the commissures. The investigational stentless porcine bioprostheses are the St. Jude Medical - Toronto SPV (Figure 20), Medtronic Freestyle® (Figure 21), Bravo stentless (Figure 22), and Edwards Prima. The various configurations of stentless porcine bioprostheses facilitate implantation in the fashion of a homograft (allograft), aortic root or miniroot depending upon the prosthesis type. The tissues of the stentless porcine bioprostheses are fixed with glutaraldehyde. The Medtronic Freestyle® bioprosthesis has supplemental treatment, same as the investigational stented Medtronic Mosaic® porcine bioprosthesis.

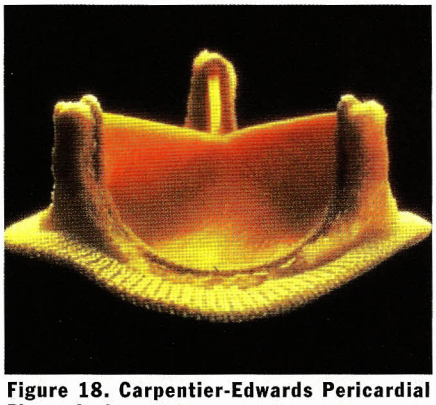

Figure 18. Carpentier-Edwards Pericardial Bioprosthesis.

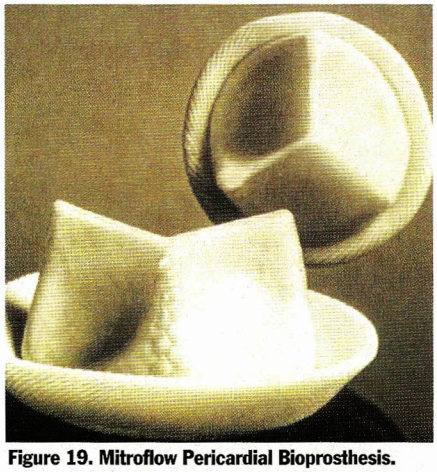

Figure 19. Mitroflow Pericardial Bioprosthesis.

HOMOGRAFTS AND AUTOGRAFTS

Cryopreserved homografts are utilized for aortic valve replacement or aortic root reconstruction in younger patients or patients with native or prosthetic valve endocarditis, especially in the presence of annular abscess. The pulmonary autograft for aortic valve replacement and aortic or pulmonary homograft for pulmonary valve replacement in the younger population is gaining popularity.

IMPLANTATION CONSIDERATIONS

The implantation of the various bioprostheses and mechanical prostheses require special considerations. Prostheses must not be oversized either in the aortic or mitral positions. Annular decalcification is important to prevent paravalvular leaks and damage to leaflet tissue with supraannular porcine bioprostheses. Interrupted horizontal mattress sutures are recommended for aortic and mitral replacements. Horizontal mattress sutures can be placed with or without pledgets from the aortic side and atrial side, respectively, for aortic and mitral replacement, or from the ventricular side for both. Supra-annular porcine bioprostheses have superior hemodynamics to the intra-annular porcine bioprostheses. The first generation intra-annular Hancock standard and Carpentier-Edwards standard, as well as the Medtronic Intact® porcine bioprosthesis, can be considered to have suboptimal hemodynamics in sizes 19 and 21 mm. The earlier generation Hancock modified orifice porcine bioprosthesis has improved hemodynamics facilitated by a composite leaflet for the muscle-shelf leaflet (Figure 23). The high stent post Medtronic Intact® porcine bioprosthesis should be utilized only with reservation in mitral valve replacement for mitral stenosis with small left ventricular cavity.

There are special considerations required for implantation of mechanical prostheses. The risk of disc immobilization from suture ends or intracardiac structures must be minimized.[14] The full orifice setting prostheses, the Medtronic Hall and Bjork-Shiley Monostrut, can experience disc entrapment from chordal fragments or suture ends. The sutures with these prostheses must exit the sewing ring near the equator so suture ends project away from the leaflets. Long suture ends must be avoided with bioprostheses because of the risk of leaflet injury with perforation. Septal hypertrophy and thickened mitral leaflet require special consideration. Rotatable mechanical prostheses must be used so orientation can be optimized for proper function. The monoleaflet prostheses, such as the Medtronic Hall, may be superior. The nonrotatable St. Jude Medical prosthesis may create partial leaflet motion in this circumstance.

The small aortic annulus also requires special considerations.[15-19] The tilting technique of prosthesis insertion for aortic valve replacement in the small aortic annulus, as an alternative to annular enlarging techniques, should be performed with a monoleaflet mechanical prosthesis or bioprosthesis. There are three documented procedures for enlargement of aortic annulus - the Konno procedure, the Nicks procedure and the Manouguian procedure. The Konno procedure is utilized when there is narrowing of the subvalvular left ventricular outflow tract. The Konno aortoventriculoplasty enlarges the annulus and subvalvular area, the procedure is

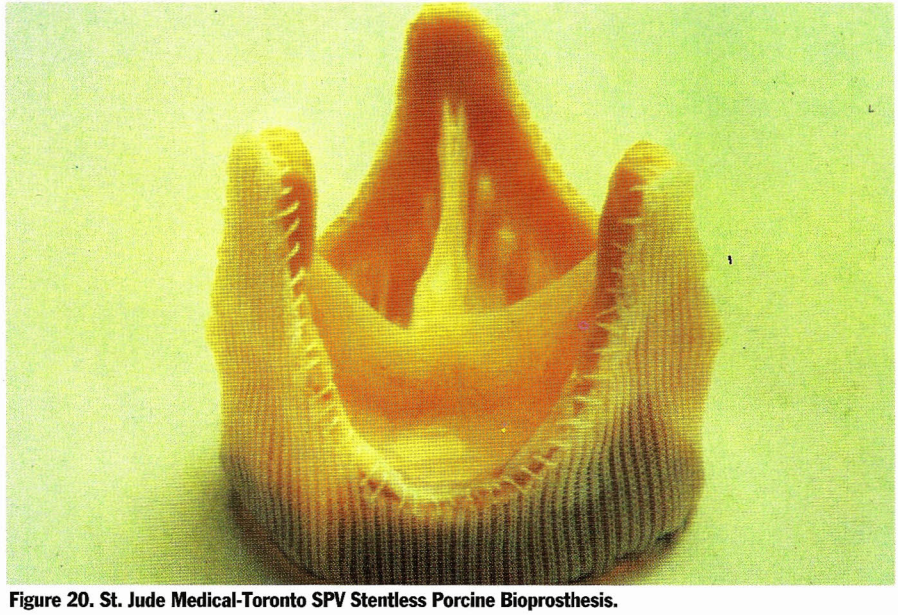

Figure 20. St. Jude Medical-Toronto SPV Stentless Porcine Bioprosthesis.

performed with a longitudinal, anteriorly placed aortotomy incision carried to the left of the origin of the right coronary artery into both the right ventricular free wall and the ventricular septum and insertion of a double patch graft for enlargement of left ventricular free wall and ventricular septum. The Manouguian procedure incorporates a patch graft into the noncoronary sinus of Valsalva, the procedure is used when narrowing is only at the supra-annular level at the top of the sinuses of Valsalva. A bovine pericardial patch is best utilized in this procedure. The Nicks procedure, utilized when the annulus enlargement is required both annular and supra-annular, with patch graft enlargement across the annulus into the aortic-mitral annulus. The enlargement of the supra-annular and annular area can be achieved by extending the aortotomy through the left coronary-noncoronary commissural area and into the underlying aortic-mitral annulus. Both mechanical and biological prostheses can be utilized with these techniques. Alternative methods could incorporate an allograft aortic valved cylinder, autograft pulmonary valved cylinder or stentless porcine bioprosthesis root. Harada and colleagues[17] reported that the Konno and Manouguian procedures enlarged the annulus between 180% and 200% and the Nicks procedure by 110%.

There are two recommended techniques for implanting an aortic bileaflet mechanical prosthesis. One technique is to locate the septum beneath one leaflet by positioning one pivot at the center of the left coronary cusp and the other at the junction of the right coronary and non-coronary cusps.[20] The other permits the leaflets perpendicular to the septum with one pivot centered to the right coronary cusp and the other at the junction of the left coronary and noncoronary cusps.[21]

The mitral valve replacement has special considerations, especially for insertion of mechanical prostheses. The preservation of leaflet, chordae, and papillary muscles enhances postoperative ventricular performance.[22-34] Experimental studies have revealed that the subvalvular apparatus of the mitral valve contributes to optimal left ventricular systolic function.[35-39] Okita and colleagues[40] have shown that left ventricular ejection fraction and fractional shortening are superior with continuity between mitral annulus and papillary muscles in mitral valve repair and replacement with chordal preservation over conventional mitral valve replacement. The posterior leaflet is most commonly preserved with special techniques described for chordae and papillary muscle suspension of the anterior leaflet. Rose and Oz[41] reported on the technique of excising the central portion of the anterior leaflet and suturing the rim of the leaflet tissue containing the marginal chordae to the region of fibrous trigones at the edge of the leaflets attached to the left atrium. David[32] has recommended resuspension of the papillary muscle in cases of calcification and fibrosis of chordae with the use of expanded tetrafluoroethylene sutures. Feikes and colleagues[42] reported an alternative technique for preservation of the entire papillary muscle and chordal apparatus. The anterior mitral leaflet is split from the center of the free edge to the annulus and bilateral incisions to the mitral commissures detaching the anterior leaflet from the annulus. The leaflet segments are trimmed preserving chordae tendineae and then swung posteriorly and sutured to the posterior mitral annulus with pledgeted mattress sutures. The techniques facilitate implanting of tilting disc and bileaflet mechanical prostheses, as well as bioprostheses. The leaflet plicating techniques facilitate insertion of the current mechanical prostheses with minimal risk of leaflet restriction. The plicating technique of horizontal mattress sutures from leaflet tissue and annulus can accomplish mechanical prosthesis inser-

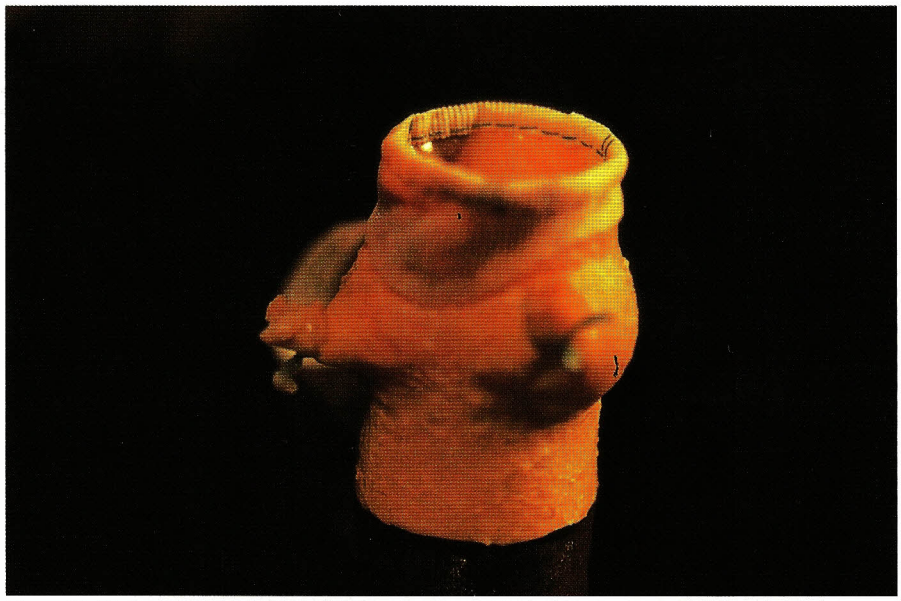

Figure 21. Medtronic Freestyle® Stentless Porcine Bioprosthesis.

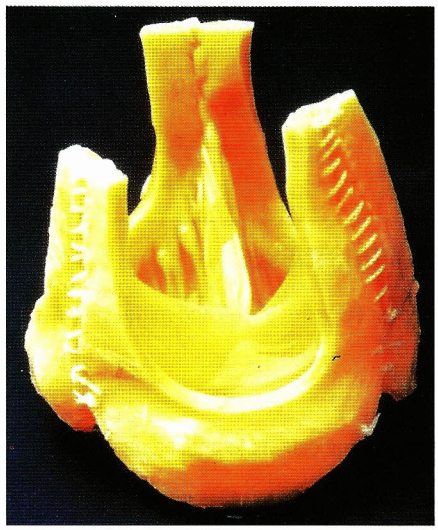

Figure 22. Bravo Stentless Porcine Bioprosthesis.

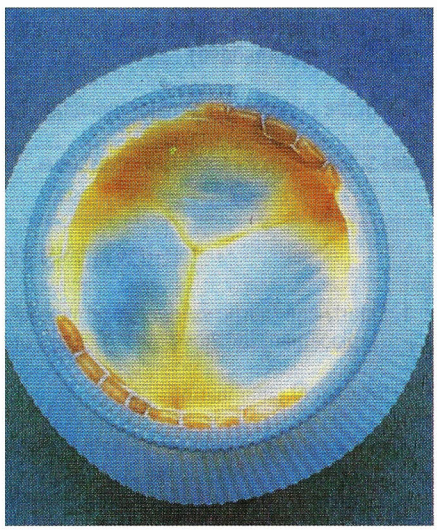

Figure 23. Hancock Modified Orifice1ce Porcine Bioprosthesis.

PROSTHESIS - FREEDOM FROM STRUCTURAL VALVE DETERIORATION (SVD)

Author	Prosthesis	Mean Age	AVR 10 Years	AVR 15	MVR 10 Years	MVR 15
Burdon et al[56]	Hancock I	45 Years	85.0%	63.0%	78.0%	45.0%
Jamieson et al[67]	CE-S	57 Years		71.0%		41.0%
Jamieson et al[69]	CE-S		79.0%		72.0%	
Jamieson et al[71]	CE-S	57 Years	84.0%		69.0%	
	< 35 Years		60.0%		50.0%	
	36-50 Years		70.0%		62.0%	
	51-64 Years		84.0%		70.0%	
	65-69 Years		95.0%		64.0%	
	≥ 70 Years		100%		95.0%	
Jamieson et al[71]	CE-SAV	62 Years	86.5%		74.5%	
	≥ 35 Years		84.0%		67.5%	
	36-50 Years		80.0%		76.0%	
	51-64 Years		80.0%		76.0%	
	65-69 Years		99.0%		70.0%	
	≥ 70 Years		99.0%		79.0%	

Table 2. Bioprostheses - Freedom from Structural Valve Deterioration (SVD).

INDICATIONS FOR MECHANICAL PROSTHESES

1. Younger age, especially patients less than 50 to 60 years old (homografts are also recommended for aortic replacement in younger age groups and especially in the presence of endocarditis).
2. Children and adolescents, except females in anticipation of childbearing
3. To replace a degenerated biological prosthesis, especially in the presence of calcification.
4. For aortic root replacement with a composite graft (homograft root replacement is also recommended).
5. In the presence of a major indication for indefinite anticoagulation.

Table 3. Indications for Mechanical Prostheses.

INDICATIONS FOR BIOPROSTHESES

1. Elderly age (aortic valve replacement for those over 65 years of age and mitral valve replacement for those over 70 years of age)
2. Women of childbearing age
3. In the setting of long-term relative or absolute contraindications to anticoagulation
4. To replace a thrombosed mechanical prosthesis, especially a bileaflet prosthesis

Table 4. Indications for Bioprostheses.

tion and especially mural leaflet preservation. There has been considerable attention to orientation of prostheses. The monoleaflet prosthesis must be positioned for posterior wall or lateral clearance, and optimal flow characteristics. The bileaflet prostheses can be positioned in the anatomical position (pivots at commissural positions) or antianatomical position. There is no general agreement but the ideal is for simultaneous leaflet opening and closing.[20,21] The rotatability of prostheses in the mitral position is of utmost importance.

The stentless porcine bioprostheses will require special techniques for valve and root replacements.[43-44] Transverse aortotomy of near full circumference at the sinotubular junction or vertical "hockey stick" aortotomy to the noncoronary sinus are both recommended. The annular inflow suture line is placed with interrupted sutures in a horizontal, nonscalloped plane and second outflow suture line with continuous sutures. The root replacement differs with coronary ostia suturing to coronary windows and the outflow of the prosthesis secured with closure of the aorta following transverse aortotomy.

Clinical Performance - Indications for Prosthesis Type

Cardiac valvular prostheses are evaluated by clinical and hemodynamic performance. The clinical performance is judged according to the "Guidelines for Reporting Morbidity and Mortality After Cardiac Valvular Operations."[45] The complications of cardiac valvular prostheses are structural valve deterioration, nonstructural dysfunction, thromboembolism (including thrombosis), anticoagulant related hemorrhage, and prosthetic valve endocarditis.

The literature has provided extensive documentation on individual prostheses and combinations of prostheses and non-randomized assessments of bioprostheses and mechanical prostheses, but few randomized clinical studies have been reported. Randomized clinical trials have included the Veterans Administration (VA) Study on Valvular Heart Disease[46-49] and the Edinburgh Heart Valve Trial.[50] The VA study compared the previous generation Bjork-Shiley spherical disc mechanical prothesis and the Hancock standard porcine bioprosthesis; the Edinburgh study compared the Bjork-Shiley spherical disc valve to the

Hancock and Carpentier-Edwards prostheses. These prostheses are not currently utilized worldwide but the conclusions provide comparison of clinical performance of bioprostheses and mechanical prostheses. The conclusions drawn from the randomized trials are as follows:

1. Bleeding complications from anticoagulation were predominant in the mechanical valve populations.
2. The prevalence rates of thromboembolism, thrombosis, and prosthetic valve endocarditis were the same for mechanical and biological prostheses.
3. Reoperations were necessary for structural failure of bioprostheses and paravalvular leak of mechanical prostheses.
4. Porcine bioprostheses failed more frequently in the mitral position than in the aortic position five or more years after implantation.
5. The increased risk of reoperation with bioprostheses appeared to be a high price to pay for the reduced risk of bleeding afforded by avoidance of anticoagulants.
6. The freedom from death, reoperation, major bleeding, major embolism and endocarditis was less with porcine bioprostheses, and specifically mitral prostheses.

The clinical performance of nonrandomized studies of biological and mechanical prostheses,[51-55] as well as specific prostheses assessment, have contributed to the development of indications for the types of prostheses. The freedom from thromboembolism with presently utilized mechanical prostheses, namely Medtronic-Hall,[56] Bjork-Shiley Monostrut,[57] St. Jude Medical[58] and Sorin,[59] range from 90% at five years, 86% at eight years,[56] 92% at nine years and 67% at 10 years,[58] undifferentiated by valve position. The freedom from anticoagulant hemorrhage ranged from 89 % at seven years[60] and 91-94 % at nine years.[59] There were no studies that combined freedom from thromboembolism and anticoagulant hemorrhage. The freedom from valve-related reoperation was 89% and 92% for aortic and mitral prostheses at nine years.[59] Structural valve deterioration is not a problem with the currently utilized mechanical prostheses. Mikaeloff and colleagues[61] concluded that monoleaflet mechanical valves in the mitral position may contribute to more early deaths, valve thrombosis, valve dysfunction and sudden late deaths than bileaflet prostheses.

The major concern with porcine bioprostheses has been structural valve deterioration, more predominant in young and intermediate age groups than in elderly age groups.[62-65] The freedom from thromboembolism with the Hancock standard porcine bioprosthesis at 15 years, as reported by Burdon and co-authors,[66] was 84% for aortic valve replacement and 78% for mitral valve replacement. Jamieson and colleagues[67] had a freedom from thromboembolism and anticoagulant hemorrhage with the Carpentier-Edwards standard porcine bioprostheses of 80% for aortic valve replacement and 72 % for mitral valve replacement, at fifteen years. The freedom from structural valve replacement with porcine bioprostheses is detailed in Table 2. There has been no clear differentiation in the freedom from structural valve deterioration between the first generation porcine bioprostheses and the second generation Carpentier-Edwards supra-annular and Hancock II porcine bioprostheses.[8,66,68-71]The freedom from reoperation parallels that of structural valve deterioration for all porcine bioprostheses with consideration of a low incidence of prosthetic valve endocarditis and non-structural dysfunction. The experience of the pressure-free glutaraldehyde-preserved Medtronic Intact by Barratt-Boyes and colleagues[72] has been very encouraging with freedom from structural failure, at eight years evaluation, of 100% for aortic valve replacement and for mitral valve replacement - 86% for age group 60 years and over, 96% for 40-59 years, 67% for 20-39 years, and 38% for patients less than 20 years.

There has been a resurgence of interest in bovine pericardium as a valvular substitute.[73-76] The Mitroflow pericardial prosthesis, reported in 1993 by Jamieson and colleagues,[75] had a freedom from structural valve deterioration at seven years of 85% for aortic prostheses and 61% for mitral prostheses. Loisance and investigators[76] have reported, in 1993, an overall freedom from structural failure of 95 % at five years and 64 % at eight and one-half years. The Carpentier-Edwards pericardial prostheses, another second generation bioprosthesis, has demonstrated freedom from structural failure at over 97% for aortic prostheses at eight years of evaluation.[73] This renewed interest in pericardium as a valvular substitute is due to better engineering of pericardium without stress related fatigue injuries.

Several additional conclusions have been drawn about mechanical and biological prostheses. Lytle and colleagues[77] have provided several conclusions, namely, bioprostheses provide better survival and event-free survival when implanted in the aortic position in patients over 40 years of age; mechanical prostheses are accompanied by a higher incidence of thromboembolism, bleeding, myocardial infarction, and cerebrovascular accident; and the incidence of reoperation and prosthetic valve endocarditis is increased with bioprostheses in the aortic position in young patients. Several authors[46,48-50] have shown that there is no clear advantage of mechanical over biological prostheses in the short and intermediate term in the general population, while the advantage shifts to mechanical prostheses in the long term, especially in the mitral position. Bloomfield et al[50] and Jamieson et al[67] have identified that structural valve deterioration of bioprostheses necessitating reoperation occurs nearly twice as frequently in the mitral position as in the aortic position.

The indications for bioprostheses and mechanical prostheses have been developed at the University of British Columbia with continuing evaluation of 6000 patients over 18 years. The risk factors for structural valve deterioration with bioprostheses are younger age and mitral prostheses. For aortic and multiple replacement the only risk factor is younger age, while for mitral replacement it is younger age and female sex. The general indications for bioprostheses and mechanical prostheses are presented in Tables 3 and 4.[1]

Mechanical prostheses have a high risk of thromboembolism and anticoagulant hemorrhage and bioprostheses have a high risk of structural valve deterioration and reoperation. Bioprostheses are especially indicated in valve replacement surgery for aortic valve replacement in the elderly and women in childbearing age desirous of children. Mechanical prostheses are indicated in younger age groups, particularly when homografts or pulmonary autografts cannot be used for aortic valve replacement and mitral

valve reconstruction is not possible. Future developments in bioprostheses will likely contribute to a reduced incidence of calcification and stress-related injuries through advanced tissue preservation formulations. Future developments in mechanical prostheses may contribute to improved flow and surface characteristics that will reduce the incidence of thromboembolism and thrombosis. STJ

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Correction:
Surgical Technology International II, page 229.
Sentence reads: " Only the Medtronic-Hall tilting-disc prosthesis is currently being used in this country."
Sentence should read: The Medtronic-Hall and the Omniscience tilting disc prostheses are currently being used in this country