IN-VITRO AND IN-VIVO HAEMODYNAMIC PROPERTIES WITH CARDIAC VALVE PROSTHESES

THESIS

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By

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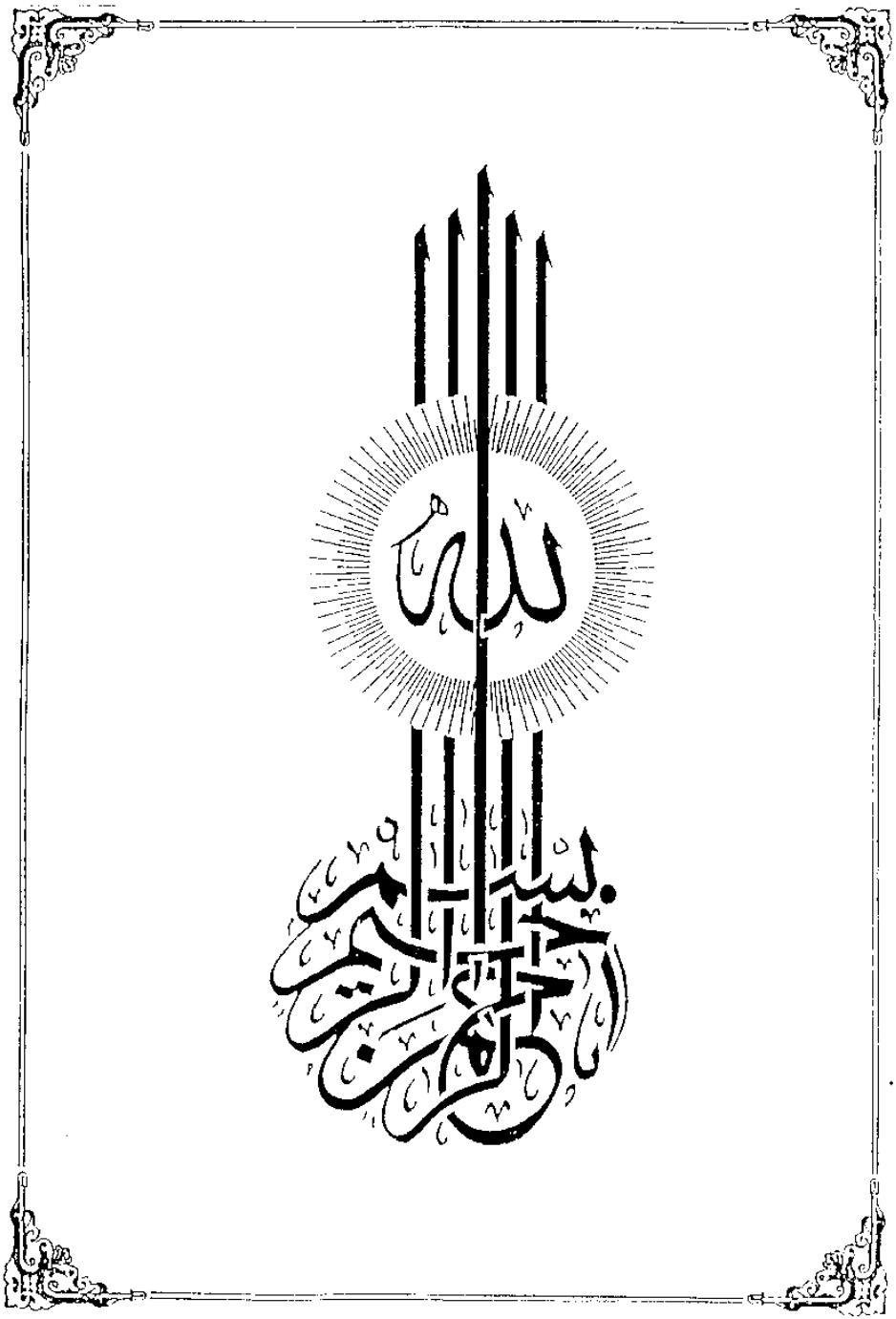
TO THE MEMORY OF MY FATHER



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CONTENTS

INTRODUCTION AND AIM OF THE WORK

Since the pioneering work of Hufnagel in 1952, and Harken and Starr in 1960, considerable effort has been devoted to the design, development and testing of prosthetic heart valves (Dellsperger et al., 1983). Notwithstanding all this effort there is, as yet, no ideal valvular prosthesis. All the currently available models offer a compromised solution based on a number of advantages and disadvantages depending on valve type (Gabbay and Kresh, 1985).

Research in the field of assessment of prosthetic valve function has been carried out both in-vitro and in-vivo. Studies in-vitro have been concerned with well known parameters of valve function, such as pressure drops, effective orifice areas, performance indices, inherent regurgitant volumes and energy losses, both to evaluate individual valve function and to compare the haemodynamic properties of different valve designs. Some sophistcated new approaches to investigate transvalvular flow patterns and shear stresses have emerged recently (Gibbs, 1987).

Although the in-vitro evaluation of haemodynamic performance should ensure that the effective orifice area of any prosthesis is adequate, an in-vivo haemodynamic evaluation is also necessary, because the haemodynamic performance may be further modified by tissue ingrowth and endothelialization after implantation, technical factors relating to the position of the prosthesis in relation to other cardiac structures, and by the size of the prosthesis in comparison with the size of the patient (Rahimtoola et al., 1978), (Gersh et al., 1986).

In-vivo haemodynamic studies have now been based on invasive haemodynamics, intra-operatively or by post-operative catheterisation, and non-invasive Doppler ultrasound. The improvement in ultrasound in technology over the past years has clearly revolutionized the use of Doppler in the haemodynamic evaluation of prosthetic heart valves (Quinones, 1987).

The aim of the present work is to study the haemodynamic performance of the currently used cardiac valve prostheses, in-vitro and in-vivo, as well as the naturally occurring changes which may occur in that performance following clinical implantation.

Review of Literature

HISTORICAL PERSPECTIVE OF PROSTHETIC HEART VALVES

The first clinical use of a prosthetic heart valve was by Charles Hufnagel who, in 1952, partially corrected aortic incompetence by inserting a caged-ball valve in the descending thoracic aorta (Hufnagel and Gomes, 1976). A few years later, Gordon Murrary succeeded in sewing aortic homografts into the descending aorta for the treatment of aortic incompetence. These operations partially corrected the physiologic problem, but were not true valve replacements (Paton and Vogel, 1985).

It was, however, Dwight Harken who in March 1960 began the modern era of prosthetic valve replacement by insertion of his double caged-ball valve into the aortic orifice below the coronary ostia following excision of the diseased cusps (Bjork, 1985). Albert Starr in September of the same year, implanted his caged-ball valve in the mitral position, and later he successfully used it for aortic valve replacement (Roberts, 1985). Attempts to reduce the overall height of the valve by a disc occluder in a flattened cage started in 1964, but were not successful. Most of these caged-disc valves enjoyed only a limited success and, at the present time, none of these valves remains in clinical use (Starek, 1987).

It was the Japanese surgeon, Juro Wada who introduced a tilting disc valve for the first time in 1966. However, the Wada valve did employ a hinge mechanism which tended to clot, and a Teflon disc which wore out at the hinge (Bjork, 1985). The most significant developments in mechanical valve design occurred in

1969 and 1970 with the introduction of the Bjork-Shiley and Lillehei-Kaster tilting disc valves. Both prostheses involve the concept of a free floating disc which, in the open position, tilts to an angle depending on the design of the disc retaining struts (Black et al., 1983).

The first bileaflet valve was developed by Gott in 1963 (Young et al., 1965). The leaflet hinges tended to clot and this design was abandoned. The bileaflet concept was revived years later with the introduction of the St Jude Medical Valve in 1977 (Starek, 1987).

The tissue valve made its first appearance in 1962 in the form of a fresh aortic valve homograft used successfully for aortic valve replacement by Ross, Duran and Barratt-Boyes (McClung et al., 1983). Other biologic materials, such as fascia lata, pericardium, and dura mater have been tried to construct valves (Starek, 1987). Work on the xenogeneic valve began in 1965, using the aortic valves of the pig and calf (Magilligan, 1987). The gluteraldehyde-preserved porcine aortic valve bioprosthesis has been commercially available for clinical use, since 1970, as the Hancock porcine xenograft. The Hancock valve remains one of the two most popular valve substitutes of this type, the other being the Carpentier-Edwards bioprosthesis, introduced in 1976 (Black et al., 1983). Pericardial valves, consisting of three leaflets of bovine pericardium mounted in a tricuspid configuration was introduced by Marian Ionescu in 1971, and has been commercially available as the Ionescu-Shiley pericardial valve since 1976 (Ionescu et al., 1977). Recently,

the bicuspid Sheffield pericardial valve (Black et al., 1983), and the monoleaflet Gabbay-Meadox pericardial valve have been employed in Europe for clinical trials (Clark, 1987).

EVOLUTION AND CHARACTERISTICS OF PROSTHETIC HEART VALVES

The history of valve replacement is one of continual changes, both in prosthetic design and materials and in selection and management of patients. Many prosthetic valves have been developed, initially widely used, and yet ultimately discarded when clinical performance did not meet initial, often intuitive, predictions. Prostheses presently in use may be superior to those used in the past but are not trouble-free (Gersh et al., 1986). Despite substantial improvements in design and characteristics, the ideal valve substitute does not yet exist, nor have we met the criteria of the perfect valve which was outlined by Harken et al., in 1962: "The optimal prosthetic valve should have lasting physical geometric features and be capable of permanent fixation in the normal anatomic site. It should be chemically inert, non thrombogenic, harmless to blood elements and must not annoy the patient. It must open and close promptly during the appropriate phase of the cardiac cycle and should offer no resistance to physiological blood flow".

All currently available prosthetic valves fall short of these standards and to make a rational decision as to which valve is best for a particular patient, several variables, important to consider, include long term complication rates, need for anti-coagulation, age of patient, coexistent disease, patient life-style, anatomic and haemodynamic factors and the surgeon's experience. No particular valve substitute is clearly superior, and operative mortality does not appear to be related to valve

selection but rather to the patient's general condition and the degree of myocardial dysfunction (Gore, 1987).

Two categories of valve substitute have been available for the last two decades, mechanical and tissue valves.

A There are three types of mechanical valves:

1. The caged-ball valve prostheses such as the Starr-Edwards, Smeloff-Cutter, Magovern-Cromie, DeBakey-Surgitool and Braunwald-Cutter (the last two are discontinued).
2. The caged disc valve prostheses such as Cross-Jones, Kay-Shiley, Cooley-Cutter, Harken-Cromie, Kay-Suzuki, Starr-Edwards (all these are discontinued) and the Beall mitral.
3. Tilting discs prostheses such as Bjork-Shiley, Lillehei-Kaster, Medtronic-Hall and Omniscience, also the bileaflet valves, the St Jude and the Duromedix.

B The tissue valves are either of human origin such as the aortic homograft or heterograft, as the porcine, Hancock and Carpentier-Edwards or the pericardial as the Ionescu-Shiley valve.

The caged-ball valve

Evolution

The Starr-Edwards valve prosthesis is probably the most widely known and extensively studied caged-ball valve since it was first implanted in the mitral position in 1960 (Fernandez, 1985). The original design was that of a bare metal cage made of

stellite and enclosing a silastic rubber ball. The cage of the mitral valve was constructed with four struts, and the aortic with three struts, anchored by a sewing ring of Teflon cloth (Starr and Edwards, 1961). The problem of ball variance in the original designs was countered in models 1260 aortic prosthesis and 6120 mitral prosthesis by a new "cure" process in the manufacturing of the silastic ball (McHenry et al., 1970). Additional alterations included an increase in the orifice to ball diameter, modification of the orifice configuration and decrease in the overall weight of the prosthesis by reducing its metallic composition (Herr et al., 1968).

Several modifications have been made including the use of a hollow stellite ball and covering the struts completely with cloth (Hodam et al., 1970), in a trial to reduce the threat of thrombus formation (Braunwald and Boncheck, 1967). Because of the cloth wear and pronounced haemolysis, the composite track valve was developed in 1972. This model incorporates strips of stellite on the inner surface of each strut, providing a metallic track that protects the Teflon covering from trauma, resulting from ball impaction (Pluth, 1986). There was no greater thrombo-embolic potential associated with this model than others if the patients were appropriately anticoagulated (Macmanus et al., 1980). Haemolysis has remained significant, however, resulting in the abandonment of cloth covered struts entirely (McClung et al., 1983). The silastic ball model 6120 mitral and model 1260 aortic prostheses, used continuously since 1965 (Starr, 1985), have given better results than any of the

modified versions introduced in the intervening years (Cobanoglu et al., 1985). They are the only available Starr-Edwards valves produced now (Roberts, 1985).

The Smeloff-Cutter valve was designed primarily for the purpose of minimizing outflow tract obstruction in the mitral position (Oxam et al., 1975). It is a caged-ball valve with open-ended cages above and below the seating ring, allowing the silicone rubber ball to sit within, rather than on, the ring, thus reducing the size of the central obstruction due to the occluding ball (Wheatley, 1986). The open cages are machined in one piece from titanium and are designed to minimize outflow tract obstruction (Jamieson, 1986), and to decrease the frequency of the thrombo-embolic events (Lee et al., 1970). The valve was introduced in 1964, and a mild cure silicone rubber ball was intoduced in the second model of the Smeloff-Cutter prosthesis in 1966 (Fernandez, 1985). There have been no further modifications up to the present time (Morse and Steiner, 1985).

The Braunwald-Cutter valve was available for clinical use in 1968 (Braunwald et al., 1971). It consists of an open ended metallic cage in which the three struts were covered with Dacron and the inflow ring was covered with an ultra thin polypropylene mesh fabric. A modified-cure silicone ball was chosen as a poppet (Tandon et al., 1978). This prosthesis was withdrawn from the market in 1979, because of the recurrent ball variance and embolisation of the ball through the open cage (Blackstone et al., 1977).