VOLUME 2

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TEXTBOOK of INTERVENTIONAL CARDIOLOGY

TOPOL

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TEXTBOOK of INTERVENTIONAL CARDIOLOGY

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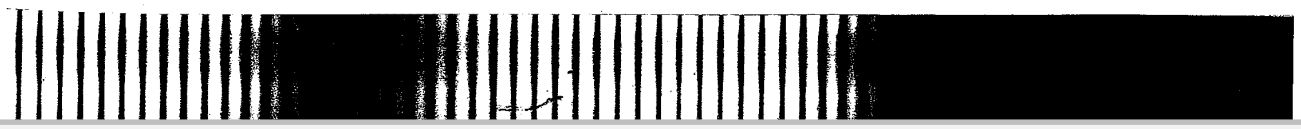

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Percutaneous Expandable Prosthetic Valves

Steven R. Bailey

The introduction of percutaneous techniques for vascular intervention has resulted in the rapid development of new devices and techniques for the treatment of coronary and vascular diseases. One important area of potential interest is the application of percutaneous techniques for the treatment of valvular heart disease. The exponential growth of percutaneous endovascular procedures is similar to that experienced in cardiovascular surgery after the introduction of cardiopulmonary bypass. The design of implantable prosthetic heart valves to be delivered using a percutaneous approach has become an important area for investigation.

The initial implantation of a prosthetic heart valve was performed in 1952 and published in 1953 by Hufnagel and Harvey,[1] with a follow-up report in 1954.[2] The Hufnagel valve is composed of a chamber with a central ball valve as seen in Figure 75–1. This bulky device was surgically placed in the descending aorta distal to the left subclavian artery. Patients did surprisingly well clinically despite the fact that only 75 per cent of the regurgitant volume was diminished using this valve in the descending aorta. Subcoronary placement of prosthetic valves became possible only after the introduction of cardiopulmonary bypass in 1960.[3] The past three decades have seen significant improvements in the performance of mechanical, tissue, and homograft prosthetic valves, with numerous alterations occurring in the designs of these prostheses.[4] These changes have improved the functional orifice area as well as decreased the complications associated with valve replacement such as thrombus formation, embolism, and late valve dysfunction.

Unfortunately, placement of prosthetic heart valves remains a relatively difficult and often dangerous procedure. The surgical risks rise rapidly in patients with serious problems such as acute valvular regurgitation and in patients whose valvular disease is associated with myocardial ischemia.[5,6]

The development of percutaneous catheter–based systems for stabilization and treatment of unstable patients with valvular disease, which could be performed at a lower risk to the patient, is therefore an important area for research. Developing a chronically implanted catheter–based valve prosthesis is an exciting new frontier in interventional cardiology.

HISTORY OF CATHETER-BASED VALVES

The demonstrated success of the Hufnagel valve in treating aortic insufficiency precipitated the initial investigation in 1965 by Hywel Davies[7] of a catheter-mounted valve for temporary relief of aortic insufficiency. This device, although crude by today's standards, was very interesting in design. As seen in Figure 75–2 this cone-shaped device was essentially an inverted parachute. The valve closed during systole due to the forward flow of blood out of the ventricle, and opened during diastole as the regurgitant flow returned to the ventricle. It was anchored onto a 5-Fr. catheter with thin guy wires. No information was provided regarding the type of material from which this valve was constructed. Initial animal experiments were promising, although no human investigations were ever reported. One significant problem displayed by this valve was the rapid development of thrombi at the base of the cone, a theme common to all prosthetic valves. This predisposition was probably enhanced by prolonged stasis of blood in the base of the conical valve.

Moulopoulos et al.[8] reported their investigations into catheter-mounted aortic valves in 1971. Utilizing the investigators' experience in developing electrocardiographically (ECG) triggered intra-aortic balloon pumps, they designed and evaluated three separate systems (Fig. 75–3). One was a spherical balloon triggered by the ECG to inflate during diastole. The second was a spherical balloon that was pressure responsive and deflated when systolic pressure exceeded a predetermined value. It inflated when pressure fell below a specified diastolic value, resulting in diastasis. Their third system was an umbrella-shaped balloon similar to that used by Davies et al. They concluded that the relatively simple umbrella system was best, significantly reducing the severity of acute aortic insufficiency without major acute complications.

There were several disadvantages of a catheter-based valve found by these investigators in the chronic animal model, including the development of significant thrombi in the base of the umbrella in all animals followed chronically. Most importantly, variable decreases in coronary flow also occurred in these animals. The decreased coronary flow was attributed

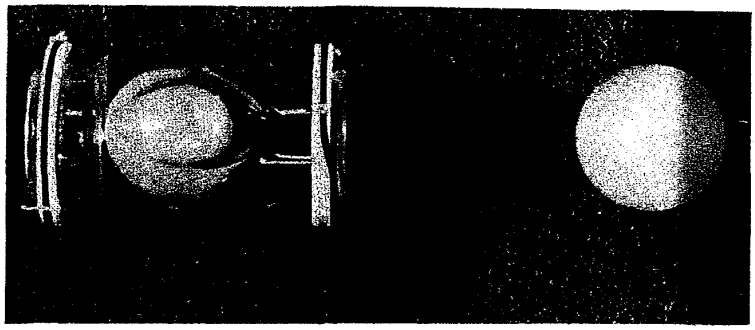

FIGURE 75–1. The Hufnagel valve, when assembled, consisted of a hollow plastic tube, the fixation rings on each end, and the polypropylene central ball.

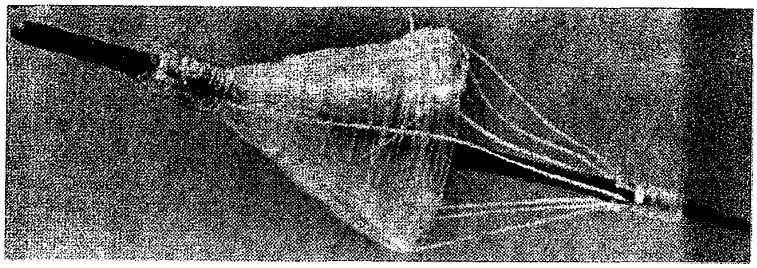

FIGURE 75–2. The Davis valve was an inverted plastic cone anchored to the shaft of a 5-Fr. catheter. Note the guy wires used to stabilize the valve.

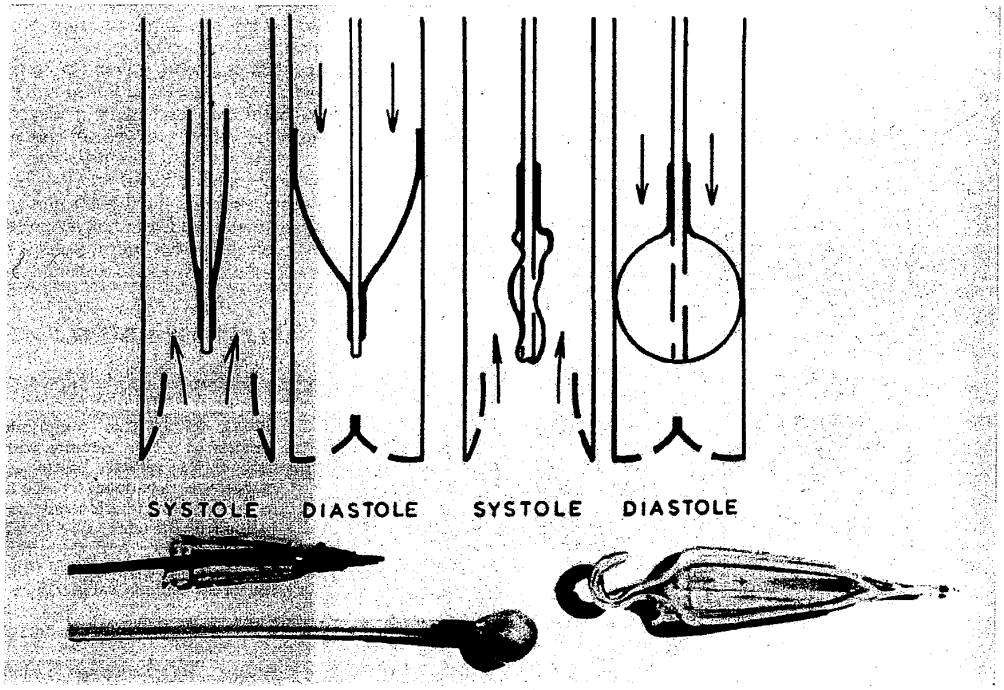

FIGURE 75–3. The top section demonstrates the valve motion during systole and diastole. The bottom left is a photograph of the umbrella valve and the middle is the balloon valve. The bottom right is a picture of the glass cast used to manufacture the umbrella valve.

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