DESIGN CONSIDERATIONS FOR LTI-CARBON HEART VALVES

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Certain critical user needs for performance of prosthetic heart valves define the over-all design problem. These include:

a) non-thrombogenic surface throughout the entire useful life,
b) minimal lost work (over broad range of flow rates) due to fluid-friction effects,
c) minimal design-related flow turbulence (which produces blood trauma) or requirement for long-term anticoagulant therapy,
d) robust total design with demonstrated, long-term wear resistance, capable of providing a useful service life not less than projected patient life.
e) radio-opacity of fixed and moving elements needed for post-operative clinical cineangiography study.

In order to produce and certify such devices as being appropriate for implantation, several other problems must be solved, i.e.:

f) establishment of optimum mechanical tolerances,
g) development of manufacturing techniques,
h) validation of procedures/apparatus for accelerated tests of wear and fatigue.

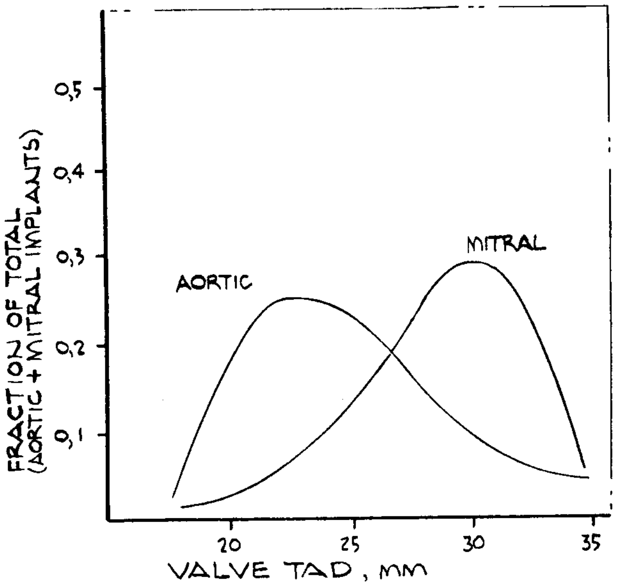
This review will examine, quantitatively, some of the unusual questions one faces in design of an all-carbon (Pyrolite-GAC) pivoting-disc heart valve.

Polished surfaces of LTI-carbon (Pyrolite) are well known to have long-term blood compatibility for heart valve occluders (both disc and ball types). Certain pivoting-and oscillating-disc heart valve body configurations involving bent-wire structural elements may pose significant technical barriers to established technology for LTI deposition on high-purity graphite preforms. Because of limitations of control of LTI deposition, certain valve body designs are inherently more feasible to produce in volume to close tolerances.

An optimum valve-mechanism design is essential to success of the prosthesis. For a pivoting disc configuration, there are a number of mechanical/fluid-mechanical variables which must be simultaneously optimized. These include opening angle, pivot-axis displacement, pivoting means (rolling/sliding bearings), and structure-elements which retain the disc within the valve and limit its travel. Analytic formalisms have been developed to calculate the true flow area as a function of open angle for pivoting-disc mechanisms.

In an actual patient, the total lost-work due to a prosthetic heart valve includes fluid and mechanical friction contributions from a number of sources. Quantitative, fundamental relationships are available for lost-work due to: (a) fluid turbulance related to flow area constriction, (b) growth of boundary layers during opening process, and (c) sliding/rolling friction between fixed and moving elements. Generally, these effects can be unambiguously demonstrated with a well-designed laboratory experiment. Optimum mechanical tolerances for various valve sizes and material combinations can be determined by precise measurements in a pulse duplicator (left-heart simulator). Recent advances in cine X-ray technology permit accurate, dynamic observations and measurements of the valve movements and size/shape changes (heart chambers as well as major vessels). These data can be extremely helpful in developing and testing new models for heart valve pressure gradient (lost work) resulting from unusual elastic and volume change effects in the flow circuit. Radio-opaque occluders and valve bodies are helpful in this work.

In order to avoid non-sequitur conclusions about a specific heart-valve design implanted in the usual range of sizes, one must examine long-term performance in a rationally selected patient follow-up sample. Some current international statistics for both mitral-and aortic-type prosthetic valves are shown below. Since small-sample statistics would require test groups of at least 30 to 50 patients, an investigator must carefully choose groups of individuals so that the resulting distribution of valve sizes [expressed as tissue annulus diameter (TAD)] closely parallels the actual demand pattern in world markets. A few exploratory observations without a null hypothesis cannot be evaluated by normal statistical methods.



Rational design of apparatus and procedures for significant accelerated testing of wear, fatigue, and performance degradation of heart valves is a topic of considerable interest (and some disagreement) to specialists. The major experimental problem areas include test-fluid properties, pressure-pulse shape, and elimination of spurious variables such as vibration, wear debris, and cavitation. Although an Arrhenius plot may be an adequate method of presentation of some types of wear data, Weibull functions may be much more useful in predicting the probability of survival. Since "survival" of a prosthesis can be defined as a certain maximum pressure gradient under fixed test condition, reliability theory may be helpful in predicting "useful life". The concepts of step-stress aging can be used to stimulate certain modes of failure which would be difficult or impossible to observe otherwise.

Because of the hardness of LTI coatings, many manufacturing methods for heart-valve elements are generally similar to those used for ceramics. While certain simple geometries, such as flat discs, can be produced by conventional methods with selected abrasives, complex shapes represent a significant challenge.