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Stress Analysis of Prosthetic Heart Valve Leaflets

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Introduction

Long-term successful replacement of the prosthetic heart valve (PHV) depends primarily upon the physical properties of the prosthesis and its ability to withstand repeated stresses. In the case of polymer PHV, low durability of valve leaflets to fatigue fracture is the most significant problem for the long-term clinical use.

Prosthetic tri-leaflet polymer valve leaflets can be considered as extremely pliable thin membranes with very small mass. The valve leaflets open up freely at systolic phase, and give almost no resistance against blood flow. Critical stresses of the leaflets in heart valve, especially aortic valve, are occured at the point of the maximal loading pressure during diastole phase.

In this paper, both analytic analysis with computer and direct stress measurement with miniature strain gauges for the valve leaflets' stresses of the polymer PHV are presented. The purpose of this investigation is to determine diastolic stress distribution through both analytic and direct means for the improvement of polymer tri-leaflet PHV's durability.

Analytic Stress Analysis

For the purpose of subsequent analyses, stress of the valve leaflets can be considered as a function of the geometrical parameters and pressure difference as follows;

$$\sigma = \sigma(\Delta P, R, H, t, f_i) \qquad (1)$$

where ΔP = loading pressure difference,
R = the radius of the valve ring,
H = the height of the valve leaflet,
t = the thickness of the valve leaflet

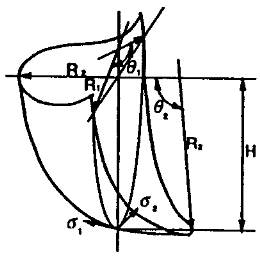

Figure 1. *Chong model (1973) representation of valve leaflets*

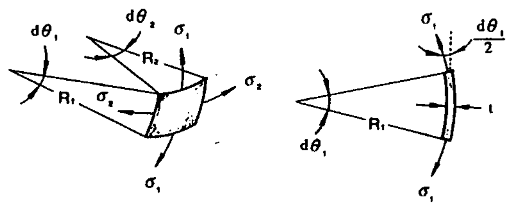

Figure 2. *Free-body diagram of polymer prosthetic heart valve leaflet element*

and f_i = geometrical stress factors for each principal stress.

Design parameters of R_1, R_2, θ_1, θ_2 defined in the Chong model are illustrated in Fig. 1. R_1, R_2 are the principal radii of curvature of the leaflet surface, θ_1, θ_2, the subtending angles and σ_1, σ_2, the principal stresses. Taking an equilibrium element of the leaflet, as shown in Fig. 2, with the boundary condition that the axial pressure component on each leaflet be balanced by the tension force supplied by the valve annulus. Thus

$$\sigma_1 = \frac{f_1}{t}\Delta P \ ; \ \sigma_2 = \frac{f_2}{t}\Delta P \qquad (2)$$

where f_1 and f_2 are determined with R_1, R_2, θ_1, θ_2 as follows :

$$f_1 = R_1 \left[1 - \frac{R_1}{2R_2} + \left[\frac{R_1}{2R_2} - \frac{(1 - \cos\theta_2)}{2} \right] * \frac{\sin(\theta_1/2)}{(\theta_1/2)} \right] \quad (3\text{-}1)$$

$$f_2 = R_2 \left[1 - \left[1 - \frac{R_2}{R_1} (1 - \cos\theta_2) \right] * \frac{\sin(\theta_1/2)}{(\theta_1/2)} \right] \quad (3\text{-}2)$$

The design parameters of R and H are not shown in the above expressions, but Chong model's parameters of R_1, R_2, θ_1, θ_2 are related with R, H as shown in the appendix.

Thus, we calculate values of f_1 and f_2 for various values of R and H. At H = 10.8 mm with R = 11.5 mm, geometrical stress factors of f_1 and f_2 have minimum values of $f_1 = 5.181$ and $f_2 = 5.624$. With above optimal values of H & R, Chong model's parameters are determined as follows;

$$R_1 = 10.30 \text{ mm}, \quad R_2 = 10.50 \text{ mm}, \quad \theta_1 = 162.096^\circ, \quad \theta_2 = 89.244^\circ \quad (4)$$

Corresponding stresses in the valve leaflet are

$$\sigma_1 = \frac{5.054}{t} \Delta P \; ; \; \sigma_2 = \frac{5.172}{t} \Delta P \quad (5)$$

In order to fabricate polymer PHVs, following requirements must be considered ; (i) smooth washout (ii) minimum loading pressure difference (iii) miminim regurgitation (iv) fatigue life estimation (v) minimum damage to blood components and (vi) fabrication convenience. And we choose design parameters of valve leaflet as follows;

$$R_1 = 10.35 \text{ mm}, \quad R_2 = 10.35 \text{ mm}, \quad \theta_1 = 160^\circ, \quad \theta_2 = 90^\circ \quad (6)$$

And then, principal stresses in the polymer PHV with 23 mm diameter are given as follows;

$$\sigma_1 = \frac{5.175}{t} \Delta P ; \quad \sigma_2 = \frac{5.175}{t} \Delta P \quad (7)$$

Experimental Stress Analysis

Direct stress measurements are performed with miniature strain gauge (B-FAE-02W-12T11 7-T11, NMB Co. Japan). To measure two principal stresses in tri-leaflet polymer PHVs, 2 fine strain gauges are inserted into the valve leaflets during fabrication processes. (Fig. 3) Before measuring the actual stresses in the valve leaflets, uni-axial tensile strength experiments are performed with dog-bone shape test slices to estimate the maximum elastic strength, proportional limit and elastic modulus in pure-elastic region.

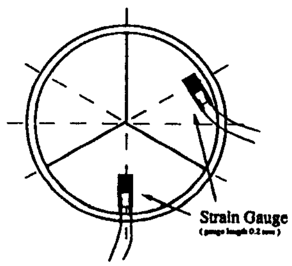

Figure 3. *Diagram of the adhesion site of strain gauges*

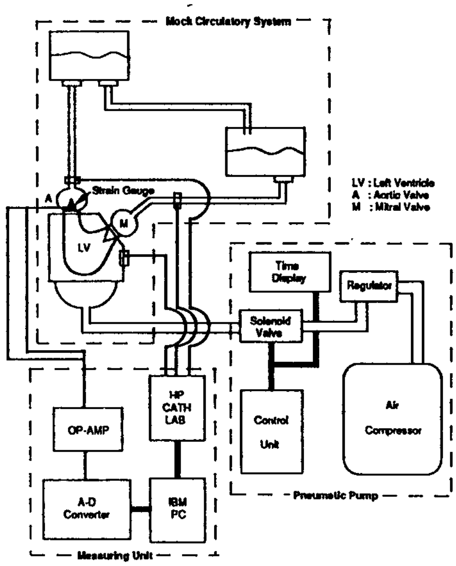

Figure 4. *Schematic diagram of stress experiment setup*

Fig. 4 shows the block diagram of the experimental setup for stress measurement. Strain guage signals are amplified with an operational amplifier by 500 times, and amplified signals are acquired by IBM PC via A-D converter. During all experiments, creep phenomina in visco-elastic polymer are not occured because loading and unloading pressures are successively repeated with small time interval.

Measured stress and pressure curves by the mock-circulation experiment are shown in Fig. 5. Stress curve shows faithful reflection of ΔP. Fig. 6 shows quantative comparision between analytic and experimental stresses with increasing ΔP.

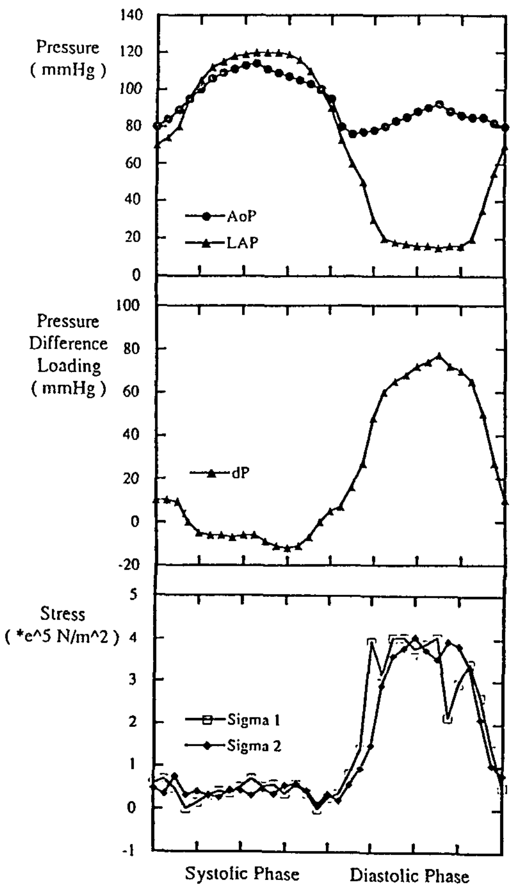

Figure 5. *Pressure and Stress curve for 1 cyclic phase (Thickness of valve leaflet = 0.15 mm)*

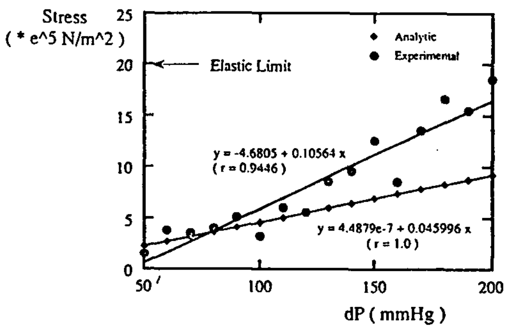

Figure 6. *Comparision of analytic and experimental stresses (Thickness of valve leaflet = 0.15 mm)*

Discussion

Both analytic and experimental results are below the bio-polymer's proportional limit. So if we exclude the creep phenomena, tri-leaflet prosthetic polymer heart valve is at the safe stress state. And, analytic method seems to be reasonable in this region.

Experimental errors may be caused by (i) high sensitivity of OP-Amp, (ii) defects in bonding the strain gauges, (iii) thermal residual stresses in strain gauges, (iv) electrical noise from wire connection between strain gauge and OP-amp, (v) finite size of strain gauge, (vi) dummy strain guages and (vii) elasticity of strain gauge base material (polyamide).

In the further analysis, fatigue test must be performed. And thin shell finite element analysis on the valve leaflets will be very profitable for detecting elastic behavior and stress field configuration of polymer PHVs.

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Appendix

The recurrence formulae for geometrical stress factors f_1 and f_2 are

$$H = R_2 \sin \theta_2 \qquad \text{(A-1)}$$

$$\frac{\sin(R/R_L)}{(R/R_L)} = 0.865 \qquad \text{(A-2)}$$

$$e = R\cos(\pi/3) + (R_L^2 - R^2\cos^2(\pi/6))^{1/2} \qquad \text{(A-3)}$$

$$g^2 = [1 - \frac{(e - R/2)^2}{R_L^2}][\frac{H^2 R_L^2}{R_L^2 - (e - R)^2}] \qquad \text{(A-4)}$$

$$\alpha = \tan^{-1}(\frac{H}{R - e + R_L}) \qquad \text{(A-5)}$$

$$\beta = \tan^{-1}(\frac{2R\sin(\pi/3)}{2g}) \qquad \text{(A-6)}$$

$$R_1 = \frac{((R\sin(\pi/3))^2 + g^2)^{1/2}}{2\cos\beta} \qquad \text{(A-7)}$$

$$R_2 = \frac{(H^2 + (R - e + R_L)^2)^{1/2}}{2\cos\alpha} \qquad \text{(A-8)}$$

$$\gamma = \cos^{-1}(\frac{R\sin(\pi/3)}{R_1}) \qquad \text{(A-9)}$$

$$\theta_1 = 2(\pi/2 - \gamma) \qquad \text{(A-10)}$$

$$\theta_2 = 2(\pi/2 - \alpha) \qquad \text{(A-11)}$$