PROCEEDINGS OF THE FIRST INTERNATIONAL CONFERENCE ON
INTERFACES IN MEDICINE AND MECHANICS

Proceedings of the First International Conference on

Interfaces in Medicine and Mechanics

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PREFACE

The thirty nine papers accepted for publication in the First International Conference on **'Interfaces in Medicine & Mechanics'** at Swansea in April, 1988 represent the current state of the art in the science of implant surgery. This initial venture was planned and undertaken when the present editors and their colleagues realised the need for a closer interaction and dialogue between the clinician and those basic scientists working in the area of implant surgery.

This interface, together with the real interface at the material/tissue borders, thus forms the basis of the present conference.

These two ideas, we felt, were nicely and effectively captured in the drawing by Edgar Rubins (1915), a perception psychologist, used on the book cover and elsewhere in our literature.

The Proceedings were planned with some difficulty, due to the wide scope of the conference. However, we felt the best format was to follow the logical progression of implant development. The introductory papers and talks therefore demonstrate the scope of surgical implants in current use. The development of an implant starts with modelling of the proposed implant and its potential environment and the proceedings follow the same format.

Following this, materials in current use are discussed. Subsequently, a series of contributions examine how implants have faired in practice and the methods used to monitor them, while also considering the interface between implant and body tissue. Both the effects of the implant on tissue and tissue on implant surface and structure are examined and considered.

The final part of the Proceedings takes into account the increasing role of industry and commerce on implant technology. Finally, to the reader who may have become over-enthusiastic with the proceedings thus far, the final contributions remind us of the adverse reactions associated with biomedical devices.

The organizers look forward to further contributions and developments in these areas with a second conference to be organised in Rimini in September 1990 with our Italian colleagues.

K R Williams
T H J Lesser
University of Wales College of Medicine
January, 1989

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CHAPTER 1

IMPLANTS IN MEDICINE AND DENTISTRY

THE IMPORTANCE OF BENDING STRESSES IN THE LEAFLETS OF PERICARDIAL HEART VALVE SUBSTITUTES

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Summary

Cyclic uniaxial load tests were performed on strip specimens of chemically modified bovine pericardium. Young's modulus and Poisson's ratio varied with uniaxial loading. Using effective incremental representations of these parameters, a simple analysis of the cylindrical bending of a flat plate showed that, under physiological closing pressures, the bending stresses in pericardial heart valve leaflets could be substantial. Their magnitude depended on the attachment conditions of the leaflet to the stent. If the tissue was clamped between a male and female frame, then large tensions were predicted on the outflow surface and significant compressive stresses could occur on the inflow surface of the leaflet. The presence of high stresses in regions close to the stent posts may explain the cuspal tears found at these sites, during wear testing of pericardial heterografts and after clinical implantation.

Introduction

The original Standard Ionescu-Shiley Pericardial heterograft was constructed from a single rectangle of chemically modified bovine pericardium wrapped around a relatively rigid stent (1). Following the clinical implantation of these valves, other heterografts have been produced from the same material. Although the fundamental design of the various pericardial valves differs, they have one common feature - when opening and closing under physiological pressures, the leaflets undergo cyclic loading and unloading as well as cyclic reversal of curvature. When the heterograft is open a circumferential tissue strip of unit width in the belly of the leaflet lies on a cylinder with the inner and outer surfaces corresponding to the inflow and outflow surfaces of the leaflet. When the valve substitute is closed the circumferential curvature is reversed. This movement results in a stress distribution throughout the tissue thickness which can change from compression to tension. There is strong experimental evidence that compressive stresses can result in collagen disruption and ultimately mechanically induced tissue fatigue. (2).

This study investigates the relative magnitude of the bending and extensional stresses with concomitant compression zones in the circumferential direction of the leaflets of pericardial heterografts.

Materials and Methods

Experimental

The lower half of pericardial sacs taken from 16-20 week old calves were transported from the abattoir in ice-cold isotonic saline (0.9% NaC1). All visible fat was stripped by hand from the tissue. The sacs were then mounted loosely on 150mm diameter embroidery rings and chemically modified by immersion for 7 days in a vat of 0.2% glutaraldenyde (BDH Chemicals Ltd) buffered to ph 7.4 in 0.15M phosphate buffer (Sorensen). A circular plastic template which contained five randomly positioned and oriented strips of length 60mm and width 10mm was placed over the pericardium. The diaphragmatic attachment and sternopericardial ligaments which were still attached to the tissue were used to identify the same five positions and directions in each sac (3).

After removal by a parallel bladed cutter, the strips were trimmed and perspex blocks glued to each end to give a length to width aspect ratio of 4:1 (length 40mm, width 10mm). The thickness and width were measured at five equally spaced positions along the longitudinal axis, the mean values obtained and the mean cross-sectional area computed. The test system was set to give a maximum load which corresponded to a maximum stress level of $0.6Nmm^{-2}$. The uniaxial test system, described earlier, (4) was set to perform cyclic load tests at an extension rate of $1mms^{-1}$. Width measurements, recorded during the unaxial loading, for the evaluation of Poisson's ratio were made using a video extensometer system which scanned the gap between two silk markers placed parallel to the direction of load (4). The test specimen was immersed in isotonic saline at room temperature throughout the procedure. A three channel calibrated pen recorder was used for the documentation of force, length and width. Changes in these parameters were recorded after mechanical conditioning of the tissue for 36 load cycles.

Theoretical

The theory developed by Timoshenko and Woinowsky-Krieger (5) was extended to investigate the relative importance of mid plane tensional and bending stresses in a narrow strip in an elastic plate. The strip is subjected to a uniform transverse force and the deflected surface of a portion of the plate a considerable distance from the end is approximately cylindrical (Figure 1). The axis of the cylinder is parallel to the length of the plate. In heart valve substitutes, to a good approximation, this theory applies to a narrow circumferential mid-leaflet strip. Hence it is developed for an elemental strip of material of thickness h, span l, where l is the circumferential length of the leaflet, and unit width.

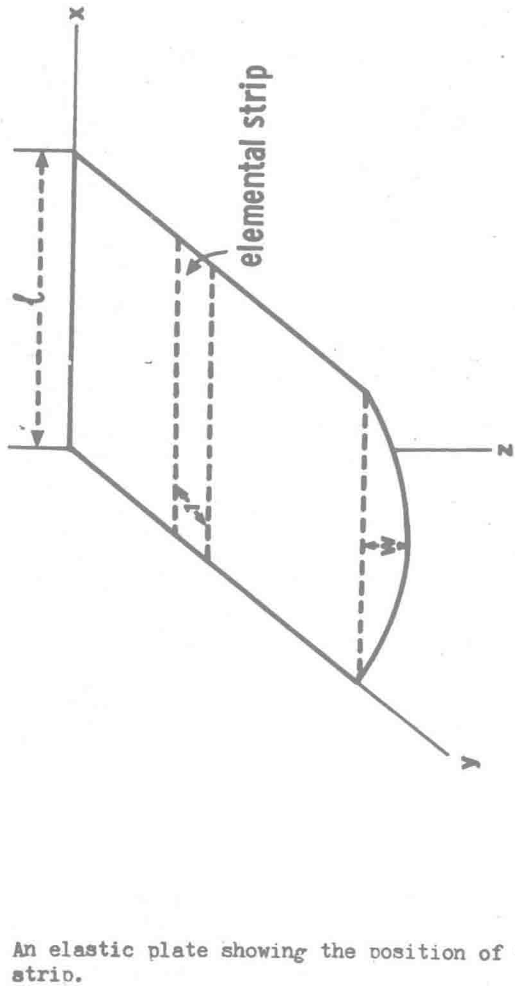


Figure I An elastic plate showing the position of the elemental strip.

If the deflection at a distance x from the end of the strip is w, then the assumption of bending to a cylindrical surface implies that the bending moment M satisfies the differential equation

$$D \frac{d^2 w}{dx^2} = -M$$

where the flexural rigidity

$$D = Eh^3/12(1-\nu^2)$$

where E and ν are the Young's Modulus and Poisson's ratio of the material.

The extremes of the spectrum of the boundary conditions applicable to tissue heart valve substitutes mounted on relatively rigid stents will be considered.

The first condition allows the strip edges to rotate freely at the stent but does not permit them to move towards each other during bending. (Unrestricted leaflet rotation, Figure 2). The strip of length l is loaded with a pressure p and balanced by two reaction forces pl/2 at the point of attachment. The leaflet is prevented from moving during bending by a force S. The balance equation of moments of force acting on a strip of length x gives

$$M = \frac{plx}{2} - \frac{px^2}{2} - Sw$$

where w is the deflection.

The direct tensile stress σ_1^U and maximum bending stress σ_2^U can be expressed in terms of u, p and material constants by

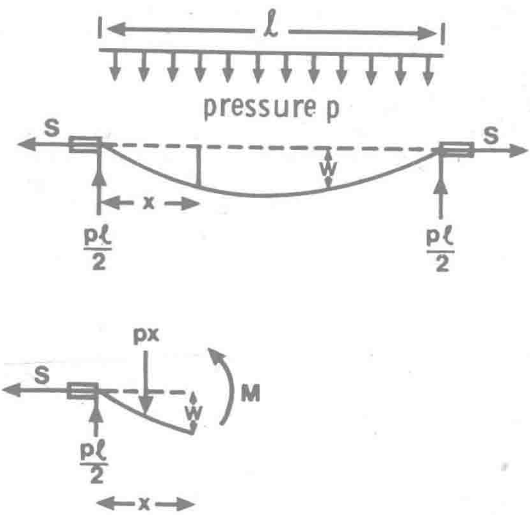
$$\sigma_1^U = S/h = Eu^2h^2/3l^2(1-\nu^2)$$

$$\sigma_2^U = 6M_{\max}/h^2 = 3pl^2(1-\operatorname{sech} u)/2h^2u^2$$

where

$$u^2 = Sl^2/4D$$

UNRESTRICTED LEAFLET ROTATION



$$M = \frac{p\ell x}{2} - \frac{px^2}{2} - Sw$$

Moment of force balance on a strip element of length x.

Figure 2 External forces acting on, and deflection of, an elemental strip with unrestricted edge rotation, thickness h, unit width and length l, which is uniformly loaded under a pressure p.

A similar moment of force balance equation can be constructed when the leaflet rotation is totally restricted at the stent by imposing a bending moment per unit length, Mo, on the edge of the strip (Figure 3). This could be achieved by clamping the tissue between a male and female frame.

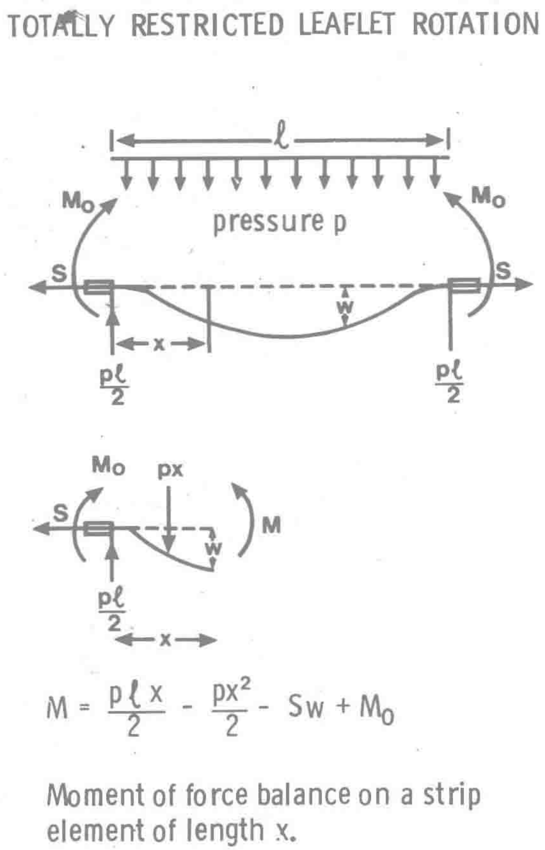


Figure 3 External forces acting on, and deflection of, an elemental strip with totally restricted edge rotation, thickness h, unit width and length l, which is uniformly loaded under a pressure p.

The balance equation of moments of force acting on a strip of length x now gives

$$M = plx/2 - px^2/2 - Sw + M_0$$

where w is the deflection.

The direct tensile stress σ_1^T and the maximum bending stress σ_2^T, can be derived and are given by

$$\sigma_1^T = S/h = Eu^2 h^2/3l^2(1-\nu^2)$$

$$\sigma_2^T = -6M_0/h^2 = 3pl^2(u - \tanh u)/2h^2 u^2 \tanh u$$

Intermediate conditions between these two extremes (partially restricted edge rotation) can be achieved by introducing a degree of elasticity into the line of attachment. As the strip is deflected the edge will rotate through an angle which is proportional to the bending moment at the edge.

The direct tensile stress σ_1^P can now be expressed as

$$\sigma_1^P = S/h = Eu^2 h^2/3l^2(1-\nu^2)$$

and the maximum bending stress is given by the greater of the two values

$$\sigma_2^P = \begin{Bmatrix} -6M_0/h^2 = 3\gamma pl^2(u - \tanh u)/2h^2 u^2 \tanh u \\ 6M_{max}/h^2 = 3pl^2(1 - \operatorname{sech} u)/4u^2 h^2 \end{Bmatrix}$$