Laboratory assessment of the design, function, and durability of pericardial bioprostheses

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The design, function, and durability of four pericardial bioprostheses have been studied in the laboratory. Variations in design and construction affected both the pressure difference across the valves and the leaflet dynamics. In the durability tests tissue failure was found in all valves, with tears at the edge of the leaflets caused by abrasion on the cloth-covered inner frames. In the Ionescu–Shiley standard valves, tears were also detected at the coaption sutures. These results have been compared with failure modes in explanted clinical valves.

INTRODUCTION

The Ionescu–Shiley (ISU) pericardial bioprosthesis has been used clinically for over 13 years with good clinical follow-up results (Ionescu *et al.*, 1982). However, concern exists over the incidence of primary tissue failure reported clinically in these valves (Gabbay, *et al.*, 1984a; Brais *et al.*, 1985; Gallo *et al.*, 1985). Tears have been found in leaflets of explanted valves close to the edge of the cloth-covered frames which have caused leaflet prolapse and regurgitation. Several different reasons have been suggested for tissue failure in ISU pericardial valves; abrasion of the leaflets on the cloth-covered inner frame (Gabbay *et al.*, 1984b); abrasion of the leaflet on the cloth buttress on the outside of the post (Martin *et al.*, 1980); stress concentrations around the coaption stitches inside the top of the posts (Rainer, 1985); and bending and flexion stresses close to the edge of the support frame (Thubrikar *et al.*, 1982; Ionescu *et al.*, 1981). More recently, three new low profile pericardial bioprostheses, the Ionescu–Shiley Low Profile (ISLP), Hancock Pericardial (HP) and Mitral Medical (MM) valves have become available for clinical use in the United Kingdom. Our early clinical experience in Glasgow with two of these valves (ISLP and HP) has shown that primary tissue failure has not been eliminated in these new valve designs (Reece *et al.*, 1986).

In this study we have investigated the design, construction, function, and durability of four different pericardial valves (ISU, ISLP, HP, MM). The leaflet geometries and valve design have been analysed for the size 29 mm mitral valves, and the function of both size 29 mm mitral and size 23 mm aortic valves has been assessed in our pulsatile flow test apparatus. Durability studies have also been carried out on size 29 mm valves. The results of these studies have given a clearer understanding of the mechanisms of primary tissue failures found in explanted clinical valves.

MATERIALS AND METHODS

Description of the valves

The key dimensions of the valves are given in Table 1. The external diameter is the diameter of the cloth-covered frames and leaflets, but excludes the flexible sewing ring, and the internal diameter defines the potential orifice for forward flow. The leaflet height, h, defines the height of the flexing portion of the leaflet and h_c the maximum depth of coaption between the closed unloaded leaflets.

Although the fundamental construction of all four valves is similar, with the leaflets sewn onto the outside of cloth-covered frames, there are significant differences in the detailed design and construction of these valves. In the ISU and ISLP valves the pericardial tissue appears to be initially fixed with glutaraldehyde in its natural shape and then mounted on the valve frame, while in the HP valve fresh tissue is mounted on the frame and fixed with glutaraldehyde under a small back pressure which defines the geometry of the unloaded closed leaflets. In the MM valve the leaflets are individually fixed on moulds which determine the shape of the unloaded flexing portion of the leaflet. The geometries of the frames and leaflets also differ (Table 1). The size 29 mm ISU and ISLP valves have an unloaded closed geometry defined by a cylindrical surface with radius R_c, approximately 20 mm. This corresponds to a broad 'U' shape cut out in the base of the frame and a parallel portion at the top of each post which gives a slightly greater coaption depth, h_c, between the leaflets. The height of the leaflets is reduced by 1 mm in the ISLP valve. The leaflets of the MM and HP valves are formed in approximately spherical shapes during fixation with a radius of curvature, R, approximately 15 mm. The overall leaflet height, h, is less; the posts have only a short parallel portion at the top and the coaption between the unloaded leaflets is less than in the ISU and ISLP valves. In all the valves the leaflets are sutured to the outside of the cloth-covered frames around the base of the valves and at the back of the posts. In addition, sutures are placed through the leaflets close to the top of the posts to ensure closure of the leaflets around the posts. In the ISU

Table 1. Key dimensions in mm for the size 29 and size 23 mm valves

Valve size	ISU 29	ISLP 29	HP 29	MM 29
Outside diameter, D_0	31/30	31/30	29	29
Internal diameter, D_i	25	24.5	24	24.5
Overall height, H	20	19	17	16.5
Leaflet height, h	16	15	12.5	12.5
Coaption depth, h_c	4	3	2.5	2.5
Valve size	ISU 23	ISLP 23	HP 23	MM 23
Outside diameter, D_0	28/25	26/25	24	22.5
Internal diameter, D_i	19.5	19.5	20	19
Overall height, H	18.5	17	16	15

valves the coaption sutures are placed inside the posts while in the ISLP valves two sutures are placed through the leaflets and the side of the posts. In the HP valve sutures are placed through the leaflets above the posts and also through the side of the posts, while in the MM valve the suture is placed over and at the outside of the post so it is less effective in closing the leaflets together. The frames in the ISLP, HP, and MM valve are manufactured from flexible polymers, while in the ISU it is manufactured from rigid titanium.

Function tests

Our pulsatile flow test apparatus has been described previously (Fisher *et al.*, 1986). Pressure difference and regurgitant volumes were measured for one size 29 mm and one size 23 mm valve of each type under a range of flow conditions A to E corresponding to cardiac outputs of 3–8.5 l min^{-1}. Leaflet dynamics were studied in the size 29 mm mitral valves under steady and pulsatile flows and movements recorded on video camera at 20 mS intervals and with synchronised flash photography at 5 mS intervals.

Durability tests

One ISU, four ISLP, three HP and two MM valves, all size 29 mm were cycled in Rowan Ash accelerated fatigue testers at 12 Hz with a closed back pressure of between 100 and 130 mm Hg and peak forward flow of between 330 and 450 ml s^{-1}. Valves were tested to failure, defined as a tear of at least 2–3 mm in one leaflet.

Clinical experience

Over the past four years 105 ISLP and 98 HP valves have been implanted in Glasgow with a mean follow-up time of 39 months per patient and 26 months per patient in each series. Primary tissue failure has occurred in six explanted ISLP valves and two explanted HP valves. In all cases the tears occurred in the leaflets close to the top of the cloth-covered posts causing leaflet prolapse and large regurgitation. A similar failure mode has been found in one explanted IS valve. The regurgitation in three of these explanted valves was measured in the pulse duplicator.

RESULTS

Measurements of mean pressure difference plotted against RMS forward flow are given in Fig. 1 for the size 29 mm valves and in Fig. 2 for the size 23 mm valves. In all cases the orifice area of the open valve was determined by the opening of the free edges of the leaflets. This opening was widest in the MM 29 mm valve which had the lowest pressure difference and smallest in the ISU 29 mm valve which had the highest pressure gradient. The opening of the free edges of the leaflets was dependent on the position of the coaption stitches at the top of the posts. The size 23 mm MM and HP valves had lower pressure drops than the size 23 mm ISLP and IS valves. The regurgitant volumes are given in Fig. 3 for the size 29 mm valves and Fig. 4 for the size 23 mm valves. There was little difference in the regurgitation between the different valves. The closing volumes in the size 29 mm valves were larger than in the size 23 mm as the volume swept back by the leaflets was greater. The closed regurgitation occurred through the cloth sewing ring on the outside of the valve frame and was greater in

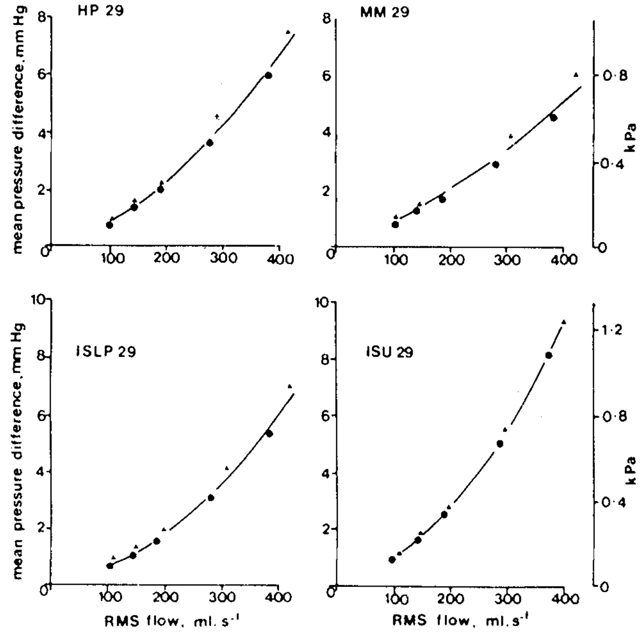

Fig. 1. Mean pressure difference plotted against rms forward flow for the size 29 mm valves

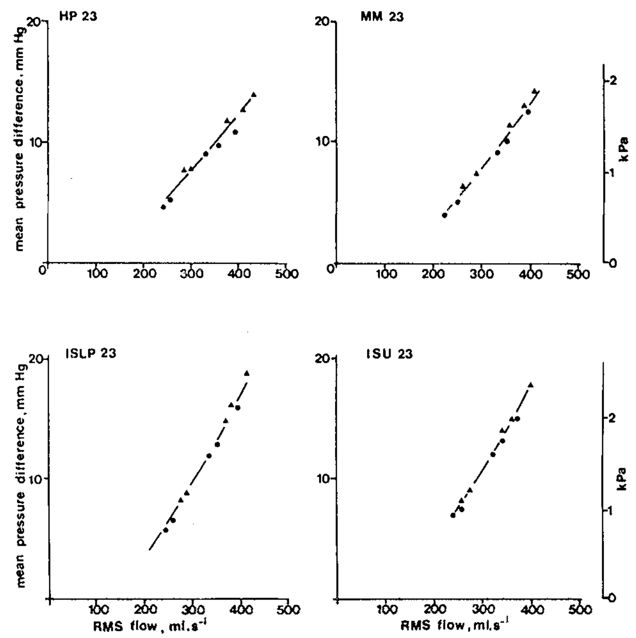

Fig. 2. Mean pressure difference plotted against rms forward flow for the size 23 mm valves

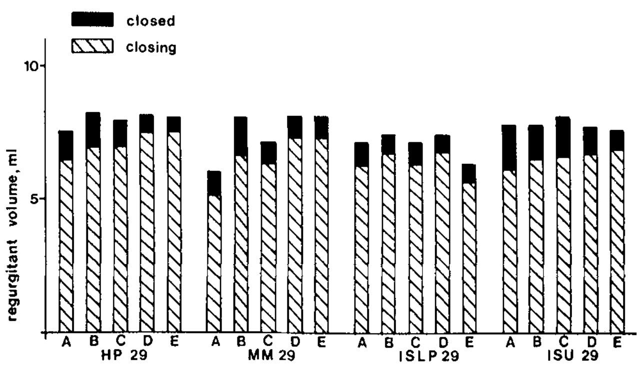

Fig. 3. Regurgitant volumes for the size 29 mm valves

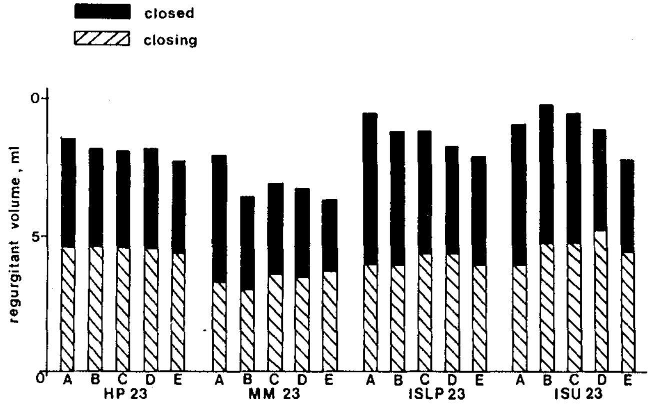

Fig. 4. Regurgitant volumes for the size 23 mm valves

the size 23 mm valves due to the longer diastolic time interval in the aortic position and a different type sewing ring.

Studies of the leaflet dynamics in the size 29 mm valves showed that the free edge symmetrical orifice in the ISU and HP valves due to the restricted opening and tension induced in the tissue by the coaption stitches, whereas in the ISLP and MM valves the tissue at the free edge was under less tension and the orifice was not as uniform. In the open position the leaflets of the IS and ISLP formed a straight line at the edge of the frame, while in the HP and MM valves the tissue which was formed in a small radius over the edge of the frame during fixation formed an 'S' configuration when the leaflets were fully open (Fig. 5). In the closed position the posts of the flexible frames deflected inwards reducing the tension at the free edge of the leaflets. At low steady flows the ISLP and ISU valves opened fully at 40 ml s^{-1}, the HP valve at 80 ml and the MM valve at 120 ml s^{-1}. All valve leaflets opened at the lowest pulsatile flow (A) corresponding to a peak flow of 150 ml s^{-1}. The methods of fixation also affected the way the valve leaflets transposed from the closed to the open position. In the ISU and ISLP valves the tissue buckled circumferentially across the leaflets, while in the HP and MM valves the tissue reversed its curvature in the base of the leaflet, first buckling in the radial direction. Closure was the reverse of opening in each valve.

All but one of the valves failed prematurely after less than 60 million cycles with tears in the leaflets at the edge

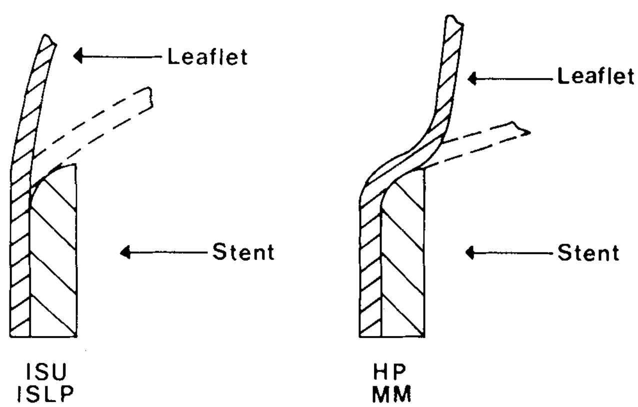

Fig. 5. A vertical section through the base of the leaflets at the edge of the frames showing the geometry of the open leaflets

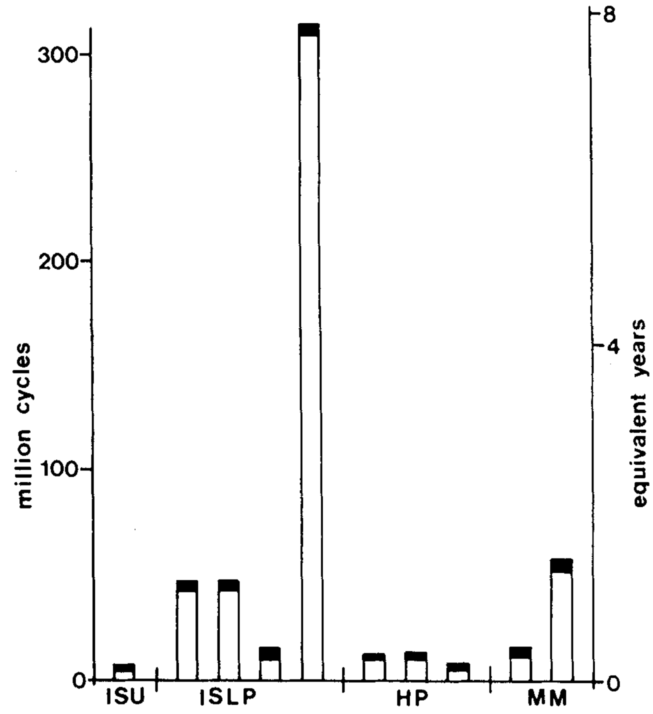

Fig. 6. Results of the accelerated fatigue tests

of the cloth-covered frames (Fig. 6). The other valve failed after 320 million cycles in a similar manner. All the leaflets of the failed valves showed excessive thinning and abrasion adjacent to the edge of the cloth-covered frames. This was greatest about half way up the posts at the shoulder of the scallop which was the origin of the tears in most of the valves. In some valves these tears extended to the free edge of the leaflet. In one ISLP and one HP valve the tears started closer to the top of the posts. In all the HP, ISLP, and MM valves the tissue was intact and in good condition around the coaption sutures at the top of the posts. In the IS valve small tears occurred in two leaflets at the coaption sutures, although the largest tear originated from half way up the post

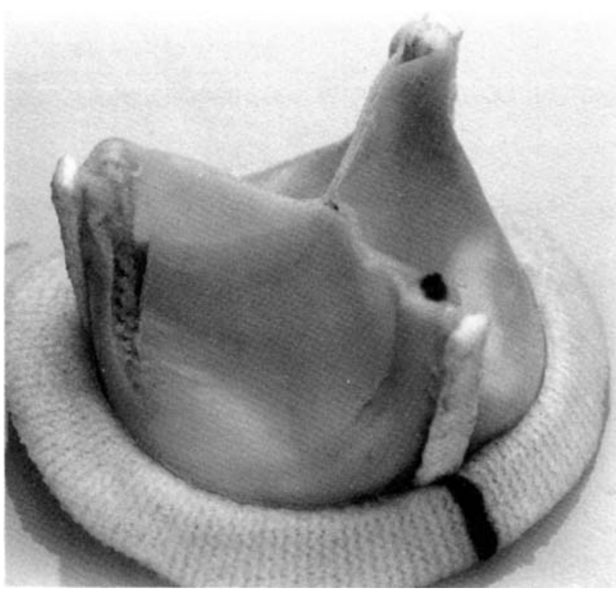

Fig. 7. Failed ISU valve from the fatigue tests

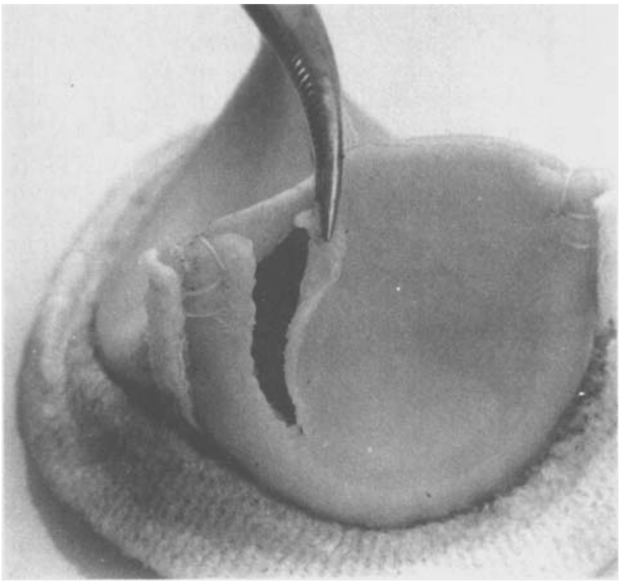

Fig. 8. A failed ISLP valve from the fatigue tests

(Fig. 7). Figures 8–10 show examples of the failed ISLP, HP, and MM valves.

Figure 11 shows an example of an explanted ISLP valve with torn leaflet, and Fig. 12 shows a failed explanted HP valve. In both cases the tears in the leaflets occurred at the top of the posts. It was difficult to determine whether the tears originated from the edge of the cloth-covered post or from the coaption sutures passing through the side of the posts. Abrasion of the leaflets adjacent to the frame was much less than in the valves cycled in the fatigue tester and the leaflets were reinforced with host tissue ingrowth over these areas. Tissue ingrowth was less towards the top of the posts. An explanted ISU valve with a torn leaflet is shown in Fig. 13. Tears appeared both at the top of the posts and at the shoulder of the scallop, and a small tear was seen at the coaption stitch in one of the other leaflets. The regurgitation measured in three explanted valves with torn leaflets was between 40 and 60 per cent.

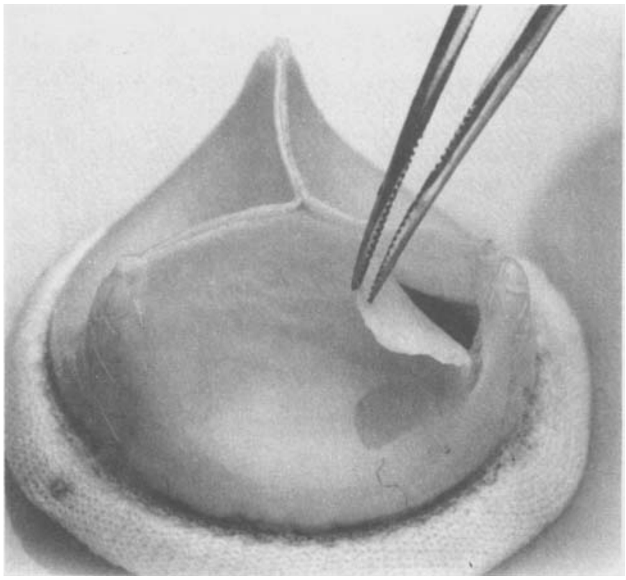

Fig. 9. A failed HP valve from the fatigue tests

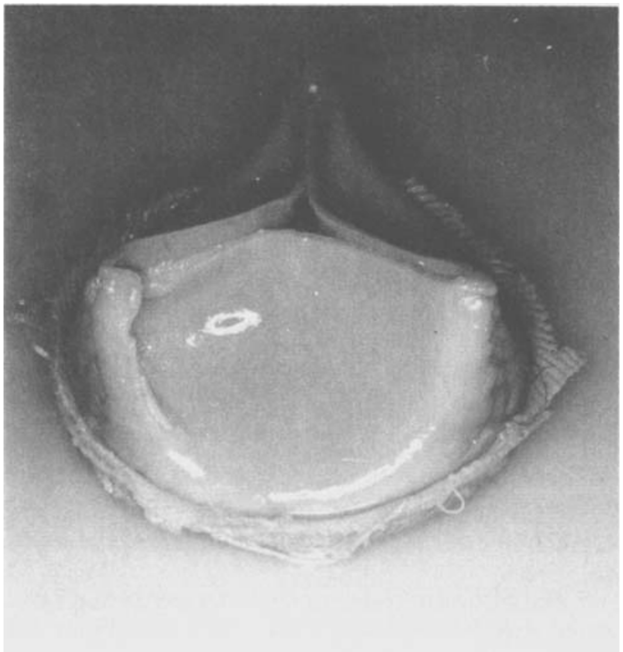

Fig. 10. A failed MM valve from the fatigue tests

DISCUSSION

Although we have shown significant differences in the design and construction of the four pericardial valves studied, there was little variation in measurements of pressure drop and regurgitation between the valves. The coaption sutures at the top of the posts did restrict the opening of the valve leaflets particularly in the ISU valve which had the largest pressure difference of the size 29 mm valves. The different design and methods of construction had a greater effect on the leaflet dynamics. Both the closed and open position of the leaflets, the movements between the two positions, and the bending stresses at the edge of the open leaflets were affected by the leaflet geometries and methods of tissue fixation. In addition, the positioning of the coaption suture affected the tension in the free edge of the open leaflet and the flexibility of the frames affected the tension in the closed leaflet. These different leaflet dynamics, however, did not affect the results of our durability tests.

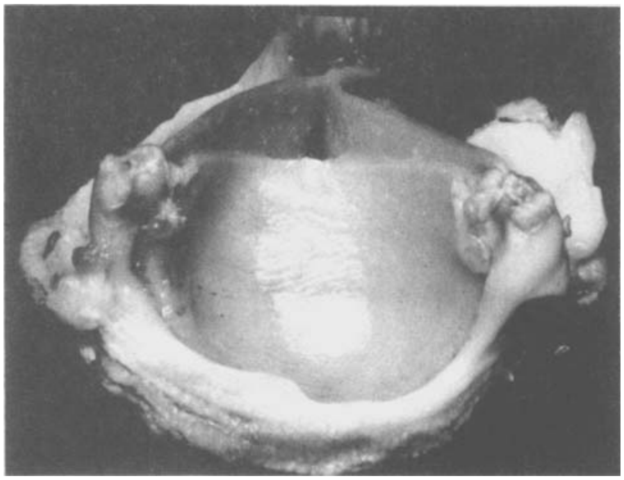

Fig. 11. An explanted ISLP valve with a torn leaflet

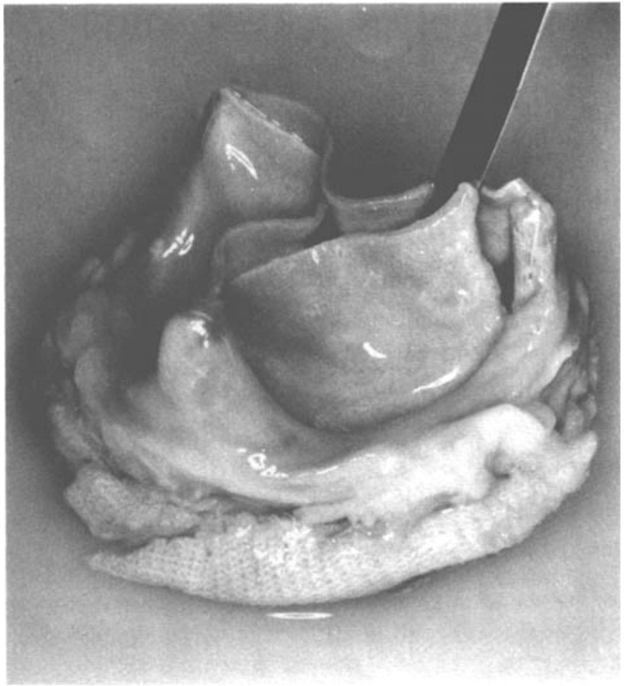

Fig. 12. An explanted HP valve with a torn leaflet

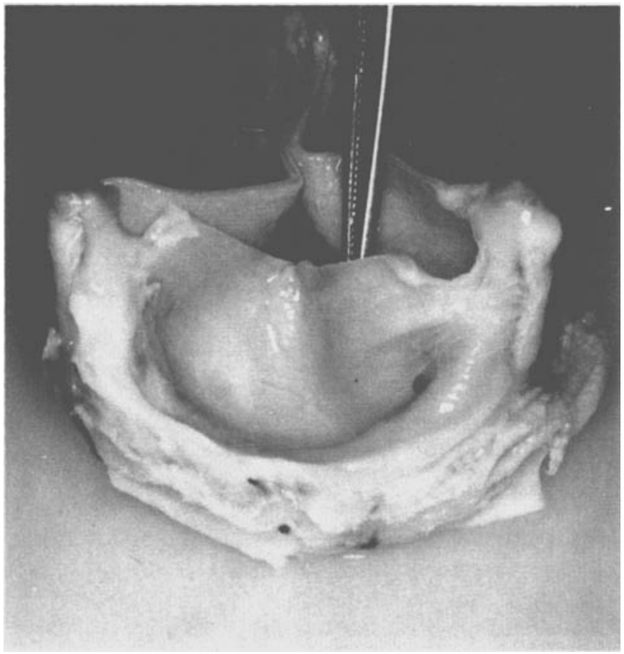

Fig. 13. An explanted ISU valve with a torn leaflet

All the valves in the fatigue tests failed due to abrasion and thinning of the leaflets as they were stretched over the edge of the cloth-covered frames in the closed position. The abrasion was greatest half way up the posts and this was the origin of the tears in most of the valves. Only in the ISU valve where the coaption stitch was placed inside the post did the tears originate at the coaption stitches. The accelerated fatigue tests can be considered artificially harsh for the pericardial valves with cloth-covered frames as biological effects such as tissue ingrowth and blood deposits on the cloth, which reduce the abrasion in vivo, are not simulated in the tests. Explanted clinical valves showed similar tears to the fatigue tested valves but the tears were usually closer to the top of the posts where the tissue ingrowth was not as great. It is likely that abrasion of the leaflets on the cloth-covered posts also caused the tears clinically in the ISLP and HP valves. Tears were only clearly detected at the coaption stitches in the explanted ISU valve, which correlates with the fatigue test findings. However, the coaption sutures could weaken the leaflets at the top of the posts in the ISLP and HP valves as they are positioned close to an area that is being thinned by abrasion. This area is also under high bending stresses in the open position.

Only after the abrasion to the leaflet at the edge of the frame has been eliminated can the effect of the different leaflet dynamics on valve durability be assessed.

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