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Metallurgical analysis of failed Björk-Shiley cardiac valve prostheses

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ABSTRACT An investigation into the mechanisms of failure of current Björk-Shiley cardiac valve prostheses is reported. Two failed valves, one apparently unfailed but defective valve, and one unused valve, were examined by scanning electron microscopy and metallographic section. In the first two valves (removed 12 and 23 months after implantation) fracture was associated with the welds joining the short strut to the valve ring. The fracture surfaces in all cases were heavily faceted and showed branching cracks. Extensive wear had occurred on one fracture surface in the first case, suggesting that one leg of the short strut had failed before the other, though this had been clinically undetectable. The third valve was removed owing to failure of the suturing (24 months after implantation) but one leg of the short strut was found to be completely fractured. The other leg showed extensive cracking and porosity in the weld region. A metallographic section taken through the weld region of the fourth (unused) valve illustrated several sizable defects directly attributable to the welding process. It is suggested that the valves failed by fatigue and that these problems could be overcome if the complete valve cage were machined as a single piece.

In 1969 the Björk-Shiley tilting disc prosthesis was introduced for replacement of diseased heart valves. The current series was introduced in 1978 after modifications to the orifice ring struts supporting the disc whereby the valve ring and major strut are machined as one piece, the minor strut, however, is still welded on afterwards. Strut fractures in valves produced since these modifications were made have been reported on only three occasions.[1–3] The manufacturers, however, have been notified of 50 strut fractures since 1976, of which 24 occurred in 8000 implants manufactured from February 1981 to March 1982 (three times the failure rate outside these dates). All unimplanted valves from this batch have therefore been recalled. The DHSS have since been notified of three more failures in Britain. Inquests in two of these cases have attracted press comment.[4–7]

Very little has been reported about the mechanism predisposing to valve failure, though metallurgical analysis in one report[1] suggested a brittle fracture of the weld joining the short strut to the valve ring. We therefore examined three failed Björk-Shiley prostheses that have been removed in this hospital since July 1983, and also an unused valve of the same type.

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Material and methods

Four Björk-Shiley valves were examined, all belonging to the current 60° tilting disc series manufactured since 1978. In the intact valve a pyrolitic carbon disc pivots in a seating assembly, comprised of an annulus with two integral retaining struts (fig 1). The latter parts are made from a cobalt chromium alloy (Haynes 25). The major strut and annulus are machined as one piece from solution annealed bar stock. The minor strut is formed from recrystallised cold drawn wire; it is put in position through two holes in the annulus and welded in place from the outer surface of the ring. No heat treatment is applied after welding. The manufacturers carry out cyclic fatigue tests on a random sample of valves.

UNUSED VALVE

Our unused valve was chosen at random from a batch of unused 29 mm Björk-Shiley valve prostheses, supplied by the manufacturers after 1982.

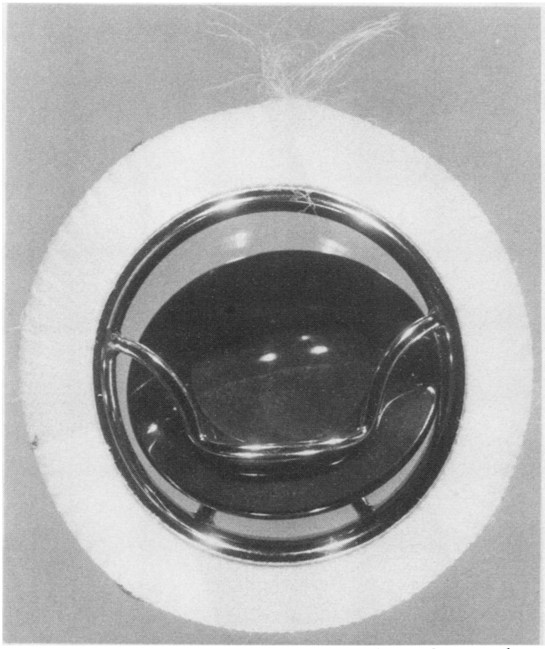


Fig 1 *A Björk-Shiley cardiac valve prosthesis showing the tilted disc and relative position of major and minor disc support struts. The white outer sleeve is the sewing ring.*

VALVES FROM PATIENTS

Case 1

Clinical details of this case have been described previously.[3] The 29 mm Björk-Shiley valve was implanted in the mitral position in July 1982 and removed in July 1983 after a sudden deterioration in the patient's condition owing to fracture of the minor (outflow) strut. The liberated strut and carbon disc were recovered in the left ventricle at operation. The valve was replaced, but the patient died later from cerebral damage due to the circulatory arrest that had occurred before operation.

Case 2

In December 1981 a 48 year old man with rheumatic heart disease underwent mitral valve replacement with a 29 mm Björk-Shiley prosthesis. He was well during the next 23 months. In November 1983 he suddenly developed pulmonary oedema and had a cardiac arrest while being transported to hospital. At operation the short strut and disc were missing from the prosthetic ring and were later located in the position of the internal carotid artery by radiography. The prosthesis was replaced but one week later the patient died from the irreversible brain damage that had followed his cardiac arrest.

Case 3

In July 1982 mitral valve replacement with a 29 mm Björk-Shiley prosthesis was undertaken in a man of 67 after an infection of his own (prolapsing) valve with *Bacteroides* sp. In July 1984 he developed sudden pulmonary oedema associated with a loud pansystolic murmur. At operation the prosthetic valve appeared to be working well but there was a large paravalvar leak where the sutures had pulled out in the region of the medial commissure. A more careful inspection of the valve after removal showed that one of the two welds holding the minor strut in place was fractured. The patient received a new prosthesis and is doing well.

Results

MICROSTRUCTURE OF AN UNUSED BJÖRK-SHILEY VALVE

Figure 2 shows a metallographic section of an unused Björk-Shiley valve illustrating the microstructure of the strut-weld region. The main body of the strut contains small ($\sim 25\,\mu m$) equiaxed (that is, roughly spherical) recrystallised grains. The lower and upper sections of the ring show a somewhat coarser grain size ($\sim 50\,\mu m$). The region that was molten during the welding procedure consists of a large grained ($\sim 250\,\mu m$) dendritic structure with coarse (1–10 μm) carbide particles that can be seen precipitated in the interdendritic areas. The fusion zone was bounded by narrow heat affected zones and further coarse carbide particles were seen in these regions. The cross sectional area of the strut is seen to be constricted at its root.

EXAMINATION OF FAILED VALVES

Case 1

The two fracture surfaces on the valve ring that corresponded to the points of attachment of the short strut were examined by scanning electron microscopy. The first showed a smooth surface with numerous depressions (fig 3*a*). In these a faceted structure of ledges and striations was seen (fig 3*b*). By contrast, the second surface (figs 3*c* and 3*d*) was entirely covered by the striated structure.

Corresponding features were present on the respective fracture surfaces of the strut. A metallographic section taken through the strut (not shown) verified that failure had occurred through the coarse carbide band at the interface between the weld and the heat affected zone.

Case 2

The two fracture surfaces in this case were alike. They were both flush with the ring, failure having occurred in the melt zone of the weld. Both showed large areas

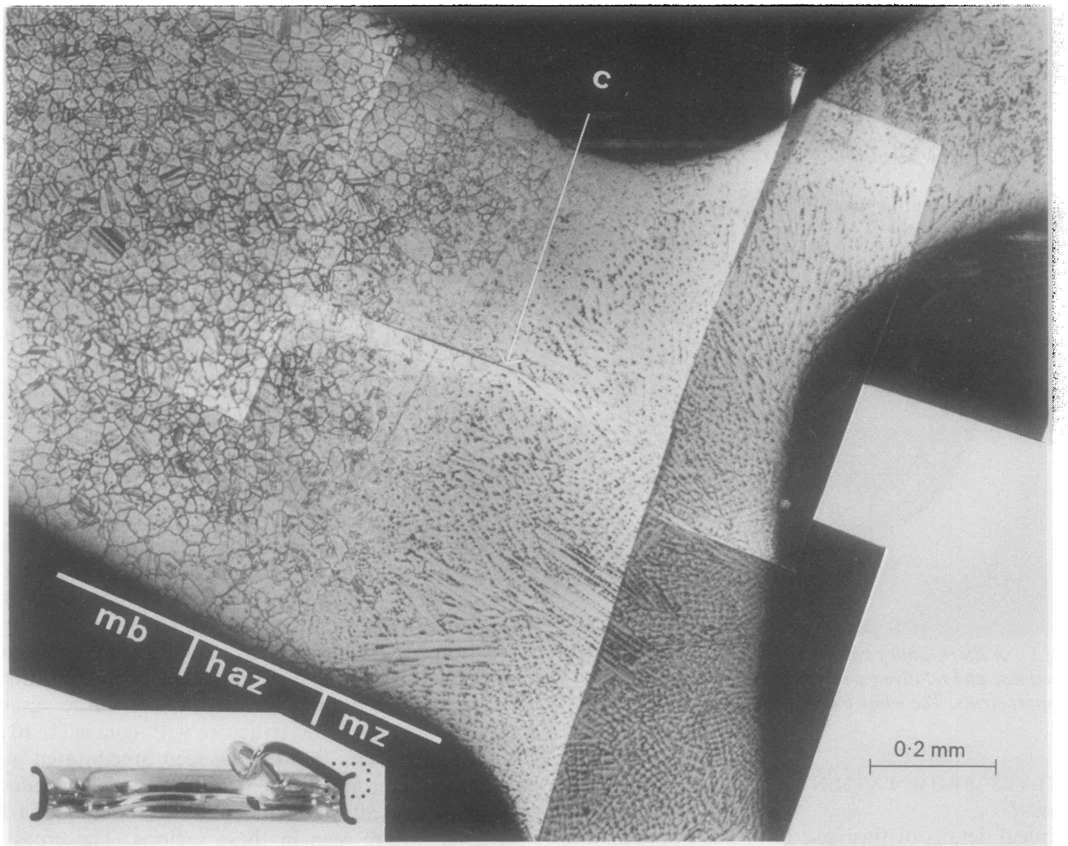


Fig 2 *Metallographic section through the minor strut, weld, and annulus of an unused Björk-Shiley prosthesis. mb—main body of the short strut; mz—molten zone; c—carbide deposits; haz—heat affected zone.*

of striated and faceted structure (fig 4*a*). In this case the fractured strut also took with it part of the ring, leaving sizable holes in the central region of each fracture surface. Extensive cracking and also some porosity was evident around the circumference of each fracture surface (figs 4*b* and 4*c*).

Case 3
This valve was removed from a patient because of failure in the suturing and was thus nominally unfailed. Examination of the undisturbed structure for evidence of fatigue cracks revealed that one leg of the short strut was completely fractured at the point of welding to the valve ring (fig 5). Furthermore, examination of the root of the second leg showed extensive cracking and porosity over most of the circumference, similar in appearance to that in case 2. A striated structure, of the type described above, was observed on the small portions of the fracture surface that were visible on the broken leg.

Discussion

Six failures have been reported with the current type of Björk-Shiley prosthesis,[1-3] including our two new cases (2 and 3). These failures have been confined to large mitral valves of sizes 29–33 mm, which have the highest closing forces. Fracture of the short strut at the point of welding to the valve ring was responsible in all reported cases, occurring on average 13 months (range 3–25 months) after implantation.

What predisposes the weld region to fracture at an early stage? In normal use the pivoting action of the disc imposes a bending moment on the short strut. A maximum stress will occur at the point of contact of the strut with the ring—that is, at the weld site. The stresses through this region may be intensified locally by several factors, some of which were present in the microstructure of our unused valve. Firstly, the reduction in cross sectional area at the weld site will increase the amount of stress throughout the cross

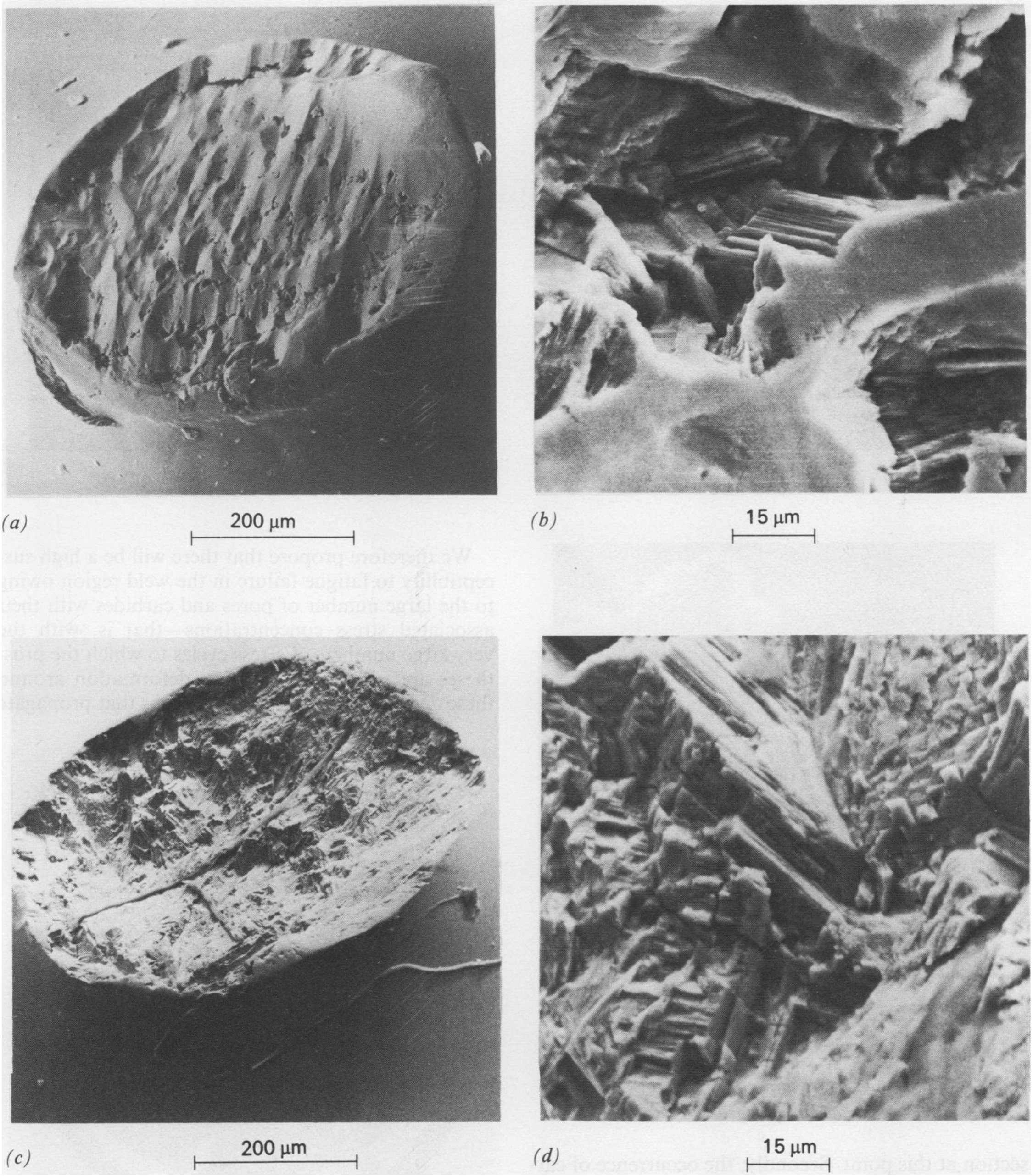
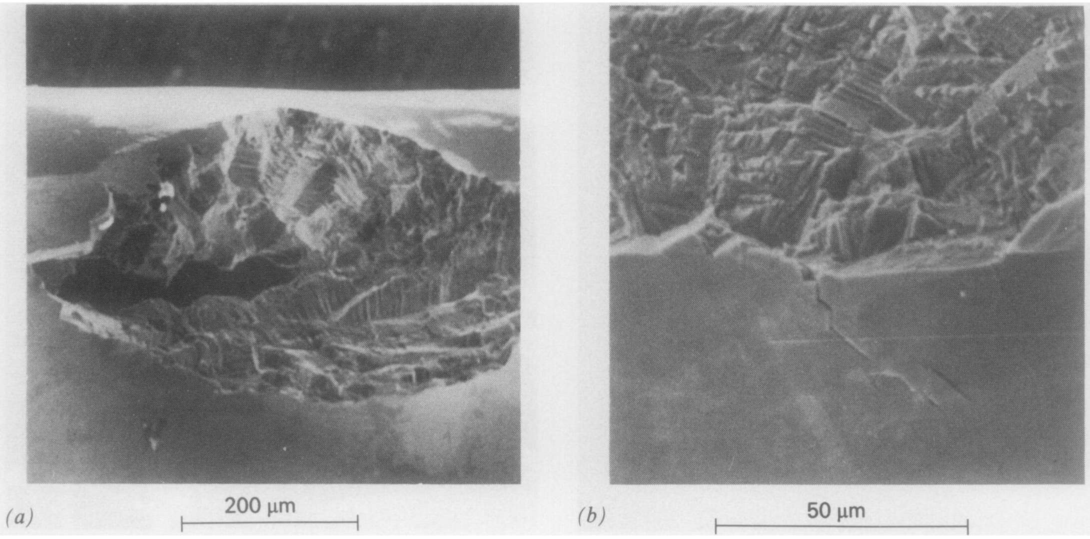


Fig 3 ***Case 1: Scanning electron micrographs illustrating (a) general view of the first fracture surface on the ring; (b) striations in a depression and "smearing" of the surface due to wear after the fracture; (c) general view of the second fracture surface on the ring; (d) striated structure at high magnification.***



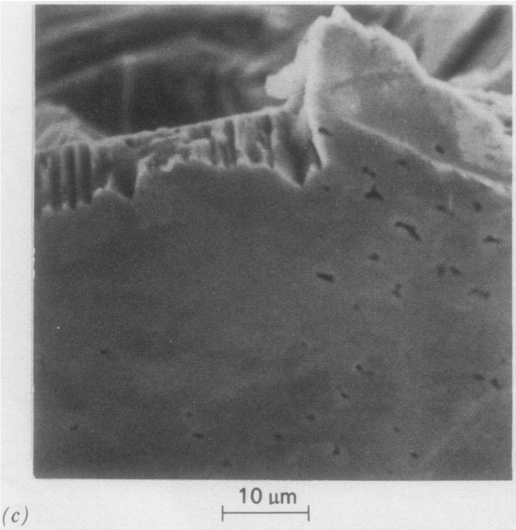


Fig 4 *Case 2: Scanning electron micrographs illustrating (a) general view of the fracture surface on the ring; (b) cracking in the weld at the point of fracture; (c) surface porosity in the weld adjacent to the fracture surface.*

section at this point. Secondly, the occurrence of carbides at the weld site may raise the local stress sufficiently to cause plastic deformation. Thus, although normal haemodynamic loading of the valve may be low, high local stresses may be present in the critical area where welding was performed. Furthermore, the non-homogeneity in grain structure at the weld site (large grains with extensive microsegregation) will lead to a reduction in strength.

We therefore propose that there will be a high susceptibility to fatigue failure in the weld region owing to the large number of pores and carbides with their associated stress concentrations—that is, with the very large numbers of stress cycles to which the prostheses are subjected in service, deformation around these defects may initiate microcracks that propagate

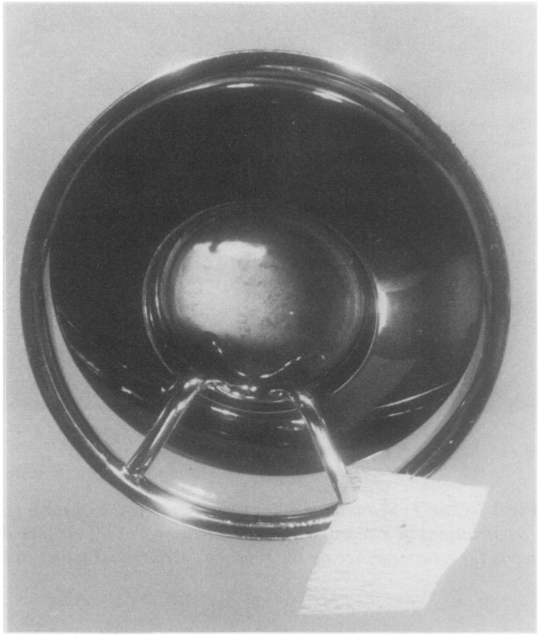


Fig 5 *Case 3: Fractured leg of the short strut.*

and coalesce, eventually leading to strut fracture at the weld. This is consistent with the finding that fracture had occurred through the band of carbides both in the present study and in that of Brubakk *et al.*[1]

Leg 1 of the first fractured strut showed a large area of smooth surface, which is typical of the "smearing" that accompanies wear. This suggests that leg 1 failed before leg 2, and that some considerable time elapsed between failures to allow wear of the opposing fracture surfaces of leg 1. A similar pattern is seen in case 3, where fortuitously the valve was removed before failure of the second leg.

The respective contributions that each microstructural feature has made to the fracture process are still under investigation. Nevertheless, we conclude that this type of failure is clearly related directly to the inhomogeneities in structure that result from the welding process. These problems might be prevented if the whole of the disc supporting structure were manufactured as one piece of metal.

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