Fatigue Evaluation of a Prosthetic Heart Valve

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Abstract

Approximately 86,000 Björk-Shiley convexo-concave (BSCC) heart valves were implanted from 1979 to 1984 and approximately 1% of these valves experienced failure due to fatigue of a critical valve component. Failures of this type are likely to yield a 70% mortality rate in patients. Although the BSCC valve was constructed from a material that possesses good fatigue properties continued operation of the valves produced cracking under certain circumstances suggesting that a small subset of valves may operate under conditions that are close to the boundary between continued safe operation and catastrophic failure. To understand the conditions that produced failure, a detailed engineering assessment has been conducted to identify the influence of valve design, manufacturing processes and physiologically related loading conditions on the potential for valve failure. Intimately coupled computational analysis procedures of the fluid-structure interaction were used to define loading of the outlet strut during valve closure. Standard structural and fracture mechanics analyses of the valve were used to identify the influence of design changes on the magnitude of the stresses at critical locations in the valve.

Introduction

In 1979 cardiologist adopted the Björk-Shiley convexo-concave (BSCC) heart valve for general use. During the eight years that the valve was on the market, approximately 86,000 valves were implanted worldwide. To date, 657 valves, ~0.7%, have experienced fracture of the outlet strut of the valve. Investigations of the phenomenon indicate that outlet strut failure (OSF) occurs as result of repeated loading during normal valve operation. Progressive crack growth across the base of the outlet strut eventually results in complete separation of the outlet strut from the valve support ring. Outlet strut fracture has been observed in valves manufactured prior to 1984, valves manufactured after April 1984 have not been observed to fail.

This paper provides an overview of a detailed investigation that has been conducted into the mechanisms that produced OSF in the BSCC valve. In particular, the role of the material's microstructure, loading of the valve during routine operation and the valve design has been clearly identified. Advanced computational analysis of the complex fluid-structure interactions occurring during valve closure have been used to identify loads on the outlet strut. Subsequent engineering analyses integrated the effects of material integrity and local stresses to identify the significance of valve design and support conditions on the expected lifetime for outlet strut fracture. Initially all analyses focused on identifying the behavior of a BSCC heart valve with a diameter of 29mm since this was the valve size most commonly implanted and for which most design records were readily available.

Analysis

To identify the key parameters that determine the lifetime of the BSCC heart valve a knowledge of valve loading during routine operation must be combined with the resistance of the material to fatigue loading. During routine operation of the BSCC heart valve (Figure 1), blood flow through the valve causes the occluder disc to open and close.

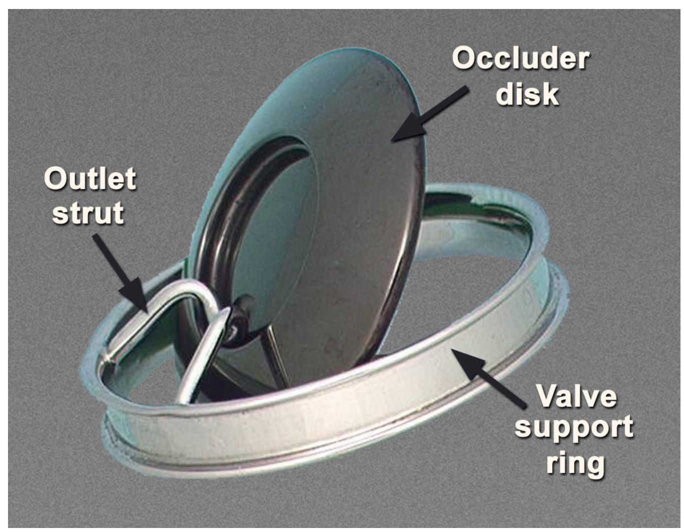

Figure 1: Björk-Shiley 60° Convexo Concave heart valve

Previous work (1-3) has used experimental approaches to identify the existence of stresses at the base of the outlet strut during normal valve operation. Although successful in showing the presence of localized stresses, these approaches cannot be used to identify the effect of small changes in the design of the valve and to quantify the magnitude of the stresses in critical locations on the valve. Alternative approaches (4, 5) have applied computational analyses to study the problem.

To analyze the relationship between fluid flow that causes disc closure and the stresses that are generated in the outlet strut it is necessary to combine the results of computational fluid dynamics analyses and finite elements analyses. Simulation of the blood flow that causes closure of the occluder disc can be performed using computational fluid dynamics (CFD) techniques in which the analytical mesh is independent of the fluid. In contrast, analyses of the stresses in the valve during operation can be performed using finite element analyses (FEA) in which a mesh defines the structural geometry. The mathematical formulations of the FEA and CFD techniques are fundamentally different and cannot be readily combined without the use of additional mathematical techniques that may reduce the accuracy of the analyses. Hence, it is mathematically inconvenient to perform analyses on mechanical structures (typically done using FEA) that deform in response to fluid pressure (typically done using CFD). The analysis of fluid flow in conjunction with analysis of the deformation of bodies belongs to a class of problems known as fluid-structure interactions (FSI).

Until recently, treatment of these complex phenomena could only be done using sequential coupling techniques that require the development of artificial links between different analytical procedures. Computational analysis procedures that do not require linkage between different computational codes can provide a more rigorous and accurate analysis of the phenomenon. Recent advances in computational algorithms now permit problems that contain these intimately coupled physical phenomena to be addressed. Using these approaches, the exact nature of the disc closure event of the BSCC heart valve and the stresses developed as a result of the disc motion have been analyzed without the need to apply unwarranted simplifications. These results have provided a more accurate assessment of the effect of fluid flow related events on the stresses in the valve and ultimately fracture of the outlet strut.

The present work used a fully-coupled element-free analysis technique to analyze the operation of the BSCC heart valve through to the full-closure position. Standard blood flow conditions that relate to those found in human patients (4) were used to analyze the motion of the occluder disc during valve closure. These analyses demonstrated that the displacement and rotation of the occluder disc during the valve closure cycle follows a complex path. Initial sliding and rotation of the occluder disc during valve closure from the fully open position is followed by impact with the inlet strut and the valve ring prior to full disc closure. The disc rebounds after impacting the inlet strut and subsequently strikes the outlet strut thus producing higher levels of stress at the base of the outlet strut. Analysis indicates that the magnitude of these stresses is dependent on a range of factors associated with the patient's physiology, including blood flow conditions and local heart muscle condition, and details of the valve design.

Compliance of the material supporting the valve and blood flow properties represents two of the most critical physiological variables. The compliance of the surrounding tissue may change with age, patient and severity of any heart disease and affects loading of the outlet strut in two ways. First, decreasing the compliance of the support increases the stresses on the outlet strut, figure 2. Secondly, compliance changes in the vessels supplying blood flow to the valve affect the mass of blood that is arrested due to disc closure; highly compliant systems will absorb the back pressure created when flow is stopped, thus the momentum associated with the valve closure event will be reduced and result in a lower stress on the outlet strut. The force with which the occluder disc impacts the outlet strut is proportional to the closing velocity of the disc. The closing velocity is affected by the pressure of the blood flow causing disc closure which in turn can be affected by a number of patient specific factors, for example blood pressure and activity. The local blood flow conditions will also affect impact of the disc on the strut depending on whether the valve is in the aortic or mitral position.

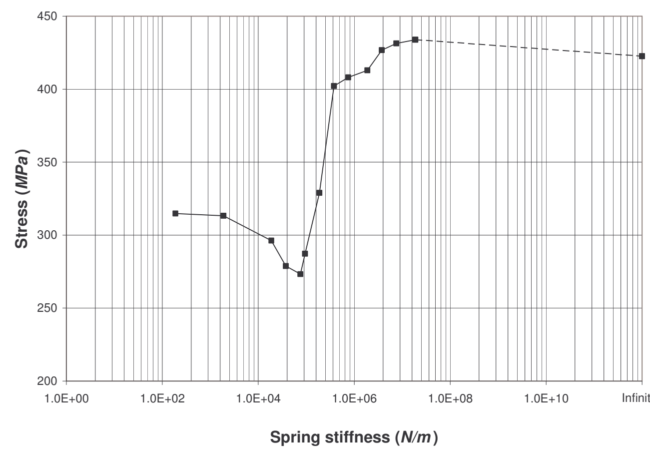

Figure 2: Outlet strut root stress as a function of equivalent aortic stiffness.

Similarly changes in the valve design may influence the stresses in the outlet strut. During production several changes to the valve design and manufacturing process occurred that strongly influenced the stress in the outlet strut. Analyses of the effect of recorded design changes that took place between 1979 and 1984 have identified two specific changes that significantly reduced the stress at the base of the outlet strut. In 1982 the distance between the tip of the outlet strut, the "hook", and the corresponding contact point in the occluder disc, the "well", was increased from 0.076 mm to a "visible gap" of approximately 0.25 mm. Then, in 1984 the position of the strut legs were moved closer to the center of the valve ring.

The distance between the "hook" of the outlet strut and the "well" in the occluder disc influences the loading of the outlet strut in two ways. First, after impact with the inlet strut the disc must travel against the operating blood pressure, as the distance that the disc travels increases more work is expended and the velocity of the disc is reduced. Thus as the distance between these two features increases the velocity with which the disc strikes the outlet strut is reduced and consequently the stress in the outlet strut falls. Secondly, if the distance the rebounding occluder disc travels prior to contacting the hook of the outlet strut is sufficiently large the occluder disc contacts the base of the outlet strut prior to contacting the hook. In this case, the bending moment on the outlet strut is reduced and thus the stress at the base of the outlet strut decreases significantly. The effect of changes in the hook-to-well distance on the stresses at the base of the outlet strut can be seen in Figure 3.

Similarly, changes in the position at which the outlet strut is attached to the valve ring affect the stresses at the base of the outlet strut. Conditions that move the point of attachment of the legs of the outlet strut closer to the closed position of the disc operate in conjunction with the hook-to-well distance to cause contact between the disc and the base of the outlet strut thus decreasing the magnitude of the stress developed by impact between the disc and the strut, figure 3.

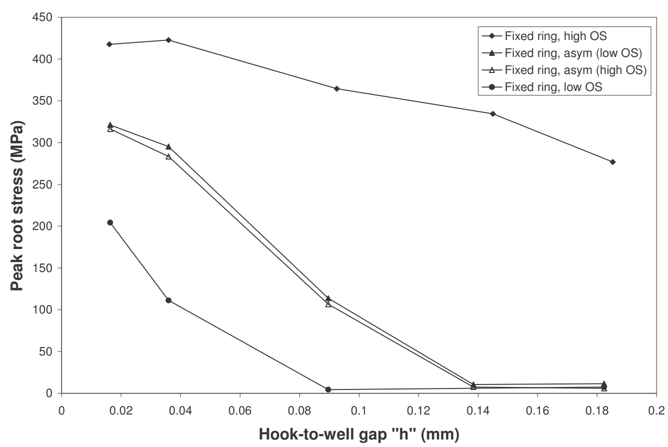

Figure 3: Effect of hook to well gap and position of attachment of outlet strut legs to valve ring on stresses at root of outlet strut for a rigidly supported valve.

The results of computational analyses that used intimately coupled fluid-structure interactions to represent the closure event indicate that typical physiological blood flow conditions (4) can produce stresses at the base of the outlet strut that range from 5 to 400 MPa. The precise magnitude of the stress is dependent on the details of valve construction and rigidity of the valve support. As the valve design evolved during manufacturing, the outlet strut position varied by approximately 0.5 mm. Inspection tolerances allowed the legs of the outlet strut to be attached towards the center of the valve ring or up to 0.5mm higher on the valve ring towards the outlet side of the valve. Although small, this variability in strut position is sufficient to have a significant effect on the stress at the base of the outlet strut, see figure 3 for the condition in which the valve is rigidly supported. When the legs of the outlet strut are attached towards the center of the valve ring, the occluder disc makes contact with the base of the outlet strut thus reducing the force on the outlet strut tip. Sufficiently large hook-to-well gaps (>0.09 mm) produce a condition where the outlet strut tip remains unloaded by the occluder disc. Thus the bending moment on the outlet strut is reduced and the stresses at the base of the strut are low. Consequently, small changes in the geometry of the valve can be seen to generate signification differences in the stress at the critical location of cracking.

The stresses presented in Figure 3 show the effect of hook-to-well distance for a rigidly supported valve; these results generally represent an upper bound. The results for a valve with compliant support typical of that expected in practice are shown in figure 4.

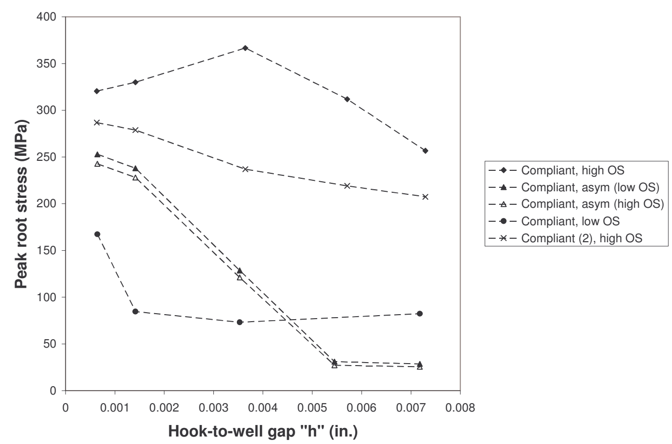

Figure 4: Effect of hook to well gap and position of attachment of outlet strut legs to valve ring on stresses at root of outlet strut for a valve with compliant support.

Thus for a valve mounted with a compliant support, stresses at the base of the outlet strut may range between 20 and 350 MPa under typical physiological related loading depending on the hook-to-well gap and the strut position on the ring. For valves in which the struts are attached low on the valve ring and in which the valve has compliant support the magnitude of the stress at the base of the outlet strut is 75 MPa, see Figure 4. This stress develops due to the vibration response of the outlet strut supported by a spring mass system when forced to vibrate due to closure of the disc. These stresses do not develop when the valve is supported rigidly since the ring is not allowed to move and vibrate within the support structure.

Fatigue Life Estimation

The effect of the stresses at the base of the outlet strut on the expected strut lifetime can be identified by comparison with the intrinsic material properties that govern fatigue failure in the Haynes 25 alloy used for valve construction. The stresses developed during disc closure are concentrated at the base of the outlet strut due to bending of the strut caused by impact of the occluder disc. During production the outlet strut was welded to the valve ring using an autogenous welding procedure. The thermal excursions applied to the material during this process produced a weld between the outlet strut and the valve ring. During solidification, intrinsic flaws may develop due to cracking in the inter-dendritic regions of the weld. Detailed examinations have shown that the weld region may contain cracks that typically range from 10-100 µm in length, see figure 5.

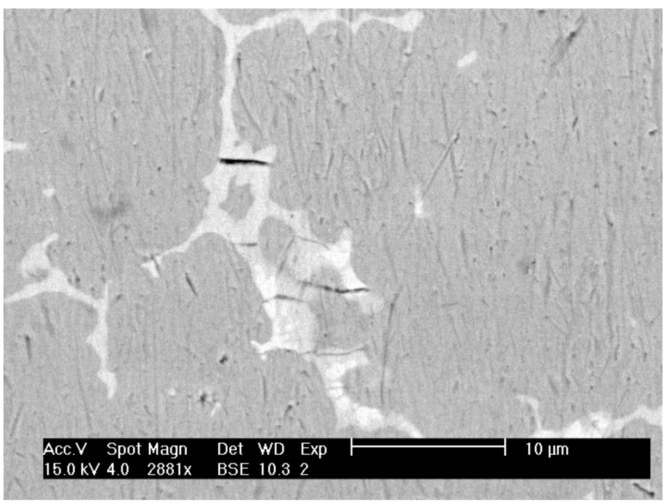

Figure 5: Incipient cracking in inter-dendritic region of weld between outlet strut and valve ring.

Current fatigue life estimation techniques of stressed components fall into two broad categories: first, stress/strain life methodologies, and secondly damage tolerant approaches. Although both techniques have been used to assess the fatigue life of the BSCC valve, given the documented existence of cracks in the outlet strut a damage tolerant approach is more relevance. This methodology assumes immediate crack initiation or the presence of pre-existing flaws and that the remaining life can be computed from the number of cycles for the largest undetected flaw to grow to failure. On loading, cracks extend according to Paris' Law (6). At extremely low crack growth rates, Paris' Law becomes conservative as cracks exhibit negligible growth. This region, typically referred to as Stage I, is dominated by the threshold response of the material specified by the threshold stress intensity, ΔK_{th}.

The concept of a threshold stress intensity applies to cracks that are large compared with the microstructure of the metal and the crack tip plastic zone. For cracks that are small relative to these length scales, additional analysis must be conducted to determine crack extension. These analyses may utilize traditional S/N data to include the effects of samples with vanishingly small cracks. Under these conditions, the threshold stress intensity factor becomes a function of crack size. For these small cracks,

$$\Delta K_{th}(a) = \Delta \sigma_e \sqrt{\pi a}\, f(g)$$

where $\Delta\sigma_e$ is the endurance limit of the material determined by S/N testing to $>10^6$ cycles.

Thus a detailed understanding of the fatigue response of the outlet strut to loading during valve closure may be developed by integrating stresses developed during valve closure with the fatigue crack propagation methodology modified for the existence of small cracks. Ritchie and Lubock (7) have identified the threshold condition for crack growth in Haynes 25. Similarly, the experimental work of Green et al. (8) can be used to identify the fatigue endurance limit of Haynes 25 thus enabling a calculation of the expected behavior of both small and long cracks in a finite sized structure.

The stress intensity factors for a specific crack size within the outlet strut, a cylindrical geometry subjected to a bending load, were determined by extending the work of Ng and Fenner (9) to consider small cracks by incorporating the approaches of Raju and Newman (10). The resulting failure envelope for the specified loading, materials and geometry of the outlet strut appears in Figure 6.

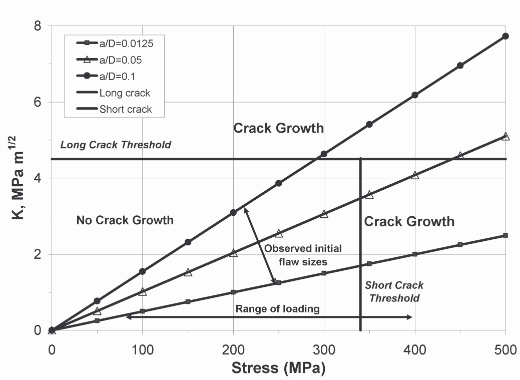

Figure 6: Calculated failure envelope for outlet strut in the BSCC heart valve.

Based on these analyses it can be seen from Figure 6 that alternating stresses in excess of 340 MPa should produce crack extension for an initial flaw of any size. Stresses between 275 and 340 MPa will produce crack extension for initial flaw sizes in which a/D > 0.075; for the outlet strut of a 29 mm BSCC heart valve this condition represents flaws whose size is > ~75 µm. For stresses less than 275 MPa, crack extension should not occur for the range of incipient flaw sizes typically observed in the BSCC heart valve. Based on the analyses presented earlier it can be seen that conditions of disc closing and valve geometry may arise under which the magnitude of the stress at the root of the outlet strut exceeds the threshold level of ~ 275 MPa at which the outlet strut would not fail. Consequently, it is possible that a small subset of valves were produced with a geometry that made them susceptible to failure during normal valve operation.

Valve Life

Over the last 25 years records indicate 657 outlet strut failures in BSCC heart valves of which 123 failures were in valves having a diameter of 29 mm. Epidemiological analyses (11) have identified a number of critical patient and valve related factors for the identification of valves with higher risk of failure. Engineering based analyses of the type performed here have been performed to provide further support for the identification of valves with an increased risk of failure. Analysis of failures from the 29 mm BSCC valves that have been implanted indicates three outlet strut fractures within a year after implanting. If loading is assumed to occur with every disc closure event, strut failure in these cases occurred after < ~3.8×10^7 cycles. Based on the analyses presented above, failures of within this timeframe are consistent with the growth intrinsic small cracks of the size typically found at the base of the outlet strut to failure. The shortest time before outlet strut failure of an implanted valve is approximately three months. The analyses developed above indicate that this timeframe is consistent with the growth of a near threshold crack under the influence of long crack fracture mechanics during typical operating stresses.

Most recorded failures of the outlet strut occurred after the valve had been implanted for more than 2 years, with some valves failing after 23 years of operation. Due to the large cycles per year experienced by these valves on an annual basis (~38 million), routine operation of the valve must generate stresses below the safe operating threshold limit of 275 MPa. Thus the loads developed during routine valve operation do not cause fatigue damage of the outlet strut, instead the damaging cycles that cause these failures must be associated with atypical, short term load excursions and not continuous loading associated with normal physiological activity. Damage is accumulated during these extreme cycles until the small cracks obtain a flaw size that grows under the stresses that arise during typical valve operation. Once the crack size reaches this critical point the outlet strut fractures within one year of typical operation.

In the later stages of valve production, changes in the design of the valve were implemented that reduced the incidence of strut failure. The effect of these changes on the incidence of valve fracture can be seen from data on the cumulative incidence of strut failure for the 29mm valve presented in Figure 7.

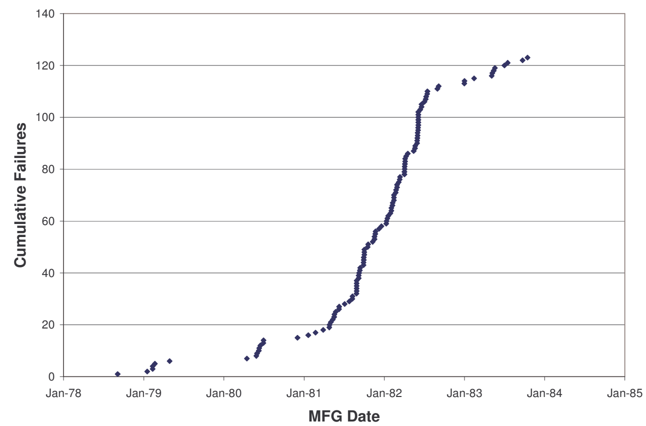

Figure 7: Cumulative failures of 29mm BSCC heart valve based on valve manufacturing date.

Initial changes in late 1983 that increased the hook-to-well gap were followed in April 1984 with more stringent controls on the location at which the strut was attached to the valve ring. The increases in the hook-to-well gap in late 1983 limited the number of valves in which a safe operational stress of < ~275 MPa is exceeded to those in which the strut legs were attached towards the upper portion of the valve ring. Consequently the rate of reported outlet strut failure decreased for valves manufactured after December 1983, see Figure 7. Subsequent changes in the position at which the legs of the outlet strut were attached to the valve ring combined with the changes in hook-to-well gap reduced the stress on the outlet strut below ~275 MPa for all loading conditions. Thus, although the manufacturing process may produce initial flaws with sizes up to 100 µm, the loading conditions are such that they remain dormant and mechanical damage is not accumulated during the lifetime of the valve. Thus these valves will not be loaded to a level sufficient to cause failure of the outlet strut and will provide continued safe operation. This interpretation is consistent with epidemiological work that indicates no failures for valves manufactured after April, 1984.

Summary and Conclusions

The Björk-Shiley convexo-concave (BSCC) heart valve experienced fracture of the outlet strut due to fatigue cracking of the outlet strut. Advanced computational fluid-structure analyses have shown that during valve closure the occluder disc rebounds after initial contact with the inlet strut before striking the outlet strut. The contact forces generated by this action are sufficient to produce stresses at the base of the outlet strut that exceed the threshold for fatigue failure. Under certain circumstances these stresses may be reduced but remain of sufficient magnitude that they can cause growth of small cracks developed during the valve manufacturing process. Consequently, the flaws at the base of the outlet strut grow under fatigue loading generated from contact forces due to closure of the occluder disc during normal valve operation.

Initial valve designs may not have considered the contact forces between the outlet strut and occluder disc that develop during valve closure. The stresses in the outlet strut are determined by both physiologically related variables and the valve design. In particular, the compliance of the tissue to which the valve is attached can significantly affect the stresses at the base of the outlet strut; highly compliant systems have lower stresses than those with rigid valve support. Similarly, individual patient related factors that affect the momentum of the blood flow during valve closure can influence the stresses at the base of the outlet strut. Two components of valve design significantly reduce the stresses in the outlet strut: first, increasing the magnitude of the gap between the tip of the outlet strut and the lowest point in the well of the occluder disc and secondly, locating the legs of the outlet strut closer to the center of the valve ring rather than toward the outlet side of the valve ring. Consequently a small subset of valves may have been manufactured in which the stresses developed during valve operation were sufficient to cause fatigue failure at the base of the outlet strut.

For a subset of valves manufactured prior to 1984, it was possible to develop combinations of valve design and loading that would produce strut failure. In some circumstances failure may have occurred rapidly when the stresses exceed the threshold for crack growth. Alternatively, failure after longer operating times, up to 20 years, may arise as a result of damage accumulation during abnormal loading conditions. This damage accumulates over many years until the crack grows to a size where the applied stress intensity exceeds threshold for nominal loading. At this point, fracture of one outlet strut leg occurs within a year of operation.

The observed incidence of outlet strut fracture decreased as a result of design changes to the valve that commenced in late 1983 and were concluded in early 1984. Changes to the hook-to-well gap and the outlet strut leg position on the valve ring resulted in the occluder disc making contact with the base of the outlet strut thus eliminating strut bending and reducing the stresses below the critical level for strut failure.

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