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Prediction of Failure in Existing Heart Valve Designs

ABSTRACT: Artificial heart valves must be designed to survive greater than 109 cycles over 40 years of operation. Thus, fatigue represents one of the primary driving forces for safe operation of these devices. The inability to maintain the long term performance of critical devices in the future may lead to catastrophic failure and patient loss of life. The Bjork-Shiley convexo-concave (BSCC) heart valve provides an excellent case study in heart valve design. Approximately 86 000 valves were implanted from 1979 to 1987 and approximately 1 % of the valves experienced failure due to fatigue. Failures of this type are likely to yield a 70 % mortality rate in patients. To understand the conditions that produced failure, a detailed engineering assessment was conducted to determine valve designs, manufacturing processes, and physiologically related loading conditions that gave rise to an increased risk of failure. The material used in constructing the valve, Haynes 25, possesses good long crack threshold fatigue properties (ΔK_{th}=4.5 MPa$\sqrt{\text{m}}$). However, continued operation of the valves produced cracking under certain physiological circumstances. These assessments indicate that a small subset of valves may operate under conditions that are close to the boundary between continued safe operation and catastrophic failure. These findings should be considered when using materials with inherently lower threshold fatigue properties. Crack growth data show that Nitinol has a threshold stress intensity factor ≈2 MPa$\sqrt{\text{m}}$, or less than half that of Haynes 25. Thus, current heart valve designs that use Nitinol should incorporate lessons learned from analyses of the BSCC heart valve to assess the likelihood of premature valve failure due to repeated loading.

KEYWORDS: Bjork-Shiley, short cracks, Haynes 25, Nitinol, threshold, heart valves

Introduction

In the year 2000, approximately one million artificial heart valves were operating in the United States. This number continues to grow as every year more than 80 000 adults undergo surgical procedures to repair or replace damaged heart valves [1]. Engineers that design and manufacture these valves must consider the need for these valves to survive extremely large cycle counts. The human heart beats approximately 38 million times per year. Thus, valves experience 10^6 cycles, typically specified as the endurance limit for most engineering materials, in less than one year of operation. Fatigue loadings with cycle counts greater than 10^6 cycles occur in many engineering structures. However, these systems often are designed with large safety factors, and have more opportunities for inspection than an artificial heart valve. Size constraints, complex loadings, and inaccessibility require these designs to operate outside of typical practices for traditional engineering structures.

Cardiologists adopted the Bjork-Shiley convexo-concave (BSCC) heart valve, as shown in Fig. 1, for general use in 1979. During the eight years that the valve was on the market, approximately 86 000 valves were implanted in patients. Six hundred and fifty-seven valves (or 0.76 %) experienced outlet strut fracture (OSF), as of October 31, 2005. These failures produced a mortality rate of approximately 70 %. Inspections of valves that experience OSF indicate progressive crack growth across the base of the outlet strut that resulted in complete separation of the outlet strut from the valve support ring. All OSFs occurred in designs manufactured prior to design changes implemented in 1984.

This paper provides an overview of a detailed investigation into the loading mechanisms that produced OSF in this valve design. In addition to providing an overview of the failure mechanism in the BSCC, this paper enumerates lessons learned from this case study in an effort to reduce the likelihood of repeating these errors in future heart valve designs.

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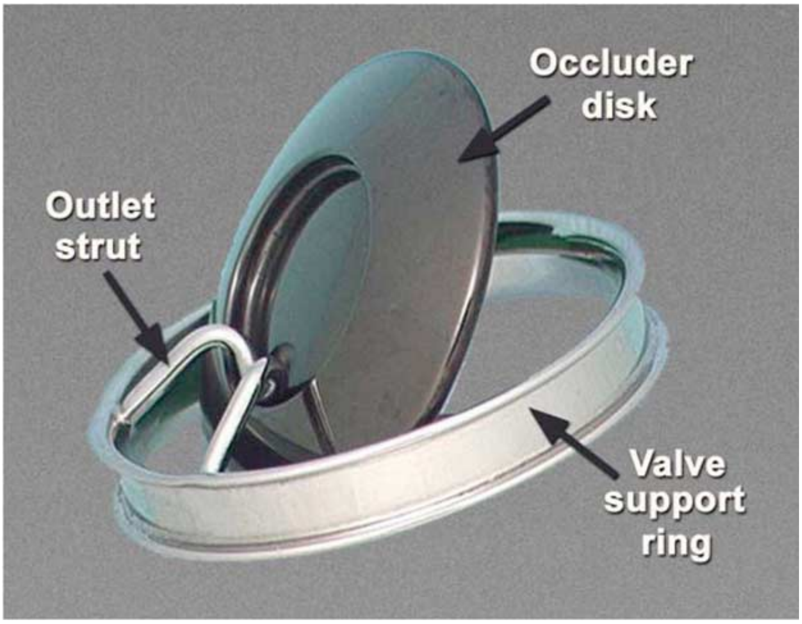

FIG. 1—*Bjork-Shiley convexo-concave heart valve.*

Fatigue Life Estimation

Current fatigue life estimation techniques fall into two broad categories: stress/strain life methodologies, and damage tolerant approaches. Although both techniques have been used to assess the fatigue life of the BSCC valve, the work presented in this paper focuses on a damage tolerant approach. This methodology assumes immediate crack initiation and that the remaining life can be computed from the number of cycles for the largest undetected flaw to grow to failure. During crack extension, the rate of growth depends on the stress intensity factor of the crack as specified by

$$K = \sigma\sqrt{\pi a}f(g) \tag{1}$$

where $f(g)$ is a function of the geometry of the part. This equation holds within the bounds of linear elastic fracture mechanics. During cyclic loading of the crack, extension per cycle, da/dN, occurs as a function of the change in stress intensity factor, ΔK, according to Paris' Law [2]

$$\frac{da}{dN} = C\Delta K^m \tag{2}$$

where C and m are constants that depend on the material, environment, and stress intensity range. This equation describes fatigue crack extension over the range $10^{-2} \leqslant da/dN \leqslant 10^{\circ}$ μm/cycle. As shown in Fig. 2, this region is typically referred to as Stage B (or II). At extremely low crack growth rates, where $da/dN \leqslant 10^{-3}$ μm/cycle, Paris' Law becomes conservative as cracks exhibit negligible growth. This region, typically referred to as Stage A (or I), is dominated by the threshold response of the material specified by ΔK_0, as shown in Fig. 2.

The concept of a threshold ΔK 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 S/N data to include the effects of samples with vanishingly small cracks. Thus, threshold ΔK becomes a function of crack size for these small cracks,

$$\Delta K_0(a) = \Delta\sigma_e\sqrt{\pi a}f(g) \tag{3}$$

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

This damage tolerant methodology provides the basis for determining the remaining life of the BSCC valve. The following sections describe the techniques developed to implement this methodology for a structure with significant geometric variability subjected to complex loadings.

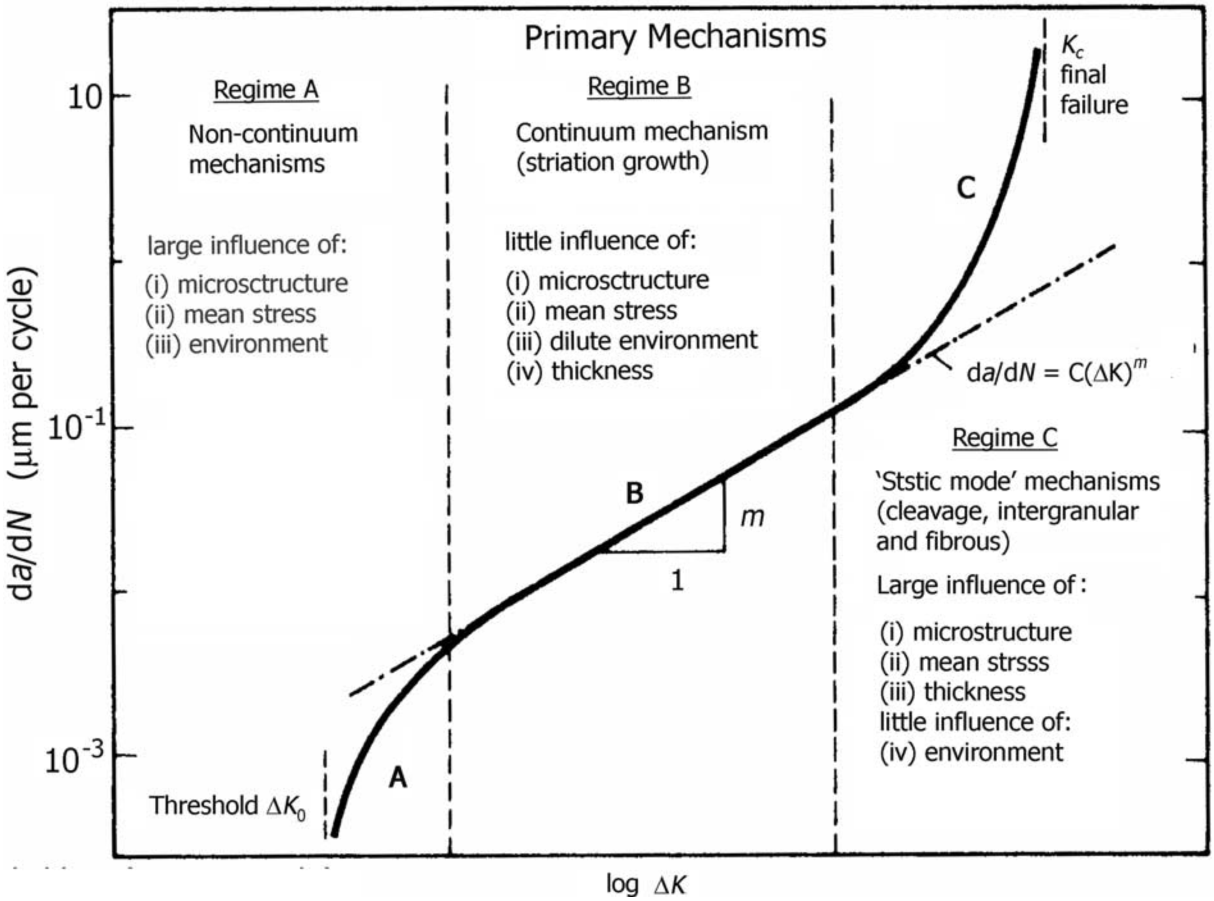

FIG. 2—*Typically fatigue crack extension response of materials.*

Load Mechanism

Experimental work on the BSCC valve [3] indicates loading of the outlet strut occurs during closing of the occluder disk. This work suggests that "over-rotation" of the disk causes the disk to contact the outlet strut. The term "over-rotation" defines the response of the disk measured by proximity detectors located on the end of the disk furthest from the outlet strut. Measurements from this sensor indicate this point on the disk has a larger displacement during the closing event than the final resting displacement of the valve. Detailed finite element analyses of the closure event show the displacement and rotation of the disk follows a complex path that could not be fully understood by measuring displacement at a single point. Figure 3 shows a simple rigid bar representation of the displaced shape calculated from the FEA. These shapes are consistent with experimental measurements. However, these results show that "over-rotation" only accounts for a part of the disk motion, and that disk "rebound" from contacting the inlet strut accounts for contact with the outlet strut that produces stress at the base of the outlet strut.

The significant difference in diameter between the inlet and outlet struts suggests designers may have assumed the inlet strut alone would support the closing of the disk. However, experimental and numerical work indicates a significant load on the outlet strut due to disk rebound during the closing event. This work shows that the rebound load is sufficient to produce cracking of the outlet strut that leads to separation from the valve ring.

Variables Affecting Loading

The load magnitude produced on the outlet strut due to disk rebound depends on patient physiology and details of the valve design that changed over time. 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 changes with age and affects outlet strut loading in two ways. First, decreasing the compliance of the support increases the stresses on the outlet strut. Secondly, compliance changes in the

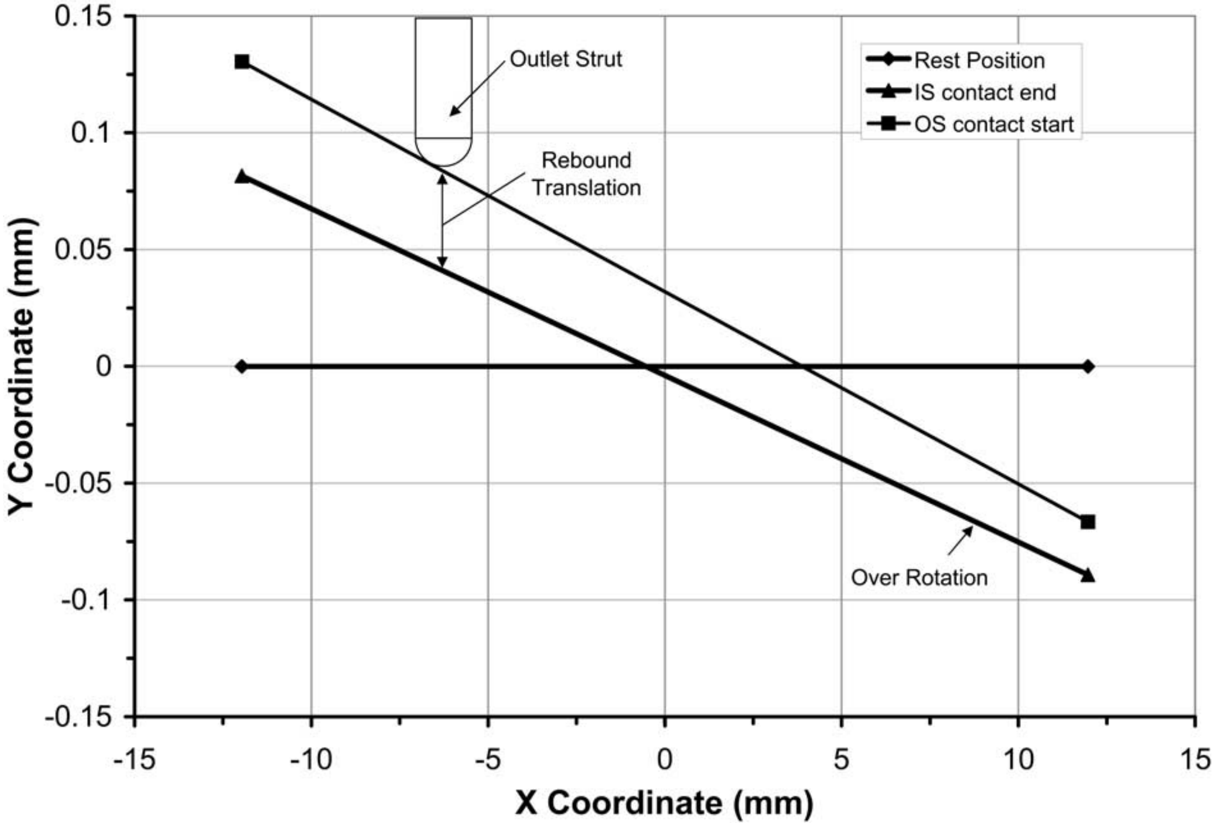

FIG. 3—*Line diagram representation of disk motion during closure event as calculated from detailed finite element analysis. The disk over rotates beyond the rest position prior to rebounding from the inlet strut (IS). Translation due to rebounding generates contact with tip of outlet strut (OS).*

vessels supplying blood flow to the valve affect the mass of blood that is arrested due to disk closure; highly compliant systems will absorb the back pressure created when flow is stopped, the momentum of the closure will be reduced and result in lower stress on the outlet strut. The force of impact of the occluder disk with the outlet strut is proportional to the closing velocity of the disk. The closing velocity is affected by the pressure of the blood flow causing disk closure which in turn can be affected by a number of patient specific factors. The local flow conditions will also produce differing impact of the disk on the strut depending on whether the valve is in the aortic or mitral position.

In addition to these physiological factors, several changes to the valve design during production strongly influence the stress on the outlet strut. The valve design underwent a large number of design changes from 1979 to 1984. Analyses conducted in this work indicate two changes significantly reduced stress at the base of the outlet strut. In 1982 the distance between the tip of the outlet strut and the corresponding contact point in the occluder disk 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 stiffener ring.

The distance between the "hook" of the outlet strut and the "well" in the occluder disk influences the loading of the outlet strut. A large distance between these two features reduces the stress on the outlet strut, because the blood pressure operates against the disk and conducts more work on the rebounding disk as this distance increases. If the distance the rebounding disk must travel prior to contacting the outlet strut hook is sufficiently large, then the occluder disk contacts the base of the outlet strut prior to contacting the hook. In this case, the stress at the base of the outlet strut decreases significantly. Thus, design changes that move the outlet strut closer to the closed position of the disk operate in conjunction with the hook-to-well distance to decrease stress on the outlet strut.

Stress in Failure Region

Finite element modeling that used intimately coupled fluid-structure interactions to represent the closure event indicates that typical physiological loading of the outlet strut can produce stresses at the base of the

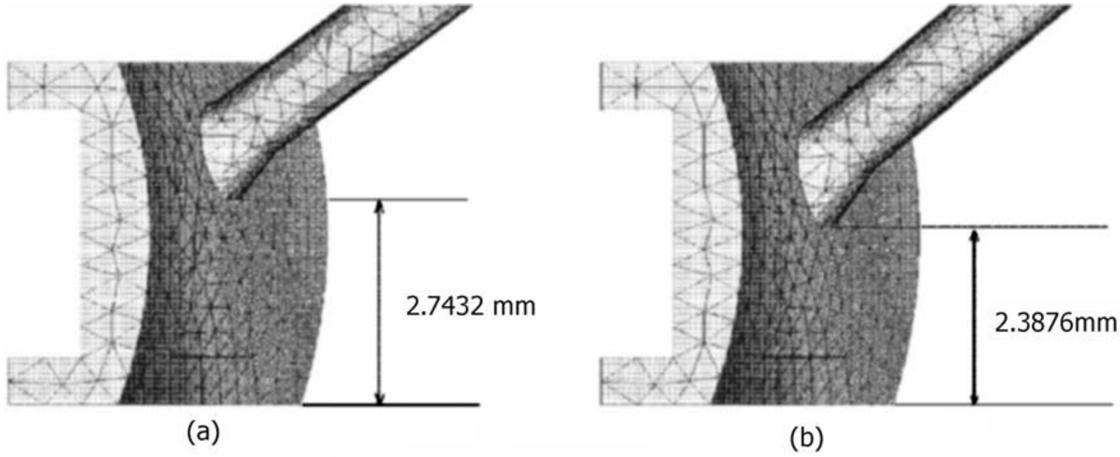

FIG. 4—*Location of outlet strut on valve support ring with legs located in the (a) high and (b) low positions.*

outlet strut that range from 5 to 400 MPa. Details of the valve construction and rigidity of the supports generate this large variation in stress, as indicated previously. The location of the outlet stress along the width of the valve support ring produces the most significant variation in stress. As the valve design evolved during the manufacturing process, the outlet strut position varied from 2.39 to 2.74 mm from the base of the ring, as shown in Fig. 4. This variation in strut position greatly affects the stress in the failure region. Figure 5 shows the variation of stress with hook-to-well distance for these two strut positions. For the lower outlet strut position, the occluder disk makes contact with the base of the outlet strut and reduces the force on the outlet strut tip. Sufficiently large hook-to-well gaps (>0.09 mm) produce a condition

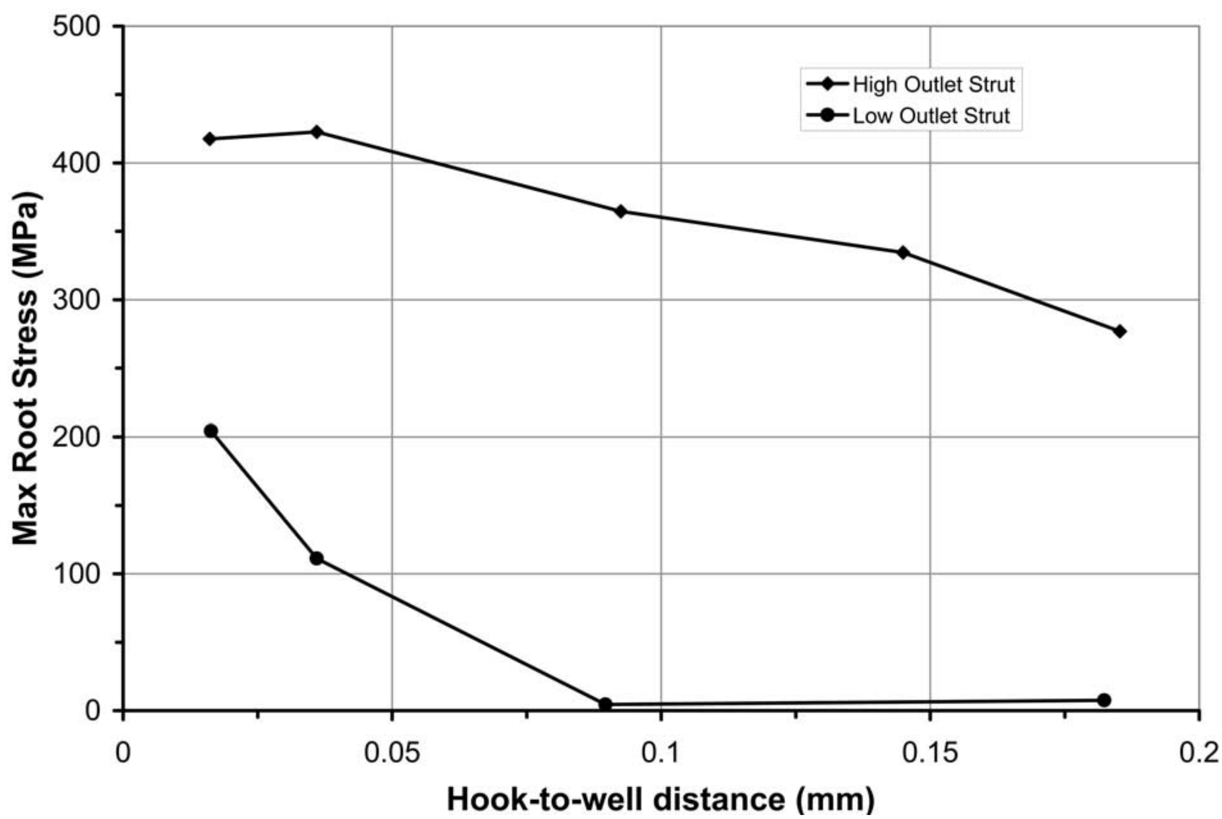

FIG. 5—*Effect of hook-to-well distance on stress at base of outlet strut—rigidly supported ring. The high outlet strut location is 2.74 mm above the base of the outlet strut. The low outlet strut position is 2.39 mm above the base of the outlet strut.*

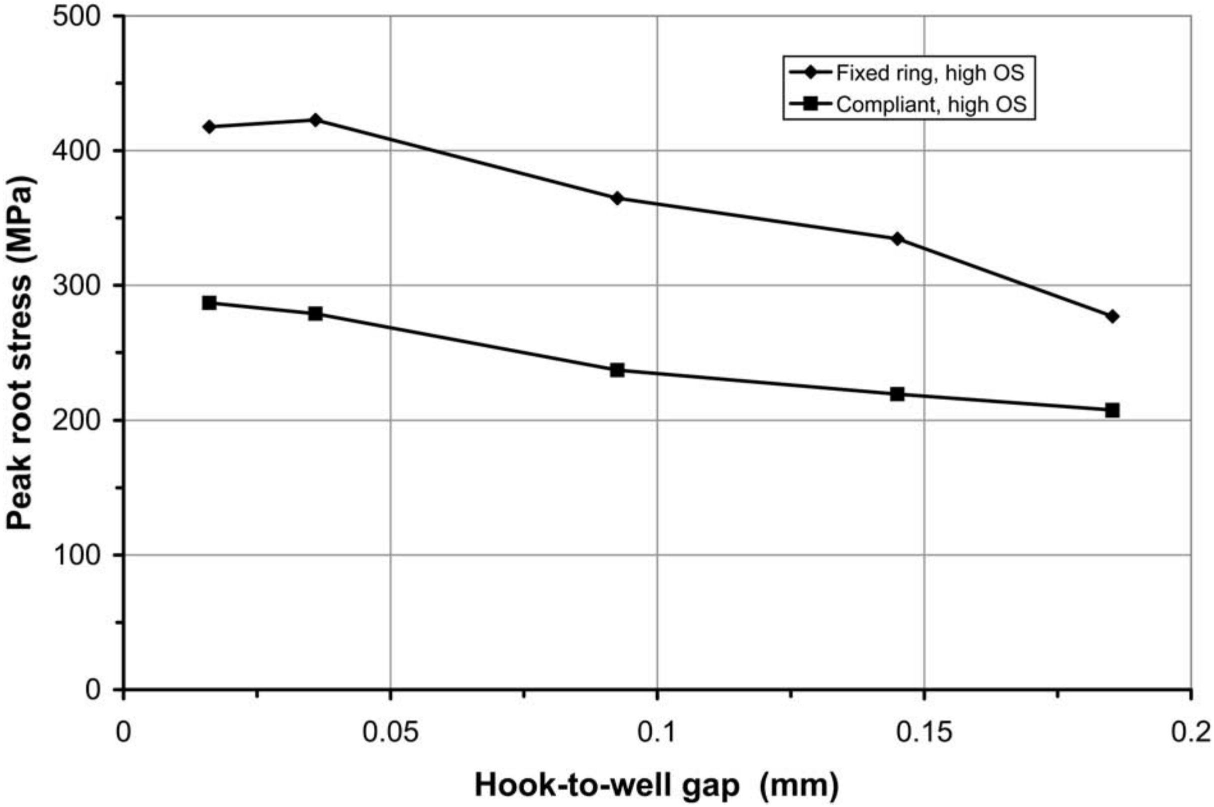

FIG. 6—*Effect of hook-to-well distance on stress at base of outlet strut for legs positioned high on support ring—compliant support* ($K_{total}=8\times10^5$ *N/m*).

where the outlet strut tip remains unloaded by the occluder disk. Thus, small changes in the geometry of the valve generate significant differences in the stress at the location of cracking.

The stresses presented in Fig. 5 show the effect of hook-to-well distance for a rigidly supported valve. These results generally represent an upper bound for the specific conditions. Figures 6 and 7 show the effect of compliance on the peak stress at the region of failure. These results were generated using a total spring constant of 8×10^5 N/m. The 75 MPa stress observed for the compliant support condition in Fig. 7 develops due to the vibrational response of the outlet strut supported by a spring mass system. These stresses do not develop in the rigid support case due to the lack of vibrational response of the ring.

Thus, finite element analysis of the valve mounted within a compliant support indicates stresses at the base of the outlet strut may range from 75 to 300 MPa under typical physiological loading. These calculations represent the most accurate estimate of the stresses in the failure region.

Stress Intensity Factor

Equation 1 provides the general form for the stress intensity factor, K. To determine K for a specific crack size within a finite geometry, the geometry function $f(g)$ must be determined. Ng and Fenner [4] determined the functional variation of K over a range of crack size to diameter ratios (a/D) for a cylindrical geometry subjected to a bending load. These solutions do not consider $a/D<0.1$. To determine K for these smaller cracks, solutions obtained by Raju and Newman [5] were used. By combining the solutions from these sources, the value of K can be calculated over the full range of typical crack sizes.

Initial Flaw Size

To determine the typical initial flaw size in the failure region, a detailed metallurgical investigation was conducted. Figure 8 shows a typical observed flaw. These cracks occur in the weld at the base of the outlet strut. Typical lengths range from 10–100 μm (or $0.009\leq a_i/D<0.09$ for $D=1.1$ mm). These flaws develop due to cracking of the interdendritic regions in the intermetallic compounds formed during solidi-

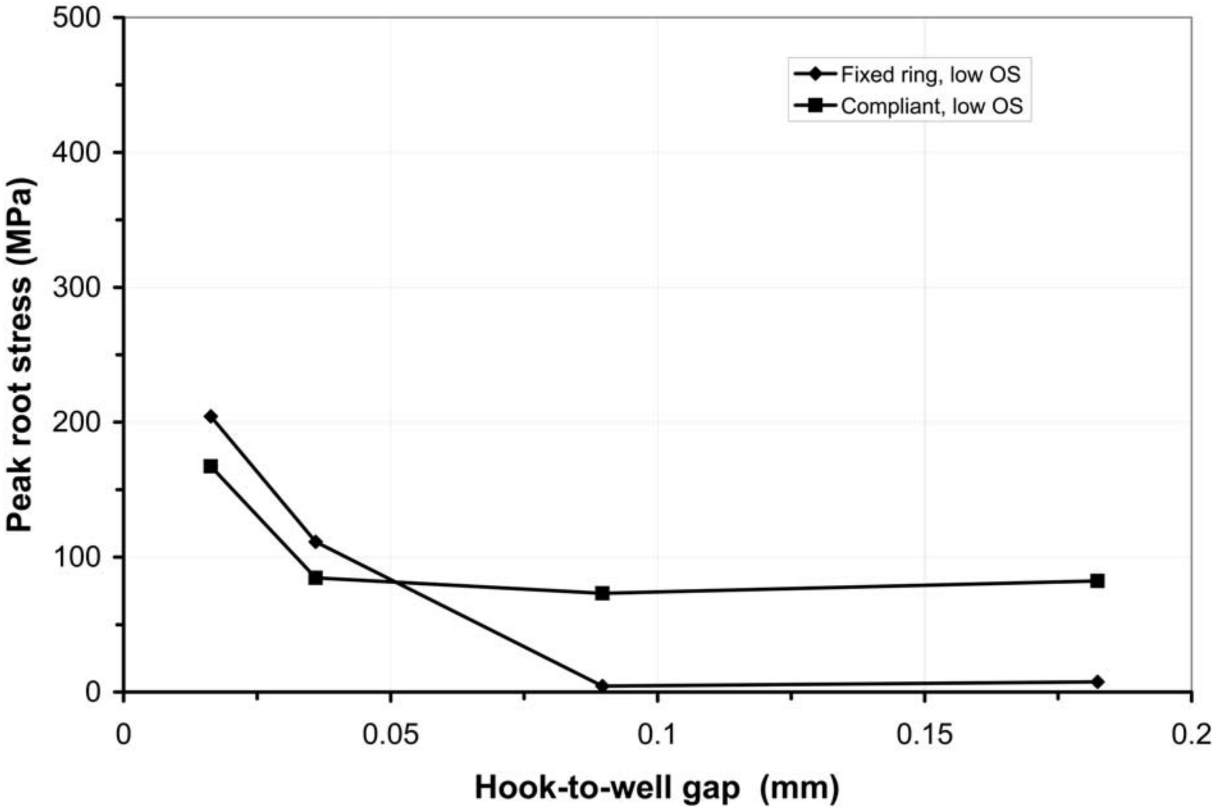

FIG. 7—*Effect of hook-to-well distance on stress at base of outlet strut for legs positioned low on support ring—compliant support ($K_{total} = 8 \times 10^5$ N/m).*

fication after welding. This range of flaw sizes, when combined with the applied stress and stress intensity solutions, provide the basis for assessing the likelihood of fatigue crack extension.

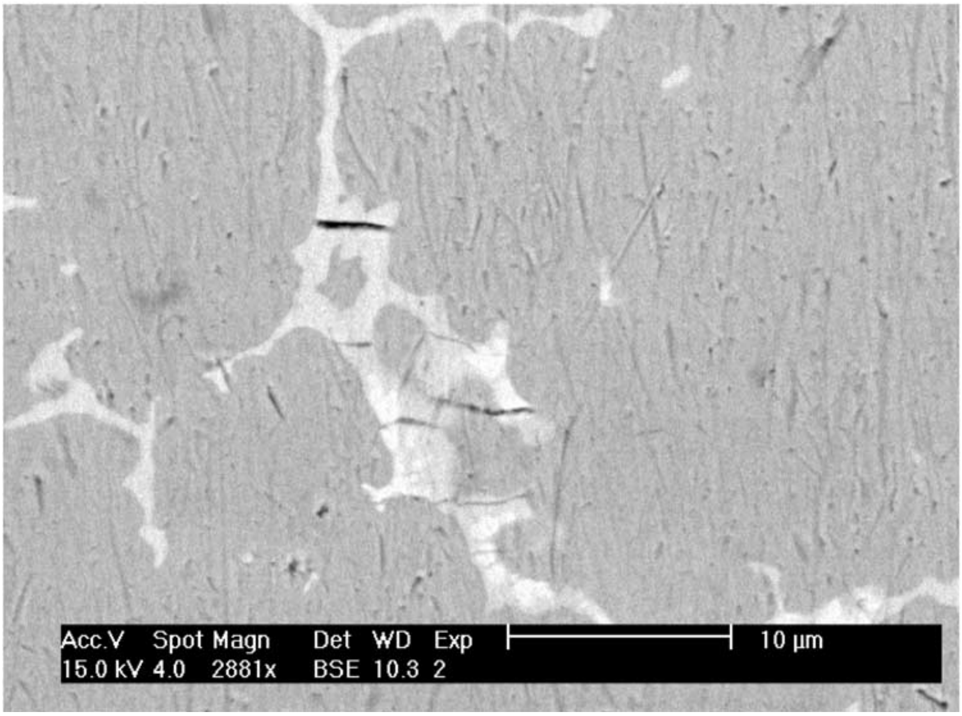

FIG. 8—*Typically observed pre-existing flaws in weldment at the base of the outlet strut.*

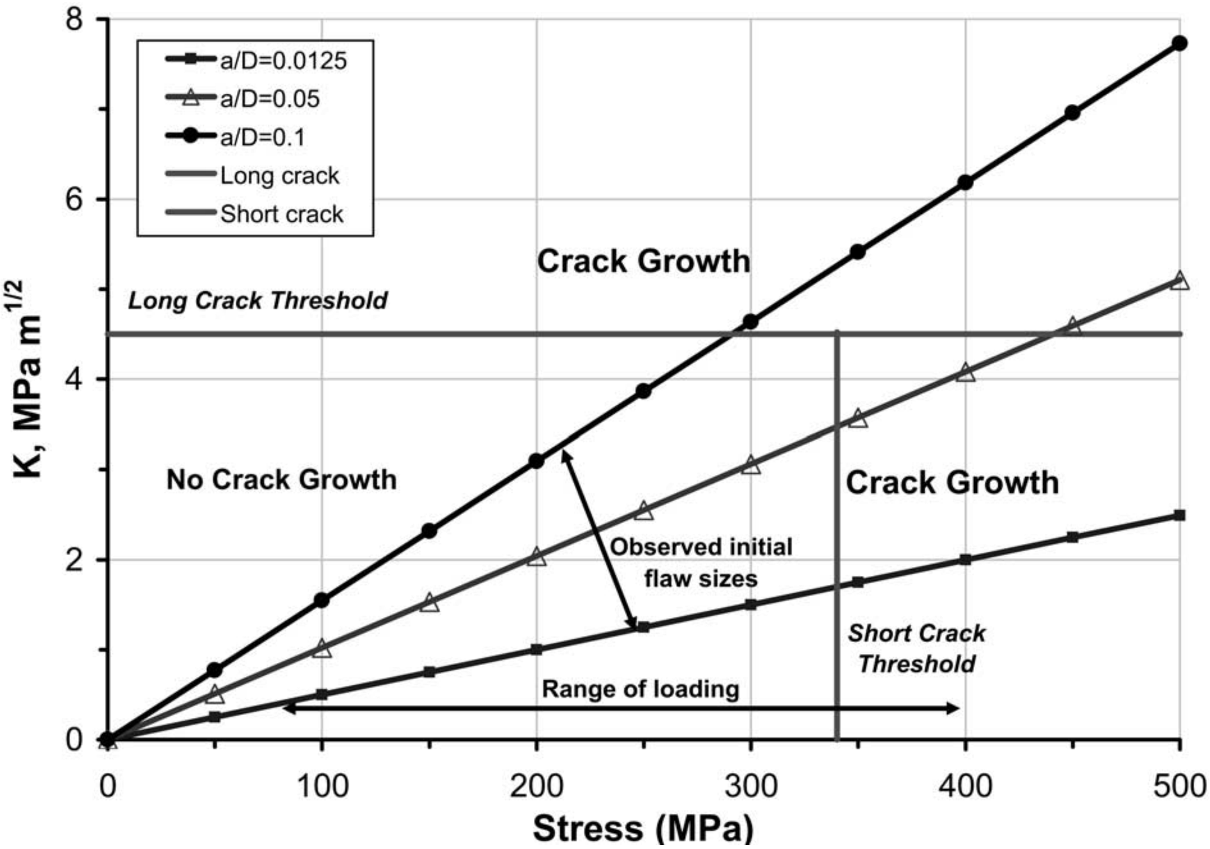

FIG. 9—*Regions of safe and unsafe operation for the 29 mm BSCC valve.*

Fatigue Crack Growth Behavior

A detailed understanding of the fatigue response of the outlet strut may be developed by using the fatigue crack propagation methodology specified in Eqs 2 and 3. This methodology requires the applied stress range, K solution, initial flaw size, and material properties. The previous sections specify the inputs for stress, K solution, and initial flaw size. Experiments conducted by Ritchie and Lubock [6] indicate that for the material of construction, Haynes 25 alloy, $\Delta K_{th}=4.5$, $C=7.1e^{-20}$, and $m=12.2$ in units of MPa$\sqrt{\mathrm{m}}$ and m/cycle. To address the issue of short cracks, experimental work conducted by Green et al. [7] indicates $\Delta\sigma_e=340$ MPa. Thus, the failure envelope for the specified loading, materials, and geometry appears in Fig. 9. Alternating stresses in excess of 340 MPa should produce crack extension for any initial flaw size. Stresses between 275 and 340 MPa produce crack extension for initial flaw sizes of $a_i/D>0.075$. For stresses less than 275 MPa, crack extension should not occur over the range of measured initial flaw size.

Valve Life

Available records indicate 657 outlet strut failures as of October 31, 2005 [8]. Of these total failures, 123 valves where designated as having a diameter of 29 mm. A statistical analysis of 29 mm valve failures indicates three outlet strut fractures within the first year after implantation. These failures may be attributed to typical operating stresses generating crack extension from flaws of typically observed sizes. Records indicate the shortest valve operating time prior to failure was approximately three months. This time frame appears consistent with a near threshold crack growing due to typical operating stresses assuming long crack fracture mechanics [9]. Outlet strut fractures between three and twelve months are consistent with crack extension from short cracks subjected to typical operating stresses in excess of 275 MPa.

In the time frame of two to ten years after implantation, approximately ten 29 mm valves failed per operation year. Failure data indicate one failure a year over the operating lives of 20 to 23 years. The most recent failure occurred in 2004 after 23 operating years. Due to the large cycles per year experienced by these valves ($\sim$38 million), typical cycles must generate stresses less than 275 MPa. Thus, these cycles do not damage the outlet strut through fatigue. The damaging cycles in these failures must be associated with atypical, short term load excursions and not continued loading associated with typical physiological conditions. Damage accumulated during these extreme cycles extends small cracks until they obtain a flaw size that grows under typical operating conditions. At this point, the outlet strut fractures within one year of typical operation.

Design changes implemented in 1984 reduce the stress on the outlet strut below 250 MPa under all loading conditions considered in this work. Thus, initial flaw sizes less than 100 μm should not extend and mechanical damage should not accumulate during the lifetime of the valve. These results are consistent with epidemiological work that indicates no failures for valves manufactured after 1984.

Summary and Conclusions

The Bjork-Shiley convexo-concave (BSCC) heart valve experienced fracture of the outlet strut due to fatigue cracking from initial weld defects. These initial flaws grew under fatigue loading generated from contact forces necessary to stop the occluder disk during closure. Initial designs may not have accounted for the contact between the outlet strut and disk during closure. However, computational analyses indicate the disk rebounds from initial contact with the inlet strut to generate significant contact forces with the outlet strut during normal operations. For the most severe cases considered, stress intensity factors at the base of the outlet strut exceed the threshold ΔK (i.e., largest nominal load and largest observed crack size). These conditions may account for the outlet strut fractures observed within the first several years of operation. For the pre-1984 design, a range of different flaw size and loading combinations indicates failure may occur after extremely large operating times, i.e., greater than 20 years. These conditions indicate fatigue damage accumulates only during occasional cycles with loads significantly larger than nominal conditions. This damage accumulates over many years until the crack grows to a size where ΔK exceeds threshold for nominal loading. At this point, fracture of one outlet strut leg occurs within a year of operation.

Design changes implemented in 1984 appear to reduce ΔK values at the base of the outlet strut below threshold values for all loading conditions and initial flaw sizes considered in this work. This design change generates contact at the base of the outlet strut instead of the tip. Thus, the bending moment that produces high stress in the failure region decreases significantly and the corresponding ΔK decreases.

The outlet strut of the BSCC valve is constructed from Haynes 25. This material has a $\Delta K_{th} = 4.5\ \mathrm{MPa}\sqrt{\mathrm{m}}$. The threshold stress intensity factor for Nitinol is approximately $2\ \mathrm{MPa}\sqrt{\mathrm{m}}$, or less than half that of Haynes 25. Thus, greater diligence must be exercised in designing and manufacturing heart valve components constructed with Nitinol than valves constructed from Haynes 25.

Previous experience with the BSCC valve suggests that engineers must seek to fully understand the operation of these complex biomechanical devices. These efforts must be expended due to the repercussions associated with heart valve designs. The necessary service life of these valves combined with the risk of explantation generates long lasting consequences for poor designs. Thus, advanced engineering tools and methods must be employed to address all possible loading scenarios, and to determine the likelihood of significant alternating stresses for parts constructed from Nitinol, or any other engineering material. The high cycle count of even infrequent loadings requires engineers to design for fatigue due to loadings several standard deviations from the mean loading. These fatigue assessments should be conducted using long crack, short crack, and stress-life methodologies. Finally, engineers should consider methods of inspecting future designs using minimally invasive procedures. Parts that have been identified as experiencing fatigue loadings should include some characteristic consistent with the health of the part that can be identified by an external probe.

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