

## RADIOGRAPHIC DETECTION OF STRUT SEPARATIONS IN BJÖRK–SHILEY CONVEXO-CONCAVE MITRAL VALVES

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**Abstract** *Background.* The outlet struts of Björk–Shiley convexo-concave heart valves can occasionally fracture. By December 31, 1994, 564 complete strut fractures had been reported to the manufacturer, approximately two thirds of which were fatal. There are no reliable diagnostic methods to detect valves that may be at risk for strut fracture. The outlet strut has two legs, and one leg often appears to break before the other, potentially permitting detection of the single-leg separation while the valve is still functionally intact.

*Methods.* We used high-resolution cineradiography and defined valve profiles to evaluate 315 patients selected on the basis of their having mitral convexo-concave valves with an estimated fracture rate of 0.46 percent or higher per year. Two examinations were scheduled six months apart, with early reimaging performed when initial ratings were indeterminate.

*Results.* Three patients had unsatisfactory studies,

the most recent examinations in 277 patients were rated as apparently normal, 23 had findings considered minimally suspicious, and 1 had findings termed suspicious. The number of false negative results in this study group is unknown. Eleven cineradiograms were rated as showing probable or definite single-leg separations. All five "definite" ratings and five of the six "probable" ratings were confirmed by removal of the valves. One valve with a "probable" rating was intact. Two complete outlet-strut fractures occurred three and seven months after apparently normal radiographic examinations. Unsuspected new positive findings were not found at six months among 288 patients who completed the examination cycle.

*Conclusions.* Cineradiographic imaging can detect some single-leg separations in mitral convexo-concave valves and may help the estimated 47,000 patients with these valves worldwide and their physicians decide about elective valve removal. (*N Engl J Med* 1995;333:414-9.)

**S**URGICAL replacement of malfunctioning aortic and mitral valves has dramatically improved the prognosis for patients with valvular heart disease,<sup>1</sup> despite the complications of infection,<sup>2</sup> thrombosis,<sup>3</sup> paravalvular incompetence,<sup>4</sup> and thromboembolism.<sup>5</sup> The search for a hemodynamically superior device posing a diminished risk of thromboembolism led to the invention of the Björk–Shiley tilting-disk valve.<sup>6,7</sup> Refinements in its design resulted in the convexo-concave model.<sup>8</sup> Between 1979 and 1986, approximately 86,000 Björk–Shiley convexo-concave valves were implanted worldwide.<sup>9</sup> Shortly after this model was introduced, the first sudden failures of the device were reported to the manufacturer.<sup>10</sup> An extensive retrospective review of failed valves that were removed and returned has been undertaken by the manufacturer. It has been determined that valves made between 1978 and 1984 are at risk of fracture of the outlet strut, with disk embolization and sudden massive valvular incompetence. The risk of strut fracture is increased for valves 29 mm in diameter or larger welded between January 1981 and June 1982. In April 1984, there was a change in quality-control procedures, and no outlet-strut fractures have been reported in valves welded after March 31, 1984. Because of the reported failures and adverse publicity, Shiley Incorporated voluntarily stopped manufacturing this device in 1986.

Overall, the convexo-concave valve has functioned very well, being associated with a 12-year actuarial sur-

vival rate of 52 percent and longer reoperation-free survival than for porcine bioprostheses.<sup>11</sup> Since patients with structurally intact valves do well and elective removal is associated with an operative mortality rate of 3 to 5 percent,<sup>12,13</sup> prophylactic removal of all these valves has not been recommended.<sup>14,15</sup> Although complete strut fracture is uncommon (564 cases had been reported to Shiley as of December 31, 1994), the outcome is usually catastrophic, with a 67 percent mortality rate. We report a new cineradiographic imaging technique that has detected separations of a single leg of the outlet-retaining strut before outlet-strut fracture, allowing the prophylactic elective removal of valves in 11 patients.

### METHODS

#### Patient Selection

We studied patients with mitral convexo-concave valves 29 mm or more in diameter that had an estimated risk of strut fracture of at least 0.46 percent per year.<sup>13</sup> A total of 315 patients from North America were recruited from a pool of 2200 patients with valves with these characteristics. Patients were identified and contacted through a registry maintained by Medic Alert Foundation International. The study was approved by the William Beaumont Hospital Human Investigation Committee, and all the study patients gave written informed consent.

#### Valve Profiles

The convexo-concave valve is shown in Figure 1A. Radiographs made with the valve inclined 30 degrees from the horizontal surface of the flange (Fig. 1B) show the larger inlet strut, which is integral with the flange, the smaller two-leg outlet strut that is welded to the flange, and the radiopaque marker in the pyrolytic carbon disk.<sup>16</sup> Single-leg separations usually occur at the base of the outlet-strut legs near the point of interception with the flange. When the *en face* view is symmetrically oriented, the two "elbows" of the outlet strut appear to be superimposed over the inlet strut, trisecting its straight portion into segments of roughly equal length (Fig. 1B). This profile is reminiscent of the tunnel-view radiograph used to assess the knee joint and has become known as the "tunnel view" of the convexo-concave

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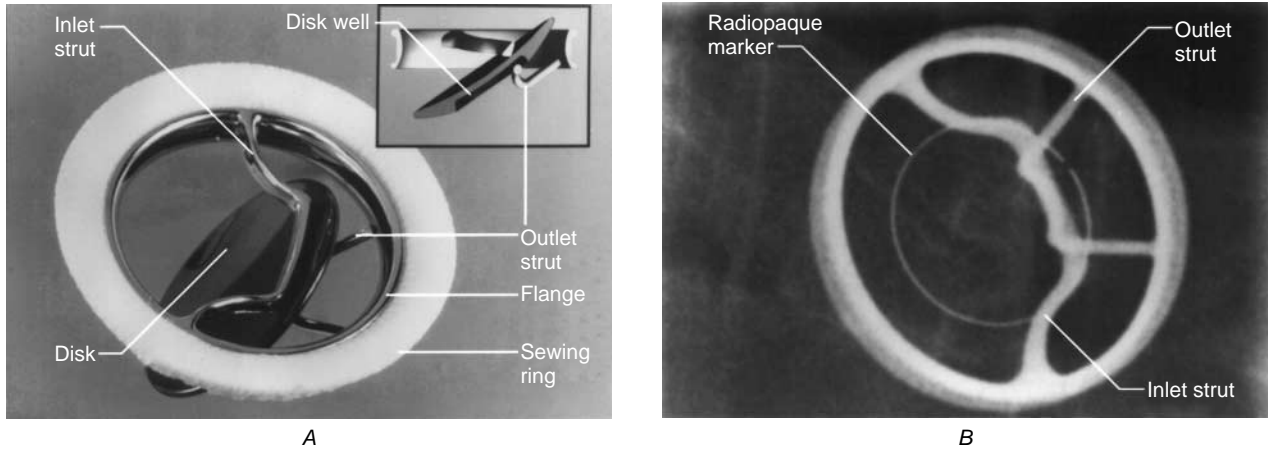


Figure 1. Convexo-Concave Valve.

Panel A shows the valve components, and Panel B the radiographic appearance of the tunnel-view profile.

valve. It offers the best opportunity to view the bases of both outlet-strut legs. Figure 2 shows a typical single-leg separation as seen by scanning electron microscopy. Although the break is complete, the broken surfaces are usually left in contact with each other. In most instances, residual stress in the strut results in displacement at the break site, causing an offset as seen in the figure. This offset appears to be at least as important in radiographic detection of separation as the partial gap in the metal at the break site. The offset may not necessarily be clearly visible by the tunnel view, because the displacement can be in line with the path of the x-ray beam. Therefore, it is

necessary to obtain a second view of each leg base that is as nearly at a right angle to the tunnel view as possible (Fig. 3).

**Radiographic-Image Validation**

Valves removed for reasons other than structural failure or radiographic detection of separation and returned to Shiley were analyzed. As of August 15, 1994, separation of one leg of the outlet strut from the flange was noted in 33 of 271 valves known to Shiley not to have failed, exclusive of those accruing from radiographic detection of separation. In addition, 149 of 155 valves with complete strut fracture

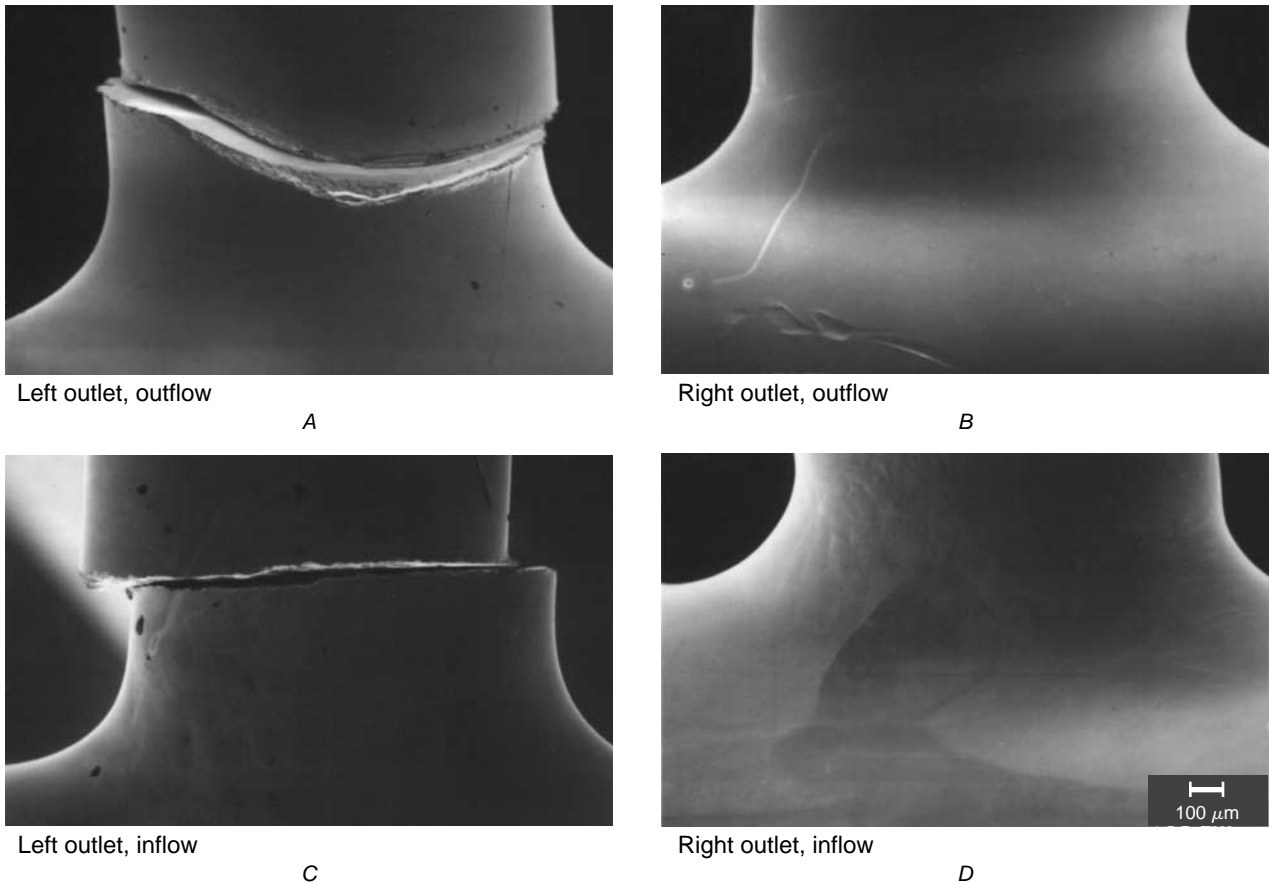
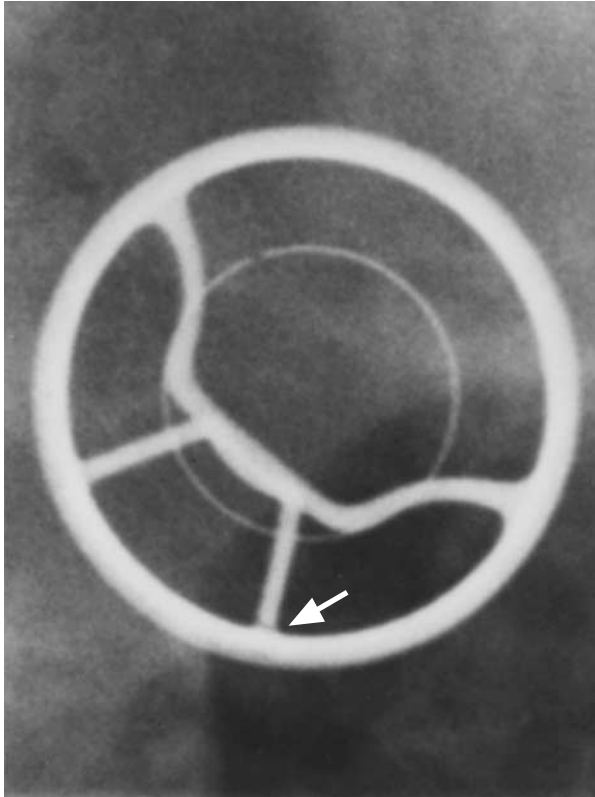
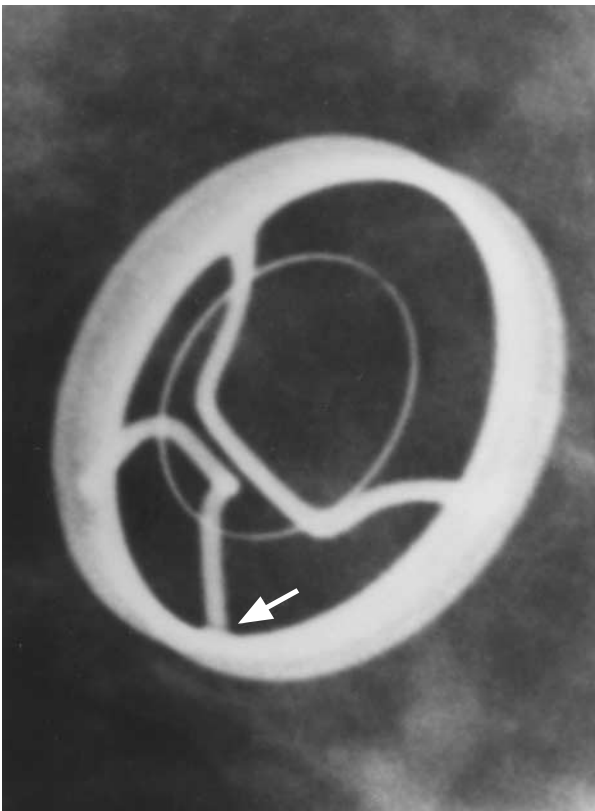


Figure 2. Single-Leg Separation in Left-Outlet Strut.

Note the continuing contact at the break site during outflow (Panel A) and inflow (Panel C) and the displacement (offset) from the base. Panels B and D show the intact right-outlet strut. (Scanning electron photomicrographs, ×60.)



A



B

Figure 3. Definite Single-Leg Separation (Arrows). Cineradiographs show a tunnel view (Panel A) and an external oblique view (Panel B).

each had a fresh fracture of one leg with wear-related burnishing of the other leg. These findings suggest that complete strut fracture was preceded by single-leg separation in the majority of valve failures. Thus, it was postulated that cineradiographic imaging might detect separations in patients with otherwise apparently intact valves.

Before clinical testing, cineradiography was performed on 25 convex-concave valves, 14 of which had intentionally manufactured single-leg separations. Imaging was performed with a Hicor Coroskop (Siemens, Erlangen, Germany) cineangiographic system. Valves were placed in a pulsatile left ventricular assist device and imaged through 22 cm of water to simulate tissue absorption. Six experienced angiographers reviewed the cineradiographs blindly, and a receiver-operator-characteristic curve was constructed. The cineradiographs were graded on the basis of visual inspection on a scale of 0 to 5. Grade 0 indicated suboptimal imaging due to poor penetration or inadequate positioning of the valve; grade 1, an apparently normal valve; grade 2, minimal suspicion of a separation on the basis of a radiolucency in one outlet-strut leg detected in one or two cine frames in one view only; grade 3, suspicion of a separation on the basis of radiolucency in several cine frames in one view only, or one or two frames in two views; grade 4, a probable separation, with radiolucency consistently appearing in multiple frames in one view or several frames in two views; and grade 5, a definite separation, with radiolucency in several frames in two or more views, or a linear discontinuity of the strut with the strut in an oblique view. The six reviewers were asked to grade the cineradiographs with the assumption that there was a 50-to-1 ratio of intact to separated valves present. Furthermore, the reviewers assigned grades with the understanding that grades 4 and 5 would elicit the recommendation that a normally functioning valve be removed. The reviewers gave grades of 2 or greater to one intact valve, and they missed one separated valve (specificity, 0.95; sensitivity, 0.93). Grades of 3 or greater had a specificity of 1.0, with sensitivities of 0.90 at grade 3, 0.85 at grade 4, and 0.61 at grade 5.

In the clinical study, one of three of us graded each magnified digital image and cineradiograph. An expert panel of one cardiac radiologist and five cardiologists independently performed a blinded review of the cineradiographs. If the on-site review was normal and the mean score of the panel was less than 1.5, the patient was asked to return for an examination in six months. Patients whose images had indeterminate grades (2 or 3) or panel scores of 1.5 or higher each had one or more additional, earlier examinations, typically at one to three months, with the score for the last of those examinations used as the definitive initial grade.

#### Radiographic-Imaging Technique

Before patient imaging was begun, line-pair resolution of at least 3.7 line pairs per millimeter through a DIN Normi phantom (PTW, Freiburg, Germany) was required. Radiographic images were typically acquired with pulse widths of 6.4 msec at 15 or 30 frames per second for 3 to 5 seconds. The automatic brightness control allowed the current in the x-ray tube to vary between 10 and 100 mA, with the x-ray-tube potential usually kept above 80 kV. An x-ray-tube focal spot with a nominal size of 0.8 mm was used. Fluoroscopic imaging of the mitral valve yielded an initial tunnel view. Orthogonal views were then obtained with a gantry-positioning program developed by one of us. Radiation exposure was measured with an area-exposure product meter (Diamentor, model M2, PTW).<sup>17</sup>

#### Statistical Analysis

A two-tailed Fisher's exact test was used to compare binomial proportions. The Kruskal-Wallis test,<sup>18</sup> a nonparametric analogue of analysis of variance, was used to examine differences in rank location for multiple groups, and the kappa statistic to assess correspondence in ranking. The method advocated by Fleiss<sup>19</sup> was used to determine confidence intervals for sensitivity, specificity, and predictive accuracy. A nominal alpha level of 0.05 was employed for all hypothesis testing.

#### RESULTS

Clinical testing began August 21, 1992, and 315 patients had initial examinations by February 15, 1994. Two hundred eighty-eight patients completed their final, six-month examinations. The patient cohort com-

prised 139 men and 176 women, ranging in age from 21 to 80 years, with a mean ( $\pm$ SD) age of  $60.9\pm 11.4$  years. There were 139 patients 60 years of age or younger. The mean weight was  $72\pm 15$  kg, and the mean height was  $170\pm 15$  cm. The mean duration of valve implantation was  $11.6\pm 0.78$  years. Valve sizes and the estimated risks of fracture are shown in Table 1.

### Cineradiographic Assessment

Technically acceptable images were initially obtained for 312 patients (99 percent). Initial examinations were repeated in 62 patients (67 examinations) because of indeterminate grades or expert-panel grade averages greater than 1.5. The definitive radiographic ratings for the initial examination were grade 5 in 5 patients, grade 4 in 4 patients, grade 3 in 4 patients, grade 2 in 13 patients, grade 1 in 287 patients, and grade 0 in 2 patients. Twenty-seven patients did not have a six-month reexamination because they died (6) or were unwilling to return (7) or because their valves were removed (13) or we were technically unable to image the valve (1).

The six-month images were rated as grade 4 in 2 patients, grade 2 in 21 patients, grade 1 in 264 patients, and grade 0 in 1 patient. Importantly, no new definite separations were noted on six-month reexamination, and only one patient had a variation in grading of more than one grade (Table 2). The only meaningful increases in grade at six months involved two patients who progressed from grade 3 on the initial examination to grade 4. When six-month scores and initial-examination scores (for those who did not complete the six-month study) were considered, the totals were grade 5 in 5 patients, grade 4 in 6 patients, grade 3 in 1 patient, grade 2 in 23 patients, grade 1 in 277 patients, and grade 0 in 3 patients. Thus, the prevalence of separations was 3.5 percent.

To determine whether outside observers could also detect single-leg separations, the expert panel conducted blinded reviews of 571 of the 670 examinations. The panel was less adept at detecting abnormal valves than the initial graders, who had the benefit of clinical information and immediate review of magnified high-resolution digital images as well as the cine images. Mean panel scores were less than grade 4 for 9 of the 10 confirmed single-leg separations. The kappa statistics were 0.20 for agreement between the panel's ratings and the on-site ratings and 0.19 for agreement between members of the panel.

### Clinical Course

On the basis of actuarial data,<sup>13</sup> a cumulative probability of fracture of 0.99 percent per year (range, 0.22 to 2.52 percent) was expected. Given the 1.5-year follow-up period, five strut fractures should have occurred. There were only two confirmed strut fractures. Both were fatal. The first occurred in a 68-year-old woman three months after an apparently normal cineradiographic examination. A chest film obtained with portable equipment confirmed strut fracture with disk embolization (Fig. 4). Permission for an autopsy was denied.

Table 1. Estimated Fracture Rate According to Structural Characteristics of the Valves.\*

ESTIMATED FRACTURE RATE	SIZE OF VALVE	OPENING ANGLE	WELDING DATES†	NO. OF PATIENTS
%/yr	mm	degrees		
2.52	33	60	7/81–6/82	20
2.25	31	70	NC	1
1.46	33	60	1/81–6/81	14
1.36	33	70	NC	1
1.33	29	70	NC	2
1.24	31	60	7/81–6/82	78
1.08	33	60	Before 1/80; 8/82–3/84	4
0.82	31	60	1/81–6/81	51
0.74	29	60	7/81–6/82	107
0.46	29	60	1/81–6/81	31
0.46	31	60	Before 1/80; 8/82–3/84	5
0.22‡	29	60	Before 1/80; 8/82–3/84	1

\*The estimated fracture rate was based on valve size, opening angle, and welding dates.<sup>13</sup>

†Welding dates are the dates on which the valves were welded in the factory. NC denotes not classified.

‡The patient whose valve had this fracture rate was screened because of an incorrect initial report of the welding date.

The second fracture occurred in a 61-year-old man with two serial, apparently normal cineradiographic examinations. The strut fractured seven months after his last examination. Microscopical study of the valve revealed one fresh and one wear-burnished break.

Twelve other patients died during follow-up. Five of these died after protracted illnesses presumably unrelated to strut fracture. Three patients whose cineradiographs were rated as normal had intact valves confirmed at autopsy. Three postoperative deaths were reported, one in a 66-year-old man who underwent prophylactic valve replacement because of a grade 4 rating on cineradiographic examination. Finally, one patient with New York Hospital Association class III disease died suddenly, and there was no autopsy or postmortem chest radiography.

### Validation of Cineradiographic Findings

Cineradiographic findings were confirmed by physical inspection of valves removed at surgery or autopsy in 21 patients (Table 3). Validation was possible in all patients with examinations rated grade 4 or 5, because they had elective surgical removal of the valves. Validation of examinations with lower ratings occurred in

Table 2. Findings of Six-Month Examinations According to Initial or Early-Reexamination Grades.

INITIAL OR EARLY-REEXAMINATION GRADE	SIX-MONTH GRADE					
	0	1	2	3	4	5
	no. of patients					
1	1	255	18	—	—	—
2	—	8	3	—	—	—
3	—	1	—	—	2	—

only the 10 patients with valves that became available for physical inspection. All were intact. Since the number of true negative and false negative examinations could not be determined, values had to be imputed to estimate the confidence intervals of sensitivity, specificity, and positive predictive accuracy. For this analysis, it was assumed that the two patients with known strut fractures had false negative examinations. Using the method advocated by Fleiss,<sup>19</sup> we determined that the apparent sensitivity of radiographic detection of single-leg separation was 0.833 (95 percent confidence interval, 0.509 to 0.971), the specificity was 0.997 (0.979 to 1.00), the positive predictive accuracy was 0.909, and the negative predictive accuracy was 0.99 (0.978 to 0.997).

### Radiation Exposure

With the exclusion of data on the first two patients, whose examinations were performed before the image intensifier locator program was fully developed, the area-exposure product was  $1521 \pm 582$  cGy per square centimeter for the 90 double-valve examinations and  $818 \pm 527$  cGy per square centimeter for the 580 single-valve examinations. Exposure for all patients was within the lower range reported for angiocardigraphic imaging in circumstances in which the operators were unaware that radiation was being measured.<sup>20</sup>

### DISCUSSION

Until now, only epidemiologic data have been available to stratify the risk of outlet-strut fracture in patients with functioning convexo-concave valves. The probability of strut fracture was increased when the occluder disk had an opening angle of 70 degrees, the valve was larger, the valve was implanted in the mitral position, and the patient was less than 50 years old at

Table 3. Radiographs with Verified Findings as of August 15, 1994.\*

NO.	VALVE GRADE	VALVE STATUS	GAP	OFFSET
			$\mu\text{m}$	
1	1	Intact	—	—
2	1	Intact	—	—
3	4	Intact	—	—
4†	1	Intact	—	—
5	3	Intact	—	—
6†	1	Intact	—	—
7	1	Intact	—	—
8	2	Intact	—	—
9	2	Intact	—	—
10	1	Intact	—	—
11†	1	Intact	—	—
12	5	Separated	≈0	132
13	5	Separated	≈0	141
14	5	Separated	≈0	210
15	4	Separated	≈0	90
16	5	Separated	≈0	37
17	4	Separated	≈0	159
18	5	Separated	4	165
19	4	Separated	≈0	90
20	4	Separated	NA	NA
21	4	Separated	≈0	133

\*NA denotes not available.

†Data were obtained at autopsy.

the time of implantation.<sup>13-15,21,22</sup> Although prophylactic removal has not been recommended for all convexo-concave valves,<sup>13,23,24</sup> it has been recommended for patients in higher risk categories.<sup>21</sup> In accordance with this recommendation, de Mol et al.<sup>25</sup> removed 23 high-risk valves, 69 percent of which turned out to be structurally intact.

Analysis of the valves returned to Shiley, independent metallurgical analysis by Sacks et al.,<sup>26</sup> and physical examination of prophylactically removed, functionally intact valves in the study by de Mol et al.<sup>25</sup> suggest that strut fracture is preceded by single-leg separation. Ibarra et al.<sup>27</sup> first suggested that 45-degree and 70-degree left anterior oblique chest radiographs might detect separations. Advances in imaging techniques, including the use of cineradiography, have now made it possible to detect some separations, as demonstrated in this report.

Although the risk of strut fracture is not entirely eliminated by cineradiographic screening, it can be reduced. Actuarial data suggest that five strut fractures should have occurred in this cohort. This type of analysis, however, may underestimate risk because of passive underreporting.<sup>21,22</sup> Had all documented separations progressed to strut fracture, there would have been 12 frac-

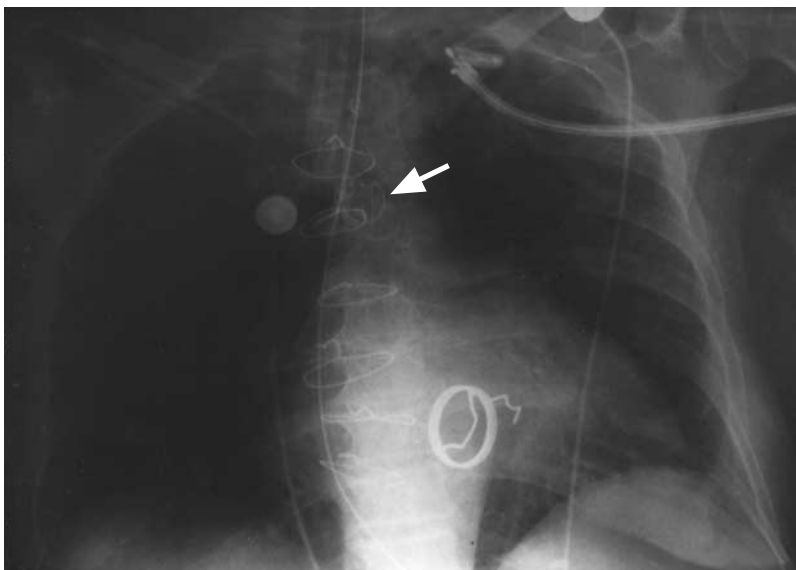


Figure 4. Chest Radiograph Obtained with Portable Equipment in One of the Patients with Outlet-Strut Fractures.

The strut is floating near the valve flange but has completely fractured. The disk (arrow) has embolized to the aortic arch. In appropriate circumstances, this single view is sufficiently diagnostic to warrant immediate cardiac surgery.

tures. There were only two. The apparent reduction in the risk of strut fracture occurred at the expense of valve removal in 11 patients (3 percent) and 1 late postoperative death (0.3 percent). It is encouraging that unnecessary surgery was performed in only one patient.

Even with careful cineradiographic screening, there were two fatal strut fractures, demonstrating that screening has not totally eliminated the problem. Visual image assessment has wide interobserver variability. For valve separations to be accurately identified, extensive training in the interpretation of images is required. The necessary expertise will be most readily available at regional referral centers. Algorithms for quantitative computer assessment must be developed to decrease variability.

Cineradiographic imaging of mitral convexo-concave valves may have clinical value. With proper training, imaging of mitral-valve struts can be accomplished in 99 percent of patients. The technique appears to be reproducible, since 258 of 288 grades (90 percent) were the same on serial examinations six months apart. There is great certainty about grade 5 assessments when radiolucency or offset or both are present consistently in two or more views. All valves with this grade were found to be abnormal when removed. Conversely, strut fracture did not occur during the two-year study period in 275 of 277 patients with grade 1 examinations. Grade 4 examinations are cause for concern, since five of six grade 4 examinations with corroboration on removal were abnormal. There is less certainty about grade 2 and grade 3 examinations, since too few patients have had valve removal to verify the radiographic findings. This screening method may help the estimated 47,000 patients with these valves worldwide and their doctors decide about elective valve removal.

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