

## Strut Fracture of Björk-Shiley Convexo-concave Valve in Japan —Risk of Small Valve Size—

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**Background:** The Björk-Shiley convexo-concave (BSCC) prosthetic valve was introduced in 1979. Between 1979 and 1986, approximately 86,000 BSCC valves were implanted. By December 31, 1994, 564 complete strut fractures had been reported to the manufacture. We experienced a case of an outlet strut fracture and investigated the risk of BSCC prosthetic valve fractures in Japan.

**Methods and Results:** To investigate the risk factor of a strut fracture in Japan, we investigated published cases of strut fractures. Between 1979 and 1986, 2021 BSCC valves were implanted in Japan. By January 31, 2000, 11 complete strut fractures of 60-degree BSCC valves including our case had occurred. The patients were eight males and three females. The average age at valve replacement was  $42.4 \pm 8.1$  years, and nine of eleven (81.8%) were patients < 50 years-old. The average age of the patients when the BSCC valve fractured was  $47.7 \pm 6.4$  years, and eight of eleven (72.7%) were patients  $\leq 50$  years old. All patients were implanted in the mitral position. The sizes of the BSCC valve were 27 mm (n=5) (45.5%), 29 mm (n=3) (27.2%), and 31 mm (n=3) (27.2%). Four patients died and seven patients survived.

**Conclusions:** Although only 11 BSCC valve struts fractured and statistical analysis could not be performed, our findings suggest that the high risk group for a strut fracture in Japan is young male patients with a mitral valve,  $\geq 27$  mm in size with BSCC models manufactured before March 1982. When following-up patients with BSCC models manufactured before March 1982, the possibility of a strut fracture in all BSCC valve sizes should be kept in mind. (*Ann Thorac Cardiovasc Surg* 2001; 7: 246–9)

**Key words:** Björk-Shiley convexo-concave prosthetic valve, strut fracture

### Introduction

The Björk-Shiley tilting-disc valve (Shiley, Inc, Irvine, CA) was first introduced for clinical use in 1969. Subsequently, a number of modifications were incorporated into the basic design, with the Björk-Shiley 60-degree

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convexo-concave (BSCC) tilting disc valve entering into clinical use in 1976.<sup>1)</sup> The BSCC valve was introduced in 1979 for aortic and mitral valve replacement.<sup>2)</sup> Between 1979 and 1986, approximately 86,000 BSCC valves were implanted worldwide.<sup>3)</sup> The first report of an outlet strut fracture was shortly after the BSCC valve's introduction.<sup>4)</sup> By June 30, 1997, 603 complete strut fractures had been reported to the manufacture,<sup>5)</sup> approximately two thirds of which were fatal.<sup>6)</sup> Mechanical failure of artificial heart valves can be a catastrophic event. Unfortunately, we experienced a patient who died due to an outlet strut fracture. This was the eleventh reported case of a strut fracture of a BSCC valve in Japan. The

**Table. Reported cases of strut fracture of the Björk-Shiley 60 convexo-concave valve in Japan**

Reference, year	Age (yr)	Sex	Implanted age (yr)	Size (mm)	Position	Parts of fracture	Interval between op. and fracture (month)	Result
Ninomiya, 1983	61	male	60	31	mitral	O	2	Dead
Satoh, 1984	54	male	52	29	mitral	O	14	Dead
Nakano, 1986	42	female	40	27	mitral	O	21	Alive
Kanazawa, 1987	42	male	40	27	mitral	O	21	Alive
Sugita, 1990	49	male	45	31	mitral	O	51	Alive
Katagiri, 1990	42	male	40	27	mitral	O	22	Alive
Katagiri, 1990	53	male	47	27	mitral	O	72	Alive
Tanaka, 1991	42	female	34	29	mitral	O	95	Alive
Saito, 1995	43	male	34	27	mitral	O	108	Dead
Ishikawa, 1995	47	male	38	31	mitral	O	108	Alive
Watarida (present case), 1998	50	female	36	29	mitral	O	168	Dead

O: outlet strut fracture.

problem of the outlet strut fracture of the BSCC tilting disc prosthesis has received much attention in the medical literature and has generated both concern and confusion among patients and physicians. We report the different risks of strut fractures of the BSCC prosthetic valve in Japan.

## Case

A 50-year-old woman who had undergone mitral valve replacement with a 29-mm, 60-degree BSCC valve in our hospital in March 1984 suddenly acquired severe dyspnea at 9:30 pm on July 18, 1998. She was hospitalized at 10:30 pm. She was unconscious upon admission. Her blood pressure could not be measured. She was intubated immediately and mechanically ventilated. Cardiologists performed emergency echocardiography, but they could not find the strut fracture of the mitral valve prosthesis. Chest roentgenography was taken at 0:30 am on July 19, 1998. After the chest X-ray examination, the cardiologists consulted us. The chest X-ray examination revealed severe pulmonary congestion and breakage of the valve with migration of the prosthetic disc and outlet strut. On auscultation of the heart, a click sound was not heard. Cardiac arrest developed and cardiopulmonary resuscitation was unsuccessful. She was taken immediately to the operating room where a cardiopulmonary bypass was established through the femoral approach. She was operated upon 5 hours after the onset of her complaints. The patient underwent emergent open heart surgery under a cardiopulmonary bypass with moderate

total body hypothermia. The aorta was cross-clamped and the right side of the left atrium was opened. Inspection of the left atrium revealed a normal structure, but the outlet strut and disc were not found in the left atrium and ventricle. The outlet strut was found in the right upper pulmonary vein and replaced with a 29 mm St. Jude Medical valve prosthesis. We decided that the disc, which had dislocated into the thoracic aorta, would be removed during a second operation. However, she could not be weaned from cardiopulmonary bypass and she died an hour after the operation.

## Source population

The source population for this study consisted of all 60-degree BSCC valves that were implanted in the mitral and aortic positions in patients in Japan.

## Results

Between 1979 and 1986, approximately 2021 valves were implanted in Japan, and 10 complete strut fractures of 60-degree BSCC valves had been reported by June 30, 1998.<sup>7-15</sup> The incidence of a strut fracture in Japan was 0.5% for all valve sizes. The 70-degree BSCC valves were not implanted in Japan at all. Our case was the eleventh in Japan (Table). The patients were eight males and three females. The average age at valve replacement was  $42.4 \pm 8.1$  years-old, and nine of eleven (81.8%) were patients < 50 years old. The average age at the BSCC valve fracture was  $47.7 \pm 6.4$  years old, and eight of eleven (72.7%) were patients  $\leq$  50 years old. The average time

interval between the mitral valve replacement and the BSCC valve fracture was  $62.0 \pm 52.6$  months. All patients were implanted in the mitral position. The sizes of the BSCC valves were 27 mm (n=5) (45.5%), 29 mm (n=3) (27.2%), and 31 mm (n=3) (27.2%). The parts that fractured were the outlet struts in all patients. Four patients died and seven patients survived.

## Discussion

Component failure of a mechanical valve is an extremely serious complication. The risk of a BSCC outlet strut fracture varies from 0.01% to 3.29% per year depending on valve size, opening angle, implant position, weld date, and welder group.<sup>5)</sup> Specific variables have been identified that can predict the relative risk of BSCC strut fractures: prosthetic size, implant position, weld date, opening angle of the occluder disc, and age of the patient at implantation.<sup>16,17)</sup> Valves manufactured in 1981 and the first half of 1982 have been found to cause greater risks than valves manufactured either before or after.<sup>18,19)</sup> No valve manufactured after March 1984 has been reported to have failed. The annual incidence of fractures reported varies from 0.02% for small valves (21 to 27 mm) to 0.62% for large mitral valves (29 to 33 mm).<sup>18)</sup> Large valve sizes (29 to 33 mm) have been consistently identified as a major risk.<sup>20,21)</sup> Currently, most reported strut fractures reported have been of large (29 mm) 60-degree BSCC mitral valves. Shiley Inc. recalled 29, 31, and 33 mm prostheses manufactured between February 1981 and March 1982. However, in Japan, such fractures have occurred mostly in 27-mm sizes. The relationship between body surface area (BSA) and the incidence of a strut fracture has been examined in a previous study. Based on the analysis of 96 cases and 634 controls, Walker<sup>22)</sup> determined that young and large patients were at a higher risk for strut fractures than older and smaller patients. Walker<sup>22)</sup> reported that a BSA < 1.5 m<sup>2</sup> had 1/16 the risk of a BSA > 2.0 m<sup>2</sup>. An increase in BSA is directly proportional to increased cardiac output in healthy people and engenders an increasing of flow and rate of pressure changes. Generally, the BSA of Japanese is smaller than other races. The incidence of a strut fracture in Japanese people (11/2,021, 0.54%) is almost the same as all other populations worldwide (564/86,000, 0.66%). Valves implanted in patients < 50 years old have been reported to fail more often than valves implanted at later ages.<sup>17)</sup> In Japan, nine of eleven (81.8%) failed valves were in young patients < 50 years old. Younger people tend to be more

active, their hearts are capable of higher maximum heart rates, greater flow rates, and more rapid pressure changes than those of older persons. Van der Graaf et al.<sup>17)</sup> reported no influence of sex on the risk of fracture. However, in Japan, eight of eleven (72.7%) were male patients, and such fractures have occurred mostly in male patients.

## Conclusions

By December 31, 1999, 564 complete strut fractures of Björk-Shiley convexo-concave valve had been reported to the manufacture, approximately two thirds of which were fatal. The problem of outlet strut fracture of the Björk-Shiley valve has received much attention in the medical literature. Generally, large valve size (29 to 33 mm) has been consistently identified as a major risk. Although only 11 BSCC valve struts fractured and statistical analysis could not be performed, our findings suggest that the high risk group for a strut fracture in Japan is young male patients with a mitral valve,  $\geq 27$  mm in size with BSCC models manufactured before March 1982. When following-up patients with BSCC models manufactured before March 1982, the possibility of a strut fracture in all BSCC valve sizes should be kept in mind.

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