Heart 1996;**76**:510–512

Welder identity, weld date, and the risk of outlet strut fracture in Björk-Shiley convexo-concave valves: the Dutch cohort study

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Abstract

***Objective*—To establish whether there is an association between subsequent fracture of the outlet strut and welder identity and the weld date of Björk-Shiley convexo-concave (BScc) valves.**

***Design*—Cohort study.**

***Patients*—All Dutch BScc valve recipients (n = 2266).**

***Mean outcome measures*—Documented outlet strut fracture during follow up.**

***Results*—Weld dates were known for 97·0% of all BScc valves (n = 2534) implanted in Dutch patients (n = 2266) and welder identity was known for 52·2%. During a mean follow up of 9·4 years, 46 fractures were documented. For 60° valves welded from 1981 to 1984 the fracture rate (0·22 per 100 person-years (95% CI 0·13 to 0·34)) was higher than that for valves welded before 1981 (0·04 (95% CI 0·01–0·10)). When all fracture related risk factors were taken into account, fracture rates per welder did not show any statistically significant differences.**

***Conclusions*—Welder identity does not contribute to the risk of strut fracture. Other factors in the production of BScc valves may explain the increased risk for valves welded from 1981 to 1984.**

(*Heart* 1996;76:510–512)

Keywords: heart valve prosthesis; welder identity; strut fracture; Björk-Shiley CC valve

Björk-Shiley convexo-concave (BScc) valves are apt to fracture at the outlet strut.[1–3] A population based follow up study conducted in the Netherlands indicated that valve opening angle (70°), valve diameter ($\geqslant$ 29 mm), valve implant position (mitral), and age at implant (< 50 years) were associated with strut fracture.[1] Metallurgical analysis of BScc valves has suggested that strut fracture is related to the welding process.[4] An examination of 24 explanted valves in the Netherlands revealed single leg fracture in seven (29%); in six of these the same welder was involved.[5] In January 1995 Shiley revised its risk estimates based on welder identity.[6]

In the first report on our follow up study no manufacturing data were available. In the present study, we reassessed the risk of fracture by use of additional data on welding obtained from Shiley.

Patients and methods

PATIENTS

The study-cohort consisted of all Dutch BScc valve recipients (n = 2266), identified during the first BScc follow up study[1]; faults in the data were corrected and the cohort was updated. The follow up was extended until 1 September 1995. Mean duration of follow up was 9·4 years. Forty eight patients (2·1%) had incomplete follow up. Forty six fractures were documented. Three fractures were reported after the closing date of the study.

WELDING INFORMATION

Welding information was obtained from weld charts, which are strip charts on which the current used during welding of BScc valves was recorded. These charts also recorded the identification number, employee number(s) of the welder(s), and weld date of the batch of valves being welded. Sometimes more than one welder worked on a batch of valves, making it impossible to determine which welder worked on which valve from that particular batch. Weld charts were first used in June 1980; their use stopped in June 1983 after the charts were found not to be useful.

For valves for which no weld charts were available, the welder identity could not be established. Weld dates for these valves were obtained from the fabrication orders.

STATISTICAL ANALYSIS

We studied the relation of welder identity and weld date to the occurrence of strut fracture. We stratified for opening angle and valve size, which are both risk factors for strut fracture.[1–3] Two different analytical approaches were used. Firstly, fracture rates were computed per single welder or combination of welders listed on the weld charts. Secondly, rates were calculated if a given welder worked solely or in collaboration with other welders on the production of a batch. 60° BScc valves welded from January 1981 through June 1982 have been reported to be at higher risk of fracture.[2,6] We therefore dichotomised weld date according to whether valves were welded before or after January 1981. Fracture rates were expressed as numbers of fractures per 100 person years of observation. Details are reported in the first report on the Dutch BScc follow up

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Accepted for publication 21 June 1996

Table 1 Fracture rates (per 100 person-years) per welder or combination of welders, stratified for opening angle for valves from 1981–1984

	60° Valves					*70° Valves*				
Welder employee-number	*Fractures*	*Valves*	*Person-years*	*Rate (per 100 person-years)*	*95% CI*	*Fractures*	*Valves*	*Person-years*	*Rate (per 100 person-years)*	*95% CI*
No weld chart	0	86	703	0	(0 to 0·52)	0	0			
Welder I	0	96	834	0	(0 to 0·44)	0	0			
Welder II	4	169	1625	0·25	(0·07 to 0·63)	7	88	569	1·23	(0·49 to 2·53)
Welder III	3	133	1160	0·26	(0·05 to 0·76)	5	51	432	1·16	(0·38 to 2·70)
Welder IV	0	15	145	0	(0 to 2·54)	2	15	106	1·89	(0·23 to 6·82)
Welders II and III	4	233	2035	0·20	(0·05 to 0·50)	2	77	588	0·34	(0·04 to 1·23)
Welders II and IV	1	34	302	0·33	(0·01 to 1·84)	3	17	145	2·07	(0·43 to 6·05)
Welders III and IV	4	74	673	0·59	(0·16 to 1·52)	1	14	114	0·88	(0·02 to 4·89)
Welders II and others	0	3	22	0	(0 to 16·77)	0	0			
Welders III and others	2	51	486	0·41	(0·05 to 1·49)	0	0			
Welders IV and others	0	11	111	0	(0 to 3·32)	0	3	19	0	(0 to 19·42)
Other welders	1	50	455	0·22	(0·01 to 1·22)	1	4	41	2·44	(0·06 to 13·59)
Three or more welders	0	15	157	0	(0 to 2·35)	1	3	18	5·56	(0·14 to 30·95)

study.[1] 95% Confidence intervals were based on the Poisson distribution.[7]

Results

Weld charts were available for 1052 (46·6%) 60° valves (n = 2257) and 272 (98·2%) 70° valves (n = 277). A single welder was involved in welding 723 valves (54·6%), two welders in 582 (44·0%), three welders in 13 (1·0%), and four welders in six (0·5%). Ten employee numbers were identified. Welders II and III were involved in welding 1117 valves (84·4%). Welder IV was listed on the weld charts of 197 valves (14·9%), most of the time in combination with another employee. Welder I was the single welder of 96 60° valves.

Only five fractures were documented among 1216 60° valves welded before 1981, compared with 19 fractures among 970 60° valves welded from 1981 onwards (fracture rates 0·04 (95% CI 0·01 to 0·10) and 0·22 (95% CI 0·13 to 0·34) per 100 person years, respectively). One 70° valve was welded before 1981. Twenty two fractures were reported among 272 70° valves welded from 1981 to 1984 (fracture rate 1·08 (95% CI 0·68 to 1·64) per 100 person years). The weld date was unknown for 75 valves (3·0%); no fractures were documented.

Further analyses were restricted to valves welded from 1981 to 1984. Table 1 shows the fracture rates per single welder or combination of welders listed on the weld charts. Among the 60° and 70° valves no single welder or combination of welders can be identified at higher risk of fracture. Although fracture rates differ, 95% confidence intervals show considerable overlap.

Table 2 presents fracture rates per employee number listed, irrespective whether a single employee number or multiple employee numbers were listed on the weld chart. For both 60° and 70° valves, and for both small (< 29 mm) and large (⩾ 29 mm) valves, fracture rates were higher if welder IV was listed on the weld chart. Again the confidence intervals were wide and no statistical differences between the welders were observed.

Discussion

In this study, no welder could be identified as risk factor for strut fracture. Fracture rates for valves welded from 1981 to 1984 were considerably higher than for valves welded before 1981.

Several of our methods deserve comment. Firstly, we could not establish welder identity for 1210 (47·8%) valves. However, among these valves only five fractures occurred; most of these valves (86·7%) were welded before 1981. Secondly, most batches were welded by two or more welders. We used two different approaches to calculate the fracture rates per

Table 2 Fracture rates (per 100 person-years) by welder involved, stratified for opening angle and valve size for valves welded 1981–1984

	60° Valves					*70° Valves*				
Welder involvement	*Fractures*	*Valves*	*Person-years*	*Rate (per 100 person-years)*	*95% CI*	*Fractures*	*Valves*	*Person-years*	*Rate (per 100 person-years)*	*95% CI*
No weld chart	0	86	703	0	(0 to 0·52)	0	0			
Welder I	0	96	834	0	(0 to 0·44)	0	0			
Welder II	9	454	4141	0·22	(0·10 to 0·41)	13	185	1320	0·98	(0·52 to 1·68)
Welder III	13	500	4437	0·29	(0·16 to 0·50)	9	145	1152	0·78	(0·36 to 1·48)
Welder IV	5	145	1344	0·37	(0·12 to 0·87)	7	52	402	1·74	(0·70 to 3·59)
Other welders	3	125	1193	0·25	(0·05 to 0·73)	1	7	60	1·67	(0·04 to 9·29)
All	19	970	8708	0·22	(0·13 to 0·34)	22	272	2031	1·08	(0·68 to 1·64)
	Size < 29 mm					*Size ⩾ 29 mm*				
No weld chart	0	38	305	0	(0 to 1·21)	0	48	398	0	(0 to 1·21)
Welder I	0	66	569	0	(0 to 0·65)	0	30	264	0	(0 to 1·39)
Welder II	4	403	3578	0·11	(0·03 to 0·29)	18	236	1882	0·96	(0·57 to 1·51)
Welder III	4	416	3672	0·11	(0·03 to 0·28)	18	229	1916	0·94	(0·56 to 1·48)
Welder IV	4	114	1093	0·37	(0·10 to 0·94)	8	83	652	1·23	(0·53 to 2·42)
Other welders	1	111	1057	0·09	(<0·01 to 0·53)	3	21	196	1·53	(0·32 to 4·47)
All	10	795	7060	0·14	(0·07 to 0·26)	31	447	3679	0·84	(0·57 to 1·20)

welder. The fracture rates yielded by both approaches were consistent with each other. Thirdly, our conclusions are hampered by the limited number of fractures, especially after stratification for the most important fracture related risk factors—opening angle and valve size. Finally, we only studied the relation between welder identity and weld date and the risk of fracture. The structure of a weld, however, depends on the raw material being used and the conditions under which a welder operates.[8] These and other factors in the welding process, which could not be identified by us, may contribute to the risk of fracture.

Shiley has suggested that the fracture problem is caused by over-rotation of the disc.[2 9] To solve this problem the manufacturing process was changed in early April 1984. No fractures have been reported among the few valves processed after that date. Our finding of a higher fracture rate for valves welded from 1981 to 1984 suggests that other factors in the manufacturing process also contribute to the risk of fracture. Recently manufacturing data, other than the weld charts, were made available to us. These documents are now being abstracted. By studying the manufacturing process we hope to determine factors that explain the difference in risk between valves welded before and after 1981.

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