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REVIEW ARTICLE

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Spontaneous leaflet fracture resulting in embolization from mechanical valve prostheses

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Abstract

Spontaneous leaflet fracture of mechanical heart valve prostheses is very rare. We describe a case of spontaneous leaflet embolization 31 years after aortic valve replacement with an Edwards-Duromedics prosthesis (Baxter Healthcare Corp., Edwards Division, Santa Ana, CA). We review the literature on this subject to increase awareness and recognition for this potentially life-threatening complication.

KEYWORDS

aortic valve replacement, Bjork Shiley, HFPF, cavitation, Edwards Duromedics, emergency surgery, leaflet escape, valve failure

1 | INTRODUCTION

Spontaneous leaflet fracture of mechanical heart valve prostheses is very rare. It is potentially life threatening and usually requires emergent surgery. There are a few valve prosthesis series well-known for having a higher risk of such mechanical structural valve failure, of which the Björk-Shiley convexoconcave (BSCC) mono-strut tilting disc prosthetic aortic heart valve (Pfizer, Rye Brook, NY) is the most documented.[1] Fractures of the BSCC valve's outlet struts and subsequent escape of the disc was estimated at 0.7% for all BSCC valves, but was up to 3.9% for the 70° opening angle model, often leading to massive regurgitation and death.[1]

Unfortunately, besides the BSCC valve, there are other mechanical heart valve prosthesis brands that have an increased risk of mechanical structural valve failure. We report a case of spontaneous leaflet fracture and escape 31 years after aortic valve replacement with an Edwards-Duromedics (ED) bileaflet mechanical prosthesis (Baxter Healthcare Corp., Edwards Division, Santa Ana, CA) in a 63-year-old male who developed life-threatening acute aortic regurgitation in whom emergent surgical treatment was necessary. To the best of our knowledge, this case presents the longest period between prosthesis implantation and leaflet escape. In addition, a review of the available literature on this subject is presented.

2 | PATIENT PROFILE

A 63-year-old male presented to a local hospital with cardiogenic shock. His previous medical history included endocarditis 31 years ago for which he underwent antibiotic treatment and aortic valve replacement with a 27-mm ED bileaflet mechanical prosthesis. A computed tomography (CT) of thorax and abdomen showed a saccular aneurysm of the ascending aorta measuring 83 × 47 mm (at the level of the previous aortotomy), and changes consistent with pulmonary edema. Coronary angiography (CAG) demonstrated no coronary abnormalities; however, it confirmed severe aortic

regurgitation and the absence of one leaflet of the mechanic aortic valve prosthesis (Figure 1A). Subsequent echocardiography confirmed a severe aortic regurgitation with preserved left ventricular function (Figure 1B). The patient was intubated and transferred to our center for emergent operative therapy.

During induction of anesthesia, the patient went into cardiac arrest and emergent surgery was performed and cardiopulmonary bypass (CPB) was initiated with cannulation of the left femoral artery and vein. A mediansternotomy was performed and the distal ascending aorta was crossclamped and the heart arrested with cold antegrade Custodiol cardioplegia (Dr. Franz Köhler Chemie GmbH, Bensheim, Germany). Inspection of the mechanical aortic valve prosthesis confirmed a missing prosthetic leaflet (Figure 2), without signs of pannus, paravalvular leakage, or thrombus formation. The valve prosthesis and diseased ascending aorta and aortic root were excised and replaced with a 2-mm Perimount Magna Ease biological aortic valve (Edwards Lifesciences®, Irvine, CA) and a vascular graft (Vascutek® Gelweave prosthesis Æ 32 mm, Terumo Cardiovascular Group, Ann Arbor, MI), with reimplantation of the coronary ostia. The patient was weaned from CPB and the arterial and venous canula were removed. Duration of aortic crossclamping was 93 min and total CPB time was 178 min. A 3D reconstruction of the previously made CT revealed the missing leaflet to be located in the left superficial femoral artery (Figures 3A and 3B). After decannulation, the left femoral artery was explored and two-thirds of the leaflet were found and removed (Figure 3C). Postoperative, an additional CT scan located the other one-third of the leaflet in the left popliteal artery. Removal was not indicated due to the non-occlusive position of the leaflet and normal ankle-brachial pressure index of 1,1. After discharge the patient received warfarin to prevent thrombotic complications of the remaining leaflet fragment. The patient made an uneventful recovery and remains asymptomatic one year following surgery.

3 | INCIDENCE AND OUTCOMES FOLLOWING MECHANICAL VALVE STRUT FRACTURES

As mentioned earlier, the BSCC valve is the most well-known example of mechanical structural heart valve failure, associated with more known serious adverse outcomes than any other implanted medical device.[1] Following its introduction in 1979, by 2003 >600 cases were known to have valve fractures, often leading to sudden cardiac deaths.[1] In addition to the BSCC valve, there are other valves that carry a higher risk for leaflet fracture and subsequent leaflet escape, of which the most prominent is the ED prosthesis (as illustrated by our case), followed by the TRI Technologies (TRI Technologies Prosthetic Heart Valve, Ltda, Belo Horizonte, Brazil) mechanical valve.[2–8]

The ED prosthesis (Baxter Healthcare Corp., Edwards Division) is a bileaflet mechanical heart valve first introduced and implanted in 1982. After approximately 20,000 valve prostheses were implanted the valve was withdrawn from the market in 1988 after at least 46 cases of leaflet escape were registered by the manufacturer.[9] The original valve was modified to correct structural problems and was reintroduced in 1990 as the Edwards TEKNA bileaflet valve. However, despite the revisions to the valve, cases of leaflet escape continued which led to the discontinuation of the TEKNA valve in 2000.

Twenty-one papers reporting 23 cases involving ED or Edwards TEKNA valves were published after discontinuation[9–28] (Table 1). In these cases, fractured leaflets occured more commonly from mechanical mitral valves compared to aortic valves (87% vs 13%). This is attributed to differences in dynamics and pressures over the mitral valve compared to protheses in the aortic position.[29] Duration between prosthesis implantation and leaflet escape varies among cases. The mean period from initial surgery until leaflet escape is 9.1 ± 7.4 years for mitral valves (n = 19) and 4.5 ± 3.1 years for aortic valves (n = 3, P = 0.908). Our current case, which is 31 years between initial surgery and leaflet escape, is the longest period between valve implantation and the event. Patients tend to present with acute severe dyspnea due to fulminant pulmonary edema and left-sided cardiac dysfunction. All patients underwent emergency surgery. Four patients did not survive acute cardiac decompensation or emergency surgery, and the mortality rate is estimated at 17% among published cases (Table 2).

Leaflet escape in mechanical heart valves of other manufactures is very rare and is limited to single case reports, including an Omnicarbon aortic valve prosthesis[30] (Medical Inc., Inver Grove

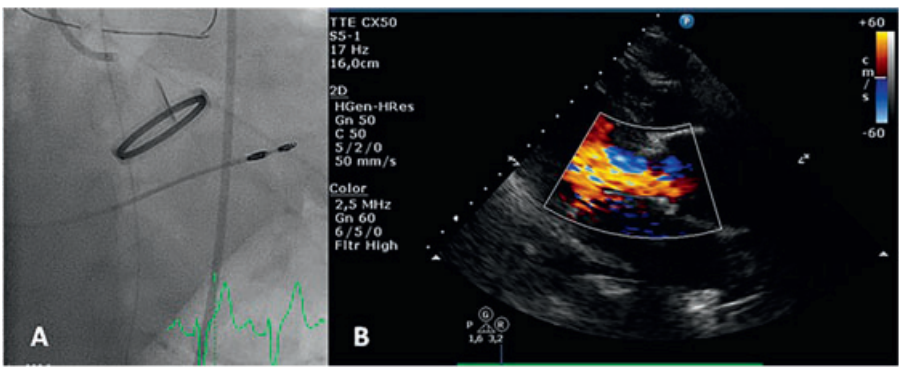

FIGURE 1 Angiography (A) and trans-thoracic echocardiography (B) showing missing leaflet and aortic regurgitation

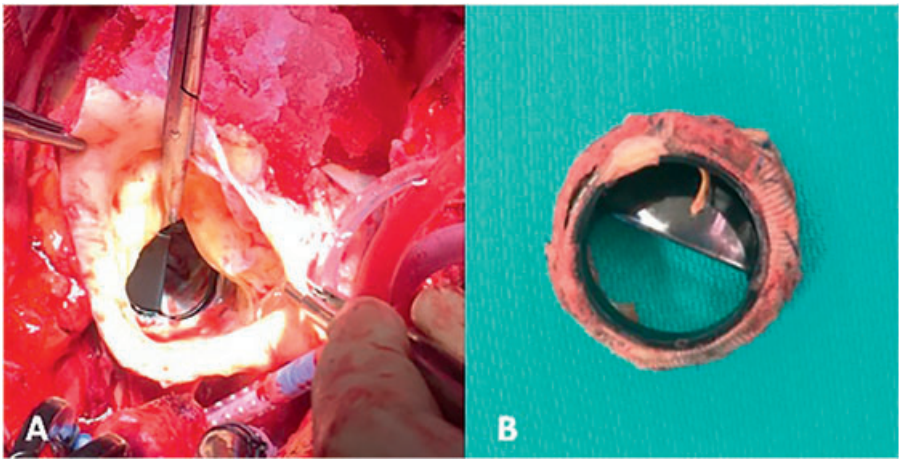

FIGURE 2 Mechanic aortic valve with missing leaflet in anatomic position (A) and after removal (B)

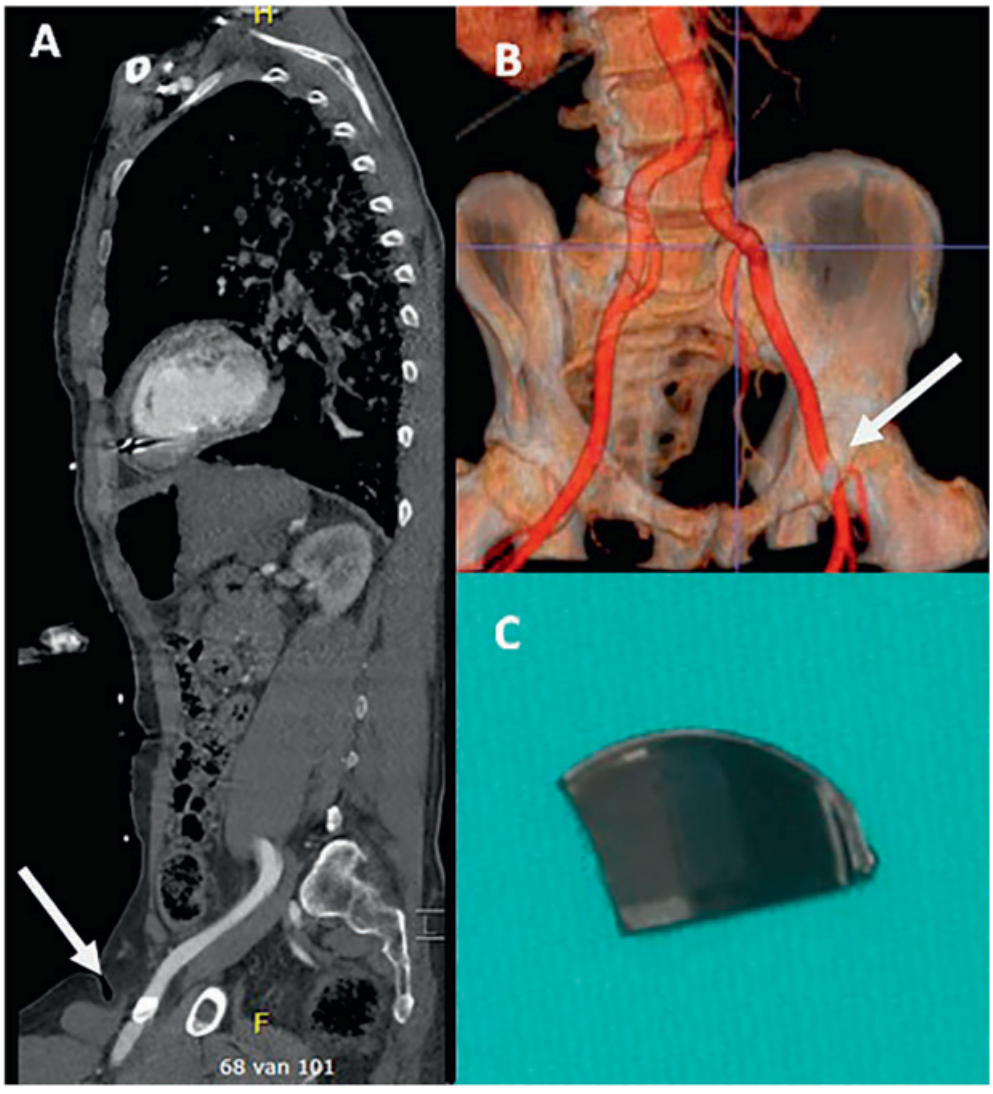

FIGURE 3 Localization of missing leaflet on computed tomography (A and B). Two-third of the leaflet was recovered (C) from the deep femoral arteries

TABLE 1 Published cases on Edwards-Duromedics (E-D) leaflet escape

(First) author, year of publication	Patient count	Type of E-D	Position	Duration to escape in years	Cardiogenic shock	Emergency surgery	Alive	Fragmentized leaflet	Location of leaflet
Deuvaert et al.[10]	1	Original	Mitral	NR	+	+	-	–	AA
Klepetko et al.[11]	2 3	Original	Mitral Mitral	3.16 3	NR	+	+ +	– –	IFA
Kumar et al.[12]	4 5	Original	Mitral Mitral	5 2	+	+	+ +	– –	IFA
Baumgartner et al.[13]	6	Original	Mitral	2	+	+	+	+	IFA
Podesser et al.[14]	7	Original	Mitral	8	NR	NR	–	–	LVOT
Hemmer et al.[15]	8 9	Original Tekna	Mitral Mitral	14 3	+ +	+ +	+ +	– +	AA, IFA
Mastroroberto et al.[9]	10	Original	Mitral	12	+	NR	–	NR	NR
Sudo et al.[16]	11	Original	Mitral	10	+	+	+	+	IFA
Christiansen et al.[17]	12	Tekna	Aortic	3.5	+	+	+	+	IFA
Jazayeri et al.[18]	13	Tekna	Mitral	5	NR	+	+	+	AA, IFA
L'Huillier et al.[19]	14	Tekna	Mitral	5	+	+	+	–	AA
Tatou et al.[20]	15	Original	Mitral	6	+	+	+	+	IFA
Youn and Yoo[21]	16	Original	Mitral	6	+	+	+	–	AA
Mert et al.[22]	17	Revised	Mitral	7.16	NR	+	+	+	IFA
Pfeiffer et al.[23]	18	Tekna	Aortic	8	+	–	–	+	IFA
Fragoulis and Palatianos[24]	19	Tekna	Mitral	12	+	+	NR	+	IFA
Yamazaki et al.[25]	20	Original	Mitral	17	+	+	+	+	BCA, IFA
Collison and Mishra[26]	21	Tekna	Aortic	2	+	+	+	–	IFA
Kim et al.[27]	22	Original	Mitral	27	+	+	+	–	IFA
Kobayashi et al.[28]	23	Original	Mitral	26	+	+	+	+	IFA
Our case	24	Original	Aortic	31	+	+	+	+	IFA

AA, abdominal aorta; BCA, brachiocephalic artery; IFA, Ileofemoral arteries; LVOT, left ventricular outflow tract; NR, not reported.

Heights, MN), a St. Jude mitral valve prosthesis[31] (St. Jude Medical, St. Paul, MN), and an On-X mitral valve prosthesis[32] (Medical Carbon Research Institute, Austin, TX). Similar to the ED valve, patients present with cardiac failure and emergency surgery was performed in all cases (Table 3).

4 | DIAGNOSIS OF LEAFLET FRACTURE AND ESCAPE

Transthoracic echocardiography is used to diagnose a missing leaflet.[14,26,27] Transthoracic echocardiography in our case showed major aortic regurgitation but did not clearly identify the missing leaflet. We diagnosed the missing aortic valve leaflet using fluoroscopy while performing CAG. The radio-opacity of the carbon that is used to design mechanic heart valves makes it very easy to observe the absence of simultaneous movement of leaflets or a stenotic valve by leaflet immobility (Figure 2). Fluoroscopy could therefore be a valuable alternative to trans-thoracic echocardiography when imaging with echocardiography is difficult such in obese patients.

Computer tomography is a reliable imaging technique to localize escaped leaflets. In our review of the ED and/or Edwards TEKNA valves, most leaflets migrated to the abdominal aorta (13%) or iliac arteries (78%), and in one case to the brachiocephalic artery (Table 1).[25] In 48% of cases a leaflet fracture was demonstrated (Table 1). Other valve brands show similar locations for leaflet embolization (Table 3). Our patient also had a fragmented leaflet, of which 2/3 of the leaflet was located in left superficial femoral artery and 1/3 in the left popliteal artery (Figure 3). In cases where the escaped leaflet is still missing or fragmentation is suspected, we recommend to perform a full-body CT, preferably with 3D reconstruction.

TABLE 2 Overview of published cases including our case of Edwards–Duromedics leaflet escape

Variable	Overall (*N* = 24)	Aortic valve (*N* = 4)	Mitral valve (*N* = 20)
Lethality	17%		
Period from initial surgery until leaflet escape (years ± SD)	9.5 ± 8.4	11.1 ± 13.5	9.1 ± 7.4*

In one case duration to escape was not reported. SD, standard deviation.

TABLE 3 Published cases on mechanical heart valve leaflet escape (excluding cases involving Edwards–Duromedics and Bjork–Shiley prostheses)

Valve type	(First) author, year of publication	Patient count	Position	Duration to escape in years	Cardiogenic shock	Emergency surgery	Alive	Fragmentized leaflet	Location of leaflet
TRI–Technologies	Bottio et al.[2]	1	Aortic	0.03	NR	–	–	–	AA
		2	Mitral	1.66	NR	+	+	–	AA
	Dikmengil et al.[3]	3	Mitral	0.33	+	+	–	–	AA
	Gerosa et al.[4]	4	Aortic	NR	NR	–	–	NR	IFA
	Cianciulli et al.[5]	5	Mitral	3	+	+	NR	NR	NR
	Zhang et al.[6]	6	Mitral	3	+	+	+	–	AA
	Barbera et al.[7]	7	Mitral	NR	NR	+	+	NR	NR
		8	Aortic	NR	NR	NR	–	NR	NR
		9	Aortic	NR	NR	NR	–	NR	NR
Omnicarbon	Kornberg et al.[30]	12	Aortic	3.5	+	+	+	+	AA
St Jude	Mosterd et al.[31]	10	Mitral	1.5	+	+	NR	+	IFA
On–X	Kageyama et al.[32]	11	Mitral	5	+	+	–	–	AA

AA, abdominal aorta; IFA, Ileofemoral arteries; NR, not reported.

5 | PATHOGENESIS AND RISK OF LEAFLET FRACTURE AND ESCAPE

Valve failure is most often due to outlet strut fracture leading to dislodgement and embolization of the occluder disc.[1] Metallurgic analyses have shown that these fractures are caused by a combination of abnormal outlet strut loading (due to its bimodal closure pattern) with inferior weld quality.[33]

Multiple factors have been hypothesized for the cause of increased risk of leaflet fracture and escape in the Edwards-Duromedics prostheses, including inadequate compliance of the sewing ring (reducing shock absorption) and surgical mishandling during prosthesis implantation.[34] In addition, other potential causes for accelerated material deterioration include assymetric valve closure with local stresses, and clustered micro-porosity of the pyrolytic carbon. Cavitation has been identified as the most contributing factor to failure of the Edward-Duromedics prosthesis.[34]

Cavitation is the process in which pressure differences in blood flow cause formation of unstable air bubbles that subsequently collapse and thereby release energy, leading to pitting and micro-cracking of the prosthesis.[35] Studies have reported that the cavitation threshold is much lower for Edwards Duromedics valves when compared to other bileaflet prostheses, leading to earlier and more severe damage.[36] The collapse of bubbles (and thus cavitation) produces a sound (high-frequency pressure fluctuations [HFPF]) that can be quantified.[37] In a 2004 review by Johansen et al, the measurement of HFPF was proposed as a promising method to detect cavitation in vivo, and might aid in the determination of valve function and imminent failure. However, HFPF measurement has not yet been validated to objectify or quantify cavitation in human subjects, and other methods are not readily available. Much work needs to be done to develop a non-invasive method to reliable quantify HFPF with relation to the extent of cavitation, with the purpose of identifying valve prostheses that are high-risk for structural detoriation.

Investigation into cases with valves other than the ED valve revealed significant tab malalignment and asymmetry in the TRI Tech valves in which tab fracture and leaflet escape had occurred.[3–5] Similar to the ED valve, valve analysis of fractured leaflets showed cavitation as the main contributing factor to valve failure and leaflet escape.[3–5]

6 | INDICATIONS FOR PROPHYLACTIC REOPERATIVE VALVE REPLACEMENT?

In the BSCC cases a Dutch research group showed that the 70° opening angle, large valve size, mitral position and young age were the most important determinants for risk of outlet strut fracture (OSF).[38] Furthermore, analysis of manufacturers data showed that several aspects of the manufacturing process (eg, repetitive testing) also increased the risk of outlet strut fractures.[1] Based on these risk factors, advisory algorithms were devised to aid cardiothoracic surgeons in making a case-to-case decision on prophylactic BSCC replacement.[38–41] It was concluded that each case should be assessed individually for a proper balance between surgical mortality and gain in life expectancy after reoperation, against the risk of OSF and subsequent loss of life expectancy. Fortunately, the majority of the BSCC patients are now over 70 years of age and the annual incidence of OSF is estimated between 0.02% and 0.04% annually.[1]

These indications for elective prophylactic reoperation can be extrapolated to patients with ED or TRI Technologies valves. Each case should be examined individually, and operative risk should be assessed compared to the risk of leaflet escape. Some clinics have offered prophylactic reoperations in asymptomatic patients to replace the TRI Technologies valve with excellent results. In one series, operative mortality was 0% in 22 patients and none of these patients experienced permanent complications.[4,5] Nevertheless, in contrast

to the large amount of data available for the BSCC cases, there is unfortunately no literature available in which large cohorts are analyzed and thoroughly examined for risk factors for leaflet fracture and escape in patients with ED or TRI Technologies valves. The incidence of BSCC leaflet fracture by far exceeds the amount of cases published on ED leaflet escape and therefore results of multivariate or survival analysis will not be statistically correct or interpretable in current ED and TRI Technologies cohorts.

Future research should therefore explore patient- and prosthesis-related factors that increase the risk of leaflet escape, performed in large groups of patients in order to make a similar algorithm for ED or TRI Technologies valve patients. Until then, routine replacement of ED or TRI Technologies heart valves in asymptomatic patients with good-functioning valves on echocardiography cannot be recommended.

7 | CONCLUSIONS

Clinicians should be aware of the possibility of leaflet instability in patients with prosthetic heart valves, especially with ED and Edwards TEKNA valves. In these patients presenting with symptoms of sudden acute decompensated heart failure or cardiogenic shock, valve dysfunction should be strongly suspected, and we recommend angiography or transthoracic echocardiography and emergency surgery when leaflet escape is present. Further research for detection of cavitations and risk factors that make asymptomatic patients prone to leaflet escape in ED and Edwards TEKNA valves is needed to identify possible high-risk cases for valve fractures and to develop guidelines for prophylactic valve replacement.

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