Despite absence of known risk factors

Early degeneration of the Sorin Mitroflow aortic bioprosthesis

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Summary

We report a series of 31 patients after surgical aortic valve implantation of a bovine Sorin Mitroflow bioprosthesis with early severe structural valve degeneration (SVD) despite absence of known risk factors. Half of the patients underwent re-intervention and more than one third died without re-intervention, mostly prematurely due to heart failure caused by SVD. The Sorin Mitroflow valve was prone to early SVD even in very old patients, which may be at least in part due its specific design with an externally mounted pericardial sheet and to a former lack of anti-calcification treatment. This led to additional suffering of the patients and added healthcare expense. The inferior durability of the advanced versions of the valve was largely undetected for almost two decades, which in retrospect was mainly because earlier studies relied on SVD diagnosis only at reoperation, lacked regular echocardiographic monitoring and did not consider the competing risk of death despite high mortality rates. To avoid a similar delay in the recognition of specific problems with new surgical valves the introduction of mandatory SAVR registries is suggested analogue to the already ongoing TAVI registries. Moreover, regular echocardiographic monitoring and uniform definition of SVD as well as broad training of all cardiologists and echocardiographers involved in SVD screening and treatment seem reasonable.

Introduction

"The surgeon carries an important responsibility in protecting the patient from valve degeneration"

Flameng W, et al. (2014)

Severe aortic valve disease – predominantly degenerative aortic valve stenosis – is the most important valve disorder in the elderly with increasing numbers and burden during the past decades [1]. The treatment of choice is valve replacement either as surgical aortic valve replacement (SAVR) or transcatheter aortic valve implantation (TAVI). In surgical aortic valve replacement, the proportion of bioprosthetic aortic valves is continuously increasing in all age groups and is overall much higher than that of mechanical aortic valves [2–4]. For bioprostheses excellent longevity and performance is mandatory, so that the prosthesis, if possible, outlives the recipient. In the case of prosthesis degeneration a valve-in-valve procedure has nowadays to be an option. The types of biological valves have different designs, tissues and preparations with implications for their durability [5].

The Sorin Mitroflow was a bovine pericardial bioprosthesis with unique features: (1) externally on the valve skeleton mounted single sheet of pericardium resulting in (2) long leaflets and (3) relatively large effective orifice area as well as (4) absence of anti-calcification treatment (until the introduction of the DLA model) [6, 7]. Surgeons appreciated the easy implantation of the Mitroflow, especially for a small aortic annulus. The Mitroflow valve was introduced in Europe for use in the aortic and mitral positions with the model 11 in 1982 [8]. As with the other bioprostheses, structural valve degeneration (SVD) occurred and was first described in detail by Loisance et al. in 1989 [9]. Subsequently abrasion of the pericardium by the ribbed side of the sewing ring resulting in tears were identified as one reason. This led to the modification of the valve with the model 12A in 1991, where the smooth side of the sewing ring was turned to the pericardium [7], the use in mitral position of the once Mitroflow labelled valve was abandoned. In 2006 after manufacturing modifications and minor design variations the model LXA followed [6]. The Sorin Mitroflow valve gained wide acceptance and the implantation rate worldwide passed 100,000 in 2011 [7]. The model DLA, introduced from 2011 on, was manufactured with anti-calcification treatment [7]. In 2015 the Sorin Mitroflow was rebranded as LivaNova Crown PRT, which differs from the Mitroflow DLA only by radiopaque and visible markers [10]. Recently data emerged that even the advanced versions of the Sorin Mitroflow (LXA, DLA, Crown PRT) was prone to specific problems. Here we report our experience with this valve.

Case vignette (Patient no. 2)

The 79-year-old female patient had suffered from shortness of breath New York Heart Association (NYHA) grade III for 3 months due to severe aortic valve stenosis. Surgical valve replacement was performed

Published online first – please cite as: Cardiovasc Med. 2022;25:w10143. doi: 10.4414/cvm.2022.w10143 EMH Media

with a Sorin Mitroflow 23-mm Bioprosthesis. Two and a half years later the cusps of the valve were thickened, fibrotic and/or calcified with reduced mobility and elevated pressure gradients (66/37 mm Hg) corresponding to a moderate aortic stenosis. Five years after SAVR the stenosis was severe (maximum velocity 5.0 m/s, effective orifice area 0.5 cm^2, mean gradient 70 mm Hg, Doppler velocity index 0.2) and a second aortic valve replacement was necessary in the now 84-year-old woman. An Edwards Perimount Magna 21-mm Bioprosthesis was implanted with excellent follow-up up to today.

Methods

We reviewed all records of prospectively collected valve patients of the in- and outpatient clinic of the Kantonsspital Münsterlingen and of a private cardiologic practice (MF). We extracted all patients who had a Sorin Mitroflow Aortic Bioprosthesis implanted. The primary SAVRs were performed between December 2008 and August 2016. The follow-up of clinical and echocardiographic data was completed in April 2021. The protocol of this study was approved by the Ethikkommission Ostschweiz (EKOS Project ID 2020-01340).

Chart review

Anthropometric data, clinical history, surgery reports with indications and procedures, prosthesis size, indications for rehospitalisation as symptoms of heart failure and all clinical reports were reviewed retrospectively.

Echocardiographic review

All echocardiograms of the patients were reviewed by a single experienced echocardiographer (FW). The examinations were recorded by different operators according to the protocol of our institutions. A few data sets were incomplete, i.e., baseline transthoracic echocardiography (TTE) 3 months after the operation was not available for every single patient. The aortic valve was imaged by TTE and in 17 of the 31 patients also by transoesophageal echocardiography (TOE). Maximum velocities, and maximum and mean Doppler gradients were recorded; the highest values until reintervention or death were reported. The severity of stenoses were calculated by different methods (effective orifice area, dimensionless index, Doppler signal contour, ratio acceleration time / ejection time, planimetry by TOE), patient-prosthesis mismatch was checked and correction for pressure recovery was applied in cases of small aorta ascendens (<3.0 cm). The morphology (thickened, calcified) and the mobility of the valve were described. The insufficiency was classified as transvalvular or paravalvular, small, moderate or severe. In summary, the structural valve degeneration was classified using the standardised definition of structural valve degeneration for surgical and transcatheter bioprosthetic aortic valves [37].

During a period of 8.5 years (December 2008 to Aufust 2016) we followedup a total of 57 patients after SAVR with a Sorin Mitroflow valve.

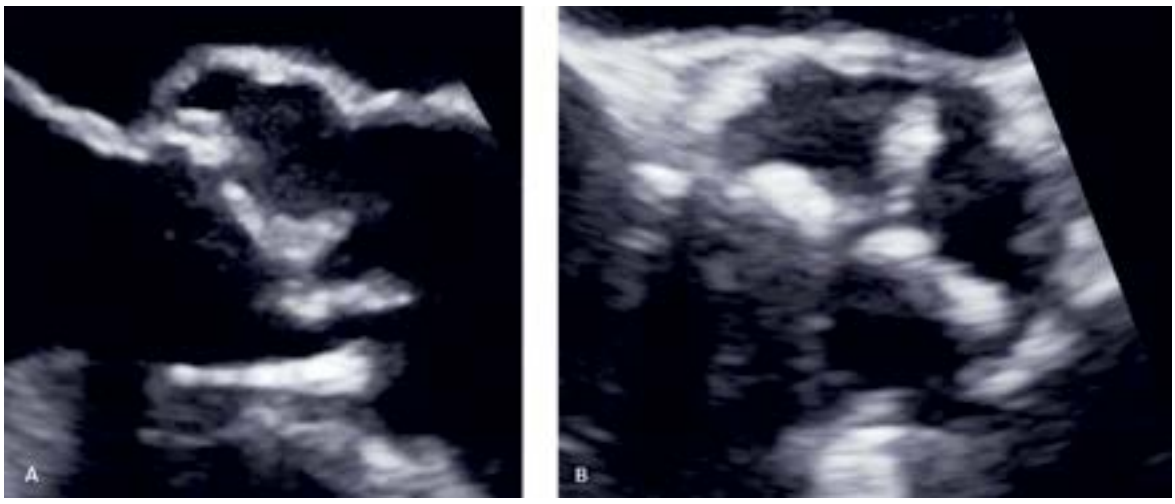

Figure 1: Structural valve degeneration of a Sorin Mitroflow Aortic Bioprosthesis of a 77-year-old female patient (no. 6) 4 years after surgical aortic valve replacement. (**A**) Transesophageal long axis view. (**B**) Transoesophageal short axis view. Videos A and B can be seen in the multimedia collection of Cardiovascular Medicine: https://cardiovascmed.ch/online-only-content.

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Statistical analysis

We used descriptive statistic for tables and figures, standard deviations (SDs) were calculated and significance was computed by Fisher's exact test.

Results

Clinical findings

During a period of 8.5 years (December 2008 to Aufust 2016) we followedup a total of 57 patients after SAVR with a Sorin Mitroflow valve. One of these patients was lost to follow-up, one patient was excluded owing to an associated hypertrophic obstructive cardiomyopathy and another one due to endocarditis 2 months after SAVR. Twenty three patients had normal valves or minor alterations 3 months to 8 years after SAVR. The remaining 31 patients constitute the study population with moderate/severe structural valve degeneration. Their demographic and medical characteristics are summarised in table 1.

Table 1: Baseline characteristics, surgical procedure and structural valve degeneration (SVD).

Baseline characteristics	Cohort (n = 54)
Non-significant SVD, n	**23**
Male sex, n (%)	16 (70)
Average age, years (range)	76.5 (52–87)
Significant SVD, n	**31**
Male sex, n (%)	14 (45)
Sorin Mitroflow LXA prosthesis (%)	18 (58)
Sorin Mitroflow DLA prosthesis (%)	13 (42)
Age at SAVR, years (range)	76.9 (63–89)
Age at diagnosis of SVD, years (range)	81.9 (69–92)
Surgical procedure	**n (%)**
Isolated AVR (maze procedure 2x)	18 (58)
AVR and CABG	7 (23)
AVR and aortoplasty	5 (16)
AVR and MVR	1 (3)
Clinical signs of SVD	
Murmur	18 (58)
Shortness of breath	3 (10)
Heart failure	20 (65)
Heart failure hospitalisation	15 (48)

AVR: aortic valve replacement; CABG: coronary artery bypass graft; MVR: mitral valve repair; SAVR: surgical aortic valve replacement; SVD: structural valve degeneration

Of these 31 patients, 14 were male and 17 were female. The indication for the primary aortic valve replacement was either aortic stenosis or aortic insufficiency. Eighteen patients (58%) received the model Mitroflow LXA and 13 patients (42%) the anticalcification-treated model DLA. The mean age at operation was 76.9 years (range 63–89, SD ± 6.4), 18 patients had isolated SAVR, in 13 patients SAVR was combined with other procedures, namely coronary artery bypass graft (CABG) (7), aortic root replacement or aorta ascendens reduction (5), mitral valve repair (1) and maze procedure (2) (table 1). The mean age of the patients at SAVR did not differ between patients with (76.9 years, range 63–89, SD ± 6.4) and without (76.5 years, range 52–87, SD ± 7.5) moderate/severe SVD (fig. 2). No statistically significant differences were found between SVD and non-SVD patients regarding sex (p = 0.0996), age younger than 70 years (p = 1.0) and prostheses size (19/21 versus >23 mm; p = 0.628). Similarly, the size of the Sorin Mitroflow valve did not to have a significant impact on the SVD severity (p = 1.0) (fig. 3).

Moderate or severe structural valve degeneration (SVD) was diagnosed at a mean of 5.3 years (range 2.4–9, SD ± 1.8) after SAVR at an average age of 81.9 years (range 69–92, SD ± 6.0). Four of 11 patients (36%) with the model LXA, 7 of 11 (57%) with the model DLA developed moderate/severe SVD within 5 years after SAVR. Clinical symptoms and signs at diagnosis of SVD were a murmur (18), shortness of breath (13) and congestive heart failure (20) (table 1). Fifteen patients (48%) were hospitalised because of heart failure.

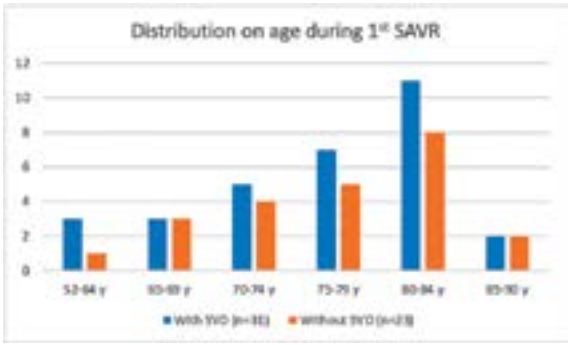

Figure 2: Structural valve degeneration (SVD) and age distribution during the first surgical aortic valve replacement (SAVR) in comparison with the cohort without SVD.

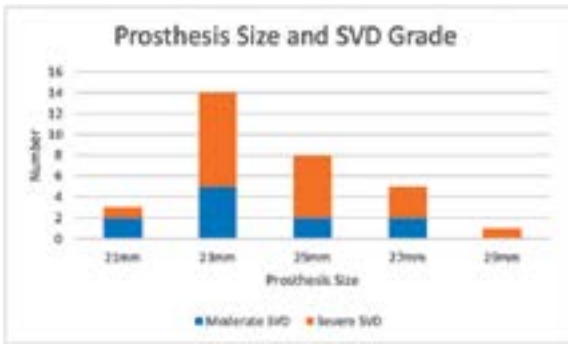

Figure 3: Prosthesis size and structural valve degeneration (SVD).

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After diagnosis of SVD 16 patients (52%) had a second aortic valve replacement (SAVR 8, TAVI 7, transapical AVR 1) and 15 patients (48%) were treated conservatively: 4 patients (13%) were only followed-up and 11 patients (35%) died without intervention. The reasons not to reintervene were non-severe SVD, serious comorbidities and/or refusal of the patient. The reinterventions in 16 patients were performed at a mean age of 79.5 years (range 69–91, SD ± 5.9), on average 6.9 years (range 5.2–11.9, SD ± 1.9) after the index operation (table 2). The indications for reintervention were severe prosthesis stenosis in five (31%), severe regurgitation in seven (44%) and severe combined bioprosthesis disease in four patients (25%). The four patients still alive without intervention had a mean age of 87 years (range 84–90, SD ± 2.5), on average 8.7 years (range 6.8–9.6, SD ± 1.3) after the primary SAVR (table 2). The 11 patients who died without reintervention passed away at a mean age of 89 years (range 82–95, SD ± 3.7), 7 years on average (range 5.2–9.9, SD ± 1.9) after the index operation. In 7 of these 11 patients, SVD was judged to be the principal cause of death, two patients died because of comorbidities and in two the cause of death is not known.

Echocardiographic findings

The signs of SVD consisted of thickening of the cusps, restricted cusp mobility, calcification or rupture of the cusps of the bioprosthesis (table 3). The changes were categorised according to the standardised definition of SVD for surgical and transcatheter bioprosthetic aortic valves [37]. The classification of SVD severity was based on the morphological appearance of the leaflets and the Doppler measurements, namely AV Vmax, AV mean gradient, effective orifice area, aortic valve area index (AVAi), Doppler velocity index (dimensionless index) and the prolonged acceleration time of the continuous wave Doppler signal >100 ms. If the left ventricular outflow tract diameter was difficult to measure, the outer diameter of the sewing ring was substituted. There were no cases of patient-prosthesis mismatch either calculated by the effective measurements or by the official Sorin Mitroflow EOAi-Chart. The effective orifice area (EOA) calculations were corrected for energy loss index in the cases of small aorta ascendens. Table 3 summarises the type of the index operation, severity of SVD, echo parameters and outcomes. We did not find a SVD-age correlation that means, the older the patient the lesser extent was the SVD (fig. 2).

Our series of 31 patients after surgical aortic valve replacement with a bovine Sorin Mitroflow bioprosthesis documents an unusual pattern of early severe SVD even in very old patients.

Discussion

Our series of 31 patients after surgical aortic valve replacement with a bovine Sorin Mitroflow bioprosthesis documents an unusual pattern of early severe SVD even in very old patients (fig. 1, videos 1 and 2). We had never seen clinically significant SVD in patients ≥75 years at operation before. Our patients had a mean age of 76.9 years, at which the implantation of the Mitroflow should have been the definitive solution of their aortic valve disease. Despite well-established predictors of bioprosthesis longevity, especially old age, significant SVD was diagnosed on average 5.3 years after Mitroflow implantation, and the earliest occurred after 2.4 years. This led to additional suffering for our old patients and increased burden to the healthcare system, particularly rehospitalisations and reinterventions. Forty-eight percent of the patients had heart failure hospitalisations, 52% of the patients underwent a reintervention 6.9 years after the primary procedure and 35% died without reintervention at a mean of 8.1 years after the surgical valve replacement, most of them prematurely due to heart failure caused by SVD. These very old patients were too sick for and/or declined reintervention.

The very early SVD in our old cohort was unexpected and is exceptional in the first decade after SAVR [11]. In general, bioprosthetic heart valves have reoperation rates of 10% and 30% at 10 and 15 years, respectively, in elderly patients [12]. None of our patients had well-es-

Table 2: Time intervals and patient outcomes.

Patient age and time intervals in years	Average (range)
Time interval in years from index operation to	
Diagnosis of moderate/severe SVD (n = 31)	5.3 (2.4–9.2)
End of follow-up without intervention (n = 4)	8.7 (6.8–9.6)
Reintervention (n = 16)	6.9 (5.2–11.9)
Death (n = 11)	7.0 (5.2–9.9)
Patients without re-intervention (n = 15)	88.5 (84–95)
Patients alive (n = 4)	87.0 (84–90)
Patients deceased (n = 11)	89.0 (84–95)
Patients with re-intervention (n = 16)	79.5 (69–91)
SAVR (n = 8)	77.9 (69–84)
TAVI (n = 7)	79.7 (76–86)
Transapical AVR (n = 1)	91

AVR: aortic valve replacement: SAVR: surgical aortic valve replacement; SVD: structural valve degeneration; TAVI: transcatheter aortic valve implementation

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Table 3: Overview of patient characteristics (n = 31).

Pat. No.	Surgery	Mitroflow, mm, model (LXA or DLA)	Degree of SVD	AV max (m/s)	AVA Index	DVI	Death after first sign of SVD (months)	Implication, re-operation procedure
1	AKE, ACBOPx5	25, LXA	Severe	2.74	1.00	0.52		TAVI, valve in valve
2	AKE, ACBOPx1	23, LXA	Severe	5.00	0.24	0.20		Redo SAVR Perimount Magna 21 mm
3	AKE	21, LXA	Moderate	3.00	0.58	0.32	24	No intervention, death
4	AKE	23, LXA	Moderate	2.40	0.73		0	No intervention, death
5	AKE, ACBOPx4	23, LXA	Moderate	3.00	0.68	0.32	65	No intervention, death
6	AKE	23, LXA	Severe	3.50	0.46	0.40		Redo SAVR Perimount Magna 21 mm
7	AKE, ACBOPx2	23, DLA	Severe	4.00	0.62	0.22	0	No intervention, death
8	AKE	23, LXA	Moderate	4.20	0.53	0.24		Watchful waiting, 84 years old
9	AKE	27, LXA	Severe		0.56			Redo SAVR Perimount Magna 23 mm
10	AKE, ACBOPx1	25, DLA	Severe	4.22	0.30	0.20		Redo SAVR Perimount Magna 23 mm
11	AKE, MKR	29, DLA	Severe	5.17	0.25	0.10		TAVI, valve in valve
12	AKE, MAZE	27, DLA	Moderate	3.05	1.13	0.43	0	No intervention, death
13	AKE	23, DLA	Severe	3.80	0.61	0.26		Redo SAVR, Perimount Magna 21 mm
14	AKE	27, DLA	Severe		0.26			TAVI, valve in valve
15	AKE, MAZE	27, LXA	Severe	2.80	1.14	0.64		Redo SAVR, Sorin Carbomedics 25 mm
16	AKE	25, LXA	Severe	4.40	0.45	0.37		TAVI, valve in valve
17	AKE	23, DLA	Severe	3.60	0.60		27	No intervention, death
18	AKE, ACBOPx2	23, LXA	Severe	4.24	0.56	0.30	12	No intervention, death
19	AKE	23, LXA	Moderate	3.60	0.71	0.34	0	No intervention, death
20	AKE	23, LXA	Moderate	2.80	0.73	0.35		Wacthful waiting, 87 years old
21	AKE, Rohrproth.	25, DLA	Severe	2.78	1.41	0.63		Redo SAVR, Perimount Magna 23 mm
22	AKE, AoReduk.	25, LXA	Severe	3.16	0.54	0.24		Watchful waiting, 86 years old
23	AKE	21, DLA	Severe	5.40	0.28	0.18		TAVI, valve in valve
24	AKE	27, LXA	Severe	2.80				TAVI, valve in valve
25	AKE	23, DLA	Severe	3.61	0.32		48	No intervention, death
26	AKE, Ao Reduk.	25, LXA	Severe	4.04	0.47	0.21		Redo SAVR, Sorin Crown PRT
27	AKE	23, DLA	Severe	3.45	0.59	0.24		Watchful waiting, 90 years old
28	AKE, Ao Reduk.	25, LXA	Moderate	3.00	0.51	0.34	40	No intervention, death
29	AKE, ACBOPx4	25, DLA	Severe	2.80	0.56			TAVI, valve in valve
30	AKE	21, LXA	Moderate	2.73	0.59	0.36	27	No intervention, death
31	AKE, suprac. Ersatz	23, DLA	Severe	3.00	0.80	0.37		Transapical AVR, valve in valve

tablished predictors of early bioprosthetic valve degeneration such as younger age (<60 years), severely reduced kidney function / haemodialysis, patient prosthesis mismatch, very small valve size and/or infective endocarditis ([11–14], table 4). Several studies report acceptable [15], favourable [16] or good [17–20] or even excellent long-term results of the Mitroflow bioprosthesis [21, 23], preferentially in patients older than 70 years. Only after the clinical series of Alvarez et al. in 2009 [24], and Saleeb et al. and Sénage et al. in 2014 [25, 26]), along with the pathology study of Butany et al. in 2011 [27], the appraisal of the Sorin Mitroflow changed markedly two decades after introduction of the Mitroflow 12A. Subsequent nonrandomised comparative single-centre series showed evidence of an inferior durability and/or survival of the Mitroflow valve compared with the Carpentier Edwards (CE) valves Perimount, Perimount Magna [28–31] and Perimount Magna Ease [32], as well as the Medtronic valve Mosaic [31]. Moreover, in a very large British registry study, the Sorin Mitroflow showed significantly lower survival than all other valves [33]. Similarly, a meta-regression analysis of studies found a significantly higher SVD risk for Sorin pericardial valves (including the Mitroflow valve) than for CE pericardial or porcine valves or Medtronic porcine valves [34]. In Switzerland its limited longevity was hitherto only addressed by a dramatic case report in 2015 [35].

Table 4: Common predictors of early bioprosthetic valve degeneration.

Young age
Severe reduced kidney function with haemodialysis
Patient prosthesis mismatch
Infective endocarditis
Early valve thrombosis (?)

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Why did it take so long until the early SVD even in very old patients was acknowledged? Retrospectively, the discrepancy between the reassuring studies stating acceptable to excellent longevity and the inferior results of more recent studies can be largely explained by the combination of the following factors in the former: (1) restrictive definition of SVD in surgical studies where it was diagnosed only at reoperation [26, 32, 36], (2) the absence of systematically recorded echocardiographic follow-up data [31, 36] and (3) no consideration of the competing risk of death [37, 38], especially in the very old patients. With a high rate of early deaths [21] and midterm mortality rates of 57.7% to 81.2% in 10 years [17–20, 22] symptomatic severe SVD could either not develop or could not be detected without frequent regular echocardiographic monitoring before death in a considerable portion of patients. Additional factors may have been small single- or oligo-centre studies and lack of direct comparison with other bioprostheses. Thus, it seems likely that SVD occurred much more frequently and was systematically underestimated in the earlier studies. This was impressively underscored by the nationwide echocardiographic study of Issa et al. in Denmark in 2018 [38]. After the substantial SVD risk of the Sorin Mitroflow became apparent, all Danish patients still alive with this valve (644 of an initial 1552) were invited for an echocardiographic follow-up examination; 574 participated, 30% of them were diagnosed with SVD and 11% had severe SVD. The incidence of newly detected severe SVD in patients not reoperated on was as high as the already known incidence of SVD at reoperation, figures that are very similar to our data. Even this comprehensive Danish study probably underestimated the absolute numbers of cases of severe SVD because undetected SVD is likely to have occurred in the patients who declined participation and in the large group of deceased patients.

Historically the diagnosis of SVD was not standardised and often based on severe SVD at reoperation, a long time after significant degeneration had ensued.

Historically the diagnosis of SVD was not standardised and often based on severe SVD at reoperation, a long time after significant degeneration had ensued. As Dvir and Bourgouignon et al., on behalf of the Valve in Valve International Data Group (VIVID), emphasised in 2018 in a *Circulation* White Paper, 20 different definitions of SVD were used in the literature [39]. Following the course of the development of a native aortic stenosis, they standardised the definition of SVD into stages 1–3 for stenosis and insufficiency. In addition to the definition of the VIVID group, the consensus of the European Association of Percutaneous Cardiovascular Interventions (EAPCI) and the European Association for Cardio-Thoracic Surgery (EACTS) published another definition of SVD in 2017 [40]. Both statements recommend similar haemodynamic and morphological echocardiographic criteria to diagnose moderate or severe SVD. We have used the more detailed definition according to the natural aortic valve disease proposed by the VIVID Group (table 5).

Table 5: Definition of bioprostetic valve degeneration.

Δp mean >50% of baseline
Thickened cusps with or without calcification
Reduced mobility of one or more cusps

A major mode of SVD in explanted Mitroflow pericardial valves was calcification as presented by Butany et al. [27]. The models 11, 12A and the next, third generation model LXA – used in our series in 58% – were not treated with anti-calcification agents to delay SVD like other contemporary bioprostheses. The absence of anti-mineralisation treatment may have been an important reason for rapid degeneration of the bioprostheses in our cohort and in other series [25, 36, 41–42], but this is not completely understood because in 25% of cases the SVD occurs without leaflet mineralisation [12]. Additionally, tears in the para stent regions were diagnosed, which may have been due to mechanical stress and abrasion associated with the special design of this valve [27]. Whether the recent anti-calcification treatment of the Mitroflow model DLA and the LivaNova Crown PRT – which is the same newly labeled valve with radiographic markers – will significantly improve the long-term durability remains uncertain. Initial studies reported discrepant performances and further publications have raised scepticism about the efficacy of the anti-calcification treatment of the Mitroflow DLA / LivaNova Crown PRT [43–45]. Likewise, the high proportion of moderate/severe SVD in our patients (42%) with the new DLA model may indicate that the problem of early SVD is not solved.

When severe SVD is diagnosed a reintervention will be contemplated unless the patient is too sick or refuses an invasive procedure.

Remarkably, there is another bioprothesis – the Trifecta – with an externally mounted single sheet of pericardium, which was introduced in 2010 and had anti-calcification treatment from the outset. This valve

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showed inferior midterm results due to SVD as well compared with the CE Perimount and Perimount Magna Ease valves, like the Sorin Mitroflow [46–49]. In the study of Lam and coworkers the worse outcomes of the Trifecta and Sorin Mitroflow were similar [46]. These results may indicate that the mechanical stress on the externally mounted pericardium could be a main factor for the development of SVD, more important than the anti-calcification treatment itself.

When severe SVD is diagnosed a reintervention will be contemplated unless the patient is too sick or refuses an invasive procedure. In our patients, the mean age at reintervention was 79.6 years, which is nowadays a typical age for attempting a valve-in-valve TAVI to avoid a second SAVR. However, this was only feasible in about half of our patients with reintervention, mainly because of the risk of coronary ostium obstruction by the cusps – a particular problem of the Sorin Mitroflow valve with its long, externally mounted cusps [50]. In the meantime, sophisticated techniques have been developed to ensure high success rates with valve-in-valve TAVI even in Mitroflow bioprostheses [51–55].

In such a SAVR registry every SAVR patient should be followed-up clinically and echocardiographically at yearly intervals, so that the performance of different valves can be compared in a timely fashion.

Given the increasing rates of bioprosthesis implantation, especially in patients less than 60 years of age, what can we do to prevent future delays in the recognition of possible problems in new surgical bioprosthetic valves? In our opinion a mandatory SAVR registry analogous to the SWISS TAVI registry should be established. This could ultimately enable even the comparison of hard endpoints, especially overall mortality. It appears to be quite inconsistent, when we follow-up the usually very old TAVI patients regularly every year, while monitoring the much younger SAVR patients who have considerably more life and valve years at risk as well as a higher risk for early SVD is only lenient. In such a SAVR registry every SAVR patient should be followed-up clinically and echocardiographically at yearly intervals, so that the performance of different valves can be compared in a timely fashion. Care must be taken to ensure uniform assessment and reporting by broad education of the standards for SVD diagnosis [39–40].

Limitations

First, due to non-uniform coding in one of our two institutions, we cannot present the overall number of patients with a Mitroflow bioprothesis seen during the period from 2008 to 2016. Thus, a selection bias is possible. In the other institution (MF Kardiologische Praxis Weinfelden) 21 such patients were monitored and significant SVD was detected in 35% (6/17) of patients with an echocardiographic follow up of >1.5 years; 24% (4/17) had severe SVD and 12% (2/17) had to undergo a reintervention or died because of SVD. During the same study period, an additional 14 patients with different bioprotheses were followed up there, none developed significant SVD. These subset data argue against a major selection bias. Second, several studies identified small valve size as a risk factor for SVD in Mitroflow valves [14, 26, 36, 38] due to patient prosthesis mismatch. This was not evident in our series, which was probably related to the small numbers and absence of the very small 19-mm Mitroflow prosthesis. Third, we did not take into account the possibility of leaflet thrombosis in our cohort of patients. This potential risk factor for early SVD of bioprosthetic valves is rare and appears 1–6 years after SAVR [50].

Conclusion

The Sorin Mitroflow bioprosthesis was prone to early SVD even in very old patients, as shown in our series. This may be at least in part due to its specific design with an externally mounted pericardial sheet and a former lack of anti-calcification treatment. The frequent SVD led to additional suffering of the patients and added healthcare expense due to reinterventions and hospitalisations. The inferior durability of advanced versions of this bioprosthesis was largely undetected for almost 2 decades mainly because earlier studies diagnosed SVD only at reoperation, lacked regular echocardiographic monitoring and did not consider the competing risk of death despite high mortality rates in this patient group. To avoid a similar delay in the recognition of specific problems with new surgical valves the introduction of mandatory SAVR registries is suggested analogous to the ongoing TAVI registries. These should embrace regular echocardiographic monitoring and uniform definition of SVD as well as broad training of all cardiologists and echocardiographers involved in SVD screening and treatment. Eventually, the results of SAVR-registries would strongly support the surgeons (and the heart teams) in the important responsibility to protect the patient from valve degeneration.

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Disclosure statement
No financial support and no other potential conflict of interest relevant to this article was reported.

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The full list of references is included in the online version of the article at https://cardiovascmed.ch/article/doi/CVM.2022.w10143.