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CASE REPORT

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A rapid deployment valve option for failing Medtronic Freestyle full root: a single centre experience

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Abstract

Background There are several high-risk treatment options for valve failure of a biological full root replacement. When tailoring the best treatment option for the patient, implantation of a rapid deployment valve (RDV) should be considered.

Case presentation Six patients presented with aortic regurgitation in a full root Freestyle bioprosthesis. Three had a history of valve endocarditis, while the remaining had non-infectious structural valve deterioration with leaflet and commissural tears. All patients were treated with a rapid deployment EDWARDS INTUITY Elite valve. Follow-up was complete for all patients. Postoperative echocardiography showed well-functioning valve prostheses with no paravalvular leaks and acceptable pressure gradients. Echocardiographic follow-up demonstrated excellent pressure gradients and a considerable decrease in the left ventricular mass index and left ventricular end-diastolic dimensions. Follow-up cardiac CT showed no signs of coronary obstruction or other pathology. During a median follow-up of 30 months neither biological valve failure, nor any events within the composite endpoint of major adverse cardiac and cerebrovascular events occurred.

Conclusions This case series presents the EDWARDS INTUITY valve as a good treatment option in patients with failing Freestyle roots.

Keywords Full root replacement, Valve failure, Structural valve degeneration, Transcatheter aortic valve implantation, Endocarditis, Rapid deployment valve

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Background

The porcine Freestyle stentless bioprosthesis (Freestyle; Medtronic Inc., Minneapolis, MN, USA) has been implanted as a full root replacement in patients at Haukeland University Hospital since 2001. The performance and durability of the valve have both been reported to be acceptable [1, 2]. Recent observations at our institution show an increasing trend of patients being readmitted with structural valve degeneration (SVD). The type of degeneration in the Freestyle prosthesis differs from that of other bioprostheses as it consists mainly of leaflet tears, and the valve itself usually does not become calcified. Although the incidence is low and it presents after many years, when it occurs the clinical presentation is often acute, with rapid symptom progression [1, 3, 4].

Severe aortic regurgitation (AR) due to SVD or endocarditis is an indication for redo surgery. However, a complete excision of the aortic root, which may be necessary for extended Freestyle root destruction, presents a significant surgical burden and risk. If only leaflet destruction without endocarditis is present, transcatheter aortic valve implantation (TAVI) is an option, but often declined due to lack of valve calcification and anatomical issues inherent to the Freestyle. An alternative strategy when one can preserve the root is to do a surgical valve-in-Freestyle replacement. Rapid deployment and sutureless valves have emerged as alternative to standard surgical aortic valves [5–10]. One such is the balloon-expandable stented EDWARDS INTUITY Elite rapid deployment valve (RDV; Edwards Lifesciences, Irvine, CA, USA). The valve has been built upon proven pericardial technology, but also shares technical aspects with TAVI, and the durability should be addressed. More data is warranted, but recent publications show convincing results [6]. The use of RDVs has been advocated in redo surgery to avoid disruption of the fragile tissue found in biological root prostheses [10]. The experience of implanting Intuity in a Freestyle full root is limited [11, 12]. Vendramin et al. have reviewed and recommend the use of RDVs and sutureless valves in challenging reoperations, but the Intuity was employed in a Freestyle full root in only two of these cases [12]. A recent multicenter study found favourable results following implantation of the sutureless Perceval prosthesis (Corcym UK Limited, London, UK) in degenerated stentless aortic valves and full root bioprostheses [13]. On this basis we aimed to assess the outcomes of 6 patients with failing Freestyle full roots treated with implantation of the Intuity valve at our institution.

Case presentation

The results of Intuity valve implantation in 6 patients with a degenerated Medtronic Freestyle full root replacement are reported (Fig. 1). All patients have provided written informed consent for inclusion and publication. Pre-, per- and postoperative data are presented in Table 1 and echocardiographic data in Table 2. Due to few observations the data are presented on an individual level. Continuous variables are presented as mean ± standard deviation (SD) or median (range). Paired-sampled t-test was used to compare echocardiographic values at discharge and follow-up. A p-value ≤ 0.05 was considered significant. All statistical analyses were performed using SPSS 26.0.

Patients

Severe AR was the main indication for surgery. Preoperative cardiac CT and transesophageal echocardiography were performed for detailed assessment of the aortic root and valve. No periannular pathology such as abscesses or pseudoaneurysms were present. All were complex high-risk patients expected to benefit both from a rapid valve insertion, and the favourable haemodynamic and structural profile of the Intuity valve.

Patients 1–3 had a history of endocarditis. At diagnosis blood cultures were positive and preoperative imaging showed involvement of the Freestyle leaflets. Truncal CT-scan and cerebral MRI demonstrated septic emboli to the spleen and brain in patients 2 and 3. Only patient 1 had active infection at surgery treated with intravenous antibiotics for 4 weeks preoperatively. At surgery C-reactive protein (CRP) was reduced to 13 mg/L and valve culture was negative. 16 S rDNA PCR of the leaflets showed *streptococcus sanguinis*. Patients 2 and 3 were operated after completed antibiotic treatment (≥6 weeks) and without any remaining signs of active infection. In patient 2, TAVI was initially performed to treat the AR, but the valve dislocated causing a large paravalvular leakage (PVL) necessitating surgery. Patients 4–6 had SVDs with leaflet tears that manifested more than 10 years after Freestyle implantation. In two of these the tears were in the commissural area.

One patient was female. Age ranged from 48 to 82 years. Mean EuroSCORE II was 12 ± 7. Patients 1 and 6 were second time redo. One patient refused blood transfusion during the complete treatment course.

Surgical technique

All patients underwent redo-sternotomy and central cannulation for cardiopulmonary bypass. Antegrade cold blood cardioplegia was administered, and in one patient supplemented with retrograde infusion. The aortotomy was distal to the Freestyle graft, except for patient 1 in which the aortotomy also included the Freestyle root for root enlargement. In patient 2 the TAVI was explanted. The degenerated Freestyle leaflets were completely excised in all patients. In line with the preoperative imaging there were no abscesses or pseudoaneurysms and the

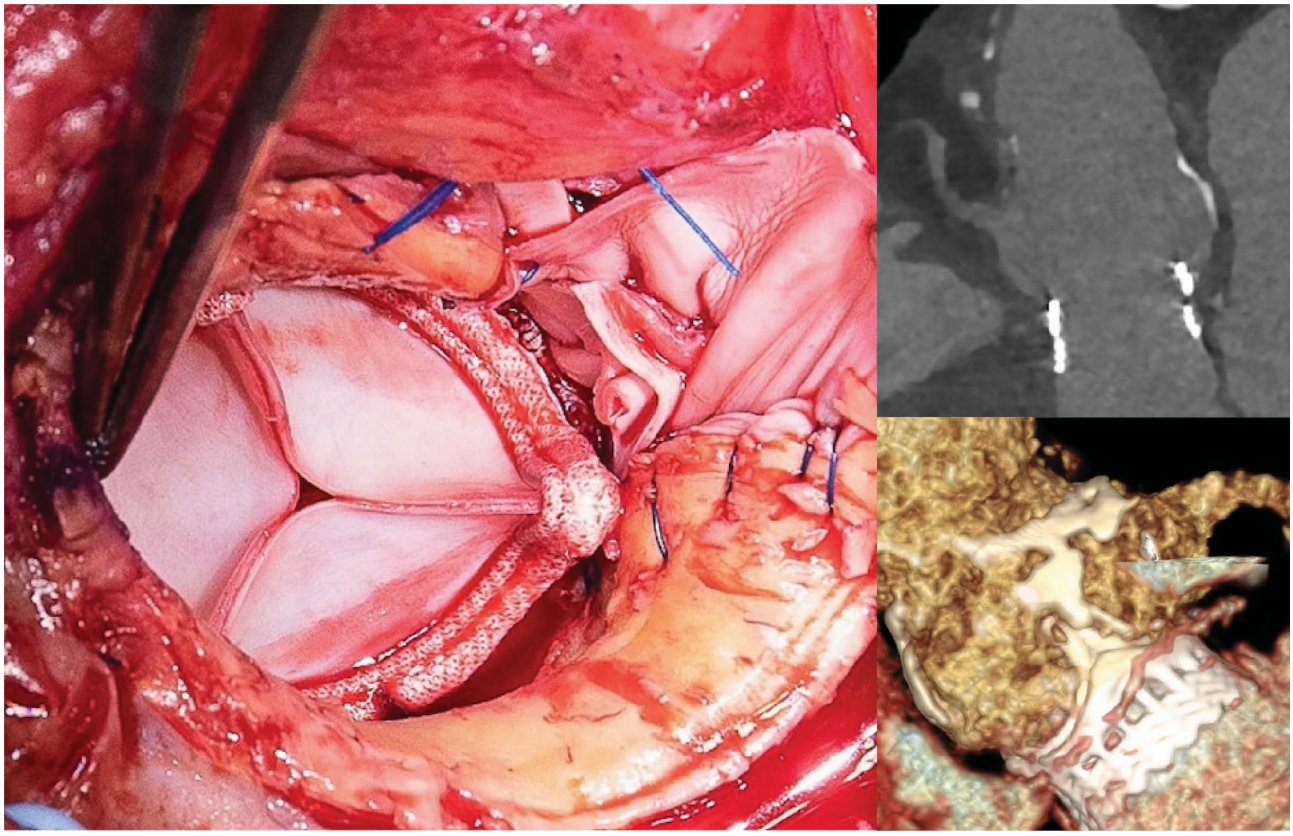

Fig. 1 Intuity in Freestyle. Clockwise from the left: Peroperative image of Intuity implanted in Freestyle after aortic root enlargement. Follow-up cardiac CT-scan as illustrated here showed adequate conditions in the Freestyle root after Intuity-implantation in all

Freestyle root could be retained in all, also in the patients with history of endocarditis. The optimal Intuity size was then determined by assessment of the Freestyle root and annulus with the Intuity sizer. It was observed that the largest possible valve implant was systematically 1–2 sizes below the original Freestyle size. The Freestyle size ranged from 21 to 29 mm, while the Intuity size ranged from 19 to 27 mm. The patient with the smallest Freestyle (21 mm) had been narrowed and only Hegar 17 sizer could pass through. The patient underwent root enlargement by an extended aortotomy through the commissure between the left and non-coronary sinus in which a bovine pericardial patch was sewn. This enabled accommodation of the smallest Intuity valve (Fig. 1). Implantation of the Intuity was performed by certified surgeons in accordance with the manufacturer's guidelines. Three guiding stitches (Ethibond 2−0) were placed at nadir. The valve was thereafter parachuted inside the annulus with the Intuity implantation system, and the balloon inflated after achieving a correct position. A safe distance between the coronary ostia and the annulus of the valve was secured.

Postoperative course and outcome

One patient was reoperated due to bleeding. Otherwise, there were no severe per- or postoperative complications such as myocardial infarction, stroke, need of postoperative mechanical circulatory support, postoperative hemofiltration/dialysis or a new indication for permanent pacemaker. The patients were treated with anti-thrombotic prophylaxis in-hospital. If no other indication for therapeutic oral anticoagulation were present, they were treated with aspirin for a minimum of 3 months postoperatively.

Postoperative echocardiography was performed at baseline (discharge) and after a median of 24 months (range 1–31), presented in Table 2. The peak gradient was 19±7 mmHg at baseline and 14±7 at follow-up. A considerable decrease in both the LV mass index (157±19 g/m^2 at baseline vs. 125±19 g/m^2 at follow-up, p=0.007) and LV end-diastolic dimension (6.4±0.6 cm at baseline vs. 5.5±0.5 cm at follow-up, p=0.005) was observed. A trend towards improvement in the LVEF was evident, but statistically insignificant (baseline 47±6% versus 54±9% at follow-up, p=0.085). No PVL was noted in any of the 6 patients. All patients had cardiac CT follow-up with no signs of coronary ostial occlusion, valve thrombosis, pseudoaneurysm or other postoperative complications

Table 1 Pre- per- and postoperative variables

BVF-subgroup	Endocarditis			SVD			Overall
Patient number	**1**	**2**	**3**	**4**	**5**	**6**	-
Preoperative variables							
Age (years)	48	72	66	82	60	61	65 ± 12
Sex	Male	Male	Female	Male	Male	Male	1/6 (Female)
EuroSCORE II	23.3	16.2	12.2	12.2	4.8	4.1	12 ± 7
REDO	2	1	1	1	1	2	1*
LVEF (%)	40	40	51	44	57	58	48 ± 8
History of endocarditis	Yes (active)	Yes	Yes	No	No	No	*n* = 3
Frestyle (mm)	21	29	25	27	29	27	**
Duration (Years)	3.0	6.0	7.6	11.9	12.2	10.2	8.5 ± 3.6
Creatinine (µmol/L)	70	106	83	95	84	82	87 ± 12
Hypertension	No	No	No	Yes	No	Yes	*n* = 2
DM	No	No	No	No	No	No	*n* = 0
Preoperative pm	Yes	Yes	No	No	Yes	Yes	*n* = 4
Peroperative variables							
Intuity (mm)	19	27	21	25	25	23	**
HLM/ACC (min)	312/252	172/113	75/49	132/85	92/75	70/52	142 ± 92/ 104 ± 76
Postoperative variables							
Intubation time (hours)	34	18	4	4	4	3	4* (3–34)
ICU-time (days)	6	4	3	1	1	1	2* (1–6)
Hospital stay (days)	16	36	12	6	9	6	10* (6–36)
AF	No	No	No	No	No	Yes	*n* = 1
New pm indication	No	No	No	No	No	No	*n* = 0

Pre- per- and postoperative variables for patients 1–6. BVF: Biological valve failure. SVD: Structural valve degeneration. REDO: Number of previous open cardiac surgical procedures. LVEF: Left ventricular ejection fraction. Duration: Years since implantation of the Freestyle bioprosthesis. DM: Diabetes mellitus. Preoperative pm: Previous permanent pacemaker implantation. HLM: Time on heart-lung machine, ACC: Aortic-cross clamp time. ICU: Intensive care unit. AF: New onset of atrial fibrillation. New pm indication: New postoperative permanent pacemaker implantation indication. Overall values are mean ± SD or *median (range). ** marks categorical data not presented in overall column

(Fig. 1). During a median follow-up of 30 months (range 7–45) there were no incidents of biological valve failure or any events within the composite endpoint of major adverse cardiac and cerebrovascular events [14].

Discussion and conclusions

At our institution an increase in valve failure rates of biological full root replacements has been observed. When the root can be preserved, a valve-in-root implantation is pursued.

In contrast to TAVI, open surgery enables inspection of the valve and root in addition to excision of the leaflets for microbiological examination. Although TAVI is contraindicated in endocarditis, it was performed in one of the patients in this case series after completed treatment with antibiotics, due to operative risk assessment. However, the lack of calcification of the Freestyle valve makes correct positioning and proper seating of the TAVI valve difficult, as exemplified in this patient case. It should also be emphasized that TAVI is less suitable for implantation in Freestyle roots due to the short distance from the annulus to the left main coronary ostium, thereby increasing the risk of acute coronary occlusion.

All implantations of an Intuity in a Medtronic Freestyle full root at our institution were surgically successful. There were no deaths during follow-up. Echocardiographic examinations have demonstrated low pressure gradients, reverse LV remodelling and no PVLs.

As implantation of the Intuity valve demands fewer sutures compared to a standard surgical valve replacement, this was our method of choice. The haemodynamic profile of Intuity should be of advantage in a calcified, degenerated Freestyle root. Further, the low profile was assumed beneficial due to the low coronary ostia of the Freestyle root. An alternative and comparable valve to the Intuity is the sutureless Perceval prosthesis. For this valve no sutures are required implicating shorter cross-clamp time, and the valve-system facilitates inspection of the annular seating. On the other hand, the Intuity has lowest gradients and is the valve of choice at our centre. Both valves have been shown to reduce cardiopulmonary bypass and cross-clamp times [7–10, 15]. In our cases we

Table 2 Echocardiography at discharge and latest follow-up

Patient number		1	2	3	4	5	6	Overall	P
Follow-up (months)		31	29	13	29	20	1	**24* (1–31)**	
Gradients peak (mmHg)	Baseline	17	9	28	12	22	23	**19 ± 7**	*0.346*
	FU	9	10	13	27	11	13	**14 ± 7**	
Gradients mean (mmHg)	Baseline	10	5	15	9	13	14	**11 ± 4**	*0.208*
	FU	5	6	7	15	5	8	**8 ± 4**	
LVEF (%)	Baseline	40	42	51	44	57	50	**47 ± 6**	*0.085*
	FU	45	48	69	57	55	50	**54 ± 9**	
LVEDd (cm)	Baseline	5.60	6.80	6.40	7.20	5.90	6.50	**6.4 ± 0.6**	*0.005*
	FU	5.40	5.70	4.70	6.30	5.10	5.50	**5.5 ± 0.5**	
LV mass index (g/m^2)	Baseline	128	158	149	180	152	176	**157 ± 19**	*0.007*
	FU	123	132	92	150	123	128	**125 ± 19**	

Postoperative aortic valve gradients (Gradients), left ventricular ejection fraction (LVEF), LV end-diastolic diameter (LVEDd) and LV mass index at discharge (baseline) and at last echocardiographic follow-up (FU). Overall values are mean ± SD or median* (range)

observed long bypass and cross-clamp times, but this was attributed to the complexity of the cases. In particular, the concomitant aortic root enlargement procedure and the TAVI explantation affected cross-clamp time. Furthermore, adhesions, rigid, hostile roots and challenging exposure complicated the valve implantation in all patients. Especially in these settings a more efficient valve employment method should be aimed for, and we argue that the RDV-approach is beneficial for redo patients with increased surgical risk [9, 10, 12, 13]. It should also be considered in other challenging settings such as after TAVI explantations in native roots [16].

Several considerations must be taken into account when selecting patients for RDV treatment. Contemporary literature addresses an increased risk of conduction failure and PVL related to implantation of RDV and sutureless prostheses compared to standard surgical valves [10, 17, 18]. To note, White et al. found the opposite result regarding indication for permanent pacemakers in their study of redo aortic valve replacement patients. They argue that less debridement and manipulation may be protective for the conduction system [9]. In line with this, the two patients without preoperative pacemaker in our series had no new indication for postoperative pacemaker implantation. Moreover, no PVL or valve migration occurred in any of our cases. Treatment of AR with Intuity in a native root has not been approved due to a less stable valve seating and often cojoined annular dilatation. This is not the case in fibrotic, degenerated Freestyle roots.

Optimal surgical endocarditis treatment includes debridement of all infected tissue. Although no evidence of periannular infection in the included endocarditis patients was present, our decision not to replace the Freestyle root could be questioned. As redo root replacement may be hazardous in some patients, we applied a pragmatic strategy to minimize surgical risk. No patients have been readmitted with endocarditis.

In conclusion, the implantation of a RDV in a degenerated Freestyle is a safe and effective alternative. We observed a favourable haemodynamic profile, reverse LV remodelling and excellent early and midterm outcomes.

Abbreviations

ACC	Aortic-cross clamp time
AR	Aortic regurgitation
BVF	Biological valve failure
CPB	Cardiopulmonary bypass
CRP	C-reactive protein
CT	Computed tomography
MRI	Magnetic resonance imaging
HLM	Time on heart-lung machine
ICU	Intensive care unit
LV	Left ventricular
LVEDd	LV end-diastolic diameter
LVEF	Left ventricular ejection fraction
PCR	Polymerase chain reaction
PVL	Paravalvular leakage
RDV	Rapid deployment valve
SD	Standard deviation
SVD	Structural valve deterioration
TAVI	Transcatheter aortic valve implantation

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Author contributions
Authors` contributions: SMK and RH contributed to the conception and design of the work. SMK, RH and SS contributed to the analysis and interpretation of the data. SMK, RH and SS wrote the main manuscript text. All authors have been included in drafting the work and have substantively revised it and have approved the submitted version AND have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated, resolved, and the resolution documented in the literature.

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Data availability
Availability of data and materials: The datasets used and/or analysed during the current study are available from the corresponding author upon reasonable request. The data supporting the results reported can be found in the local electronic patient journal at Haukeland University Hospital. The dataset and statistics are anonymized, performed and saved on an electronic data server at our hospital.

Declarations

Consent for publication
All patients have provided written informed consent for inclusion and publication in this case report series.

Competing interests
The authors declare no competing interests.

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