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Performance of the Transcatheter Lotus™ Valve System in Patients at High Risk of Paravalvular Regurgitation

Mounir Riahi MD[1], Jean-Bernard Masson MD[1-2], Charbel Naim MD[1], Jean-François Gobeil MD[1], Nicolas Noiseux MD[1-2], Louis-Mathieu Stevens MD[1-2], Marco Spaziano MD[3], Nicolo Piazza MD[3], Giuseppe Martucci MD[3], Benoit de Varennes MD[3], Kevin Lachapelle MD[3], Jeannot Potvin MD[*1-2]

[1]*Centre Cardiovasculaire du Centre Hospitalier de l'Université de Montréal*

[2] *Centre de Recherche du Centre Hospitalier de l'Université de Montréal*

[3] *McGill University Health Centre*

**Corresponding author: Dr. Jeannot Potvin, Centre Hospitalier de l'Université de Montréal 3840 St-Urbain, Montréal, Québec, H2W1T8, Tel : 514-890-8000; Fax : 514-412-7212; Email :jeannotpotvin@hotmail.com*

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Abstract

Background
Transcatheter aortic valve implantation (TAVI) with currently available systems has been associated with the potential of paravalvular aortic regurgitation (PVR) and device malpositioning. The Lotus™ is a second generation, fully repositionable and retrievable transcatheter heart valve that features an outer membrane specifically designed to prevent PVR.

Method
Patients were selected among TAVI candidates upon evaluation by the heart team. They showed a higher risk for PVR as determined by high excentricity index or heavy annular and valvular calcification on cardiac computer tomography. TAVI procedures were performed by experienced operators in two different sites.

Results
A total of ten patients underwent TAVI with the Lotus valve system. Mean age was 83.4±4.1 years. Average Logistic Euroscore II and STS mortality risk score were 6.6% and 5.7% respectively. Eight of these patients were at high risk of PVR (eccentricity index > 0.25 and/or cover index < 8%). All procedures were successful. The valve was partially resheathed and repositioned in 5 cases. No PVR was observed in 9 patients; one had a moderate leak immediately after implant, which resolved to trace at day one. Three patients required permanent pacemaker implantation.

Conclusion
In our initial experience, the Lotus™ Valve System allowed precise positioning and prevented PVR despite high-risk anatomy.

Keywords: Transcatheter aortic valve implantation (TAVI); Lotus™ Valve System; paravalvular aortic regurgitation; aortic stenosis.

Introduction

Transcatheter aortic valve implantation (TAVI) is now a proven and recognized alternative to surgical aortic valve replacement (SAVR) for high-risk or inoperable patients with severe symptomatic aortic stenosis [1-4]. However, current devices and techniques have been associated with a higher risk of paravalvular regurgitation (PVR) compared to SAVR and more-than-mild PVR has been linked to adverse outcomes in TAVI patients [5,6]. Multiple factors have been identified as potential causes for PVR including annular eccentricity, lack of oversizing, non-symmetric distribution and/or high burden of calcification and malpositioning [7-9]. While better patient selection and procedural awareness may mitigate this risk, system improvements enabling precise valve positioning and better annular sealing may improve outcomes. The Lotus™ Valve System (Boston Scientific, Natick, MA, USA) is a fully repositionable and retrievable device designed to facilitate precise positioning while its Adaptative Seal™ technology aims to minimise PVR. The REPRISE I and II studies [10,11] showed promising outcomes in an all-comers TAVI population but have not specifically enrolled patients with high-risk features for PVR. The Lotus™ system received CE mark in October 2013 [12] and is currently available under the Special Access Program in Canada. We hereby describe its main features and present the results of a series of 10 patients, the majority being at high risk of paravalvular regurgitation.

SYSTEM OVERVIEW

The system has two main components: a bioprosthetic aortic valve (sizes: 23, 25 or 27mm) and a delivery system designed for a transfemoral retrograde approach.

The valve implant comprises three bovine pericardial leaflets supported by a braided nitinol frame. A radiopaque marker is located at the vertical centre of the frame for visual guidance during deployment. The Adaptive Seal™ is a polymer membrane circling the bottom half of the device designed to reduce PVR by conforming to the irregular surfaces of the calcified native anatomy (Figure 1).

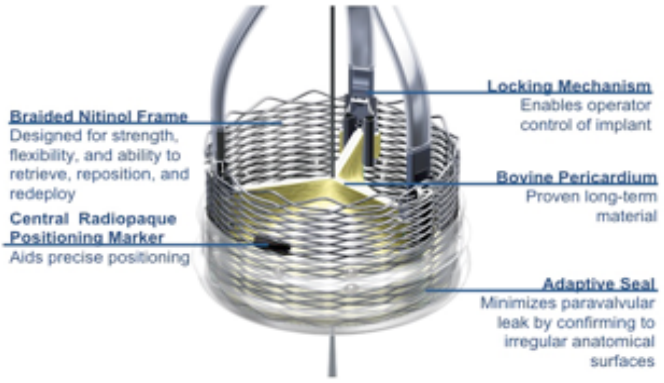

Figure 1. Overview of the different components of the Lotus™ valve. Image copyright: Boston Scientific.

The valve is premounted on the delivery system and is loaded within the catheter after adequate rinsing. A handle with two controls (control knob and release collar) allows for deployment/locking of the device by counterclockwise rotation of the knob and unlocking/recapture by a clockwise movement. The distal portion of the delivery system is curved to facilitate crossing of the aortic arch (Figure 2).

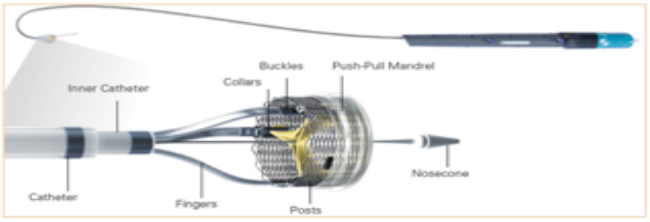

Figure 2. The Lotus™ Valve delivery system. Image copyright: Boston Scientific.

As the device is unsheathed, the frame shortens and radially expands to provide anchoring within the aortic annulus. Once anchored, further unsheathing produces mechanical expansion of the valve frame until it is locked into its final conformation. At any time prior to final release, including when it is completely deployed and locked, full recapture and retrieval of the valve is possible. The Lotus™ valve leaflets become functional early in the deployment process, providing hemodynamic stability and enabling controlled positioning with no need for rapid pacing.

METHOD

Patient selection

Procedures were performed at the Centre Hospitalier de l'Université de Montréal (CHUM) and the McGill University Health Center (MUHC). High-risk patients referred for management of severe aortic stenosis underwent clinical evaluation and, when appropriate, transthoracic echocardiography (TTE), multisliced computed tomography and coronary angiography. The multidisciplinary Heart Team discussed all patients and reached an agreement for the best available treatment.

Among transfemoral TAVI candidates, patients were considered for Lotus™ implantation over commercially available transcatheter heart valves if they presented one or more of the following criteria: higher risk of PVR (elliptic annulus and/or eccentric distribution of annular or leaflet calcification) (Figure 3), prohibitive risk of emergent sternotomy in case of malpositioning (restrosternal mammary grafts) or potential instability associated with rapid pacing (severe LV dysfunction

or significant non-revascularizable coronary disease).

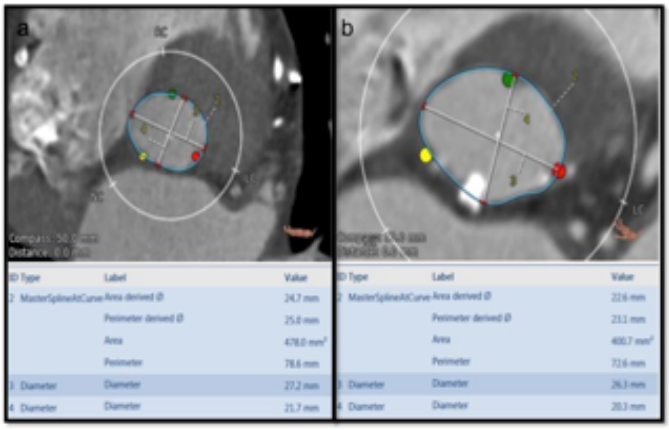

Figure 3. Examples of CT scan morphometric evaluation.
(a) Patient #1 and (b) Patient #2. Note the ovaloïd shape of the annulus in both patients and the heavy calcification over the non-coronary cusp in patient #2

Procedure overview

The procedure can either be performed under general anaesthesia with transesophageal echocardiography (TEE) guidance or under conscious sedation with TTE imaging as needed. After confirmation of proper puncture site and femoral artery pre-closure, the Lotus™ introducer sheath is inserted in the common femoral artery and advanced into the abdominal aorta. Contralateral arterial and venous accesses are obtained for aortography and temporary pacemaker placement, the later being placed as a back-up only. The Lotus™ valve is advanced over a preshaped extrastiff Safari™ wire. Correct orientation of the pre-curved delivery catheter is ensured by positioning the radiopaque marker of the undeployed valve towards the greater curvature of the arch. The catheter is then advanced across the annulus and positioned so that the ventricular end of the frame is at the annular level or slightly inside the outflow tract (Figure 4a). Unsheathing is initiated and early valve function provides continuous hemodynamic stability for careful and controlled positioning. Typically, the central marker should be maintained 4 to 6mm above the annular plane (middle height of the curved segment of a pigtail catheter sitting in the right or non-coronary cusp can be used as a reliable marker). Aortography and echocardiography are used to confirm valve position, coronary patency and absence of significant PVR. After fluoroscopic confirmation that the locking process has been successfully completed, the valve is released by sliding the release window and rotating the collar clockwise. The nosecone is then resheathed to its original position and the catheter is retrieved through the introducer sheath. The temporary pacemaker is removed within a few hours if no conduction delay is observed.

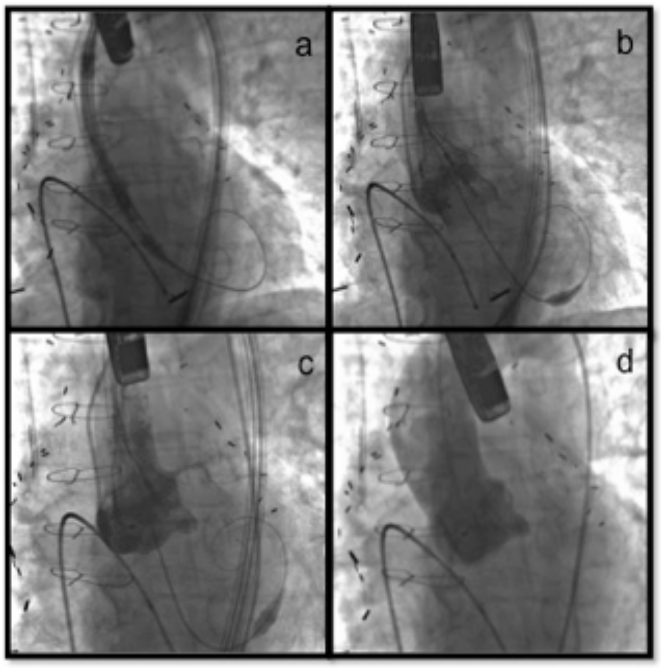

Figure 4. Deployment steps.
(a) Valve crossing; (b) The initial position was lower than desired; (c) Adjusted position with the marker slightly above the annular plane; Final release aortogram showing no aortic regurgitation (d).

Definitions and Outcome

Device success and early safety were recorded according to the VARC-2 criteria [13]. Aortic annulus eccentricity index was determined using the previously described formula 1 – (Dmin/Dmax) [7]. Clinical evaluation was performed at discharge and 30 days. Prosthetic valve hemodynamic profile was documented at TTE during index hospitalization.

RESULTS

A total of ten patients underwent TAVI with the Lotus valve system. Mean age was 83.4±4.1 years. Average Logistic Euroscore II and STS mortality risk score were 6.6 and 5.7 respectively. Five patients were deemed at high SAVR risk due to a retrosternal mammary graft. Mean aortic valve area was 0.75±0.12cm^2 and mean transvalvular gradient was 49.4±13.9mmHg by TTE. Baseline characteristics are presented in Table 1. CT-Scan evaluation revealed an elliptic annulus in most patients, with an average eccentricity index of 0.24 (Table 2).

General anaesthesia was used in all but one patient. Direct TAVI without balloon valvuloplasty was performed in all patients. Hemodynamic instability was not observed. VARC-II defined device success was achieved in all cases and there were no vascular complication. A permanent pacemaker was implanted in three patients.

Table 1. Patient characteristics

	N= 10
Age (y)	83.4 (±4.1)
F	5 (50%)
CAD	5 (50%)
Previous CABG	5 (50%)
NYHA	
I	0
II	4 (40%)
III	4 (40%)
IV	2 (20%)
GFR≤60 ml/min	4 (40%)
GFR≤30 ml/min	0
	0.75 ±0.12
Mean TransAortic Gradient (mmHg)	49.4 ± 13.9
LVEF < 40 %	1 (10 %)
Significant aortic regurgitation*	0

GFR: Glomerular filtration rate; **AVA:** Aortic valve area; **LVEF:** Left ventricle ejection fraction; **CAD:** Coronary artery disease. * Aortic regurgitation >mild.

In order to optimize an initially low implant (n=4) or correct moderate PVR (n=1), partial resheathing and redeployment was successfully performed in half of the cases (Figure 4). In one patient, moderate PVR was observed upon partial deployment of the valve. It was repositioned three times in a slightly higher position in attempts to obtain better sealing of the annulus and reduce PVR. Moderate AR persisted despite what was judged the highest implantation possible without impingement in coronary flow (Figures 5a and 5b). TTE performed in this patient one day after implant showed reduction of PVR from moderate to trace (Figure 5c).

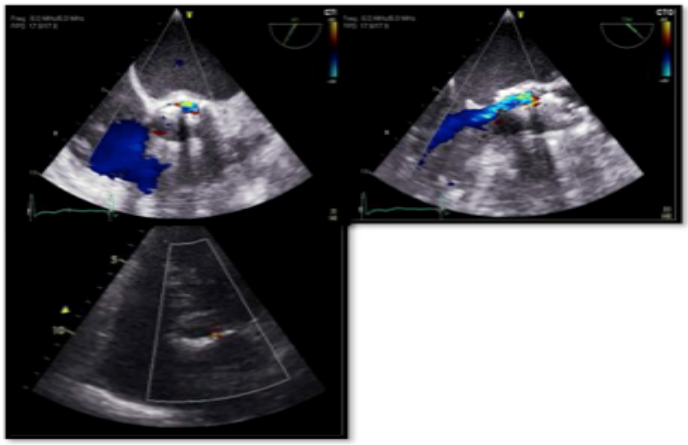

Figure 5. Resolution of a moderate PVL after 24h in patient #2. Post release TEE showing a moderate PVL (a,b). A four chamber TTE at 24h showing trace AR (c).

PVR was not seen by echocardiography or angiography in the other 9 patients. In another patient, transient QRS enlargement was resolved by redeploying the valve in a higher position.

Table 2. Morphometric characteristics.

	Eccentricity Index[$]	Basal ring area (mm^2)	LVOT area (mm^2)	Valve Size (area mm^2)	Cover Index[#]	Annular Oversizing	Annular Calcification	Partial resheating
#1	0.21 (22 x 28)	474	523	27mm (572)	9,0%	20.7%	Moderate	1
#2	0.27 (19 x 26)	386	377	23mm (415)	3,6%	7.5%	Heavy	3
#3	0.35 (20 x 31)	522	568	27mm (572)	4,5%	9.6%	Mild	0
#4	0.24 (19 x 25)	375	350	23mm (415)	4,9%	10.7%	Moderate	0
#5	0.16 (21 x 25)	410	495	25mm (491)	8,6%	19.8%	Mild	0
#6	0.26 (20 x 27)	437	356	23mm (415)	-2,6%	-5.0%*	Moderate	1
#7	0.19 (22 x 27)	471	492	25mm (491)	2,0%	4.2%	Moderate	1
#8	0.29 (20 x 28)	507	558	27mm (573)	5,9%	13.0%	Heavy	0
#9	0.26 (23 x 31)	546	462	27mm (573)	2,4%	4.9%	Heavy	2
#10	0.21 (22 x 28)	443	460	25mm (491)	5,0%	10.8%	Moderate	0
Average (SD)	**0,24 (0.05)**	**457 (57.5)**	**464 (79.7)**	-	**4,3% (3,4)**	**9.6% (7.5)**		

*Decision was made to undersize the valve because of a small LVOT area and prevision of a deep implantation site due to a low left main ostium position (10mm). [$] **Excentricity index**= 1-(minimal annular diam/ maximal annular diamter). # **Cover index**= 100 x ((valve diameter-annulus area derived diameter) / valve diameter)). **LVOT**: Left ventricular outflow tract.

Conduction disturbances were observed in 5 patients, including 3 that required permanent pacemaker placement (Table 3). There was no difference in annulus or LVOT oversizing in patients with or without new PPM implantation (10.2% vs 10.1% and 7.8% vs 9.4% respectively, p=NS for both). Median length of stay was 4.5 days (IQ 3-5) but only 3 (IQ 3-3) in patients who did not require permanent pacing. Follow-up at 30 days was completed in the 10 patients and VARC-2 early safety criteria were met in all (Table 4).

Table 3. Conduction outcomes.

	Baseline Conduction abnormality	New Conduction abnormality	Annular Oversizing	LVOT Oversizing	Management	Follow up
#1	None	None	20.7%	9.4%	Surveillance	Stable at 1 mo
#2	None	New LBBB	7.5%	10.1%	Surveillance	Resolution at 3 mo.
#3	None	None	9.6%	0.7 %	Surveillance	New LBBB at 1mo
#4	LBBB	None	10.7%	18.6%	Surveillance	Stable at 1mo
#5	None	New LBBB+ 1st Degree AVB	19.8%	-0.8%	PPM (prophylactic)	No pacing
#6	None	Complete AVB	-5.0%*	16.6 %	PPM	Paced rhythm
#7	1st Degree AVB	None	4.2%	-0.2%	Surveillance	Stable at 1mo
#8	None	None	13.0%	2.7 %	Surveillance	Stable at 1mo
#9	1st Degree AVB	LBBB	4.9%	24.1%	Surveillance	Stable at discharge
#10	AF (permanent)	Complete AVB	10.8%	6.7%	PPM	No pacing at discharge

LBBB: Left Bundle Branch Bloc; **AVB:** Atrioventricular Bloc; **PPM:** Permanent Pacemaker. **AF:** Atrial Fibrillation

Table 4. Procedural outcome and early safety

	N (10)
Device success¥	10 (100%)
30 days follow-up completed	8 (80%)
Aortic valve area (mean)*	2,0 cm^2
Transvalvular gradient (mean)*	10,2 mmHg
Significant PVL *&	0
Stroke/TIA	0
Major vascular complication	0
Coronary artery disease requiring intervention	0
Repeat procedure for valve-related dysfunction	0
Acute kidney injury	0
AVB	2 (20 %)
PPM	3 (30 %)
Median hospital stay (days)	4,5 (IQ:3-5)
Median hospital stay (No PMP) (days)	4 (IQ;2.5-4.5)

¥ According to VARC-2 criteria. * TTE at 24h. & Aortic regurgitation >mild.

AVB: Atrioventricular block. **PPM:** Permanent Pacemaker. **TIA**: transient ischemic stroke.

Discussion

Our initial experience with the Lotus™ valve illustrates potential advantages of this second generation system. As TAVI continues to show promising results in high-risk populations, wider application will require improvements in some of the weaknesses of the current technology. First, PVR prevention is increasingly recognized as a determinant factor with multiple reports suggesting that PVR is correlated with increased late mortality [5,6,14]. Imaging studies have suggested that native valve burden of calcification, an annulus eccentricity index >0.25 and a cover index <8% are predictors of post-procedural PVR [7-9,15-17]. The Lotus valve showed high rates of circularity 12 months post-implantation in a small CT scan study [18] which, in combination with the Adaptive Seal™, may have contributed to the low rate (1.1%) of significant PVR seen in the Reprise II trial [12]. In our cohort, 8 of 10 patients were at high risk of PVR based on either an eccentricity index over 0.25 (5 patients) and/or a cover index under 8% (8 patients). Despite these high-risk characteristics, none of them had moderate or severe PVR at discharge, including both patients with extreme eccentricity (indexes of 0.35 and 0.29 respectively). This may reflect the predominant role played by the Adaptive Seal™ in PVR reduction. The only moderate leak observed during the procedure spontaneously regressed to trace at 24 hour. This may be due to continued dynamic conformation of the Adaptive Seal™ to the heavily calcified apposition area. Nevertheless, the absence of significant PVR in our small but high-risk cohort suggest that an integrated PVR prevention system may translate into improved clinical outcome. This will require further investigation in a larger population at high risk of PVR.

Second, precise positioning is crucial to avoid serious complications such as device embolization, coronary obstruction or valve-in-valve (TV-in-TV) deployment. TV-in-TV with first generation systems has been associated with increased 1-year mortality [19]. With the Lotus system, partial resheathing can be performed as many times as needed to achieve the optimal desired position within the native annulus. Prior to final release, full recapture of the valve is possible, allowing for device retrieval if a native leaflet obstructs a coronary ostium or if missizing has occurred. These features contribute to increased procedural control and precision and could explain the absence of ectopic or valve-in-valve deployment in the Reprise trials [10-12]. In our series, the repositioning capability proved useful to optimize implant location in half of the cases, including cases where (a) PVR due to a heavily calcified leaflet was reduced and (b) QRS enlargement was corrected with repositioning. Although minimizing native valve manipulation is generally desirable, recent literature does not show signals of

increased stroke risk with repositionable systems [10-12,20] and the need for repositioning may decrease as operators become more familiar with the valve behavior during deployment.

The current Lotus™ system version has potential limitations. First, the delivery sheath profile is higher than other second generation systems, requiring minimal access vessel diameter of 6 and 6.5mm, and alternative access experience is limited to the direct aortic approach thus far. Second, post-procedural pacemaker implantation rate was relatively high in the Reprise program, reaching up to 29.7% [12], similar to what was observed in our cohort. This is likely due to an interaction between the Adaptive Seal™ and the conduction system in the LVOT, with oversizing of both annulus and LVOT playing a potential role [21]. Our study could not corroborate this finding as no apparent trend between LVOT or annular oversizing and PPM implantation was observed. This may be due to our small sample size, but alternative hypotheses such as implantation depth or technique should be explored. Further studies evaluating the mechanical interaction with the underlying conduction system and its causative effects of dysrhythmia are warranted to better understand this issue.

In the modern TAVI era, the paradigm is shifting from utilization of one universal system to a more tailored therapy for specific populations. Owing to its PVR-reducing capabilities, hemodynamic stability during deployment and repositionability, the Lotus system adds to the overall TAVI arsenal. The results of the real-world RESPOND registry and the REPRISE III randomized trial comparing the Lotus and CoreValve (Medtronic) systems will provide important insights into the role of this technology in the growing field of TAVI.

Conclusion

The Lotus™ Valve System provides a combination of advanced features that allow precise positioning. In our selected population at increased risk, paravalvular regurgitation was consistently prevented. Introduction of next generation technology into established TAVI programs may promote individualized therapy and improve outcomes.

Aknowledgement

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Disclosures

Dr Jeannot potvin is consultant and proctor for Boston Scientific. Dr Jean-Bernard Masson is speaker for Boston Scientific. Dr Nicolo Piazza is consultant and proctor for Medtronic. Dr Giuseppe Martucci is proctor for Medtronic. Other co-authors have no potential conflict of interest.

Summary

The Lotus™ Valve is a second generation TAVI system specifically designed to prevent ParaValvular Regurgitation (PVR). We describe ten of the first Canadian Lotus patients. They were selected based on higher risk anatomic features for PVR. All patients underwent a successful procedure. Three patients needed pacemaker implantation. At 30 days follow-up no PVR was observed. The Lotus™ Valve System allowed precise positioning and prevented PVR despite high risk anatomy.

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