SoloPath® sheath for transfemoral transcatheter aortic valve replacement

Strength and limitations and report of a failure due to a kink in tortuous access

Stéphane Noble[a], Nils Perrin[a], Anne-Lise Hachulla[b], Marco Roffi[a]

[a] Cardiology Division, University Hospital of Geneva, Switzerland

[b] Department of Radiology, University Hospital of Geneva, Switzerland

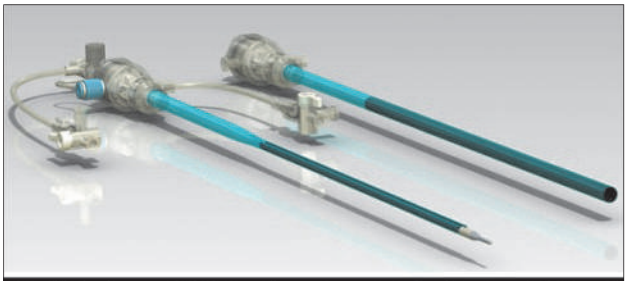
Summary

We share a case of unsuccessful use of the SoloPath® balloon-expandable sheath (Onset Medical, a subdivision of Terumo Medical Corporation, Irvine, CA) in a transfemoral transcatheter aortic valve replacement due to kinking in a patient with large diameter ilio-femoral access and moderate vessel tortuosity. Subsequently, we discuss the advantages and disadvantages of this new technology that may further expand the transfemoral option in transcatheter aortic valve replacement, especially with borderline diameter and/or non-circumferential calcification, but we believe that particular caution should be paid in the presence of significant tortuosity.

Key words: transcatheter aortic valve replacement; vascular access; balloon-expandable sheath; SoloPath® sheath; tortuosity

Introduction

The transfemoral retrograde approach is the most commonly used access for transcatheter aortic valve replacement (TAVR). Detailed vascular screening remains essential in order to avoid vascular complications. Particular attention should be paid to ilio-femoral tortuosity, calcification, as well as minimal lumen diameter: a minimal lumen diameter of at least 6 mm is required for a safe transfemoral procedure using an 18-French (F) sheath. Recently, the SoloPath® balloon-expandable sheath (Onset Medical, a subdivision of Terumo Medical Corporation, Irvine, CA) became available and has been approved by the Food and Drug Administration in the United States since 2011 [1]. The underlying interesting concept consists of a balloon-expandable sheath with a reduced profile when folded (outer diameter of 13 F) allowing facilitated vessel entry and device advancement. The sheath is subsequently inflated by means of an incorporated balloon, up to an inner diameter of between 18 F and 21 F according to the SoloPath® model selected (fig. 1). At the end of the procedure, it is designed to collapse upon withdrawal [2, 3]. Herein we share a case of unsuccessful use of this expandable sheath and discuss the advantages and disadvantages of this new technology.



Model Number	Folded sheath Outer diameter	Expanded sheath Outer diameter	Expanded sheath Inner diameter
STFI-1435	11.5Fr (3.83 mm)	17Fr (5.67 mm)	14Fr (4.67 mm)
STFI-1635	15FR (5 mm)	19Fr (6.33 mm)	16Fr (5.33 mm)
STFI-1835	15FR (5 mm)	21Fr (7 mm)	18Fr (6 mm)
STFI-1935	**15FR (5 mm)**	**22Fr (7.33 mm)**	**19Fr (6.33 mm)**
STFI-2035	15FR (5 mm)	23Fr (7.67 mm)	20Fr (6.67 mm)
STFI-2135	15FR (5 mm)	24Fr (8 mm)	21Fr (7 mm)

Figure 1
SoloPath® characteristics and different sizes.
The left hand side picture shows the folded SoloPath® sheath whereas the right hand side picture shows the expanded version.
The sheath is available in different sizes: inner diameter from 14 F to 21 F with two different lengths: 25 and 35 cm. For TAVI usually the 35-mm long sheath is used. The diameter tip for all models is 5.3 F.
The sheath usually used for CoreValve® is the STFI-1935. The STFI-1835 can be used but there is more friction while advancing the CoreValve® system through the sheath since the end of the delivery system (the capsule) is 18 F. (The upper part of the figure was provided by Terumo Medical.) F = French.

Funding / potential competing interests:
S. Noble, MD, is a trainer for Medtronic CoreValve®. Medtronic had no role in the design, subject recruitment or preparation of this case report.

Correspondence:
Stéphane Noble, MD
Interventional Cardiology Unit
University Hospital of Geneva
CH-1211 Geneva
Switzerland
Stephane.noble[at]hcuge.ch

Case report

A 91-year-old active patient, who had been followed for several years for critical aortic stenosis (mean gradient of 60 mm Hg, normal left ventricular ejection fraction, valve area of 0.6 cm^2) with mild symptoms, was admitted for overt heart failure. The coronary angiogram did not show any significant coronary artery lesions while the left–right heart catheterisation confirmed the severity of the aortic stenosis. The logistic EuroSCORE and the STS (Society of Thoracic Surgeons) scores were 11.4 and 4.4% risk of mortality, respectively. Considering the frailty of this nonagenarian, the heart team decision was to propose transfemoral TAVR since the ilio-femoral vascular access was considered suitable. Indeed, the minimum diameter at ilio-femoral angiography was around 8 mm, while moderate vessel tortuosities were present (fig. 2).

Under local anaesthesia and conscious sedation, we punctured the common femoral artery and per-

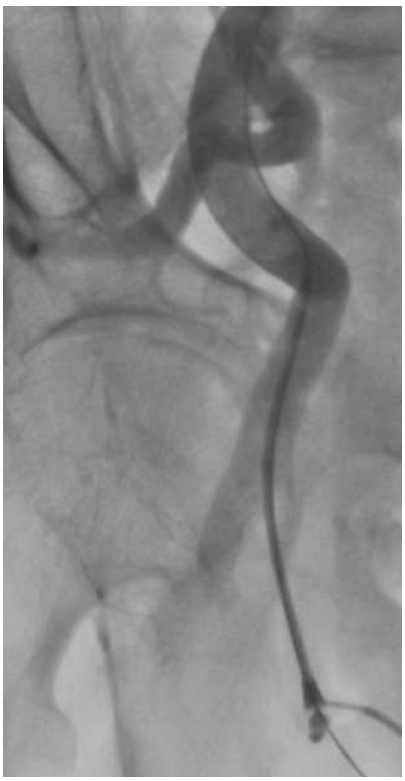


Figure 2
Right ilio-femoral access before large sheath insertion with moderate tortuosity and mild calcification.

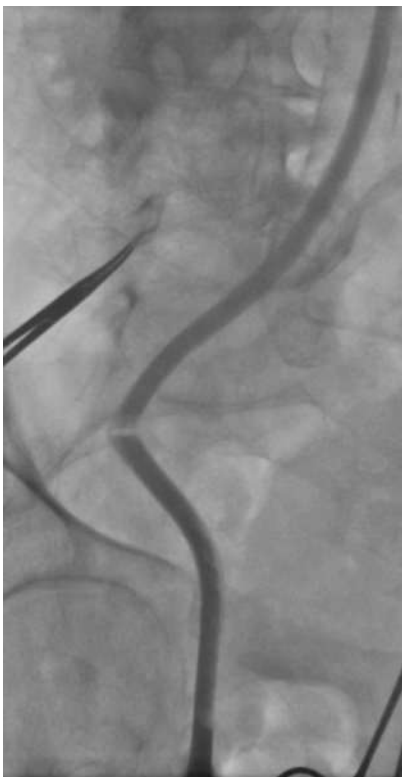


Figure 3
19-F SoloPath® sheath (Onset Medical) with a kink.

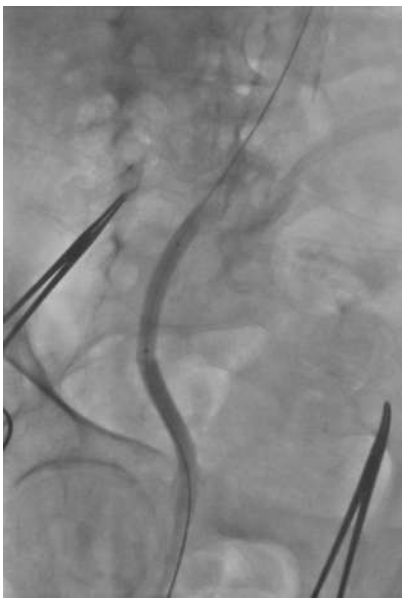


Figure 4
Admiral Xtreme 7 × 40 mm (Medtronic) balloon inflated in the SoloPath® sheath.

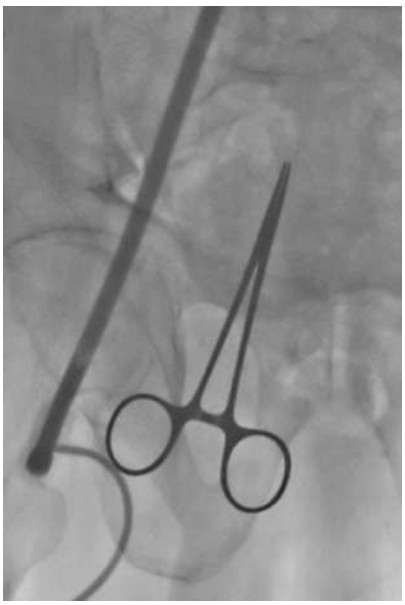
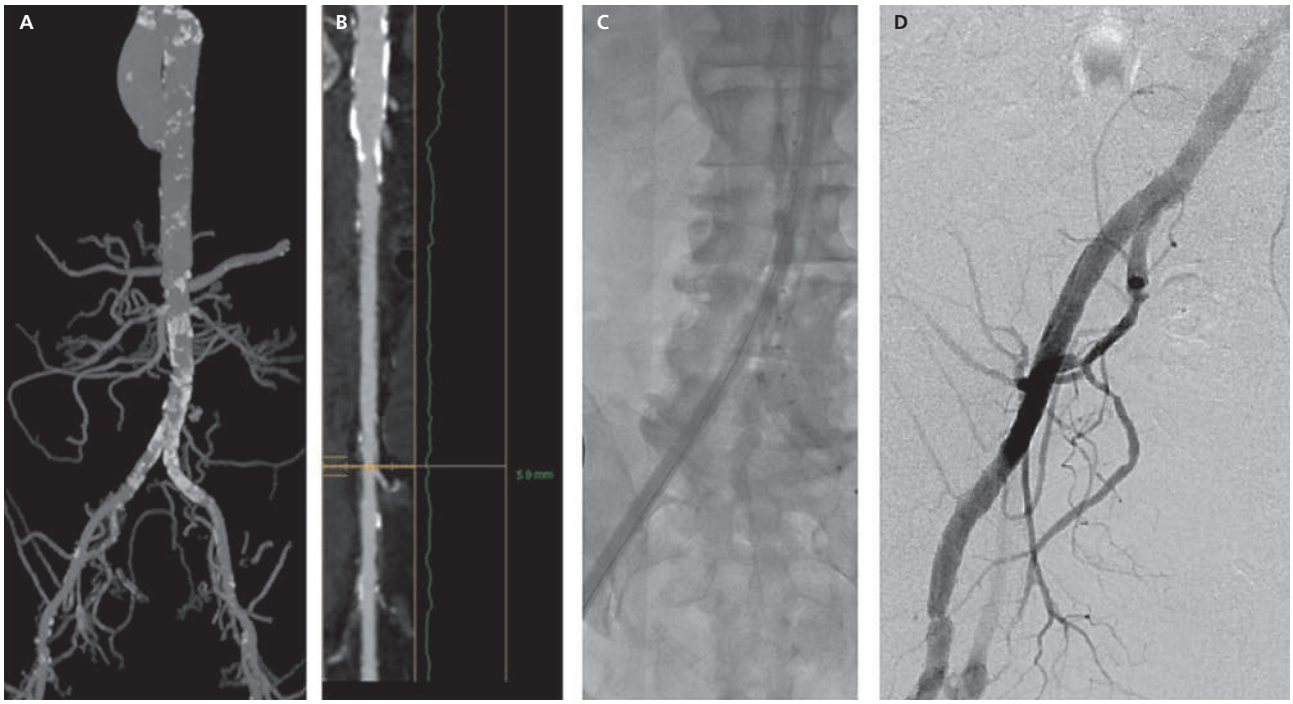


Figure 5
18-F Cook sheath (Cook Medical) which straightened the ilio-femoral access.

Figure 6
Successful case of SoloPath® use in a borderline anatomy (patient 9).
A CT scan assessment using MIP (Maximum Intensity Projection) showing the bilateral ilio-femoral axis with calcification at the level of the common iliac arteries.
B Reconstruction of the right ilio-femoral axis with the smallest diameter measured at 5.9 mm.
C SoloPath® 19-F sheath inflated.
D Final angiographic control.



formed the pre-closure technique using the Prostar® XL10 (Abbott Vascular, Reedwood City, CA). Over a Super Stiff™ ST-1 wire (Boston Scientific, Maple Grove, MN, USA) we inserted a folded 19-French SoloPath® sheath without any difficulties. As recommended by the instructions for use, once the sheath was full inserted we inflated the sheath balloon at 20 atmospheres for one minute. As we commonly did with other large-bore sheaths, the stiff wire was retrieved simultaneously with the dilator. At this time we noticed a kink in the sheath at the level of the iliac tortuosity (fig. 3), this kink was overcome with some difficulty by advancing a 0.035" wire. Subsequently, the kinked portion of the sheath was dilated with a peripheral balloon catheter (Admiral Xtreme 7 × 40 mm; Medtronic, MN, USA) (fig. 4). However, since we were not satisfied with that aspect of the sheath and we feared difficulties in advancement or retrieval of equipment during the procedure, we preferred to exchange the SoloPath® sheath for an 18-F Cook sheath (Cook Medical, Bloomington, IN, USA), which completely straightened the vessel (fig. 5). The procedure was then completed by pre-dilatation and successful implantation of a 29 Medtronic CoreValve®. The final ilio-femoral angiography from the contralateral femoral access showed no vascular complication or bleeding.

Discussion

We report the unsuccessful use of a SoloPath® sheath in a transfemoral TAVR due to kinking in a patient with large diameter ilio-femoral access and moderate vessel tortuosity. Only a limited number of reports are available addressing this interesting new technology [2–4] which may potentially expand the indication for transfemoral TAVR. The device provides enhanced manoeuvrability, utilises the natural elasticity of vessels and thus enables delivery through challenging ilio-femoral anatomies. This expandable sheath provides a clear advantage in the case of borderline vessel diameter or potentially in vessels where advancing an 18-F sheath would be difficult in the presence of calcification. However, particular attention should be paid to vessel tortuosity because kink resistance of the SoloPath® sheath may be inferior to other introducer sheaths. In the case reported, the fact that we retrieved the stiff wire at the time of introducer retrieval likely contributed to the worsening of the kink. However, since in our practice we separate the "access phase" from the "valve phase" (i.e., the native valve crossing, balloon valvuloplasty and prosthetic valve placement), we do not always have a stiff wire in place.

In our experience of 10 cases (table 1, fig. 6), we were confronted with two CoreValve® embolisations

Table 1

Patient	Age[1]	Sex[2]	CoreValve® size[3]	Diabetes[4]	Reason[5] to use SoloPath®	Vascular complication[6]	CV death at 30 days[6]
Pt 1*	83	F	26	1	Calcification	0	0
					Small vessel		
Pt 2*	86	F	26	0	Small vessel	0	0
Pt 3**	91	M	31	0	Mild	0	0
					Calcification		
					Tortuosity		
Pt 4	91	F	29	0	Calcification	0	0
					Mild stenosis		
Pt 5	78	M	29	1	Small vessel	0	0
					Calcification		
					Mild stenosis		
Pt 6	68	F	26	0	Small vessel	0	0
Pt 7	88	F	29	0	Calcification	0	0
					Small vessel		
Pt 8***	90	F	26	1	Calcification	0	0
					Small vessel		
Pt 9	78	F	26	0	Calcification	0	0
					Small vessel		
Pt 10	84	M	31	0	Calcification	0	0
					Small vessel		

* valve recapture; ** patient with SoloPath® failure; *** valve in series; Pt = patient.

[1] Mean age 83.7 ± 7.3.
[2] Female: 70%.
[3] CoreValve® size: 50% 26 mm, 30% 29 mm and 20% 31 mm.
[4] Diabetes in 30% of the cases.
[5] Reasons to use the SoloPath® sheath were small vessel diameter (<7 mm) in 80% of the cases, significant calcifications in 70%, mild stenosis in 20%. The reason to use the SoloPath® sheath in patient 3 (patient with SoloPath® failure) was the combination of mild calcification and moderate tortuosity and the fact that we were assessing this new technology.
[6] No vascular complication and no cardiovascular death at 30 days.

with successful extraction of the valve through the SoloPath® sheath. The distal tip of the sheath was strong enough to allow recapture. One additional downside of the technology is that the haemostatic valve leaks once a stiff wire is in place. We obviate this limitation by inserting a 9-F sheath into the SoloPath® during the procedure phase of native valve crossing and baseline hemodynamic assessment. Finally, when advancing the folded sheath, it should be deeply advanced quite rapidly to avoid significant blood leakage through the folded portion and its W-shaped channel.

Of note, the first experience with the second generation SoloPath® balloon-expandable and re-collapsible transfemoral access system has been reported by Sedaghat et al. [5]. This second generation can be actively deflated by injection of sterile saline into an additional port. This new technology may allow safer retrieval of the sheath and further decrease major vascular complications. However, kink as well as longitudinal resistances still need to be evaluated.

In conclusion we believe that the SoloPath® sheath is an interesting technology that may further expand the transfemoral option, especially with borderline diameter and/or non-circumferential calcification, but particular caution should be paid in the presence of significant tortuosity.

References

1 Available at: http://www.accessdata.fda.gov. Accessed February 20, 2011.
2 Dimitriadis Z, Scholtz W, Faber L, Borgermann J, Kleikamp G, Horstkotte D, et al. Balloon expandable sheath for transfemoral aortic valve implantation: a viable option for patients with challenging access. J Interv Cardiol. 2013;26(1):84–9.
3 Eggebrecht HKP, Thielmann M, Plicht B, Erbel R. Usefulness of a novel balloon-expandable vascular sheath for facilitated large-bore arterial access for transcatheter aortic valve implantation. Euro Intervention. 2011;6(7):893–4.
4 Fusari MBV, Biglioli P. Case series of bail-out procedures with a balloon-expandable sheath after unsuccessful introduction of the NovaFlex device. Innovations. 2010;7:45–51.
5 Sedaghat A, Sinning JM, Werner N. First experience with a new balloon-expandable and re-collapsible vascular sheath in transfemoral percutaneous aortic valve replacement. Catheter Cardiovasc Interv. 2013; 82(4):E613–6.