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Pachyderm-Shape Guiding Catheters to Simplify BASILICA Leaflet Traversal

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ABSTRACT

Objectives: To test custom-shape guiding catheter curves intended to simplify aortic valve leaflet laceration.
Background: Bioprosthetic Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction (BASILICA) is an adjunct to transcatheter aortic valve replacement. It can be technically demanding using popular coronary guiding catheters and catheter-in-guide coaxial systems. New elephant-trunk shaped Pachyderm Left (PAL1,PAL2,PAL3, *Launcher*, Medtronic) and Right (PJR4) guiding catheters match the geometric requirements to engage aortic cusp hinge points. We evaluate whether these catheters ease BASILICA compared with conventional-shape coronary guiding catheters used in the BASILICA IDE trial.
Methods: This is a single-center, consecutive, retrospective observational cohort of patients who underwent BASILICA for risk of TAVR-induced coronary obstruction defined as virtual valve-to-coronary distance <4 mm, immediately upon commercial availability of the new Pachyderm shaped catheters. Clinical, procedural, and angiographic details were abstracted from medical records of their index procedure, and were compared to adjudicated findings in the BASILICA IDE trial.
Results: Nine leaflets in 6 patients were traversed and lacerated using BASILICA and Pachyderm curve guiding catheters for traversal, including three solo left and three doppio left and right leaflets. Leaflet traversal was universally successful. Leaflet time-to-leaflet traversal was shorter using Pachyderm catheters compared with the BASILICA IDE trial (8.3 min (5.6–15) vs 45 min (20, 61), $p = 0.016$). There were no deaths, strokes, or vascular complications.
Conclusions: The new Pachyderm shaped guiding catheters significantly hastened the leaflet time-to-traversal during BASILICA TAVR. We recommend they be used instead of conventional coronary-shaped guiding catheters.
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1. Background

Bioprosthetic or native Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery (BASILICA) is an effective and reproducible transcatheter electrosurgery procedure adjunct to TAVR [1,2]. The procedure can be technically challenging and protracted without purpose-built commercial catheter tools. Coronary guiding catheters are designed to provide stable positions at coronary artery ostia, whereas BASILICA leaflet traversal requires stable positioning of guiding catheters along the midline of aortic leaflet hinge points. For the left coronary cusp these catheters can have a two-dimensional curve, but for the right coronary cusp the catheter trajectory is more complex. To date we have accomplished these shapes using long Amplatz Left curves, sometimes with a coaxial internal mammary catheter, and using Judkins Right curves further deformed with stiff guidewires [3].

To simplify the BASILICA procedure, we specified new coronary guiding catheters shaped like elephant trunks. The "Pachyderm" PAL1, PAL2, and PAL3 (*Launcher* 6Fr, Medtronic, Minneapolis, MN) [Fig. 1] curves fit progressively larger left aortic roots, and the corresponding Pachyderm PJR4 curve engages the right coronary cusp [Fig. 2]. We applied these guiding catheter shapes in patients and report initial clinical findings.

2. Methods

2.1. Patients

The Emory University Hospital Institutional Review Board approved this single-center retrospective review.

Abbreviations: BASILICA, Bioprosthetic Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction during transcatheter aortic valve replacement.; IDE, Investigational Device Exemption; TAVR, Transcatheter aortic valve replacement; VTC, Virtual valve-to-coronary distance.

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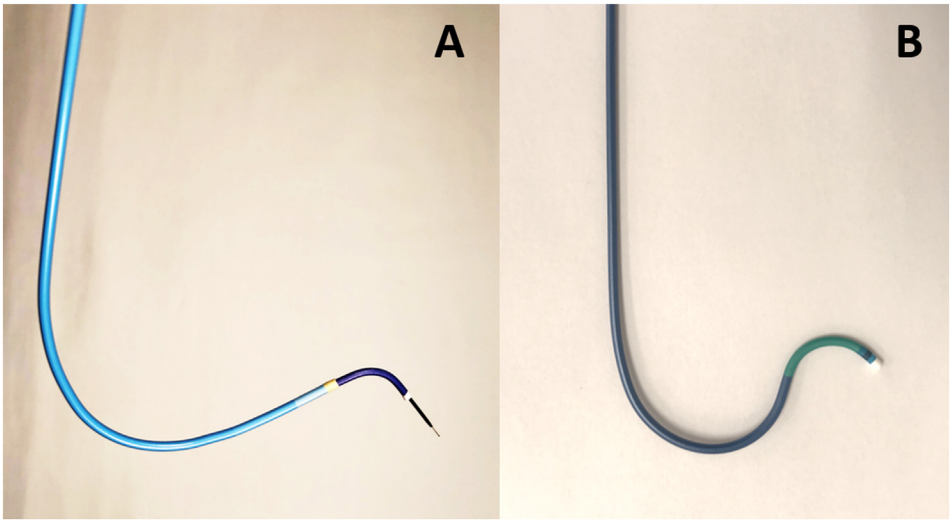

Fig. 1. Left cusp: old coaxial and new Pachyderm guiding catheter configurations. (A) Coaxial internal mammary inside of a EBU shape guiding catheter achieves the desired shape but the relation is unstable and technically demanding. (B) A Pachyderm Amplatz Left 1 guiding catheter, and longer variants, simplify access of the left coronary cusp and aiming across the left coronary leaflet hinge point into the left ventricular outflow tract.

Consecutive patients underwent TAVR who were considered at high or prohibitive risk of TAVR-induced coronary artery obstruction, immediately upon commercial availability of Pachyderm-shaped coronary guiding catheters. Coronary obstruction risk was defined as virtual transcatheter heart valve-to-coronary distance <3 mm. Clinical, procedural, and angiographic details were abstracted from medical records of their index procedure.

As a control, these findings were compared with independently-adjudicated subject-specific data from the 30-subject prospective BASILICA IDE trial (NCT03381989) [2].

2.2. BASILICA and pachyderm-shape guiding catheters

The technique of BASILICA is described elsewhere [3].

The design of the Pachyderm-shape guiding catheter shapes was informed by early experience with BASILICA. For the left coronary cusp, we used PAL1, PAL2, and PAL3 shapes (*Launcher* 6Fr, Medtronic, Minneapolis, MN) that are derived from Amplatz Left 1, 2, and 3 curves, respectively. For the right coronary cusp, we used PJR4 shapes, which have more complex 3-dimensional curves.

The work was done independently of the manufacturer, which is not aware of the findings. The authors have full custody of the data.

2.3. Analysis

Complications are defined according the second valve academic consortium (VARC-2) consensus [4]. Data are represented as mean ± standard deviation or median (1st quartile – 3rd quartile) as appropriate. Data were compared using a two-tailed Student *t-test*.

3. Results

3.1. Patients

Nine leaflets in six patients were lacerated using BASILICA and the new Pachyderm-curve traversal guiding catheters. Three were *solo* left coronary cusp BASILICA and three were *doppio* procedures involving both left and right coronary cusps. Baseline characteristics are listed in [Table 1]. There was a non-significant trend to lower STS predicted risk of mortality than in the BASILICA IDE trial.

Leaflet traversal was universally successful using the Pachyderm guiding catheters. Procedure characteristics are summarized in [Table 2]. Most important, time-to-leaflet traversal was significantly lower using Pachyderm catheters compared with the BASILICA IDE trial (8.3 min (5.6, 15) vs 45 min (20, 61), $p = 0.005$). There was a non-significant trend towards fewer crossing attempts per leaflet using the new catheters (1.3 ± 1 vs 3.8 ± 5.5, $p = 0.199$). There were no deaths, strokes, or vascular complications in this small clinical series.

Representative traversal images are shown of the left coronary cusp [Fig. 3] and right coronary cusp [Fig. 4].

4. Discussion

This consecutive open-label cohort series demonstrates the utility and ease-of-use of new guiding catheter shapes for the BASILICA procedure. Compared with the adjudicated BASILICA IDE trial, these "Pachyderm" shape guides significantly shorten the most time-consuming part of the procedure, which is engaging the coronary cusp with the traversal guiding catheter and then crossing the leaflet with the guidewire.

Previously, left coronary cusp traversal required Amplatz-left-style guiding catheters that were specifically chosen to be "too long" to engage the left coronary artery. Often these would point away from the leaflet hinge point or bioprosthetic valve nadir, risking non-target leaflet traversal or failure to traverse due to proximity to the surgical sewing ring. In order to point the traversal guidewire "inwards" towards the left ventricular outflow tract centerline, operators have been forced to use coaxial guiding catheters such as a long mammary curve diagnostic catheter inside an Amplatz Left or EBU guiding catheter. Such coaxial catheters are technically difficult to maintain in the required "trans" configuration. To recapitulate the shape achieved with coaxial catheters, the Pachyderm Amplatz Left curves (PAL1, PAL2, and PAL3, *Launcher,* Medtronic, Minneapolis, MN) was developed [Fig. 1B].

The guide catheter shape required for the right coronary cusp curve is more complex, and is informed by the non-planar geometric relation between the aortic arch and aortic root. A transfemoral guiding catheter needs to aim anterior towards the aortic root and then again downwards towards the leaflet hinge and left ventricular outflow tract. This trajectory is replicated by the Pachyderm Amplatz Right curves (PJR4, *Launcher,* Medtronic, Minneapolis, MN) [Fig. 2].

By virtue of better "fitting" the targets, reducing the time required to engage and traverse the target coronary cusp, reducing manipulations, and reducing the number of electrosurgical traversal attempts, we believe these Pachyderm guiding catheters may enhance the safety of the BASILICA procedure.

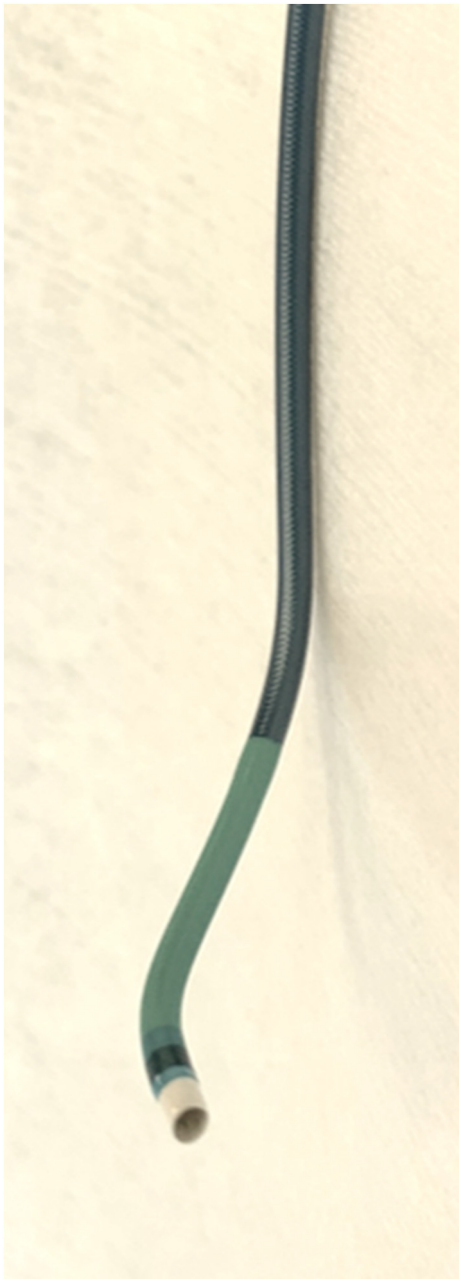

Fig. 2. Right cusp: Pachyderm right guiding catheter. The three-dimensional shape aims anterior for the right aortic root and then down towards the leaflet hinge point and left ventricular outflow tract.

4.1. Limitations

Some limitations of this work include the arbitrary small sample size. However, the dramatic reduction in time-to-traversal was demonstrable in only nine attempts. We do not believe the Hawthorne effect, of operators performing BASILICA more rapidly with the knowledge that they are being timed, influenced the results because this was a retrospective experience. However, traversal time may intrinsically be reduced because operators have accrued more experience since the BASILICA IDE trial completed enrollment eight months previously. The strength of this report is the availability of systematically-adjudicated comparator data.

Table 2
Procedure characteristics and outcomes compared with BASILICA IDE trial.

	Pachyderm traversal catheter (n = 6)	Basilica Ide (n = 30)	p-Value
Procedural characteristics			
Successful Leaflet Traversal	9 (100%)	28 (93%)	0.440
Time to Leaflet Traversal (min)	8.3 (5.6, 15)	45 (20, 61)	**0.005**
Time from Laceration to TAVR	14.3 (10.5, 17)	9 (7, 16)	0.736
Successful Target Leaflet Laceration	9 (100%)	28 (93%)	NS
Number of Traversal Attempts	1.3 ± 1	3.8 ± 5.5	NS
Hemodynamic Compromise	0	7%	NS
Traversal of Non-Target Structure	0	1	NS
Coronary Obstruction	0	0	NS
In hospital outcomes			
Death	0	0	NS
Vascular complications			
– Major Vascular complications	0	2	NS
– Minor Vascular complications	0	4	NS
Stroke			
– Disabling stroke	0	1 (3%)	NS
– Non-disabling stroke	0	2 (7%)	NS

5. Conclusions

The new Pachyderm shaped guiding catheters significantly hastened the leaflet time-to-traversal during BASILICA TAVR. We recommend they be used instead of conventional coronary-shaped guiding catheters.

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Declaration of Competing Interest

VCB is a consultant for Edwards Lifesciences and Abbott Vascular, and his employer has research contracts for clinical investigation of transcatheter aortic, mitral, and tricuspid devices from Edwards Lifesciences, Abbott Vascular, Medtronic, St Jude Medical, and Boston Scientific. He has an equity interest in Transmural Systems.

ABG is a proctor for Edwards Lifesciences, Medtronic, and Abbott Vascular. He has an equity interest in Transmural Systems.

TR is a consultant/proctor for Edwards Lifesciences and Medtronic.

No other author has a financial conflict of interest related to this research.

Table 1
Demographic characteristics.

	Pachyderm Traversal Catheter ($n = 6$)	BASILICA IDE ($n = 30$)	*p*-Value
Age, years	77 (70, 79)	76 (69, 82)	0.573
Women	5 (83%)	24 (80%)	NS
STS-PROM AVR, %	3.5 (1.8, 6.4)	6 (3, 15)	0.192
Bioprosthetic Aortic Valve	4 (67%)	17 (57%)	NS
VTC	2.7 ± 1.0	3.5 ± 1.4	0.128

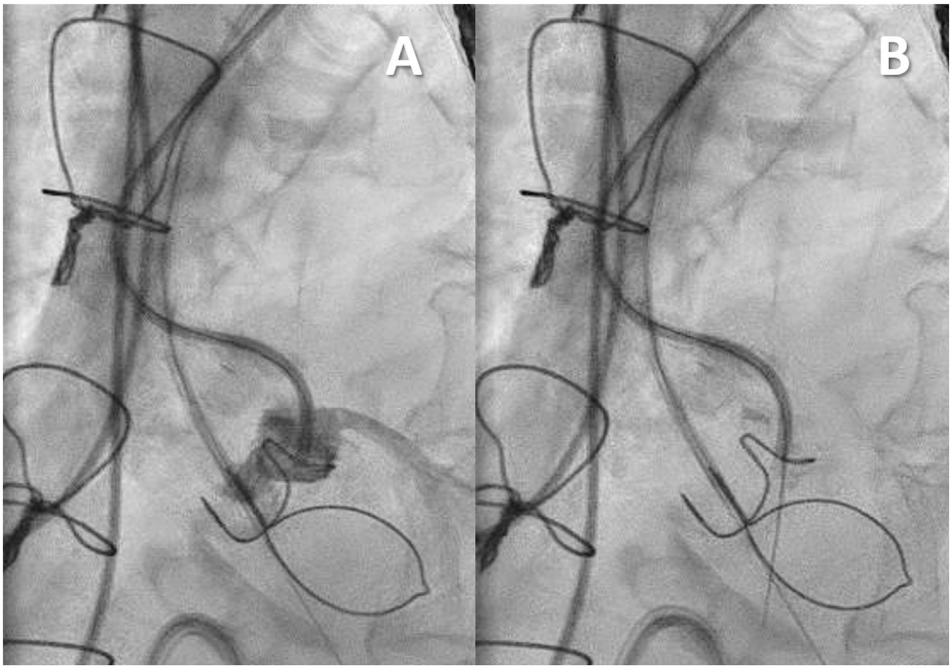

Fig. 3. Traversing L coronary cusp. PAL1 guiding catheter abuts (A) and traverses (B) the left coronary cusp on a bioprosthetic valve to enable BASILICA, in a side-projection.

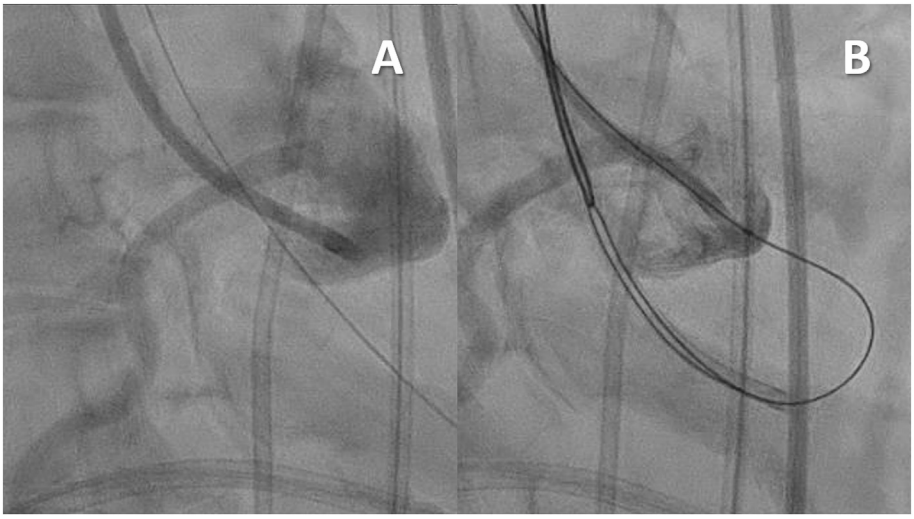

Fig. 4. Traversing R coronary cusp. PJR4 guiding catheter abuts (A) and traverses (B) the right coronary cusp on a native aortic valve, in an en face projection.

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