Anatomical reasons for failure of dual-filter cerebral embolic protection application in TAVR: A CT-based analysis

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Abstract

Background: The dual-filter Sentinel™ Cerebral Protection System (Sentinel-CPS) is increasingly used during transcatheter aortic valve replacement (TAVR). However, complex vascular anatomy may challenge Sentinel-CPS deployment.

Aim of the study: We sought to investigate the impact of anatomic features of the aortic arch and the supra-aortic arteries on technical device failure of Sentinel-CPS application.

Methods: Analysis of the multislice computed tomography pre-TAVR aortograms of all patients undergoing TAVR with Sentinel-CPS between 2016 and 2020 (n = 92) was performed. We investigated the impact of aortic arch anatomy, configuration, and the angles of the supra-aortic arteries, including the determination of vascular tortuosity index on device failure of Sentinel-CPS application.

Results: The Sentinel-CPS was applied successfully in 83 patients (90.2%). Device failure in nine patients (9.8%) was due to the infeasibility to perform correct deployment of both filters (n = 7) and to obtain peripheral radial access (n = 2). Patients with a failure of Sentinel-CPS application had a higher right subclavian tortuosity index (217 [92–324] vs. 150 [42–252], p = .046), a higher brachiocephalic tortuosity index (27 [5–51] vs. 10 [0–102], p = 0.033) and a larger angulation of the brachiocephalic artery (59° [22–80] vs. 39° [7–104], p = .014) compared with patients with successful application. A brachiocephalic angle more than 59° was predictive for device failure. No differences in aortic arch anatomy or common carotid artery tortuosity were detected between the groups.

Conclusions: Brachiocephalic tortuosity was found to be associated with failure of Sentinel-CPS application. Filter-based usage should be avoided in TAVR patients with a brachiocephalic angle more than 59°.
KEYWORDS
cerebral embolic protection, device failure, dual-filter embolic protection, TAVR

1 | INTRODUCTION

Cerebral embolization during transcatheter aortic valve replacement (TAVR) is common, causing symptomatic stroke in up to 2.3%–9.1% of patients.1–3 Adjunctive mechanical strategies to reduce the peri-procedural risk of brain damage include the deployment of dedicated protection systems such as the dual-filter-based Sentinel™ Cerebral Protection System (Sentinel-CPS) (Boston Scientific). Randomized studies investigating the Sentinel-CPS during TAVR demonstrated a strong safety profile and an effective debris capture in almost all patients (86%–99%).1,4–6 However, complex anatomy of the aortic arch and the supra-aortic vessels can challenge Sentinel-CPS application.7–9 Especially vascular tortuosity has been reported to be a possible cause of technical failure to appropriately deliver filter-based protection devices, which might expose the patient to a risk of atheroembolism from the arch, increased contrast administration, and vessel injury.7,10–12 Objective data determining anatomical characteristics and potential cut-off values that might influence the procedural success of Sentinel-CPS application are lacking. We, therefore, sought to investigate the impact of anatomic features of the aortic arch and the supra-aortic arteries on technical device failure of Sentinel-CPS application in our patients.

2 | MATERIALS AND METHODS

2.1 | Patients

This retrospective analysis was conducted at the Department of Cardiovascular Surgery at the German Heart Center Munich. All patients who underwent transfemoral TAVR with Sentinel-CPS usage between February 2016 and February 2020 were identified in our institutional TAVR database. The study complied with the Declaration of Helsinki and was approved by the local ethics committee of the Technical University of Munich (approval reference number: 49/20 S-KH).

2.2 | Sentinel™-CPS

The Sentinel-CPS consists of a steerable catheter (100 cm) carrying two cone-shaped, polyurethane filters equipped with 140-µm pores. After administration of heparin with a target ACT above 250 s, the six French-compatible delivery catheter was introduced through the right radial artery and the filters were targeted to the brachiocephalic artery and the left common carotid artery as previously described in detail.12,14 After finishing the TAVR procedure, both filters were retrieved and the Sentinel-CPS removed. The Sentinel-CPS was used according to the official instructions for use.15

2.3 | Three-dimensional MSCT analysis

All multislice computed tomography (MSCT) data were evaluated using automated software for three-dimensional (3D) CT reconstruction (3mensio structural heart version 10.2, Pie Medical Imaging). The following imaging parameters were defined before assessment and subsequently analyzed as described below.

2.3.1 | Aortic arch characteristics

Aortic arch anatomy was evaluated and classified as normal aortic arch (separate origins for the brachiocephalic, left common carotid, and left subclavian arteries), bovine arch Type I (common origin for the brachiocephalic and left common carotid artery) bovine arch Type II (separate origin of the left common carotid artery from the brachiocephalic artery).

Arch configuration according to Muller et al.16 was assessed by drawing two horizontal lines, marking the highest point of the outer and inner curvature of the arch (Figure 1). Determination of arch configuration was performed in the sagittal plane as well as in the 3D volume rendering view and defined as follows:

Type 1, if all supra-aortic branches originate from the arch at the level of the upper horizontal line; Type 2, if at least one of the supra-aortic branches originates between the two lines; and Type 3, if at least one of the supra-aortic branches originates at the level or below the lower line16 (Figure 1).

FIGURE 1 Aortic arch configuration according to the origin of the supra-aortic arteries demonstrating a Type II configuration
2.3.2 | Take-off angles

The angle between the aortic arch (AA) and the brachiocephalic artery (BA) or the left common carotid artery (CCA), and the inner great vessel angle between the BA and the left CCA were calculated.

The take-off angles of the supra-aortic arteries (AA/BA angle; AA/CCA angle) were measured by drawing a straight line connecting the external origin of the left subclavian artery and the brachiocephalic artery in the sagittal view. The accurate positioning of the reference points was verified in the axial and coronal planes. The distal vascular course of the corresponding supra-aortic branch was determined by generating a centerline across the vessel lumen. To measure the corresponding angle, one angle leg was placed following the previously marked central course of either the brachiocephalic or left common carotid artery and one angle leg was positioned parallel to the straight line\(^16\) (Figure 2).

The inner great vessel angle (BA/CCA angle) was calculated by measuring the most pronounced 3D angle along the central course of the originating part of the brachiocephalic artery, the aortic arch, and the originating part of the left common carotid artery.

2.3.3 | Vascular tortuosity

Vascular tortuosity in the area of the filter target vessels and the right subclavian artery was assessed. The 3-mensio tortuosity angle tool served to quantify the extent of 3D tortuosity in the vessels. The software used the previously defined centreline with a given point and two evenly spaced points, creating 15 mm arms in opposite directions of the former given point. By scrolling the given point up and down across the centreline, the maximal tortuosity angle of the according vasculature could be detected (Figure 3A). The brachiocephalic artery was evaluated from the origin at the aortic arch to the brachiocephalic bifurcation, and the left common carotid artery from its origin until 40 mm of the length according to the filter landing zones. The subclavian artery was evaluated along its course originating from the brachiocephalic artery to the level of the humeral head. Besides the maximal tortuosity angle, a tortuosity index (TI) was calculated. Brachiocephalic and left common carotid artery TI was determined by calculating a distance factor: \(\frac{\text{centre-line distance}}{\text{straight-line distance}} - 1\times 100\)\(^17\) (Figure 3B). Right subclavian TI was defined as the sum of all tortuosity angles along its course \((\sum = \alpha_1 + \alpha_2 + \alpha_3 + \ldots + \alpha_n)\)\(^18\) (Figure 3C).

2.3.4 | Interobserver and intraobserver agreement

All measurements were done by two independent cardiac surgeons experienced in cardiovascular imaging. Inter- and intraobserver reliability for MSCT measurements was evaluated by calculating the inter- and intraclass correlation coefficient (ICC) as previously described\(^19\). Therefore, data from 15 randomly selected patients were
remeasured by another observer and by the same observer, respectively.

2.4 Clinical data analysis

Patient data were collected from the electronic medical record. Baseline factors analyzed were patient age, sex, weight, Logistic EuroSCORE, Society of Thoracic Surgeons predicted risk of mortality Score, EuroSCORE II, glomerular filtration rate, history of stroke, and peripheral arterial disease. Procedural factors were access routes for TAVR, type of transcatheter heart valve implanted, total fluoroscopy/procedure time, amount of contrasts used, dose area product (µgy/cm²), and reasons for the failure of Sentinel-CPS application. Failure of Sentinel-CPS application was defined as the inability to insert the system and correctly deploy both filters in the proximal and distal target vessel.

2.5 Statistical analysis

Frequencies are given as absolute numbers and percentages, continuous data as median and range. Normality of distributions for continuous variables was tested using the Shapiro–Wilks test, and data were analyzed appropriately then using either the two-sided t-test or the Wilcoxon rank-sum test. Categorical variables were compared calculated using Fisher’s exact test. A receiver operating curve (ROC) analysis was performed to determine an optimal threshold value of the previously identified significant anatomical factors and to measure the effectiveness of these diagnostic parameters in predicting the risk of device failure. ICC estimates and their 95% confident intervals (CI) were calculated based on the two-way random effects, absolute agreement, multiple raters/measurements ICC model (2,k). ICC values below 0.5 were classified as poor reliability, values between 0.5 and 0.75 as moderate reliability, values between 0.75 and 0.9 as good reliability, and values above 0.90 as excellent reliability. Statistical analysis was performed by using IBM SPSS Statistics 25.0 software (IBM Corp.). A p value less than .05 was considered statistically significant.

3 RESULTS

3.1 Patients

A total of 97 patients underwent transfemoral TAVR with Sentinel-CPS usage at our center between February 2016 and February 2020. Five patients were excluded from the analysis because their MSCT datasets had insufficient quality for analysis. Therefore, the study cohort included 92 patients with a mean age of 79 ± 7 years. The median logistic EuroSCORE and Society of Thoracic Surgeons Predicted Risk of Mortality Score were 2.7 [1.0–27.3] and 2.5 [0.8–12.4], respectively. Further baseline data are provided in Table 1.

3.2 Procedural characteristics

Sentinel-CPS implantation was performed in 14 patients with an increased risk for cerebral embolization due to severely calcific aortic valves (n = 6), history of previous stroke (n = 2), thromboembolic deposits on the aortic valve (n = 1), significant bioprosthetic aortic valve degeneration (n = 3), and porcelain aorta (n = 2). Further Sentinel-CPS usage (n = 78) was practiced as part of our ongoing single-center, randomized PROTECT TAVI trial (clinicaltrials.gov NCT02895737 328), in which patients are randomly assigned to either undergo TAVR with a balloon-expandable or a self-expandable valve, with and without Sentinel-CPS.

In 83 patients (90.2%), the Sentinel-CPS device was successfully delivered to the aortic arch and both filters were correctly positioned in the brachiocephalic and left carotid arteries. Sentinel CPS insertion failed in two patients because of significant kinking of the right radial artery. Due to vascular tortuosity of the supra-aortic vessels, neither of both filters could be deployed in 6 patients, and distal filter positioning was impossible in one patient. Retraction of the device was uneventful in all patients. Thus, failure of Sentinel-CPS application...
occurred in 9.8% (n = 9). Detailed procedural and anatomic characteristics in patients with Sentinel-CPS failure (n = 9) are summarized in Table 4.

Total operation time, fluoroscopy time, and amount of contrast dye did not differ between TAVR patients with and without the procedural success of Sentinel-CPS usage (Table 2).

### TABLE 1 Baseline demographics

| Patient characteristics | Sentinel-CPS success n = 83 | Sentinel-CPS failure n = 9 | p value |
|-------------------------|-----------------------------|---------------------------|---------|
| Age, years (median, range) | 79 ± 7 | 82 ± 6 | .266 |
| Female, n (%) | 40 (48.2) | 7 (77.8) | .159 |
| Body mass index, kg/m² (median, range) | 26.1 ± 4.3 | 29.3 ± 7.8 | .266 |
| Peripheral arterial disease, n (%) | 13 (15.7) | 0 (0.0) | .349 |
| History of stroke, n (%) | 6 (7.2) | 1 (11.1) | .526 |
| Society of Thoracic Surgeons Score (median, range) | 2.5 [0.8–12.4] | 2.3 [1.8–4.7] | .655 |
| Logistic EuroSCORE (median, range) | 11.0 [1.7–46.0] | 8.9 [4.3–25.1] | .703 |
| EuroSCORE II (median, range) | 2.6 [1.0–27.3] | 3.0 [1.5–5.7] | .803 |

Abbreviation: Sentinel-CPS, Sentinel™ Cerebral Protection System.

### TABLE 2 Procedural data

| Patient characteristics | Sentinel-CPS success n = 83 | Sentinel-CPS failure n = 9 | p value |
|-------------------------|-----------------------------|---------------------------|---------|
| Self-expandable valve (CoreValve/Evolut R), n (%) | 43 (51.8) | 4 (44.5) | .736 |
| Balloon-expandable valve (Sapien 3/Sapien Ultra), n (%) | 40 (48.2) | 5 (55.5) | |
| Total procedure time, min (median, range) | 73 [46–248] | 70 [53–84] | .572 |
| Total fluoroscopy time, min (median, range) | 18 [9–54] | 21 [15–276] | .078 |
| Amount of contrast agent, ml (median, range) | 132 [75–165] | 130 [105–160] | .790 |
| Dose area product, µgy/cm² (median, range) | 3825 [687–16,794] | 3118 [1533–16,695] | .767 |

Abbreviation: Sentinel-CPS, Sentinel™ Cerebral Protection System.

### 3.3 MSCT measurements

MSCT measurements revealed no difference regarding the anatomy and configuration of the aortic arch in TAVR patients with Sentinel-CPS success (n = 83) and device failure (n = 9) (Table 3). Also, the supra-aortic take-off angles (AA/BA angle, AA/CCA angle) and the inner great vessel angle (BA/CCA angle) did not differ significantly between the two groups. Patients with failed Sentinel-CPS application had a larger median brachiocephalic tortuosity angle (59° [22°–80°] vs. 39° [7°–104°], p = .014) (Figure 4) and a higher median brachiocephalic (27 [5–51] vs. 10 [0–102], p = .033) and right subclavian Tl (217 [92–324] vs. 150 [42–252], p = .046) than patients with successful deployment. Tortuosity measurements of the left common carotid artery were similar between the groups. By ROC analysis, a brachiocephalic angle more than 59°, a brachiocephalic TI more than 26 and a right subclavian TI more than 191 were identified as predictors for technical device failure with a sensitivity and specificity of 71.4% and 91.5%, 71.4% and 90.3%, and 85.7% and 79.2%, respectively (Figure 5). The area under the curve (AUC) was 0.86 for the brachiocephalic angle, 0.81 for the brachiocephalic, and 0.81 for the right subclavian TI.

The overall inter- and intraobserver reproducibility for all MSCT measurements were excellent with a mean ICC of 0.975 and 0.932, respectively. Estimated inter- and intraobserver agreement for each MSCT parameter including their 95% CIs is given in eTables S1 and S2.

### 4 DISCUSSION

The dual-filter Sentinel-CPS has shown its potential to filter and remove debris safely and effectively,14-6 supporting its increasing use during TAVR. As there is currently only one size of filter system available, one-third of patients may be ineligible due to inappropriate target vessel dimensions.15 However, even if the official criteria for Sentinel-CPS implantation are met, filter deployment might fail due to complex anatomical features such as vascular tortuosity, aortic arch variants, or arch steepness.7-9 Unfavorable anatomic conditions
require repeated wire exchanges and special catheter maneuvers associated with a higher risk of atheroembolism and vessel injury. Thus, it is important to identify patients that have an anatomical barrier before starting Sentinel CPS implantation. To date, there is no data on vascular anatomy potentially associated with technical failure of Sentinel CPS application.

Failure of Sentinel CPS implantation was observed in 9.8% of our patients undergoing filter protected TAVR. This is in line with previous studies, demonstrating rates of unsuccessful device placement in 3.1%-40% of patients. We detected vascular tortuosity of the supra-aortic arteries as the main reason for the failure of Sentinel-CPS application in our cohort. Extreme vessel tortuosity hinders torqueing of the guidewire and catheter and thus sufficient advancement of the Sentinel CPS. Tortuous anatomy has been previously identified but not quantified as a factor contributing to technical difficulties or device failure. In the instructions for use it is clearly stipulated that Sentinel-CPS insertion should be avoided in patients with "excessive" vessel tortuosity. However, "excessive" is not further defined. The present MSCT analysis showed a brachiocephalic angle of 59°, a brachiocephalic TI of 26, and a right subclavian TI of 191 as threshold values beyond which failure of Sentinel-CPS application is likely to occur. Of those, the brachiocephalic tortuosity angle could be detected as the most significant predicting factor with a sensitivity, specificity, and AUC of 71.4%, 91.5%, and 0.86, respectively. Our findings demonstrate that difficulties of filter placement can be anticipated by anatomy assessment and highlight the importance of preoperative, standarized tortuosity calculation. Consequently, filter-based usage should be avoided in TAVR patients with a brachiocephalic angle more than 59°. Moreover, Case et al. reported on post-market surveillance data from the FDA MAUDE database and found that periprocedural stroke (n = 4) was associated with filter deployment difficulties because of tortuosity. Repeated attempts to advance catheters through an angulated vessel may cause endothelial damage or dislodge debris, ultimately causing cerebral emboli and ischemia.

Besides vascular morphology, the aortic arch anatomy has also been considered a key factor in the success of neuro-interventional procedures. The most common variants in the branching pattern of the aortic arch are bovine arch types 1 and 2 with a prevalence ranging from 8% to 30%. Carotid artery studies have associated bovine arch anomalies with an increased technical failure rate and neurological events. Recently, Tagliari et al. investigated the feasibility and safety of implantation of the Sentinel-CPS in patients with (n = 20) and without (n = 145) bovine arch anatomy. In this retrospective data analysis a significantly higher

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**TABLE 3** MSCT measurements

| Patient characteristics          | Sentinel-CPS success n = 83 | Sentinel-CPS failure n = 9 | p value |
|---------------------------------|-----------------------------|---------------------------|---------|
| Aortic arch anatomy, n, (%)     |                             |                           |         |
| Normal                          | 66 (79.5%)                  | 7 (77.8%)                 | 1.000   |
| Bovine Type I                   | 15 (18.1%)                  | 2 (22.2%)                 | .670    |
| Bovine Type II                  | 2 (2.4%)                    | 0 (0.0%)                  | 1.000   |
| Aortic arch configuration, n, (%)|                             |                           |         |
| Type I                          | 12 (14.5%)                  | 3 (33.3%)                 | .160    |
| Type II                         | 69 (83.1%)                  | 6 (66.7%)                 | .359    |
| Type III                        | 2 (2.4%)                    | 0 (0.0%)                  | 1.000   |
| Take-off angle, degree (median, range) |                           |                           |         |
| AA/BA                           | 112 [41–149]                | 110 [87–122]              | .318    |
| AA/CCA                          | 127 [104–156]               | 129 [120–138]             | .498    |
| BA/CCA                          | 57.0 [38.0–96.0]            | 68.0 [55.0–77.0]          | .076    |
| Maximal tortuosity angle, degree (median, range) |            |                           |         |
| Brachiocephalic                 | 39 [7–104]                  | 59 [22–80]                | .014    |
| Left common carotid             | 28 [7–76]                   | 31 [14–84]                | .502    |
| Tortuosity Index (median, range) |                             |                           |         |
| Brachiocephalic                 | 10 [0–102]                  | 27 [5–51]                 | .033    |
| Left common carotid             | 3 [0–49]                    | 4 [2–51]                  | .168    |
| Right subclavian*               | 150 [42–252]                | 217 [92–324]              | .016    |

Abbreviations: MSCT, multislice computed tomography; Sentinel-CPS, Sentinel™ Cerebral Protection System.

*Right subclavian artery measurements were only performed in 87 patients due to incomplete three-dimensional reconstruction.
rate of Sentinel-CPS failure in patients with bovine anatomy compared with normal aortic arch (p = .002) was revealed without this being reflected in an increased complication rate.9 Technical failure in this branching pattern might result from the complexity to navigate the Sentinel-CPS through the sharp turn between the aortic arch and the orifice of the left common carotid artery.25 However, extreme flexion of the distal part of the device using the integrated articulation sheath may help advance the wire into the ostium of the left common carotid artery.

### TABLE 4 Procedural and anatomic characteristics of TAVR patients with Sentinel-CPS failure

| Intraoperative reasons for Sentinel-CPS failure | Aortic arch anatomy | Brachiocephalic tortuosity > 59° | Subclavian TI > 191 |
|-----------------------------------------------|---------------------|--------------------------------|---------------------|
| Patient 1 Brachiocephalic tortuosity prevented the deployment of both filters | Normal | Yes | No |
| Patient 2 Kinking of the right radial artery prevented advancement of the Sentinel-CPS | Normal | No | No |
| Patient 3 Brachiocephalic tortuosity prevented deployment of both filters | Normal | Yes | No |
| Patient 4 Kinking of the right radial artery prevented advancement of the Sentinel-CPS | Normal | No | Yes |
| Patient 5 Subclavian and brachiocephalic tortuosity prevented deployment of both filters | Normal | No | Yes |
| Patient 6 Subclavian and brachiocephalic tortuosity prevented deployment of both filters | Bovine I | No | Yes |
| Patient 7 Brachiocephalic tortuosity prevented deployment of both filters | Bovine I | Yes | No |
| Patient 8 Brachiocephalic and carotid tortuosity prevented deployment of the distal filter* | Normal | Yes | Yes |
| Patient 9 Brachiocephalic tortuosity prevented deployment of both filters | Normal | Yes | Yes |

Abbreviations: Sentinel-CPS, Sentinel™ Cerebral Protection System; TAVR, transcatheter aortic valve replacement.

*Positioning of the proximal filter was successful and thus TAVR procedure was performed with one filter.

**FIGURE 4** Brachiocephalic tortuosity in a patient with failure (A) and success (B) of Sentinel™ Cerebral Protection System application.
With this technique, no differences in the rate of device failure were observed in our patients with and without bovine anomaly. Also, other morphometric parameters such as an elongated aortic arch, especially a Type III configuration, and sharp take-off angles of the supra-aortic branches might increase the technical difficulty of interventions resulting in technical errors and periprocedural complications as previously described in carotid artery studies.\textsuperscript{16,21,26} Both anatomical features were not associated with Sentinel-CPS failure in our patients.

Kinking of the right radial artery precluded successful Sentinel-CPS insertion in two patients. Seeger et al.\textsuperscript{22} reported access site-related device failure in 5.9% of patients. Device tracking can be combersome in cases of the tortuous radial artery, vasospasm, or hypoplastic radial artery. In these situations, the tip of the guiding catheter can create a "razor blade effect" that prevents catheter navigation and may lead to perforation of the radial artery.\textsuperscript{8,27} Pigtail-assisted tracking of the guiding catheter might help to overcome this effect by nontraumatic navigation of the guiding catheter through complex radial anatomy.\textsuperscript{27}

5 | LIMITATIONS

Our study reports the results of a retrospective, single-center investigation of limited size. As this study focuses on MSCT-based identification of anatomical features potentially associated with Sentinel-CPS application failure, the correlation between frustrated device use and neurological outcome was not assessed. In addition, technical factors in our cohort might be confounded by advances in technique, operators’ experience, and patient selection over the study period.

6 | CONCLUSION

We identified vascular tortuosity of the right brachiocephalic artery as a predictive anatomic factor for technical failure of Sentinel-CPS application in TAVR. The results of our MSCT-based study might aid in the selection of patients for dual-filter embolic protection usage. Due to a detected cut-off angle of 59°, we recommend avoiding filter implantation in patients with brachiocephalic measurements above this threshold. Evaluation of vascular tortuosity is simple, rapid, and requires no additional imaging, as the pre-TAVR MSCT aortogram provides all necessary calculations. In addition, standardized failure-reporting policies may improve existing device technology and enhance patient safety and outcomes.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Stephanie Voss: Concept/design, Data collection, Drafting, Data analysis/interpretation. Caterina Campanella: Concept/design, Data collection, Drafting, Data analysis/interpretation. Melchior Burri: Data analysis/interpretation, Statistics. Teresa Trenkwalder: Concept/design, Critical revision of article. Konstantinos Sideris: Critical revision of article. Magdalena Erlebach: Critical revision of article. Hendrik Ruge: Critical revision of article. Keti Vitanova: Concept/design, Data analysis/interpretation. Markus Krane: Critical revision of article. Rüdiger Lange: Critical revision of article.

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SUPPORTING INFORMATION
Additional supporting information may be found in the online version of the article at the publisher’s website.

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