Endovascular navigation with Fiber Optic RealShape technology

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ABSTRACT

Objective: Fiber Optic RealShape (FORS) technology has recently been introduced as an adjunctive guidance technology that allows real-time three-dimensional visualization of dedicated endovascular devices while avoiding radiation exposure. It consists of equipment which sends pulses of light through hair-thin optical fibers that run within a dedicated hydrophilic wire and selective catheters. The purpose of the study was to report the observed benefits and limitations related to the first edition of FORS technology.

Methods: Data were collected prospectively from the first 50 patients undergoing FORS-guided endovascular repair at a single center between February 2020 and February 2021 as part of the global multicenter FORS Learn registry. All consecutive, elective procedures with one or more navigation tasks attempted with FORS were included. Factors related to FORS navigation task success were assessed. The time required for the catheterization of each task as well as the amount of radiation exposure (fluoroscopy time, dose area product, and estimated skin dose) were collected. A per-task analysis was conducted. End points included the success rate in achieving a stable FORS-guided catheterization, catheterization time, and radiation dose during catheterization.

Results: During the study period from February 2020 to February 2021, 50 patients were treated using FORS technology. Forty-five patients were treated for aortic aneurysm, 4 for iliac artery aneurysm, and 1 for splenic artery aneurysm. Overall, 201 navigation tasks were completed for these procedures and FORS was used in 186 tasks (92.5%). No FORS-related complication was recorded and a success rate of 60.2% (n = 116) was observed. Target vessel (TV) angle of 45° or greater, TV stenosis, and the renal arteries as navigation tasks (compared with celiac artery or superior mesenteric artery) were associated with a lower success rate. Catheterization of a TV through a branch more frequently required a standard catheter in combination with the FORS-enabled guidewire. Successful task catheterization using FORS guidance was associated with a shorter catheterization time 6 minutes (interquartile range, 3-11 minutes) versus 16 minutes (interquartile range, 10-24 minutes) ($P < .001$) and lower radiation exposure compared with unsuccessful catheterization (dose area product, 4.4 cGy/cm^2 vs 12.5 cGy/cm^2; $P < .001$).

Conclusions: FORS technology was implemented successfully as a new guidance technology in a complex endovascular aortic repair program and was associated with an encouraging success rate and a high potential for radiation reduction. (J Vasc Surg 2023;77:3-8.)

Keywords: Endovascular aortic repair; 3-Dimensional imaging; Radiation; Fiber optic technology; Endovascular navigation; Digital OR

Over the last decade, multimodality fusion technologies have become an important adjunct during endovascular procedures, offering a better intraoperative understanding of patients' vascular anatomy. The overlay of preoperative computed tomography angiography (CTA) data on conventional fluoroscopy provides three-dimensional (3D) information of vascular anatomy and key landmarks such as target vessel (TV) origins and orientation. Although fusion technologies can display underlying anatomy and landmarks, the visualization of wires and catheters during

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Supported by an unrestricted research grant from Philips Medical Systems.

Author conflict of interest: G.P., A.S., and T.K. are consultants for Philips Medical Systems. B.W. is an employee of Philips Medical Systems. The views expressed in this article are those of the authors and do not necessarily reflect those of Philips Medical Systems.

Additional material for this article may be found online at www.jvascsurg.org.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

https://doi.org/10.1016/j.jvs.2022.08.002

navigation continues to rely on constant x-ray-based fluoroscopy. This need for continuous x-ray presents a radiation exposure risk to patients and care team providers, and is inherently limited to visualization in two dimensions.

In an effort to overcome these limitations, Fiber Optic RealShape (FORS) technology (Philips Medical Systems, Best, The Netherlands) was introduced recently and obtained regulatory approval in Europe in December 2019. FORS uses light reflected along optical fibers embedded within wires and catheters to generate real-time, high-fidelity, 3D visualization of endovascular devices without fluoroscopy. This technology has the potential to simplify complex endovascular procedures by improving wire and catheter visualization in 3D, allow for multiple working angles to be visualized simultaneously, all while decreasing radiation exposure. Preclinical and preliminary clinical reports have demonstrated system precision and technical feasibility in small series of selected endovascular procedures.[1,2]

The aim of the present study was to evaluate safety and feasibility of endovascular navigation using FORS technology in the first 50 patients treated at a single center.

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center, open-label retrospective cohort study
- **Key Findings:** The use of Fiber Optic RealShape (FORS) technology first generation resulted in 62% of endovascular navigational tasks being completed successfully during complex endovascular aortic aneurism repair procedures. Less success was observed in angulated or stenotic vessels (33% and 17%, respectively). When comparing radiation dose between tasks successfully completed with and without FORS technology, a 65% decrease in radiation dose was achieved.
- **Take Home Message:** The use of FORS technology by endovascular procedure is safe and offers a high potential for radiation reduction.

METHODS

Patients and study design. This analysis is a retrospective review of prospectively collected, single-center, data from the first consecutive 50 patients undergoing FORS-guided endovascular repair between February 2020 and February 2021 as part of the global multicenter FORS Learn registry. The FORS Learn Registry is a prospective, multicenter, postmarket registry evaluating how FORS technology can be integrated into standard-of-care clinical practice and to describe the procedural characteristics and outcomes in the early clinical experience using FORS guidance. The FORS Learn registry is sponsored by Philips. All patients provided written, informed consent, and the study was approved by the local ethical committee.

Three experienced endovascular operators took part in the study (TK, GP, and FR) and were responsible for patient inclusion without influence of the sponsor.

Materials and equipment. Details about FORS technology have been described in previous publications.[3-5] One hydrophilic wire with an angled tip configuration (0.035" × 120 cm length) and two different selective catheters (both 5.5 F, 80 cm with a Berenstein and Cobra 2 configuration) are available. Procedures were performed in a hybrid operating room equipped with a ceiling-mounted fluoroscopy imaging system with flat panel detectors and a floating table (Allura FD20 Flexmove with ClarityIQ; Philips Medical Systems) coupled with a workstation equipped with a dedicated image fusion software (FORS; Philips Medical). Additionally, hardware containing the optical engine connected with the FORS enabled device, allows the spatial localization of the device position (Fig 1).

The setup for a procedure using FORS guidance requires registration of the devices in 3D space and a fusion overlay with a preoperative CTA. At the start of the case, the CTA is fused with the patient's on-table position using either cone beam computed tomography scans (3D/3D) or fluoroscopy (two-dimensional/3D). The FORS-enabled devices are then prepared, first by connecting to the bedside docking hub, then by obtaining two fluoroscopy images of the device oriented 30° or more from one another. The operator can then manually register and adjust the position of the device using the on-screen interface. Intraoperatively, FORS-enabled wires and catheters are rendered on-screen in 3D with distinct colors and at 50% larger than actual size to improve visibility. The viewing plane can be adjusted by the surgeon in real time and a biplane viewing option allows multiple orientations to be viewed simultaneously.

All FORS-enabled devices are radiopaque, can be used as regular endovascular devices, and can be combined with other regular endovascular devices. Because the FORS-enabled wire is tethered to the laser pulse source, it is not back-loadable; therefore, it is not possible to change out the catheter during the navigation phase while leaving the wire in place. The FORS-enabled wire and catheter can be used independent of each other.

Procedure description and study end points. The FORS system is intended to be used only during the catheterization phase of endovascular procedures, whereas the therapeutic phase, such as stent graft deployment and balloon angioplasty, are performed with conventional fluoroscopy, as in standard practice. Before each procedure, one or more navigation tasks were identified. Examples of intended endovascular tasks include catheterization of the contralateral gate of a bifurcated

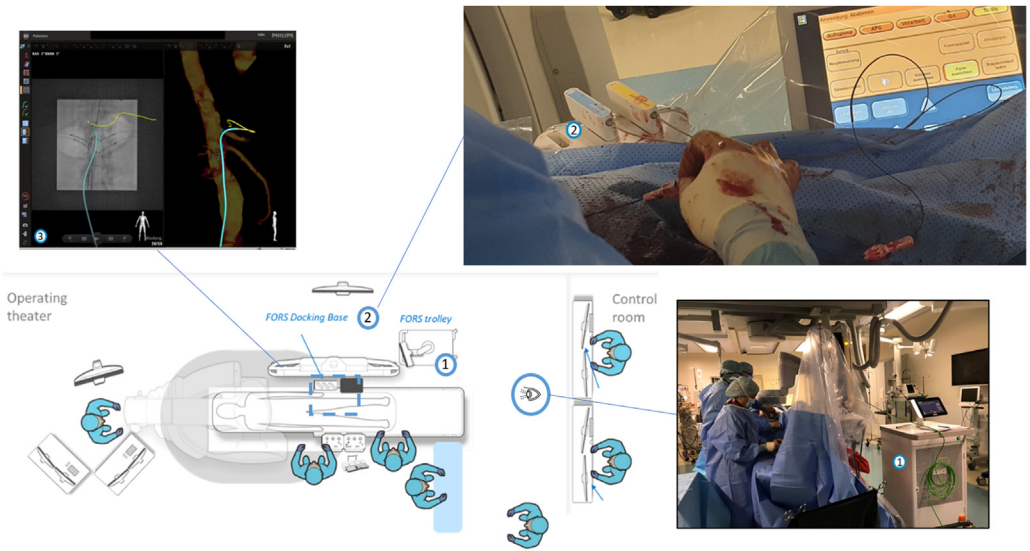

Fig 1. Operative setup. (1) Trolley containing the laser pulse source and the workstation to localize the Fiber Optic RealShape (FORS) device position. (2) Docking base to connect the FORS device with the operating table. (3) Intraoperative monitor showing the real-time position of the FORS wire (yellow) and catheter (blue) overlayed on the fluoroscopy as well as on the preoperative computed tomography (CT) scan. Different visualization are possible. In this case a anteroposterior fluoroscopy is combined with a lateral 3d visualization of the aorta to follow the catheterization of the CT scan.

aortic graft or the catheterization of a TV during fenestrated and/or branched endovascular aortic repair (EVAR). The operator was always able to switch from FORS-enabled devices to conventional devices or a combination thereof based on procedural advancement, anatomic situation, and anticipated challenges.

All navigational tasks in this study were started with the FORS guidewire. During catheterization, the operator could switch between available catheters and guidewires, as in regular practice. All time points when devices were switched were recorded. Although available FORS materials did not change during the study period, the way in which they were used did. The main change concerned the use of the FORS catheter. Initially, the FORS guidewire was used in combination with the FORS catheter, but owing to the limited choice of catheter shapes and the mechanical properties of the FORS catheters, they were used less frequently in the later experience and the FORS guidewire was more frequently used with a regular catheter that currently cannot be visualized with the FORS technology.

All navigational tasks were performed through transfemoral access in this study. In case of branched thoracoabdominal endografts, TV catheterization was performed using a steerable sheath coupled with a preloaded wire as described elsewhere.[6] Visualization of the FORS guidewire on the screen was defined as the starting point of the navigation phase. Exchange and placement of a stiff guidewire was defined as the time point for stable vessel catheterization and end of navigation (eg, a Rosen wire in the TV, a Lunderquist wire in the contralateral limb). When the navigation passes through fenestrations or branches, the fenestration/branch catheterization phase was also taken into account. All navigation metrics were collected prospectively and included time points as described elsewhere in this article, fluoroscopy time, radiation dose area product, and type of devices used.

Technical success was defined as the ability to complete the navigation task using the FORS-enabled guidewire, with or without a FORS-enabled catheter. The need to use an additional guidewire for a navigation task was considered a technical failure.

The following potential determinants of FORS technical failure were analyzed:

- Type of navigation task:
  - TV type: celiac artery, superior mesenteric artery, renal arteries, and internal iliac arteries
  - TV stenosis >50%
  - Branch versus fenestration
- Challenging TV catheterization angle:
  - Upward orientation of 45° or more for branches
  - Downward orientation of 45° or more for fenestrations

Further end points were navigation time and radiation dose (fluoroscopy time; dose area product).

The statistical analysis was performed with SPSS version 22.0 (IBM, Armonk, NY). A per-task analysis in an intention-to-treat protocol was performed and each

Table I. Cohort comorbidities and procedural characteristics (n = 50)

Male:female (n)	40:10
Age, years	74 (64-78)
CKD	12 (24.0)
COPD	4 (8.0)
Connective tissue disease	1 (2.0)
Coronary artery disease	13 (26.0)
Heart failure	1 (2.0)
Hypertension	40 (80.0)
Insulin-dependent diabetes mellitus	2 (4.0)
Prior aortic surgery	5 (10.0)
Procedure type	
BEVAR	19 (38.0)
FEVAR	17 (34.0)
IBD	4 (8.0)
EVAR	6 (12.0)
Embolization peripheral aneurysm	2 (4.0)
Stent grafting peripheral vessel	1 (0.5)
BTEVAR	1 (0.5)
Hospitalization days	9.0 (8.0 – 15.0)
ICU days	3.0 (3.0-4.0)

BEVAR, Branched endovascular aortic repair; *BTEVAR*, branched thoracic endovascular aortic repair; *CAD*, coronary artery disease; *CKD*, Chronic kidney disease; *COPD*, chronic obstructive pulmonary disease; *EVAR*, endovascular aortic repair; *IBD*, iliac branched device; *ICU*, intensive care unit; *FEVAR*, fenestrated endovascular aortic repair; *PAU*, Penetrating atherosclerotic ulcers; *TAAA*, thoracic aortic abdominal aneurysm.
Values are number (%) or median (interquartile range) unless otherwise noted.

task was analyzed independently. Measured values were reported as percentages or media and interquartile range (IQR). The Fisher exact test and χ^2 analysis were used to test the association of categorical variables with perioperative outcomes.

RESULTS

During the study period, 50 patients (40 men; median age, 74 years) were enrolled, and 36 (72%) underwent fenestrated/branched EVAR. Ninety percent of procedures were performed for degenerative aortic aneurysm, 8% were isolated iliac artery aneurysm, and 2% aneurysm of visceral arteries. Details about patient baseline characteristics, comorbidities, and procedures are shown in Table I.

The median number of navigation tasks per procedure was four (IQR, 3-5) with a total of 201 tasks performed. In 15 tasks (7.5%), FORS technology was not used and the tasks were excluded from the analysis. Details about the excluded tasks and reason for exclusion are reported in Supplementary Table I (online only). Of the remaining 186 tasks, 28 (15%) were a contralateral gate and 137 (51%) were TVs catheterized through a fenestration or a branch. Two renal artery ruptures were found in the control angiography. One rupture occurred during the stent delivery and the other during the stent deployment.

Table II. Univariate analysis for technical success and associated risk factors (n = 186)

	No.	%	*P* value
Catheterization through			.01
Branch	33	52	
Fenestration	44	59	
None	39	80	
TV with challenging catheterization angle	6	33	.007
TV with ostial stenosis >50%	2	17	.001
TV type			.01
Celiac trunk	13	46	
Superior mesenteric artery	26	81	
Renal arteries	35	50	
Accessory renal arteries	6	86	
AII	9	75	
Contralateral gate	19	73	
Others	8	73	

TV, Target vessel.

Adjudication determined that both TV ruptures were not FORS technology related.

Success rates. In 116 of 186 tasks (62%), catheterization with a FORS-enabled guidewire was successful. Fifty-two tasks (27%) were successfully completed with both a FORS-enabled catheter and FORS-enabled guidewire. The C2 catheter configuration (n = 90 [48%]) was more frequently used than the BER configuration (n = 81 [43%]). In 70 tasks (38%), a complete switch to conventional devices requiring x-rays was made. In 52 of these tasks (74%), a regular 0.035", 180 cm hydrophilic wire enabled catheterization, and in 18 of these tasks (26%), a 0.014" hydrophilic wire was used.

TVs with a challenging catheterization angle and TVs with ostial stenosis were associated with a lower success rate of 33% ($P = .007$) and 17% ($P = .001$) respectively, compared with a success rate of 70% in TVs without a challenging catheterization angle and without ostial stenosis (Table II). Catheterization of the superior mesenteric artery and of the contralateral limb were both associated with a higher success rate of 81% and 73%, respectively, when compared with the celiac artery (46%) and the renal arteries (50%; $P = .01$). Direct catheterization of a TV had a higher success rate of 80% compared with catheterization of a TV through a fenestration (59%) or through a branch (52%; $P = .01$).

Navigation times and radiation exposure. The cumulative duration and radiation dose for each type of procedure is shown in Supplementary Table II (online only). The median navigation and fluoroscopy time by task successfully completed with FORS technology were respectively 6 minutes (IQR, 3-11 minutes) and 0.9 minutes (IQR, 0.3-2.7 minutes). When comparing navigation time and radiation dose between tasks successfully

Table III. Comparison of the navigation time and radiation exposure for each task based on the technical success (n = 186)

	Technical success				
	No (n = 70)		Yes (n = 116)		
	Median	IQR	Median	IQR	*P* value
Navigation duration, minutes	16	10-24	6	3-11	<.001
Fluoroscopy duration during navigation, minutes	5.2	3-11.6	0.9	0.3-2.7	<.001
Fluoroscopy duration during navigation normalized, %	37.5	27.5	19.7	9.2-29.4	<.001
Air Kerma during navigation	195.8	69-349.1	61.3	20-153	<.001
Dose area product during navigation, CGy	12.5	5-20	4.4	2.0-10.7	<.001

IQR, Interquartile range.

completed with and without FORS technology, a significant decrease in time ($P < .0001$) and radiation dose ($P < .001$) was observed in tasks successfully performed with FORS (Table III; Fig 2). No cone beam computed tomography scans were performed during the registration phase of the fusion technology.

DISCUSSION

The successful implementation of this completely new guidance technology into the hybrid operating room during complex EVAR is encouraging. In this early experience, we were able to obtain technical success in 62% of tasks attempted with FORS and no complications attributed to FORS technology were identified. When comparing catheterization time and radiation dose in tasks that were successfully catheterized with FORS, significant advantages were observed for both. For these tasks, almost the entire navigation phase could be performed without the use of radiation. Radiation was only used to perform angiography to confirm correct catheterization and TV patency without endoleak. Our experience suggests that FORS technology offers the potential to be a transformative guidance technology that enables intraoperative 3D visualization with a marked decrease in radiation dose.

The technical success rate (62%) was lower compared with the only other published FORS first-in-man series by van Herwaarden et al.[2] In their study, 91% of the 66 navigation tasks were successful. The few failures they reported were primarily attributable to limitations in the length and shape of the investigational devices.[2] Our success rate was significantly higher for the superior mesenteric artery, compared with the renal arteries and the celiac trunk. We experienced decreased torque control of the FORS enabled catheters compared with regular catheters when operating through a steerable sheath in branched EVAR procedures and were restricted by the limited availability of catheter configurations. This early learning point about the FORS-enabled catheters resulted in a change of strategy with the use of a conventional 5F BER catheter in combination with the FORS enabled guidewire, even if this meant the loss of a visualization of the catheter. To overcome the limitations of catheter torquability and configuration, the manufacturer will be introducing a catheter-agnostic 3D Hub that allows full FORS-enabled visualization of standard catheters by connecting this 3D Hub to the back of a conventional catheter using a standard Luer-lock system.

The FORS-enabled hydrophilic wire is currently available in a single configuration that has a mechanical profile designed to enable use across aortic and above-the-knee peripheral procedures as well as integration of an optical fiber into the wire while maintaining a low profile. We observed limitations in the mechanical properties of this first version of the FORS-enabled hydrophilic wire while completing certain specific tasks compared with current standard hydrophilic wires of choice in our practice. The integration of an optical fiber into catheters and wires with low profile and complex performance requirements represents a high-end engineering challenge with obvious impact on functional behavior and device robustness. The ultimate goal for FORS technology is to create a portfolio of FORS-enabled devices with mechanical properties that are further tuned for specific procedures and tasks, while adding the described 3D visualization and radiation reduction benefits. This portfolio of devices with FORS-enabled visualization will allow for a better spatial understanding in real time while offering multiple projections that can include angles not physically achievable within the constraints of a standard C-arm system.

Limitations of the present study include a lack of standardized selection criteria for procedures and tasks, which were operator defined. These data are based on initial experience and the effects of a learning curve should not be underestimated. Even though some members of the team had collected in vitro experience, the clinical application cannot be simulated fully, especially because the whole operating team has to be trained. Furthermore, the high-volume experience of

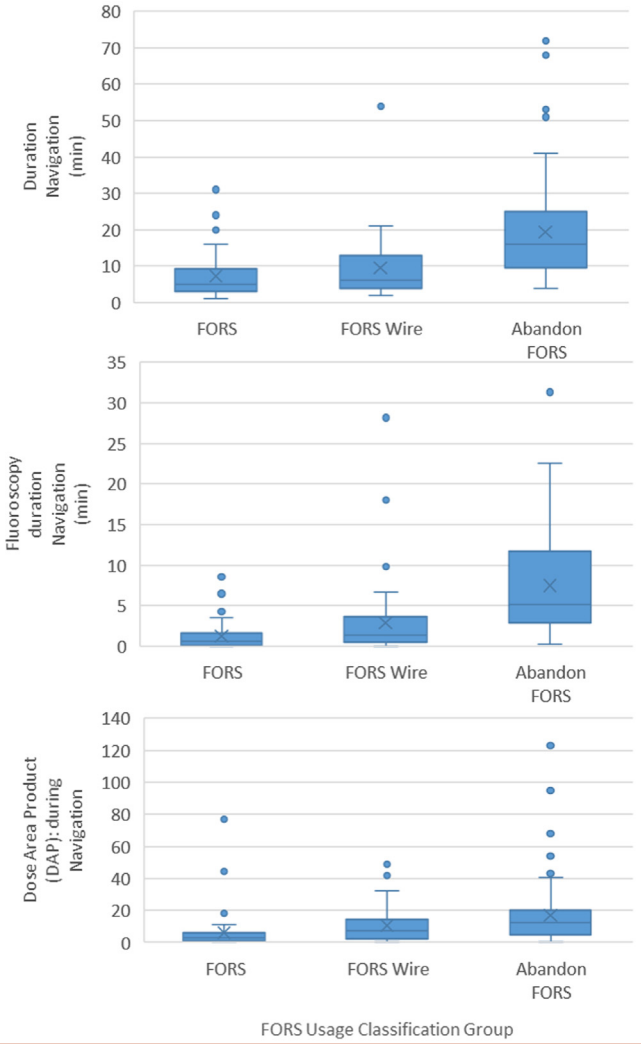

Fig 2. Boxplot of navigation time, fluoroscopy time, and dose area product of the three group. *FORS*, Fiber Optic RealShape.

the operators with standard fluoroscopy for complex aortic work may have affected outcomes, and this experience may not be generalizable to other centers. This study was also not designed to quantify radiation reduction using FORS technology, and further comparative studies are needed. Finally, the use of FORS technology currently involves a two-stage registration process for the preoperative CTA, intraoperative fluoroscopy, and the FORS system. Efforts are currently in progress to make these registration steps automated, further streamlining the workflow.

CONCLUSIONS

FORS technology was successfully implemented as a new guidance technology in a complex EVAR program and was associated with an encouraging success rate and a high potential for radiation reduction.

The authors thank Roland Bullens of Philips Medical Systems Nederland B.V. and the study team of the German Aortic Center Hamburg for their continuous effort to support this publication.

AUTHOR CONTRIBUTIONS

Conception and design: GP, BW, TK
Analysis and interpretation: GP, AS, GS, JvH, TK
Data collection: GP, FR, FH, BW, TK
Writing the article: GP, AS, BW, TK
Critical revision of the article: GP, AS, FR, FH, BW, GS, JvH, TK
Final approval of the article: GP, AS, FR, FH, BW, GS, JvH, TK
Statistical analysis: GP, BW
Obtained funding: TK
Overall responsibility: GP

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Submitted Mar 28, 2022; accepted Aug 3, 2022.

Additional material for this article may be found online at www.jvascsurg.org.

Supplementary Table I (online only). Details about excluded task (n = 15)

	No.	%
Type of target		
Celiac trunk	4	27
Contralateral gate	4	27
Internal iliac	1	7
Renal artery	2	13
Superior mesenteric artery	4	27
Cannulation trough fenestration or branch		
Branch	3	20
Fenestration	7	47
Native vessel	5	33
Wire used, cm		
0.0035-260	4	27
0.0035-180	7	47
0.0014-300	4	27
Reason of exclusion		
Excessive bend radius	10	67
Anatomy not suitable for FORS guidewire	5	33

FORS, Fiber Optic RealShape.

Supplementary Table II (online only). Procedure time and related radiation exposure for each type of procedure (n = 50)

	Procedure time, minutes				Contrast agent, mL			Air Kerma, mGy			Dose area product, Gy*cm^2		
Procedure type	Count	Median	Percentile 25	Percentile 75	Median	Percentile 25	Percentile 75	Median	Percentile 25	Percentile 75	Median	Percentile 25	Percentile 75
EVAR	6	149,00	106,00	227,00	100,50	76,00	117,00	973,05	742,00	1826,00	102,70	58,00	147,00
FEVAR	17	223,00	180,00	302,00	88,00	72,00	125,00	2396,00	1377,00	3798,00	175,00	116,00	279,00
BEVAR	19	240,00	188,00	308,00	110,00	84,00	134,00	2353,00	1757,00	3311,00	188,00	144,00	278,00
IBD	4	182,00	145,00	247,00	79,50	55,50	109,00	2764,50	1208,50	3904,00	228,00	87,20	364,00
BTEVAR	1	233,00	233,00	233,00	116,00	116,00	116,00	1459,00	1459,00	1459,00	156,00	156,00	156,00
Embolization	2	77,50	55,00	100,00	96,00	16,00	176,00	2609,50	321,00	4898,00	293,50	24,00	563,00
Stent graft in peripheral vessel	1	64,00	64,00	64,00	60,00	60,00	60,00	139,00	139,00	139,00	16,00	16,00	16,00

BEVAR, Branched endovascular aortic repair; *BTEVAR*, branched thoracic endovascular aortic repair; *EVAR*, endovascular aortic repair; *FEVAR*, fenestrated endovascular aortic repair; *IBD*, iliac branched device.