From the New England Society for Vascular Surgery

Initial single-center experience using Fiber Optic RealShape guidance in complex endovascular aortic repair

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ABSTRACT

Objective: In the present study, we have described the technical success using Fiber Optic RealShape (FORS) endovascular guidance and its effects on the overall procedural time and radiation usage during complex endovascular aortic repair (EVAR).

Methods: Fenestrated and branched EVARs performed at a single center from 2017 to 2022 were prospectively studied. FORS-guided procedures were matched retrospectively 1:3 to non–FORS-guided procedures by the incorporated target arteries and body mass index. Technical success was defined as successful target vessel cannulation using FORS for the entirety of navigation (wire insertion to exchange for a stiff wire). The predictors of technical success were evaluated via logistic regression. The procedural times and radiation doses were compared between the matched cohorts using the Wilcoxon rank sum test.

Results: A total of 21 FORS-guided procedures were matched to 61 non–FORS-guided procedures. A total of 95 FORS cannulations were attempted (87 for the visceral target artery and 8 for the bifurcate gate). Technical success was achieved in 81 cannulations (85%); 15 (16%) were completed without the use of live fluoroscopy. The univariate predictors of FORS technical success included <50% target artery stenosis, <50% target artery calcification, and the target vessel attempted ($P < .05$ for each). FORS failures were attributed to device material properties in six cases, device failure in two cases, and the wire/catheter combination in six. The use of FORS guidance was associated with shorter median procedural and fluoroscopy times and a lower dose area product and air kerma ($P \leq .0001$ for each).

Conclusions: The results from our initial experience with FORS during complex EVAR, including our learning curve, has shown promise, with acceptable technical success and reductions in procedural times and radiation usage. (J Vasc Surg 2023;77:975-81.)

Keywords: Endovascular guidance; EVAR; Fiber optics; FORS; Three-dimensional

Fluoroscopy has remained a cornerstone technology for endovascular aortic procedures since Volodos et al[1] and Parodi et al[2] first introduced endovascular aortic repair (EVAR). The versatility and real-time imaging possible with fluoroscopy have enabled a diverse array of minimally invasive diagnostic and therapeutic vascular applications. However, repeated exposure to ionizing radiation over time carries the risk of adverse health effects for both patients and healthcare staff.[3,4] These tradeoffs are particularly important for complex interventional procedures, which will frequently require extensive fluoroscopy usage.[5]

As endovascular case complexity has increased, the reliance on live fluoroscopy has not been overcome. The establishment of radiation best practices (ie, "as low as reasonably achievable") have helped minimize the length and amount of radiation exposure during endovascular interventions. Hybrid imaging suites have also evolved to incorporate many new dose-reducing technologies. During endovascular aortic surgery, the introduction of fusion imaging using preoperative computed tomography angiography (CTA) is one such adjunct that has yielded reductions in both fluoroscopy time and exposure.[6,7] Alternative methods of guidance, such as intravascular ultrasound, electromagnetic positioning, and endovascular robotics, have also been

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Clinical Trail Registration: NCT02050113.

Author conflict of interest: The University of Massachusetts Chan Medical School has a research and consultancy agreement with Philips Medical. E.J.F., J.P.S., D.W.J., D.R.J., F.A.A., L.T.B., C.M.S., T.T.N., and A.S. have no conflicts of interest.

Presented at the plenary session of the Forty-ninth Annual Meeting of the New England Society for Vascular Surgery, Newport, RI, October 14-16, 2022.

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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.2022.11.041

developed to reduce, or even eliminate, our reliance on fluoroscopy.[8-11] However, to date, these alternatives have been slow to achieve usage in the broader field of endovascular surgery, in part owing to the costs, device material properties, and susceptibility to outside interference.

Fiber Optic RealShape (FORS; Philips Medical Systems Nederland BV, Best, The Netherlands) is a novel alternative endovascular guidance system that uses reflected light to reconstruct the three-dimensional shape of wires and catheters in real time. This is accomplished by optical fibers embedded within the devices, which reflect specific wavelengths of light when bend is applied along a device. FORS-enabled wires and catheters will interface with a bedside docking adapter and can be used with conventional endovascular devices. On-table navigation can be performed without live fluoroscopy and will be facilitated by either fusion with preoperative CTA or on-table digital subtraction imaging, which will serve as an anatomic roadmap. At present, FORS serves as an adjunct to fluoroscopy during endovascular procedures rather than as a total replacement. The early study of the guidance technology has demonstrated the feasibility, safety, and technical success with its use during complex fenestrated and branched EVAR (F/B-EVAR).[12-14] However, the effects of FORS on case complexity and radiation usage in F/B-EVAR have not yet been demonstrated in a clinical study.

The present study had two primary aims. The first was to characterize the technical success of FORS-guided target vessel cannulation in F/B-EVAR, with the hypothesis that the vessel characteristics would be predictive of success. The second aim was to estimate the effect of FORS guidance on the overall operative time and radiation use, hypothesizing that FORS use would reduce both.

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, retrospectively matched observational cohort study
- **Key Findings:** We matched 21 fenestrated/branched endovascular aortic repairs (F/B-EVARs) performed with Fiber Optic RealShape (FORS) guidance to 61 cases performed without such guidance. Technical success with FORS-guided cannulation was 85%. The median procedure time and dose area product were lower for the F/B-EVAR procedures performed with FORS guidance ($P < .0001$ for both).
- **Take Home Message:** The early use of FORS guidance during complex F/B-EVAR has shown acceptable technical success and reductions in operative times and radiation usage.

METHODS

Study cohort. We performed an observational, retrospective, matched cohort study with prospective data collection performed at a single center. Data were collected as part of an institutional review board–approved physician-sponsored investigational device exemption (IDE) clinical trial of F/B-EVAR (IDE no. G130210; ClinicalTrials.gov identifier, NCT02050113), which had been supported solely by institutional funding and resources. FORS has been approved by the Food and Drug Administration for commercial use and, as such, the system is not used at present under an IDE. The study institution has a research and consultancy agreement with the manufacturer, Philips Medical Systems; however, the usage and study of FORS was conducted solely with institutional support. The patients provided written informed consent for the use of FORS guidance technology and the recording of usage data into a separate prospective database. All procedures had been performed at a single academic medical center in a hybrid operating room with the same primary surgeon (A.S.).

F/B-EVAR procedures performed for patients aged ≥18 years between January 2017 and March 2022 were eligible for study inclusion. Within this cohort, all procedures that had incorporated FORS guidance were selected for inclusion. FORS technology had been introduced at our institution in May 2021, and all subsequent patients who had undergone F/B-EVAR had provided written informed consent for the use of the technology. Procedures performed with FORS guidance differed from those without in that the data from the target vessel and contralateral device gate cannulation attempts were prospectively recorded in real time by trained study personnel in the operating room. The collected data included vessel anatomy clinically deemed to contribute to cannulation difficulty (ie, branch angulation, ostial calcification, degree of stenosis, and presence of a preexisting stent), the devices used, duration of navigation, fluoroscopy time, dose area product (DAP), air kerma, and technical success. Technical success was defined as successful cannulation of a target vessel using a FORS-enabled wire and/or catheter for the entirety of the task. A cannulation attempt was considered to have begun with the first introduction of a FORS-enabled wire and/or catheter into the field and successfully completed when a stiff wire had been delivered into the target vessel. Adjunctive fluoroscopy was used as needed during a cannulation task to verify the device positions and delineate the anatomy. The surgeons were queried in real time for the causes of cannulation attempt failure. For all the procedures, with and without FORS guidance, data on the components of the custom endograft were collected, including branches, fenestrations, scallops, usage of bifurcate devices, and iliac branched devices. Overall, the procedure

Fig 1. The in suite equipment necessary to use Fiber Optic RealShape (FORS), including, from right to left, a dedicated computer workstation, the FORS engine, and a bedside docking adapter.

operative time (incision to closure), fluoroscopy time, and radiation dose were also prospectively collected.

Cohort matching. Each F/B-EVAR procedure in which FORS guidance had been used was matched to three similar procedures performed without FORS guidance. Matching was performed using R statistical software, version 4.1.2 (R Core Team 2022; R Foundation for Statistical Computing, Vienna, Austria) using the MatchIt R package, version 4.3.4.[15,16] The cases were matched using a nearest neighbor method, which used differences in the propensity scores as a measure of the distances between the cases. The propensity scores were calculated with separate covariates for the body mass index and each of the device components used in the repair. Stratum matching was used to ensure that the cases matched exactly for their incorporated target vessels, the use of a bifurcate device, and the use of concomitant iliac branched devices. Each non–FORS-guided procedure was only allowed to match with a single FORS-guided case.

FORS guidance and equipment. The dedicated in suite equipment to facilitate FORS guidance included a computer workstation, the FORS engine (light source and reconstruction), and a bedside docking adapter for FORS-enabled devices (Fig 1). At present, for procedures with FORS guidance, three FORS-enabled devices are available for navigation: a 120-cm angled glidewire (not back-loadable), an 80-cm, 5.5F Berenstein catheter, and an 80-cm, 5.5F Cobra C2 catheter. All devices use an 0.035-in. diameter system. The FORS-enabled devices were used with conventional wires, catheters, and steerable sheaths, when deemed appropriate by the operating surgeon. When appropriate, FORS guidance was preferentially used for the first cannulation attempt of each target vessel. Some target vessels were cannulated more than once during F/B-EVAR, and the data from these attempts were also recorded. Repeat cannulation was necessary when wire access to a target vessel was unexpectedly lost. All cases included in the present study used preoperative CTA, which was fused with the patient's on-table cone-beam computed tomography scan to generate a fusion overlay anatomic roadmap. All FORS devices were purchased from Philips Medical by our institution within the context of a clinical research agreement. At present, the market prices for FORS system installation and endovascular devices have not been publicly announced by the manufacturer.

Study outcomes. The primary outcome of the present study was the technical success of attempted FORS target vessel cannulation during F/B-EVAR. The secondary outcomes were the overall procedural time and radiation usage (ie, fluoroscopy time, DAP, air kerma).

Statistical analysis. The median and interquartile range were used to summarize the continuous data. Counts and percentages were used for discrete data, as applicable. A nonparametric Fisher exact test and Wilcoxon rank sum test were used to test for differences in the continuous and discrete data between the cohorts, respectively. When multiple comparisons were made, the resultant *P* values were adjusted using Bonferroni's correction. The univariate predictors of technical success with FORS-guided cannulation were modeled with logistic regression, and the models were evaluated using the likelihood ratio test. All statistical analyses were conducted using R statistical software, version 4.1.2 (R Core Team 2022; R Foundation for Statistical

Table I. Baseline patient characteristics and aortic endograft design stratified by Fiber Optic RealShape (FORS) guidance

Variable	FORS guidance		*P* value
	Yes	No	
Cases	21	61	
Age, years	75 (72-82)	75.1 (71.1-82.1)	.74
Female sex	4 (19)	25 (41)	.09
BMI, kg/m^2	24.1 (21-27.6)	24.6 (20.7-30.8)	.62
White race	16 (76)	54 (86)	.33
Staged TEVAR	2 (10)	12 (20)	.5
Aneurysm extent			.002
Suprarenal	0 (0)	2 (3)	
Pararenal	6 (29)	8 (13)	
Juxtarenal	7 (33)	8 (13)	
Type II	1 (5)	11 (18)	
Type III	4 (19)	15 (25)	
Type IV	3 (14)	14 (23)	
Type V	0 (0)	3 (5)	
Device components			
Total incorporated arteries	4 (4-4)	4 (4-4)	1.00
Celiac artery	18 (86)	54 (88)	.7
Superior mesenteric artery	20 (95)	60 (98)	.5
Left renal artery	21 (100)	61 (100)	–
Right renal artery	19 (91)	55 (90)	1.00
Bifurcate device	11 (52)	32 (52)	1.00
Iliac branched device	0 (0)	0 (0)	–

BMI, Body mass index; *TEVAR,* thoracic endovascular aortic repair. Data presented as number, median (interquartile range) for continuous variables, or number (%) for discrete variables.

Computing).[15] An a priori cutoff of $\alpha = 0.05$ was used to determine statistical significance.

RESULTS

During the study period, 340 F/B-EVAR procedures had been performed, with 21 incorporating FORS guidance. The cases with FORS guidance were matched 1:3 to 61 F/B-EVAR procedures without FORS guidance. The cohort patient characteristics and device details are described in Table I. The only evaluated factor that differed significantly between the two cohorts was the aneurysm extent ($P = .002$).

FORS-guided cannulation. In the procedures using FORS guidance, 95 cannulations had been attempted: 87 for visceral target arteries and 8 for contralateral gate cannulation on a bifurcate device (Fig 2). Technical success was achieved in 81 of the 95 cannulations (85%; Table II). Of these, 15 tasks (16%) could be completed entirely without live fluoroscopy assistance. The lowest rate of technical success with FORS guidance was observed with cannulation of the right renal artery (n = 13; 65%). A preexisting stent was present in 16 target vessels (17%), >50% ostial calcification in 38 (40%), >50% vessel stenosis in 42 (44%), and upward or downward angulation in 53 (55%). The univariate predictors of FORS technical success included <50% target artery stenosis ($P = .04$), <50% target artery calcification ($P = .04$), and the cannulation target artery ($P = .01$). Pairwise testing did not demonstrate statistically significant differences in technical success between the cannulation targets (all corrected $P = .2$). Factors such as angulation of the vessel takeoff ($P = .2$), aortic diameter ($P = .4$), preexisting stent ($P = .6$), and branch vs fenestration ($P = .7$) were not predictive of technical success.

Task failure was attributed to an insufficient shape or the material conformity of the FORS-enabled devices in six cases by the study surgeon. Other reported causes of failure included device failure in two cases and an unworkable wire and/or catheter combination in six cases. Both device failures had resulted from severe kinking of the FORS-enabled glidewire, which resulted in device reconstruction failure. With each task failure, the surgeons switched to conventional wires and catheters to successfully complete those tasks. No negative patient outcomes or complications were attributed to FORS use.

Procedural time and radiation dose. The overall procedure time was shorter for procedures that had used FORS guidance compared with the matched procedures without FORS guidance ($P < .0001$; Table III), although fusion imaging had been used in all procedures. Similarly, the radiation dose, measured using the fluoroscopy time, DAP, and air kerma, were significantly lower with FORS guidance ($P < .0001$ for each). The median contrast usage was similar between the matched cohorts ($P = .06$).

DISCUSSION

FORS is a novel endovascular guidance technology that aims to reduce radiation usage and mitigate the complexity of endovascular interventions. Our initial experience has demonstrated acceptable technical success with FORS guidance for target vessel cannulation in complex EVAR. As expected, the vessel disease burden and target vessel selected were predictive of cannulation technical success. Compared with a matched cohort that had undergone similar repairs in patients with a matched body habitus, the procedures using FORS had had a shorter median operative time and had required lower radiation doses. These findings are particularly noteworthy because these data come from our initial

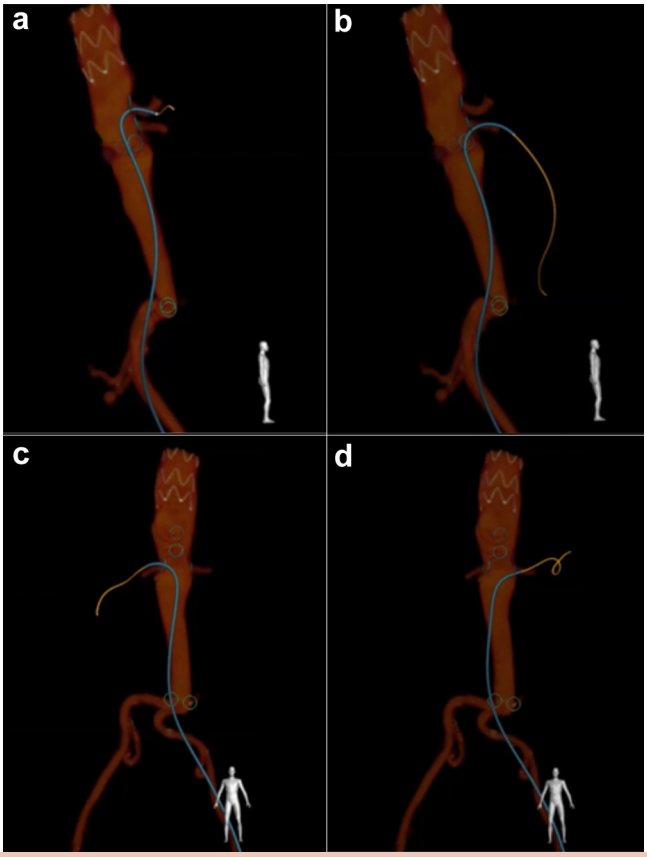

Fig 2. Fiber Optic RealShape (FORS) guidance during visceral target artery fenestration and vessel cannulation as depicted on screen during fenestrated/branched endovascular aortic repair (F/B-EVAR). The FORS wire is shown in *yellow* and the FORS catheter in *blue*. **a,** Celiac artery. **b,** Superior mesenteric artery. **c,** Right renal artery. **d,** Left renal artery.

experience, which incorporates our learning curve with FORS technology.

To date, nonradiation-based guidance technologies for endovascular procedures have been slow to achieve popularity in the endovascular community. Electromagnetic position tracking is one alternative technology in use at present, which determines the device position by the induced potentials generated within an electromagnetic field.[9] However, the early iterations of the technology have experienced difficulties with field interference and the material and design constraints of the available devices. Robotic-assisted catheterization systems are another alternative that enable operators to perform endovascular interventions remotely and with high precision.[11] However, these systems have been hindered by high costs and have not yet been shown to reduce patient radiation doses. As a new entry, FORS seeks to circumvent some of these limitations by using embedded optical fibers, which are less susceptible to outside interference, to facilitate real-time device shape reconstruction without fluoroscopy. The findings from the present study have addressed some of the integration challenges encountered with prior guidance technologies by demonstrating the utility of FORS guidance during F/B-EVAR.

FORS was previously granted approval by the Food and Drug Administration for marketing in the United States and is in limited commercial distribution. In this early iteration of the technology, FORS was primarily used as a navigational system during endovascular procedures. This is, in part, owing to the limited selection of FORS-enabled wires and directional catheters at present. However, even when used in this limited capacity, our early data have demonstrated associated reductions in the overall procedural time and radiation usage. As more devices are introduced to the market and the technology is incorporated into routine interventional tools, such as balloons and stent deployment systems, the potential exists for even further reductions.

Our prospective data collection enabled standardized evaluation of FORS-guided cannulation. A matched cohort design also reduced confounding in the direct comparison of the F/B-EVAR procedures performed with and without FORS guidance. However, it is possible that nonmatched factors such as the predominance of thoracoabdominal aortic aneurysms in the non–FORS-guided cohort could still have influenced the operative time and fluoroscopy usage. However, the more extensive aneurysms had undergone separate staged thoracoabdominal EVAR before F/B-EVAR, and the matching method used was chosen to keep the steps and devices components of F/B-EVAR as similar as possible between the two cohorts. The generalizability of our study findings was also limited by our focus on a highly specialized procedure performed at a single center by a single primary surgeon. The inclusion of consecutive procedures that had been performed immediately after FORS adoption at our center means that the study findings could also have been tempered by our learning curve with the technology. It is possible that the differences observed in the present study will be more pronounced once we are further along our learning curve. Finally, the prolonged 5-year study period could have also captured unaccounted for shifts in clinical practice and technologies, which could have influenced the study results. As a general practice, steerable sheaths were used throughout the entire study period to aid in target vessel cannulation.

CONCLUSIONS

The results from our initial experience with FORS guidance during complex endovascular aortic surgery, which incorporated our learning curve, have shown promise with acceptable rates of technical success and reductions in the overall radiation dose and procedure time.

Table II. Technical success, operative time, and radiation dose for target vessel cannulations performed with Fiber Optic RealShape (FORS) guidance

Cannulation target	Total attempted	Success	Navigation time, minutes	Fluoroscopy time, minutes	DAP, Gy × cm^2	Air kerma, mGy
Celiac artery	16	14 (88)	4.5 (2.8-7.5)	0.4 (0.2-1.7)	4 (0.2-7.2)	20 (0.6-79.3)
SMA	19	18 (95)	4 (2.5-6)	0.2 (0.1-0.5)	1.9 (0.4-2.8)	11.7 (2.1-21)
Left renal artery	32	28 (88)	4 (2.5-6.5)	0.4 (0.1-1.3)	1.1 (0.3-2.4)	8.5 (2.8-21.5)
Right renal artery	20	13 (65)	5 (4-7.2)	0.8 (0.2-2)	3 (1.7-5.2)	17.9 (10.8-37.6)
Contralateral device gate	8	8 (100)	5 (4-7)	0.4 (0-0.6)	0.4 (0-0.7)	2 (1-4)

DAP, Dose area product; *SMA*, superior mesenteric artery.
Data presented as number, number (%) for discrete variables, or median (interquartile range) for continuous variables.

Table III. Procedural time and radiation use stratified by Fiber Optic RealShape (FORS) guidance

Variable	Overall	Cohort		*P* value
		FORS	Non-FORS	
Cases, No	82	21	61	
Procedure time, minutes	209 (156-288)	140 (121-191)	222 (180-296)	<.0001
Fluoroscopy time, minutes	56 (45-75)	37 (26-52)	63 (51-81)	<.0001
DAP, Gy × cm^2	299 (159-457)	160 (111-189)	363 (245-516)	<.0001
Air kerma, Gy	3.3 (1.8-5.7)	1.2 (0.8-2)	3.8 (2.6-7.1)	<.0001
Contrast, mL	81 (62-96)	93 (79.5-103)	80 (56-94)	.06

DAP, Dose area product.
Data presented as median (interquartile range) for continuous variables, unless noted otherwise.

The findings from the present study support the feasibility and utility of nonradiation-based guidance technologies in endovascular procedures.

AUTHOR CONTRIBUTIONS

Conception and design: EF, JS, DWJ, DRJ, FA, LB, CS, TN, AS
Analysis and interpretation: EF, AS
Data collection: EF
Writing the article: EF, AS
Critical revision of the article: EF, JS, DWJ, DRJ, FA, LB, CS, TN, AS
Final approval of the article: EF, JS, DWJ, DRJ, FA, LB, CS, TN, AS
Statistical analysis: EF
Obtained funding: Not applicable
Overall responsibility: EF

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Submitted Aug 26, 2022; accepted Nov 7, 2022.