Fiber Optic RealShape imaging using upper extremity and transfemoral access for fenestrated-branched endovascular aortic aneurysm repair

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ABSTRACT

We report our initial experience using Fiber Optic RealShape (FORS), an innovative real-time three-dimensional visualization technology that uses light instead of radiation, to achieve upper extremity (UE) access during fenestrated/branched endovascular aortic aneurysm repair (FBEVAR). An 89-year-old male patient with a type III thoracoabdominal aortic aneurysm, unfit for open aortic repair, underwent FBEVAR. Dual fluoroscopy, intravascular ultrasound, and three-dimensional fusion overlay were used, in addition to FORS. All target artery catheterizations were successfully accomplished using FORS, from UE access, without radiation. Our experience demonstrates that FBEVAR with FORS using UE access can be used for target artery catheterization without radiation. (J Vasc Surg Cases Innov Tech 2023;9:1-6.)

Keywords: Endovascular navigation; FBEVAR; Fiberoptic technology; FORS; Imaging; Radiation; Upper extremity access

Since the first aortic endovascular repair reported by Volodos et al[1] in 1987, the history of aortic aneurysm treatment has increasingly switched from open surgical to endovascular treatment as a first-line strategy. Increasing complexity and longer procedures, however, have resulted in increased radiation exposure for patients and medical staff, particularly during fenestrated and branched endovascular aneurysm repair (FBEVAR).[2-5]

Over the past decades, imaging technologies have been developed to diminish radiation exposure, including real-time intravascular ultrasound (IVUS), three-dimensional (3D) fusion overlay, low-dose machine settings, and personal protective equipment, among others.[6] Following the same direction of radiation reduction, Fiber Optic RealShape (FORS) might be considered a technology that crosses boundaries between radiation exposure and the time of procedures, because FORS technology achieves submillimeter precision, provides full 3D shape visualization, and might potentially attenuate the need for fluoroscopy.[7] FORS uses light reflected from optical fibers embedded in specially designed wires and catheters. In 2021, van Herwaarden et al[8] reported the first-in-human clinical study using FORS. Although the primary end point was the technical success of all navigational tasks, they concluded that FORS has the potential to improve intraoperative image guidance and reduce radiation exposure. In that first-in-human FORS study,[8] 60 of the 66 tasks were successfully completed (90.9%) using at least one component of FORS technology (AltaTrack catheter or guidewire; Philips Healthcare Inc). According to a qualitative scoring questionnaire, the usefulness of FORS technology was rated as "better than standard guidance" during navigation.

In a recent report, Panuccio et al[9] reported 201 navigation tasks, 186 with FORS guidance, achieving 62% technical success, using transfemoral (TF) access in all procedures (72% were FBEVARs). The few reported failures were attributed to limitations in the length and shape of the FORS equipment. In the present report, we demonstrate the feasibility of FORS using upper extremity (UE) access for target artery catheterization, without guidewire or catheter length limitations.

CASE REPORT

An 89-year-old male patient, with multiple comorbidities and deemed unfit for open aortic repair, underwent FBEVAR for a type III thoracoabdominal aortic aneurysm. A preloaded fenestrated patient-specific device planned and manufactured by Cook Medical Inc was used as part of an investigational device

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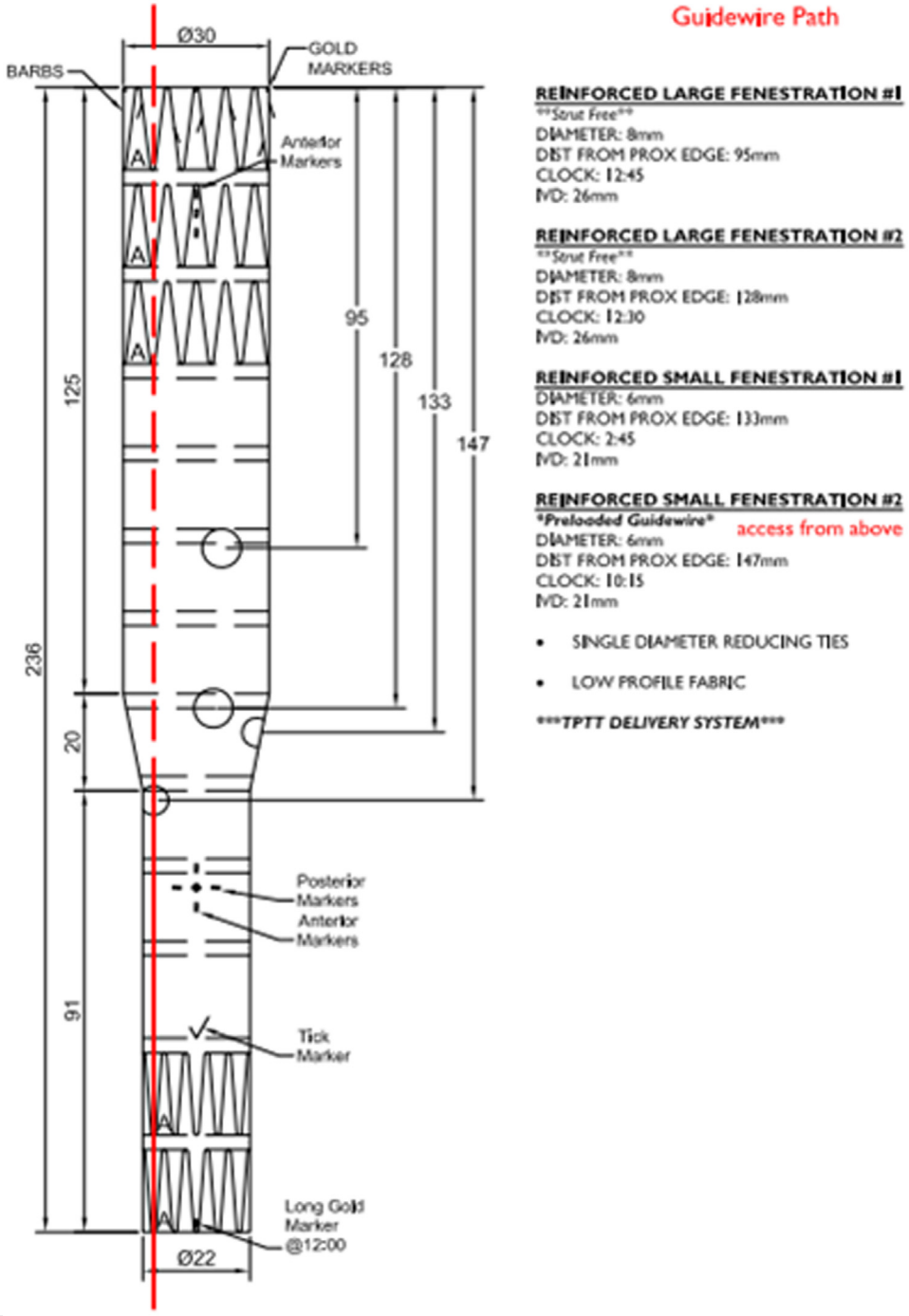

Fig 1. Device design. A preloaded guidewire system attached to a fenestrated endograft was used to facilitate all target vessel cannulations from right upper extremity (UE) access.

exemption study protocol (approval no. G140108; NCT no. 02266719; Fig 1). The patient provided written informed consent for the report of his case details and imaging studies.

In a hybrid operation room, all the settings for FORS equipment were arranged as recommended,[10] except for positioning of the docking base, which was fixed on the right side of the patient closer to the operator (Fig 2). The preoperative computed tomography angiogram was used to generate the 3D fusion overlay. After bilateral common femoral and right brachial artery access, the IVUS probe was inserted through the groin access. The fusion overlay registration was further adjusted using live IVUS guidance. UE access was chosen, given the angulation and tortuosity of the paravisceral aorta.

The FORS AltaTrack guidewire (0.035-in.; 120-cm working length) was attached to the docking base, using the right upper extremity artery as the gateway.[11] The FORS shape system was

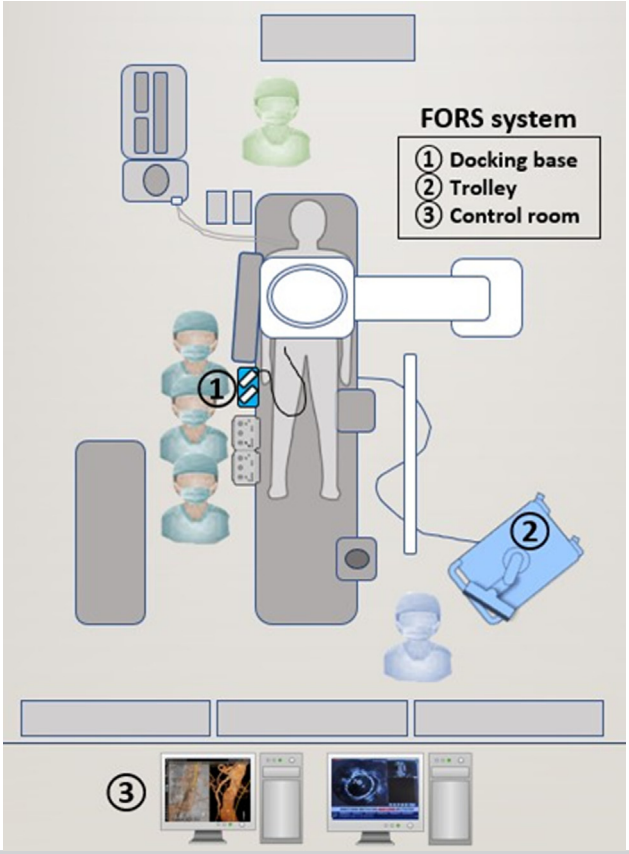

Fig 2. Fiber Optic RealShape *(FORS)* technology settings. The docking base was placed on the right side of the patient, closer to the operator.

registered using two different angulation fluoroscopy images (anteroposterior and right anterior oblique 30°), which semiautomatically recognized the device tip and guidewire shape. Catheterization of the descending aorta was performed using the AltaTrack guidewire and conventional curved catheters through proximal right brachial artery access under FORS visualization and without using radiographs (Fig 3, *A*). A 12F, 45-cm Ansel sheath (Cook Medical Inc) was advanced using UE access, across the aortic arch, allowing wire exchanges and snaring from the right femoral artery access. The 12F sheath was advanced and placed in the descending thoracic aorta. Also, to avoid arch manipulation during target artery (TA) cannulation, all catheterizations were performed within this sheath, which was rarely displaced. The patient-specific endograft was advanced from the right groin over a through-and-through brachiofemoral guidewire. A thoracoabdominal preloaded through-and-through delivery system was used. The endograft was partially deployed under IVUS and fusion live image guidance, exposing the most proximal fenestration. The sequential catheterization amid progressive endograft deployment technique was used.[12] Through a 7F, 70-cm sheath and using the FORS guidewire and a standard 4F, 100-cm Bernstein catheter, one TA was cannulated each time and confirmed angiographically. The celiac and superior mesenteric arteries were catheterized first (Fig 3, *B*), followed by the renal arteries. The FORS wire was then exchanged for a 0.035-in. working wire with an atraumatic tip, such as the Magic Torque (Boston Scientific) or the TAD II (Abbott Vascular Inc) wires. The available AltaTrack catheter (5.5F Bernstein or Cobra 1 design/80-cm working length) was not used.[13] Once all four arteries were successfully catheterized, the endograft was fully deployed, releasing the constraining wires. The bifurcated device was then advanced and deployed under fluoroscopy. The FORS wire was used for contralateral gate cannulation using left femoral access (Fig 3, *C*). The FORS system did not need additional registration or adjustments.

Technical success of the navigation task was defined as accomplishment of the entire TA cannulation using FORS technology. The necessity to switch the method to conventional fluoroscopy without an AltaTrack guidewire was designated as failure. The data regarding each target cannulation is reported in the Table. In total, all five navigation tasks were accomplished within 23 minutes, using UE access for all TAs and left lower extremity access for the contralateral gate. The technical success rates were 100% in all cannulation tasks. During all cannulations, 4 minutes and 18 seconds of fluoroscopy time were required. The reference air kerma and dose area product for the cannulations were 13.45 mGy and 0.13 Gy • cm^2, respectively. Most of these radiation doses were related to subtraction angiography obtained before and after target vessel stenting. As bridging stents for the target vessels, the Gore Viabahn VBX Balloon Expandable Endoprosthesis (W.L. Gore & Associates) was used. Overall, the procedure required 4 hours and 12 minutes, requiring 59.1 minutes of fluoroscopy time, 105 mL of contrast load, 769.62 mGy reference air kerma, and 77 Gy • cm^2 dose area product. Individually, the operator, fellow, circulator, scrub technician, and anesthesia personnel received 46 μSv, 36 μSv, 1 μSv, 2 μSv, and 2 μSv, respectively. The completion angiogram revealed patent TAs and no significant endoleak, which was confirmed by the predischarge computed tomography angiogram (Fig 4). The patient was discharged 4 days after the procedure, with no major adverse events.

DISCUSSION

UE access is frequently used for complex aortic endovascular repairs. The advent of steerable sheaths has allowed for the use of exclusive TF access for many patients undergoing FBEVAR. UE is, thereby, no longer the access of choice because of the slightly higher stroke rates compared with TF access.[14] Current experience with FORS has primarily included aortic endovascular repairs performed using exclusively TF access. The limitations in length with the current FORS guidewires and catheters have favored the use of TF access. In the present report, however, we describe the applicability of FORS technology using UE access. Not only was its use feasible during FBEVAR with UE access, but also the FORS guidewires could be used with ease and confidence, allowing for the benefits of this innovative and multimodality imaging technique with real-time 3D visualization and reduced fluoroscopy.

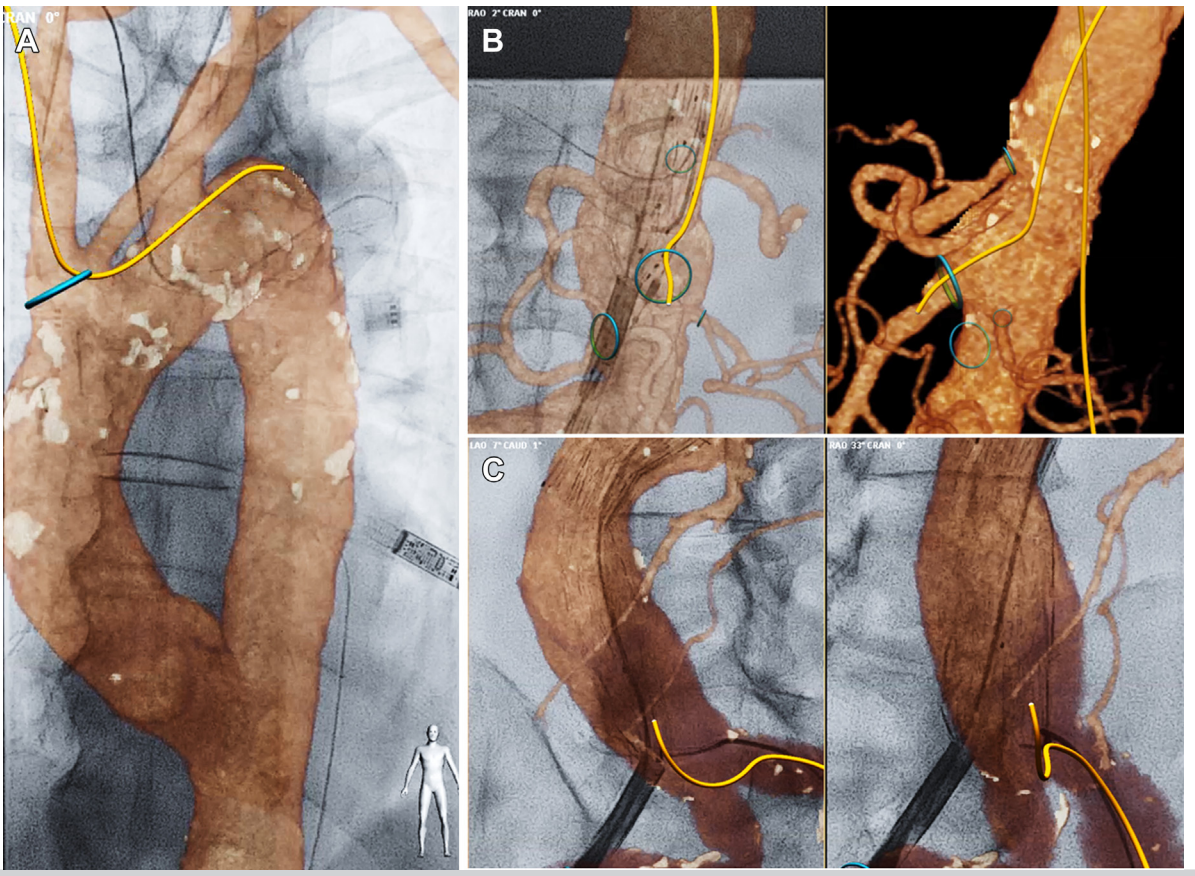

Fig 3. Cannulation with Fiber Optic RealShape (FORS) technology. **A,** Descending aorta. **B,** Target vessels, represented by the superior mesenteric artery. **C,** Contralateral gate.

Table. Cannulation details using Fiber Optic RealShape (FORS) technology during fenestrated/branched endovascular aortic aneurysm repair (FBEVAR)

TA	Artery access	RAK, mGy	DAP, Gy • cm^2	Duration, minutes	Fluoroscopy time, seconds
Celiac artery	Right brachial	1.67	0.2	4	30
SMA	Right brachial	0	0	2	0
Left renal artery	Right brachial	0.54	0.1	3	6
Right renal artery	Right brachial	5.95	0.4	9	120
Contralateral gate	LCFA	5.29	0.6	5	102

DAP, Dose area product; *LCFA*, left common femoral artery; *RAK*, reference air kerma; *SMA*, superior mesenteric artery; *TA*, target artery.

FORS technology is a low-radiation 3D guidance technology that enables the operator to navigate in real-time through simple and complex anatomies using fiberoptic light pulses, reducing radiation exposure. Despite Food and Drug Administration approval and CE mark (Conformite Europeenne), FORS technology is not widely available. The manufacturer (Philips Healthcare) is currently running a clinical study at 10 centers in Europe and the United States using the 0.035-in. AltaTrack guidewire with a 120-cm working length and 5.5F AltaTrack catheters with an 80-cm working length in Bernstein or Cobra1 configuration. Our findings confirm the feasibility of using the current AltaTrack guidewire with the operator's preferred catheter, using multiplanar projections. FORS technology is in evolution, and new upgrades and devices are underway that will allow for the use of most standard catheters and longer guidewires.

Despite the benefits of FORS, it is important to emphasize that radiographs are still required during key portions of the FBEVAR procedure. Endograft deployment must still be performed under fluoroscopic guidance, and digital subtraction angiography is required for TA visualization and stenting. Fluoroscopy was also required

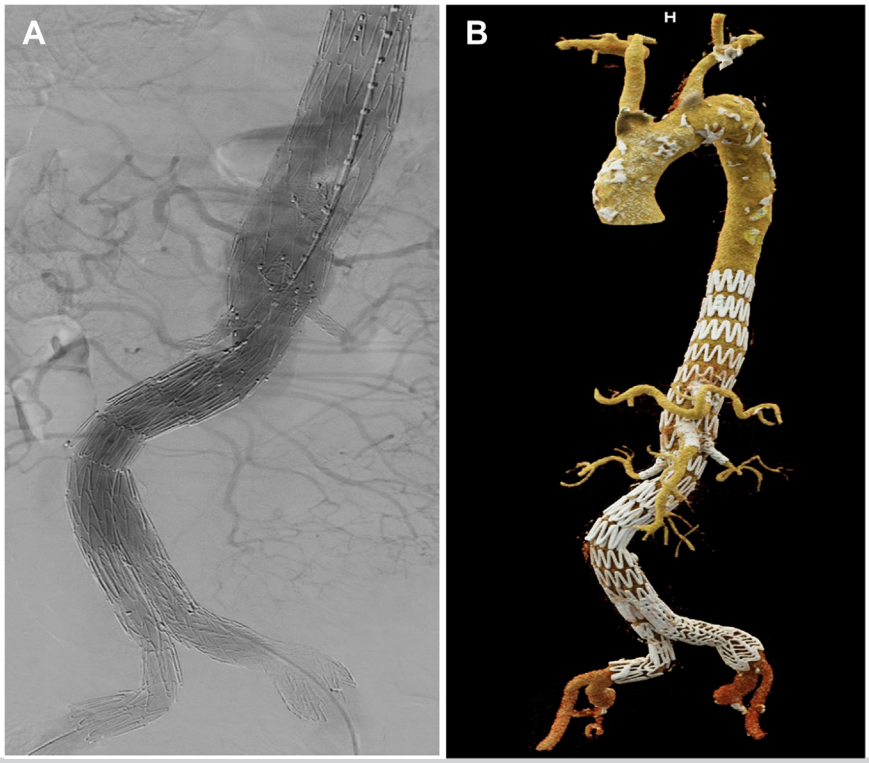

Fig 4. Final results. **A,** Angiogram once all tasks were completed. **B,** Three-dimensional (3D) computed tomography angiogram reconstruction before discharge.

for some TA catheterizations when increased difficulty in advancing the wire and/or catheter was met, which was usually related to anatomic reasons (Table). The current limitations with FORS equipment, as stated, are also related to rare distortions in the visualization of the FORS guidewire. Increased tension or resistance in advancing the guidewire and the surgeon's proximity to the docking area, because it is located on the right side of the patient in the proposed setup for UE access, could affect and momentarily interfere with the system signal if excessive manipulation occurs. Loss of registration of the FORS devices can occur; however, manual modifications of the imaging using fluoroscopy and IVUS can restore proper positioning and visualization. Nonetheless, we have demonstrated the feasibility of using FORS for all TA and contralateral gate catheterizations.

CONCLUSIONS

Complex aortic endovascular procedures with FORS technology using UE and TF access is feasible and facilitates TA catheterization without the need for radiation. A new endovascular era with minimal radiation has begun that allows for endovascular procedures, even complex ones, using light-based imaging. Notwithstanding the promising benefits of this technology, FORS is still in development, and further experience is required to demonstrate its overall benefits and applicability for complex endovascular procedures using both TF and UE access.

REFERENCES

1. Volodos NL, Karpovich IP, Shekhanin VE, Troian VI, Iakovenko LF. [A case of distant transfemoral endoprosthesis of the thoracic artery using a self-fixing synthetic prosthesis in traumatic aneurysm]. Grudn Khir 1988:84-6.
2. Thakor AS, Winterbottom A, Mercuri M, Cousins C, Gaunt ME. The radiation burden from increasingly complex endovascular aortic aneurysm repair. Insights Imaging 2011;2:699-704.
3. Little MP, Wakeford R, Tawn EJ, Bouffler SD, Berrington de Gonzalez A. Risks associated with low doses and low dose rates of ionizing radiation: why linearity may be (almost) the best we can do. Radiology 2009;251:6-12.
4. Kirkwood ML, Arbique GM, Guild JB, et al. Surgeon education decreases radiation dose in complex endovascular procedures and improves patient safety. J Vasc Surg 2013;58:715-21.
5. Kirkwood ML, Chamseddin K, Arbique GM, et al. Patient and operating room staff radiation dose during fenestrated/branched endovascular aneurysm repair using premanufactured devices. J Vasc Surg 2018;68:1281-6.
6. Rohlffs F, Spanos K, Debus ES, Heidemann F, Tsilimparis N, Kolbel T. Modern image Acquisition system reduces radiation exposure to patients and staff during complex endovascular aortic repair. Eur J Vasc Endovasc Surg 2020;59:295-300.
7. Megens M, Leistikow MD, van Dusschoten A, et al. Shape accuracy of fiber optic sensing for medical devices characterized in bench experiments. Med Phys 2021;48:3936-47.
8. van Herwaarden JA, Jansen MM, Vonken EPA, et al. First in human clinical feasibility study of endovascular navigation with fiber optic RealShape (FORS) technology. Eur J Vasc Endovasc Surg 2021;61:317-25.
9. Panuccio G, Schanzer A, Rohlffs F, et al. Endovascular navigation with fiber optic RealShape (FORS) technology. J Vasc Surg 2023;77:3-8.e2.

10. Panuccio G, Torrealba J, Rohlffs F, Heidemann F, Wessels B, Kolbel T. Fiber optic RealShape (FORS) technology for endovascular navigation in severe tortuous vessels. J Endovasc Ther 2023;30:29-33.
11. DEVICE: AltaTrack Guidewire (00884838070974). US National Library of Medicine. AccessGUDID, https://accessgudid.nlm.nih.gov/devices/00884838070974. Accessed March 1, 2022.
12. Timaran CH, Stanley GA, Baig MS, Timaran DE, Modrall JG, Knowles M. The sequential catheterization amid progressive endograft deployment technique for fenestrated endovascular aortic aneurysm repair. J Vasc Surg 2017;66:311-5.
13. DEVICE: AltaTrack Catheter (00884838070967). US National Library of Medicine. AccessGUDID, https://accessgudid.nlm.nih.gov/devices/00884838070967. Accessed March 1, 2022.
14. Porras-Colon J, Knowles M, Timaran CH. Outcomes and strategies for utilization of brachial access and preloaded systems during F/BEVAR. Semin Vasc Surg 2022;35:287-96.

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