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Editor's Choice – Radiation Dose Reduction During Contralateral Limb Cannulation Using Fiber Optic RealShape Technology in Endovascular Aneurysm Repair

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WHAT THIS PAPER ADDS

Fiber Optic RealShape (FORS) is a newly developed technology that uses specially designed endovascular devices with embedded optical fibres that use laser light instead of fluoroscopy to visualise endovascular guidewires and catheters. These devices are shown in real time in bright colours with added 3D aspects such as shading and a white dot at the tip of the device to enhance spatial understanding, improve navigation, and reduce radiation exposure during navigation or cannulation tasks in endovascular procedures. This study is the first to demonstrate radiation dose reduction using FORS during contralateral limb cannulation in standard endovascular aneurysm repair.

Objective: The increasing number of endovascular procedures has resulted in an increasing radiation burden, particularly for the treatment team. Fiber Optic RealShape (FORS) technology uses laser light instead of fluoroscopy to visualise the endovascular guidewire and catheters. These devices can be used during the navigational part of procedures, such as cannulation of the contralateral limb (CL) in endovascular aneurysm repair (EVAR). The aim of this study was to describe the effect of using FORS on radiation dose during CL cannulation in standard EVAR.

Methods: This was a non-randomised, retrospective comparison study of prospectively collected, single centre data from FORS guided EVAR compared with a conventional fluoroscopy only guided EVAR cohort. A total of 27 FORS guided cases were matched 1:1 based on sex, age, and body mass index (BMI) with 27 regular (fluoroscopy only) EVARs. This study primarily focused on (1) technical success of FORS and (2) navigation time and radiation dose (cumulative air kerma [CAK], air kerma area product [KAP], and fluoroscopy time [FT]) during cannulation of the CL. In addition, overall procedure time and radiation dose of the complete EVAR procedure were studied.

Results: In 22 (81%) of the 27 FORS guided cases the CL was successfully cannulated using FORS. All radiation dose parameters were significantly lower in the FORS group (CAK, $p < .001$; KAP, $p = .009$; and FT, $p < .001$) for an equal navigation time ($p = .95$). No significant differences were found when comparing outcomes of the complete procedure.

Conclusion: Use of FORS technology significantly reduces radiation doses during cannulation of the CL in standard EVAR.

Keywords: Endovascular aneurysm repair, Endovascular navigation, Endovascular procedure, Fibre optic technology, Radiation
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INTRODUCTION

Since the first endovascular aneurysm repair (EVAR) was reported more than three decades ago by Volodos *et al.*,[1,2] rapid developments have led to a major shift from open to endovascular treatment strategies. The continued evolution of endovascular therapies makes it possible to treat

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increasingly complex pathologies in a minimally invasive way, with lower peri-operative complication risks and reduced hospital stay.[3–7] However, a major drawback to this shift is the need for fluoroscopy to visualise endovascular devices. Because exposure to fluoroscopy can lead to DNA damage and long term health risks, current radiation guidelines are based on the as low as reasonably achievable (ALARA) principle.[8–12] This principle aims to use the lowest possible radiation dose to achieve an image quality that allows the procedure to be performed adequately and safely. However, the increasing number of endovascular interventions has led to increasing cumulative radiation doses, especially for the interventional team.[13–15] Another limitation of fluoroscopy guidance is the fact that 3D devices, such as endovascular wires and catheters, are projected onto screens as 2D grayscale images, making it difficult to identify the direction of the tip and the exact spatial shape of these devices.

Although the need for additional radiation reducing navigation techniques is high, many of these technologies are still under development and therefore have hardly been used in a clinical context to date.[16] Fiber Optic RealShape (FORS) technology (Philips Koninklijke N.V., Best, the Netherlands) is a promising new technology that has recently been introduced for endovascular interventions such as EVAR. This technology directs laser light through specially designed endovascular devices with embedded optical fibres to enable real time endovascular navigation without the use of fluoroscopy.[17] To enhance visualisation against the grayscale 2D anatomical background, these endovascular devices are projected in bright colours with 3D features such as shading and a white dot at the tip of the device. In addition, FORS overcomes the limitation of current C arm hardware to only view from one direction while navigating by using a so called biplane view. This means that the devices can be viewed simultaneously from two directions, independent of the viewing angle of the C arm hardware, further enhancing the spatial perception of the devices used in relation to the anatomy and stent graft shown by background (single shot) fluoroscopy image(s). The first published results of FORS regarding radiation exposure and cannulation success are promising,[18–21] however only the study by Finnesgard *et al.*[21] has described the results of a comparison between a FORS guided and conventional fluoroscopy guided group in complex EVAR. The aim of this study was to describe the effect of FORS on radiation exposure during cannulation of the contralateral limb (CL) during non-complex EVARs.

MATERIALS AND METHODS

Study design and patient selection

This study was a retrospective comparison of prospectively collected, single centre data of FORS guided EVAR for treatment of infrarenal or isolated common iliac artery aneurysms between August 2020 and November 2022. During this period, all elective standard EVAR procedures with a bifurcated stent graft were included consecutively. FORS guided cases were matched 1:1 according to sex, age, and body mass index (BMI) with consecutive cases from a historical conventional fluoroscopy guided EVAR cohort treated between February 2015 and August 2020. Case – control matching was performed using IBM SPSS Statistics version 27 (IBM Corp., Armonk, NY, USA) using its case control matching application. Each conventional fluoroscopy guided EVAR was only allowed to match once with a single FORS guided EVAR. All patients who underwent FORS guided EVAR provided written informed consent to participate in the FORS Learn Registry, which has been approved by the local ethics committee (METC protocol number 20-467/c non-WMO study). The study was performed according to the Declaration of Helsinki and the STROBE guidelines.[22]

Procedure description

All procedures in both cohorts were performed in a dedicated hybrid operating room (OR) equipped with a ceiling mounted Allura FD20 FlexMove or Azurion C arm (Philips Medical Systems Nederland B.V., Best, the Netherlands) with ClarityIQ technology (Philips Medical Systems Nederland B.V.). In addition, all procedures were performed by vascular surgeons who either gained experience using FORS technology during previous studies,[17,18] or gained experience by attending multiple (i.e., five or more) FORS guided procedures and performing multiple FORS guided cannulation tasks in a phantom setup. Three different single use FORS devices were available: 0.035” hydrophilic floppy guidewire, 5.5 F Berenstein catheter, and Cobra C2 catheter. More details about FORS technology and setup in the hybrid OR during EVAR have been published previously.[19–21] In addition, Figure 1 shows a schematic overview of the operative setup during a FORS guided EVAR that, with the exception of the FORS equipment, is identical to the conventional fluoroscopy guided EVAR operative setup. All included procedures were performed according to standard medical care from a transfemoral access and were divided into a navigation and a conventional treatment phase. Since FORS was developed to improve navigation and cannulation in endovascular procedures, this technology was only used during the CL cannulation of the EVAR stent graft. The cannulation phase was defined as the first moment when the guidewire appeared in the field of view until the moment when the stiff wire, e.g., Rosen or Lunderquist, was introduced in the CL. Cannulation of the CL was successful without conversion towards an ipsilateral or brachial approach in all cases. All procedures were recorded to accurately determine the start and end of this phase post-operatively. In the FORS guided group, the navigation phase always started with at least the FORS guidewire. When cannulation with FORS seemed impossible, operators switched to conventional catheters and guidewires. No specific time point for conversion towards a standard fluoroscopy guided approach was defined. Conversion depended on the inability of FORS to angle for CL cannulation, e.g., due to reduced torqueability or lack of the preferred shape configurations of available FORS

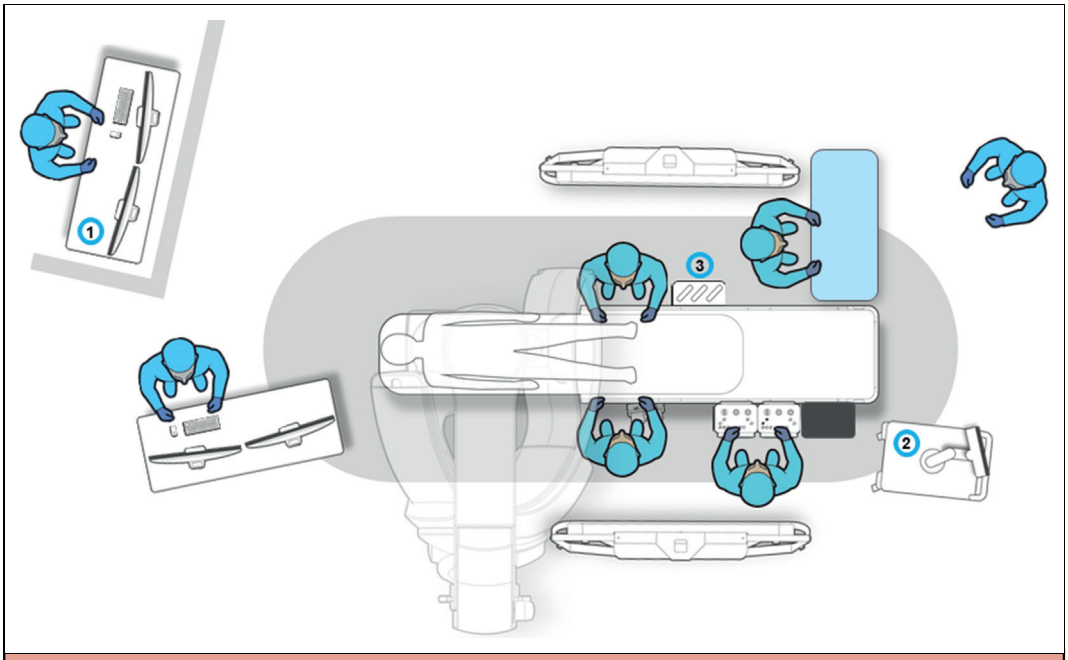

Figure 1. Schematic overview of the operative setup in hybrid operating room during a Fiber Optic RealShape (FORS) guided standard endovascular aneurysm repair (EVAR), which is similar to conventional fluoroscopy guided EVAR with the exception of the positioned FORS system parts. The following FORS components are used in the hybrid operating room: (1) In the control room, FORS workstation used to connect the FORS technology to the fixed fluoroscopy system and to register the FORS compatible devices; (2) FORS trolley containing the main hardware and software components of the system; and (3) FORS docking base and top used to connect the FORS enabled devices. The FORS docking base is attached pre-operatively to the rail of the operating table and provides a fixed point relative to the changing position coordinates of the fluoroscopy system during procedures, allowing coupling of the coordinate systems of the fixed fluoroscopy system to interface with FORS compatible devices.

devices. The success of FORS guided cannulation was registered peri-operatively, together with, if applicable, the reason for switching to conventional devices. The conventional treatment phase, performed with fluoroscopy, consisted of all other tasks, such as positioning and deployment of the EVAR stent graft, introduction and deployment of the iliac limbs, and performing a control angiogram.

Outcome and statistical analysis

This study primarily focused on (1) technical success of FORS attempted CL cannulation and (2) navigation time and radiation exposure parameters (cumulative air kerma [CAK], air kerma area product [KAP], and fluoroscopy time [FT] [digital subtraction angiography time not included]). In addition, overall procedure time and radiation exposure parameters for the complete procedure were studied. Definitions of analysed radiation exposure parameters are described in the European Society for Vascular Surgery (ESVS) radiation guidelines.[12] Navigation phase radiation exposure parameters were derived from the captured recording of the OR screens showing real time cumulative radiation collected from the C arm, whereas radiation parameters of the complete procedure were derived from the automatically generated dose reports of the C arm.

Table 1. Baseline characteristics of 54 patients with Fiber Optic RealShape (FORS) guided or conventional fluoroscopy guided navigation during endovascular aneurysm repair (EVAR)

Characteristic	FORS (n = 27)	Conventional (n = 27)	p value
Sex male	25 (93)	25 (93)	1.0
Age − y	73.0 (67.0, 77.0)	72.0 (69.0, 76.0)	.71
BMI − kg/m^2	27.16 (24.69, 28.73)	25.86 (24.64, 27.74)	.56
Comorbidities			
Coronary artery disease	12 (44)	13 (48)	1.0
Heart failure	2 (7)	0 (0)	.49
Cerebrovascular disease	3 (11)	5 (19)	.70
Hypertension	17 (63)	18 (67)	1.0
COPD	8 (30)	3 (11)	.18
Diabetes mellitus	6 (22)	8 (30)	.76
Hypercholesterolaemia	9 (33)	9 (33)	1.0
Connective tissue disease	0 (0)	0 (0)	–
Renal insufficiency	6 (22)	4 (15)	.73
Prior aortic surgery	0 (0)	0 (0)	–

Data are presented as n *(%)* or median (interquartile range). BMI = body mass index; COPD = chronic obstructive pulmonary disease.

Table 2. Overview of cannulation attempts both with Fiber Optic RealShape (FORS) guidewire and catheter, FORS guidewire with conventional catheter, and only conventional devices, along with success rate for cannulation of the contralateral limb in endovascular aneurysm repair

Device	Attempts	Success (n = 27)
FORS guidewire and catheter	25 *	16 (59)
FORS guidewire and conventional catheter	11	6 (22)
Conventional guidewire and catheter	5	5 (19)

Data are presented as n (%).
* Due to a FORS system error, it was not possible to start with both FORS guidewire and catheter in two cases.

Table 3. Cannulation time and radiation exposure parameters in Fiber Optic RealShape (FORS) guided *vs.* conventional fluoroscopy guided cannulation of the contralateral limb during endovascular aneurysm repair

Parameter	FORS * (n = 26)	Conventional (n = 27)	p value
Cannulation time − min	8.0 (3.0, 10.3)	7.0 (4.0, 11.0)	.95
CAK − mGy	5.0 (1.9, 14.0)	22.1 (10.0, 37.6)	<.001
KAP − Gy·cm^2	2.0 (0.6, 4.7)	4.3 (1.8, 8.5)	.009
FT − sec	37.0 (16.5, 86.5)	176.0 (83.0, 259.0)	<.001

Data are presented as median (interquartile range). CAK = cumulative air kerma; KAP = air kerma area product; FT = fluoroscopy time.
* One FORS guided case was excluded from the analysis because it was not possible to determine the contralateral limb cannulation time or the results of the radiation parameters post-operatively due to difficulties during recording of one of the FORS guided procedures.

Dichotomous data are presented as number and percentage, whereas continuous data showed a non-parametric distribution and are therefore presented as median and interquartile range (IQR). Wilcoxon rank sum test was used to test for differences in continuous data. All statistical analyses were performed using IBM SPSS Statistics version 27.

RESULTS

During the study period between August 2020 and November 2022, 111 subjects were enrolled in the FORS Learn Registry, of whom 27 were treated for an infrarenal or isolated common iliac artery aneurysm. The conventional fluoroscopy guided EVAR cohort consisted of 84 consecutive cases treated between February 2015 and August 2020. Execution of the matching strategy resulted in a total study group of 54 subjects (27 FORS guided *vs.* 27 conventional fluoroscopy guided EVAR). Both groups had a 25:2 male:female distribution with a median age of 73.0 years (IQR 67.0, 77.0) in the FORS guided cohort and 72.0 years (IQR 69.0, 76.0) in the conventional fluoroscopy guided cohort. Moreover, the presence of comorbidities was not significantly different between the groups. An overview of all baseline characteristics is presented in Table 1.

Fiber Optic RealShape success rate, navigation time, and radiation dose

In 22 of 27 FORS guided EVARs, the CL was successfully cannulated using FORS, 16 times using both a FORS guidewire and catheter and six times using only a FORS guidewire in combination with a conventional catheter (Table 2). In two cases the FORS catheter could not be used due to an error in the FORS system that prevented it from being reconstructed on the screen. Due to difficulties while recording one of the FORS guided procedures, it was not possible to determine the CL cannulation time and radiation parameter outcomes in one case. Hence, radiation data of the navigation phase of 26 FORS guided EVARs were compared with those of 27 conventional fluoroscopy guided EVARs. All radiation dose parameters were significantly lower in the FORS guided group (CAK, $p < .001$; KAP, $p = .009$; and FT, $p < .001$), while navigation time ($p = .95$) was similar in both groups (Table 3).

Overall procedure time and radiation dose

Overall procedure radiation data of 27 FORS and 27 conventional fluoroscopy guided standard EVARs were compared. No significant differences were found between the two groups (procedure time, $p = .74$; CAK, $p = .82$; KAP, $p = .35$; and FT, $p = .29$). An overview of the overall procedure time and radiation dose is presented in Table 4.

DISCUSSION

This study is the first to compare radiation exposure parameters during standard EVAR in a FORS guided cohort with a matched conventional fluoroscopy guided cohort. Of the 27 CL cannulations, 22 (81%) were successfully performed using at least the FORS guidewire. In five cases the operators switched from FORS to a conventional guidewire because of manoeuvrability constraints within the anatomy while using FORS devices. In the FORS guided group, all radiation parameters during the navigation phase were significantly reduced with similar CL cannulation times. On the other hand, as expected, no significant differences were observed at the procedural level between the FORS and conventional fluoroscopy guided cohorts.

In addition to the reduction in radiation, FORS was expected to decrease navigation time by increasing spatial awareness by adding 3D features, coupled with the ability to view the devices from two directions simultaneously in a so called biplane view (Fig. 2). However, the navigation time was comparable between the groups. This is probably due to the fact that the so called shape registration process (done during the set up at the beginning of the procedure) needed to be performed again during the navigation phase when switching to a different FORS catheter ($n = 3$) or to correct for reduced accuracy ($n = 1$). Since additional shape registrations were performed after the start of the

Table 4. Total procedure time and radiation exposure parameters in Fiber Optic RealShape (FORS) guided *vs.* conventional fluoroscopy guided endovascular aneurysm repair

Parameter	FORS (n = 27)	Conventional (n = 27)	p value
Procedure time − min	120.0 (111.0, 130.0)	118.0 (104.0, 154.0)	.74
CAK − mGy	293.0 (252.0, 434.0)	313.0 (236.0, 570.0)	.82
KAP − Gy·cm^2	84.4 (69.4, 128.0)	75.6 (63.0, 118.3)	.35
FT − sec	1037.0 (877.0, 1276.0)	1 148.0 (900.0, 1 499.0)	.29

Data are presented as median (interquartile range). CAK = cumulative air kerma; KAP = air kerma area product; FT = fluoroscopy time.

navigation phase, shape registration was considered part of this phase and therefore extended the navigation time. In addition, due to its tethered connection to the FORS system, the FORS guidewire is not back loadable and therefore additional steps are required when changing catheters. As a result, it is well possible that, in combination with the added time due to additional shape registrations, the faster navigation time actually achieved with FORS is negated.

Besides improving 3D perception during navigation, FORS has also been developed to limit radiation exposure during endovascular procedures. The recently published ESVS radiation safety and practice guidelines emphasise the importance of reducing radiation exposure and the possible contribution of a technique such as FORS during endovascular procedures.[12] However, the present results only show a significant reduction of radiation dose during CL cannulation using FORS, which is not reflected in an overall procedure radiation dose. This may be due to the fact that the FORS guided phase in standard EVAR is a relatively small part of the complete intervention. This is probably different for complex (fenestrated or branched) EVARs, since those interventions consist of multiple FORS guided navigation tasks (cannulation of the different target vessels). As a result, FORS is used in a greater part of the procedure and can therefore also lead to a significant reduction in the total radiation dose. This is demonstrated by Finnesgard *et al.*

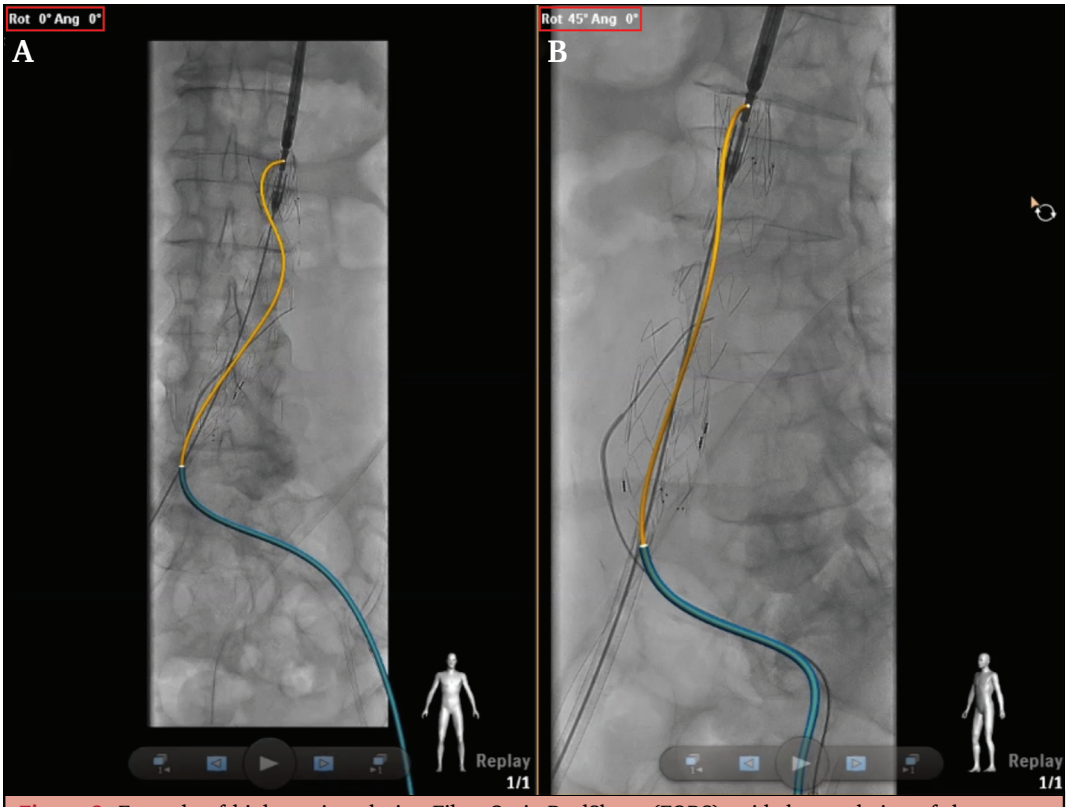

Figure 2. Example of biplane view during Fiber Optic RealShape (FORS) guided cannulation of the contralateral limb (CL) of endovascular aneurysm repair (EVAR) stent graft using 0.035" angled hydrophilic floppy FORS guidewire (yellow) and a 5.5 F FORS Berenstein catheter (blue). (A) The background left of the vertical yellow line is a single acquired anteroposterior fluoroscopy image, while (B) the background right of the vertical yellow line is a single shot image of the stent graft acquired at a 45° rotation angle.

who reported a reduction in procedure time and overall radiation exposure when using FORS during complex EVAR procedures.[21] Nevertheless, at this moment, the radiation reducing contribution of FORS in these cases also remains limited to a relatively small part of the procedure. The combination of FORS with other radiation reduction technologies, such as intravascular ultrasound (IVUS), offers the potential to further reduce radiation exposure at a procedural level and has already been described during endovascular treatment of peripheral arterial disease.[23] Recent studies have shown that the use of IVUS during EVAR procedures contributes to a reduction in radiation exposure during stent graft sizing and positioning and determining limb landing zones.[24,25] Illuminati *et al.*[26] even describe a fully ultrasound assisted EVAR strategy, which not only reduces procedural radiation exposure but also eliminates the need to use nephrotoxic iodine contrast. In contrast, while until now FORS only contributes to radiation reduction during the navigation phase, in this case cannulation of the CL, the use of ultrasound may also reduce radiation exposure in all other steps of the procedure. The combination of FORS and ultrasound during these procedures thus seems to be a step closer to a radiation free interventional environment, as radiation exposure can then be limited during all phases of the EVAR procedure.

This study demonstrates that FORS has a radiation reducing effect during CL cannulation. In order to achieve even more radiation reduction and possibly ultimately reduce procedure time while using FORS, expansion of the FORS portfolio is necessary. This has already started with introduction of the 3D Hub, which is a small device that connects to the back of conventional catheters using a standard Luer lock system and has replaced both available FORS catheters. When used in conjunction with the FORS guidewire, the technology can fully visualise conventional catheters over a FORS wire without using fluoroscopy.[27] To further expand the application of the product, it is important that back loadable FORS guidewires with different lengths and properties for specific tasks are developed in the future. But development should not be limited to expansion of the number of available FORS guidewires and compatible catheters. The technology has the potential to further reduce radiation exposure when integrated into other endovascular devices such as stent graft delivery systems and percutaneous transluminal angioplasty balloon catheters. This makes it possible to perform more and more procedures with a minimal amount of radiation, or even without radiation at all.

A limitation of this prospective, single centre study is that only 27 standard EVARs have been performed using FORS. This small sample size, coupled with the fact that this is the first comparative study for CL cannulation in EVAR, made it impossible to perform a proper power analysis to determine the minimum number of FORS cases needed. In addition, the conventional fluoroscopy guided cohort turned out to be too small to perform a proper 2:1 or 3:1 matching strategy with strict matching conditions. However, power is especially limited by the relatively small sample size of the FORS group. Although both groups were matched based on sex, age, and BMI, a potential risk of bias could not be excluded because possible anatomical confounders, such as aortic tortuosity and CL position, were not included during matching. However, large variations in anatomical complexity are reduced to some extent by the fact that all included patients underwent regular infrarenal EVAR. Furthermore, due to a procedure registration error, it was not possible to derive the radiation parameters from the navigation phase in one case, and therefore only 26 FORS guided cases were included in this analysis. Finally, the conventional fluoroscopy guided EVAR group was treated from 2015 until 2020, and the FORS guided EVAR group between 2020 and 2022. As all surgeons benefit from experience, there might have been a learning curve favouring the later FORS group. In addition, despite the fact that the EVARs were all performed by surgeons experienced in using FORS technology,[18] it is still possible that there was a learning curve during clinical use, especially in the first cases. Unfortunately, this is a limitation of the current study setup and is very hard to correct for, especially since FORS was not available earlier and since its introduction is used per protocol. Ideally, a large, multicentre, randomised controlled trial should be designed, which also includes anatomical confounders in order to address these limitations. Future larger prospective studies enabling extensive matching strategies should further confirm the radiation reducing effect of FORS and show its additional value in the future endovascular field.

Conclusions

Use of FORS technology significantly reduced radiation dose during cannulation of the CL in standard EVARs in this small study population. To pursue further reduction of radiation doses during endovascular interventions, expansion of the FORS portfolio is necessary, and continued technology evolution, such as the recent introduction of the 3D Hub, is mandatory. These novel technologies are promising to ultimately achieve the goal of a radiation free interventional environment.

CONFLICTS OF INTEREST

The authors declared the following potential conflicts of interest with respect to the research, authorship, and or publication of this article: Philips Medical Systems Netherlands B.V. provided a research grant according to fair market value to the Division of Surgical Specialties of the University Medical Centre Utrecht (Utrecht, the Netherlands) to support the FORS Learn registry. The Division of Surgical specialties of the University Medical Centre Utrecht has a research and consultancy agreement with Philips. The Department of Vascular Surgery is part of the Division of Surgical Specialties.

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