

## ORIGINAL RESEARCH

# 3D Visualisation of Navigation Catheters for Endovascular Procedures Using a 3D Hub and Fiber Optic RealShape Technology: Phantom Study Results

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**Objective:** Fiber Optic RealShape (FORS) is a new technology that visualises the full three dimensional (3D) shape of guidewires using an optical fibre embedded in the device. Co-registering FORS guidewires with anatomical images, such as a digital subtraction angiography (DSA), provides anatomical context for navigating these devices during endovascular procedures. The objective of this study was to demonstrate the feasibility and usability of visualising compatible conventional navigation catheters, together with the FORS guidewire, in phantom with a new 3D Hub technology and to understand potential clinical benefits.

**Methods:** The accuracy of localising the 3D Hub and catheter in relation to the FORS guidewire, was evaluated using a translation stage test setup and a retrospective analysis of prior clinical data. Catheter visualisation accuracy and navigation success was assessed in a phantom study where 15 interventionists navigated devices to three pre-defined targets in an abdominal aortic phantom using an Xray or computed tomography angiography (CTA) roadmap. Additionally, the interventionists were surveyed about the usability and potential benefits of the 3D Hub.

**Results:** The location of the 3D Hub and catheter along the FORS guidewire was detected correctly 96.59% of the time. During the phantom study, all 15 interventionists successfully reached the target locations 100% of the time and the error in catheter visualisation was 0.69 mm. The interventionists agreed or strongly agreed that the 3D Hub was easy to use and the greatest potential clinical benefit over FORS is in offering interventionists choice over which catheter they used.

**Conclusion:** This set of studies has shown that FORS guided catheter visualisation, enabled by a 3D Hub, is accurate and easy to use in a phantom setting. Further evaluation is needed to understand the benefits and limitations of the 3D Hub technology during endovascular procedures.

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## INTRODUCTION

Fluoroscopically guided endovascular interventions have become the gold standard to treat a variety of vascular pathologies. However, fluoroscopically guided navigation has several limitations. First, the devices are navigated in complex 3D anatomies but are visualised on 2D projection images. For simple manoeuvres this may be acceptable, but for complex and tortuous vasculature, commonly encountered in abdominal aortic aneurysm repairs, it can be especially challenging to understand the spatial relationship between the

devices and anatomy, potentially leading to extended navigation time.<sup>1,2</sup> Secondly, for complex procedures, like fenestrated or branched endovascular aneurysm repairs, the complexity of navigating devices can lead to extensive fluoroscopy usage, resulting in high radiation doses to the patient and staff.<sup>3,4</sup>

To overcome some of these challenges, interventional image fusion tools<sup>5,6</sup> have been developed, which combine real time 2D fluoroscopy images with static pre-operative 3D volumes, such as computed tomography angiography (CTA) or magnetic resonance angiography. This enables the interventionist to see a projection of the device in real time on the 3D volume. These tools have been shown to decrease radiation dose,<sup>7,8</sup> contrast volume,<sup>7–10</sup> and procedure time<sup>8,9</sup> by providing better anatomical guidance; however, they do not improve the visualisation of devices.

The Fiber Optic RealShape (FORS) technology<sup>11</sup> offers 3D device visualisation by embedding an optical fibre, capable

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of measuring 3D shape, in specially designed guidewires. A first in human study with 22 patients showed the safety of using FORS in abdominal and peripheral endovascular procedures with the potential to improve intra-operative image guidance.<sup>2</sup> In that study, two FORS enabled catheters (80 cm 5.5F Cobra C2, 80 cm 5.5F Berenstein) were used in addition to the FORS enabled guidewire for catheter visualisation. To enable 3D visualisation of additional catheters, without having to embed an optical fibre in each catheter, the 3D Hub technology was developed. The 3D Hub, when used with a FORS guidewire, enables 3D visualisation of compatible conventional navigation catheters, when the FORS guidewire is at the tip of the catheter or beyond. This is the first phantom study to demonstrate the ability to navigate and visualise compatible conventional catheters in 3D using FORS without any adaptation of the catheter itself. The present study describes the 3D Hub technology, the accuracy of localising the 3D Hub with respect to the FORS guidewire, the accuracy of visualising conventional catheters in a phantom setting, and the potential benefits and usability as perceived by end users.

## METHODS

### Study design

Multiple experiments were used to demonstrate feasibility and usability of the 3D Hub technology. Accuracy of localising the 3D Hub with respect to the FORS guidewire was evaluated with a bench top study and a retrospective analysis of prior clinical data. A phantom study with interventionists was used to evaluate the accuracy of visualising navigation catheters and success of navigating to predefined target locations. The same interventionists were surveyed about the usability of the 3D Hub and the potential benefits of the technology.

### FORS technology

The FORS technology platform (Philips Medical Systems Nederland BV, Eindhoven, Netherlands) consists of: (1) single use devices, (2) a trolley, (3) a docking top and docking base, and (4) a workstation. The details of the platform have been described previously.<sup>12,13</sup> Briefly, the trolley includes a laser that sends light through a multicore optical fibre integrated in a specially designed guidewire. Twists and bends in the optical fibre influence the wavelength spectrum of the reflected light, which enables the reconstruction of the 3D shape of the optical fibre. Integrating the optical fibre in a single use 0.035" 120 cm angled hydrophilic guidewire enables radiation free visualisation of the 3D shape of the entire length of the device.

Visualisation of the guidewire alone without anatomical context has limited use. Therefore, the FORS technology works in conjunction with a commercially available fluoroscopy system, either the Philips Allura Xper FD20 or the Philips Azurion FD20 (Philips Medical Systems Nederland BV). The fluoroscopy system is used to generate static anatomical roadmaps of the vessels, by means of either a DSA or CTA co-registered to the

live fluoroscopy images.<sup>13</sup> As the shape of the guidewire is also co-registered, it enables the interventionist to visualise the 3D device shape in real time (~60 fps) overlaid on the fluoroscopy image and or the 3D volume of the anatomy (Fig. 1A).<sup>13</sup>

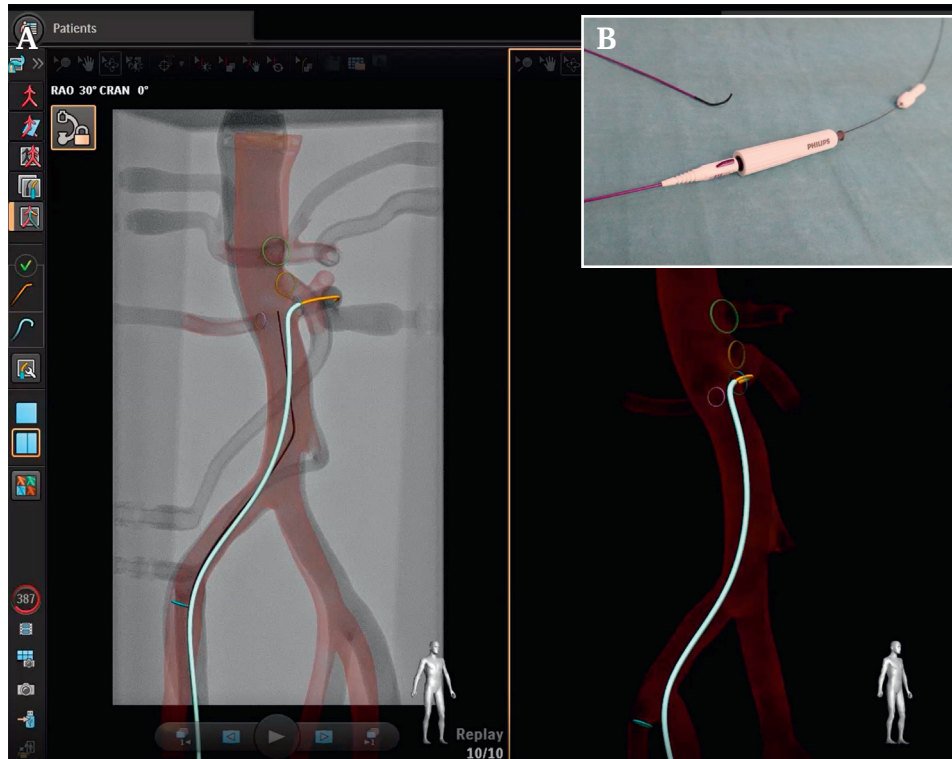
### 3D Hub technology

The 3D Hub technology (Philips Medical Systems Nederland BV) is an add on to the FORS technology, which enables 3D visualisation of compatible conventional navigation catheters. A compatible catheter has a luer lock complying with [Standard.80369–7], a length of  $\leq 95$  cm, and a lumen compatible with a 0.035" guidewire. A 3D Hub (Fig. 1B), which weighs 8 g and is 9 cm long, attaches to a catheter via a luer lock. The 3D Hub contains a channel for the FORS guidewire which creates a unique signature that is sensed in the 3D reconstruction of the shape of the guidewire.<sup>14</sup> To visualise the shape of the catheter two things must be known: (1) the position of the 3D Hub along the FORS guidewire, defined by the location of the unique signature, and (2) the length of the catheter. There are three possible methods for registering the length of the catheter. The first two methods involve aligning the tips of the guidewire and catheter, either by eye outside of the body or under Xray visualisation inside the body. The third method involves acquiring an Xray image of the guidewire extended beyond the tip of the catheter and selecting the guidewire and catheter tips in the Xray image. During device navigation, the 3D Hub position is continuously tracked with respect to the guidewire based on the location of the unique signature in the FORS guidewire signal. The 3D shape of the catheter is derived from the reconstructed 3D shape of the guidewire in the region where the catheter overlaps the guidewire. If the catheter extends beyond the tip of the FORS guidewire, the shape of the catheter is extrapolated in the segment where no guidewire is present.

### Accuracy of tracking the 3D Hub

The accuracy of tracking the position of the 3D Hub was calculated from a bench top experiment using a custom designed translation stage setup; a motorised guidewire feeding mechanism with a 3D Hub holder was mounted on a frictionless stage. A FORS guidewire was pushed through the 3D Hub and retracted over a distance of ~20 cm, at a speed of 10 mm/s (estimate of navigation speed). This measurement was repeated for 34 3D Hubs and two FORS guidewires. Each measurement ( $n = 136$ ) consisted of multiple frames of FORS data. The percentage of data frames where the unique signature of the 3D Hub was correctly detected and an exact binomial 95% confidence interval (CI), determined the accuracy.

An additional analysis, using data from the first in human study,<sup>2</sup> was completed to determine whether the unique signature of the 3D Hub was indeed unique and did not resemble other over the wire devices or the interventionists' hands. The 3D Hub was not used during that study; therefore, the unique 3D Hub signature should be absent from the FORS data. In term of data, ~1.5 million



**Fig. 1.** (A) Visualisation as seen by the interventionalist of the Fiber Optic RealShape (FORS) guidewire (yellow) and a Terumo Cobra 2 catheter (blue) overlaid on a pre-operatively acquired computed tomography angiogram (left and right) and an Xray image (left) (B) Picture of the 3D Hub (white) along with the FORS guidewire (black), a conventional catheter (purple), and a torquer.

frames of data were analysed and the percentage of frames where the 3D Hub signature was detected, along with an exact binomial 95% CI, were calculated.

### Phantom study

The phantom was a 3D silicone model of an abdominal aorta with renal and iliac arteries and the coeliac trunk (A-S-N-003 Elastrat, Switzerland). A non-pulsatile pump was used to perfuse the model with a solution of water and soap, to reduce wall friction. Vascular access was provided by haemostatic valves in both external iliac arteries. A contrast enhanced CTA of the model was available for roadmap purposes. The study was performed using a Philips Azurion FD20 FlexMove Xray system (Philips Medical Systems Nederland BV) and the FORS system described above.

Interventionists were recruited by a recruiting company and received an honorarium. Inclusion criteria included: interventional radiologist or vascular surgeon performing more than 40 peripheral endovascular procedures per year. Interventionists were excluded if they had prior (within one year of this study) experience with the 3D Hub. Fifteen interventionists were recruited, consisting of 10 interventional radiologists and five vascular surgeons, with 10 from the Netherlands, four from Belgium, and one from Germany. Three interventionists were using the FORS technology without the 3D Hub in clinical practice (one under contract

with Philips). The remaining 12 had no clinical experience with the FORS technology.

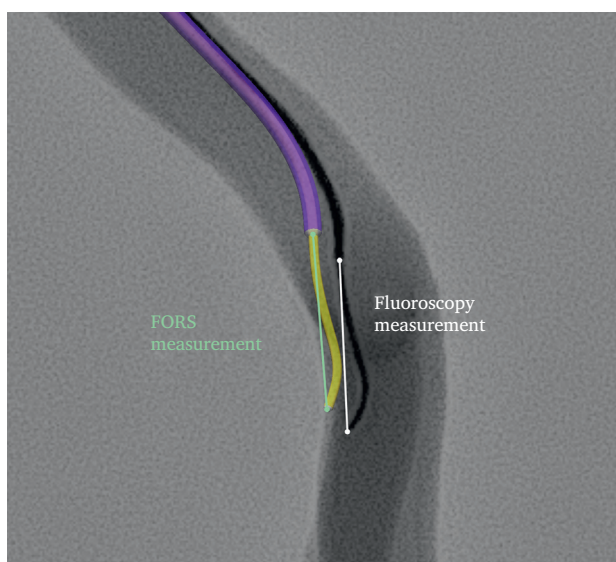
Each interventionist was asked to select a conventional catheter of their choice (maximum length of 95 cm for compatibility with the 120 cm FORS guidewire), attach the 3D Hub, complete the registration steps, and then navigate the guidewire and catheter to three pre-defined targets (right and left renal arteries, and over the aortic bifurcation into the contralateral common iliac artery). Navigation was completed once with a CTA roadmap and once with an Xray roadmap. Each navigation sequence was scored as a success or failure. Successful cannulation was achieved when the FORS guidewire and catheter were placed in a stable position (based on the interventionist's judgement) inside the target vessel. Use of Xray during navigation was recorded but was not considered a failure, as Xray use would be acceptable in the clinical workflow. FORS shape data and a recording of the monitor were saved for each navigation sequence, totalling 90 sets of data (three target locations, with and without CTA, 15 interventionists). An Xray image was acquired to confirm the target location had been successfully reached.

Catheter visualisation accuracy was measured using a custom software tool which calculates the distance between the catheter and guidewire tips in the fluoroscopic image obtained at the completion of each navigation task (ground truth), compared with the distance measured between the

reconstructed FORS device shapes at the same time point (Fig. 2). Tasks were excluded if the guidewire was not extended beyond the tip of the catheter, or if either the catheter or guidewire tip was not visible in the fluoroscopic image. An additional analysis was conducted to determine the number of occurrences where the guidewire was retracted inside the catheter as well as the length of unsensed catheter.

### User experience survey

At the end of the phantom study, each interventionist was asked to respond to a set of questions about the usability of the 3D Hub and the potential benefits the 3D Hub



**Fig. 2.** Method for measuring the accuracy of the catheter visualisation.

technology may bring to their clinical practice. The survey questions were asked with a Likert scale (strongly agree, agree, neutral, disagree, and strongly disagree) and analysed with descriptive statistics (total responses, averages, standard deviations, percentages).

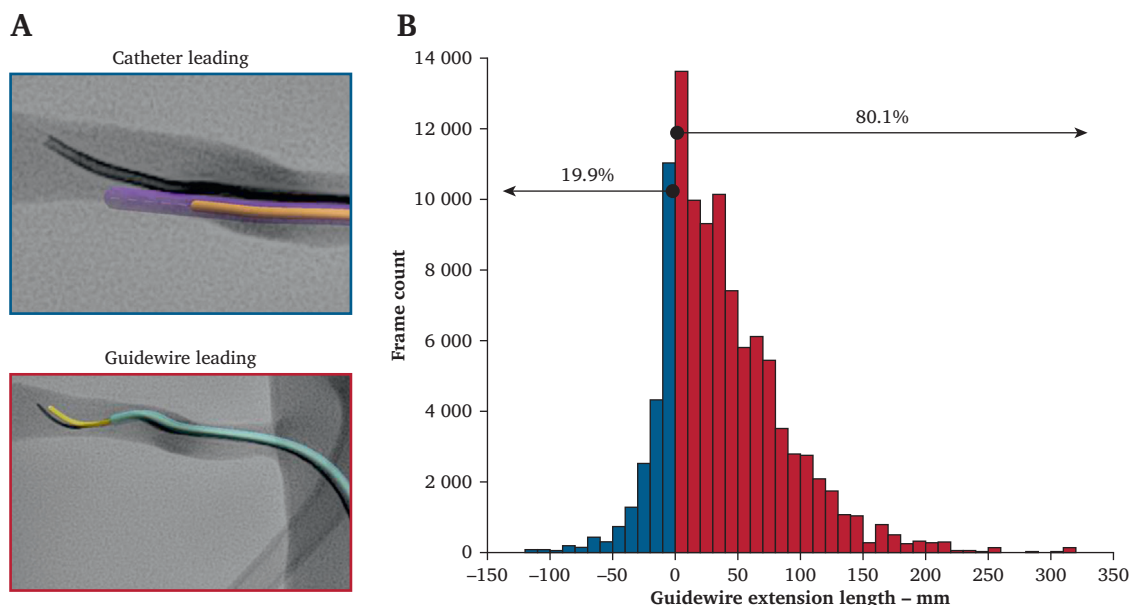
## RESULTS

### Accuracy of tracking the 3D Hub

In the bench top experiment, the 3D Hub signature was correctly detected 96.59% of the time (173 073 detections of the 3D Hub signature in 179 182 frames [95% CI 96.506–96.674]). In the retrospective clinical study data, a 3D Hub signature was erroneously detected 0.022% of the time (329 of 1 494 293 frames [95% CI 0.020–0.025]). It is unknown whether another over the wire device resembled the 3D Hub signature or if it was related to the manipulation of the guidewire by the interventionist.

### Phantom study

The interventionists recruited for the phantom study and survey had on average, 13.1 years of experience with a range of 2–25 years, and they self reported performing approximately 195 interventional procedures per year on average with a range of 50–600 procedures. One interventionist chose a Terumo Glidecath Cobra 2 (5F, 80 cm) and a Merit Medical Vector 4 Impress (5F, 65 cm) for their navigation tasks. A second interventionist used a Merit Medical Berenstein (5F, 65 cm) and a Cordis Cobra II (5F, 80 cm). The remaining 13 interventionists used a single catheter: Merit Medical Vector 4 Impress ( $n = 5$ ), a Cordis Cobra II ( $n = 3$ ), a Terumo Glidecath Cobra 2 ( $n = 1$ ), a Terumo Glidecath Cobra 2 (5F, 80 cm) ( $n = 2$ ), or a Merit Medical Berenstein ( $n = 2$ ).



**Fig. 3.** (A) Example images of a catheter or guidewire leading. (B) Percentage of frames where catheter (blue) or guidewire (red) is leading during navigation to the targets. Not all data are shown for the “guidewire leading” length.

Fig. 1A shows an example of an interventionist navigating with a CTA roadmap towards the left renal artery. All 15 interventionists successfully (100% success rate) reached the three target locations with the Xray (exposure or fluoroscopy) or CTA as a roadmap. Fluoroscopy was not used in 85 of the 90 navigations. In one navigation, fluoroscopy was required due to poor registration accuracy of the guidewire. The other four times it appeared to be used of habit by the interventionist but this could not be confirmed. The accuracy of catheter visualisation was assessed on 55 navigation sequences after removing sequences that were missing data or where the tip of a device was not clearly visible in the saved fluoroscopic image. The median error was 0.69 mm (0.71 mm IQR). During the navigation tasks the guidewire was leading 80.1% of the time (Fig. 3A, bottom), which was quantified by the total number of frames across the 76 navigation sequences with complete data. When the catheter was leading (Fig. 3A, top), it was extended by 7.7 mm (median, 14.5 mm IQR) (Fig. 3B).

### User experience survey

Fig. 4 shows the results of the survey questions related to the usability of the 3D Hub. All 15 interventionists strongly agreed or agreed that the 3D Hub was easy to connect and the friction on the guidewire was acceptable; additionally, it was easy to manipulate and flush the catheter. Fourteen of the 15 interventionists strongly agreed or agreed that the weight of the 3D Hub was acceptable and the visualisation of the catheter extrapolation when the guidewire was retracted inside the catheter was acceptable. The greatest variability in responses was in whether or not the 3D Hub may add a notable change to the current clinical workflow.

Despite this, all interventionists felt confident in navigating a FORS guidewire with the 3D Hub for catheter visualisation in the phantom.

All 15 interventionists strongly agreed or agreed that it was easy to register the length of the catheter and the added time for this was acceptable. Eleven of the 15 interventionists preferred the method where the tips of the guidewire and catheter are aligned outside the body, while three preferred aligning the tips inside the body, and one preferred using an Xray image.

The data in Fig. 5 include responses from seven interventionists; six did not feel they had sufficient knowledge of FORS without the 3D Hub to compare with their experience of using the 3D Hub, and two did not provide complete responses to the questions. Based on the use of the 3D Hub during the phantom study, the interventionists felt that the greatest benefit of the 3D Hub to the FORS technology was in giving interventionists more choices over which catheter to use and increasing the amount of time FORS can be used for guidance.

### DISCUSSION

To enable 3D visualisation of FORS devices, an optical fibre must be embedded inside the device. Interventionists use a wide variety of navigation catheters, and therefore embedding an optical fibre in every type of catheter is challenging from a manufacturing perspective. Other technologies, like electromagnetic tracking<sup>15–18</sup> or magnetic navigation<sup>19</sup> that have been pursued for improving guidance or visualisation have also faced similar challenges of requiring adaptations to the devices. The 3D Hub technology was developed to overcome this manufacturing challenge to provide interventionists with a way to visualise

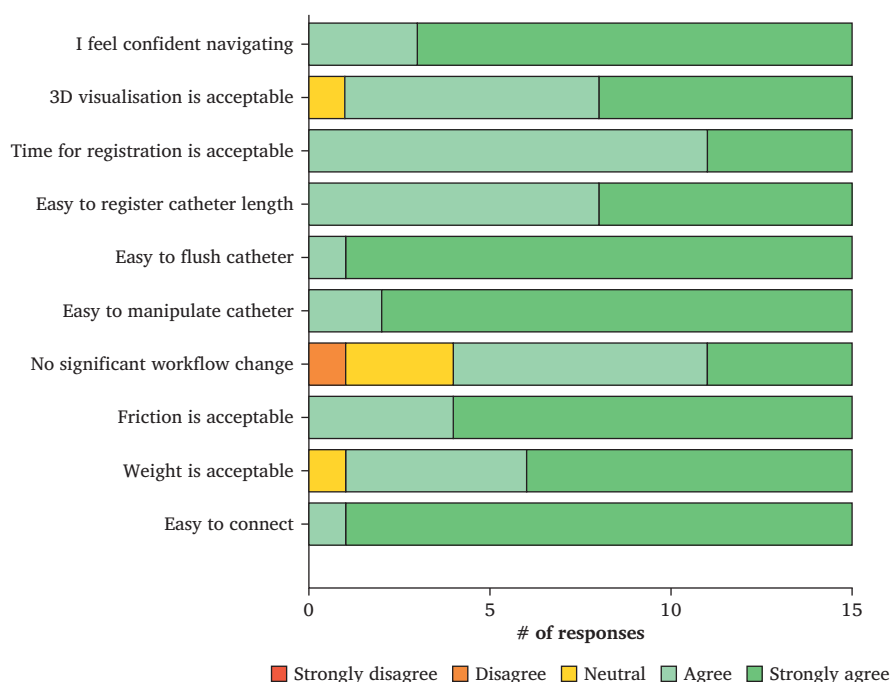
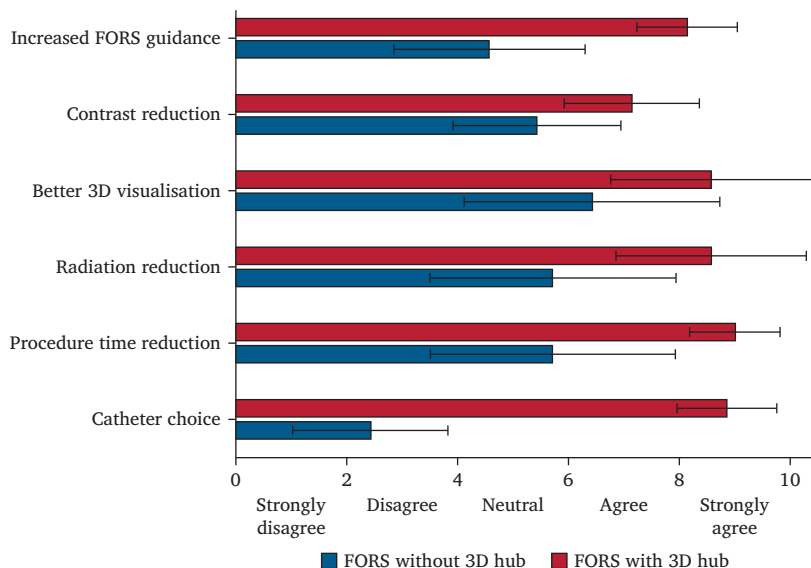


Fig. 4. User responses regarding the usability of the 3D Hub and the impact on their workflow.



**Fig. 5.** User responses regarding the perceived benefits of Fiber Optic RealShape (FORS) guided catheter navigation enabled by the 3D Hub compared with FORS without the 3D Hub. The bar represents the average and the whiskers the standard deviation.

their desired navigation catheters without having to modify the catheter in any way.

The signature of the 3D Hub was found to be unique and trackable, and the signature rarely resembled anything else that may be encountered in a normal clinical procedure, such as a torquing device, introducer, or the interventionists' hands. In the phantom, interventionists navigated to the pre-defined targets successfully 90 of 90 times using the catheter of their choice. In total, only five catheters were chosen by the interventionists. One factor that may have influenced this and the navigation success was the simplicity of the phantom; navigation would be more challenging in complex anatomies and navigation success and catheter choice should be further evaluated in a clinical setting where more complex manoeuvres and device angulations are expected.

To visualise the catheter, a registration step is required. The majority of the interventionists preferred to align the tips outside the body. One benefit of this method is that this could be done by someone else at the end of the table while the interventionist was completing other tasks or prior to the procedure. The visualisation of the catheter was found to be very accurate (0.69 mm error) but if the interventionist is concerned with this small error, fluoroscopy may always be used as an alternative to confirm device position. One limitation for the visualisation is that when the FORS guidewire is retracted inside the catheter, there is no shape information for the distal segment of the catheter. To the best of the authors' knowledge there are no data reported in literature about how often the guidewire is retracted inside the catheter during clinical practice. In this phantom study the guidewire was retracted 19.9% of the time during navigation; however, the interventionists may have already adapted their way of working to the 3D Hub. It remains to be seen whether this will be a limitation in

clinical use but based on the interventionists' responses, the visualisation of the extrapolation is an acceptable mitigation. Although it was not evaluated in this phantom study, no impact is expected on the visualisation of the guidewire or catheter when used in combination with a guide sheath or introducer.

With regards to the proposed clinical workflow, most interventionists felt the workflow change was acceptable and the 3D Hub was easy to use. The 3D Hub may offer workflow or clinical benefits, such as reducing procedure time, radiation, or contrast use by enabling 3D visualisation of various catheters, but this will require further clinical evidence. Additionally, limitations still exist including that the 3D Hub and FORS technologies require integration with a Philips Allura Xper FD20 or Azurion FD20 Xray system and the guidewire is not back loadable.

### Conclusion

FORS guided catheter visualisation, enabled by a 3D Hub, is accurate and easy to use in a phantom setting. The 3D Hub technology enables interventionists to visualise conventional catheters of their choice with the FORS technology, thus expanding the use of FORS. The 3D visualisation of a broader set of catheters is advantageous for procedures like aortic aneurysm repair where the vasculature is complex, tortuous, and patient specific, which often requires a range of catheters.

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### CONFLICT OF INTEREST

All authors are employees of Philips.

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