FORS LUMIGUIDE FIBEROPTIC GUIDANCE (PHILIPS) REDUCES RADIATION EXPOSURE COMPARED TO STANDARD IMAGING DURING COMPLEX EVAR

Marc L. Schermerhorn, MD, FACS

Chief, Division of Vascular and Endovascular Surgery
Beth Israel Deaconess Medical Center

George H.A. Clowes Professor of Surgery
Harvard Medical School

Beth Israel Lahey Health

Beth Israel Deaconess Medical Center | HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Disclosures

- No disclosures

Background

- Incidence of complex aortic pathology increasing as population ages
- Endovascular aortic surgery is accompanied by radiation exposure
  - Patients
  - Staff

FORS

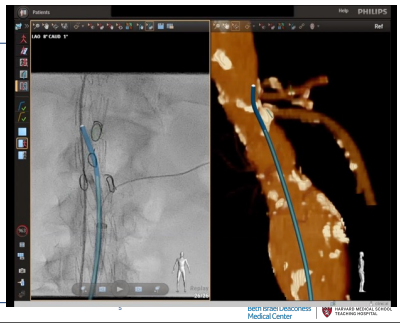
- Fiber Optic RealShape (FORS) technology was developed as an alternative to conventional fluoroscopy
- FORS uses fiber optics to determine the wire position within a vessel in real time

SMA Cannulation

2 views,

Fluoro and 3D background

Hand Injection background



Clinical Feasibility

Miscellaneous

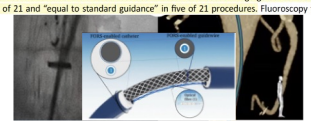
Eur J Vasc Endovasc Surg (2021) 61, 317–325

First in Human Clinical Feasibility Study of Endovascular Navigation with Fiber Optic RealShape (FORS) Technology

Joost A. van Herwaarden [1,*], Marloes M. Jansen [1], Evert-Jan P.A. Vonken [2], Trijntje Bloemert-Tuin [3], Roland W.M. Bulkens [3], Gert J. de Borst [1], Constantijn E.V.B. Hazenberg [1]

[1] Department of Vascular Surgery, University Medical Center Utrecht, Utrecht, the Netherlands
[2] Department of Radiology, University Medical Center Utrecht, Utrecht, the Netherlands
[3] Philips Medical Systems Nederland, Best, the Netherlands

technology related complications and involved 66 navigational tasks. In 60 tasks (90.9%), technical success was achieved using at least one FORS enabled device. Users rated FORS based image guidance "better than standard guidance" in 16 of 21 and "equal to standard guidance" in five of 21 procedures. Fluoroscopy time ranged from



van Herwaarden et al, 2021 (Eur J Vasc Endovasc Surg)

FORS Navigation Tasks

	Technical success				
	No (n = 70)		Yes (n = 116)		
	Median	IQR	Median	IQR	P value
Navigation duration, minutes	16	10-24	6	3-11	<.001
Fluoroscopy duration during navigation, minutes	5.2	3-11.6	0.9	0.3-2.7	<.001
Fluoroscopy duration during navigation normalized, %	37.5	27.5	19.7	9.2-29.4	<.001
Air Kerma during navigation	195.8	89-349.1	61.3	20-153	<.001
Dose area product during navigation, CGy	12.5	3-20	4.4	2.0-10.7	<.001

JVS Journal of Vascular Surgery — Panuccio et al. *J Vasc Surg January 2023*

Panuccio et al, 2023 (JVS)

Reduction in Radiation

The effect of Fiber Optic RealShape technology on the reduction of radiation during complex endovascular surgery

Andrew P Sanders [1], Nicholas J Swerdlow [2], Gabriel Jabbour [1], Marc L Schermerhorn [3]

	Non-FORS		FORS		P value
No.	45		19		
Procedure time, minutes	177.0	(145.0-232.0)	192.0	(160.0-271.0)	.17
Total contrast, mL	108.0	(50.0-188.0)	140.0	(110.0-165.0)	.11
Total air kerma, mGy	964.0	(651.0-1469.0)	527.0	(327.0-893.0)	.002
Total DAP, Gy*cm²	186.1	(126.9-310.5)	121.0	(84.0-165.0)	.006
Total DSA, Gy*cm²	51.1	(34.8-82.9)	42.5	(30.0-64.4)	.26
Total fluoro dose, Gy*cm²	132.5	(82.4-226.5)	72.1	(45.7-97.9)	.003
Total fluoro time, minutes	72.0	(56.0-90.0)	45.1	(34.7-49.0)	<.001

DAP, Dose area product; DSA, digital subtraction angiography; FORS, fiber optic RealShape.
Values are median (interquartile range).
[a]Values are median (interquartile range).
[b]Normalized represents the navigation fluoro time as a percentage of the total navigation time.

Sanders et al, 2024 (JVS)

Initial Experience

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

Eric J. Finnesgard, MD, MS, Jessica P. Simons, MD, MPH, Douglas W. Jones, MD, MS, Dejah R. Judelson, MD, Francesco A. Aiello, MD, MBA, Laura T. Boitano, MD, MPH, Caitlin M. Sorensen, MD, Tammy T. Nguyen, MD, PhD, and Andres Schanzer, MD, *Worcester, MA*

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 × cm²	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.

Finnesgard et al, 2023 (JVS)

Updated Institutional Data

		Standard		FORS		P value
		N=100		N=85		
Procedure Time	[Median (range)]	170	(141-210)	171	(140-230)	0.90
Contrast Dose	[Median (range)]	126	(100-162)	132	(110-170)	0.30
Fluoro Time	[Median (range)]	56	(45-78)	38	(28-64)	<0.01
Air Kerma	[Median (range)]	655	(485-1,237)	429	(258-790)	0.01
Dissection		2	2.1%	6	6.7%	0.20
Perforation		1	1.0%	2	2.3%	0.6
Branch Endoleak (1C/3C)		0	0%	1	1.2%	0.5

Darling et al, 2024 (JVS Submission)

Conclusion

- Complex EVAR with FORS technology had lower radiation compared to conventional fluoroscopy
- Implementation of FORS technology was feasible and there were minimal barriers to its implementation
- No increase in complications (dissection?)
- Ongoing improvements should increase utility / safety / radiation reduction
  - Longer, softer, more torquable wire
  - Backloadability

Thank You

Beth Israel Deaconess Medical Center | Harvard Medical School Teaching Hospital