Updated Experience With The Fiberoptic RealShape (FORS From Philips) System:

Results From The Completed Multicenter ***LEARN Registry***

What Are Its Limitations And Can FORS Work With Very Complex Anatomy?

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Disclosure

- [x] Consulting: Terumo Aortic, Cook Medical, Gore Medical
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [x] Other(s): Research collaboration with Philips

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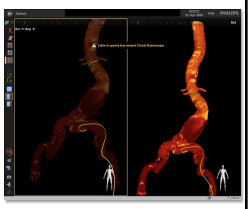
What is Fiber Optic RealShape (FORS) technology?

- Displays the full shape of devices in 3D
- in real-time and in distinctive colors
- in multiple, unrestricted viewing angles
- using light instead of X-ray



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What is Fiber Optic RealShape (FORS) technology?

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What has been our journey so far?

FIH study in UMC-Utrecht **2018**

CE

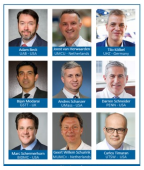
Limited Edition 510(k) cleared **End 2020**
Ready to start installs in the USA in **2021**

> 800 cases completed **end Oct. 2023**
Installs in the USA: UMass, BIDMC, UAB, UTSW, Penn

FORS Limited Edition CE label **End 2019**

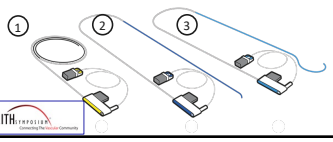
Start of the in EU, UKE **Limited Edition** as first install. UMC-U, MUMC+…

FDA



Fiber Optic RealShape (FORS) technology

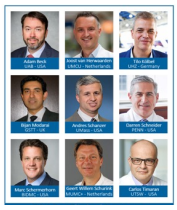
FORS Limited Edition



#	Devices
1	FORS guide wire, 120 cm
2	FORS Berenstein catheter
3	FORS Cobra catheter

FORS Learn multi-center registry – first 540

- Learn registry started in 2020
- Prospective perioperative data from high-volume centers in the USA and Europe



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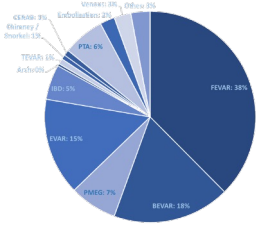
FORS Learn multi-center registry

Total: 540 subjects



- High Variety of different procedures
- Focus on BEVAR & FEVAR

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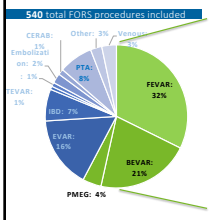
FORS Learn multi-center registry



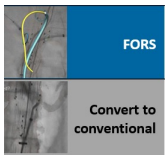
Complex Aortic Aneurysm (BEVAR/FEVAR/ PMEG)

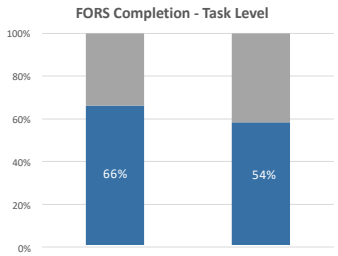
Parameter	Statistics (N=313)
Demographics	
Age [median (IQR)]	73 (68-78)
BMI [median (IQR)]	25.825 (23.15-29.395)
Aneurysm diameter (mm) [median (IQR)]	60 (56-67)
Gender	
Female	85 (27.2)
Male	220 (70.3)
Type of Repair Intervention	
Primary intervention	217 (69.3)
Re-intervention	48 (15.3)
Staged intervention	40 (12.8)
Procedure Context	
Number of tasks (target vessels)	1101
Branched	317 (28.8)
Fenestrated	730 (66.3)
Type of Aneurysm repair	
Thoracic Aortic Aneurysm (TAA)	6 (2.0)
Thoracic Aortic Abdominal Aneurysm (TAAA	104 (34.1)
Pararenal Aortic Aneurysm	68 (22.3)
Infrarenal Aortic Aneurysm	42 (13.8)
Isolated Iliac Aneurysm	1 (0.3)
Juxtarenal Aortic Aneurysm	78 (25.6)
Other	6 (2.0)

Catheterization of target vessels– FEVAR/ BEVAR

- Physicians decided for which tasks FORS was used

FORS used 815/1040 VTV (78%)





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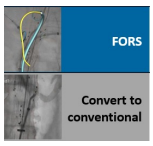

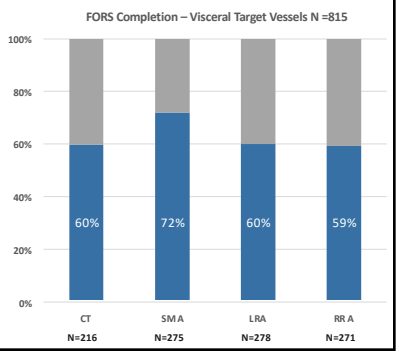

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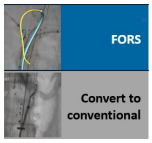


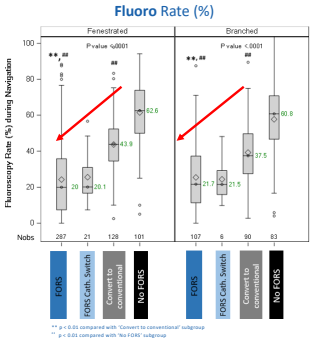
FORS Completion – Visceral Target Vessels N =815

Technical success:

66% No Stenosis (n=447) *vs* 40% stenosis (n=38)

65% No prior stent (n=493) *vs* 44% prior stent (n=15)

Fluoroscopy Rate (%) in FEVAR & BEVAR



Takeaway:

Fluoroscopy rate (%) is decreased by 66% in FORS group compared to No FORS

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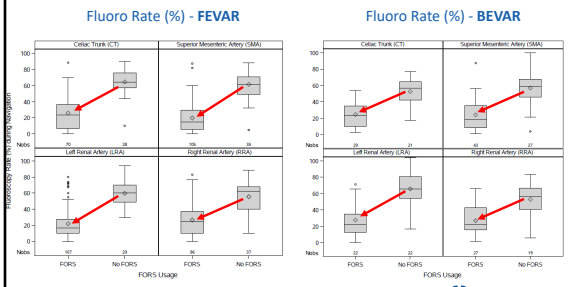
Fluoroscopy Rate (%) in FEVAR & BEVAR



Takeaway: **Fluoroscopy rate (%) is decreased by 60-70%** in FORS group compared to No FORS

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FORS Learn registry (global multi-center study)

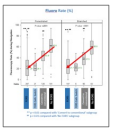
Summary

- **Not only nice to have :**
  - **3-D view of wire and catheter in color**
  - **Unlimited viewing angles**
  - **Bi-plane view**
  - **Visibility of Entire wire & catheter**

FORS Learn registry (global multi-center study)

Summary

- **Successful use of FORS for target vessel catheterization during complex EVAR reduces radiation exposure significantly**



VEITH SYMPOSIUM

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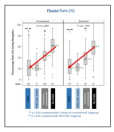
FORS Learn registry (global multi-center study)

Summary

- **Successful use of FORS for target vessel catheterization during complex EVAR reduces radiation exposure significantly**
- **Technical success rate of TV catheterization was limited (BEVAR < FEVAR)**



VEITH SYMPOSIUM

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FORS Learn registry (global multi-center study)

- ***Why was technical success rate Limited ?***
  - **Only 2 different catheter configurations available**

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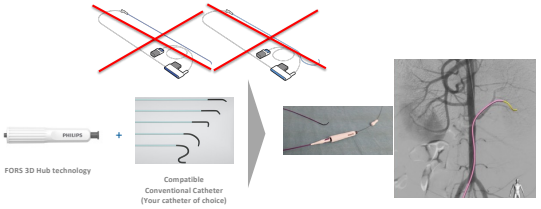

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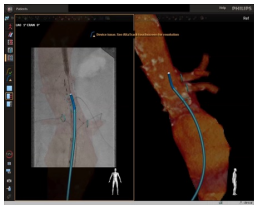
FORS Learn registry (global multi-center study)

- **Why was technical success rate Limited ?**
  - Only 2 different catheter configurations available
  - Difficulties visualizing wire & catheter in "tight-bend configurations" (e.g. SOS-like catheters or through fully bended Steerable sheath)



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Improved in "LumiGuide", which replaced "Fors Limited Edition" from October 2023

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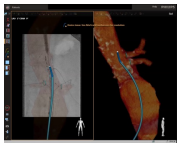
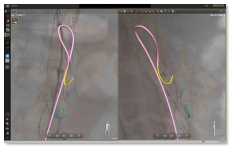

Fors Limited Edition


LumiGuide

FORS Learn registry (global multi-center study)

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  - The guidewire had an in-body section of only 120 cm

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  - The guidewire had an in-body section of only 120 cm

LumiGuide wire in USA (pending CE mark) Has longer in-body section 160 cm

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FORS Learn registry (global multi-center study)

Conclusion

- **FORS is a promising new technology**
- **Real-world data from the LEARN Registry shows that FORS technology reduces X-ray doses significantly in complex aneurysm repair**
- **Technical success rates were acceptable, but will further increase with the Technical improvements implemented in "LumiGuide", the newest FORS powered system**

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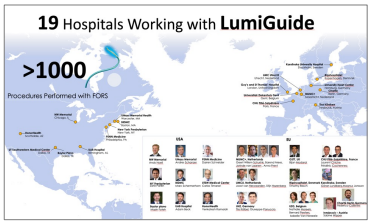
Acknowledgements

Thanks to international partners, Philips, and UMC-Utrecht FORS team



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Thank you for your attention

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