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MicroNet-Covered Anti-Embolic Stent in Consecutive Increased-Risk Iliac Artery Stenotic Lesions to Reconstruct Anatomy and Guard The Flow: A Multi-Center, Multi-Specialty Study

FLOWGUARD-ILIAC NCT04461717

Piotr Paluszek, MD PhD

on behalf of FLOWGUARD-ILIAC Investigators

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DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS

I, PIOTR PALUSZEK DO NOT HAVE ANY RELEVANT FINANCIAL RELATIONSHIPS TO DISCLOSE.

BACKGROUND

IN INCREASED-RISK LESIONS, CONVENTIONAL (SINGLE-LAYER) STENTS USED IN ILIAC ARTERY REVASCULARIZATION HAVE IMPORTANT LIMITATIONS:

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- **THROMBOTIC LESIONS** (WHERE THE "CHEESE-GRATER" EFFECT MAY LEAD TO DISTAL EMBOLISM)

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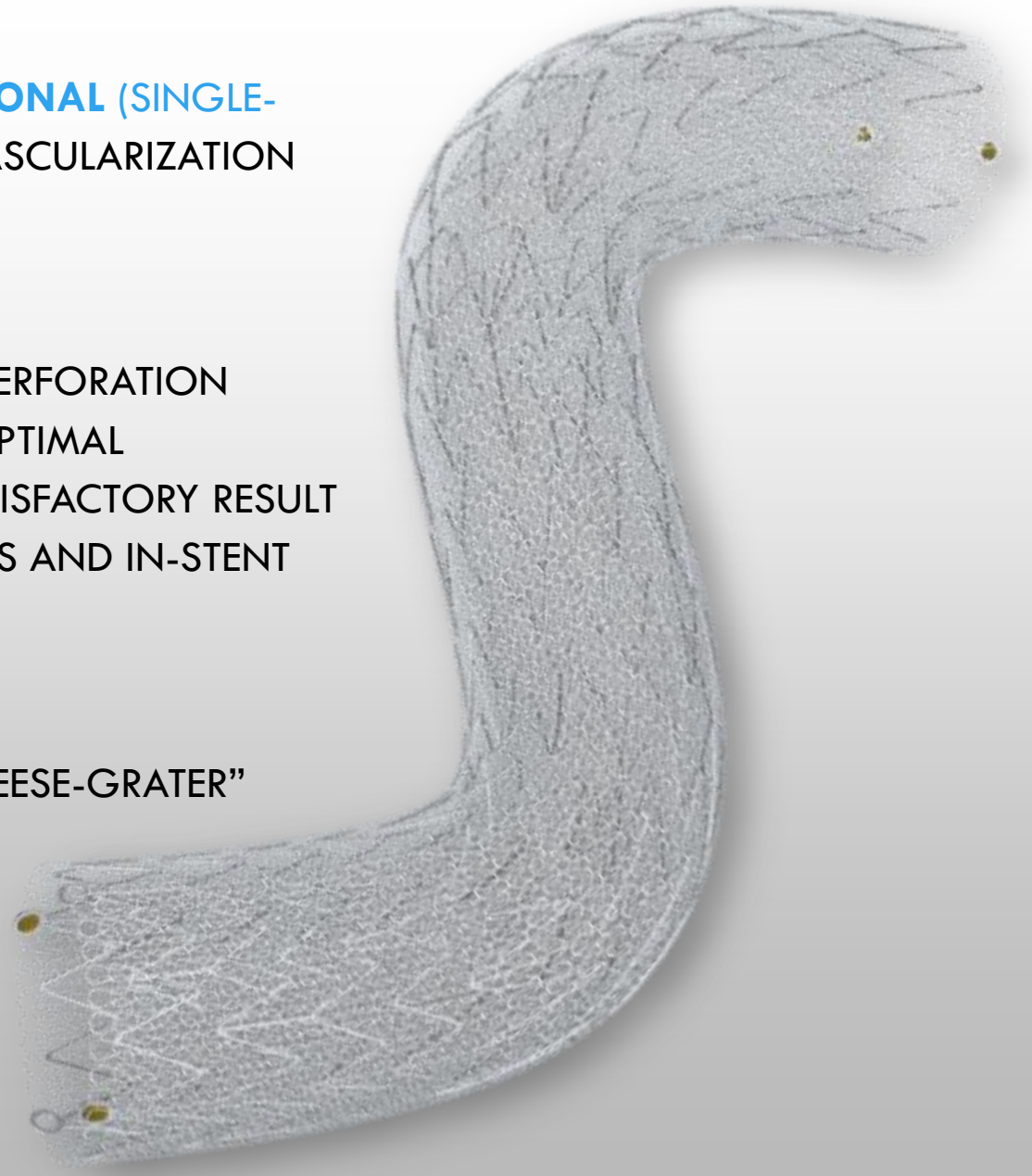

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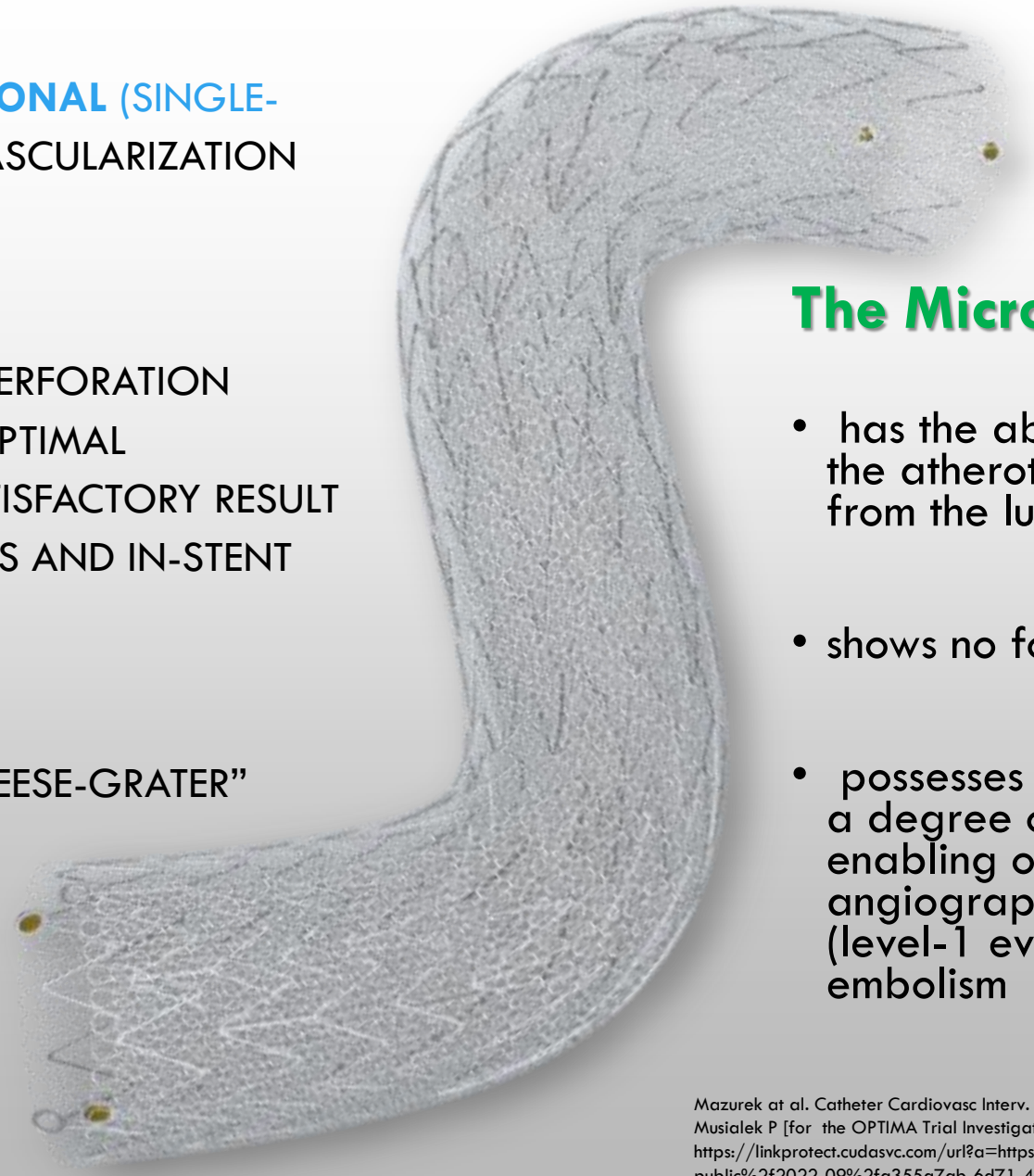
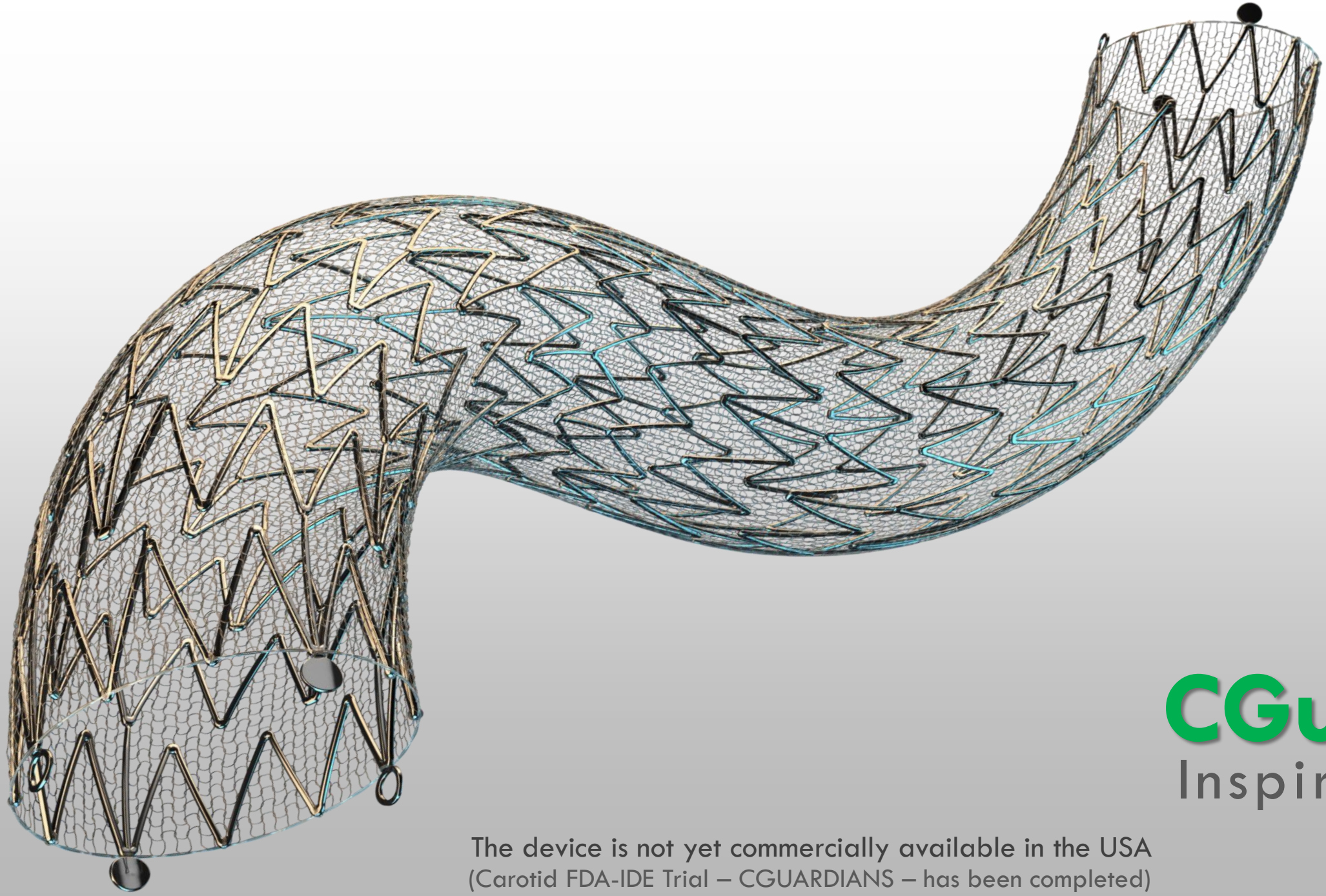


The MicroNET-covered stent

- has the ability to sequestrate the atherothrombotic material from the lumen
- shows no foreshortening/elongation
- possesses high radial force with a degree of sealing properties, enabling optimization of the angiographic result paralleled by (level-1 evidence) prevention of embolism

Mazurek at al. Catheter Cardiovasc Interv. 2019 Jul 1;94(1):149-156.
Musialek P [for the OPTIMA Trial Investigators]. TCT 2022 Featured Research.
https://linkprotect.cudasvc.com/url?a=https%3a%2f%2fd14d5nk8lue86f.cloudfront.net%2fs3fs-public%2f2022-09%2fa355a7ab-6d71-44de-8ecf-6712bd763300.pdf&c=E,1,xK2Fw9O-JSi5KXyomTPyXu-tja-oloF8cvo8Ajkh1x8MazTh421XPOZs3ZxftkaVmHvbZjcsZgWbXdPCx-9KyxO4KL31rY3OvE2GyUYr1eglWddOwVC2omNpCdUQ&typo=1



CGuard

InspireMD

The device is not yet commercially available in the USA

(Carotid FDA-IDE Trial – CGUARDIANS – has been completed)

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Investigator-initiated, industry-independent study

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Aim: to test, in a multi-center, multi-specialty setting
(vascular surgery, radiology, cardiology, angiology)

use of **MicroNET-covered stent** to treat **increased-risk iliac lesions**
in consecutive patients undergoing percutaneous iliac artery revascularization

(claudicants or iliac-related limb-threatening ischemia)

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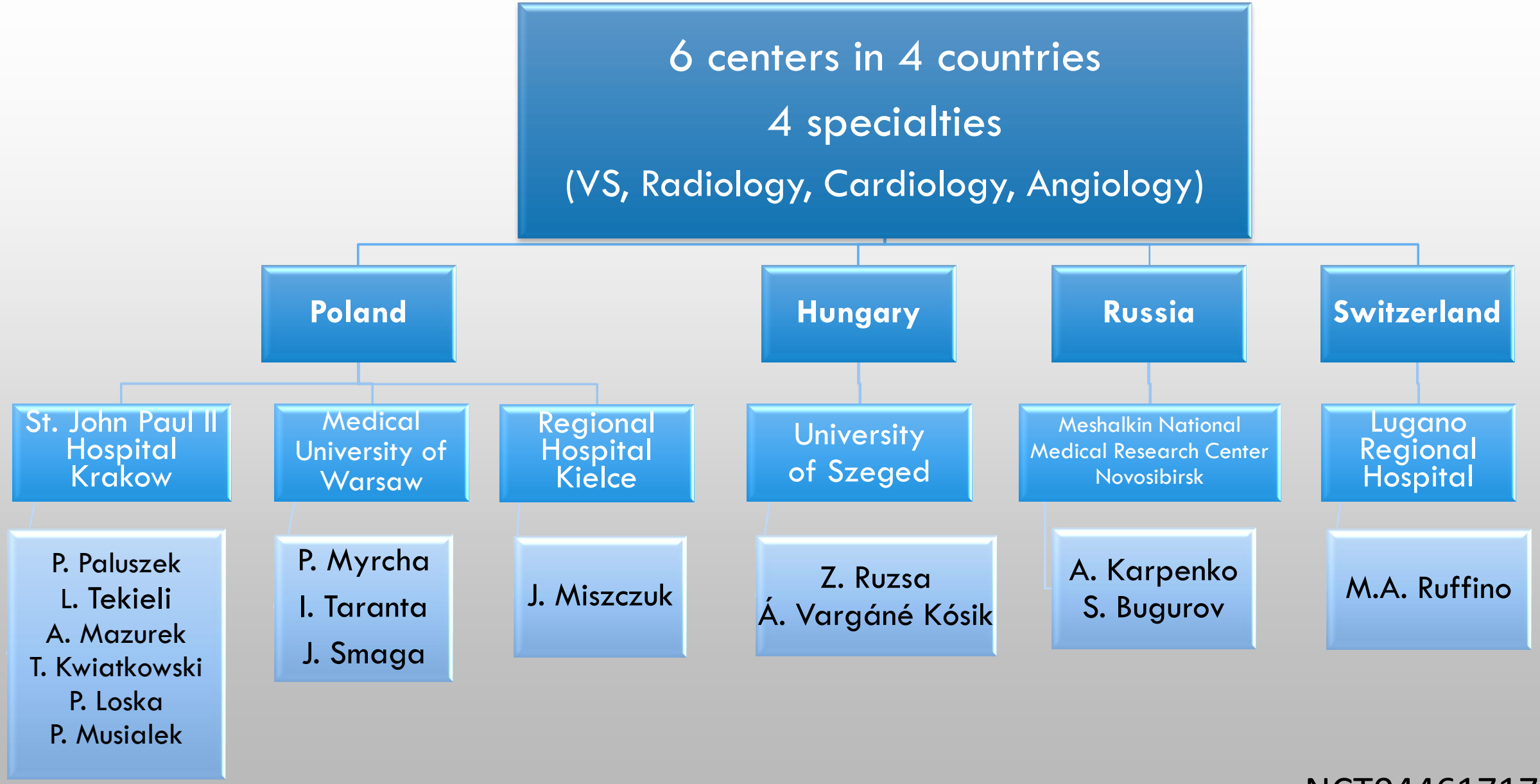
Methods:

1. ***Increased-risk lesion***: consensus by the operator intending to perform the case + 2 other operators
2. Intention to avoid internal iliac artery covering
3. Protocol-recommended drive to 'optimal angiographic result'
4. **Primary endpoint** = target vessel patency at 6mo in absence of study device ISR (CTA recommended)
5. **Angiographic analysis by an Independent CoreLab Analyst**
6. Study recruitment: 34 months

FLOWGUARD-ILIAC Centers and Investigators



NCT04461717

Patients n = 105

66 Men (62.9%)

39 Women (37.1%)

Age: 53-83 years (mean 69.5 years)

Claudicants – 93 (88.6%)

Critical limb ischemia – 12 (11.4%)

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Coronary artery disease	57 (54.2%)
Congestive Heart Failure	26 (24.7%)
Previous stroke	22 (20.9%)
Hypertension	100 (95.2%)
Dyslipidaemia	99 (94.3%)
Diabetes	43 (40.9%)
Previous PCI/CABG	36 (34.3%)
Previous CAS/CEA	35 (33.3%)
Smoking	Current – 40 (38.1%) Past – 52 (49.5%) Never – 13 (12.4%)

The iliacs treated

The iliacs treated

105 patients

125 arteries

129 MicroNET stents

Side

- Left – 36 patients
- Right – 60 patients
- Both – 9 patients

Arteries

- LCIA – 31 (24.8%)
- RCIA – 41 (32.8%)
- LEIA – 18 (14.4%)
- REIA – 35 (28.0%)

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Stents used

Nominal diameter

6 – 10 mm

mean 9.2 mm

Length

20 – 60 mm

mean 37.8 mm

DIAMETER	6 mm	1
	7 mm	14
	8 mm	27
	9 mm	29
	10 mm	**58**
LENGTH	20 mm	13
	30 mm	41
	40 mm	**54**
	60 mm	21

100% intended device use (No stents other than the study device)

Access	
Femoral	**83**
Femoral bilateral	10
Radial	8
Brachial	4

Lesion characteristics n=125

(incl. tandems; CoreLab Analyst verified)

- **Highly–calcific** **59 (47.2%)**
- **Thrombotic** (incl. thrombotic dissection) **58 (46.4%)**
- **Other high–risk** **8 (6.4%)**

Mean baseline stenosis severity

83.8 ± 9.6% (angiolab analysis)

Complex CTO recanalization – 10 arteries (8.1%)

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Predilatation

68 arteries (54.4%)

Balloon diameters
3.5 – 9 mm
average 5.8 mm

Pressures
6 – 24 atm
average 12.5 atm

Postdilatation

117 arteries (**93.6%**)

Balloon diameters
6 – 10 mm
average 7.6 mm

Pressures
8 – 24 atm
average 14.1 atm

Procedural results

- Procedure performed with intended device – **100%**
- **Technical success** (study device delivery + residual stenosis < 30%) – **100%**
- **Clinical success** (technical success + no MACE) – **100%**
- Residual stenosis: **8.3 ± 6.3 %** (Angiographic CoreLab analysis)

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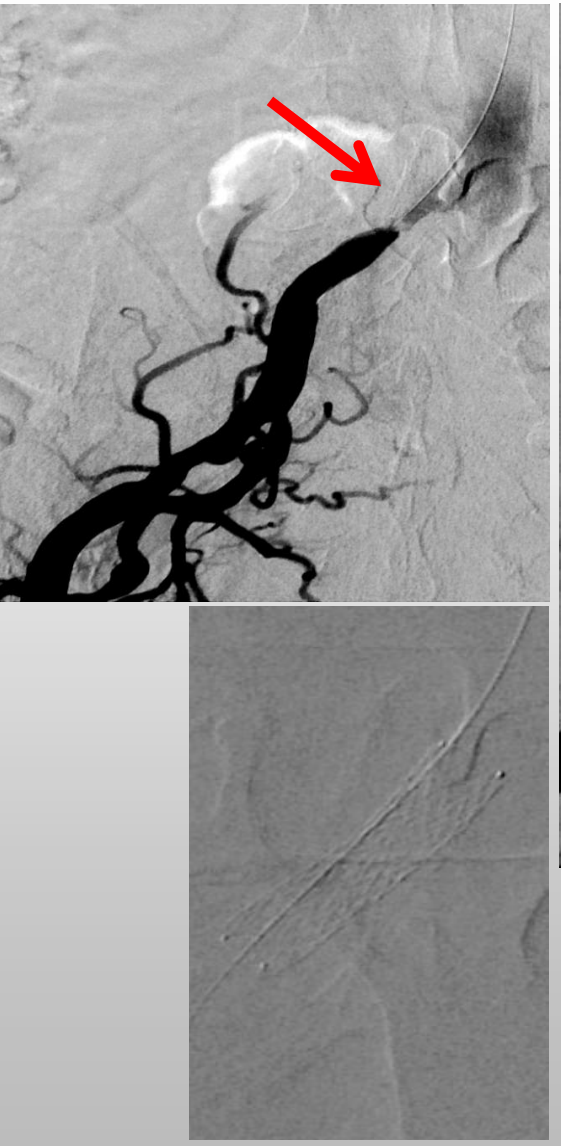
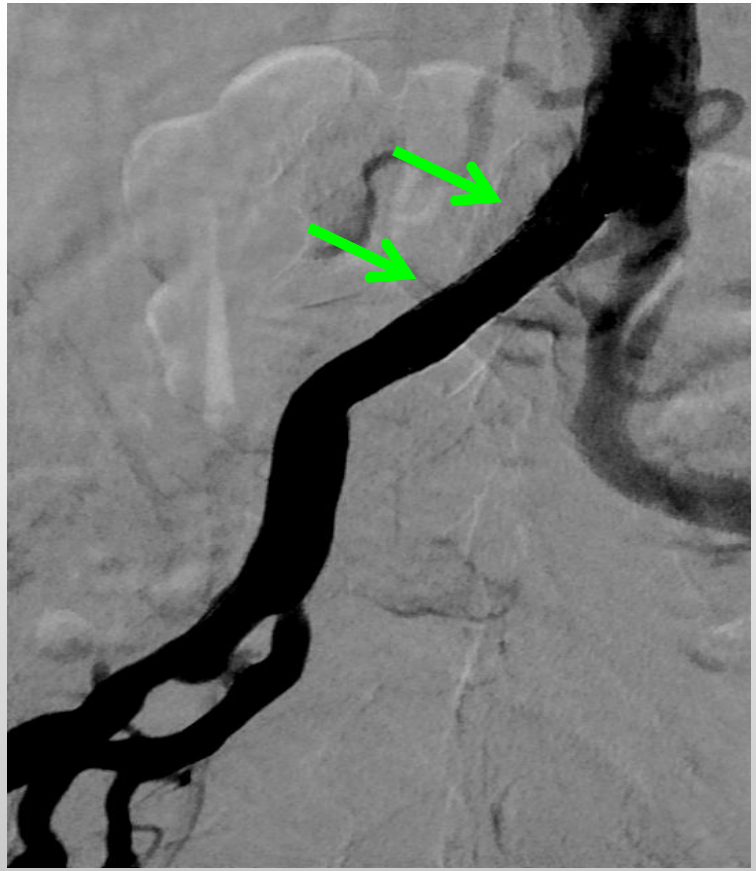
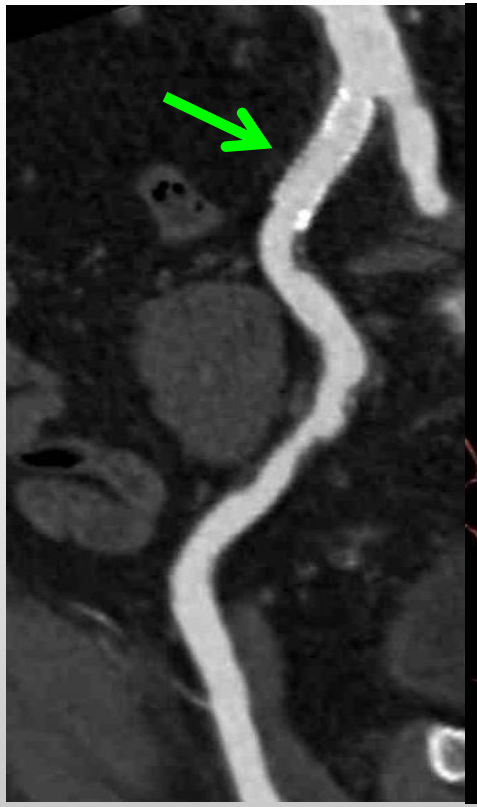
Procedural complications:

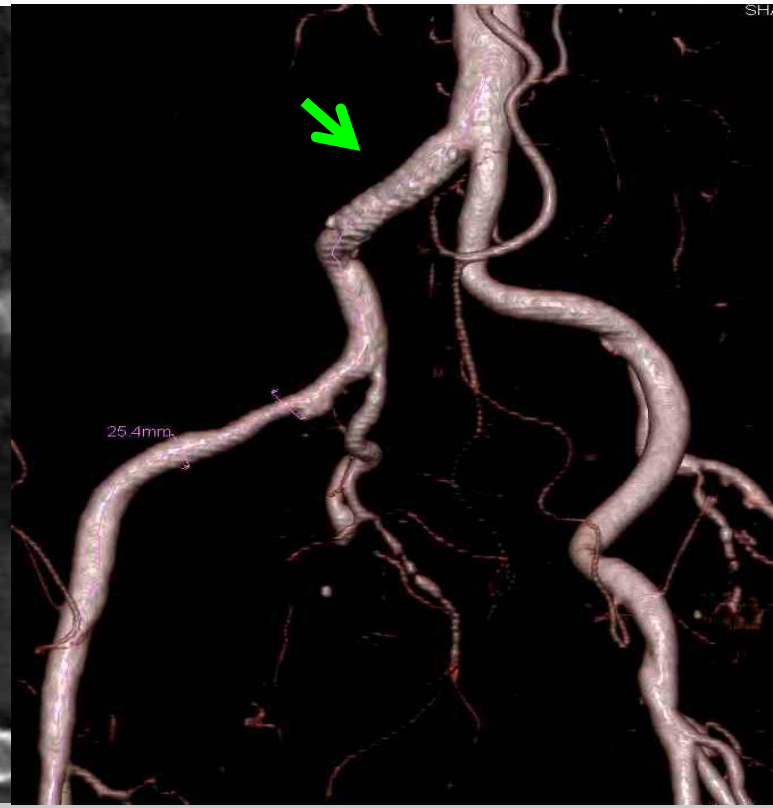
Death/MI/Stroke/Transfusion-requiring bleeding:	0
Perforation:	0
Embolism:	0
Groin hematoma:	3 (2.9%)

Thrombus-containing/high-embolic risk lesion





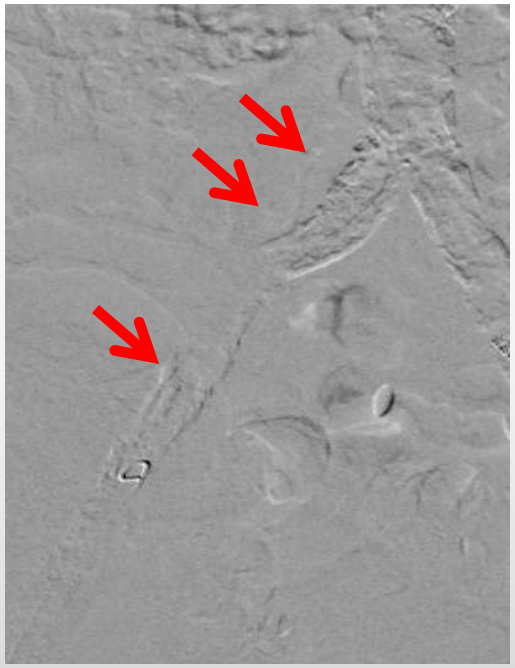


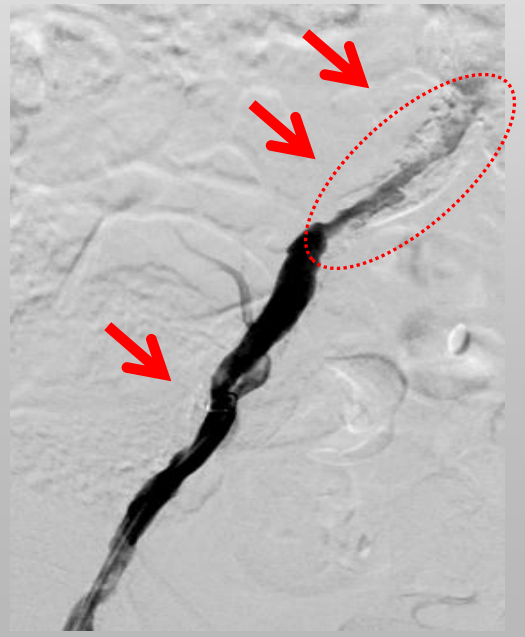


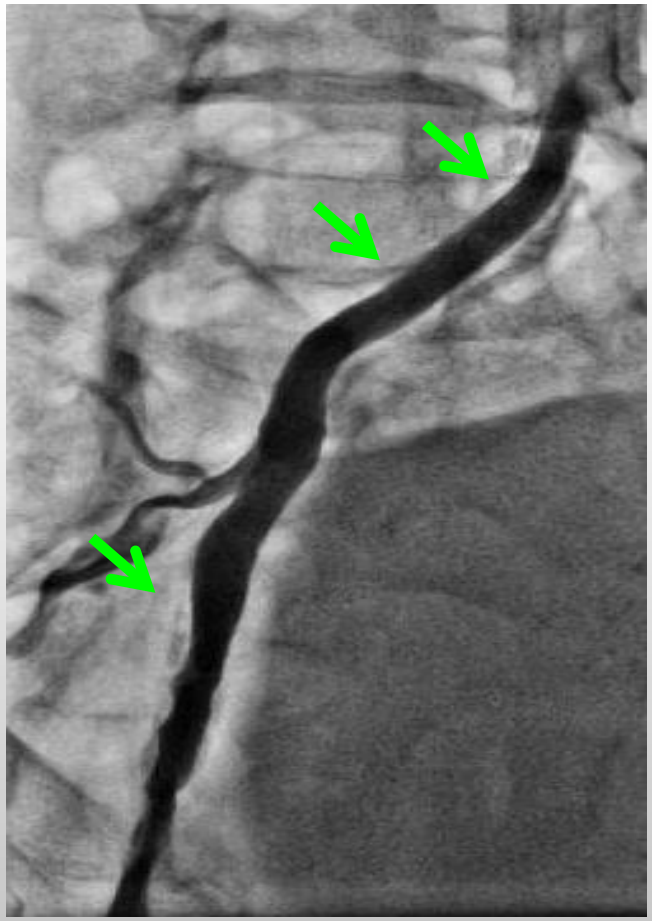
Acute procedural result

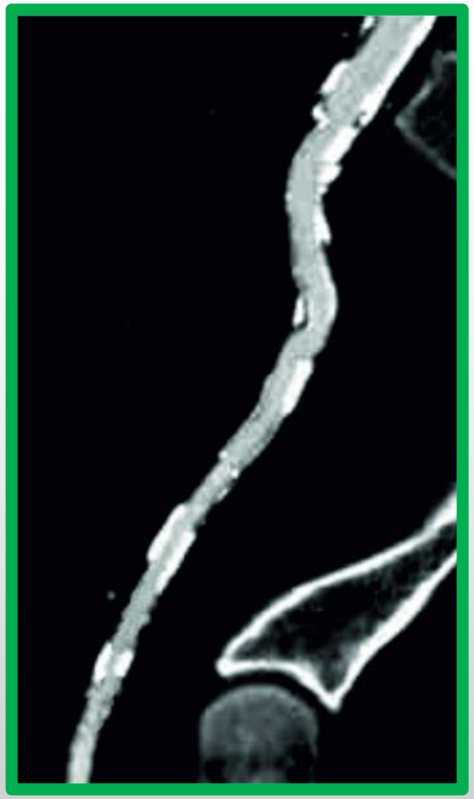
Optimal anatomic result @ 6mo CTA follow-up

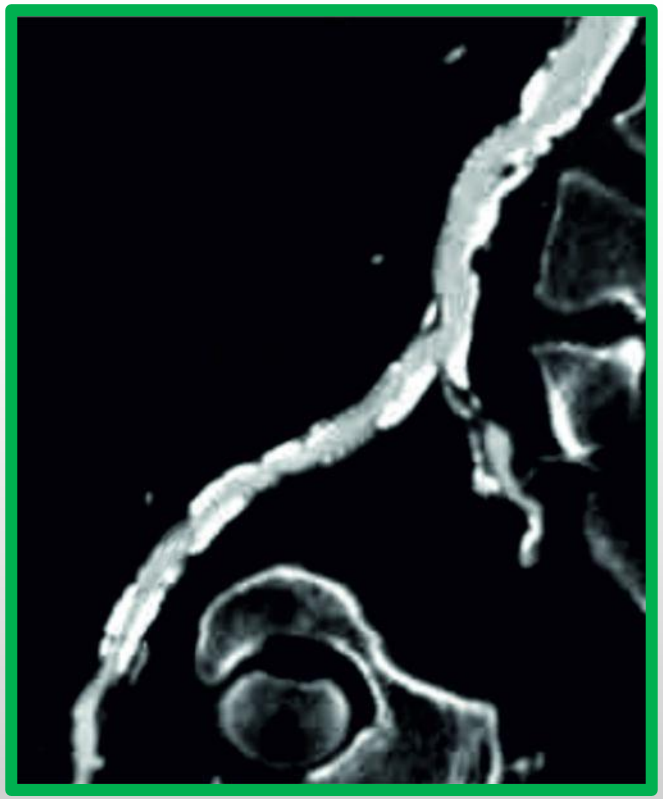
Highly calcific disease











Optimal anatomic result @ follow-up

Acute procedural result

6 MO OUTCOMES (PRIMARY ENDPOINT) 105 PATIENTS (100%)

Imaging follow-up	
CTA	81 (77.1%)
Catheter Angiography	3 (2.9 %)
Doppler-Duplex ultrasound	21 (20.0 %)*

* One center unable to perform routine protocol-recommended CTA follow-up for financial/logistic reasons; renal disease progression in 6 pts

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Clinical (per patient)

Claudication distance increase – 98.1%

Death/MI/Stroke – 1 (MI)

Per limb

Amputation – 0

Limb saved – 100%

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ISR rate

(per lesion treated n=125)

1 (0.8%)

In addition, one target segment intervention distal to the stent on 6-mo follow up (overlapping MicroNET stent added)

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CONCLUSIONS

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IN **INCREASED-RISK ILIAC ARTERY LESIONS** WITH CLINICAL INDICATION TO REVASCULARIZATION, THE **MICRONET-COVERED STENT** USE:

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IN **INCREASED-RISK ILIAC ARTERY LESIONS** WITH CLINICAL INDICATION TO REVASCULARIZATION, THE **MICRONET-COVERED STENT** USE:

- WAS **ROUTINELY FEASIBLE** (100% INTENDED DEVICE USE, NO OTHER STENT TYPES REQUIRED)
- WAS **SAFE** – ALLOWING TO **OPTIMIZE THE ANGIOGRAPHIC RESULT** IN ABSENCE OF EMBOLISM OR OTHER COMPLICATIONS
- WAS ANGIOGRAPHICALLY **EFFECTIVE** (100% ACUTE PROCEDURAL SUCCESS) AND WAS **EFFECTIVE** CLINICALLY
- ACHIEVED **100% PRIMARY PATENCY RATE** AT 6 MO (ISR RATE OF 0.8%)