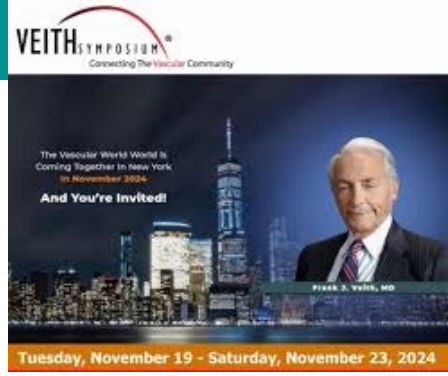

Can Mesh Covered Stents Replace Stent-Grafts For The Treatment Of Complex Iliac Occlusive Lesions: Advantages And Disadvantages

Piotr Myrcha

I Chair and Clinic of General and Vascular Surgery,
Faculty of Medicine, Medical University of Warsaw,

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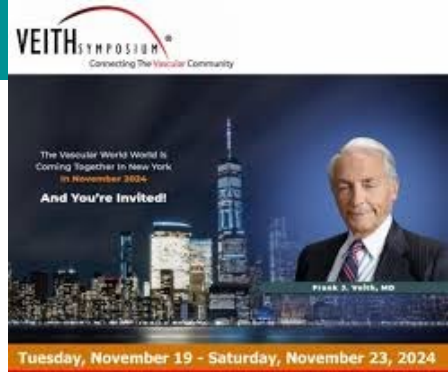
Mazovian Brodnowski Hospital, Warsaw,
Poland

Disclosure

Speaker: Piotr Myrcha, MD

✓ I do not have any potential conflict of interest



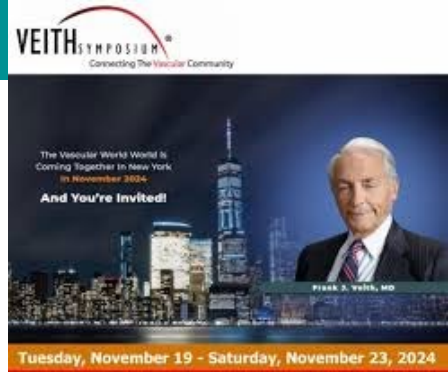
Iliac artery occlusive disease

Open surgical procedures:

- Excellent patency rates
- Substantial morbidity and mortality

Endovascular treatment:

- Good safety
- Good short-term efficacy
- Decreased morbidity, complications and costs



Iliac artery occlusive disease

Endovascular treatment of significant iliac artery stenosis with claudication:

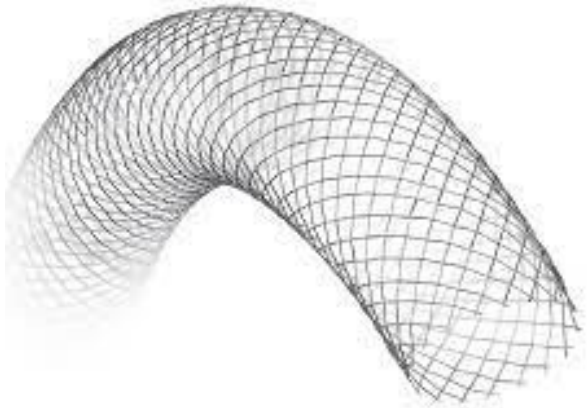
- PTA alone
- Stenting for suboptimal or failed result from PTA (e.g., persistent gradient, residual diameter stenosis >50%, or flow-limiting dissection).
- Primary stenting for CIA/EIA stenosis and occlusions

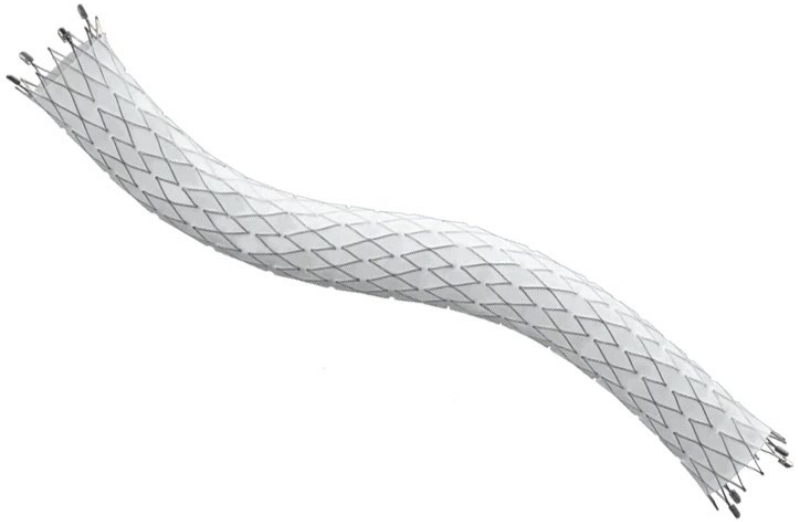
Major complications occurred more often in the PTA group (20%, 11/55), compared to the PS group (5%, 3/57) (OR 4.50, 95% CI 1.18 to 17.14)

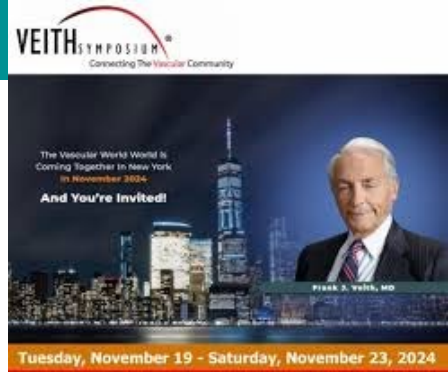
Jongsma H, Bekken J, Ayez N, Hoogewerf CJ, Van Weel V, Fioole B. Angioplasty versus stenting for iliac artery lesions. Cochrane Database Syst Rev. 2020.1;12(12):CD007561

Iliac artery occlusive disease

High-risk morphology stenosis with complex/thrombotic lesions- embolisation







Iliac artery occlusive disease

Endovascular treatment

JABFM Journal of Applied Biomaterials & Functional Materials

Review

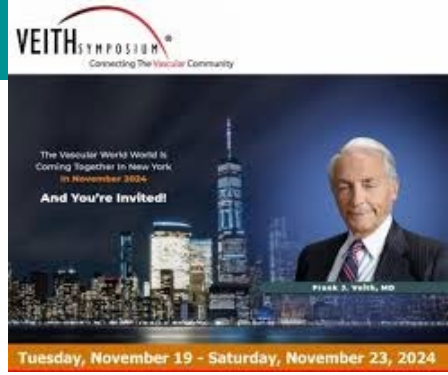
Endothelialization strategy of implant materials surface: The newest research in recent 5 years

Journal of Applied Biomaterials & Functional Materials
1–19

DOI: 10.1177/22808000221105332
journals.sagepub.com/home/jbf
SAGE

Qihao Bian[1,2], Junying Chen[1,3], Yajun Weng[1,3] and Suiyan Li[2]

Endothelialization is a key factor for the long-term effect of cover stents implantation.



Iliac artery occlusive disease

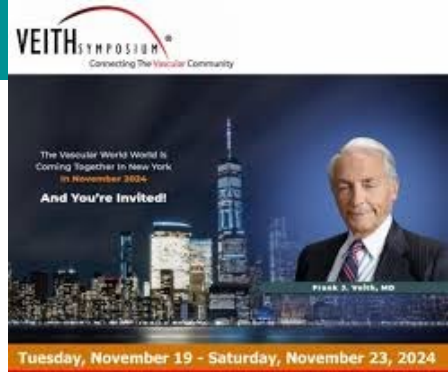
Endovascular treatment

› Int J Biol Macromol. 2021 May 15:179:567-575. doi: 10.1016/j.ijbiomac.2021.03.008.
Epub 2021 Mar 3.

Evaluation of human umbilical vein endothelial cells growth onto heparin-modified electrospun vascular grafts

Pablo C Caracciolo [1], Patricia Diaz-Rodriguez [2], Inés Ardao [3], David More
Florencia Montini-Ballarin [4], Gustavo A Abraham [4], Angel Concheiro [2],
Carmen Alvarez-Lorenzo [2]

The delay of endothelialization on the surface of the material is the main cause of restenosis and…



Iliac artery occlusive disease

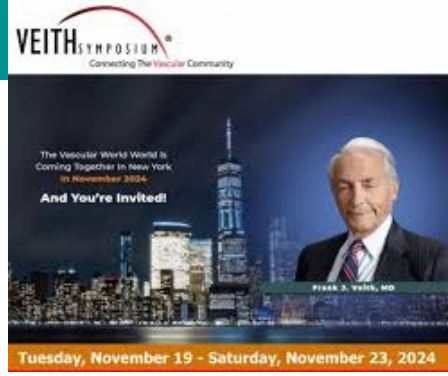
Endovascular treatment

RSC Adv. 2021 Feb 3;11(11):5903-5913. doi: 10.1039/d1ra00053e. eCollection 2021 Feb 2.

Endothelialization of an ePTFE vessel prosthesis modified with an antithrombogenic fibrin/heparin coating enriched with bound growth factors

Johanka Táborská [1], Zuzana Riedelová [1], Eduard Brynda [1], Pavel [illegible] Riedel [1]

The delay of endothelialization on the surface of the material is the main cause of … advanced thrombosis after implantation.



Iliac artery occlusive disease

Endovascular treatment

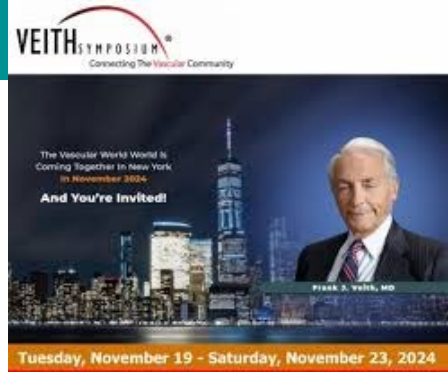
Review > Vascular. 2022 Oct;30(5):960-968. doi: 10.1177/17085381211036548.
Epub 2021 Aug 4.

Late onset infection of covered and bare metal arterial stents

Ottavia Borghese [1 2], Angelo Pisani [3], Dan Andrei Fu

Twenty two studies- 24 patients with graft infection

- Infection- a median of 22 months postoperatively
- 4 cases (16.7%)- haemorrhagic shock upon arterial rupture.
- 3 patients (12.5%) died from a septic shock or multi-organ failure.



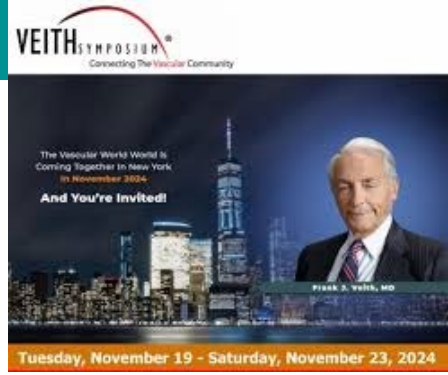
Mesh Stents Study in ILIAC Complex Lesions (IMS-Study)

ClinicalTrials.gov : NCT05377775

Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	50 participants
Allocation:	Medical University of Warsaw, Poland (Dept. of General and Vascular Surgery)
Intervention Model:	Single Group Assignment
Intervention Model Description:	Prospective, single-center, open-label, single-arm, non-randomized clinical trial.
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Mesh Stents Study in Iliac Complex Lesions Iliac-Mesh Stent Study (IMS-Study)
Estimated Study Start Date :	June 10, 2022
Estimated Study Completion Date:	December 31, 2024
Principal Investigator:	Piotr Myrcha, MD Medical University of Warsaw, Poland

Mesh Stents Study in ILIAC Complex Lesions (IMS-Study)

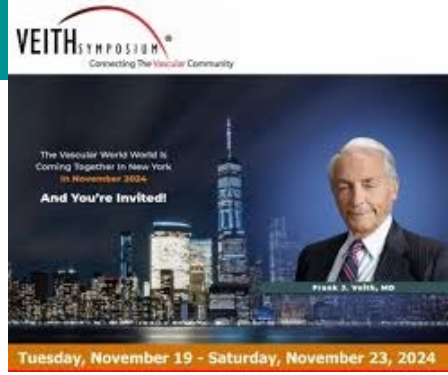
ClinicalTrials.gov : NCT05377775



Caution: The CGuard Stent system is investigational only and not for sale in the USA.

Caution: The CGuard Stent system is not licensed for use in the iliac region.

Consent of the Bioethics Committee of the Medical University of Warsaw (Poland) No. KB/11/2021 to conduct a study on the use of CGuard mesh stents in iliac arteries.



Mesh Stents Study in ILIAC Complex Lesions (IMS-Study)

ClinicalTrials.gov : NCT05377775

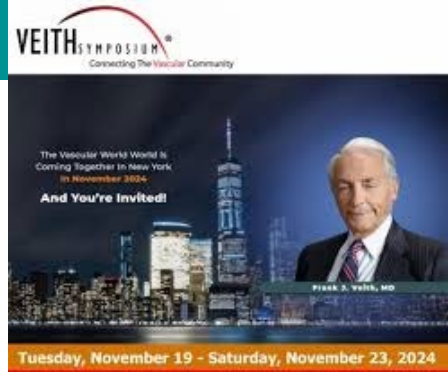
Inclusion Criteria:

General Inclusion Criteria (principal):

- Patients older than 18 years, after Vascular Team evaluation, according to local standards, eligible for Iliac artery
- Written, informed consent to participate
- Agreement to attend Protocol required (standard) follow up visits and examinations

Angiographic Inclusion Criteria (principal):

- De novo iliac stenosis
- Stenosis eligible for endovascular treatment per Vascular Team evaluation (according to current standards and guidelines)
- High-risk morphology stenosis with complex/thrombotic lesions (1 independent, experienced operator).



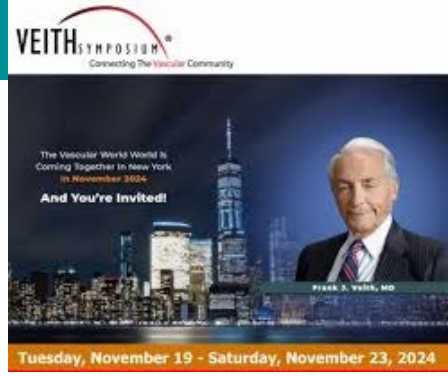
Mesh Stents Study in ILIAC Complex Lesions (IMS-Study)

ClinicalTrials.gov : NCT05377775

Exclusion Criteria:

General Exclusion Criteria (principal):

- Life expectancy <1 year (e.g., active neoplastic disease).
- Chronic kidney disease with creatinine > 3.0 mg/dL.
- Coagulopathy.
- Contraindication for decoagulation
- History of uncontrolled contrast media intolerance
- Myocardial infarction in 72 hours preceding the stenting procedure (if possible, postponing the procedure)
- Stroke in 6 weeks preceding the stenting procedure (if possible, postponing the procedure)
- Pregnancy (positive pregnancy test)



Mesh Stents Study in ILIAC Complex Lesions (IMS-Study)

ClinicalTrials.gov : NCT05377775

Exclusion Criteria:

AngiographicExclusion Criteria (principal):

- Chronic total occlusion not amenable to re-canalization
- Stent in the target vessel/lesion
- Anatomic variants precluding stent implantation
- Mobile (free-floating) plaque elements in aorta or arteries proximal to the target lesion

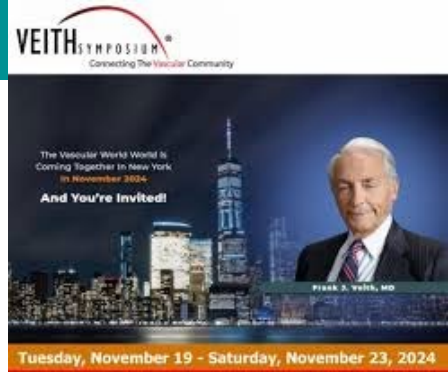
Outcome Measures

Primary Outcome Measures : MACNE (Major Adverse Cardiac or Neurological Event) [Time Frame: 48 hours after procedure]

In-hospital MACNE (death, stroke, myocardial infarction, acute limb or target organ ischemia)

Mesh Stents Study in ILIAC Complex Lesions (IMS-Study)

ClinicalTrials.gov : NCT05377775



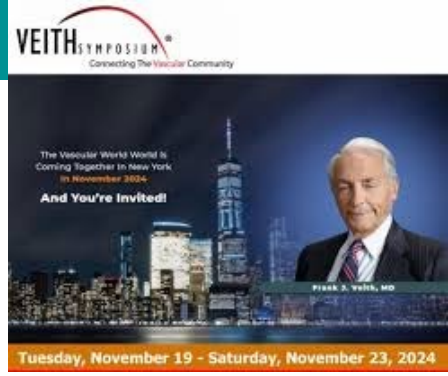
J Endovasc Ther. 2019 Aug;26(4):578-582. doi: 10.1177/1526602819849078. Epub 2019 May 6.

Initial Clinical Results and In Vitro Testing of the New CGuard MicroNet-Covered "One-Size-Fits-All" Carotid Stent

Christian Wissgott [1], Christoph Brandt-Wunderlich [2], Christoph Kopetsch [1], Wolfram Schmidt [2], Reimer Andresen [1]

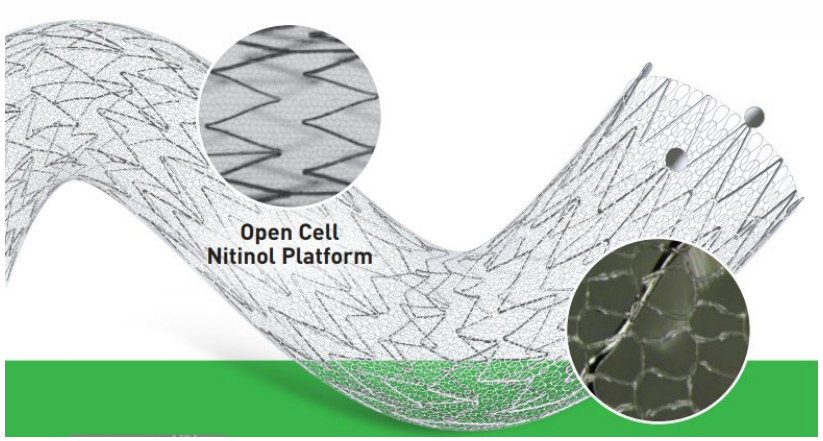
Table 2. Chronic Outward Force During Expansion of the One-Size-Fits-All CGuard Stent.

Diameter, mm	Chronic Outward Force Normalized to Stent Length, N/mm	Maximum Force, %	Minimum Force, %
5	0.386	117	198
5.5	0.330	100	169
6	0.318	96	163
6.5	0.307	93	157
7	0.297	90	152
7.5	0.282	85	145
8	0.259	78	133
8.5	0.237	72	122
9	0.195	59	100
9.5	0.138	42	
10	0.037	11	



Mesh Stents Study in ILIAC Complex Lesions

"One-Size-Fits-All" Carotid Stent

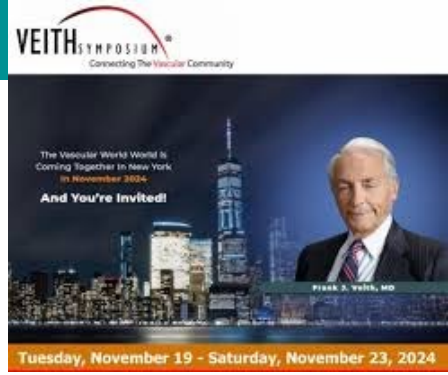


	Diameter				
Length	6mm	7mm	8mm	9mm	10mm
20mm	CRX0620	CRX0720	CRX0820	CRX0920	CRX1020
30mm	CRX0630	CRX0730	CRX0830	CRX0930	CRX1030
40mm	CRX0640	CRX0740	CRX0840	CRX0940	CRX1040
*60mm	CRX0660		CRX0860		CRX1060

*60mm sizes are not available in Australia

Wissgott C, Brandt-Wunderlich C, Kopetsch C, Schmidt W, Andresen R. Initial Clinical Results and In Vitro Testing of the New CGuard MicroNet-Covered "One-Size-Fits-All" Carotid Stent. J Endovasc Ther. 2019;26(4):578-582

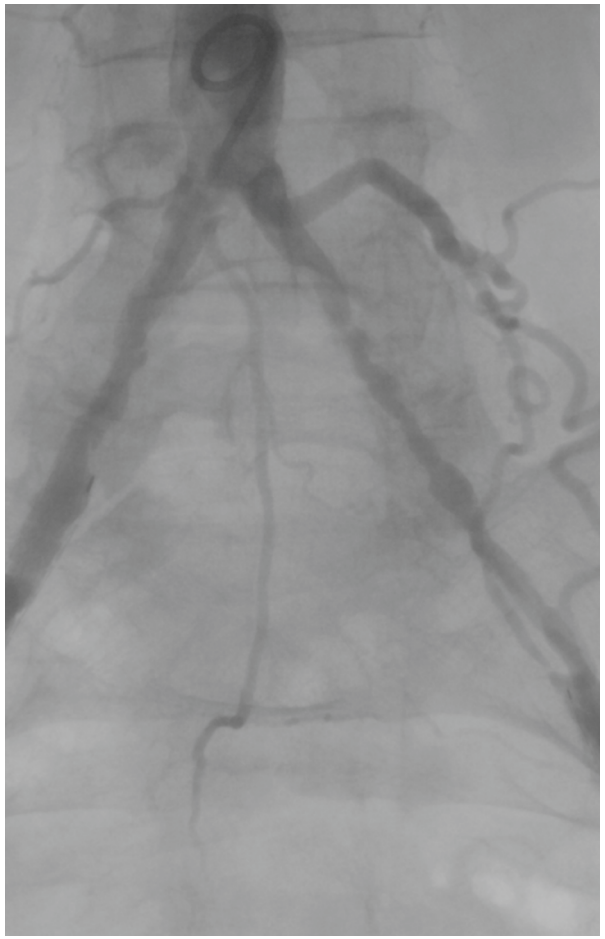
IMS-Study became part of the international FLOWGUARD-ILIAC, NCT04461717 (2024)

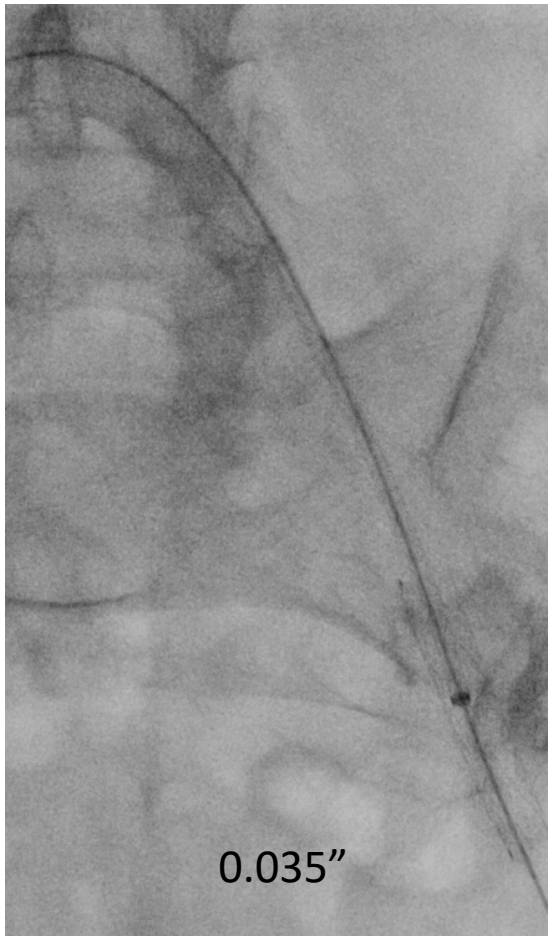


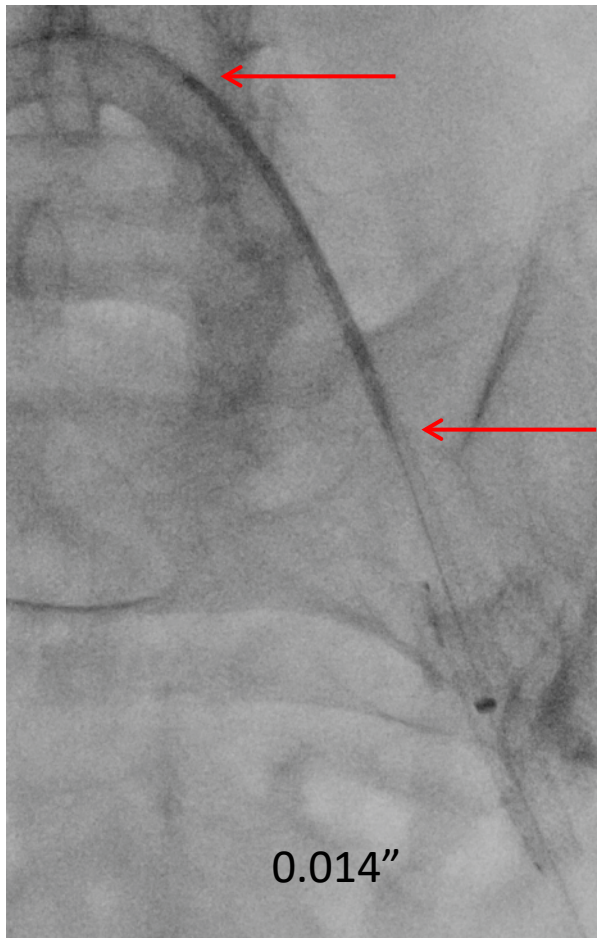
Challenges when using the CGuard mesh stent:

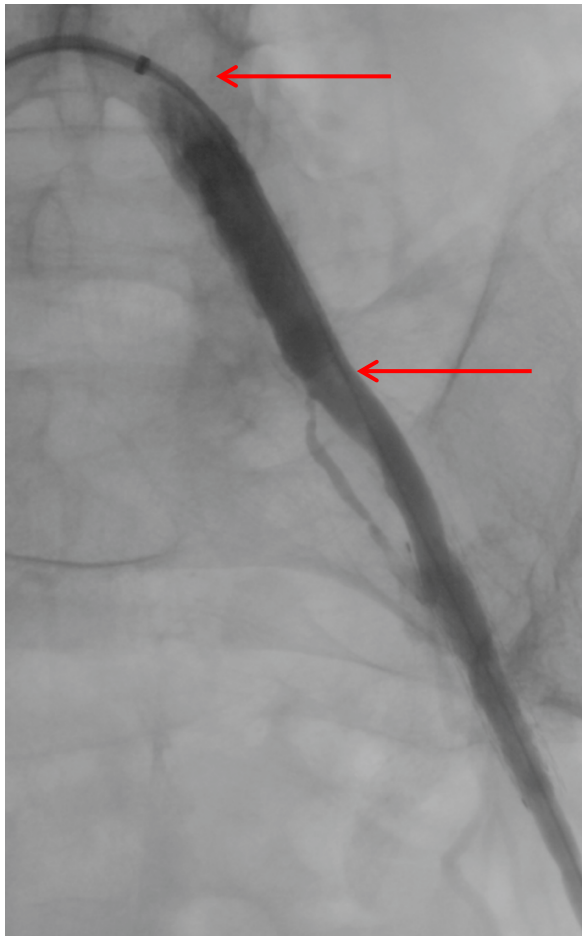
- 0.014" guidewire
- „One-Size-Fits-All” diameter (10 mm)
- Maximum length of 60 mm
- Cross-over technique

FLOWGUARD-ILIAC, NCT04461717

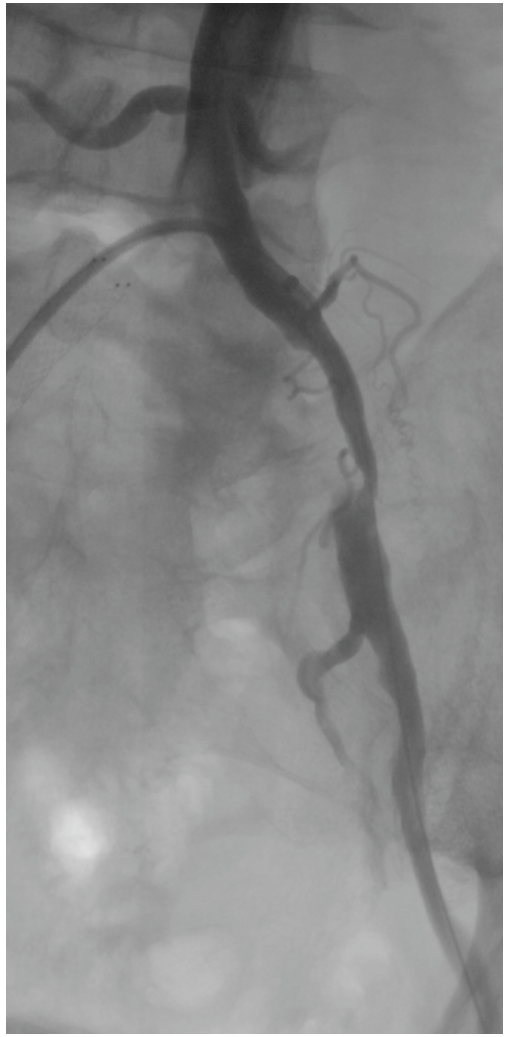


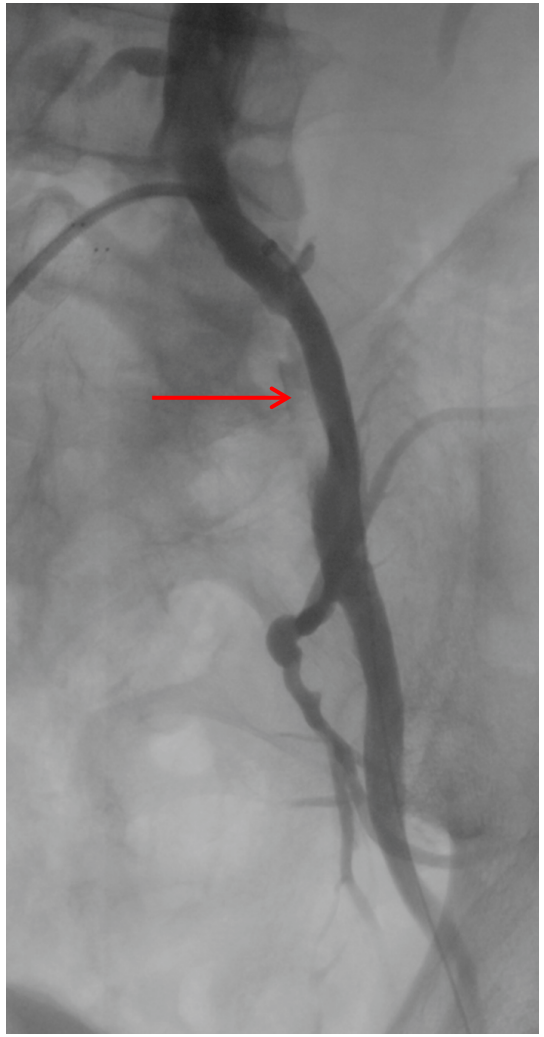


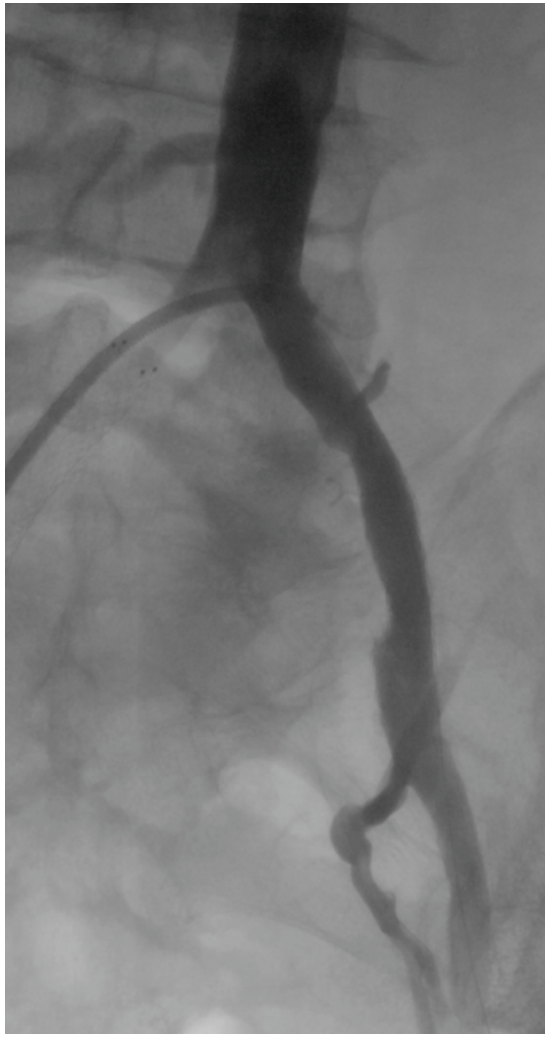




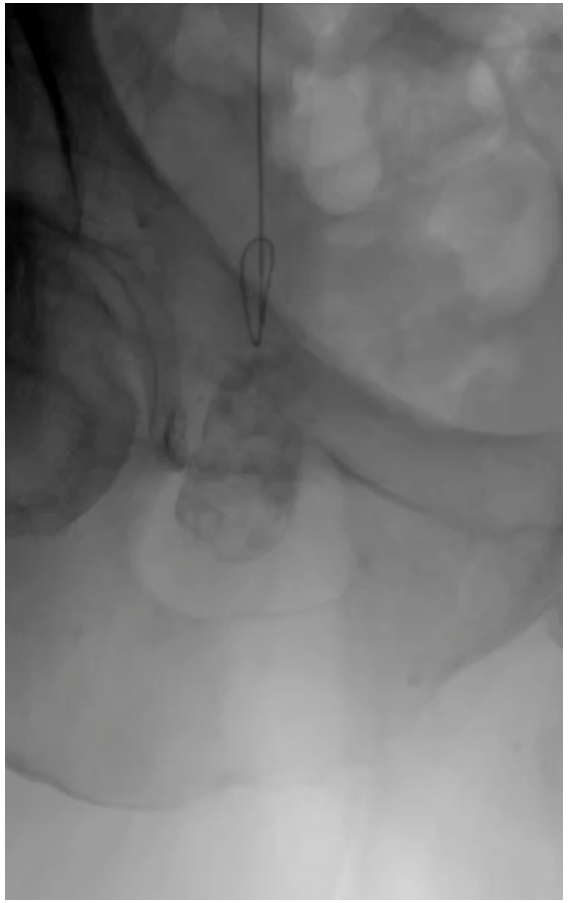
FLOWGUARD-ILIAC, NCT04461717

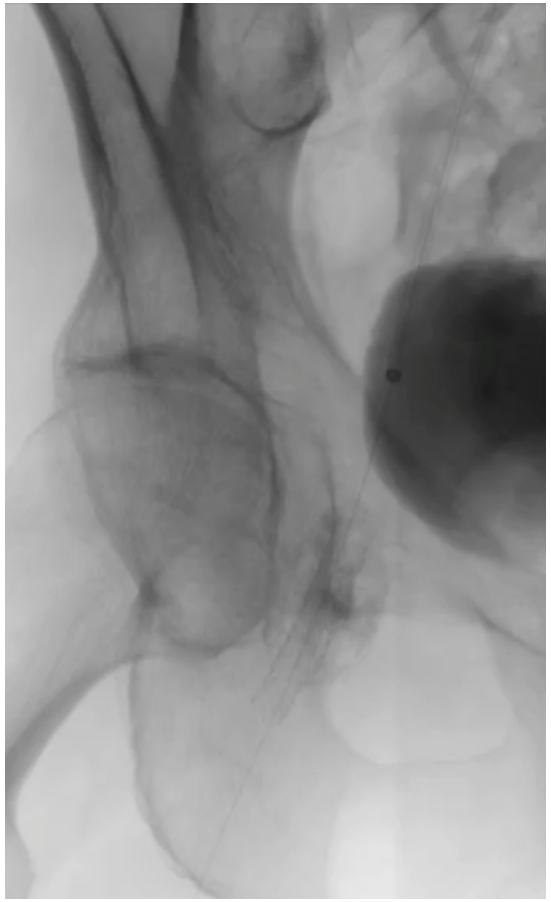


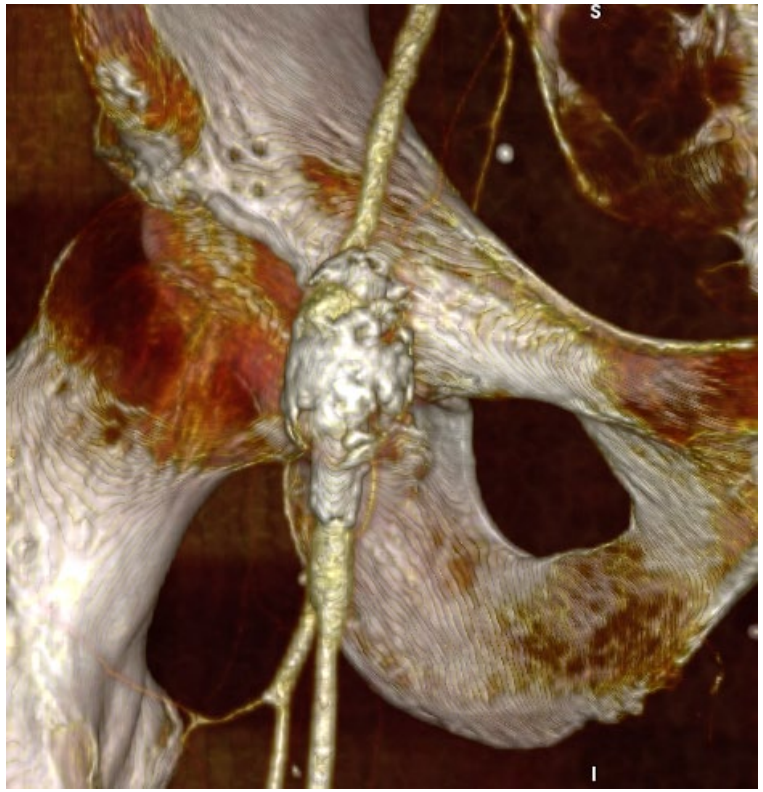




FLOWGUARD-ILIAC, NCT04461717

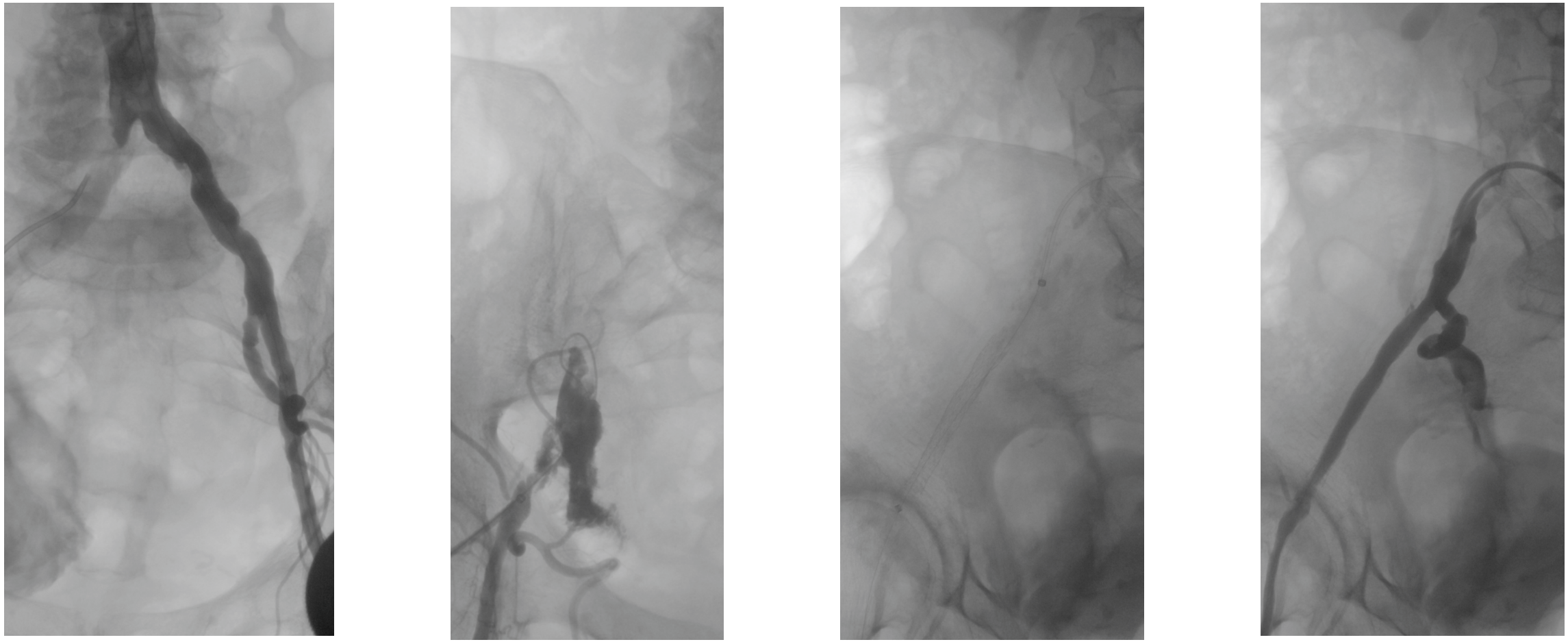




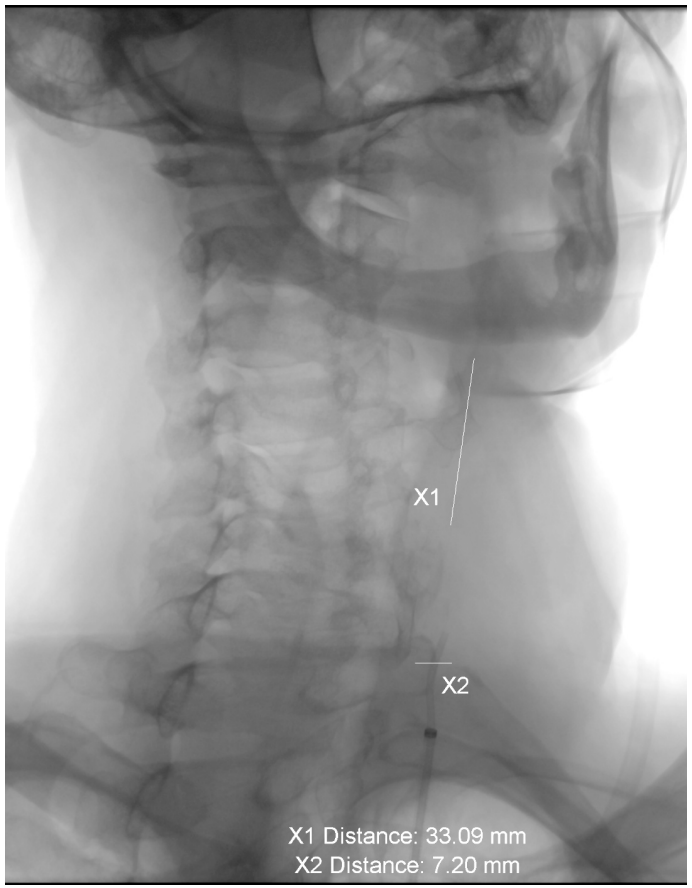


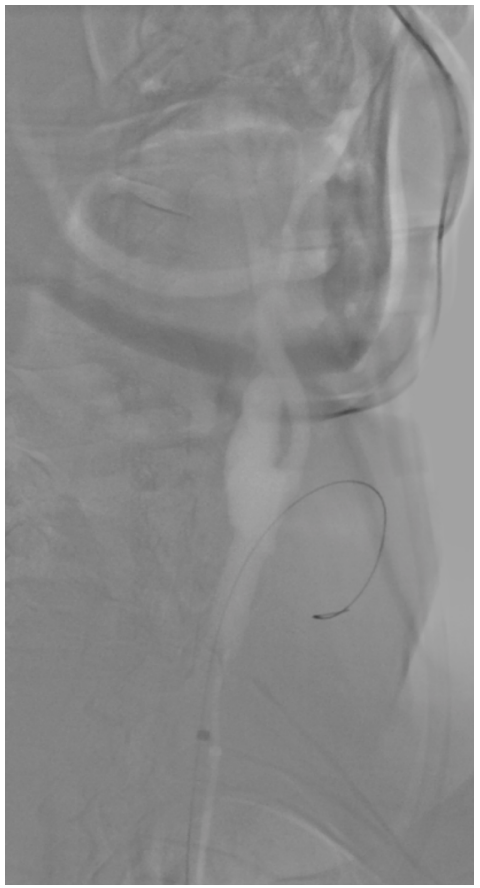
CGuard: Flow-diveter effect

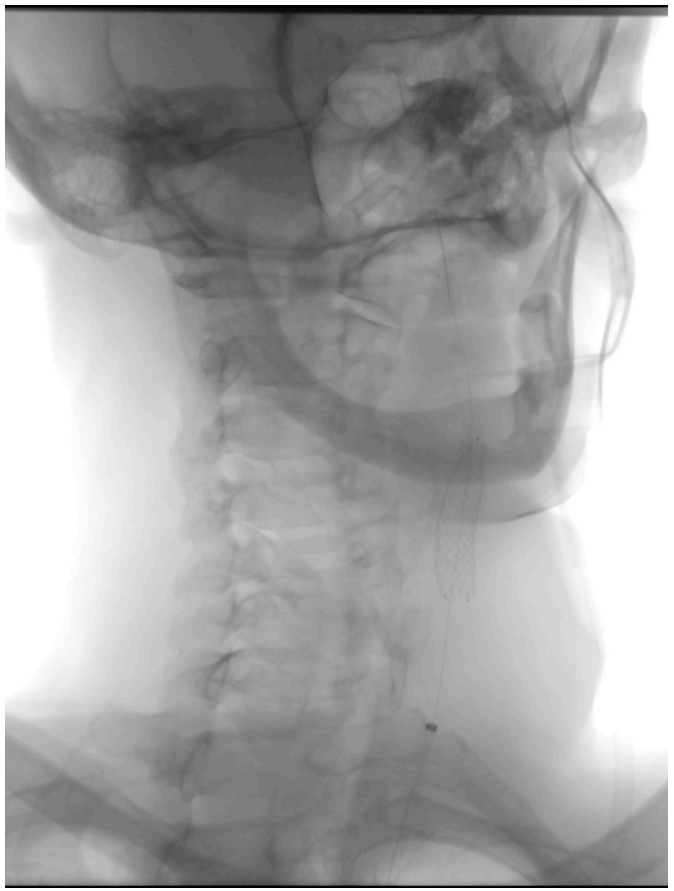
FLOWGUARD-ILIAC, NCT04461717



CGuard: Flow-diveter effect







CGuard: Flow-diveter effect

Preliminary conclusions

1. CGuard implantation into the iliac artery is feasible and safe.
2. The use of a mesh stent may be a cheaper alternative to a peripheral stent graft.
3. The use of the 0.014 ” guidewire requires some technical modifications to the implantation.
4. "One-Size-Fits-All" facilitates implantation in the common iliac artery

Thank you for your attention

piotr.myrcha@wum.edu.pl