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

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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:

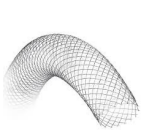
- PTA alone
- Stenting for suboptimal or failed result from PTA (e.g., persistent gradient, residual diameter stenosis >50%, or flow-limiting dissection).
- Primary stenting for CIA/EIA stenosis and occlusions

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- cover stents

JABFM Journal of Applied Biomaterials & Functional Materials

Review

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

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

The healing of grafts primarily consists of endothelialization.

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

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Endovascular treatment- cover stents

> 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 Moro[illegible], 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- cover stents

> 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], Pavla[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- cover stents

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 Fe[illegible]

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 dedicated 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

> 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], Christo[illegible]-Wunderlich [2], Christoph Kopetsch [1], Wolfram Schmidt [2], Reimer Andresen [1]

Table 2. Chronic Outward Force[illegible]ion of the One-Size-Fits-All CGuard Stent.

Diameter, mm	Nor[illegible]	Force [illegible], N/mm	Maximum Force, %	Minimum Force, %
5				198
5.5				169
6				163
6.5				157
7				152
7.5				145
8				133
8.5				122
9				100
9.5				
10				

"One-Size-Fits-All"

CGuard has an almost equivalent radial force at expansion diameters ranging from 5.5 to 9.0 mm.

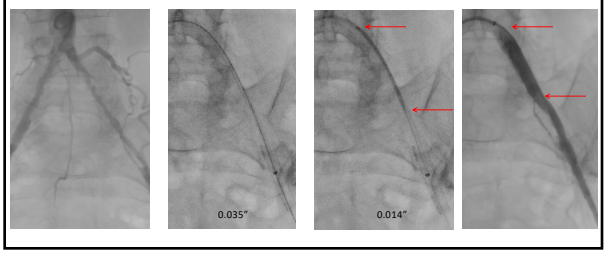
Stent can be safely implanted in internal carotid arteries with reference diameters within this range.

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

Challenges when using the CGuard mesh stent:

- **0.014" guidewire**- unstable stent deployment in calcified lesions
- **„One-Size-Fits-All"-** does not work for small EIA diameters
- **Maximum length of 60 mm**
- **Cross-over technique** - challenging deployment of a 10x60 mm stent at an acute aortic bifurcation angle.

FLOWGUARD-ILIAC (NCT04461717)



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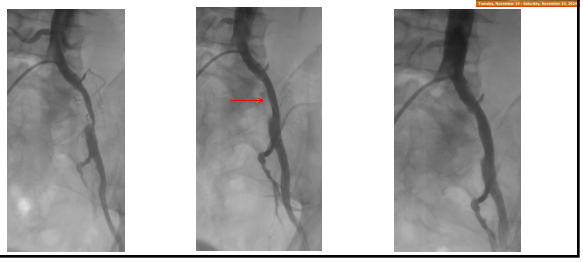
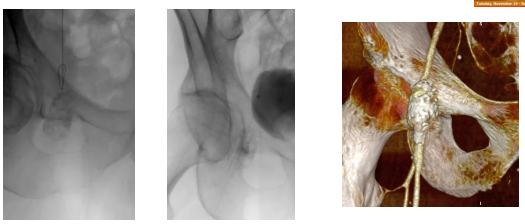
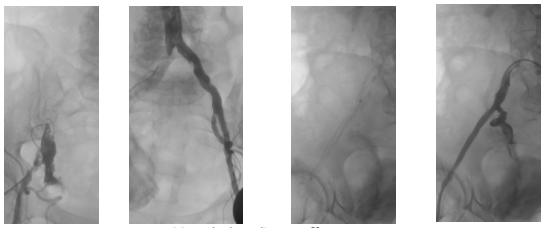


FLOWGUARD-ILIAC (NCT04461717)

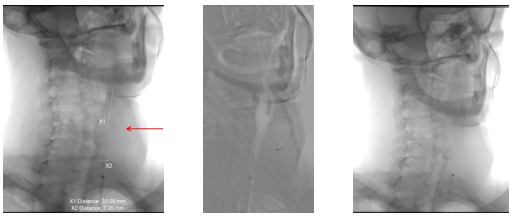


CGuard: Flow-diveter effect

FLOWGUARD-ILIAC (NCT04461717)



CGuard: Flow-diveter effect



CGuard: Flow-diveter effect

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

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