MicroNET-Covered Self-EXpandable STent In High-Risk Vascular Lesions Beyond The CArotid Bifurcation:

The EXTRA-GUARD Multi-center Multi-specialty Study

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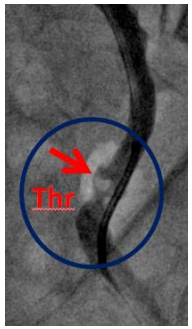
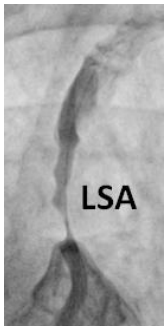
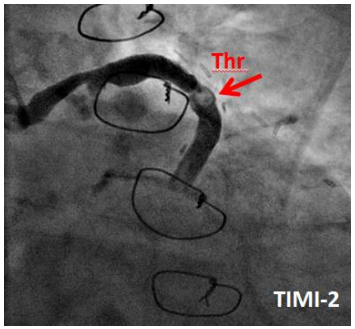
Addressing *unmet endo-vascular needs…*



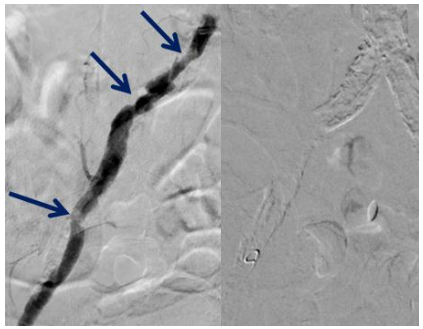
Symptomatic, Thrombotic High-risk **Iliac**

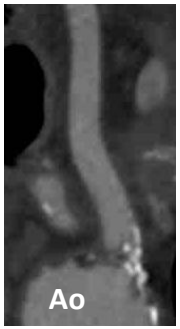


Symptomatic, v. large plaque burden **Subclavian**

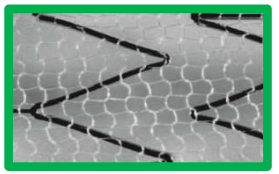


V. Highly Symptomatic (NSTEMI) Large-Diameter Thomboltic **Saphenous Vein Graft**


V. Highly Calcific Large-Diameter Thomboltic **Saphenous Vein Graft**



TIAS -> Retinal Stroke **ostial CCA**



…beyond the carotid bifurcation

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• *Background*

Thrombotic (T), Highly-Calcific (HC) and High-plaque burden (HPB), symptomatic arterial lesions pose a significant clinical and procedural challenge in vascular medcine because of the risk of embolism (on the one side of the complication/risk spectrum) and perforation (on the other); the endovascular procedres in T, HC and HPB are oftern hard –or impossible- to optimize using conventional stents.

• *The Device* CGuard™ Embolic Prevention Stent System


EUROPCR LATE BREAKING TRIALS

Novel PARADIGM in carotid revascularisation: Prospective evaluation of All-comer peRcutaneous cArotiD revascularisation in symptomatic and Increased-risk asymptomatic carotid artery stenosis using CGuard™ Micronet-covered embolic prevention stent system

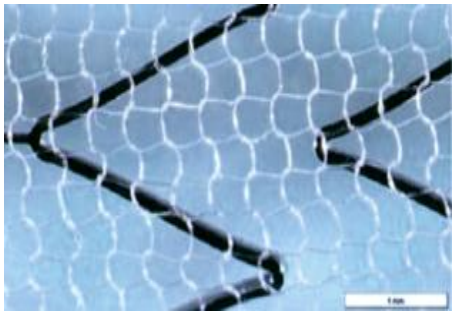

ORIGINAL STUDIES WILEY

Highly-calcific carotid lesions endovascular management in symptomatic and increased-stroke-risk asymptomatic patients using the CGuard™ MicroNet-covered carotid stent system: Analysis from the PARADIGM registry study

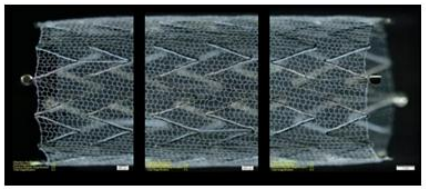
Calcified carotid lesion management using CGuard™

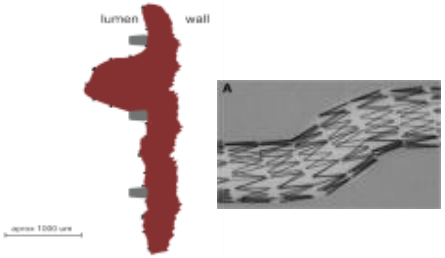
This stent design performs very well in high-risk (such as thrombotic &highly calcific) carotid lesions

System specifications	
Stent type	Nitinol – self expanding
Micronet aperture size	150-180 µm
Guidewire	0.014”
Sizes - Diameter - Length	 6-10mm 20-60mm



CE Mark – March 2014



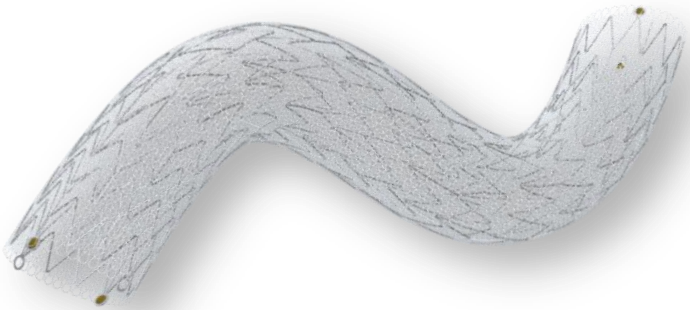


Nitinol frame open-cell area ≈ 21 mm²

MicroNet closed-cell area ≈ 0.3mm²

LARGEST √

SMALEST √



Aim

- To evaluate feasibility/efficacy of the CGuard™ Embolic Prevention Stent System use *to address unmet needs* in consecutive high-risk angioplasty (symptomatic T, HC, HPB) in vascular beds beyond the carotid bifurcation.

Methods

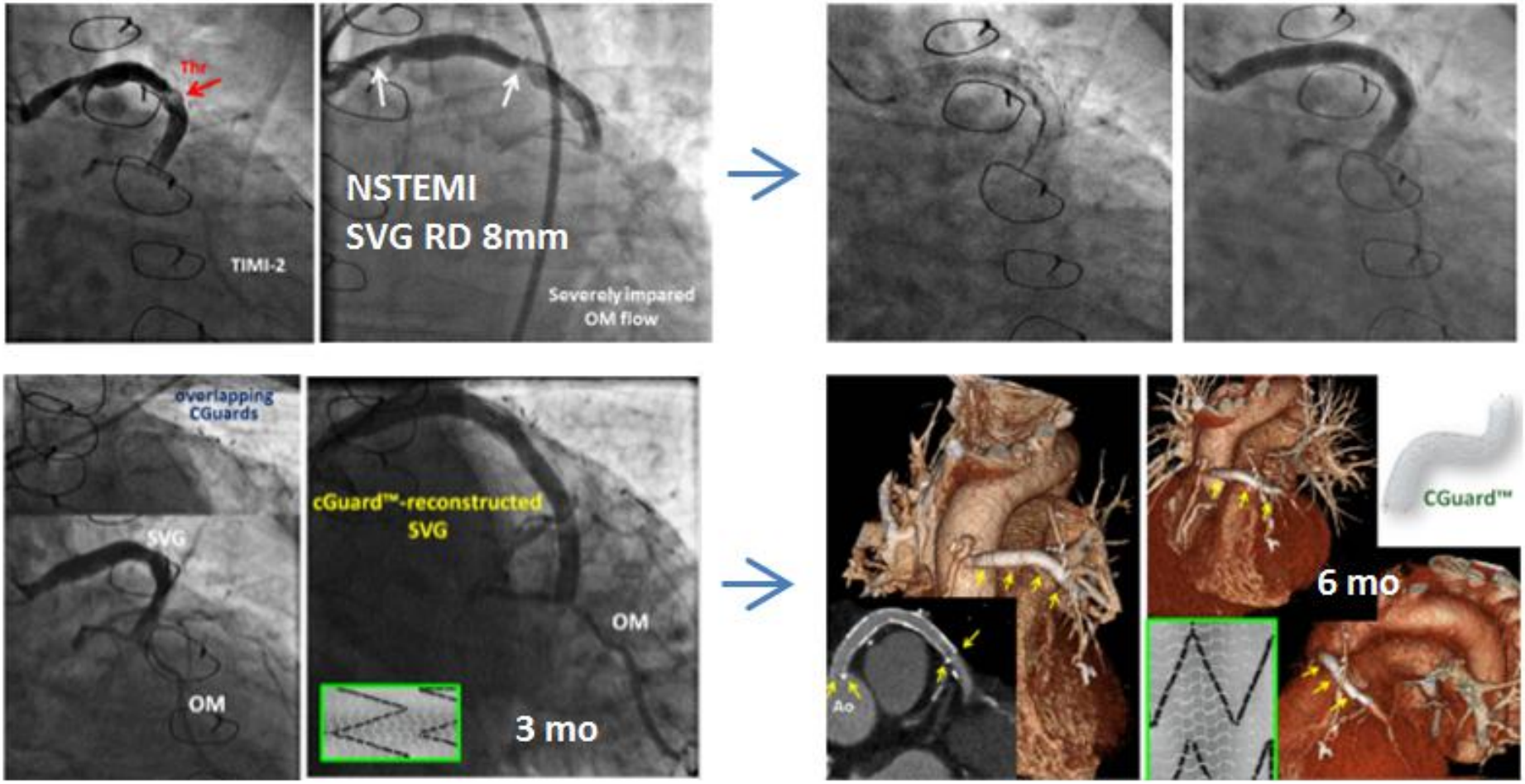
- Multi-center, multi-specialty study in high-risk (T, HC and HPB) endovascular revascularization
- Currently 25 consecutive patients recruited (9 women); 31 arteries treated
- Mandatory clinical and CT angiographic follow-up at 6-12mo

  Already completed in 17 (in-the-window) out of the presently total 25 subjects

References

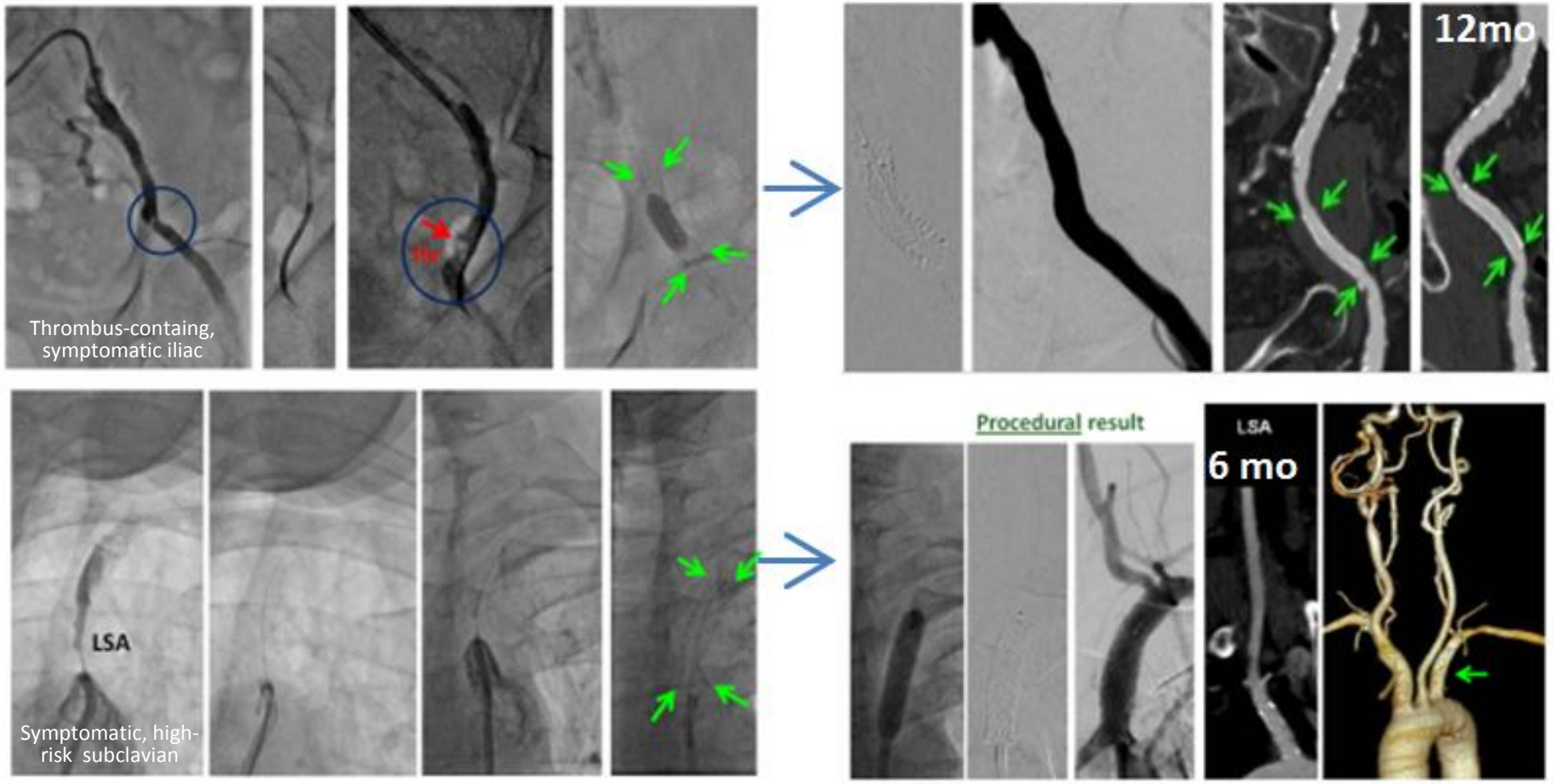
1. Schofer J, Musiałek P, Bijuklic K et al. A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent: The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet). *JACC Cardiovasc Interv.* 2015;8:1229-1234.
2. Musialek P, Mazurek A, Trystula M, et al. Novel PARADIGM in carotid revascularisation: Prospective evaluation of All-comer peRcutaneous cArotiD revascularisation in symptomatic and Increased-risk asymptomatic carotid artery stenosis using CGuard™ MicroNet-covered embolic prevention stent system. *EuroIntervention.* 2016;12:e658-670.
3. Wissgott C, Schmidt W, Brandt-Wunderlich C, et al. Clinical results and mechanical properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent. *J Endovasc Ther.* 2017;24:130-137.
4. Mazurek A, Partyka L, Trystula M, et al. Highly-calcific carotid lesions endovascular management in symptomatic and increased-stroke-risk asymptomatic patients using the CGuard™ dual-layer carotid stent system: Analysis from the PARADIGM study. *Catheter Cardiovasc Interv.* 2019 ;94:149-156 .
5. Musialek P. Roubin GS. Double-Layer Carotid Stents: From the Clinical Need, through a Stent-in-Stent Strategy, to Effective Plaque Isolation… the Journey Toward Safe Carotid Revascularization Using the Endovascular Route. *J Endovasc Ther*. 2019;26:572-577.

Thrombus-containing / ruptured lesions



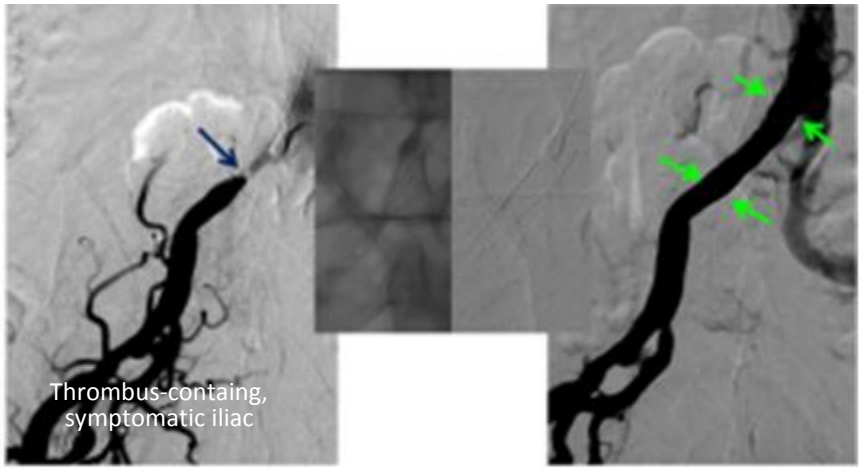
Safe & Effective endovascular reconstruction in absence of restenosis

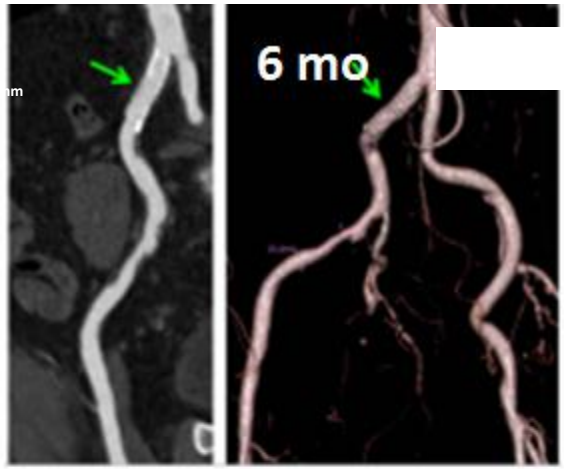
Thrombus-containing / ruptured lesions

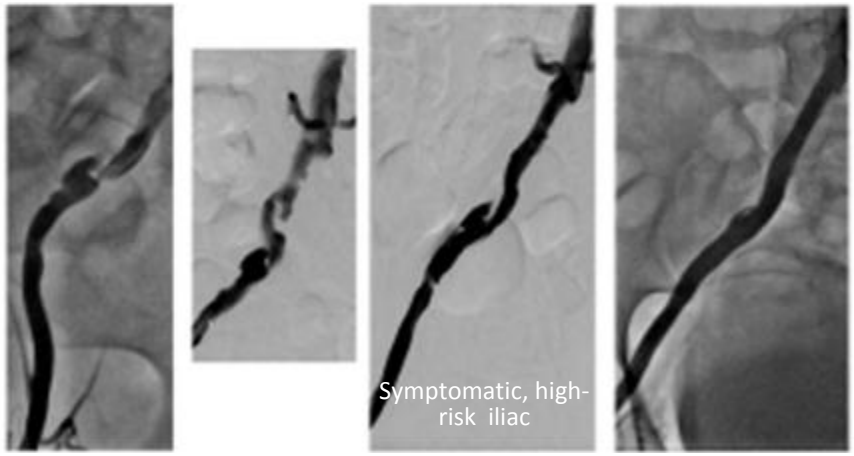


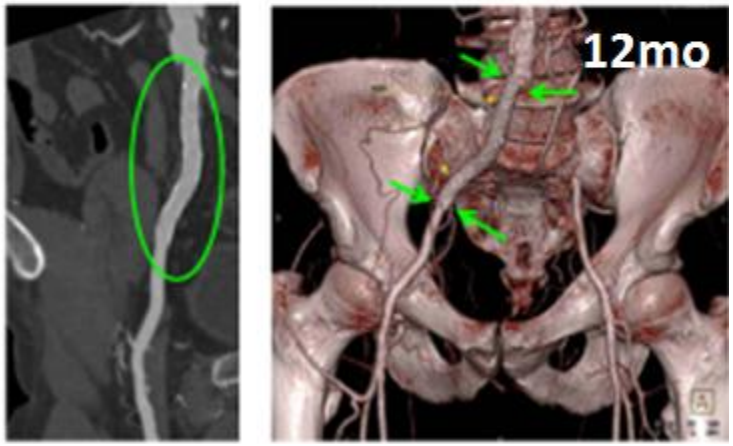
Safe & Effective endovascular reconstruction in absence of restenosis

Thrombus-containing / ruptured lesions









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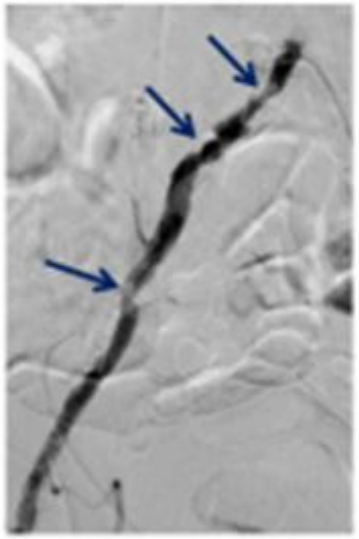
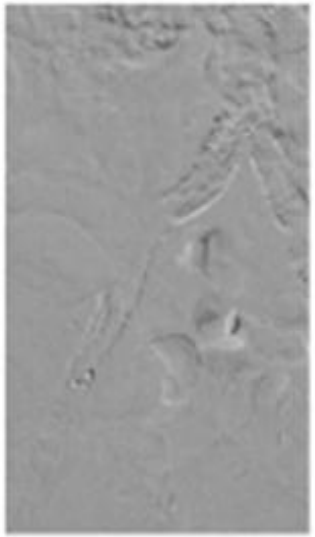
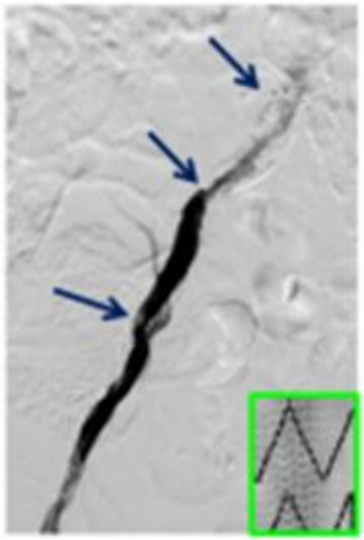
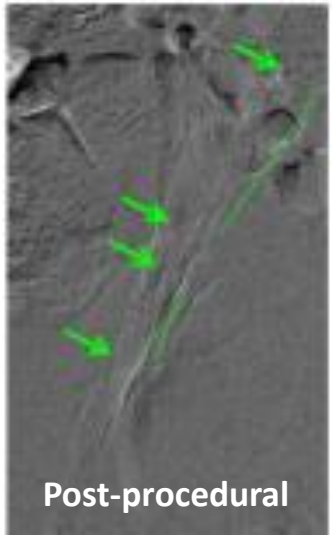
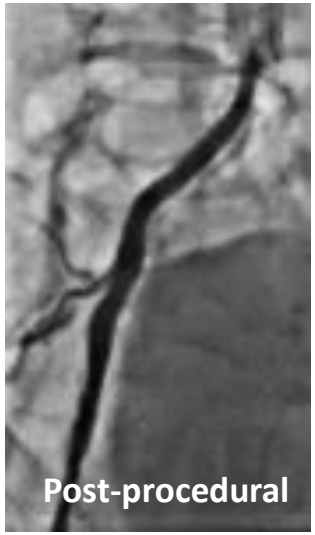
Highly-calcific lesions











Safe & Effective endovascular reconstruction in absence of restenosis

EXTRA-GUARD Study

High-risk Ostial Lesions

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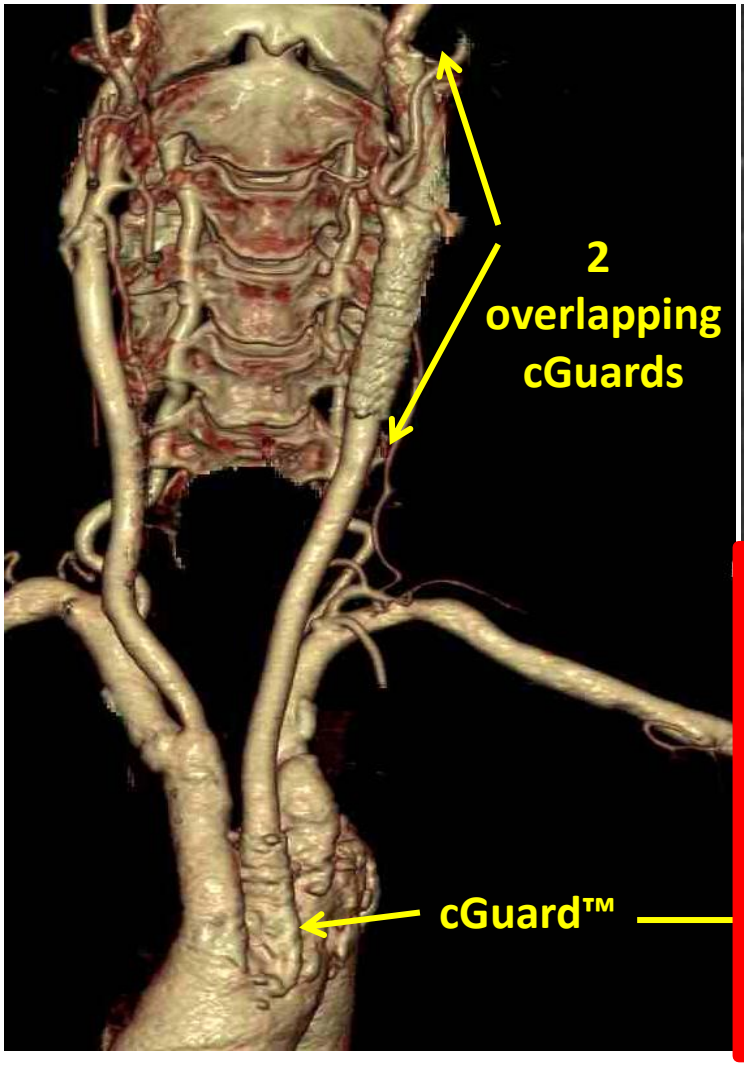
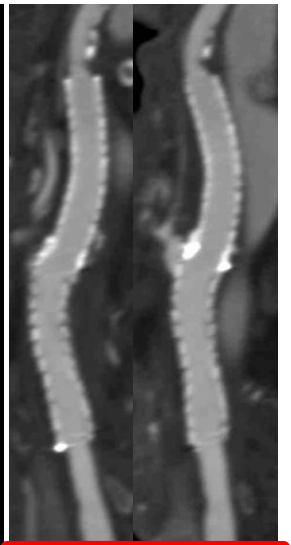
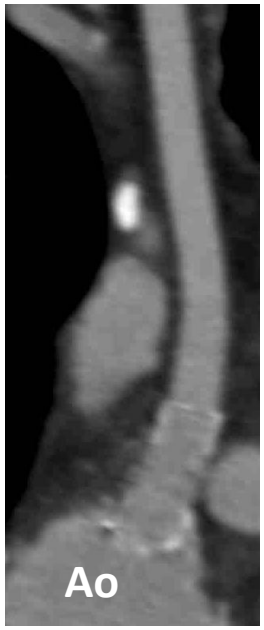
(note adequate radial force and placement percision)

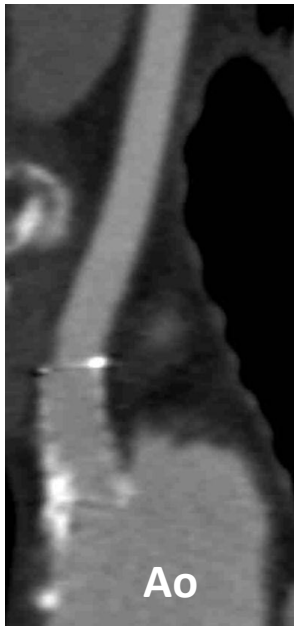




OPTIMAL angiographic + clinical + duplex result @ 12mo

(and LECA patent)





Safe & Effective endovascular reconstruction in absence of restenosis

MicroNET-Covered Self-EXpandable STent In High-Risk Vascular Lesions Beyond The CArotid Bifurcation:

The EXTRA-GUARD Multi-center Multi-specialty Study

Conclusions

- **The MicroNET-Covered self-expandable stent system is well-suited to address unmet needs in high-risk PTA beyond the carotid bifurcation due to its unique mechanical properties (very high conformability and optimal radial force combined with plaque sequestration).**
- **The lesion spectrum extends from high-thrombus burden to high-calcium burden, through complex ostial lesions where this stent specific behavior (including lack of foreshortening/ elongation) enables high placement precision.**
- **Sealing properties of the MicroNET enable gradual, large-balloon, high-pressure optimization of the angiographic effect – and absence of residual stenosis.**
- **EXTRA-GUARD study procedures showed no procedural complications, no device-elated issues, and optimal clinical and (per-protocol mandatory) CT angio result at 6-12months.**
- **The study demonsrates full, optimal, endovascular reconstruction in absence of restenosis in vascular beds beyond the carotid bifurcation, consistent with**

Combined properties of self-expandable and balloon-expandable stent PLUS plaque sequestration

ENDOVASCULAR RECONSTRUCTION of normal anatomy √

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Supported by a research grant from the Jagiellonian University Medical College (ZDS/007819)

STUDY UPDATE

PARADIGM – Extend

402 patients / 436 arteries (f/u ≥30d; 31 Aug 2019)

CAROTID PARADIGM REVASCULARIZATION

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- *Peri-procedural outcome*

  0 death/major stroke – 0%
  1 minor stroke – 0.25%
  1 MI (type2) **– 0.25%**

- *By 30 days*

  1 haemorrhagic transformation of prior ischaemic cerebral infarct leading to **death – 0.25%**

  1 bleeding-related death – 0.25%

- **Total**
  30-day death/MI/any stroke – **0.995 %** (4/402)
- **no post-proc. ischaemic stroke by 30 days – 0.0 %** (0/402)

Normal in-stent velocities; Low ISR rate: n=1 by 12mo, total of n=4; effective DEB-PTA

NB. ALL–Comer, Unselected Population (eg. AFib 8.9%)

	1-12 mo	13-24 mo	25-36 mo	37-48 mo
	n=311	n=205	n=108	n=61
ipsilateral stroke	**0**	**0**	**0**	**0**
any stroke	**0**	**2** 1 cerebellal 1 contralat.	**1** brain stem	**2** 1 contralateral 1 under adjudiaction
stroke-related death	**0**	**1**	**0**	**1**
MI or other non-cerebral VA	**3**	**3**	**2**	**2**
any death	**13** CHF-4, Ca-3, PE-1, MI-2 COPD-1,uroseps-1, surg-1	**10** CHF-3, Ca-2, MI-2 surg-2, intrac. bleed-1	**6** CHF-2, Ca-2, MI-1 urosepsis-1	**4** CHF-2, Ca-2, MI-2
in-stent velocities	PSV **0.79**±0.41m/s EDV **0.21**±0.11 m/s	PSV **0.75**±0.36 m/s EDV **0.19**±0.09 m/s	PSV **0.75**±0.36 m/s EDV **0.20**±0.09 m/s	PSV **0.74**±0.28 m/s EDV **0.20**±0.07 m/s

P Musialek @ TCT 2019