

Dual layer stents for treatment of symptomatic and asymptomatic carotid artery stenosis: 6-year data of a high volume centre - Is reocclusion an issue?



S.Müller-Hülsbeck, MD, EBIR, FCIRSE, FICA, FSIR

ACADEMIC HOSPITALS Flensburg
of Kiel University – Faculty of Medicine
Ev.-Luth. Diakonissenanstalt zu Flensburg
Knuthstraße 1, 24939 FLENSBURG

**Dept. of Diagnostic and Interventional
Radiology / Neuroradiology**



Disclosure

Speaker name:

.....Stefan Müller-Hülsbeck.....

I have the following potential conflicts of interest to report:

Consulting: Terumo, Boston Scientific, Eurocor Tech, Alvimedica

Employment in industry

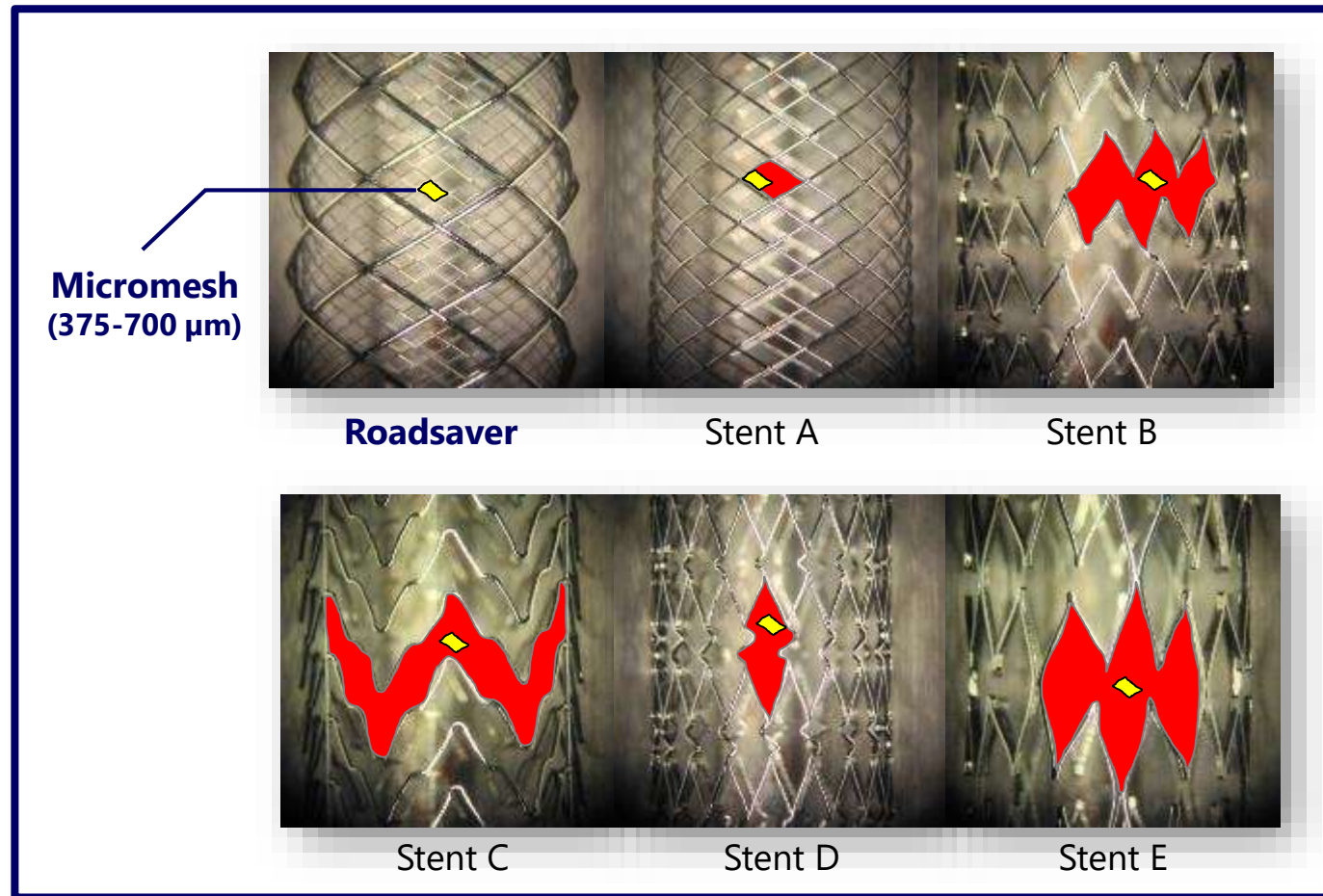
Stockholder of a healthcare company

Owner of a healthcare company

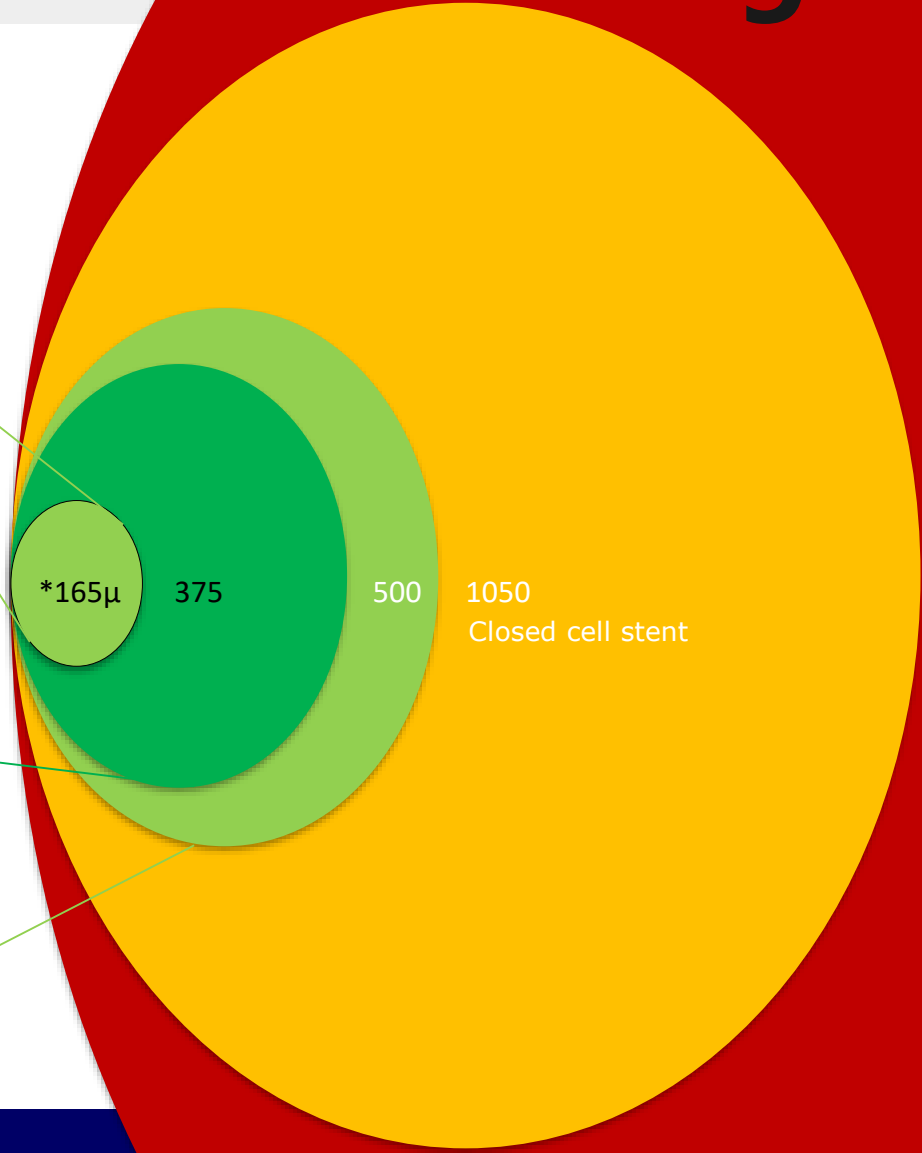
Other(s)

I do not have any potential conflict of interest

Value: Cell Size Comparison



Smaller Pore Size – More Material: Enhanced Thrombogenicity?



* Average in lesion at expanded state

Dual Layer Stent Designs: **Early Reports**



CGUARD

CARENET: 30 pts, EPDs were used in all procedures

- Procedure success 100%
- Procedural complications 0%
- 30-day MAE cardiac or cerebrovascular 0%**
- New ipsilateral ischemic lesions at 48 h 37.0%

Schofer et al. JACC Cardiovasc Interv. 2015 Aug 17;8(9):1229-34.



Roadsaver

Clear-Road: 100 pts, multi-center, prospective

- Procedure success 100%
- Procedural complications 0%
- 30-day MAE cardiac or cerebrovascular 2.1%**

Bosiers et al. EuroIntervention. 2016 Aug 5;12(5):e671-6



GORE

Scaffold-Trial: 312 pts, multi-center, prospective

- Procedure success 100%
- Procedural complications 0%
- 30-day MAE cardiac or cerebrovascular 1.1%**

VEITH 2017 presentation

Dual Layer CAS in acute ischemic stroke (I): The Homburg Experience 2017

Limitations



Dual-Layer
Carotid Stents:
**45% ACUTE
OCCLUSION!**

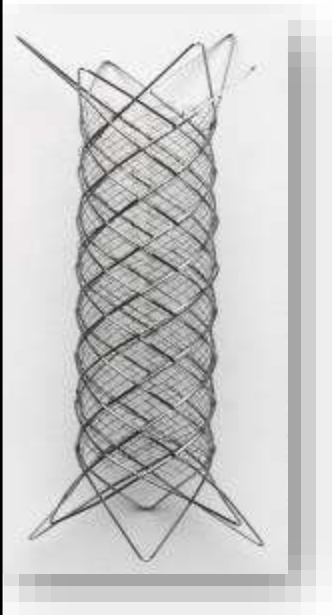
Yilmaz et al. Stroke. 2017 Aug;48(8):2171-2175.

Dual Layer CAS in acute ischemic stroke (I): The Homburg Experience

Limitations

Potential explanation for acute occlusion in dual layer stent group by the authors:

- Increase of thrombogenic material (micromesh)
- Insufficient preparation with antiplatelet medication
- Higher platelet counts
- Smaller stent diameters
- Not administered IV r-tPA (Bridging)
- All patients received 500 mg acetylsalicylic acid peri-interventionally, but the decision when to start the clopidogrel administration was made on an individual case basis



Yilmaz et al. Stroke. 2017 Aug;48(8):2171-2175.

Dual Layer CAS in acute ischemic stroke (II): The European and Australian Experience 2019

Limitations

Acute Occlusions of Dual-Layer Carotid Stents After Endovascular Emergency Treatment of Tandem Lesions significant ICA stenosis

		acute occlusion (%)	
Dual-layer stents CASPER-RX™/ ROADSAVER™	n=21	n=11 (52)	Bartolini et al. J Neurointerv Surg. 2019 Aug;11(8):772-774.
Dual-layer stents CASPER-RX™/ ROADSAVER™	n=27	n=5 (18.5)	De Vries et al. Stroke. 2019 Jul;50(7):1898-1901.
Dual-layer stents CASPER-RX™/ ROADSAVER™	n=19	n=2 (10.5)	Lamanna A et al. World Neurosurg. 2019 Jul;127:e1003-e1012.



Dual Layer CAS in acute ischemic stroke (V): The European Experience 2019 - II

Acute Occlusions of Dual-Layer Carotid Stents After Endovascular Emergency Treatment of Tandem Lesions significant ICA stenosis

	April 2014 – November 2018	acute occlusion (%)	Favorable early neurological outcome was similar in patients with (n=15; 45.5%) and without (n=63; 49.6%) thrombus formation at the CASPER stent"
Dual-layer stents CASPER-RX™ ROADSAVER™	n=160	n=12 (7.5) within 72hrs	

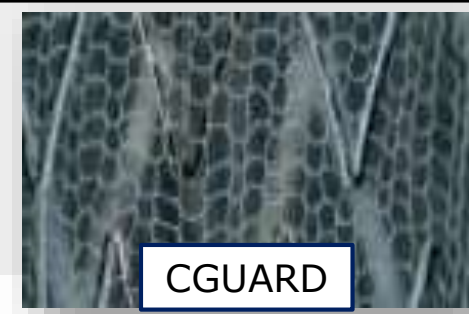
Acute thrombosis or occlusion of CASPER stents ..., were less frequent than previously reported, and showed no impact on early neurological outcome.

Pfaff et al. J Neurointerv Surg. 2019 Jul 15.

Dual Layer CAS: The Flensburg Experience



Roadsaver



CGUARD

Flensburg Dual-Layer Carotid Stents Experience 2014 – 2019: ongoing

	2014	2015	2016	2017	2018	2019	total	stroke rate (%) @30 days	ISR & occlusion within 12 months based on US
Total	n=11	n=30	n=30	n=23 Roadsaver™	n=28 Roadsaver™	n=36 Roadsaver™	n=158 Roadsaver™	6/181 3.3% Major stroke n=1 TIA n=5 3.3%/0%	7/181 3.8% ISR 2/181 1.1% Occl.
Symptomatic/ asymptomatic	11/0	26/4	23/7	n=8 CGuard™	n=9 CGuard™	n=6 CGuard™	n=23 CGuard™		
symptomatic (acute stroke) Tandem lesion	n=3	n=17	n=11	n=8 Roadsaver™	n=10 Roadsaver™	n=15 Roadsaver™	n=69	1/69 1.4% acute occlusion –pat. wasn't on ASA!	1/69 1.4% asymptomatic occlusion

RoadSaver & CGuard: Safety

[JACC Cardiovasc Interv.](#) 2018 Dec 10;11(23):2405-2411. doi: 10.1016/j.jcin.2018.06.047.

Use of Dual-Layered Stents in Endovascular Treatment of Extracranial Stenosis of the Internal Carotid Artery: Results of a Patient-Based Meta-Analysis of 4 Clinical Studies.

[Stabile E¹](#), [de Donato G²](#), [Musialek P³](#), [De Loose K⁴](#), [Nerla R⁵](#), [Sirignano P⁶](#), [Chianese S⁷](#), [Mazurek A³](#), [Tesorio T⁸](#), [Bosiers M⁴](#), [Setacci C²](#), [Speziale F⁶](#), [Micari A⁴](#), [Esposito G⁷](#).

[+ Author information](#)

Abstract

OBJECTIVES: The aim of this study was to evaluate the clinical efficacy of dual-layered mesh-covered carotid stent systems (DLS) for carotid artery stenting (CAS).

BACKGROUND: The need to minimize the risk for plaque debris prolapsing between stent struts following CAS has resulted in the development of DLS. Small clinical studies evaluating 2 available devices, **Roadsaver and CGuard**, have been recently published; none of these studies is sufficiently powered to test the role of common risk factors on the occurrence of stroke at 30 days post-CAS.

METHODS: A search was performed of multiple electronic databases for studies larger than 100 cases of CAS with DLS. Four single-arm prospective studies were identified, and individual patient data were collected. The primary endpoint was the occurrence of stroke at 30 days; secondary endpoints were technical and procedural success, periprocedural stroke, and in-hospital and 30-day rates of death.

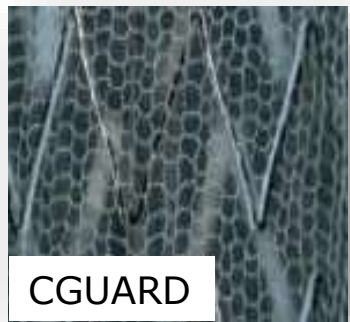
RESULTS: The Roadsaver and CGuard stents were used in similar proportions, and technical success was achieved in all procedures (100% **[n = 556]**). There were 6 periprocedural strokes (1.08%; all minor). During 30-day follow-up, there was 1 death (0.17%) from myocardial infarction and 1 additional minor stroke (0.17%). The cumulative 30-day mortality rate was 0.17%, and the **incidence of stroke at 30 days was 1.25%**. No predictors of stroke at 30 days could be identified.

CONCLUSIONS: This meta-analysis suggests that DLS can be safely used for CAS, and their use minimizes the incremental risk related to symptomatic status and other risk factors.

Tips & Tricks (I):

How do I today treat patients with Roadsaver & CGuard

Emergency treatment of tandem lesions:



CGUARD



Roadsaver

- Bridging

- ✓ 0.9mg/kg BW r-tPA

- Antiplatelet medication

- Peri-procedural

- ✓ 5000 units Heparine (ACT 250s-300s)

- ✓ 500mg ASA i.v.

- ✓ 300mg Clopidogrel after control (conebeam-)CT, usually @ day 1

- Post-procedural

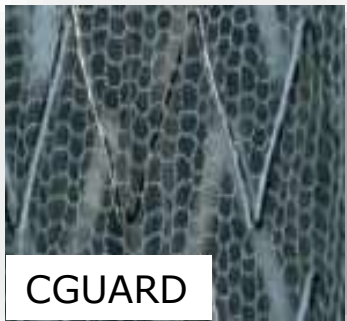
- ✓ 75mg Clopidogrel for **6 months**

- ✓ 100mg ASA life-long

Tips & Tricks (I):

How do I today treat patients with Roadsaver & CGuard

Elective treatment:



- Antiplatelet medication

Pre-procedural

- ✓ 300mg Clopidogrel and 100mg ASA (5 days before or loading dose 300mg Clopidogrel)



Peri-procedural

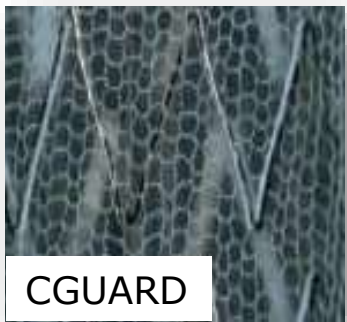
- ✓ 5000 units Heparine (ACT 250s-300s)

Post-procedural

- ✓ 75mg Clopidogrel for **6 months**
- ✓ 100mg ASA life-long

Tips & Tricks (II):

How do I today treat patients with Roadsaver & CGuard



- Stent sizing
 - ✓ 7mm or 8mm diameter
 - ✓ 18mm to 25mm length
- Stent-deployment
 - ✓ Continuous
- Stent –post-dilatation
 - ✓ 5mm in all cases!!

Emergency treatment
of tandem lesions

&

Elective treatment

Conclusions



- Acute thrombosis or occlusion of CASPER/ROADSAVER occur less frequently than previously reported – 0.6% to 1.1% in the Flensburg population
- In-stent restenosis doesn't seem an issue, however reports on that are limited
- Stent sizing, stent post-dilatation should be adapted to established knowledge from single layer stents
- The ideal antiplatelet and anticoagulation regime is not clearly established and proven
- Future prospective studies should clarify the role of double layer mesh stents in high-risk stroke patients, symptomatic and asymptomatic CAS patients

ROADSAVER study

Design:

Prospective, single-arm, multi-center, observational study

Primary endpoint:

The rate of **Major Adverse Events (MAE)** defined as cumulative incidence of **any death** or **stroke** up to **30 days** after the index procedure.

Sponsor:

TERUMO

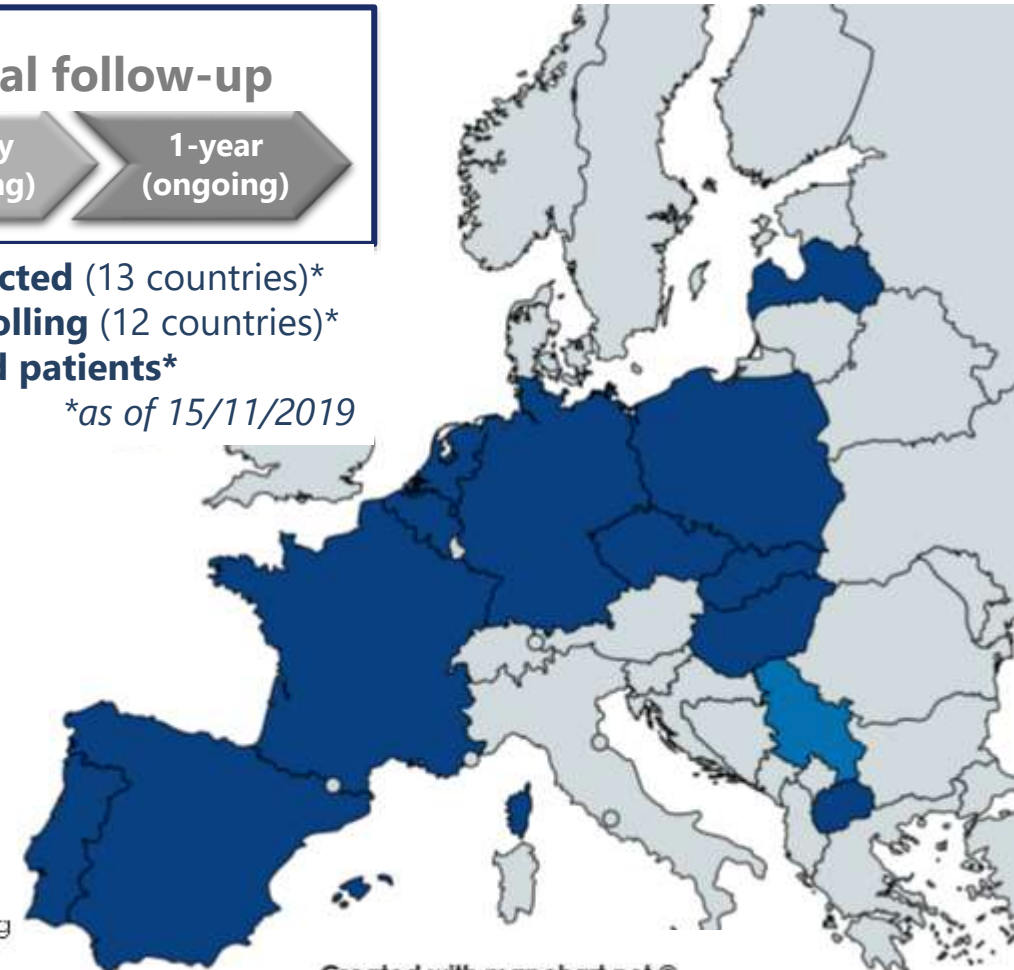
Clinical follow-up



58 sites selected (13 countries)*
42 sites enrolling (12 countries)*
937 enrolled patients*

**as of 15/11/2019*

■ Enrolling
■ Non-enrolling



Created with mapchart.net ©

Dual layer stents for treatment of symptomatic and asymptomatic carotid artery stenosis: 6-year data of a high volume centre - Is reocclusion an issue?



S.Müller-Hüsbeck, MD, EBIR, FCIRSE, FICA, FSIR

ACADEMIC HOSPITALS Flensburg
of Kiel University – Faculty of Medicine
Ev.-Luth. Diakonissenanstalt zu Flensburg
Knuthstraße 1, 24939 FLENSBURG

**Dept. of Diagnostic and Interventional
Radiology / Neuroradiology**

