

Dual layer stents for CAS: All you need to know to avoid acute occlusion



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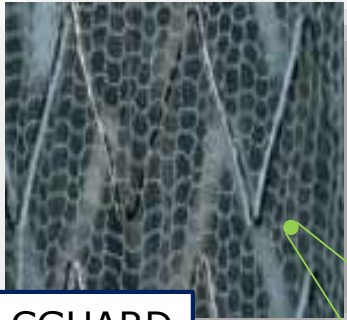


Disclosure

I have the following potential conflicts of interest to report:

- ✓ Consulting – Boston Scientific, Terumo, Eurocor Tech

Smaller Pore Size – More Material: Enhanced Thrombogenicity?



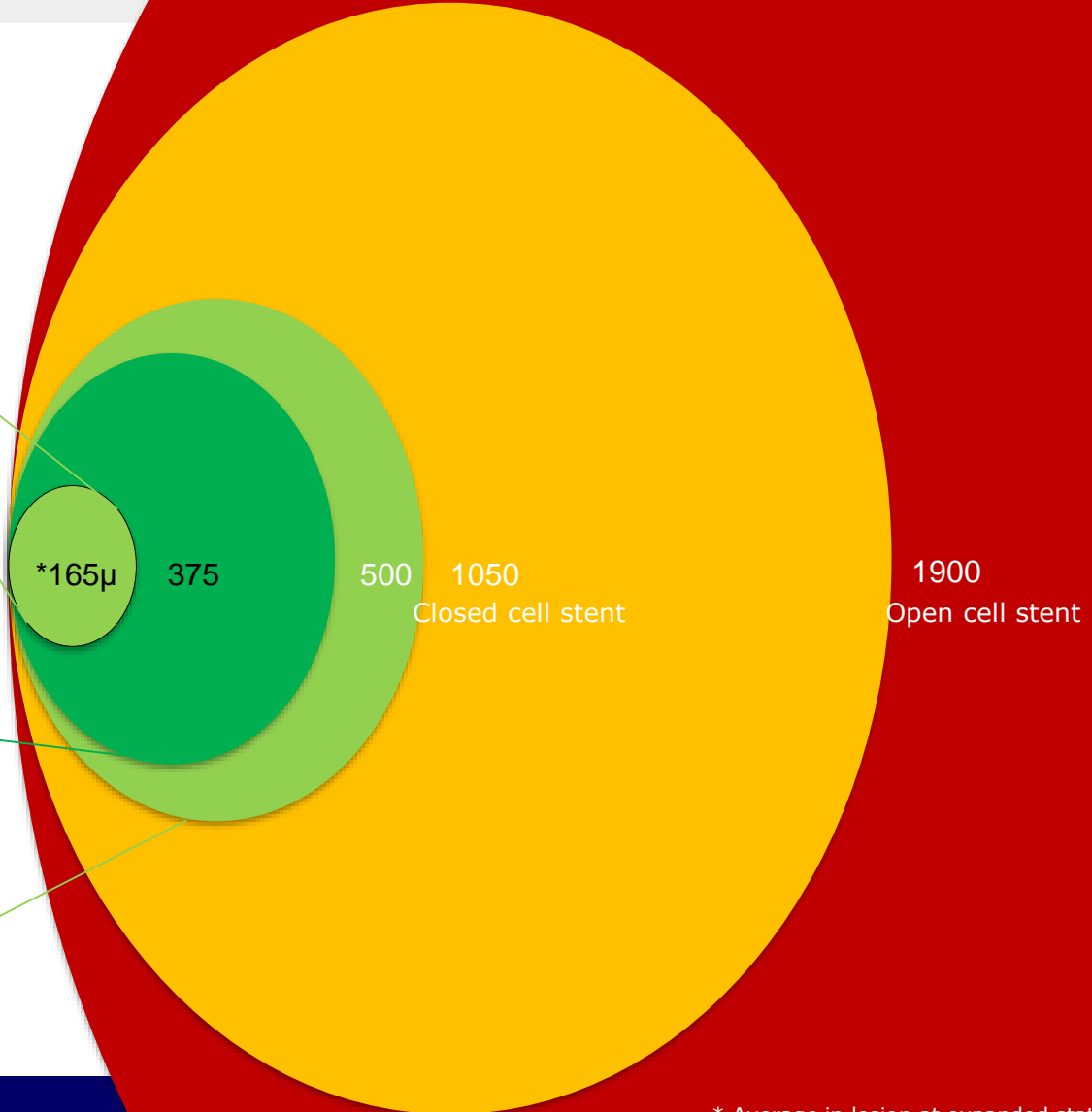
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* Average in lesion at expanded state

Dual Layer Stent Designs: Early Reports



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CARENET: 30 pts, EPDs were used in all procedures

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

Schofer J, Musialek P, Bijuklic K, Kolvenbach R, Trystula M, Siudak Z, Sievert H. A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent: The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet). JACC Cardiovasc Interv. 2015 Aug 17;8(9):1229-34.



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

-Procedure success	100%
-Procedural complications	0%

Bosiers M, Deloosse K, Torsello G, Scheinert D, Maene L, Peeters P, Müller-Hülsbeck S, Sievert H, Langhoff R, Bosiers M, Setacci C. The CLEAR-ROAD study: evaluation of a new dual layer micromesh stent system for the carotid artery. EuroIntervention. 2016 Aug 5;12(5):e671-6



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


-Procedure success	100%
-Procedural complications	0%

Presented at Veith 2017

Dual Layer CAS: The Homburg Experience

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

	2011 - 2016	acute occlusion (%)	
Dual-layer stents CASPER-RX™ ROADSAVER™	n=20	45	} P=0.001
Single-layer stents Wallstent™ VIVEXX™	n=25 n=2	3.7	



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Yilmaz U, Körner H, Mühl-Benninghaus R, Simgen A, Kraus C, Walter S, Behnke S, Faßbender K, Reith W, Unger MM. Acute Occlusions of Dual-Layer Carotid Stents After Endovascular Emergency Treatment of Tandem Lesions. Stroke. 2017 Aug;48(8):2171-2175.

Acute Occlusions of Dual-Layer Carotid Stents After Endovascular Emergency

Dual-Layer Carotid Stents:

45%

ACUTE

OCCLUSION!?

Dual Layer CAS: The Homburg Experience

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



- increase of thrombogenic material
- 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 U, Körner H, Mühl-Benninghaus R, Simgen A, Kraus C, Walter S, Behnke S, Faßbender K, Reith W, Unger MM. Acute Occlusions of Dual-Layer Carotid Stents After Endovascular Emergency Treatment of Tandem Lesions. Stroke. 2017 Aug;48(8):2171-2175.

Dual Layer CAS: The Homburg Experience

- ✓ What is a small stent diameter?
- ✓ Post-dilatation at what diameter?
- ✓ What about stent apposition?
- ✓ Correct stent deployment?
- ✓ ACT-adjusted heparinization?

Yilmaz U, Körner H, Mühl-Benninghaus R, Simgen A, Kraus C, Walter S, Behnke S, Faßbender K, Reith W, Unger MM. Acute Occlusions of Dual-Layer Carotid Stents After Endovascular Emergency Treatment of Tandem Lesions. Stroke. 2017 Aug;48(8):2171-2175.

Dual Layer CAS: The Flensburg Experience

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Flensburg Dual-Layer Carotid Stents Experience 2014 – 2018 ongoing

	2014	2015	2016	2017	2018	total	stroke rate (%) @30 days	ISR after 12 months based on US (asymptomatic)
Total	n=11	n=30	n=30	n=23 Roadsaver™	n=28 Roadsaver™	n=122 Roadsaver™	2/139	5/139
				n=8 CGuard™	n=9 CGuard™	n=17 CGuard™	1.4%	3.6%
Symptomatic/ asymptomatic	11/0	26/4	23/7	17/14	25/12	102/37	1.4%/0%	1.4%/2.2%
symptomatic (acute stroke) Tandem lesion	n=3	n=17	n=11	n=8 Roadsaver™	n=10 Roadsaver™	n=53	No acute occlusion!!	1/53 asymptomatic occlusion 1.9%
				n=1 CGuard™	n=3 CGuard™			

Dual Layer CAS: The Flensburg Experience

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Flensburg Dual-Layer Carotid Stents Experience 2014 – 2018 ongoing

**DUAL-LAYER CAROTID STENTS:
NO
ACUTE
OCCLUSION!!**

How to minimize / avoid stent thrombosis I

Emergency treatment:

- 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

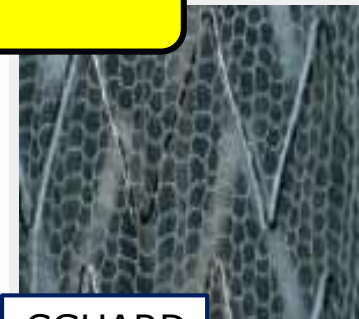
Post-procedural

✓ 75mg Clopidogrel for 6 months

✓ 100mg ASA life-long



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How to minimize / avoid stent thrombosis I

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



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How to minimize / avoid stent thrombosis II

- Stent sizing
 - ✓ 7mm or 8mm diameter
 - ✓ 18mm to 25mm length
- Stent-deployment
 - ✓ Continuous, no re-sheath manoeuvre
- Stent –post-dilatation
 - ✓ 5mm in all cases!!



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Dual-Layer Carotid Stents: proven concept of safety



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n=7

Hopf-J Jensen S, Marques L, Preiß M, Müller-Hülsbeck S. Initial clinical experience with the micromesh Roadsaver carotid artery stent for the treatment of patients with symptomatic carotid artery disease. J Endovasc Ther. 2015 Apr;22(2):220-5.

Nerla R, Castriota F, Micari A, Sbarzaglia P, Secco GG, Ruffino MA, de Donato G, Setacci C, Cremonesi A. Carotid artery stenting with a new-generation double-mesh stent in three high-volume Italian centres: clinical results of a multidisciplinary approach. EuroIntervention. 2016 Aug 5;12(5):e677-83.

n=150

Ruffino MA, Faletti R, Bergamasco L, Fonio P, Righi D. Incidence of New Ischaemic Brain Lesions After Carotid Artery Stenting with the Micromesh Roadsaver Carotid Artery Stent: A Prospective Single-Centre Study. Cardiovasc Intervent Radiol. 2016 Nov;39(11):1541-1549

n=23

Machnik R, Paluszek P, Tekieli Ł, Dzierwa K, Maciejewski D, Trystuła M, Brzychczy A, Banaszekiewicz K, Musiał R, Pieniążek P. Mesh-covered (Roadsaver) stent as a new treatment modality for symptomatic or high-risk carotid stenosis. Postepy Kardiol Interwencyjnej. 2017;13(2):130-134.

n=41


Bosiers M, Deloose K, Torsello G, Scheinert D, Maene L, Peeters P, Müller-Hülsbeck S, Sievert H, Langhoff R, Bosiers M, Setacci C. The CLEAR-ROAD study: evaluation of a new dual layer micromesh stent system for the carotid artery. EuroIntervention. 2016 Aug 5;12(5):e671-6

n=100

Preparation + ongoing antiplatelet medication

Double layered stents for carotid angioplasty: A meta-analysis of available clinical data

Catheter Cardiovasc Interv. 2017 Dec 14.

Anna Sannino, MD^{1,2*} | Giuseppe Giugliano, MD, PhD^{1,2*} | Evelina Toscano, MD^{1,2} |
Gabriele G. Schiattarella, MD^{1,2} | Anna Franzone, MD, PhD^{1,2} | Tullio Tesorio, MD³ |
Bruno Trimarco, MD^{1,2} | Giovanni Esposito, MD, PhD^{1,2} |
Eugenio Stabile, MD, PhD^{1,2} 

**Roadsaver subgroup demonstrated very low rates of post procedural AEs at 30-day.
299 patients
Death and Stroke Rate 0.02%**

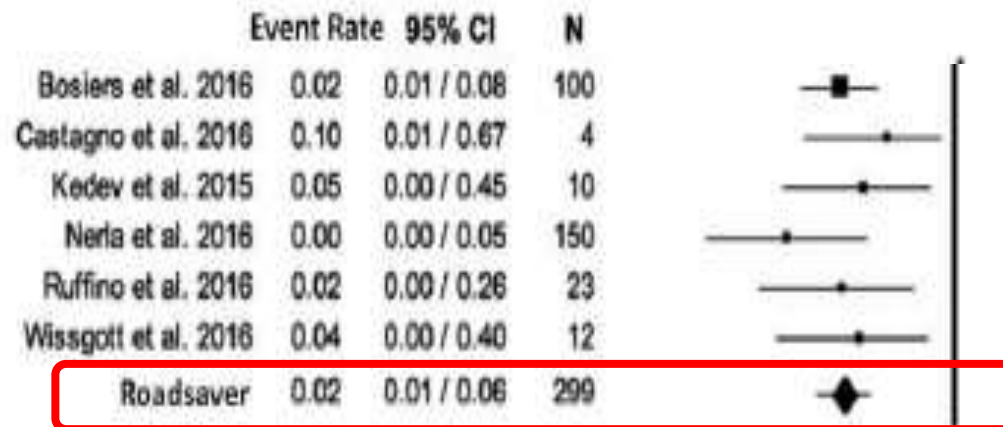


FIGURE 2 30-day mortality and stroke rate. Random effects event rate and 95% confidence interval for 30-day mortality and stroke (A) and relative subgroup analysis (B)

CAS - ROADSAYER Study



- **Study Design:** Prospective, single-arm, multi-center, observational study of the Roadsaver™ Carotid Stent
- **Primary Objective:** The purpose of ROADSAYER study is to further confirm the safety and efficacy of the Roadsaver™ Carotid Stent device for the treatment of carotid artery stenosis in patients considered eligible for elective stenting procedure.
- **Patient Population:** 2000 patients
- **Enrollment Period:** 2 years + 1 year FU
- **Study Timelines:** First patient enrolled 23-Jan-2018, current **>200** patients enrolled
- **Site Locations:** +/- 50 centers across 14 countries in Europe
- **Study Organization:**
 - Independent Clinical Events Committee (CEC)
 - Steering Committee (SC)
 - Sponsored by Terumo Europe
 - European Medical & Clinical Division (EMCD)



Status of dual layer stents for CAS: *Is acute occlusion an issue?*



**No, neither in acute nor in elective cases...
... since you start an immediate preparation
with antiplatelet medication!**

- *Pre-procedural* (elective treatment)
- *Peri-procedural* (stroke treatment) combined with bridging
 - ✓ 500mg ASA i.v.
 - ✓ 300mg Clopidogrel after control (conebeam-) CT, usually @ day 1
- *Post-procedural*
 - ✓ 75mg Clopidogrel for 6 months
 - ✓ 100mg ASA life-long

Be aware of adequate

- Stent-sizing, deployment and post-dilatation !!!

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September 7-11
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