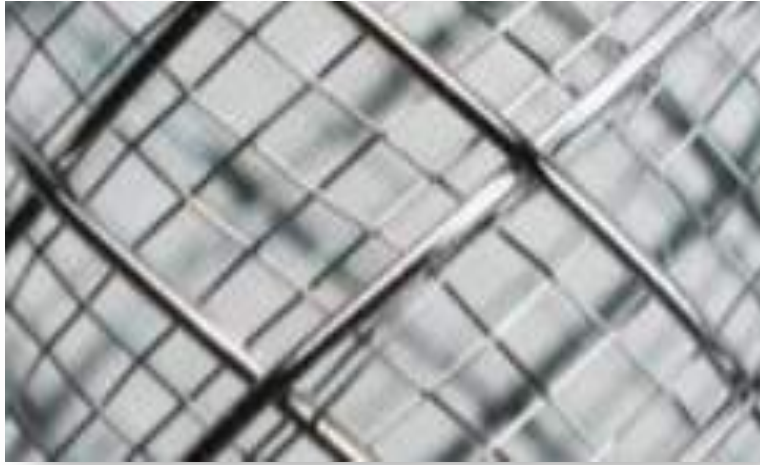


Are Dual-Layer Micromesh Stents The Breakthrough for Carotid Stenting?

Roadsaver



CGUARD



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Disclosure

Speaker name:

Prof. Dr. 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

Pioneer of CAS

Sonderdruck aus **FORTSCHRITTE DER MEDIZIN** 95. Jg., Nr. 15 vom 21. 4. 1977, S. 1007—1011

Ein neuartiges Katheter-System zur perkutanen transluminalen Angioplastie von Karotisstenosen



Von *K. Mathias*

Aus der Abteilung für Röntgendiagnostik des Zentrums Radiologie
(Direktor: Prof. Dr. med. *W. Wenzl* der Universität Freiburg/Br.

1989 - First Patient with Stent

intimal flap attached to vessel wall after placement of a Wallstent across the bifurcation

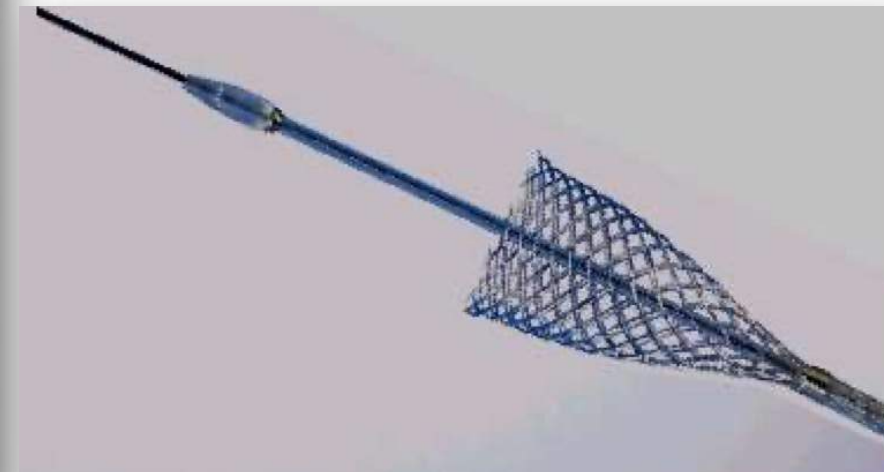


Options for stent placement

- Palmaz balloon-expandable
- rolling membrane Wallstent

Wallstent developed by a small
Swiss company in early eighties

- bought by Schneider
- bought by Pfizer
- bought by Boston Scientific



Value: Cell Size Comparison (Open vs. Closed Cell)

**Micromesh
(375-700 μm)**



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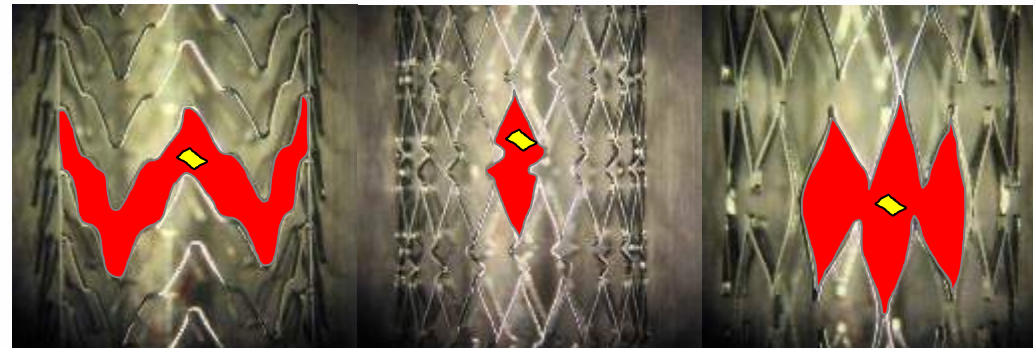
Stent A

Stent B



CGuard

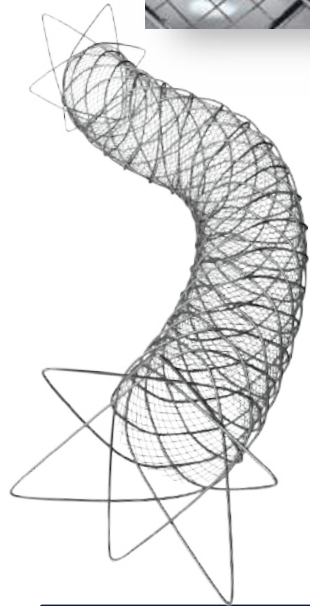
**Micromesh
(165 μm)**



Stent C

Stent D

Stent E



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Open-Cell vs. Closed-Cell Stents

- reduced new ipsilateral changes in diffusion-weighted MRI of the brain with closed-cell vs. open-cell stents (51% vs. 31%; $p < 0.01$)
- open-cell stents are associated with a 25% higher chance ($p = 0.03$) of developing postprocedural new ischemic lesions
- open-cell design stents with a free cell area $> 7.5 \text{ mm}^2$ may be associated with an increased 30-day stroke risk
- CREST: around 40% of strokes in the CAS arm have occurred 24 hours post endovascular treatment (median 3.5 days) and were predominantly major (including hemorrhages).

*Schnaudigel S, Groschel K, Pilgram SM, Kastrup A. New brain lesions after carotid stenting versus carotid endarterectomy: a systematic review of the literature. *Stroke*. 2008;39:1911–9.

**de Vries EE, Meershoek AJA, Vonken EJ, den Ruijter HM, van den Berg JC, de Borst GJ, Endorse SG. A meta-analysis of the effect of stent design on clinical and radiologic outcomes of carotid artery stenting. *J Vasc Surg*. 2019;69:1952–1961 e1.

***Stabile E, Giugliano G, Cremonesi A, Bosiers M, Reimers B, Setacci C, Cao P, Schmidt A, Sievert H, Peeters P, Nikas D, Sannino A, de Donato G, Parlani G, Castriota F, Hornung M, Rubino P, Esposito G, Tesorio T. Impact on outcome of different types of carotid stent: results from the European Registry of Carotid Artery Stenting. *EuroIntervention*. 2016;12:e265-70.

****Hill MD, Brooks W, Mackey A, Clark WM, Meschia JF, Morrish WF, Mohr JP, Rhodes JD, Popma JJ, Lal BK, Longbottom ME, Voeks JH, Howard G, Brott TG. Stroke after carotid stenting and endarterectomy in the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST). *Circulation*. 2012;126:3054–61.

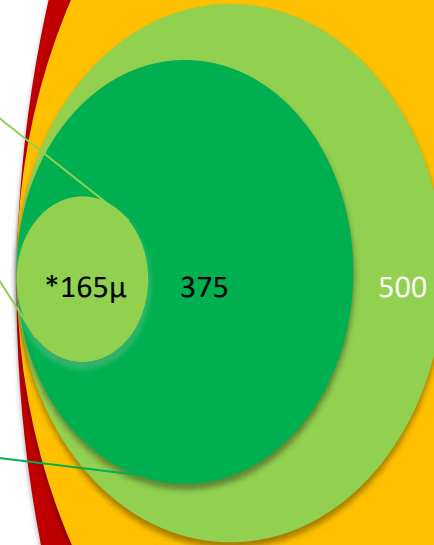
Smaller Pore Size Higher Efficacy, the Breakthrough ?



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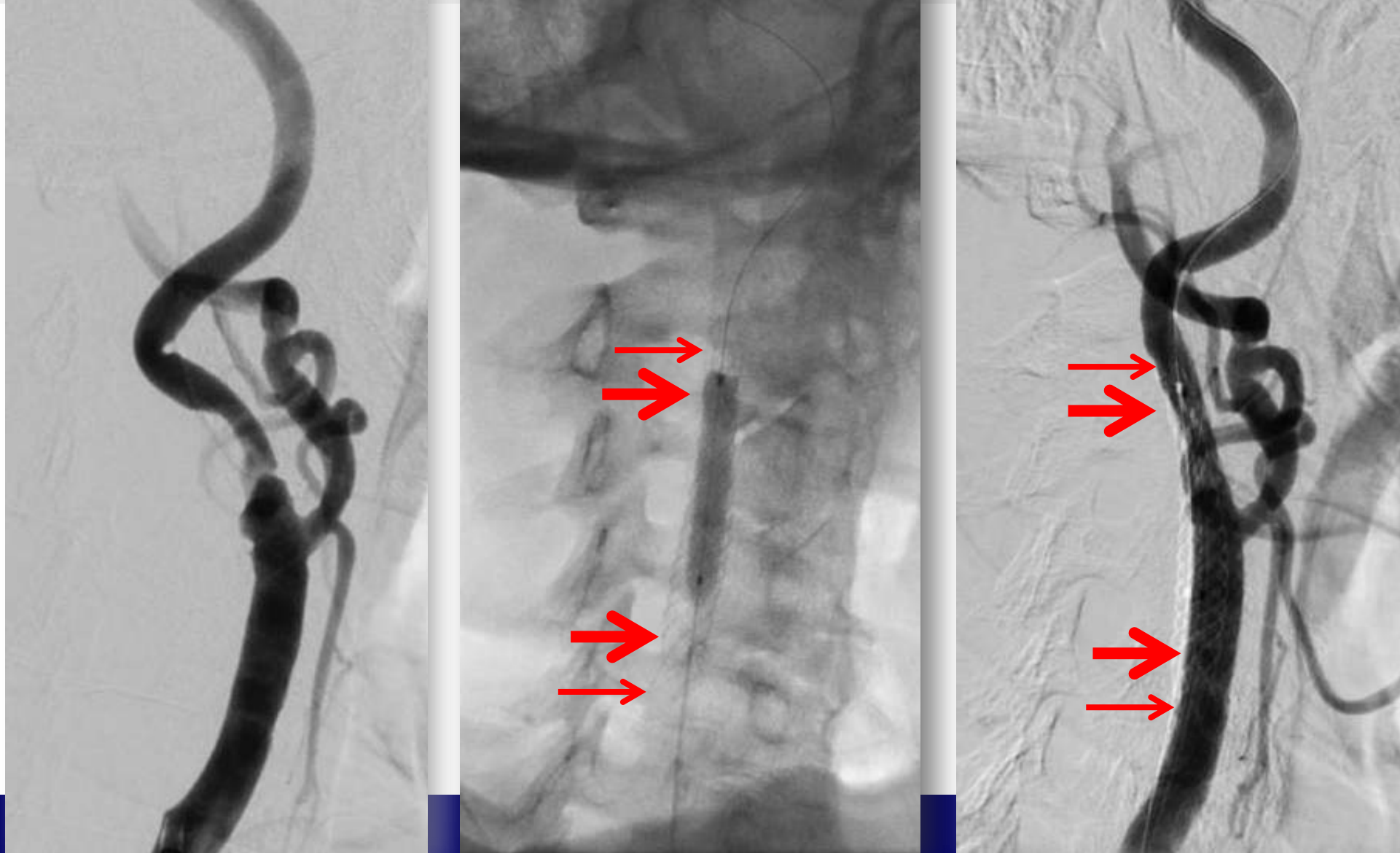
Roadsaver



* Average in lesion at expanded state

Male, 80yrs, symptomatic CAS RoadSaver™ 7x30

Hopf-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. doi: 10.1177/1526602815576337.



Male, 80yrs, symptomatic CAS Roadsaver™ 7x30

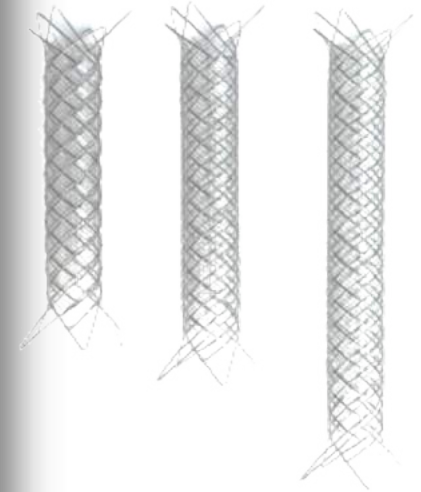
Hopf-Jensen S, Marques L, Preiß M, Müller-Hülsbeck S. Initial clinical experience with the micromesh Roadsaver carotid artery stent for the treatment of patients with symptomatic carotid artery disease. J Endovasc Ther. 2015 Apr;22(2):220-5. doi: 10.1177/1526602815576337.



- Plaque coverage
- scaffolding



→ Goal: sustained embolic protection by preventing emboli release



ROADSAVER - Published Clinical Outcomes 30-days & 12-months

	Italian Registry (Roadsaver)	CLEAR-ROAD (Roadsaver)	Ruffino et al. (Roadsaver)	Machnik et al. (Roadsaver)
# Patients	150	100	23	40
Independent neurologist	Y	Y	Y	N/A
Symptomatic	29%	31%	61%	51%
EPD	100%	58%	100%	100%
30-days: D/S (MI)	0 % of DS	2.1 % of DSMI • 1 pt MI leading to death • 1 pt minor stroke due to AF	0 % MACCE	2.5 % of DS • 1 pt minor stroke device-unrelated
12 months D/S (MI)	2% of DS • 3 device-none related deaths • No cerebrovascular events • 3 Ax restenosis (2%)	9.3% of DSMI • 4 pts ipsilateral stroke - 2 AF + insufficient OAC - 2 ISR-related • 1 pt contralateral stroke • 3 pts deaths: 2 MI + 1 RF	N/A	N/A
ECA at 30-day / 12-month	100% Patent	N/A	100% Patent	N/A
DW-MRI new lesions (after CAS)	N/A	N/A	30.4% (24hrs) ipsilateral new lesions	N/A
Mean PSV baseline / 30-days (m/s)	2.7±0.7 / N/A	N/A	N/A	3.9±1.0 / 1.1±0.3
Mean stenosis baseline / post pcd / 30-days (%)	80.9±7.5 / 12.4±4.7 No ISR	85.3±8.0 / 5.2±7.4 No pt >50% stenosis	N/A	82.9 ±9.1 / 19.3 ±7.3

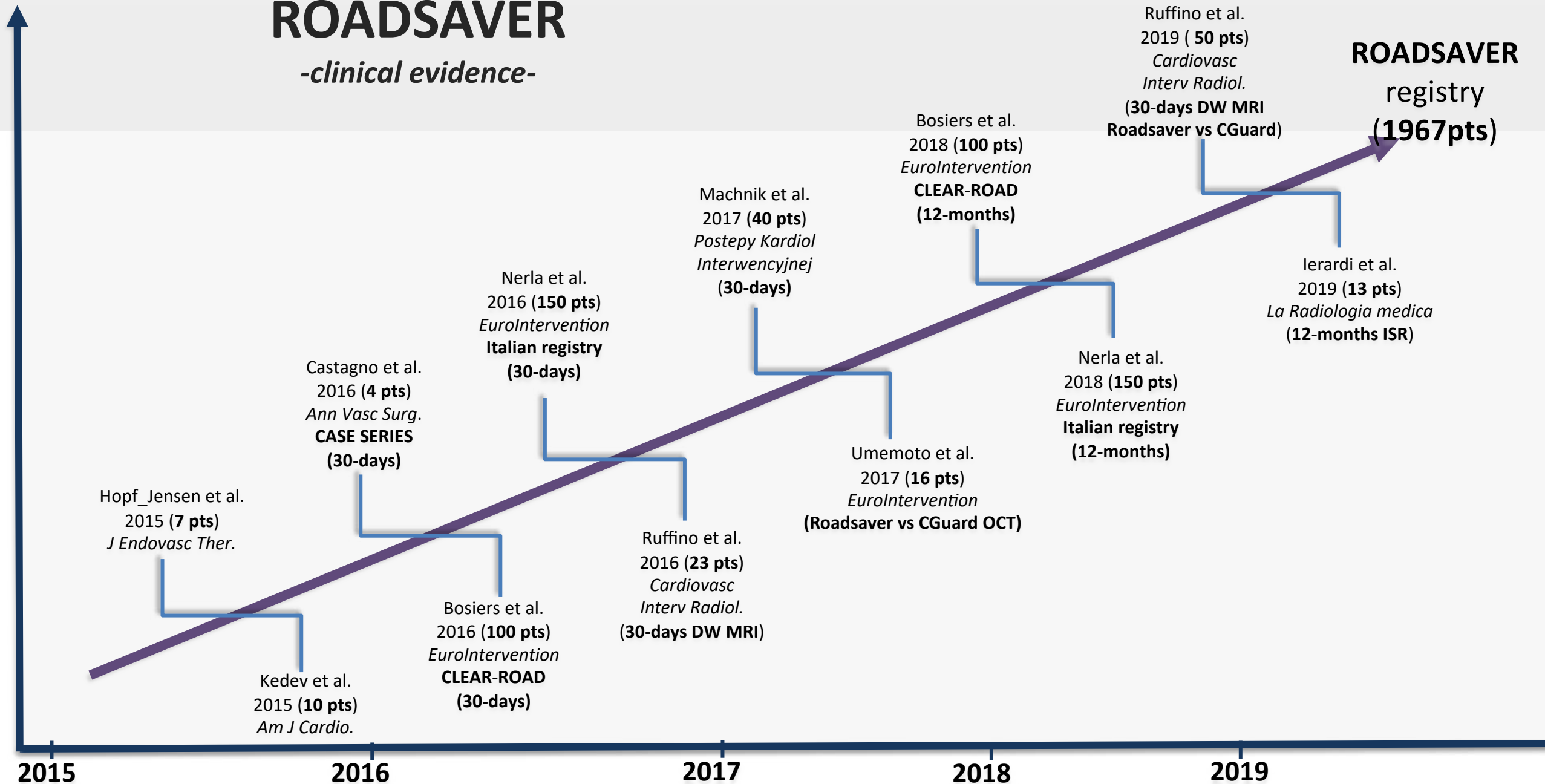
ROADSAVER

-clinical evidence-

MACCE: major cardiac and cerebrovascular events; **DW MRI:** diffusion weight magnetic resonance imaging; **CAS:** carotid artery stenting; **PSV:** Peak systolic velocity; **EPD:** embolic protection device; **D/S:** death/stroke **MI:** myocardial infarction; **ECA:** external carotid artery; **AF:** atrial fibrillation; **RF:** renal failure **OAC:** oral anticoagulant; **ISR:** in-stent restenosis; **pt(s):** patient(s); **pcd(s):** procedure.

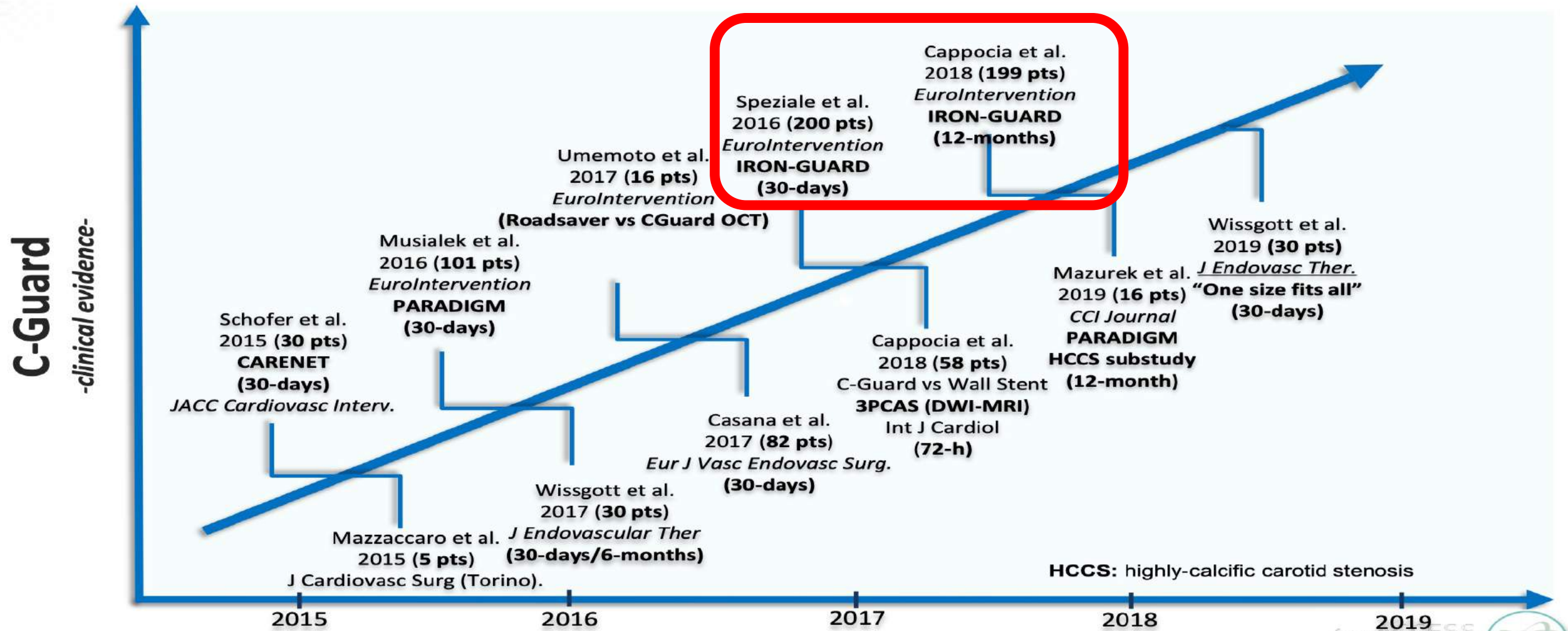
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-clinical evidence-



CGuard

-clinical evidence-



Meta-Analysis Evaluates Dual-Layered Stents for CAS I

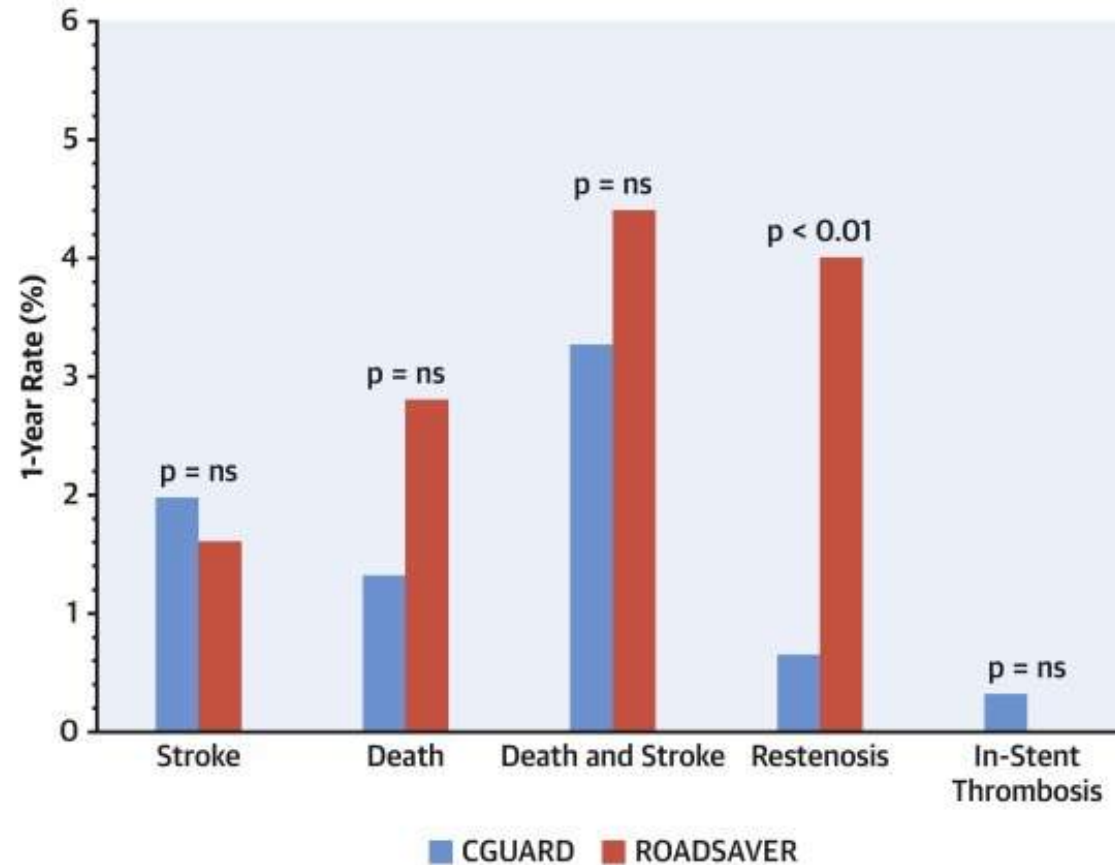
TABLE 2 Incidence of Adverse Clinical Events up to 30 Days of Follow-Up

	Peri-Procedural (in Hospital)	Discharge to 30 Days	Total 30 Days
Minor stroke	1.07 (6)	0.17 (1)	1.25 (7)
Major stroke	0 (0)	0 (0)	0 (0)
Death	0 (0)	0.17 (1)	0.17 (1)
Any stroke and death	1.07 (6)	0.36 (2)	1.44 (8)
Values are % (n).			

- 556 asymptomatic or symptomatic patients (Roadsaver™ or CGuard™)
- no independent predictors of peri- or post-procedural adverse events, including symptomatic status, were identified.
- suggests that DLS as a device class are safe to use in guidelines-based CAS and that they may have a possible clinical benefit over the conventional single-layer stents

Meta-Analysis Evaluates Dual-Layered Stents for CAS II

CENTRAL ILLUSTRATION: Event Rates at 1 Year



Stabile, E. et al. J Am Coll Cardiol Interv. 2020;13(14):1709-15.



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Dual Layer CAS: The Flensburg Experience – 7yrs



CGUARD™

Flensburg Dual-Layer Carotid Stents Experience 2014 – 2020 ongoing

	2014	2015	2016	2017	2018	2019	2020	total	stroke rate @30 days	ISR >70% since 2014 based on US + occlusion (asymptomatic)
Total	n=11	n=30	n=30	n=23 Roadsaver™ n=8 CGuard™	n=28 Roadsaver™ n=9 CGuard™	n=35 Roadsaver™ n=4 CGuard™	n=22 Roadsaver™ n=7 CGuard™	n=179 Roadsaver™ n=28 CGuard™	1/207 (0.5%) RS 0.6% / CG 0%	8/207 +2/207 3.9% + 1% ISR occl. RS 4.5 (5/3) +1.1% / CG 0% + 0%
Symptomatic/ asymptomatic	11/0	26/4	23/7	17/14	25/12	36/3	23/6	154/46		
symptomatic (acute stroke) Tandem lesion	n=3	n=16	n=11	n=8 Roadsaver™ n=1 CGuard™	n=10 Roadsaver™ n=3 CGuard™	n=15 Roadsaver™ n=1 CGuard™	n=6 Roadsaver™ n=1 CGuard™	n=75	1/75 (1.3%) acute occlusion - pat. wasn't on ASA RS 1.7% / CG 0%	1/75 asymptomatic occlusion 1.3%

Prospective, single-arm, multi-center, **observational study** in one of the **largest CAS** patient **cohorts** to date

1967

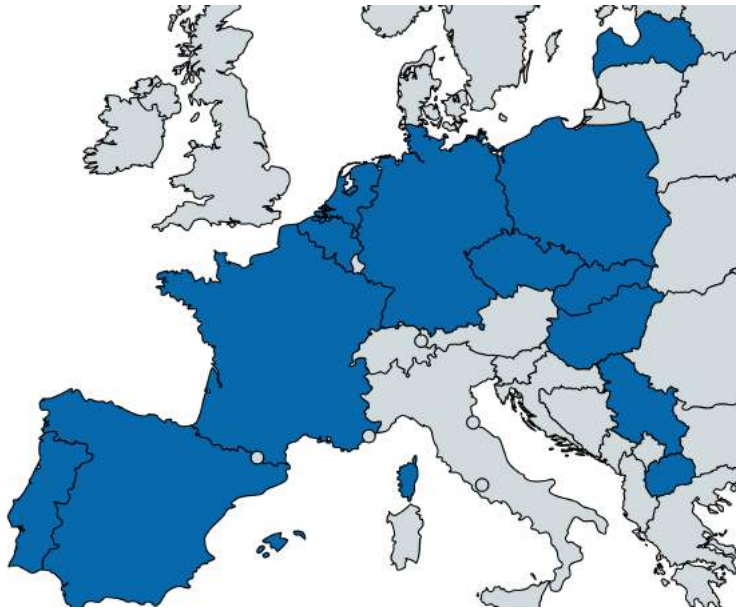
Patients enrolled

13

Countries

52

Sites



ROADSAVER study

n=1940

with 30-day follow-up

Asymptomatic
n=985

Symptomatic*
n=955

0

30d

Clinical follow-up

1y

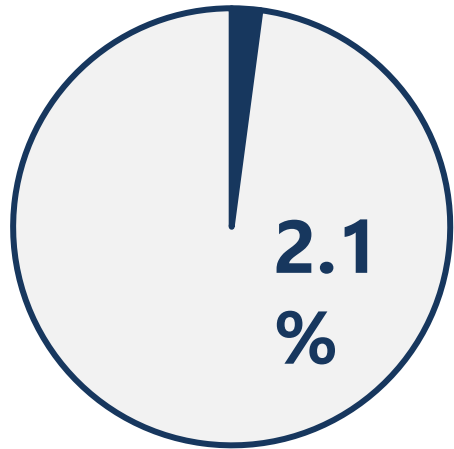
Population:

Patients with **non-occlusive & non-thrombotic** carotid artery stenosis eligible for **elective** CAS treatment as per standard hospital practice

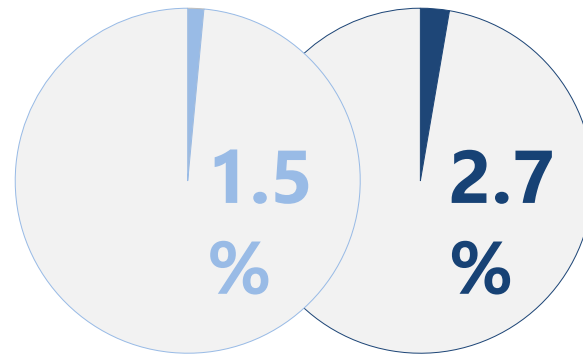
Primary Endpoint:

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

The study **confirms** the **safety** of CAS with **Roadsaver™** **DLMS** in a **large**, contemporary **pan-European** patient cohort



Low cumulative
30-day MAE incidence
in „**real-world**“ **elective**
patients treated as per
routine hospital practice



Low and **comparable**
30-day cumulative
MAE incidence in
asymptomatic and
symptomatic patients



Lower rate of **any stroke**,
and **less major strokes**
in **asymptomatic** vs
symptomatic patients

An Old Saw ...



- „Tempora mutantur, nos et mutantur in illis“
(OVID 43 B.C., ancient roman poet)
- ... Times are changing, and we have to change with them ...



- ✓ Stent design
- ✓ Education

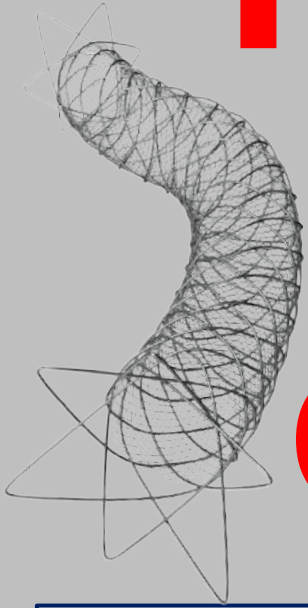
FEB 2014

1st Roadsaver

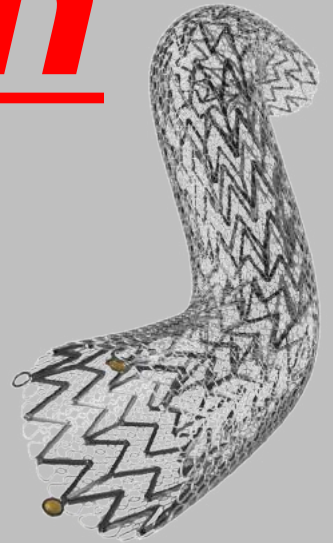
Roadsaver™
6x30 mm

- Current data and meta-analyses suggests dual layered carotid stents are safe for the treatment of extracranial carotid artery stenosis, with a low rate of procedural events, and allow achieving a quite low rate of postprocedural adverse events.

Dual-Layer Micromesh Stents - The Breakthrough For Carotid Stenting



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