Latest Real-World Results Of ≈2,000 Patients Treated With The Roadsaver (Terumo) Dual-Layer Micromesh Carotid Stent: "Identifying Predictors of Complications"

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On behalf of the ROADSAVER study investigators

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Disclosure

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I have the following potential conflicts of interest to report:

- ☑ Consulting: Terumo
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ I do not have any potential conflict of interest

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Background & **aim**

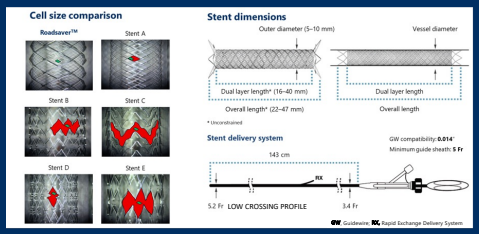
Peri- and early post-procedural **cerebral embolization** events related to the carotid artery stenting (CAS) warrant further attention in both **symptomatic** and **asymptomatic** patients

Dual-layer micromesh stents (DLMS) were designed to **limit the embolization risk** and provide **sustained cerebral protection** during and after CAS

The **ROADSAVER study** aims to further assess the **safety & efficacy** of the **Roadsaver ™ DLMS** in a large "**real-world**" **European** patient **cohort** eligible for **elective CAS**

DLMS: Dual Layer Micromesh Stent

Roadsaver™ is a **dual-layer carotid stent** with a **micro-mesh**



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

1967 Patients enrolled* | **13** Countries | **52** Sites

ROADSAVER study

ANALYSED N=1965

*Symptomatic** N=971 (49.4%)*
Asymptomatic N=994 (50.6%)

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-procedure

*1965/1967 subjects received the Roadsaver™ carotid stent (for 2 enrolled subjects adequate Roadsaver™ stent size was unavailable, and another stent was implanted).
Symptomatic: Patients who experienced ipsilateral to the carotid lesion: TIA or non-disabling stroke within 180 days of the procedure within the territories supplied by the target vessel. **CAS, Carotid Artery Stenting; **TIA,** Transient Ischemic Attack; **d**, days; **y**, year.

ClinicalTrials.gov ID NCT03036059

Lesion **characteristics**

% or mean ± SD or median (IQR)	Total population (N=1965)
Target lesion localisation	
▪ Right side	51.6
▪ ICA/bifurcation	97.7
▪ CCA	2.3
Lesion length (mm)	18.1 ± 8.4
Lesion calcification	58.5
Lesion ulceration	24.9
Concentric lesion	44.4
Irregular surface lesion	56.5
Target-vessel tortuosity (>90°)	7.6
Diameter stenosis* (%), pre-procedure	80.0 (72.0-90.0)
Diameter stenosis* (%), post-procedure	0.0 (0.0-14.0)
Residual stenosis ≥30%	1.0

*Is are based on the number of patients in the analysis set (N) with non-missing data (%, without/observations/unknowns are not shown). * as per angiography by NASCET (North American Symptomatic Carotid Endarterectomy Trial) criteria. **CCA,** common Carotid Artery; **ICA,** Internal Carotid Artery; **IQR;** interquartile range (Q1, Q3); **SD,** Standard Deviation

Procedure **characteristics**

%	Total population (N=1965)
Access	
▪ Femoral	70.3
▪ Radial*	26.3
▪ Other**	3.5
Embolic protection use	63.8
EPD type	
▪ Distal filter	87.2
▪ Proximal protection***	12.6
▪ Mix distal & proximal	0.2
Pre-dilatation	25.6
Post-dilatation	96.1

*Including 11 ulnar cases; **Including 31 Brachial & 27 Cervical cases; ***Including: MoMa, TCAR Emboshield NXT & FlowGate balloon;
%s are based on the number of patients in the analysis set (N) with non-missing data (%s without /unknowns are not shown). **EPD**: Embolic Protection Device

Stent size **distribution**

Roadsaver™ stent sizing N_{PCI}=1965 N_{RSVR}=2002

STENT LENGHT

STENT DIAMETER	16 mm	18 mm	20 mm	25 mm	30 mm	40 mm
5 mm			0	3	1	
6 mm	7		35	16		
7 mm		53	234	210		
8 mm			183	279	344	66
9 mm			159		284	
10 mm			39		200	

Most commonly used Roadsaver™ **stent diameter** (8 mm)	**43.6 %**
Most commonly used Roadsaver™ **stent length** (30 mm)	**48.8 %**

1-stent used	**97.5%** (1916/1965)
2-stents used*	**2.5%** (49/1965)

*37 subjects received a 2nd Roadsaver™ stent, while 12 pts received a second stent, other than Roadsaver™

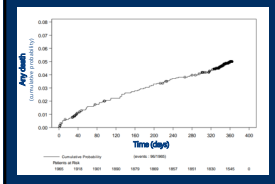
1-Year **Safety & Efficacy Outcomes**

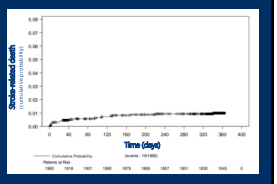
%(n)	30-day (N=1965)	31-365 days (N=1965)	365 days (N=1965)
❑ **Primary endpoint** MAE (*i.e. any death or stroke*)	2.2 (43)		
▪ **Any death**	0.8 (15)	4.3 (81)	5.1 (96)
○ Stroke-related death	0.5 (9)	0.5 (10)	1.0 (19)
▪ **Any stroke**	1.9 (37)	1.5 (28)	3.4 (64)
○ Ipsilateral stroke	1.7 (33)	1.0 (19)	2.7 (51)
• Minor	0.9 (17)	0.5 (9)	1.4 (26)
• Major*	0.8 (16)	0.5 (10)	1.3 (25)
▪ **TLR**	0.8 (15)	1.3 (24)	2.1 (39)

All deaths, strokes & TLRs were adjudicated by an independent Clinical Event Committee (CEC)

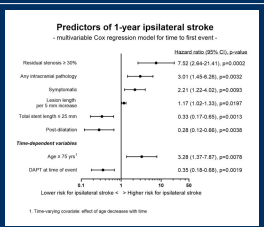
***Major stroke**: a neurological event that persists for > 24 hours and results in a >4 points increase in the NIHSS score compared to baseline or any subsequent lower score. %s are based on the number of patients in the analysis set (N) who either experienced an event or have sufficient data out to (30/180/365 days (respectively) to confirm the absence of an event. **n**=number of patients with at least one event; Note that 4 subjects have experienced 2 strokes and that the magnitude of 1 stroke was impossible to determine. **MAE**, Major Adverse Event; **NIHSS**: National Institutes of Health Stroke Scale/Score; **TLR,** Target Lesion Revascularisation

Time-to-event analysis: **Any death & Stroke-related death**



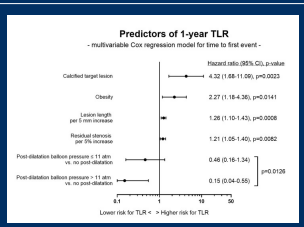


Predictors of **Ipsilateral stroke up to 1-year**

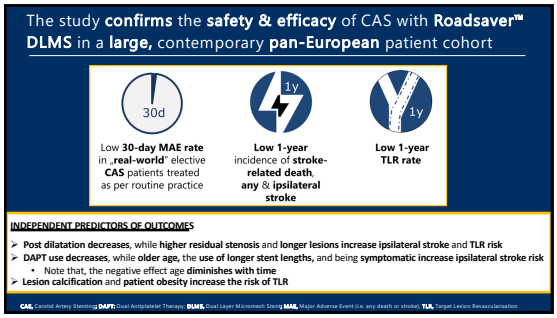


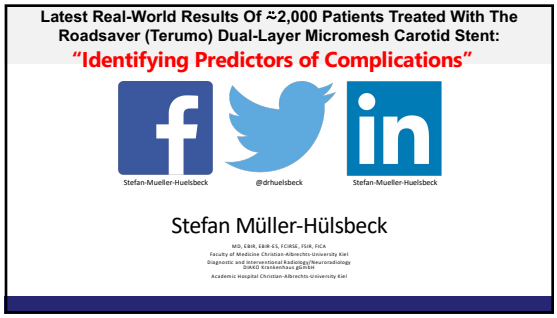
Approximately 70 variables, describing baseline patient, lesion and procedural characteristics, were entered into univariable Cox proportional hazard regression models as time independent covariates to investigate their association with time to first ipsilateral stroke out to 1 year. Where "unknown" response counts were small (<100) these were collapsed into the "No" response category to improve model fit. DAPT (dual antiplatelet therapy) use as a time-dependent variable was also investigated. Variables significant at the 10% level in the univariable models were entered into a multivariable model which was stepwise reduced, retaining those non-collinear and significant at the 5% level. The assumption of proportional hazards was tested, where assumptions were not met, time-varying covariates were created.

Predictors of **TLR up to 1-year**



Approximately 70 variables, describing baseline patient, lesion and procedural characteristics, were entered into univariable Cox proportional hazard regression models as time independent covariates to investigate their association with time to first TLR out to 1 year. Where "unknown" response counts were small (<100) these were collapsed into the "No" response category to improve model fit. DAPT (dual antiplatelet therapy) use as a time-dependent variable was also investigated. Variables significant at the 10% level in the univariable models were entered into a multivariable model which was stepwise reduced, retaining those non-collinear and significant at the 5% level. The assumption of proportional hazards was tested and met.


The study **confirms** the **safety & efficacy** of CAS with **Roadsaver™ DLMS** in a **large,** contemporary **pan-European** patient cohort
30d
Low **30-day MAE rate** in „**real-world**" elective **CAS** patients treated as per routine practice
1y
Low 1-year incidence of **stroke-related death, any** & **ipsilateral stroke**
1y
Low 1-year TLR rate
INDEPENDENT PREDICTORS OF OUTCOMES
Post dilatation decreases, while **higher residual stenosis** and **longer lesions increase ipsilateral stroke** and **TLR risk**
DAPT use decreases, while **older age,** the **use of longer stent lengths,** and being **symptomatic increase ipsilateral stroke risk**
Note that, the negative effect age **diminishes with time**
Lesion calcification and **patient obesity increase the risk of TLR**
CAS, Carotid Artery Stenting; **DAPT:** Dual Antiplatelet Therapy; **DLMS,** Dual Layer Micromesh Stent; **MAE,** Major Adverse Event (ie. any death or stroke); **TLR,** Target Lesion Revascularisation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