



A.Z. Sint-Blasius, Dendermonde



Marc Bosiers  
Koen Deloose  
Joren Callaert



Imelda Hospital, Bonheiden

Patrick Peeters  
Jürgen Verbist  
W. Van den Eynde



OLV Hospital, Aalst

Lieven Maene  
Roel Beelen

R.Z. Heilig Hart, Tienen



Koen Keirse  
Bart Joos

# The CLEAR-ROAD study

a physician-initiated study investigating  
the RoadSaver stent in carotid lesions

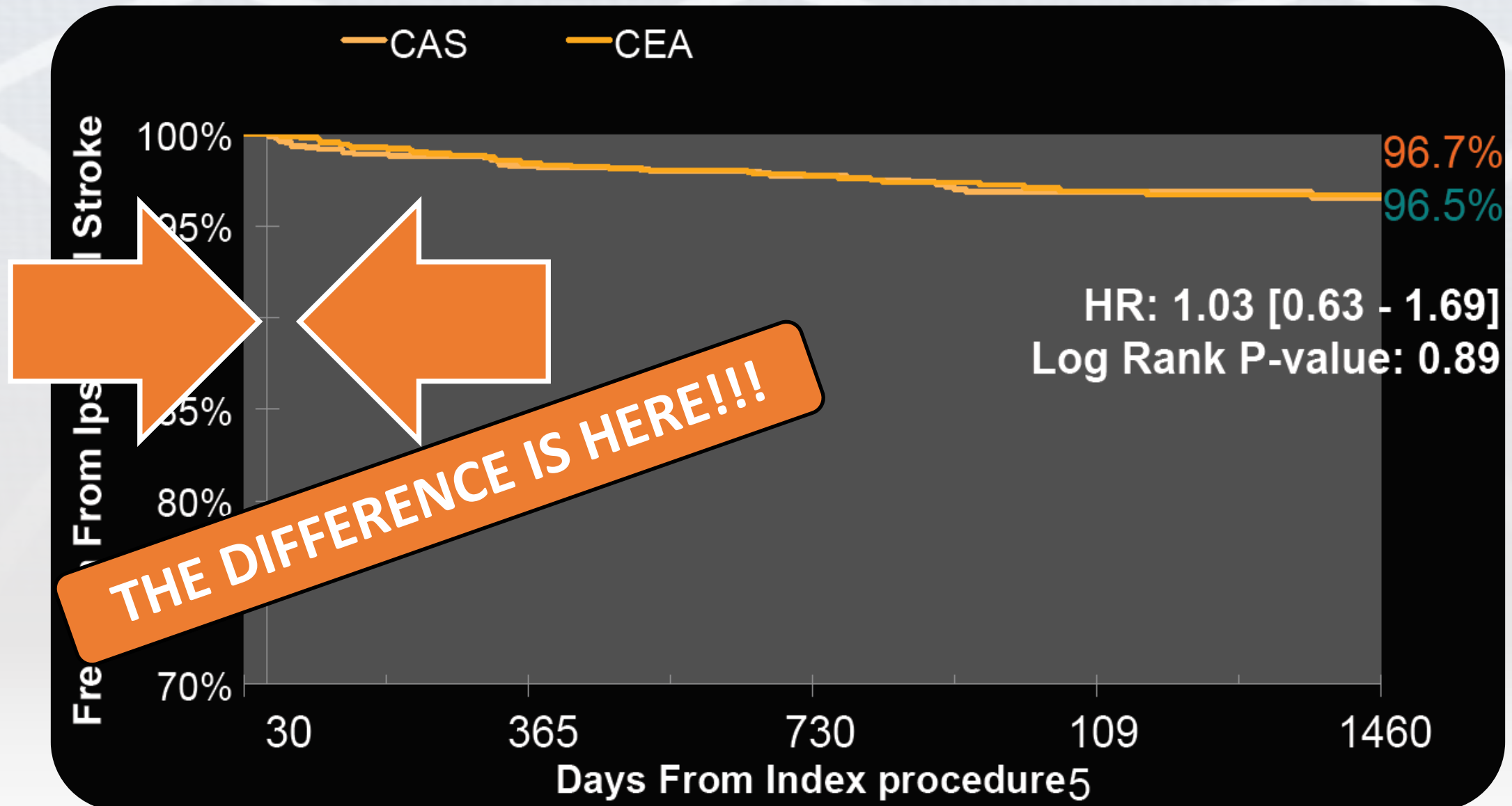
**Dr. Michel Bosiers**

# Conflict of interest

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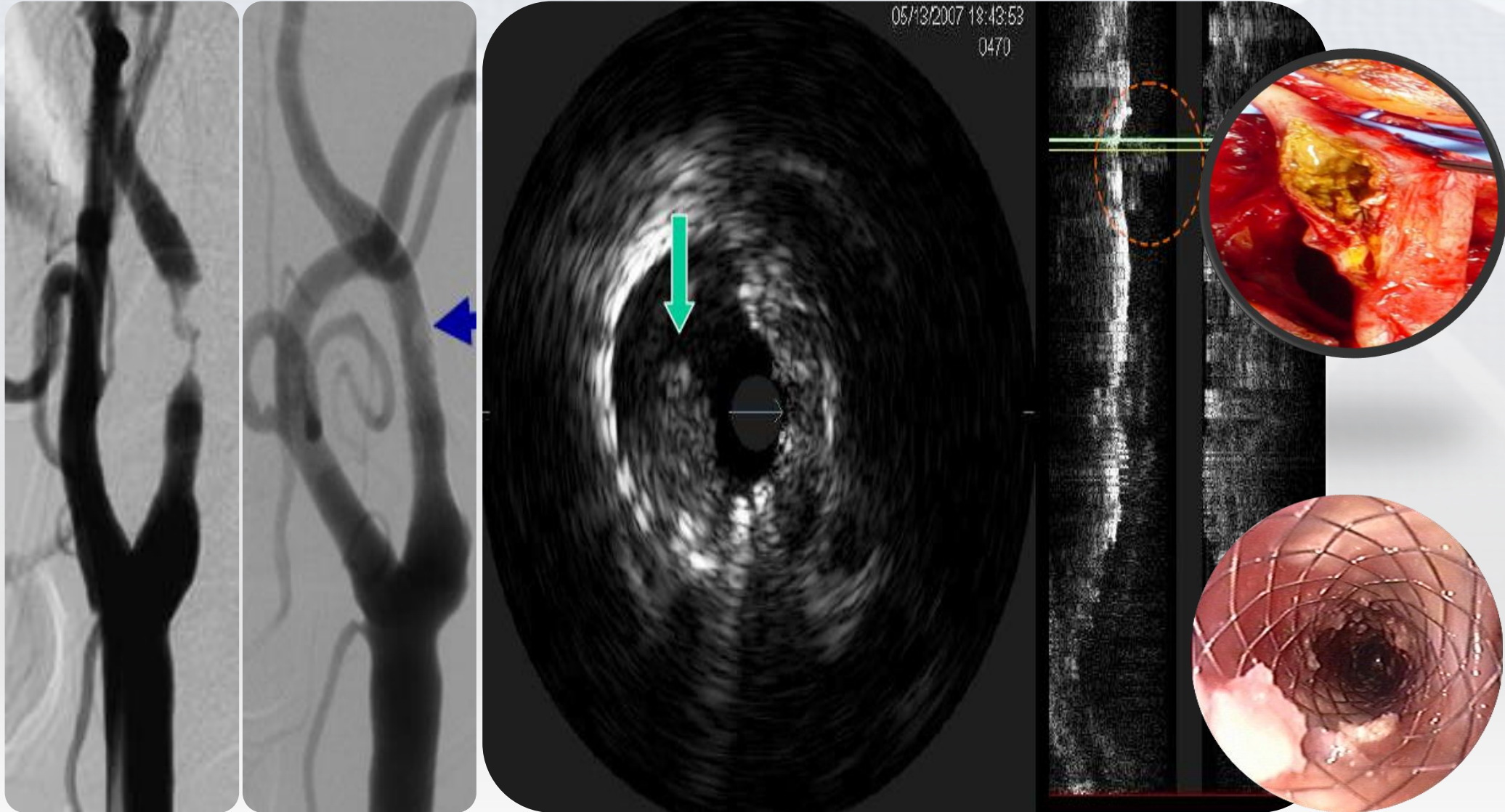
- have the following potential conflicts of interest to report:
  - Consulting
  - Employment in industry
  - Stockholder of a healthcare company
  - Owner of a healthcare company
  - Other(s)
  
- I do not have any potential conflict of interest

# Long term CREST results : Similar freedom from ipsilateral stroke D30 & 4yr

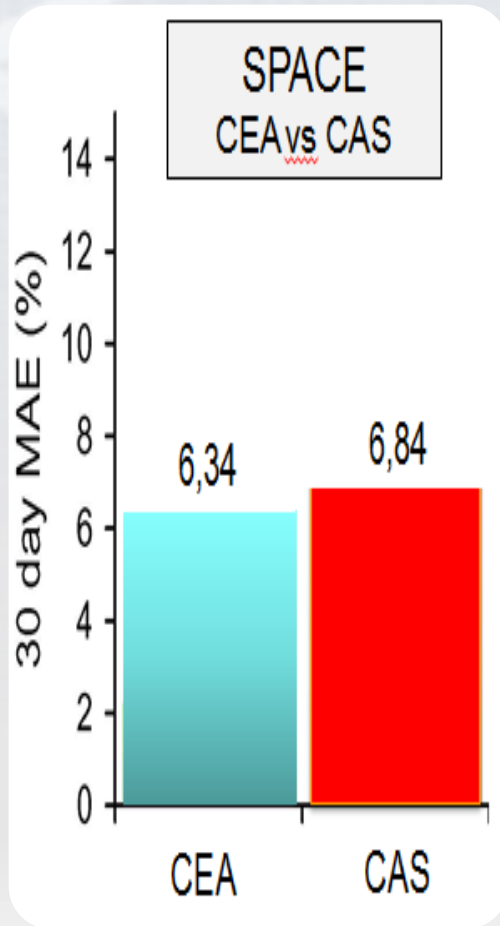




# We need better protection against emboli



# We need better protection against emboli



SPACE does confirm these findings!!!

Stent	Acculink	Precise	Wallstent
No. of patients	92	35	436
Pat. with OE	9	5	24
OE rate (95% CI)	9.8% (4.6–17.8%)	14.3% (4.8–30.3%)	5.5% (3.6–8.1%)
Combined OE rate: 11.0% (6.2–17.8%)			

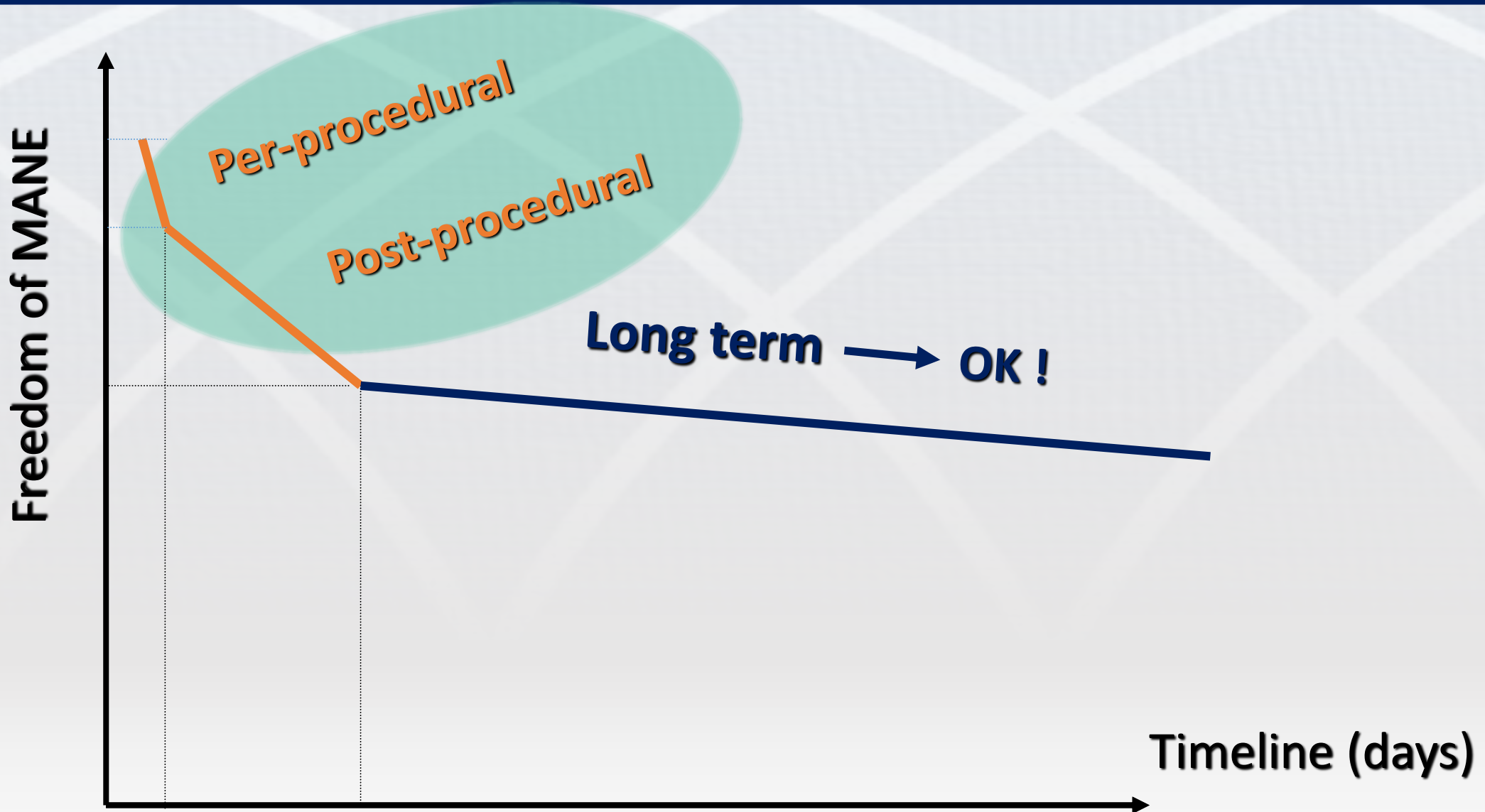
open cell / large free cell area

closed cell

OR 2.13 [1.07-3.76]



# Room for periprocedural improvement : D0->D31



# Room for **periprocedural** improvement : D0->D31

Besides:

- Operator experience
- Patient selection
- Lesion selection

...we need a...

**Scaffolding Stent** to provide better protection  
against **SMALL** and **LATE** embolisation



# Is there an ideal stent?

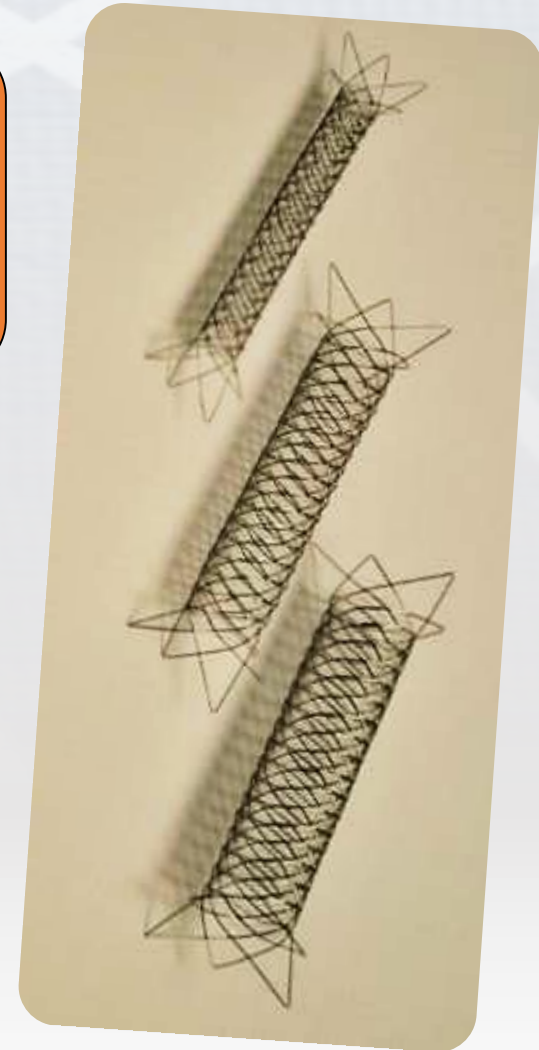
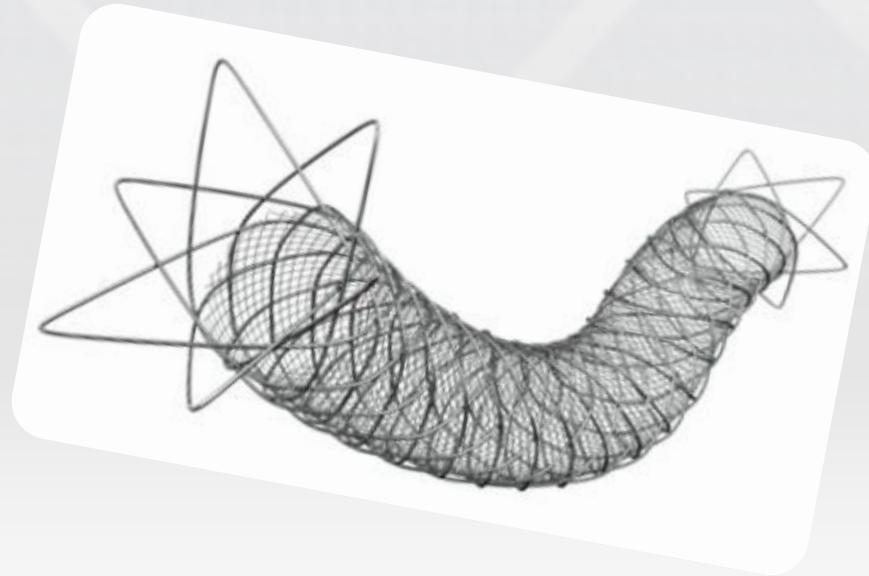




# RoadSaver stent

## A novel design

- Closed cell structure (450  $\mu$  lattice)
- Dual layer design



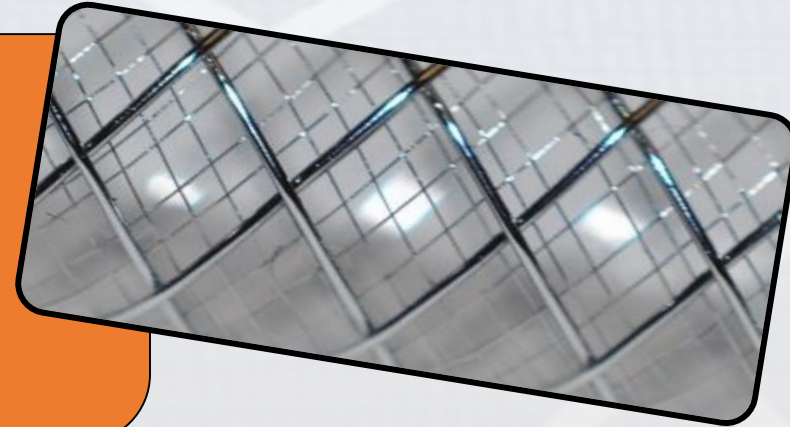
# Primary Attributes

## Double layer micromesh design

- Chronic embolic protection

## Flexible weave

- Excellent wall apposition



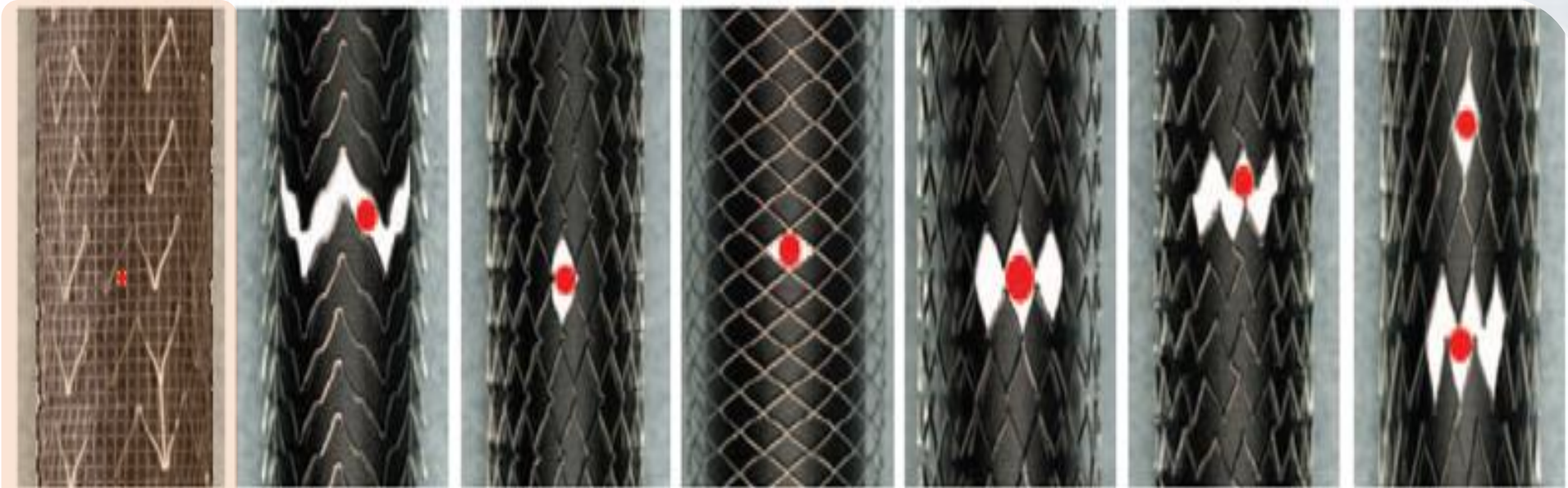
## Repositionable Stent

- Improves accuracy of placement
- Potentially compensates for shortening of the stent
- Upon stent migration during implantation, repositioning is feasible





# 450-500 $\mu$ lattice



<b>Manufacturer</b>	Terumo & Gore	Abbott Laboratories	Abbott Laboratories	Boston Scientific Corporation	ev3 Inc./ Covidien	Cordis Corporation	Medtronic, Inc./ Invatec
<b>Device</b>		ACCULINK® RX DEVICE	XACT® DEVICE	WALLSTENT® MONORAIL® DEVICE	PROTÉGÉ RX® DEVICE	PRECISE® DEVICE	CRISTALLO IDEALE DEVICE

# CLEAR-ROAD study

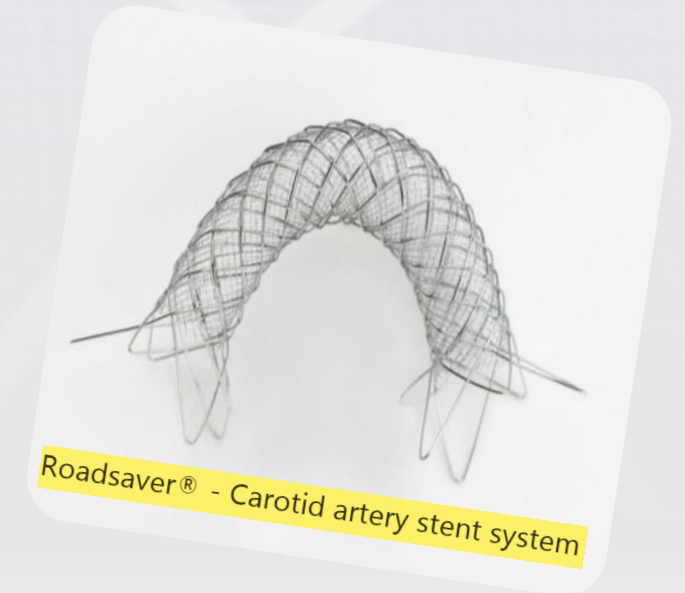


## Primary Endpoint

30-day rate of Major Adverse Events (MAE), defined as the cumulative incidence of any peri-procedural death, stroke or myocardial infarction ( $\leq 30$  days post-procedure)

## Secondary Endpoints

- Late ipsilateral stroke (D31 – D365)
- Technical success rate & device malfunctions
- MAE by sub-group symptomatic/asymptomatic
- TLR – ISR
- Serious Device/Procedure Related Adverse Events (SAE)



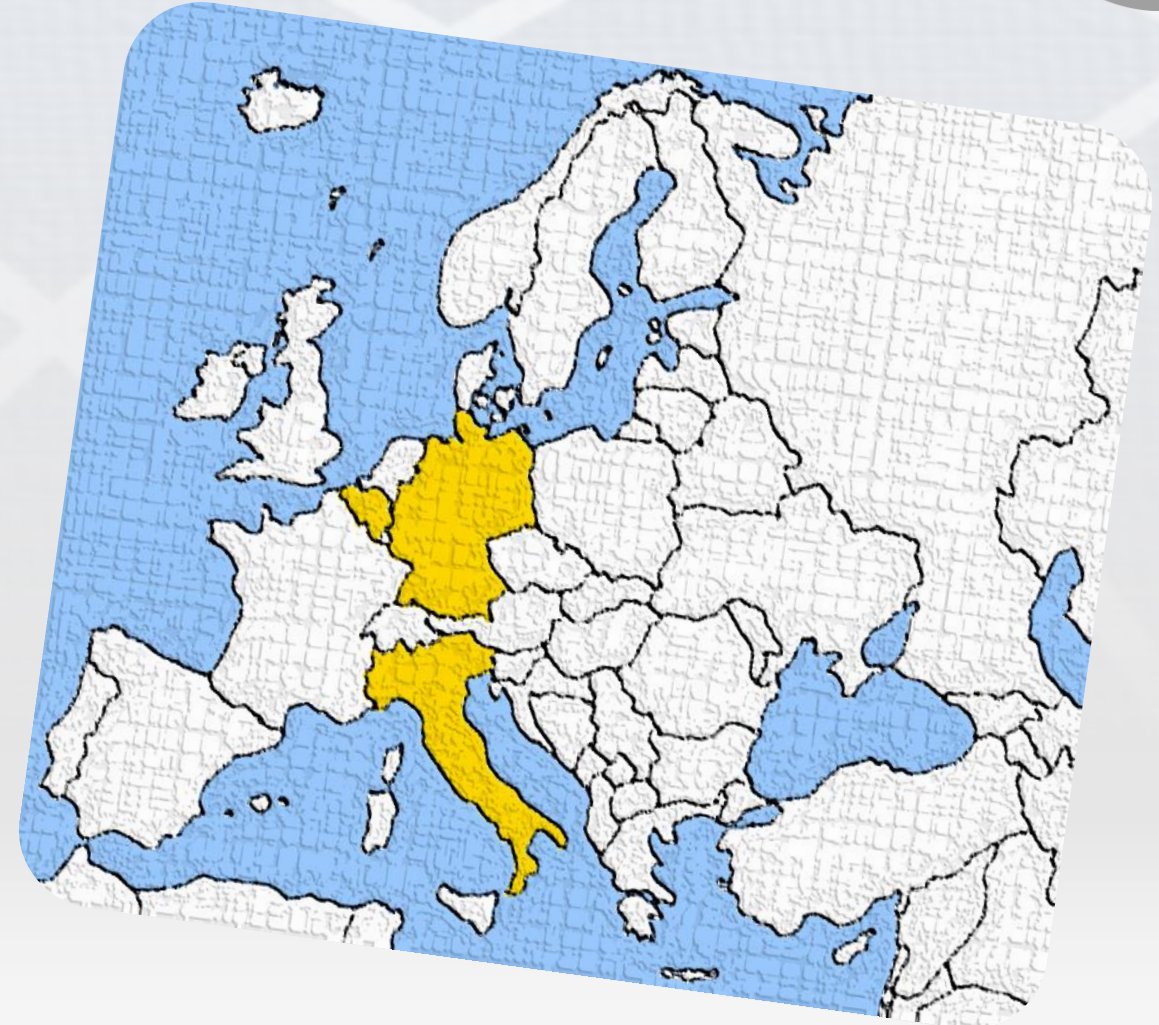


# CLEAR-ROAD study



## Participating centers

- 3 Belgian centers
- 5 German centers
- 1 Italian center



# Inclusion / Exclusion criteria



- High risk for carotid endarterectomy due to anatomical or co-morbid conditions
- Symptomatic +  $\geq 50\%$  stenosis, or asymptomatic and  $\geq 80\%$  stenosis (QVA)
- Arterial diameter 4-9 mm
- Age  $\geq 18$  years
- Life expectancy  $> 12$  months post-procedure

- Contraindication for CAS
- Severe vascular tortuosity or anatomy
- Ostial CCA lesions
- Carotid occlusion
- Intraluminal thrombus
- Previous CAS
- Evolving stroke or intracranial haemorrhage



# Study Timeline



**Final 6-month data available for full study cohort!**

	Screen	Proc	Disch	1M	6M	12M
Patient informed consent	■					
In- & exclusion criteria check	■					
Medical & clinical history	■					
Medication	■	■	■	■	■	■
Physical examination	■			■	■	■
Angiography	■	■				
Duplex Ultrasound				■	■	■
Device functionality		■				
Adverse Events		■	■	■	■	■

# Neurological assessment



Done by neurologist or a NIHSS certified person

**NEUROLOGICAL ASSESSMENT**

Subject ID:  -

Subject Initials:

1. Visit Interval:  Baseline  Discharge  1MFU  6MFU  12MFU

2. Completion Date:

Day    Month    Year

DESCRIPTION	SCALE DEFINITION	SCORE
<p><b>1a. Level of consciousness:</b> The investigator must choose a response if a full evaluation is prevented by such obstacles as an endotracheal tube, patient makes no movement (other than reflexive posturing) in response to the noxious stimulation.</p>	<p>0 = Alert; keenly responsive                      1 = Not alert; but arousable by minor stimulation to obey, answer, or respond                      2 = Not alert; requires repeated stimulation to attend, or is obtunded and requires strong or painful stimulation to make movements (not stereotyped)                      3 = Coma; Responds only with reflex motor or autonomic effect or totally unresponsive and flaccid.</p>	<input type="text"/> 1a
<p><b>1b. LOC Questions:</b> The patient is asked the month and his/her age. The answer must be correct - there is no partial credit for being close. Aphasic and stuporous patients who do not comprehend the questions will score 2. Patients unable to speak because of endotracheal intubation, orotracheal trauma, severe dysarthria from any cause, language barrier, or any other problem not secondary to aphasia are given a 1. It is important that only the initial answer be graded and that the examiner not "help" the patient with verbal or non-verbal cues.</p>	<p>0 = Answers both questions correctly                      1 = Answers one question correctly                      2 = Answers neither questions correctly</p>	<input type="text"/> 1b
<p><b>1c. LOC Commands:</b> The patient is asked to open and close the eyes and then to grip and release the non-paretic hand. Substitute another one step command if the hands cannot be used. Credit is given if an unequivocal attempt is made but not completed due to weakness. If the patient does not respond to command, the task should be demonstrated to him or her (pantomime), and the result scored (i.e., follows none, one or two commands). Patients with trauma, amputation, or other physical impediments should be given suitable one-step commands. Only the first attempt is scored.</p>	<p>0 = Performs both tasks correctly                      1 = Performs one task correctly                      2 = Performs neither tasks correctly</p>	<input type="text"/> 1c
<p><b>2. Best Gaze:</b> Only horizontal eye movements will be tested. Voluntary or reflexive (oculocephalic) eye movements will be scored, but caloric testing is not done. If the patient has a conjugate deviation of the eyes that can be overcome by voluntary or reflexive activity, the score will be 1. If a patient has an isolated peripheral nerve palsy (CN III, IV or VI), score a 1. Gaze is testable in all aphasic patients. Patients with ocular trauma, bandages, pre-existing blindness, or other disorder of visual acuity or fields should be tested with reflexive movements, and a choice made by the investigator. Establishing eye contact and then moving about the patient from side to side will occasionally clarify the presence of partial gaze palsy.</p>	<p>0 = Normal                      1 = Partial gaze palsy; gaze is abnormal in one or both eyes, but forced deviation and total gaze paresis is not present.                      2 = Forced deviation, or total gaze paresis not overcome by the oculocephalic maneuver</p>	<input type="text"/> 2
<p><b>3. Visual:</b> Visual fields (upper and lower quadrants) are tested by confrontation, using finger counting or visual threat, as appropriate. Patients may be encouraged, but if they look at the side of the moving fingers appropriately, this can be scored as normal. If there is unilateral blindness or enucleation, visual fields in the remaining eye are scored. Score 1 only if a clear-cut asymmetry, including quadrantanopia, is found. If patient is blind from any cause, score 3. Double simultaneous stimulation is performed at this point. If there is extinction, patient receives a 1, and the results are used to respond to item 11.</p>	<p>0 = No visual loss                      1 = Partial hemianopia                      2 = Complete hemianopia                      3 = Bilateral hemianopia (blind including cortical blindness)</p>	<input type="text"/> 3



# Patient Demographics



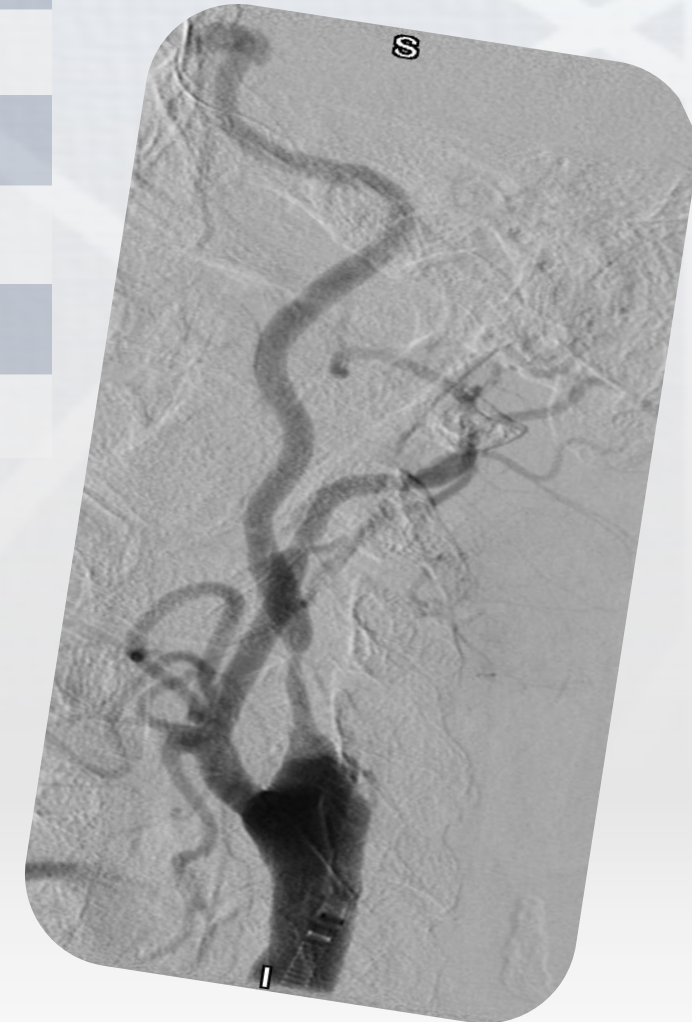
	N=100
Male (%)	70 (70.0%)
Age (min – max; $\pm$ SD)	73.44 (47.78 – 89.12 $\pm$ 9.55)
Neurological Status:	
- Symptomatic (%)	31 (31.0%)
- Asymptomatic (%)	69 (69.0%)
Nicotine abuse* (%) *former & current	67 (67.0%)
<b>Hypertension (%)</b>	<b>80 (80.0%)</b>
Diabetes mellitus (%)	31 (31.0%)
<b>Hypercholesterolemia (%)</b>	<b>74 (74.0%)</b>
Obesity (%)	28 (28.0%)
Cerebrovascular disease (%)	24 (24.0%)

# Lesion Characteristics



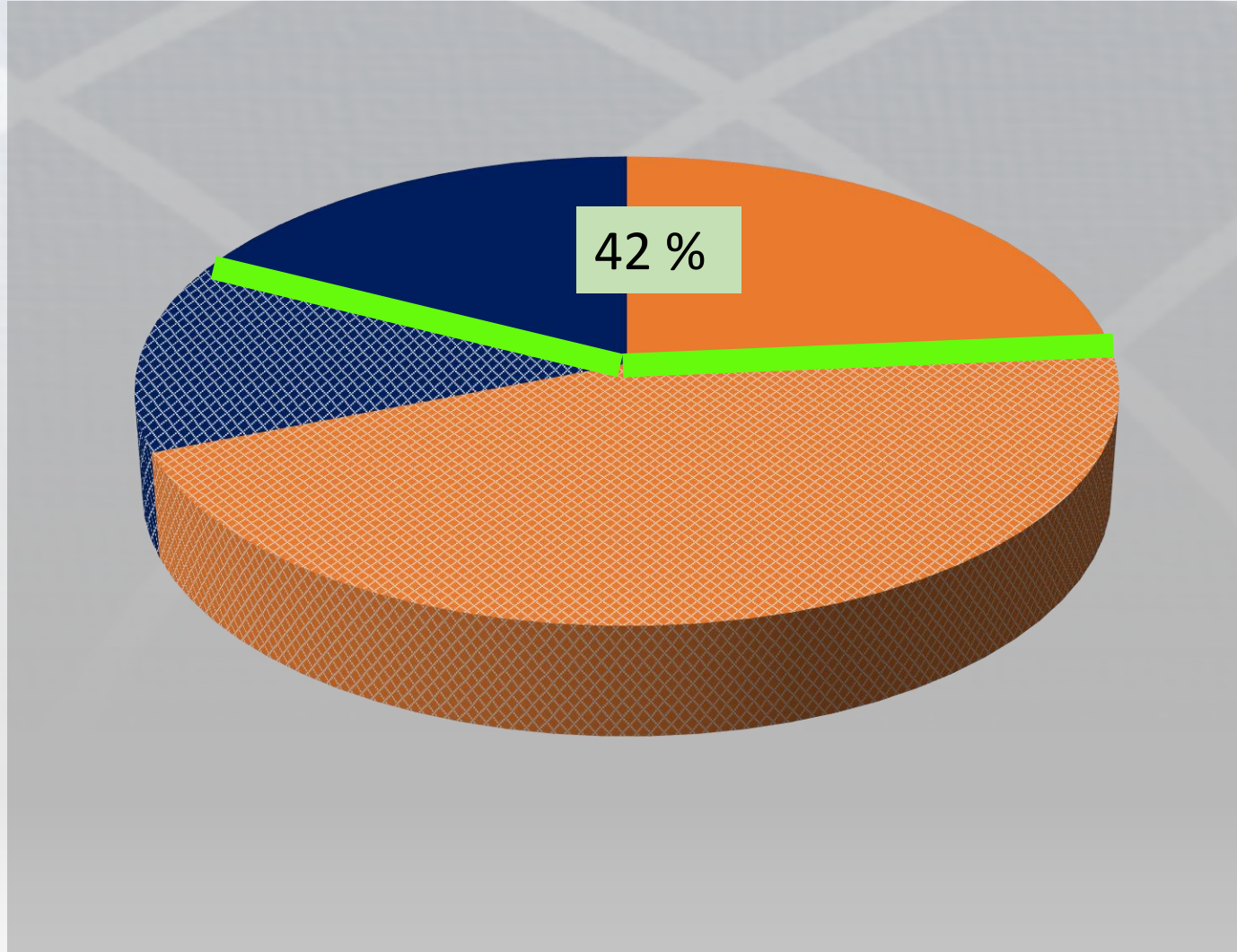
**N=100**

Left/Right (%)	49 (49.0%) / 51 (51.0%)
Lesion length ( <i>min – max; ±SD</i> )	19.14 mm (2.0 – 50.0; ±8.20)
Reference vessel diameter ( <i>min – max; ±SD</i> )	6.88 mm (4.0 – 9.0; ±1.36)
Mean lumen diameter ( <i>min – max; ±SD</i> )	1.29 mm (0.08 – 4.05; ±0.77)
Degree of stenosis ( <i>min – max; ±SD</i> )	85.30% (55 – 99 ; ±8.02)





# Treatment characteristics



Symptomatic (N=31)	Asymptomatic (N=69)
18 without an EPD	24 without an EPD
13 with an EPD	45 with an EPD

# Results – 30 days



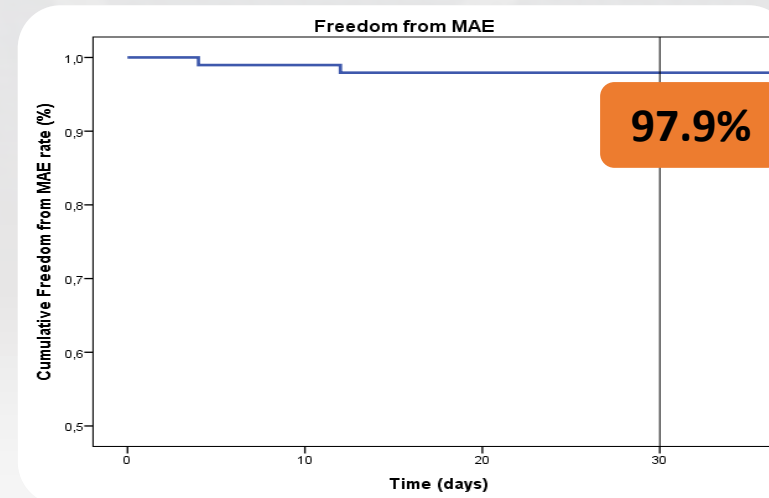
**Primary Endpoint:** 30-day rate of Major Adverse Events (MAE), defined as the cumulative incidence of any peri-procedural death, stroke\* or myocardial infarction ( $\leq 30$  days post-procedure)

\*Stroke is defined as an acute neurologic event with local symptoms and signs lasting more than 24 hours consistent with focal cerebral ischemia.

Per Protocol	MAE's
All Death, Stroke, or MI	2.10%
Death	1.00%
Any Stroke	1.00%
- Major Stroke	0.00%
- Minor Stroke	1.00%
MI	1.00%

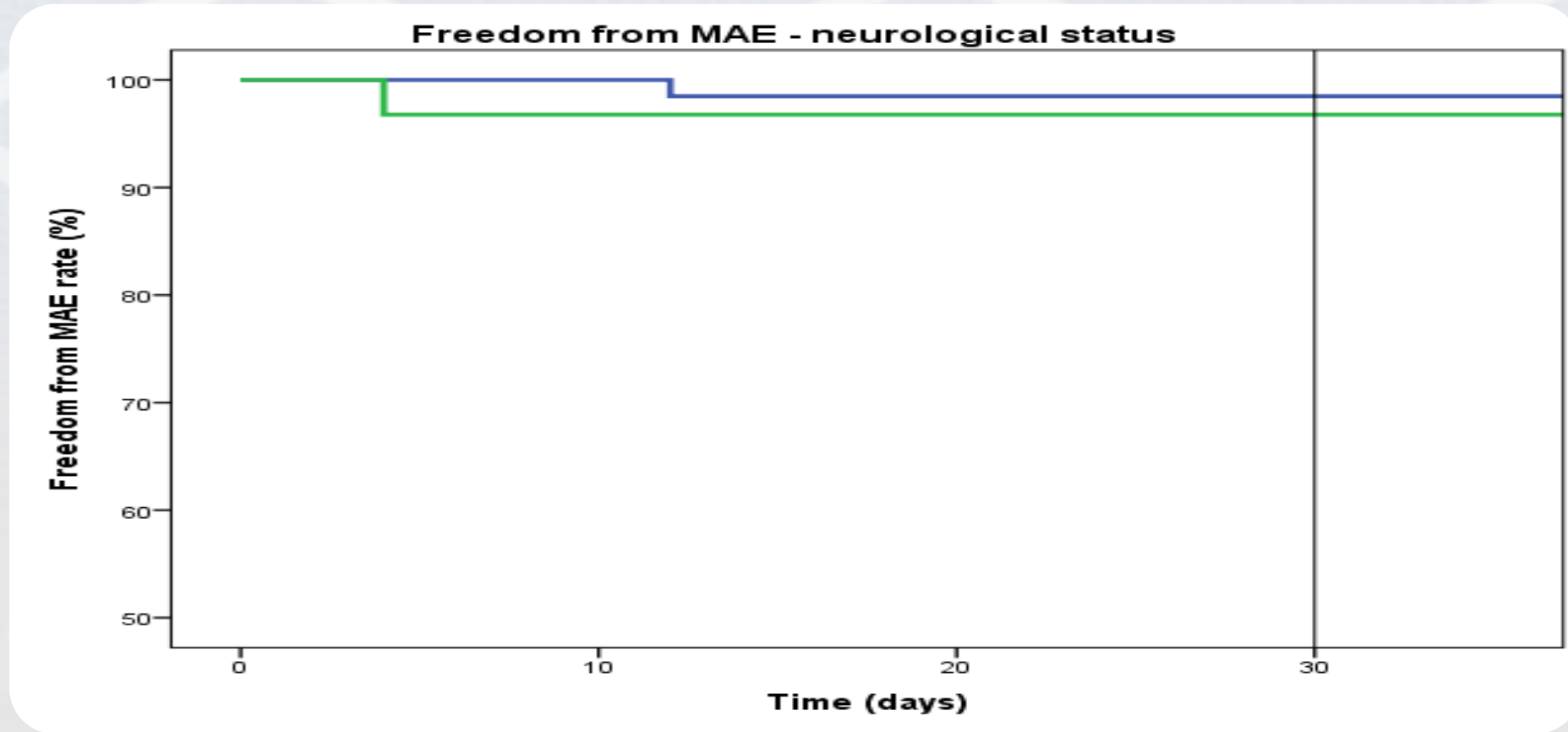
1 patient died at Day 4.

1 patient experienced an ipsilateral stroke (Day 12) because of AF and inadequately anticoagulantia medication.





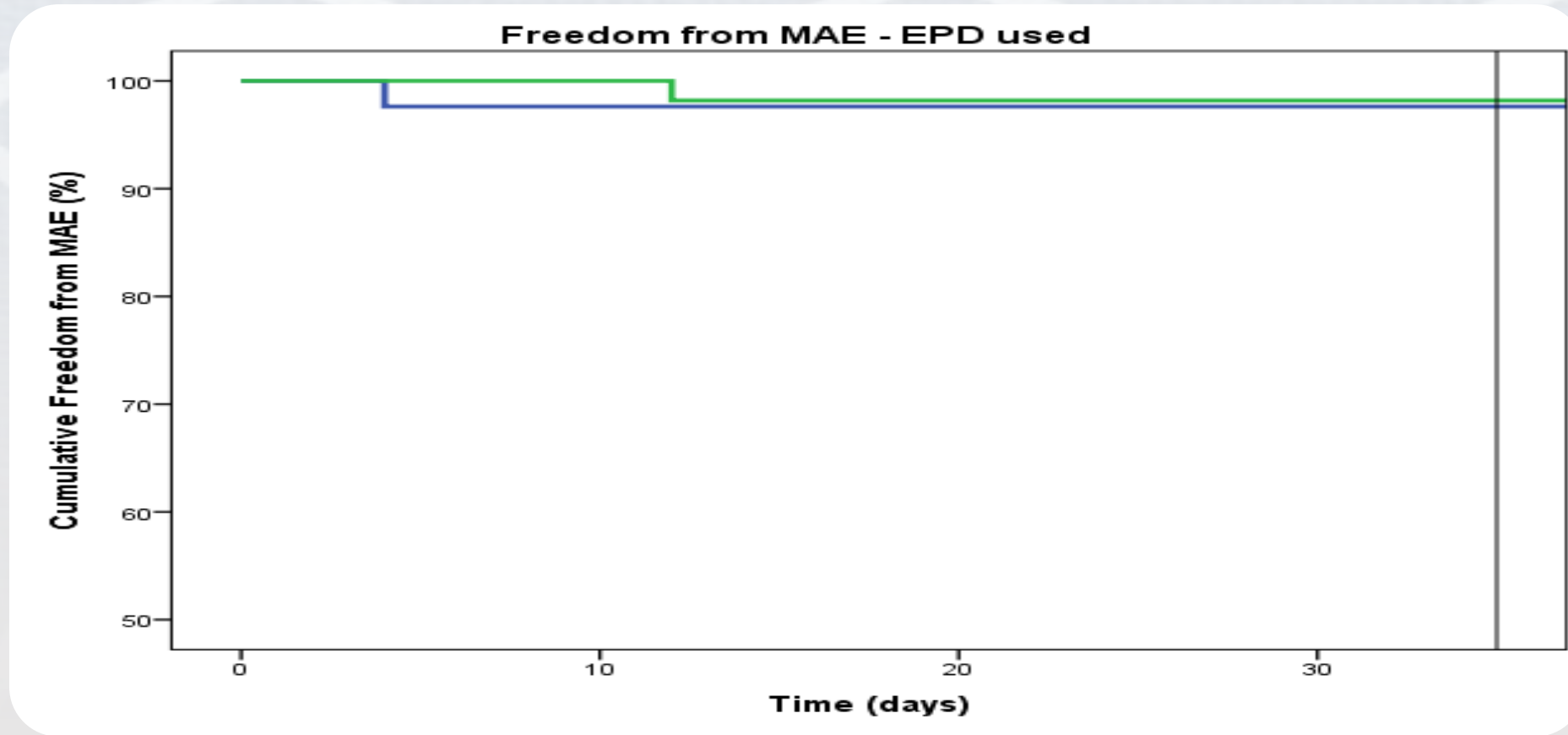
# Results – 30 days



98.5 %  
96.8 %

	time	baseline	30 days	Significant
Symptomatic	at risk	31	30	P = 0.576
	%	100	96.8	
Asymptomatic	at risk	69	63	
	%	100	98.5	

# Results – 30 days



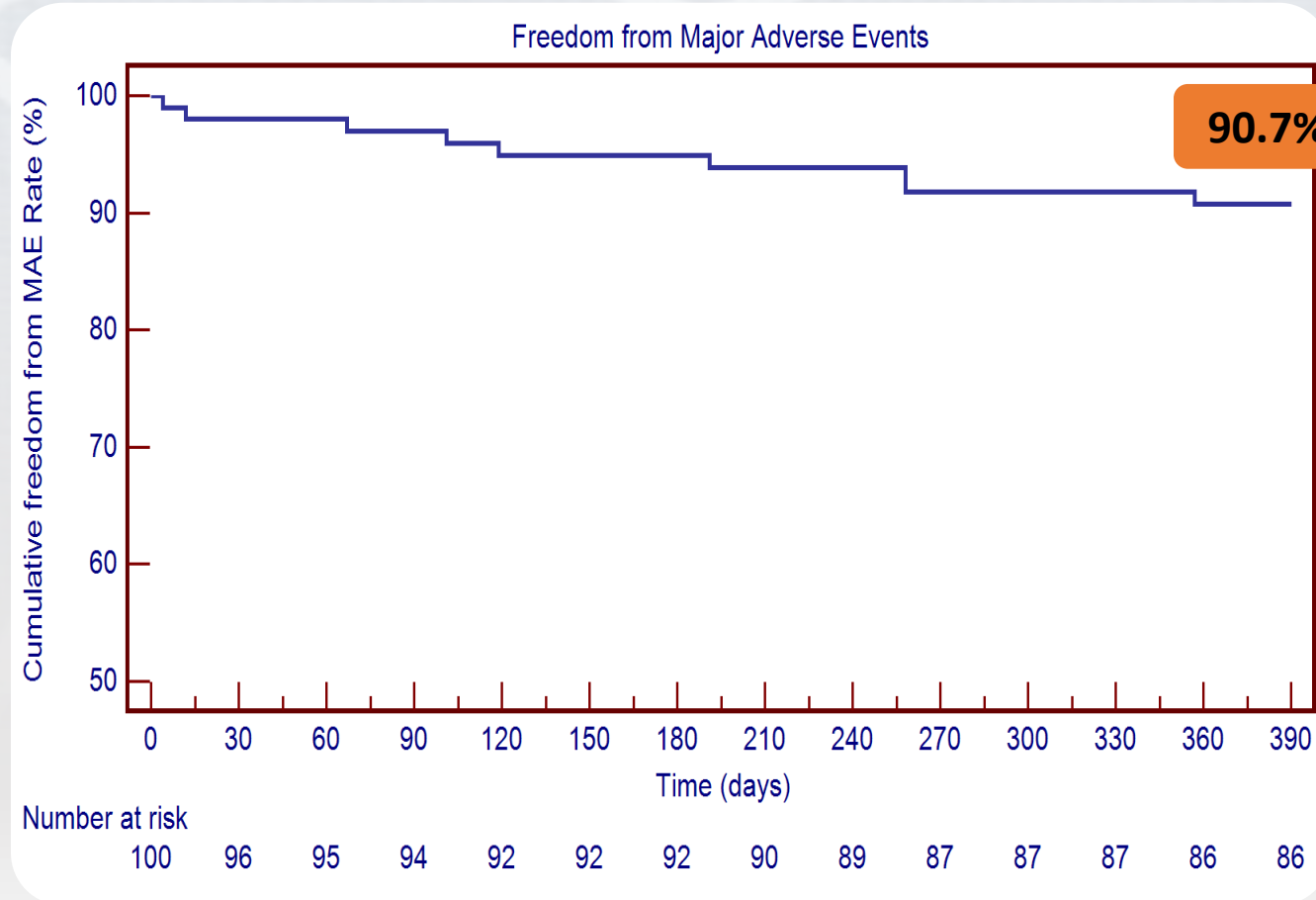
98.2 %

97.6 %

	time	baseline	30 days	Significant
With Embolic Protection Device	at risk	58	52	P = 0.842
	%	100	98.2	
Without Embolic Protection Device	at risk	42	41	
	%	100	97.6	

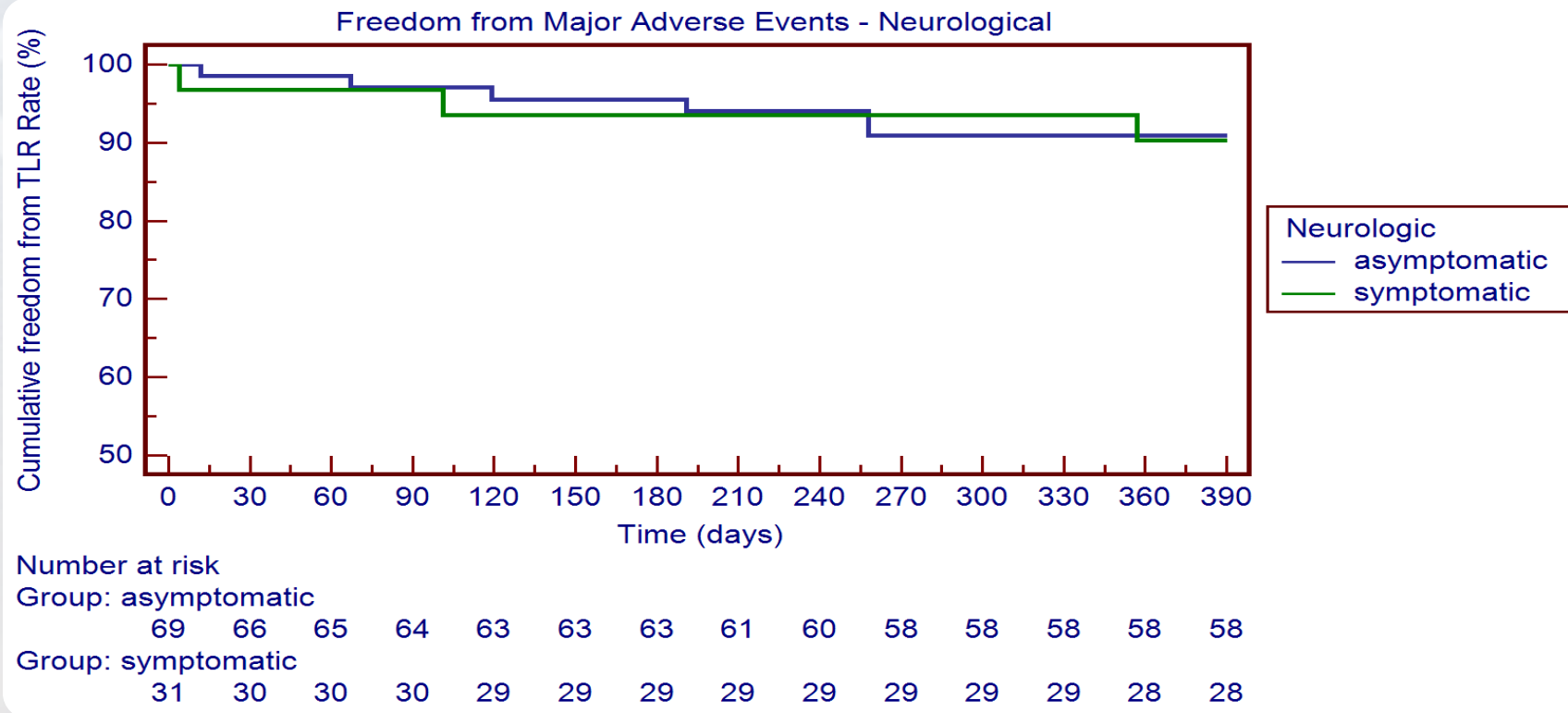


# 12-month freedom from MAE



<b>Ipsilateral Stroke</b>	<b>4 patients</b>
<b>Contralateral Stroke</b>	<b>1 patients</b>
<b>Death</b> - due to M.I. - due to kidney failure	<b>3 patients</b> - 2 patients - 1 patient

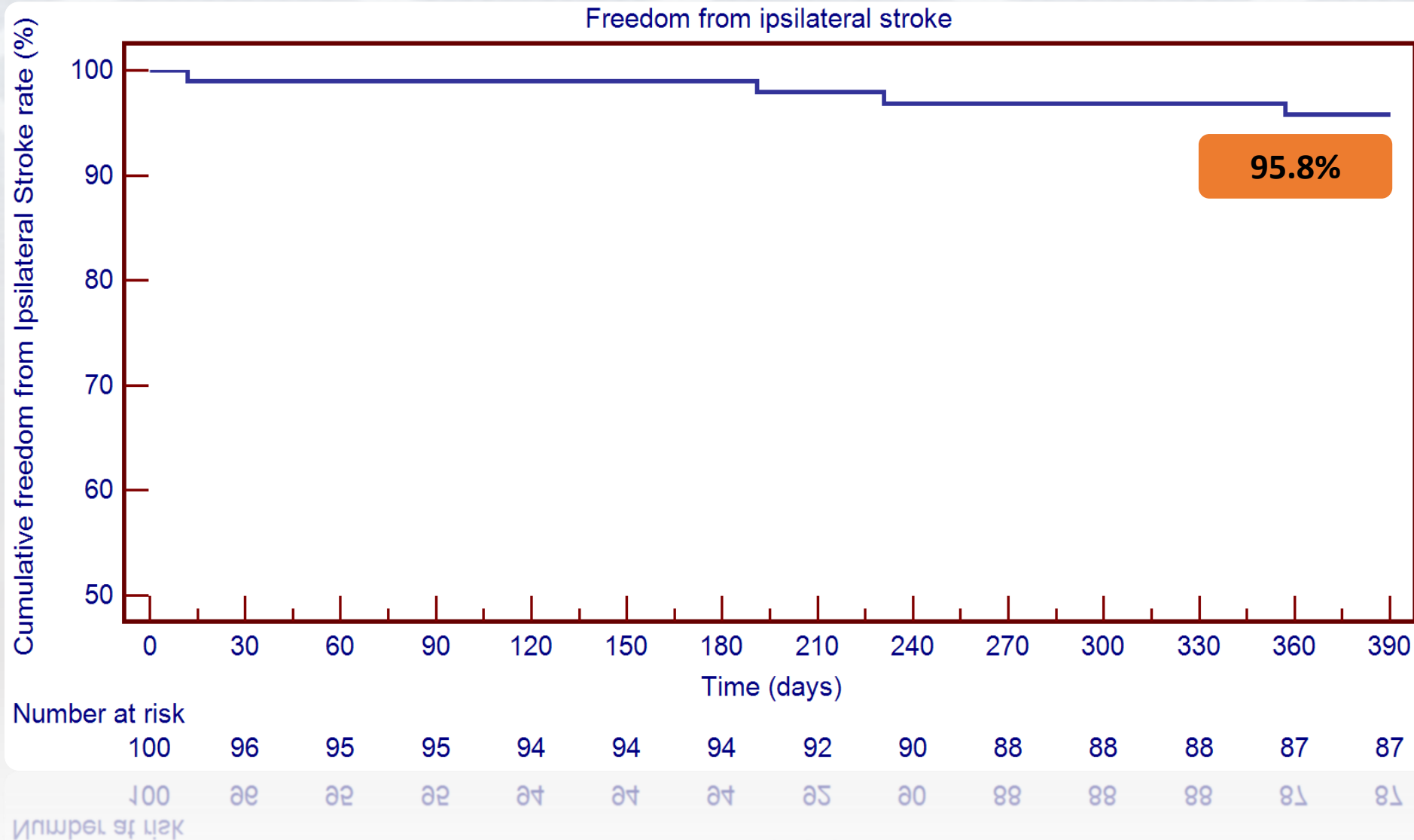
# 12-month freedom from MAE



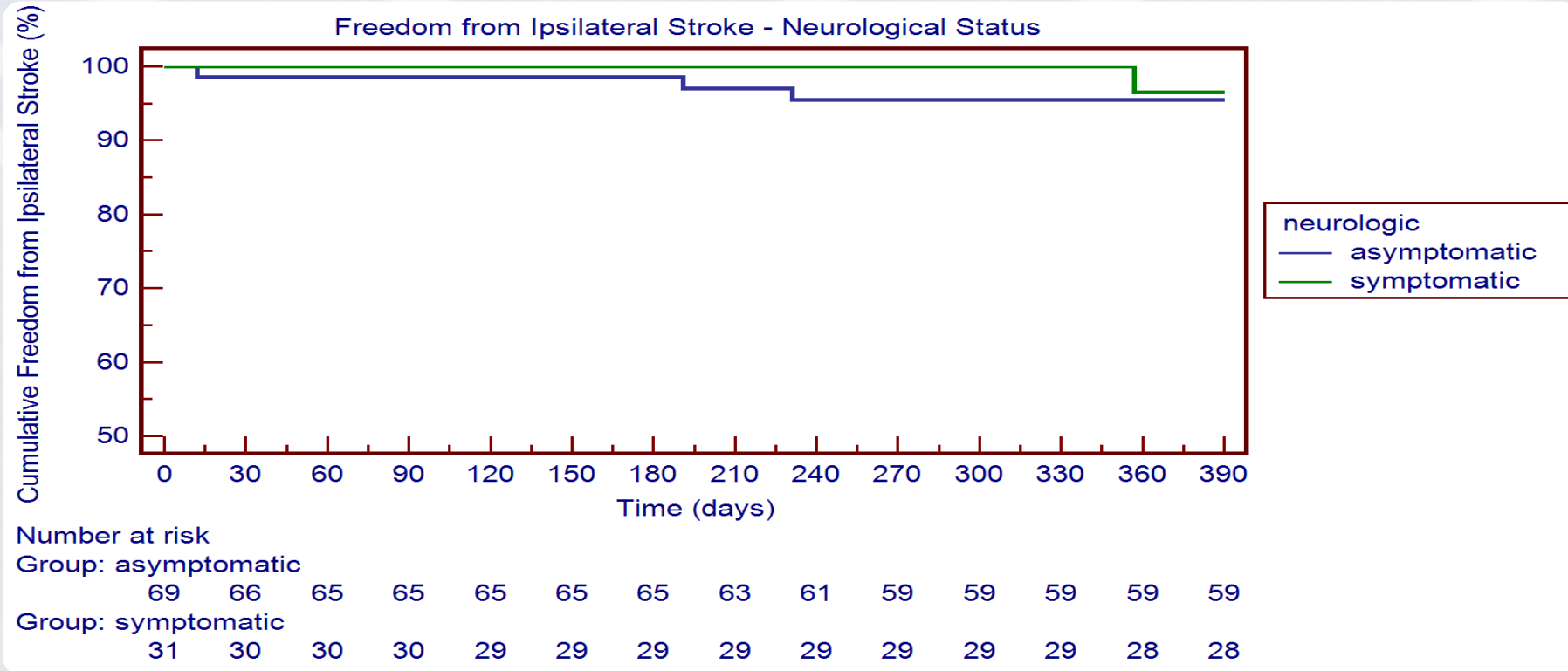
	time	baseline	30 days	6MFU	12MFU	Significant
Symptomatic	at risk	31	30	29	28	<b>P = 0.6167</b>
	%	100	96.8	93.5	90.3	
Asymptomatic	at risk	69	66	63	58	
	%	100	98.6	95.5	90.9	



# 12-month freedom from ipsilateral stroke



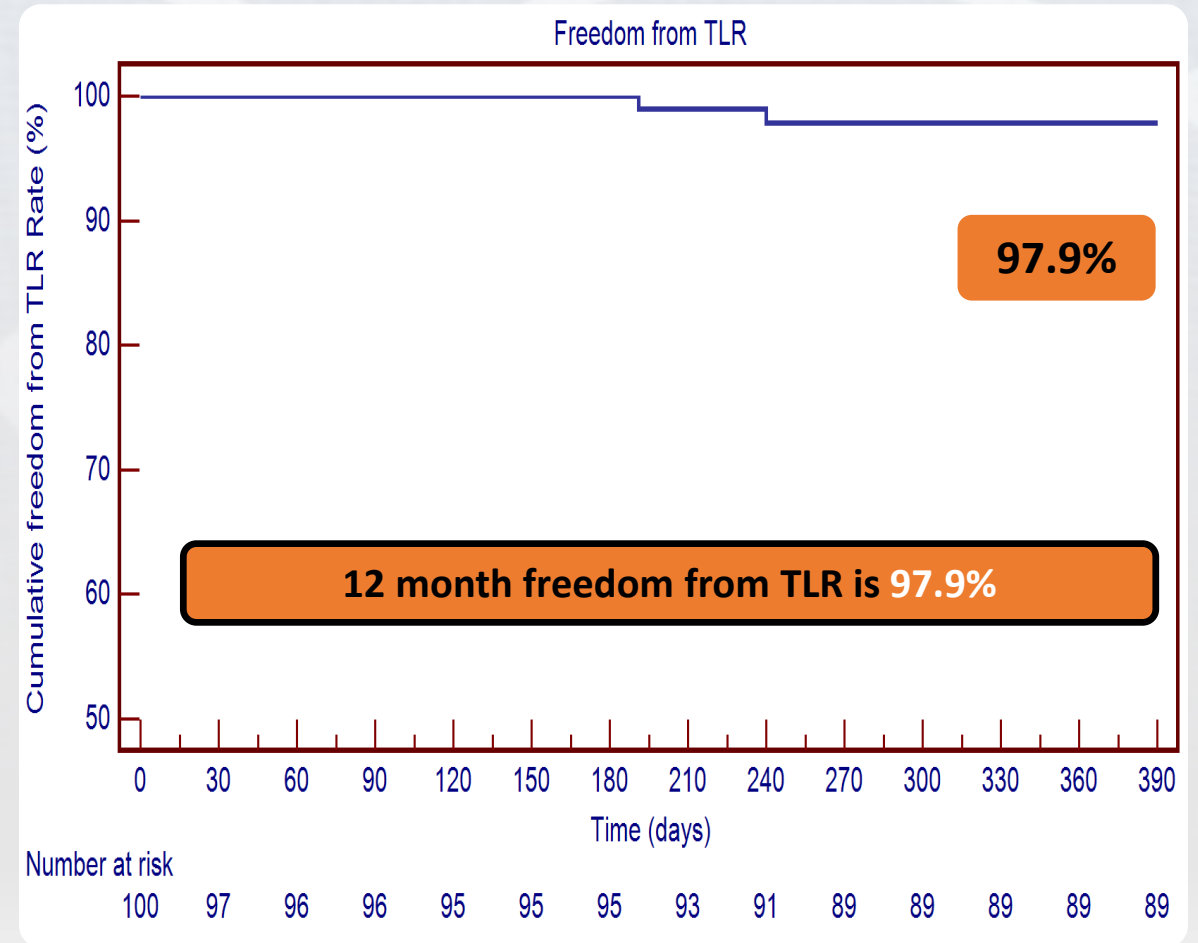
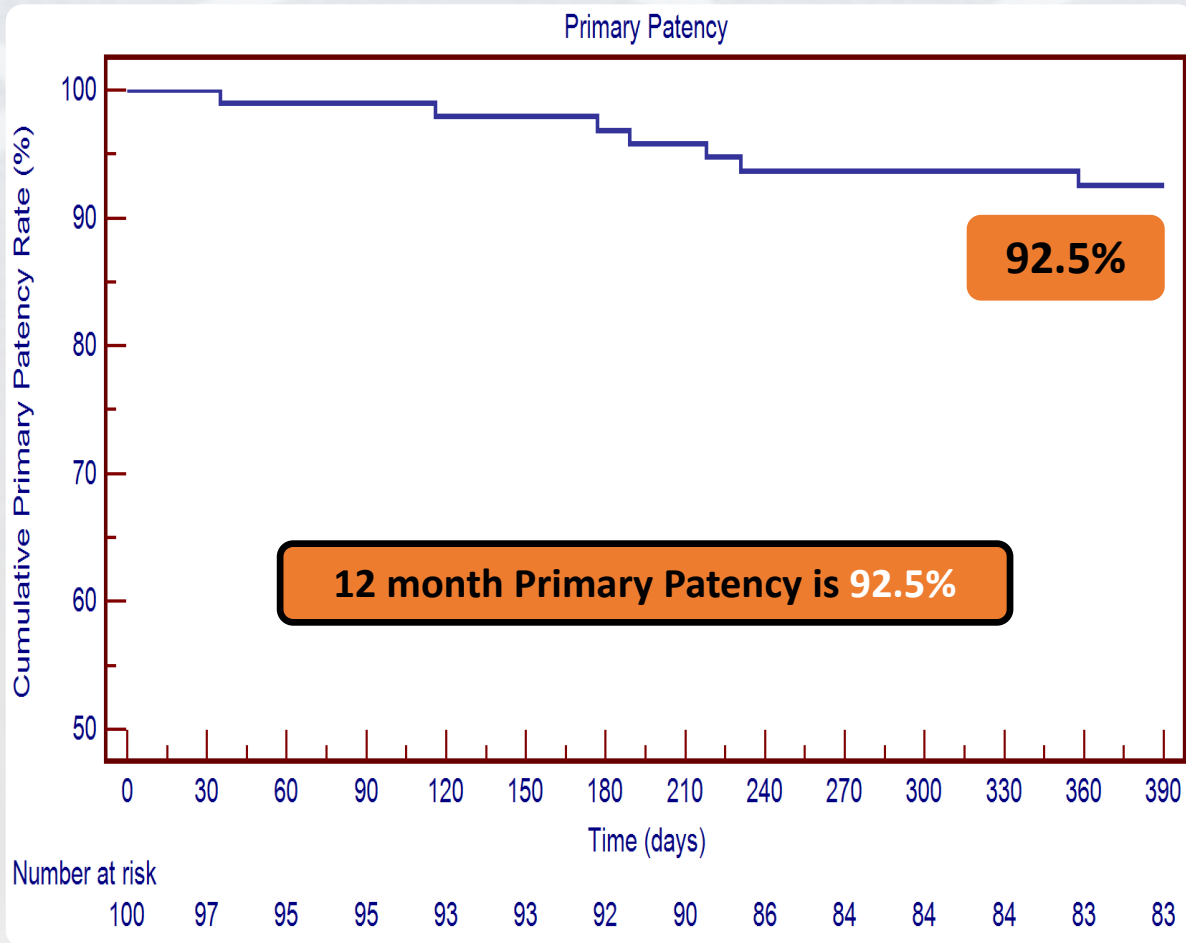
# 12-month freedom from ipsilateral stroke



	time	baseline	30 days	6MFU	12MFU	Significant
Symptomatic	at risk	31	30	29	28	<b>P = 0.7797</b>
	%	100	100	100	96.6	
Asymptomatic	at risk	69	66	65	59	
	%	100	98.6	98.6	95.5	



# 12-month patency and TLR



# Conclusion

The **RoadSaver Stent** seems to be a valid, safe and effective treatment option to treat **carotid lesions** in symptomatic & asymptomatic patients. Even without the use of an embolic protection device

