

# CACVS 2014, Paris



*A.Z. Sint-Blasius, Dendermonde*



**Marc Bosiers**  
**Koen Deloose**  
**Joren Callaert**

*Imelda Hospital, Bonheiden*



**Patrick Peeters**  
**Jürgen Verbist**

*OLV Hospital, Aalst*



**Lieven Maene**  
**Roel Beelen**

*R.Z. Heilig Hart, Tienen*



# CAS, My favorite stent is...?

## Marc Bosiers, MD

# Disclosure slide

- I 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

# I) Sufficient radial force

- Resists elastic recoil & radial crush
- Excessive force can result in plaque disruption in vulnerable lesions



# Moderate expansive force

- Provides stent stabilization without excessive chronic outward radial force



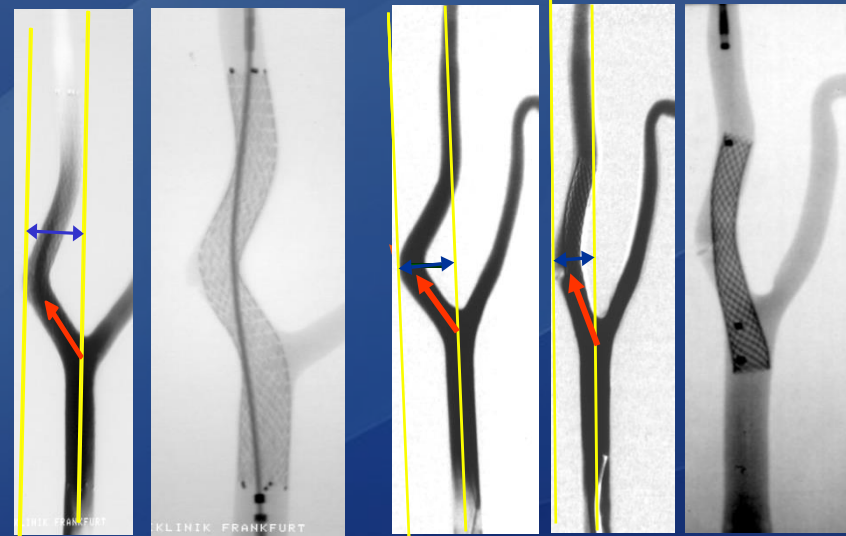
Reduces intimal hyperplasia



## II) Conformability

- Ability to conform to vessel tortuosity

The higher the tortuosity is, the higher the conformability needs to be to maintain original anatomy

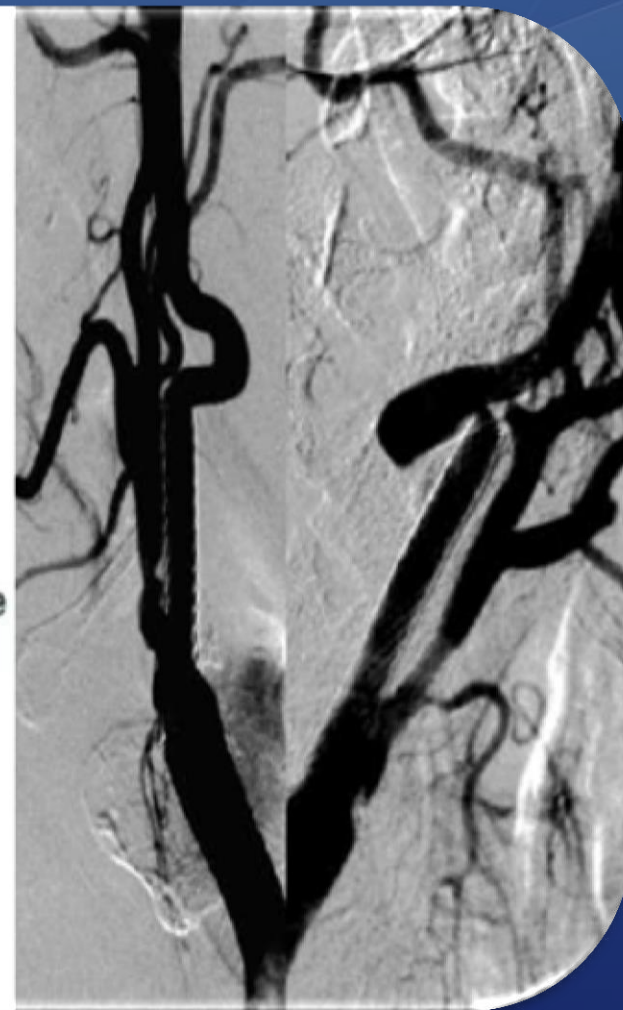
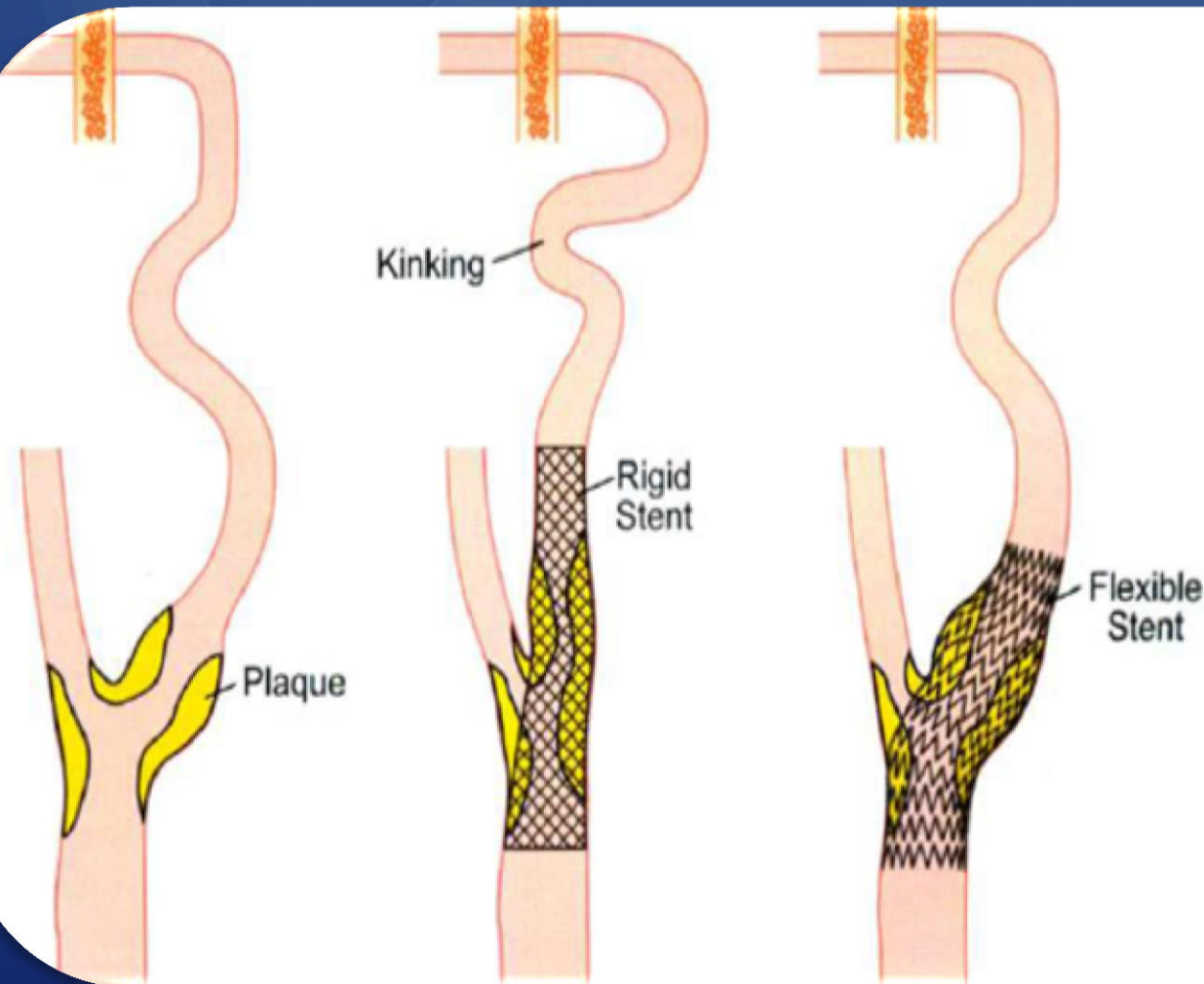


higher  
conformability

lower  
conformability



# Conformability



# Vessel wall adaptability

- Ability to adjust to tapered anatomy carotid region

*The higher the difference in diameter between the ICA and CCA, the higher the vessel wall adaptability needs to be to maintain the original anatomy*



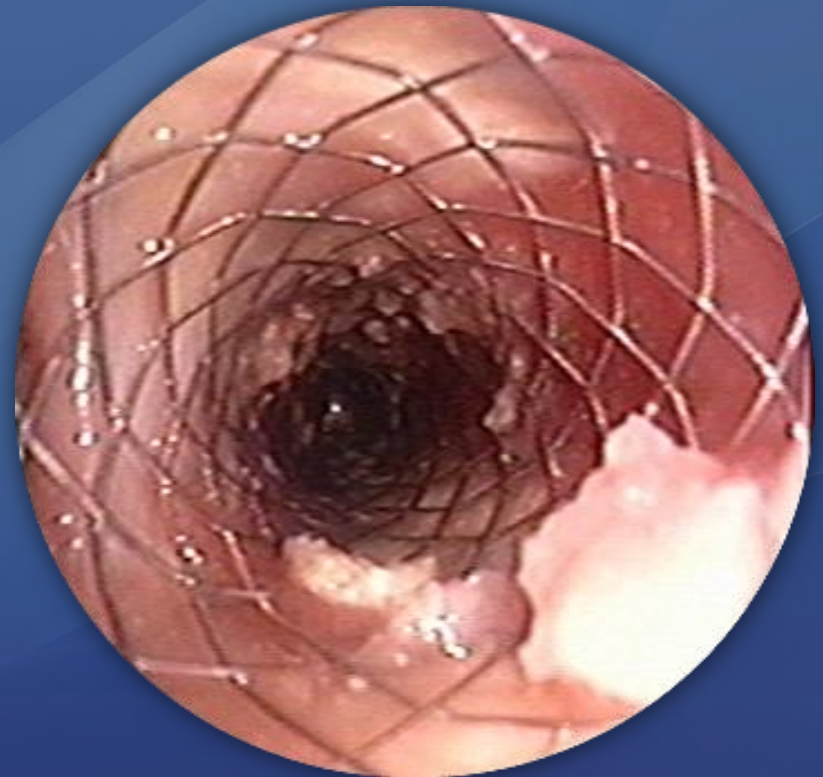
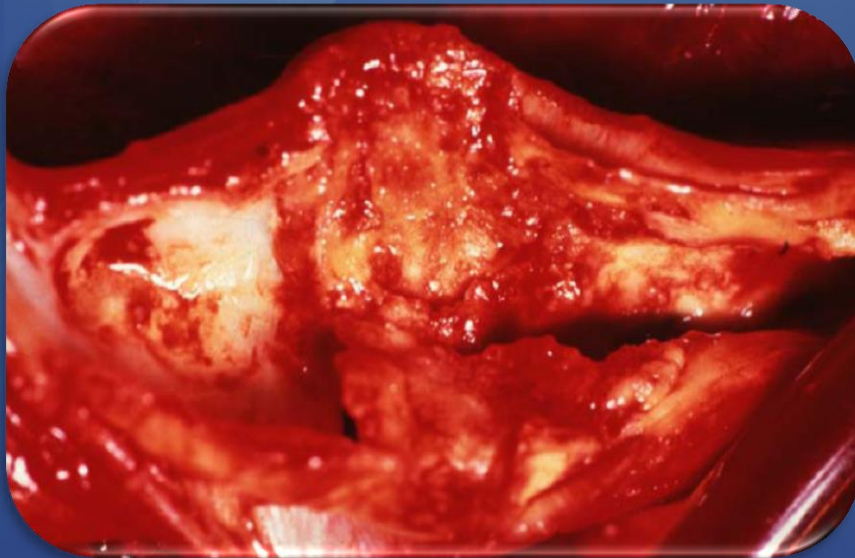
poor vessel wall adaptability



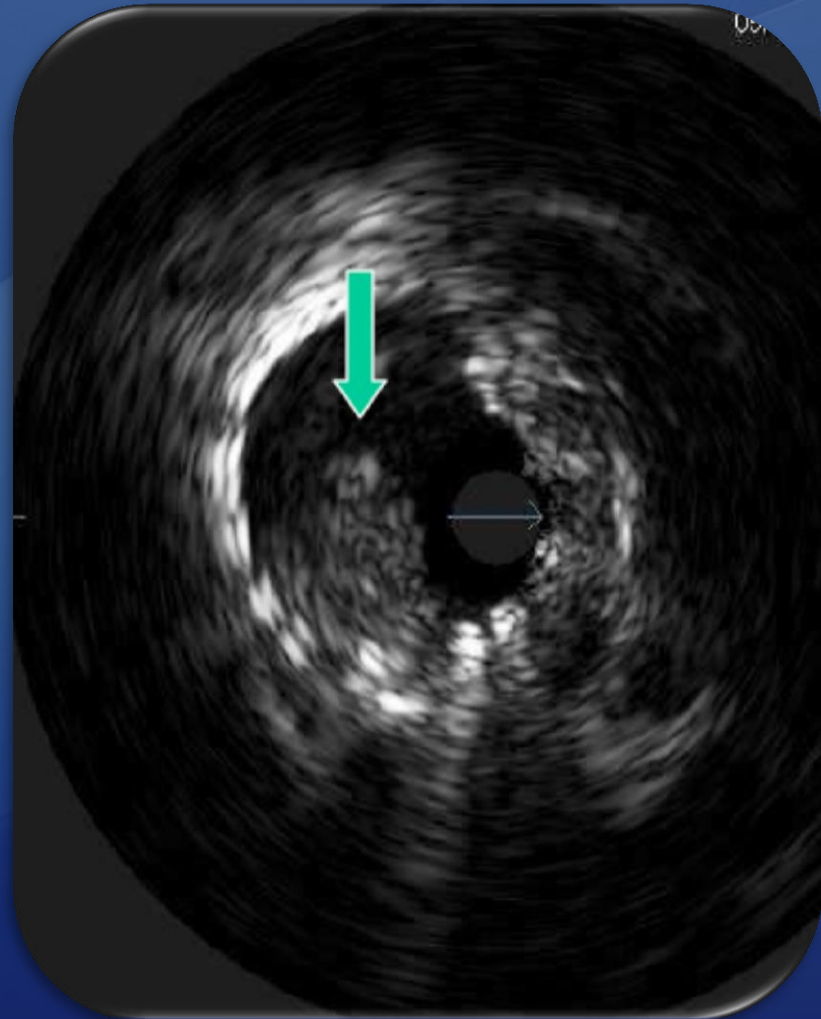
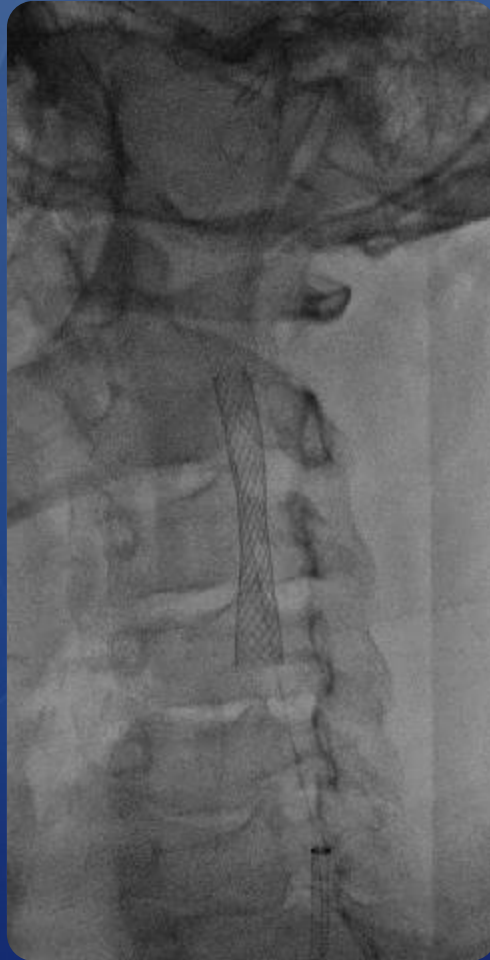
better vessel wall adaptability

### III) Scaffolding

→ Scaffolding ~ plaque containment



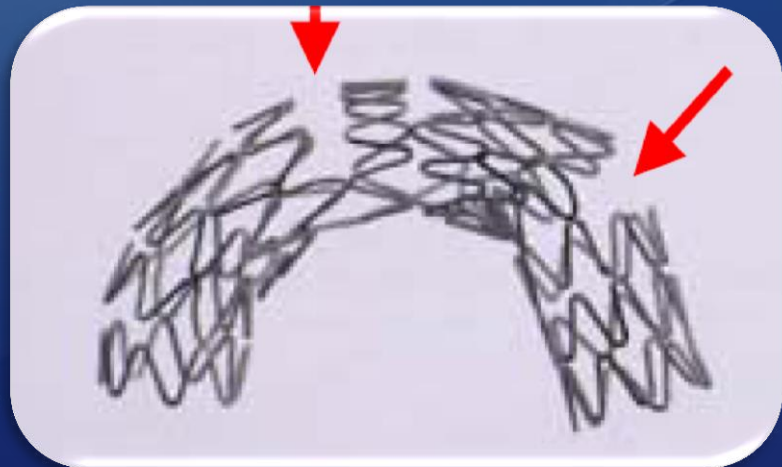
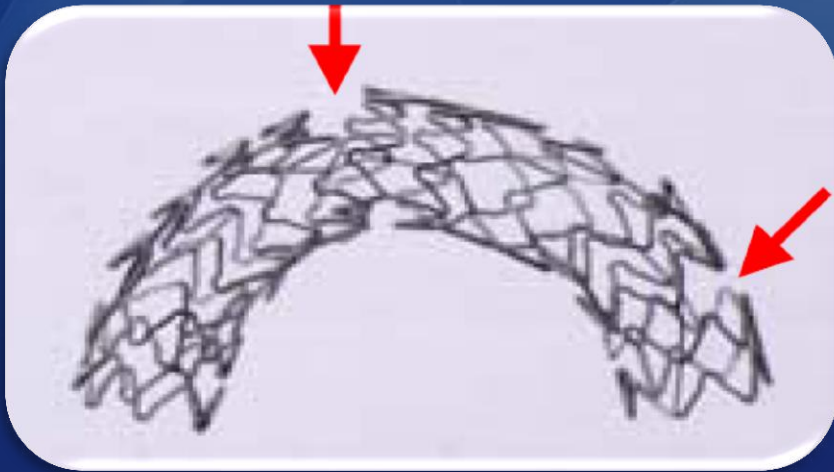
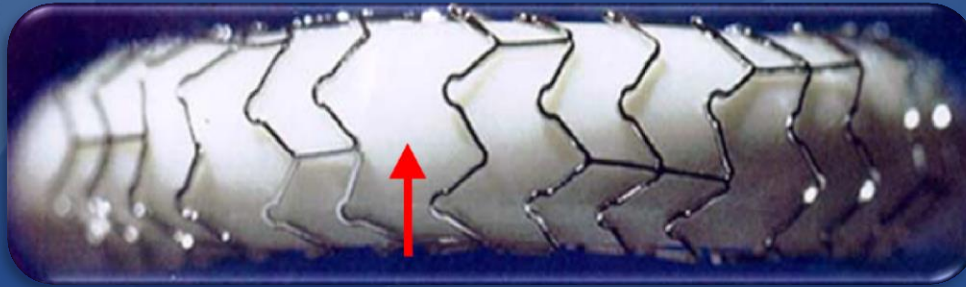




# The correct stent for the correct lesion

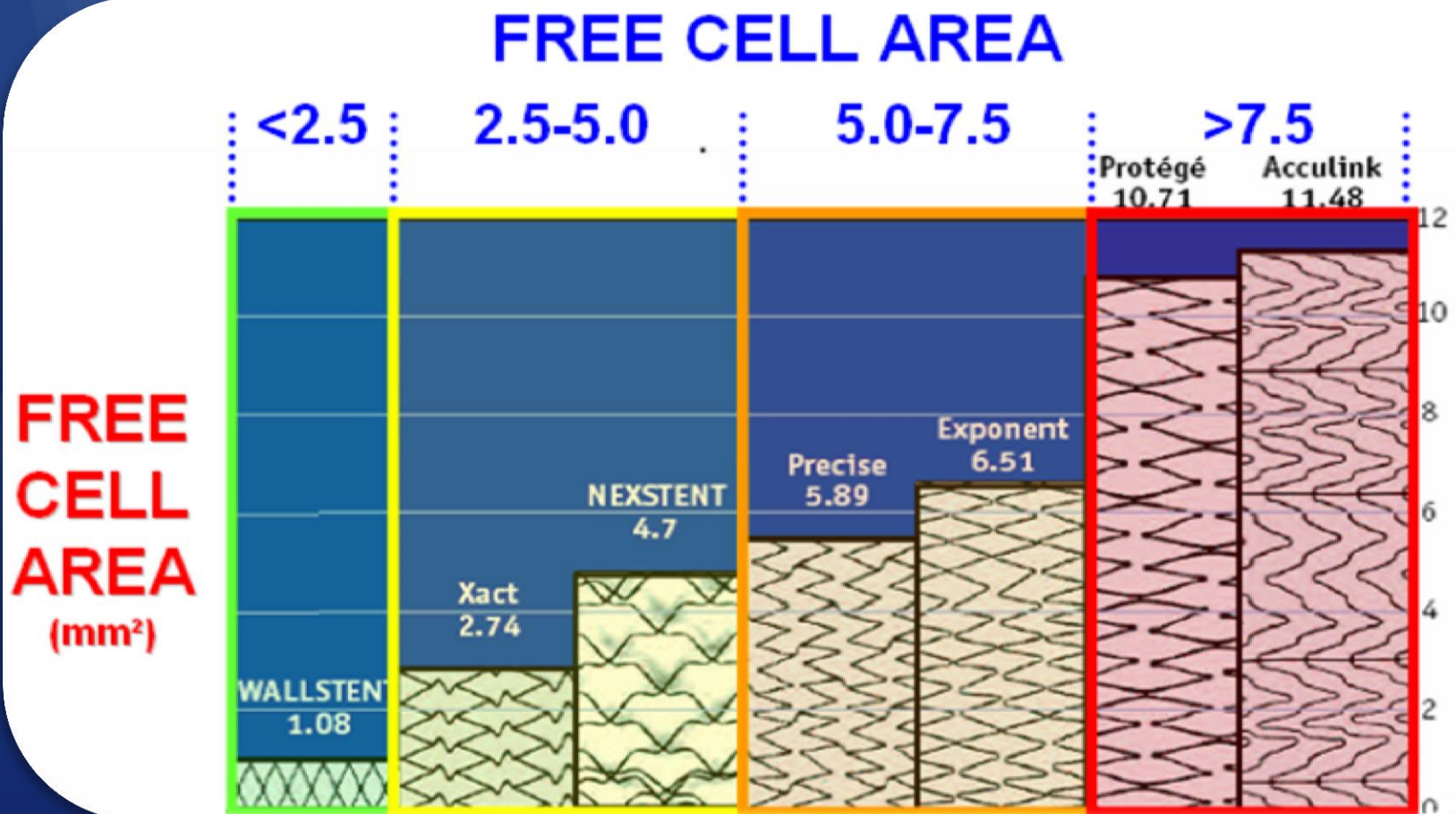
- Prolaps – fish scaling

Open cell design in tortuous curvature



# The correct stent for the correct lesion

## “Free cell area” based analysis

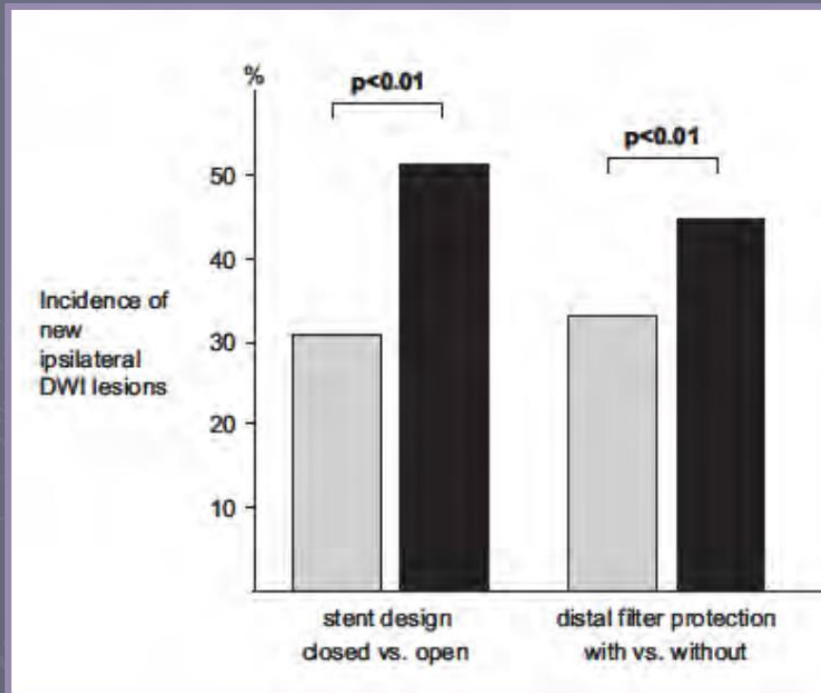




# The correct stent for the correct lesion

## New Brain Lesions After Carotid Stenting Versus Carotid Endarterectomy: A Systematic Review of the Literature

Sonja Schnaudigel, Klaus Gröschel, Sara M. Pilgram and Andreas Kastrup



Black = Open Cell

Gray = Closed Cell

(*Stroke*, 2008;39:1911-1919.)

# The correct stent for the correct lesion

## SPACE:

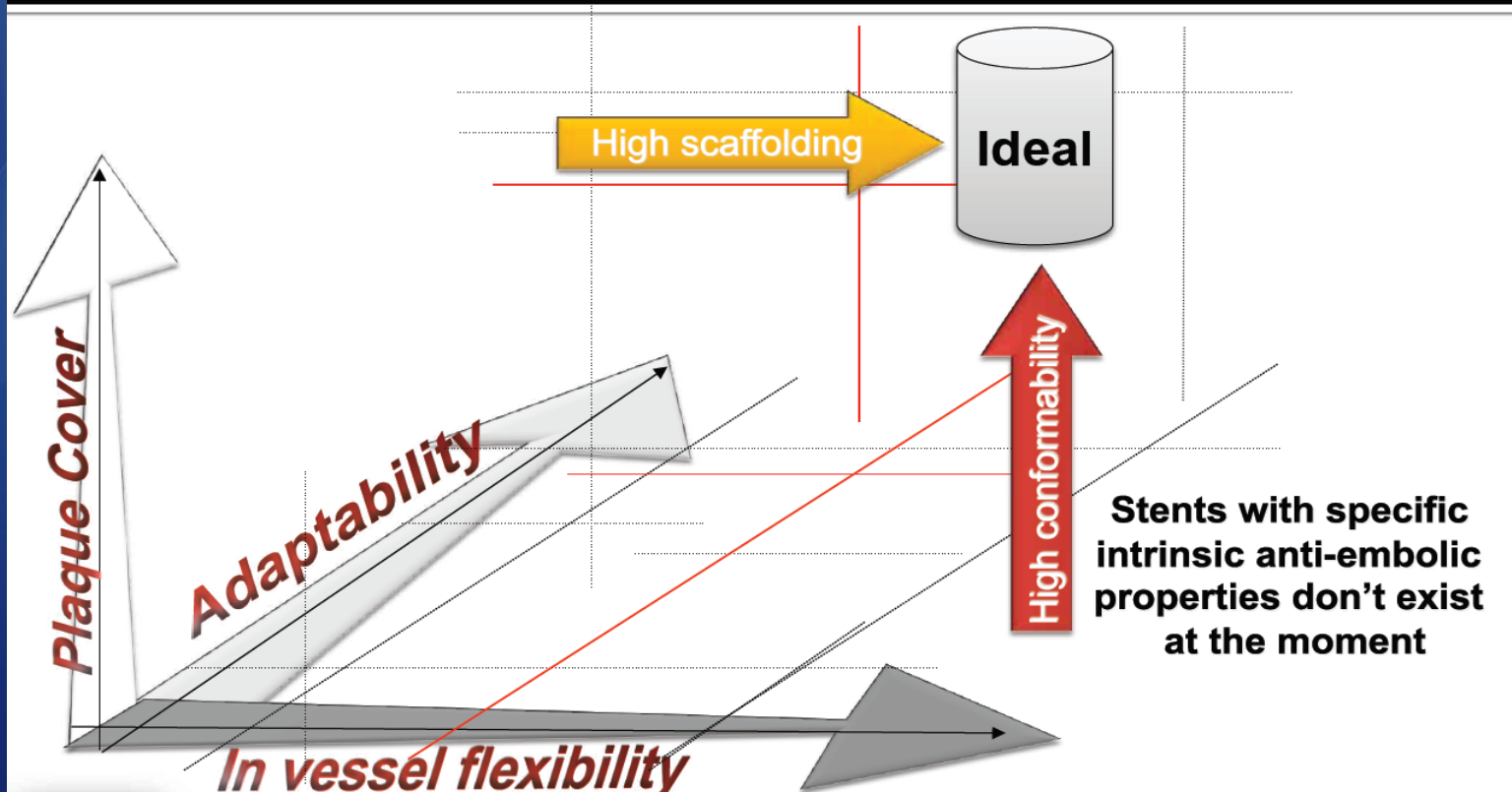
**Table 4. Influence of Different Stent Types on OE Rate**

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



# The correct stent for the correct lesion

## Lesion specific stenting: an unresolved problem



**Is there an ideal stent?**

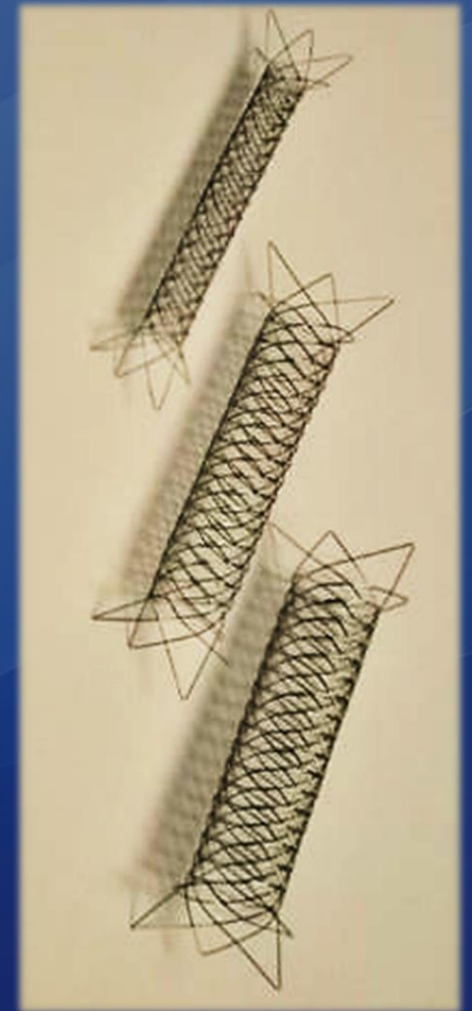


# Roadsaver™

- TERUMO

A novel design

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





# Primary Attributes

*Roadsaver*<sup>™</sup>



Double layer micromesh design

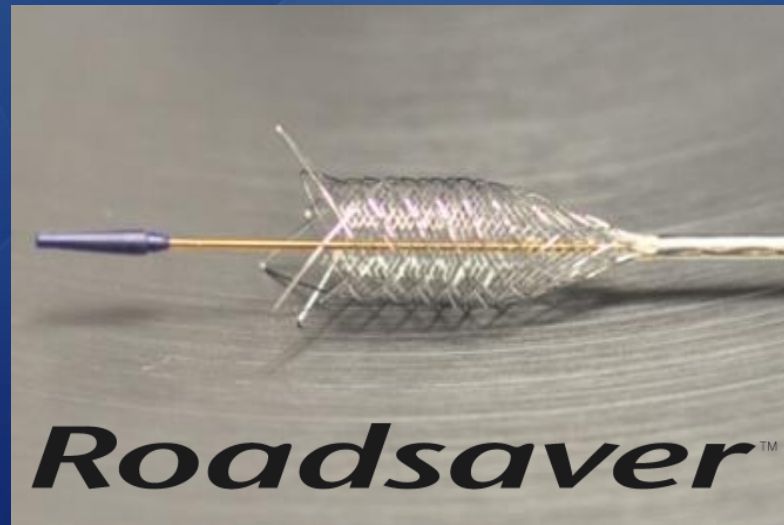
- Chronic embolic protection

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





# CLEAR-ROAD trial

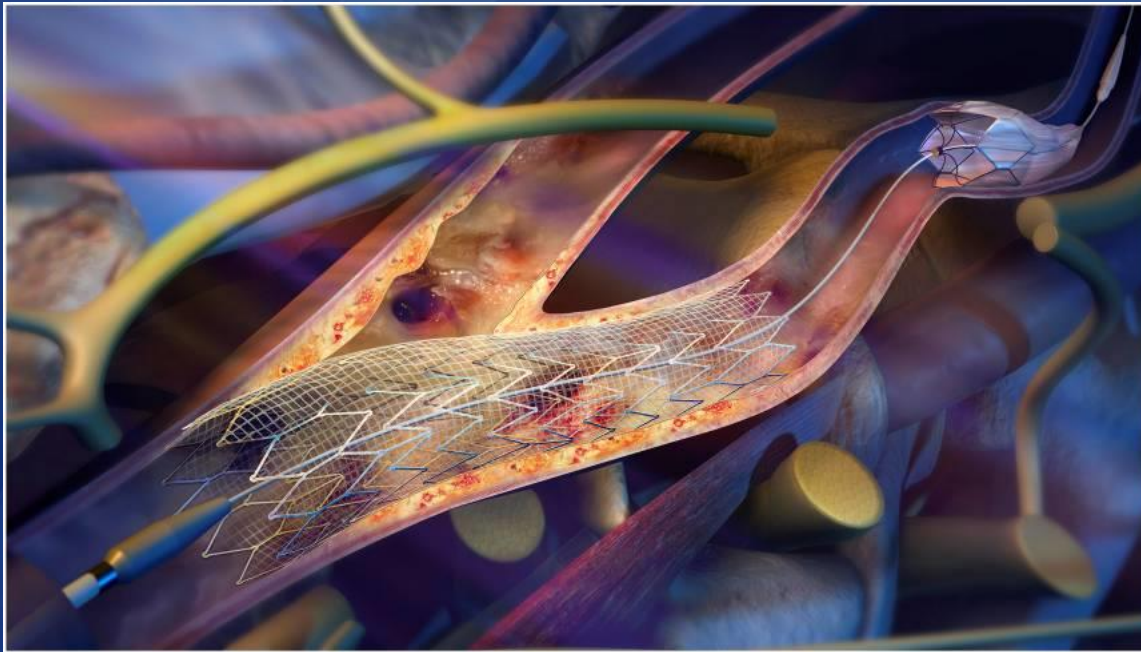
- Physician-Initiated **C**arotid **T**rial Investigating the Efficacy of **E**ndovascular Treatment of Carotid **A**rterial Disease with the multi-layer **R**OADsaver stent
- multi-center trial with 100 patients
- **Primary Endpoint:**  
30-day rate of major adverse events (MAEs), defined as the cumulative incidence of any peri-procedural ( $\leq 30$  days post-procedure) death, stroke or myocardial infarction (MI).

# Gore<sup>®</sup> Carotid Stent








## Attributes

### – Stent:

- Open Cell NiTi Frame
- Closed Cell 500  $\mu$  lattice on outside of NiTi Frame
- Permanently Bound CBAS Heparin on all device surfaces



**CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.**

							
<b>Manufacturer</b>	W.L. Gore and Associates*	Abbott Laboratories	Abbott Laboratories	Boston Scientific Corporation	ev3 Inc./ Covidien	Cordis Corporation	Medtronic, Inc./ Invatec
<b>Device</b>	GORE® Carotid Stent	ACCULINK® RX DEVICE	XACT® DEVICE	WALLSTENT® MONORAIL® DEVICE	PROTÉGÉ® RX® DEVICE	PRECISE® DEVICE	CRISTALLO IDEALE DEVICE

**\*CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.**

**GORE<sup>®</sup> Carotid Stent Clinical Study for  
the treatment of carotid Artery stenosis  
in patients at increased risk For adverse  
events From carotid endArterectomy**

**The Gore SCAFFOLD Clinical Study**

**\*CAUTION: Investigational Device. Limited by United States Law to Investigational Use only.**

# Study design

- Number of Sites

Up to 50 sites in the US, Europe, and Japan

- Number of Subjects

312 subjects (max 40 at each site)

- General Population

Patients must have either anatomic or medical co-morbidities that place them at **high perioperative risk for CEA**

≥ 50% (by angiography) stenosis if symptomatic  
(stroke, TIA, TMB within 180 days of procedure),

OR

≥ 80% (by angiography) stenosis if asymptomatic



# Study Endpoints

- **Primary Endpoint**

Composite of Major Adverse Events (MAE) defined as death, any stroke, or myocardial infarction through 30 days post index procedure plus ipsilateral stroke between 31 days and 1 year

**\*All primary endpoint events will be determined by the study Clinical Events Committee**

**\*CAUTION:**

**Investigational Device. Limited by United States Law to Investigational Use only.**

# Conclusion

- The ideal carotid stent must comprise:
  - Sufficient radial force
  - Vessel conformability
  - **Scaffolding ++**
- My favorite carotid stent was not yet on the market...  
... but **new technologies** offer promising tools
  - Terumo Road-Saver
  - Gore Carotid Stent