VEITH SYMPOSIUM

Optical Coherence Tomography (OCT) Proves CAS Is Rendered Safer Because Mesh Covered Stents Decrease Emboli: The Imaging Evidence And Ehat It Shows About The Interaction Between Stent And Plaque

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Faculty Disclosure

Disclosure

Speaker name: Francesco Setacci, MD

I have the following potential conflicts of interest to report:

- ❑ **Consulting**
- ❑ **Employment in industry**
- ❑ **Shareholder in a healthcare company**
- ❑ **Owner of a healthcare company**
- ❑ **Other(s)**
- ✓ **I do not have any potential conflict of interest**

Background

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THE PRESENT AND FUTURE

JACC STATE-OF-THE-ART REVIEW

Carotid Artery Stenting

JACC State-of-the-Art Review

Christopher J. White, MD,[a] Thomas G. Brott, MD,[b] William A. Gray, MD,[c] Sean P. Lyden, MD,[d] David Christopher Metzger, MD,[e] Kenneth Rosenfie Ravish Sachar, MD,[f] Adnan Siddiqui, MD[g]

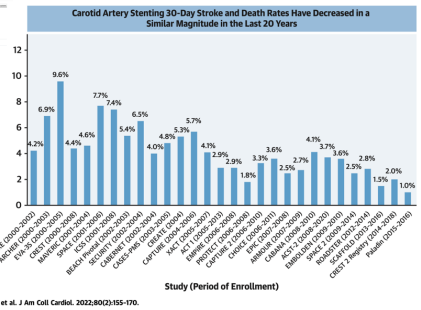
HIGHLIGHTS

- Improved patient selection, technological advances, and refined techniques have improved the results of CAS.
- Carotid stenting has achieved parity with carotid surgery for stroke prevention.
- The data support updating the national coverage decision for carotid stenting from the Centers for Medicare and Medicaid Services to equal coverage for carotid surgery.

Background

Stroke

Systematic Review of the Perioperative Risks of Stroke or Death After Carotid Angioplasty and Stenting



Study (Period of Enrollment)

White CJ, et al. J Am Coll Cardiol. 2022;80(2):155-170.

Background

Effect of the Distal-Balloon Protection System on Microembolization During Carotid Stenting

Nadim Al-Mubarak, MD; Gary S. Roubin, MD, PhD; Jiri J. Vitek, MD, PhD; Sriram S. Iyer, MD; Gishel New, MD; Martin B. Leon, MD

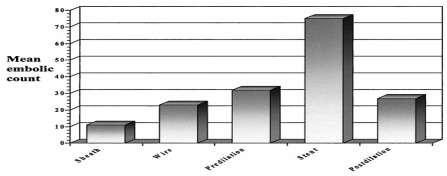


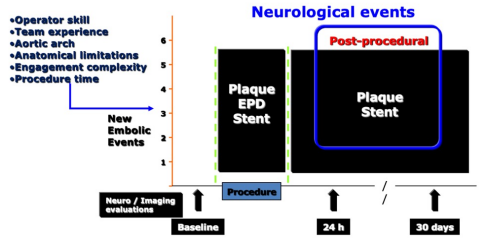
Figure 1. Microembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.

Background

Lesions in the Carotid arteries are often anatomically and morphologically very challenging

Stroke prevention by plaque coverage with a dedicated stent is mandatory.

Background



What Stent Type

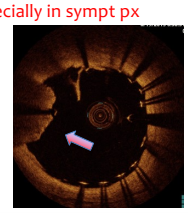
CAS can be broadly categorized into 3 designs:

- **Open Cell**
- **Closed Cell**
- **Dual layered**

What Stent Type

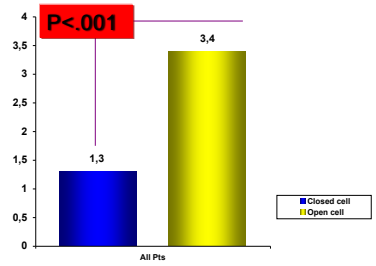
Open cell

Some studies have suggested that stent designs with higher free cell areas may result in worse outcome do to a higher risk of plaque protrusion expecially in sympt px



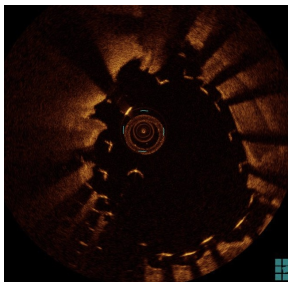
What Stent Type

- Sample 3179 Pts -



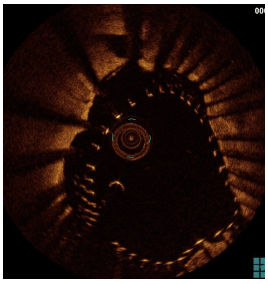
M. Bosiers, C Setacci et al *EJVES 2007*

Ideal Stent to Avoid Malapposition

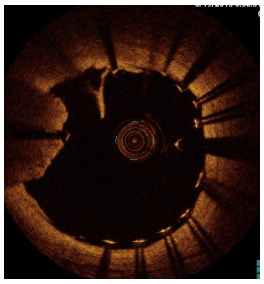


Distal not complete wall apposition

Ideal Stent to Avoid Plaque Protrusion

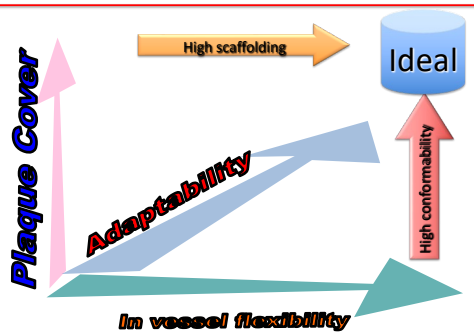


Proximal not complete wall apposition



Prolapse of plaque*dissection

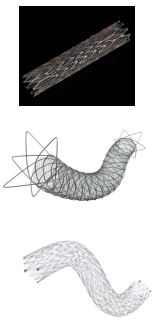
Ideal Stent



New Stents

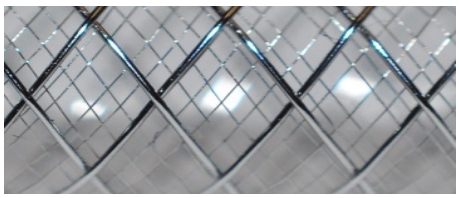
In order to reduce the risk of plaque protrusion 3 types of dual layered stents have been developed:

- Scaffold
- Roadsaver
- CGuard



The CAS New Waves

Double layered Micromesh Stent

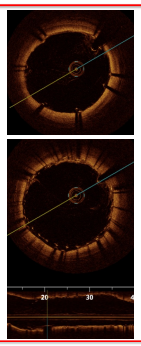


Smallest stent cell size

The CAS New Waves

Primary Attribute

- **Chronic Embolic Protection**
  - Double layer micromesh design
  - Smallest stent cell size - preventing emboli release
- **Lesion specific scaffolding**
  - Extremely high plaque coverage
  - Superior in-vessel flexibility
  - Excellent wall apposition

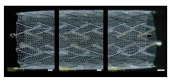


The CAS New Waves

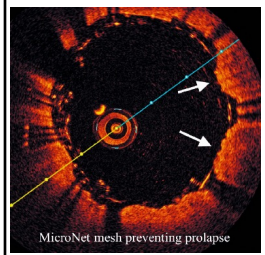
CGuard™– Carotid Embolic Prevention System

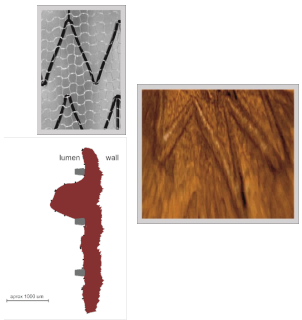
System specifications	
Stent type	Nitinol – self expanding
Micronet aperture size	150-180 µm
Guidewire	0.014"
Sizes	
- Diameter	6-10mm
- Length	20-60mm

CE Mark – March 2014



The CAS New Waves





New Stents Data

Clinical Trial > JACC Cardiovasc Interv. 2018 Dec 10;11(23):2396-2404.
doi: 10.1016/j.jcin.2018.07.040.

A First-in-Human Evaluation of a Novel Mesh-Covered Stent for Treatment of Carotid Stenosis in Patients at High Risk for Endarterectomy: 30-Day Results of the SCAFFOLD Trial

Peter A Schneider [1], Elad Levy [2], J Michael Bacharach [3], D Christopher Metzger [4], Bryan Randall [5], Andrew Garcia [5], Adnan Siddiqui [6], Claudio Schonholz [7], William Gray [8]

30-day stroke rate 2.9%

> EuroIntervention. 2018 Nov 20;14(10):1144-1146. doi: 10.4244/EIJ-D-18-00230.

Evaluation of a new dual-layer micromesh stent system for the carotid artery: 12-month results from the CLEAR-ROAD study

Marc Bosiers [1], Koen Deloose, Giovanni Torsello, Dierk Scheinert, Lieven Maene, Patrick Peeters, Stefan Müller-Hülsbeck, Horst Sievert, Ralf Langhoff, Joren Callaert, Carlo Setacci, Jeroen Wouters

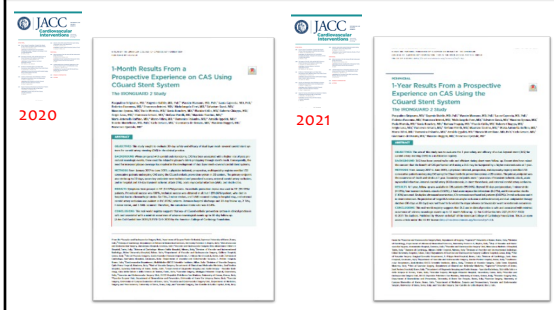
30-day MAE rate 2.1%

Multicenter Study > JACC Cardiovasc Interv. 2021 Sep 13;14(17):1917-1923.
doi: 10.1016/j.jcin.2021.05.045. Epub 2021 Aug 11.

1-Year Results From a Prospective Experience on CAS Using the CGuard Stent System: The IRONGUARD 2 Study

1-year MAE rate of 1.9%

New Stents Data



New Stents Data

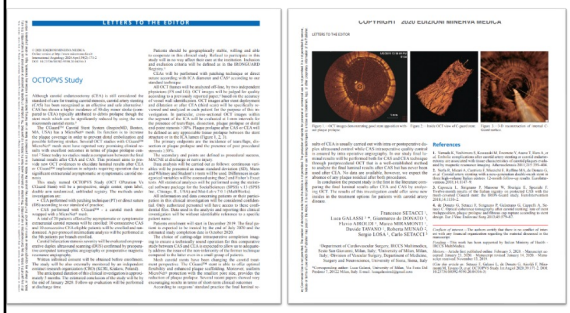
IRONGUARD 2
733 CAS Procedure
in 20 enrolling Italian Centers

	24 hours	30 days	1 year
Stroke	3; 0.41%	4; 0.54%	5; 0.68%
Death	1; 0.13%	1; 0.13%	9; 1.22%
Stroke & Death	4; 0.54%	5; 0.68%	14; 1.90%
AMI	1; 0.13%	4; 0.54%	6; 0.81%

CONCLUSIONS

The 1-year results of the IRONGUARD 2 study suggest that the use of DLS could make it possible to achieve low rates of MACE and restenosis, regardless of patients' clinical and anatomical features or the procedural techniques adopted. Undeniably, our data should be validated in a randomized trial, prospectively evaluating results with a proper control population.

CGuard OCT Control



Final Consideration

- Technical self-evidence and scientific data suggest carotid stent design impacts CAS outcomes, especially in *symptomatic patients (unstable plaque)*
- Stents may exert intrinsic anti-embolic properties
- Stent scaffolding and conformability may contribute to improve procedural results, as well as to solve the problem of post-procedural events