Consultant/Advisor
Boston Scientific
Endologix
Terumo

Why A Reinvigoration Of CAS Is Justified By Better Embolic Protection And Newer Mesh Covered Stents; OCT Proves It

Carlo Setacci
Vascular and Endovascular Surgery Siena

CAS (and CEA) are –and will remain– emboli-generating procedures

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

CAROTID ARTERY STENTING
AS AN ENDOVASCULAR ORIENTED VASCULAR SURGEON
I BELIEVE IN THE RENAISSANCE OF CAS

WHY?

LONG TERM CREST RESULTS :
RESULTS AT 4 YEAR

THE ONLY DIFFERENCE IS HERE!!
In conclusion, the long-term follow-up results of CREST did not show significant differences between carotid-artery stenting and carotid endarterectomy with respect to the primary composite end point of periprocedural stroke, myocardial infarction, or death and postprocedural ipsilateral stroke over a time period that was appropriate for elderly asymptomatic patients and symptomatic patients with severe carotid artery disease.

In conclusion, in this multicenter trial involving patients 79 years of age or younger with asymptomatic severe carotid stenosis, carotid-artery stenting was noninferior to carotid endarterectomy at 1 year with regard to the primary composite end point of death, stroke, and myocardial infarction within 30 days or ipsilateral stroke within 365 days after the procedure. The rates of stroke and survival after the procedure did not differ significantly between the two study groups over a period of 5 years.

### Should we protect the brain?

**An old, yet unsettled issue**

<table>
<thead>
<tr>
<th>30 day analysis</th>
<th>Combined stroke/death rate (%)</th>
<th>Death rate (%)</th>
<th>Major stroke (%)</th>
<th>Minor stroke (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without Distal Protection (n=2357, 26 studies)</td>
<td>5.5</td>
<td>0.8</td>
<td>1.1</td>
<td>3.7</td>
</tr>
<tr>
<td>With Distal Protection (n=839, 11 studies)</td>
<td>&gt;0.001</td>
<td>&gt;0.6</td>
<td>0.05</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

**Kastrup A.** Stroke 2003;34:813

**ESC/AHA Guidelines for diagnosis and treatment of PAD**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>The use of embolic protection devices should be considered in patients undergoing carotid artery stenting.</td>
<td>IIa</td>
<td>C</td>
</tr>
</tbody>
</table>

**AHA Guidelines.** Stroke 2011;42:e420

**ESC Guidelines.** Eur Heart J 2017

**LOE C:** consensus of opinion of the experts and/or small studies, retrospective studies, registries

#### Cerebral distal protection with filters

**Strengths & Weaknesses**

- Intuitive approach
- Easy to use (in easy cases)
- Preserve ICA flow
- Angiographic lesion control during the entire procedure
- Do not significantly prolong procedural time (in easy cases and in experienced hands)
- Wire/filter crossing of the stenosis is unimpeded
- Lack of capture of particles smaller than filter pores (<80-100 mic.’s)
- Filter suboptimal wall apposition (due to tortuous anatomy) may lead to particles passage between the filter basket and the vessel wall
- “Squeezing” of the captured material during filter withdrawal

Currently used in 80-85% of CAS procedures

#### Cerebral proximal protection

**Strengths & Weaknesses**

- Complete brain protection all the time
- Tight, soft plaques, tortuous ICA (no landing zone required)
- Any 0.014” guidewire may be used to cross the lesion
- Wire “squeezing” or “tearing” of the vessel
-Blood flow interruption
- True intolerance rate: 0.3%-0.6%
- No angiography
- The balloons may be inflated
- Potential CCA/CCA stenosis
- Potential ECA/CCA spasm/dissection
- Blood flow interruption
- True intolerance rate: 0.3%-0.6%

Currently used in 15-20% of CAS procedures

**ECA/ICA:** External Carotid Artery, Internal Carotid Artery
Proximal protection devices in CAS

Type of cerebral embolic protection in Europe: 2016/2-2017/3

Italy

Distal filter

Rest of Europe

Mo.Ma

Only prospective studies including a population cohort larger than 100 patients.

Carotid artery stenting with a new generation double-mesh stent in 3 high-volume Italian centres: 12-month follow-up results

Roberto Nerli; Antonio Micari; Fausto Castriota; Eligio Micciche; Maria Antoinetta Ruffino; Giannario de Donato; Carlo Setacci; Alberto Cremonesi;


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

Marc Bosiers; Koen Deloose; Giovanni Torsello; Dierk Scheinert; Lorne Maress; Patrick Peerers; Stefan Müller-Hulsbeck; Hans Sailer; Ralf Langhoff; Joren Callaert; Carlo Setacci; Jeroen Wauters


A total 556 patients, who underwent CAS stenting with the use of DLS, RoadSaver® (Terumo Corp, Tokyo, Japan) or CGuard® (InspireMD, Boston, USA), were included in the study.

Incidence of adverse events at 30 days (%)

<table>
<thead>
<tr>
<th>Event</th>
<th>Incidence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Hospital</td>
<td></td>
</tr>
<tr>
<td>Major Stroke</td>
<td>1.09%</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>0.57%</td>
</tr>
<tr>
<td>Death</td>
<td>0%</td>
</tr>
<tr>
<td>Dis+</td>
<td>1.29%</td>
</tr>
<tr>
<td>Discharge to 30 Days</td>
<td></td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0%</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>0%</td>
</tr>
<tr>
<td>Death</td>
<td>0%</td>
</tr>
<tr>
<td>Events at 30 Days</td>
<td></td>
</tr>
<tr>
<td>Major Stroke</td>
<td>0%</td>
</tr>
<tr>
<td>Minor Stroke</td>
<td>0%</td>
</tr>
<tr>
<td>Death</td>
<td>0%</td>
</tr>
</tbody>
</table>

Stabile et al. JACC Cardiovasc Int 2018
**Safety and Feasibility of Intravascular Optical Coherence Tomography Using a Nonocclusive Technique to Evaluate Carotid Plaques Before and After Stent Deployment**

Carlo Setacci, MD; Giovanni de Donato, MD; Francesco Setacci, MD; Giuseppe Galvano, MD; Pasquale Stigliano, MD; Alessandro Cappelli, MD; and Giuneta Pulcinella, MD

Department of Surgery, Vascular and Endovascular Surgery Unit, University of Siena, Italy.

**Conclusions:** Intravascular OCT during a nonocclusive flush appears to be feasible and safe in carotid arteries.

---

**IMPACT OF NEW STENT DESIGN**

**Why do I use OCT in carotids?**

**UTILITY - results**

1. High definition of carotid plaque
2. Interaction between plaque & stent

---

**OCT in carotids – new frontiers**

1. High definition of carotid plaque
   - Plaque type
   - Degree of stenosis
   - Area of stenosis
   - Fibrous cap integrity
   - Rupture of fibrous cap
   - Ulceration

---

**OCT in carotids – new frontiers**

1. High definition of carotid plaque
   - Plaque type
   - Degree of stenosis
   - Area of stenosis
   - Fibrous cap integrity
   - Rupture of fibrous cap
   - Ulceration

---

** utility**

- Attenuation & backscattering of infrared signals
OCT in carotids – new frontiers

1. High definition of carotid plaque
   - Plaque type
   - Degree of stenosis
   - Area of stenosis
   - Fibrous cap integrity
   - Rupture of fibrous cap
   - Ulceration
   - Thrombus

Why do I use OCT in carotids?

UTILITY - results

1. High definition of carotid plaque
2. Interaction between plaque & stent

OCT in carotids – new frontiers

2. Interaction between plaque & stent
   Intraop control:
   - Residual stenosis
   - Stent apposition
   - Stent malapposition
   - Cell area modification
   - Fibrous cap rupture
   - Plaque micro-prolaps
   - Branch side coverage

Follow-up control:
- neointimal thickness
- complete/incomplete stent struts coverage

OCT in carotids – new frontiers

2. Interaction between plaque & stent
   Intraop control:
   - Residual stenosis
   - Stent apposition
   - Stent malapposition
   - Cell area modification
   - Fibrous cap rupture
   - Plaque micro-prolaps
   - Branch side coverage

Follow-up control:
- neointimal thickness
- complete/incomplete stent struts coverage
OCT in carotids – new frontiers

2. Interaction between plaque & stent

**Intraop control:**
- Residual stenosis
- Stent apposition
- Stent malapposition
- Cell area modification
- Fibrous cap rupture
- Plaque micro-prolaps
- Branch side coverage

**Follow-up control:**
- Neointimal thickness
- Complete/incomplete stent struts coverage

**Outcomes**

- No procedural neurological complications occurred (TIA/stroke/death 0% at 30 days).
- Slice-based analysis
- Compared with conventional stents, the incidence of plaque prolapse was lower.

**Conclusions**

- Better Embolic Protection
- Newer Mesh Covered Stents

Definitively, OCT Proves It!