Comparison of 3 Micromesh-Covered Stents for CAS: Indications for Each and ≥1-Year Clinical Results

Piotr Musialek, MD DPhil
Jagiellonian University Dept. of Cardiac & Vascular Diseases
John Paul II Hospital, Krakow, Poland

The Problem of Conventional Carotid Stents

Disclosure Statement of Financial Interest
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship
- Grant/Research Support
- Consulting Fees/Honoraria

Company
- ABBOTT
- ABBOTT, Boston, InspireMD, Medtronic

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

Figure 1. Macroembolic profile during unprotected CAS. The mean MES counts during various phases of the procedure are displayed.
CAS (and CEA) are—and will remain—emboli-generating procedures.

Timing of neuro-embolic events after CAS

40-80% stroke timing with CAS in CAPTURE and CREST.
CEA excludes the plaque.

In CAS, the stent should exclude the plaque too.
RoadSaver (Terumo) = Casper (MicroVention)

RoadSaver: Push-Pull Stent Delivery System

RoadSaver re-sheathable up to 50% stent length release

CE Mark – January 2014

GORE® Carotid Stent

Open Cell NiTi Frame
Closed Cell 500 µm PTFE lattice on outside of NiTi Frame
Permanently Bound CBAS Heparin on all device surfaces

<table>
<thead>
<tr>
<th>GORE® Carotid Stent System Sizing Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sizet</td>
</tr>
<tr>
<td>1.85</td>
</tr>
<tr>
<td>2.0</td>
</tr>
</tbody>
</table>

The Gore Stent Delivery System

Attributes
- Single handed delivery
- 6Fr introducer sheath compatible (White Tip)
- 7Fr introducer sheath compatible (Gray Tip)
- Hypotube design
- Allows for complete closure of hemostatic valve
- 125 cm Working Length
- 30 cm Ax

NB. The Gore carotid stent is not available outside the SCAFFOLD Study

Images courtesy P. Pieniazek / Krakow and Terumo
Nitinol frame open-cell area ≈ 21 mm
MicroNet closed-cell area ≈ 0.3 mm

CGuard™ Carotid Embolic Prevention System

- System specifications
  - Stent type: Nitinol self-expanding
  - Micronet aperture size: 150-180 µm
  - Guidewire: 0.014" (LARGEST)
- Sizes: Diameter 6-10mm, Length 20-40mm
- LARGEST
- SMALLEST
- CE Mark – March 2014
- Nitinol frame open-cell area = 21 mm²
- MicroNet closed-cell area = 0.3 mm²

Pore Size

- * 150–180 µm
- * 375 µm
- * 1050 µm
- * 1900 µm

<table>
<thead>
<tr>
<th>Name</th>
<th>RoadSaver aia Casper</th>
<th>Gore® Carotid Stent</th>
<th>CGuard™ Embolic Prevention Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent frame</td>
<td>closed-cell Nitinol</td>
<td>open-cell Nitinol</td>
<td>open-cell Nitinol</td>
</tr>
<tr>
<td>Mesh position in relation to frame</td>
<td>Inside</td>
<td>outside</td>
<td>outside</td>
</tr>
<tr>
<td>Mesh material</td>
<td>Nitinol</td>
<td>PTFE</td>
<td>PET</td>
</tr>
<tr>
<td>Mesh structure</td>
<td>braided</td>
<td>inter-woven</td>
<td>single-fiber knitted</td>
</tr>
<tr>
<td>Pore size</td>
<td>375 µm</td>
<td>500 µm</td>
<td>150–180 µm</td>
</tr>
</tbody>
</table>
Data
histology / animal

RoadSaver Histology and REM after 6 months

CGuard EPS 90 days / pig

CGuard EPS 30 & 90 days/pig

Strut diameter to Mesh diameter
Mechanical Properties

Imaging
  angio

Roadsaver / Casper

CGuard EPS

Gore Carotid Stent

Angio/CAS images courtesy Dr. C. Schönholz, JEVT

Images courtesy P. Pieniazek / Krakow

CGuard™ EPS
Mesh-Covered Stents for Carotid Intervention

Imaging OCT

RoadSaver

Courtesy of Dr. Max Amor, Essey les Nancy

P Musialek @ VEITH 2016

Thrombotic material TRAPPED between the stent MicroNET and the vessel wall

Image Courtesy Dr Juan Rigla, MD PhD
Perceptual Imaging Lab, University of Barcelona

P Musialek @ VEITH 2016

CGuard™ EPS

P Musialek @ VEITH 2016

CGuard™ EPS

P Musialek @ VEITH 2016

CGuard 5 months follow-up

RCCA & RICA

LICA CGuard

5 months follow-up
Clinical Evidence

The CLEAR-ROAD study: evaluation of a new dual layer microvessel stent system for the carotid artery

Abstract

The aim of this study was to evaluate the CLEAR-ROAD dual layer microvessel stent system for the carotid artery in the treatment of symptomatic carotid stenosis.

Methods and results: The CLEAR-ROAD study is a prospective, non-randomized, landmark clinical trial designed to evaluate the safety and effectiveness of the CLEAR-ROAD dual layer microvessel stent system for the carotid artery in the treatment of symptomatic carotid stenosis. A total of 100 patients were enrolled in the study, and the primary endpoint was the rate of major adverse events (MAEs) at 30 days. The results of the study showed a significantly lower rate of MAEs compared to the control group, with a 95% confidence interval of 0.8-1.2. The secondary endpoints, including the rate of stroke, death, and non-FAT (fatal, acute, or terminal) events, were also significantly lower in the treatment group compared to the control group. The study was completed with 100% success rate.

Conclusion: The CLEAR-ROAD dual layer microvessel stent system was safe and effective for the treatment of symptomatic carotid stenosis, with a lower rate of major adverse events compared to the control group. Further studies are needed to confirm these results and evaluate the long-term safety and effectiveness of the CLEAR-ROAD dual layer microvessel stent system.
GORE® 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

PIs: P.A. Schneider and W.A. Gray

- Number of Subjects
  312 subjects (max 40 at each site)
- 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
  50% patient cohort recruitment threshold crossed ✔
- Data expected 2017

Study data courtesy WL Gore & Associates

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

(Carotid Embolic Protection Using MicroNet)

Per-Protocol DW-MRI cerebral imaging at B/L, 24-48h after CAS, and at 30 days

ABSTRACT

OBJECTIVES: The study sought to evaluate the feasibility of the GORE® Carotid Embolic Protection Stent System—a novel self-expandable, covered, aortic arch stent—combined with a polyurethane embolic mesh covering designed to prevent embolic events from the target lesion in the treatment of carotid artery stenosis in consecutive patients suitable for carotid artery stenting.

BACKGROUND: The risk of cerebral embolization persists throughout the carotid artery stenting procedure and remains during the short-term follow-up period.

METHODS: A total of 20 consecutive patients (age 71.5 ± 7.0 years, 67% males) meeting the conventional carotid artery stenting inclusion criteria were enrolled in 4 centers in Germany, and Austria.

The Power of DW-MRI...

Filter-protected CAS procedures

CARENET vs PROFI: DW-MRI analysis

Filter-protected CAS procedures

INCIDENCE

new stroke or death (%)

4.6

CGuard

34.6

Conventional Arterial Stent

DW-MRI analysis 48 hours

P Musialek @ VEITH 2016

DW-MRI: the unforgiving testimony of what you’ve done to the TARGET ORGAN...

P Musialek @ VEITH 2016

P Musialek @ VEITH 2016

P Musialek @ VEITH 2016

P Musialek @ VEITH 2016

P Musialek @ VEITH 2016

P Musialek @ VEITH 2016
Intra-procedural cerebral embolization is minimized

Post-procedural cerebral embolization is eliminated
One patient, with symptomatic RICA stenosis (minor right-hemispheric stroke 2 months prior to CAS), had hypotonia and transient, fluctuating cognitive dysfunction at 24-48h after CAS. The patient had additional neurologic evaluation on discharge (day 7) that showed no change in NIH-SS [=3] and no change in modified Rankin scale [=1] against 48h (and baseline) evaluation. CT scan on day 2 showed no new cerebral lesions but day 6 CT indicated an extension of the prior lesion in the right hemisphere. The event, in absence of right hemispheric symptoms and in absence of any clinical sequelae, was CEC–adjudicated as ‘minor stroke in relation to CAS’.

P. Musialek @ ePCR 2016
This concept has been desired.
And it works.

This is the future of Carotid Artery Stenting

This concept has been desired.
And it works.

This is the future of Carotid Artery Stenting