Update On Results With The CGuard™ MicroNet
Covered Stent (InspireMD) For CAS:
Does It Prevent Strokes:
Does It Cause ISR Or Other Long-Term Problems:
Can It Have Value In Other Vascular Beds?

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OPINIONS
matter
(ASSUMPTIONS – less so)

but what is critical to the decision-making Physician...

FACT #1
ZERO evidence
that OMT is sufficient to prevent strokes

As per the Disclosure Statement of Financial Interest:

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tbody>
<tr>
<td>Grant/Research Support</td>
<td>ABBOTT</td>
</tr>
<tr>
<td>Consulting Fees/Honoraria</td>
<td>ABBOTT, Boston, InspireMD, Medtronic</td>
</tr>
</tbody>
</table>

HYPOTHESES
may be interesting
**FACT #1**

**ZERO evidence** that OMT is sufficient to prevent strokes

*We CONTINUE to receive patients with SYMPTOMS (incl. Strokes) DESPITE OMT*

**FACT #2**

Assumptions are not powered to dismiss

Large-scale level 1 evidence (ACST, >3100 pts)

"Systematic Review and Analysis" ...

where is ACST？(n=3120)

| Study          | Sample Size | Baseline Stroke Rate | Baseline Stroke Rate% | Any-Term Brush | Any-Term Stroke | Any-Term Death | All-Comers | Any-Term Death | Any-Term Death
<table>
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Stroke reduction with carotid stenosis revascularization

*A. Halliday et al. (10-year ACST data) Lancet 2010*

**FACT #2**

If someone wants to dismiss it, they need to show new (different) level 1 evidence!
FACT #3 Conventional Carotid Stents Do Have A Problem

Human carotid artery treated using a conventional stent, OCT

FACT #4 • CEA excludes the plaque

• In CAS, the stent should exclude the plaque too

FACT #5 The CGuard™ MicroNet-Covered Embolic Prevention Stent System

is effective in reducing peri- and post-procedural cerebral embolism

(Routine DW-MRI data in CARENET; results reproduced by 2+ other studies)
CARENET DW-MRI analysis

All but one peri-procedural ipsilateral lesions

RESOLVED

DW-MRI analysis @ 30 days

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
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<tr>
<td>Incidence of new ipsilateral lesions</td>
<td>1</td>
</tr>
<tr>
<td>Average lesion volume (cm³)</td>
<td>0.08 ± 0.00</td>
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<tr>
<td>Permanent lesions at 30 days</td>
<td>1</td>
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*Internal/external analysis (DK)

FACT #6

Also, CGuard™ enables routine Endovascular Reconstruction of the Carotid Bifurcation (systematic CEA-like effect of CGuard™ CAS)
FACT #7

Procedural risk level

(vs. the disease natural history risk)

is critical for physician decision-making

"Asymptomatic" Carotid Stenosis
Decision-making

PHARMACOTHERAPY + INERVENCIÓN

? ISOLATED PHARMACOTHERAPY

"People" with Carotid Stenosis

Vascular Clinic Referral Patient ≠ General Population Subject

annual ipsilateral stroke risk 2.5-3.0%

annual ipsilateral stroke risk =0.5%
**FACT #8**

CGuard™ - CAS can achieve peri-procedural and 30-day complication rate at the level of ≈1% - not only in "selected" patients but also in All-comers.

**The PARADIGM Study**

**Objective**
- to evaluate feasibility and outcome of routine anti-embolic stent system use in unselected consecutive patients referred for carotid revascularization ('all-comer' study).

**CIRCADIAN FIBRILLATION**

Evaluates ischemic stroke risk in patients with atrial fibrillation.

<table>
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<tr>
<th>CHADS² Points</th>
<th>CHA²DS²-VASc Points</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
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</tbody>
</table>

**Results**

- **Total CHADS² Points**
- **Total CHA²DS²-VASc Points**

**PARADIGM**

Methods (cont’d):
- **ASYMPTOMATIC** patients treated interventionally only if at stroke risk
- established lesion-level increased-risk criteria used:
  - thrombus-containing
  - documented progressive
  - irregular and/or ulcerated
  - contralateral ICA occlusion/stroke
  - asymptomatic ipsilateral brain infarct

**Evidence**

**10+ studies**
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’.

Evidence is accumulating that CGuard™ accompanied by OMT (that is ALWAYS the fundament) shows effective stroke prevention throughout 3 years in absence of device-related issues.
The Outcome Difference
Between the MicroNet-Covered Stent
Vs.
Conventional Carotid Stent(s)
is driven
by HIGH-RISK
Plaques and Patients

Flow reversal time 7min 10sec
Intolerance in the last 80sec
(active aspiration still performed)

Patient A/S, discharged home, unremarkable follow-up
Normal stent image
Normal velocities ECA patent
FACT #10

There is more than that...

CGuard™ MicroNet Covered Stent:

ADDRESSING UNMET NEEDS IN OTHER VASCULAR BEDS

Moving beyond routine CAS...

Thrombus-containing/high-embolic risk lesions in iliacs or subclavians

Optimal procedural result Normal 6mo follow-up

Thrombus-containing/high-embolic risk lesions in iliacs or subclavians

Procedural result LSA Normal 6mo follow-up
Thrombus-containing/high-embolic risk lesions in iliacs or subclavians

Thrombus-containing/high-embolic risk lesions in iliacs or subclavians and

Large-diameter SVG disease problem

Large-diameter SVG disease problem
Large-diameter SVG disease / NSTE-acute MI
post PCI/direct stenting with overlapping MicroNet-covered CGuard™ stents

OPTIMAL acute result

Large-diameter SVG disease treated with CGuards (angio @3mo)

OPTIMAL result @ 3mo

Large-diameter SVG disease treated with CGuards (CT-angio @6mo)

OPTIMAL result @ 6mo

(V) Highly calcific disease
(note: adequate radial force need)

(V) Highly calcific disease
(note: adequate radial force provided)

OPTIMAL result @ 6mo
Neo-Atherosclerosis In A Conventional LSA Stent: Treated With CGuard™ under IVUS

Conventional Carotid Stent Design Allows Atherosclerotic Plaque In-Growth (ie., Neo-Atherosclerosis)

Atherosclerotic Plaque Growth Into The Open-Cell Stent Lumen Treated with Neropro|ected PTA Under IVUS – and CGuard™

Atherosclerotic Plaque Growth Into The Open-Cell Stent Lumen Treated with Neropro|ected PTA Under IVUS – and CGuard™

CGuard™ For Symptomatic In-stent Neotherosclerosis: 2-year follow-up

Aneurysm/Dissection with recurrent symptoms

Immediate Post-Procedural Result
Aneurysm/Dissection with recurrent symptoms

Totally SEALED @ 24h

Aneurysm/Dissection with recurrent symptoms

Normal Follow-up @ 6 months

Aneurysm/Dissection with recurrent symptoms

Immediate SEALING

Aneurysm/Dissection with recurrent symptoms

Normal Result @ 6 mo
(Patient Asympt.)

Non-Healing Dissection with recurrent symptoms

Immediately SEALED

Non-Healing Dissection with recurrent symptoms

Normal 12 mo Follow-up Result
Ostial CCA lesions (note adequate radial force and placement precision need)

Retrograde Cannulation from the neck
(to wire and predilate the subtotal ostial LCCA; NB. failed access from the arch)

LCCA

Retrograde Cannula removed following tranfemoral wire passing with success to the ostial LCCA from the top

Lady 68 yo, retinal TIAs followed by retinal stroke while on OMT (mother to cathlab nurse)

LCCA

Ao

Ostial CCA lesions (note adequate radial force and placement precision)

OPTIMAL angiographic + clinical + duplex result @ 12mo (and LECA patent)

Ostial CCA lesions

2 overlapping cGuards

cGuard™

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This concept has been desired.
And it works.

This is the future of Carotid Artery Stenting
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