Carotid Artery Stenting - Latest Technology

Ralf Langhoff, MD
Vascular Center Sankt Gertrauden
Berlin
Charité, CC11
Academic Teaching Hospitals — Charité
What Would Be a Gamechanger in CAS Procedures for You?

...if you could add safety?
...if you could add safety by don’t change your strategy?
...if you don’t have to consider on device choice?
...if you could reduce procedural steps to a minimum?
...if you reduce procedural time?
While CAS Results Are Steadily Improving

30 Day Death/Stroke/MI

References available for individual study results
Prospective multi-center studies with >100 patients
MINOR STROKE DURING CAS: REMAINS AN UNSOLVED ISSUE

30-DAY RISK OF MINOR STROKE
CEA vs CAS

ACT 1
SAPPHIRE
CREST
EVA 3S

CAS (%)
CEA (%)
The Solution: Paladin

✓ The first device that combines an embolic protection filter and balloon/stent

✓ 40 micron pore size allows micro-embolic capture

✓ Filter size can be adjusted to suit each patient’s unique anatomy

✓ The Post-Dilation Solution for EVERY Carotid Stent Procedure

Integrated Filter:
- 40 Micron pores
- Baseline closed
- Sheathless
Clinical Data: Comparison of Paladin With Other Carotid Studies

Paladin demonstrates lowest stroke rates compared to other CAS studies*

Paladin Study:
- 106 patients
- No procedural stroke
- 1 unrelated stroke

30-Day Death, Stroke or MI

ESC Guidelines on the diagnosis and treatment of peripheral artery disease, 2011 Paladin results, 2016 study
*Prospective multi-center studies with >100 patients
Incidence and Size of New Lesions on MRI Were Significantly Lower Than Other Technologies

<table>
<thead>
<tr>
<th>Comparative DW-MRI Results</th>
<th>Paladin (n=33)</th>
<th>PROFI¹ Proximal group (n=31)</th>
<th>PROFI¹ Filter group (n=31)</th>
<th>ICSS² Filter group (n=37)</th>
<th>CARENET³ CGuard (n=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence of New Lesions</td>
<td>21.2%</td>
<td>45%</td>
<td>87%</td>
<td>73%</td>
<td>48%</td>
</tr>
<tr>
<td>Mean number of lesions per pt.</td>
<td>0.24</td>
<td>1.0 +/- 1.4</td>
<td>3.6 +/- 3.2</td>
<td>NA</td>
<td>0.05</td>
</tr>
<tr>
<td>Mean Lesion Volume (cm³)</td>
<td>0.005</td>
<td>0.16</td>
<td>0.59</td>
<td>NA</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Data courtesy Joachim Schofer MD et al.

Filter Histological Analysis:
Particle Size

Majority Of Particles Captured Were <100 Microns
Filter Histological Analysis:
Major Points

- >90% of particles captured were less than 100 microns in size
- These are **NOT** captured by current filters, but **ARE** captured by PALADIN
- Consistent with MRI findings
Paladin
Clinical Experience

>1600 Cases With No Reported Strokes to Date
NeuroVascular Devices

Paladin®
Making every Carotid Artery Stenting procedure safer

2 in 1: PTA balloon + IEP
- Targeting All CAS Cases
- >1100 Cases Done with no reported strokes

Approval Timing:
- CE Mark: ✔
- US 510(k): ✔

Neuroguard®
End-to-end solution for Carotid Artery Stenting

3 in 1: Stent + PTA balloon + IEP
- Poised to capture a significant portion of the CAS market worldwide

Approval Timing:
- CE Mark: 1Q 2019
- US PMA: 2021
How can we further improve the carotid stenting procedure?

• Stent deployment in most current procedures is still protected by a distal filter which may not be well opposed to the vessel wall and has > 100 micron pores

• The number of steps in CAS is >10

• Number of steps increases risk of procedure
Steps of Carotid Stenting

1. Vascular Access (femoral - brachial)
2. Angiographic evaluation
3. Guiding Sheath Placement
4. Crossing the Stenosis
   - without protection
   - with distal protection
   - with proximal protection
5. Lesion Predilatation
6. Removing the Balloon
7. Advancing the Stent
8. Stent Deployment
9. Removing the SDS
10. Advancing Postdilation Balloon
11. Removing Postdilation Balloon
12. Advancing the Filter Retrieval Catheter
13. Removal of Protection Device
14. Final Angiographic Control
15. Sheath removal/ Access Care

10 times crossing of the lesion

This can be reduced to 3 steps with Neuroguard IEP
Neuroguard
Neuroguard IEP
3-in-1 Carotid Stent and Post-Dilation Balloon System
Neuroguard Stent

Stent Lengths (30, 40 mm)
Mid Stent OD (6, 7 mm)
Neuroguard Stent – Apposition / Flexibility

Abbott Xact Stent

Neuroguard

Neuroguard Flexibility
# Neuroguard IEP Carotid Stent

## Stent Free Cell Area

<table>
<thead>
<tr>
<th>Stent Type</th>
<th>Stent Design</th>
<th>Free Cell Area (mm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wallstent</td>
<td>Closed cell</td>
<td>1.08</td>
</tr>
<tr>
<td>Xact</td>
<td>Closed cell</td>
<td>2.74</td>
</tr>
<tr>
<td><strong>Neuroguard</strong></td>
<td><strong>Closed cell</strong></td>
<td><strong>3.5</strong></td>
</tr>
<tr>
<td>Nexstent</td>
<td>Closed cell</td>
<td>4.7</td>
</tr>
<tr>
<td>Precise</td>
<td>Open cell</td>
<td>5.89</td>
</tr>
<tr>
<td>Protégé</td>
<td>Open cell</td>
<td>20.71</td>
</tr>
<tr>
<td>Acculink</td>
<td>Open cell</td>
<td>11.48</td>
</tr>
</tbody>
</table>
**PERFORMANCE I**

Protection against Emboli during carotid stenting using a 3-in-1 delivery system comprising a Post-dilation balloon, intregated Embolic filter and Novel Carotid stEnt I

The primary endpoint is the 30-day rate of MAE, defined as the cumulative incidence of any periprocedural (≤ 30 days post-procedure) death, stroke or MI.

<table>
<thead>
<tr>
<th>Country</th>
<th>Principal Investigator</th>
<th>Hospital</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>Ivo Petrov, MD</td>
<td>Acibadem City Clinic, Sofia</td>
<td>23 patients</td>
</tr>
<tr>
<td>Italy</td>
<td>Alberto Cremonesi, MD (Coordinating PI)</td>
<td>Maria Cecilia Hospital, Cotignola</td>
<td>2 patients</td>
</tr>
<tr>
<td>Italy</td>
<td>Eugenio Stabile, MD</td>
<td>University of Naples Frederico II, Naples</td>
<td>5 patients</td>
</tr>
<tr>
<td>Germany</td>
<td>Dierk Scheinert, MD</td>
<td>Universitätssklinikum Leipzig, Leipzig</td>
<td>2 patients</td>
</tr>
<tr>
<td>Germany</td>
<td>Ralf Langhoff, MD</td>
<td>Sankt Gertrauden Krankenhaus, Berlin</td>
<td>6 patients</td>
</tr>
<tr>
<td>Germany</td>
<td>Joachim Schofer, MD</td>
<td>Medizinische Versorgungszentrum, Hamburg</td>
<td>1 patient</td>
</tr>
<tr>
<td>Germany</td>
<td>Horst Sievert, MD</td>
<td>Sankt Kathariene Krankenhaus, Frankfurt</td>
<td>3 patients</td>
</tr>
<tr>
<td>Macedonia</td>
<td>Sasko Kedev, MD</td>
<td>University Clinic of Cardiology, Skopje</td>
<td>12 patients</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Zoran Milosevic, MD</td>
<td>MC Medicor, Izola</td>
<td>5 patients</td>
</tr>
<tr>
<td></td>
<td><strong>Total Patients enrolled</strong></td>
<td></td>
<td><strong>59 Patients</strong></td>
</tr>
</tbody>
</table>

*51 patients have completed 30 day follow up
*13 patients have completed 6 month follow up
To Conclude:

- Minor stroke remains the ‘Achillles Heel’ during CAS
- The use of the Paladin System for post-dilation during CAS resulted in no procedural strokes and adds safety to our patients
- Hypothetically the use of Neuroguard IEP adds additional safety due to less procedural steps and a very unique, closed cell, flexible Nitinol stent integrating the Paladin System
- The Neuroguard IEP has the potential to become a gamechanger
Thank You!

Dr. Ralf Langhoff
Vascular Center Sankt Gertrauden
Berlin
Sankt Gertrauden-Hospital
Charité, CC11
Academ. Teaching Hospital of Charité-University Berlin
Carotid Artery Stenting - Latest Technology

Ralf Langhoff, MD
Vascular Center Sankt Gertrauden
Berlin
Charité, CC11
Academic Teaching Hospitals — Charité