Carotid Stents and Embolic Protection Systems: Differentiating the Devices

Joachim Schofer
Hamburg University Cardiovascular Center
Prof. Mathey, Prof. Schofer & Partners
Hamburg, Germany
Disclosure Statement of Financial Interest

I, Joachim Schofer, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.
Carotid Stents

Self-expanding

Braided mesh wire (Super Alloy)

Nitinol (Nickel-Titanium)

Open-cell design

Closed-cell design
Carotid Stents
Braided Mesh Wire (Super Alloy)

- Super-alloy wires braided to a tubular mesh
- Braided to different diameters
- Spring-like expansion
- “Closed cell”-like

e.g. Carotid Wallstent (Boston Scientific)
Carotid Stent Designs
Nitinol Stents

Open-cell design
Closed-cell design
Carotid Stents
Varying-Size Closed-Cell Design

- e.g., Xact Stent (Abbott), Cristallo (Invatec)

Central: smaller cells: increased coverage

Edges: larger cells: increased flexibility
Carotid Stents
(Random Selection)

Wallstent (BSCI)

NexStent (Endotex)

Precise (Cordis)

Acculink (Guidant)

Cristallo Ideale (Invatec)

Xact (Abbott)

Protégé (ev3)
Embolic Protection Systems

- Distal balloon-occlusive systems
- Distal filter systems
- Proximal balloon-occlusive (flow-blockage) systems
EPDs (Random Selection)

GuardWire (Medtronic)

Angioguard (Cordis)

FilterWire (Boston Scientific)

SpiderFX (ev3)

Emboshield BW (Abbott)

Accunet (Guidant)

Mo.Ma (Invatec)
Is there evidence that carotid stent design impacts the 30-day stroke/death rate?
The Belgian-Italian CAS Study

- Retrospective analysis of **3179 patients**
  - Symptomatic
  - Asymptomatic
  - EPD use
    - Filters (n=8)
    - Proximal balloon (1)
    - Distal balloon (1)

<table>
<thead>
<tr>
<th>Closed-Cell Stents</th>
<th>n = 2242 (70.5%)</th>
<th>Open-Cell Stents</th>
<th>n = 937 (29.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wallstent (BSCI)</td>
<td>[n=2107]</td>
<td>Acculink (Abbott)</td>
<td>[n=409]</td>
</tr>
<tr>
<td>Xact (Abbott)</td>
<td>[n=105]</td>
<td>Precise (Cordis)</td>
<td>[n=293]</td>
</tr>
<tr>
<td>NexStent (Endotex)</td>
<td>[n=30]</td>
<td>Protégé (ev3)</td>
<td>[n=201]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exponent (Medtronic)</td>
<td>[n=34]</td>
</tr>
</tbody>
</table>

→ Marked imbalance in numbers of stents used

Bosiers M et al., Eur J Vasc Endovasc Surg 2007
The Belgian-Italian CAS Study

- Retrospective analysis of 3179 patients
  - Endpoint: 30-day TIA, stroke, and death
    - TIA = immediate resolution of symptoms
    - Minor stroke = symptoms persisting < 24 h
    - Major stroke = symptoms persisting ≥ 24 h
  - Results: Significant differences between Wallstent and Acculink

- No difference between stents in asymptomatic patients

Bosiers M et al., Eur J Vasc Endovasc Surg 2007
Definition of Neurological Endpoints

- **TIA**
  - New neurological deficit that resolved completely within 24 hours

- **Minor stroke**
  - New neurological deficit that resolved completely $\leq 30$ days or increased the NIH Stroke Scale by $\leq 3$

- **Major stroke**
  - New neurological deficit that persisted for more than 30 days and increased the NIH Stroke Scale by $\geq 4$

Despite different existing definitions of stroke, all agree on the fact that symptoms must last for $>24$ hours.
The Belgian-Italian CAS Study

- Retrospective analysis of 3,179 patients
- 30-day stroke (as defined by the authors)/death rates

Adapted from Table 3 of Bosiers M et al., *Eur J Vasc Endovasc Surg* 2007
The Belgian-Italian CAS Study

- Retrospective analysis of 3,179 patients
- 30-day stroke (as defined by the authors)/death rates

Difference: 0.3% (95% CI -0.5% to 1.4%, \( P=0.495 \))

Adapted from Table 3 of Bosiers M et al., *Eur J Vasc Endovasc Surg* 2007
Recent CAS Registries

- **30-day** all strokes and deaths

![Bar chart showing 30-day all strokes and deaths in various registries.]

Is there evidence that **EPD design** impacts the 30-day stroke/death rate?
No!
Periprocedural Complications of CAS

- The 30-day stroke/death rate after CAS is most likely a multifactorial process affected by
  - **Patient** characteristics
  - **Lesion** and **vessel** characteristics
  - **Procedure** characteristics
  - **Possibly stent** design
  - **Possibly EPD** design

- **MANY patients** and **logistic regression** techniques needed to assess predictive factors
The Italian-German CAS Registry

- Italian/German registry for routine use of cerebral protection during CAS:
  - ITALY: Cotignola, Milan (2 centers), Mirano
  - GERMANY: Hamburg

695 patients/754 procedures

Diabetics
160 pts/177 proc
- Stents \( n = 9 \) (72% Wallstent)
- EPDs \( n = 8 \) (79% filters)

Nondiabetics
535 pts/577 proc

TCT2007
Objective:
To assess the impact of
- symptomatic lesion status
- gender
- age
- diabetes

on the **30-day stroke/death rate**

Methods:

*Post hoc* univariate and multivariate analyses
The Italian-German CAS Registry

- 30-Day Incidence of **Any Stroke** or Death: Impact of **Diabetes** and **Age**

![Bar chart showing 30-Day Incidence of Any Stroke or Death: Impact of Diabetes and Age](image)

Schlüter M et al., *J Endovasc Ther* 2007
### The Italian-German CAS Registry

- **30-day incidence of any stroke or death**

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>2.1</td>
<td>1.0 – 4.8</td>
<td>0.068</td>
</tr>
<tr>
<td>Age (1-year increase)</td>
<td>1.06</td>
<td>1.01 – 1.12</td>
<td>0.031</td>
</tr>
<tr>
<td>Diabetes and age &lt;75 years</td>
<td>1.1</td>
<td>0.3 – 3.6</td>
<td>1.000</td>
</tr>
<tr>
<td>Diabetes and age ≥75 years</td>
<td>4.3</td>
<td>1.3 – 12.3</td>
<td>0.016</td>
</tr>
</tbody>
</table>

- **No impact** of gender

Schlüter M et al., *J Endovasc Ther* 2007
The Italian-German CAS Registry

- 30-day incidence of **major** stroke or death

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>5.9</td>
<td>1.6 – 21.8</td>
<td>0.007</td>
</tr>
<tr>
<td>Age (1-year increase)</td>
<td>1.13</td>
<td>1.02 – 1.25</td>
<td>0.018</td>
</tr>
<tr>
<td>Diabetes and age &lt;75 years</td>
<td>2.4</td>
<td>0.2 – 17.1</td>
<td>0.557</td>
</tr>
<tr>
<td>Diabetes and age ≥75 years</td>
<td>12.0</td>
<td>2.1 – 66.5</td>
<td>0.005</td>
</tr>
</tbody>
</table>

- **No impact** of gender

Schlüter M et al., *J Endovasc Ther* 2007
Periprocedural Complications of CAS

The patient matters!
Protected CAS in Hamburg

- 1/15/1999 to 8/21/2007

569 patients
631 procedures

30-day stroke/death rate:
15/569 = 2.6%
[95% CI 1.5% - 4.3%]

Device Studies:

86 patients
92 procedures

30-day stroke/death rate:
5/86 = 5.8%
[95% CI 1.9% - 13.1%]

Routine:

483 patients
539 procedures

30-day stroke/death rate:
10/483 = 2.1%
[95% CI 1.0% - 3.8%]

*P = 0.061 vs. Device Studies
Most frequently used vs. miscellaneous stent/EPD combinations

483 patients  
539 procedures

**Most Frequent Combos**
- 344 patients  
  385 procedures (71%)

- Combos  
  n = 3
- Stents  
  n = 2
- EPDs  
  n = 3

**Miscellaneous Combos**
- 139 patients  
  154 procedures (29%)

- Combos  
  n = 31
- Stents  
  n = 9
- EPDs  
  n = 11
**Routine Protected CAS in Hamburg**
01/99–08/07

- Most frequently used stent/EPD combinations

<table>
<thead>
<tr>
<th></th>
<th>Stent/EPD Combination</th>
<th>Patients</th>
<th>Procedures</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Acculink + Emboshield BW</td>
<td>194</td>
<td>213</td>
<td>40%</td>
</tr>
<tr>
<td></td>
<td>1/03–8/07</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Wall Stent + GuardWire</td>
<td>83</td>
<td>91</td>
<td>17%</td>
</tr>
<tr>
<td></td>
<td>1/99–3/01</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Acculink + Accunet</td>
<td>67</td>
<td>81</td>
<td>15%</td>
</tr>
<tr>
<td></td>
<td>1/03–5/06</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Carotid Stents
Stent cell area

Houdart E, CIRSE 2006
Most Frequently Used EPDs

**Emboshield** (Abbott)
- Bare-wire filter system

**Accunet** (Guidant)
- Fixed-wire filter system

**GuardWire** (Medtronic)
- Distal balloon-occlusive system
Temporal distribution of most frequently used stent/EPD combinations
**Routine Protected CAS in Hamburg**

01/99–08/07

- Most frequently used stent/EPD combinations

<table>
<thead>
<tr>
<th></th>
<th>A (Aclk+ES BW)</th>
<th>B (Wall+GW)</th>
<th>C (Aclk+Acnt)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients, n</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age, yrs</td>
<td>69 ± 9</td>
<td>68 ± 9</td>
<td>70 ± 9</td>
<td></td>
</tr>
<tr>
<td>Age ≥75 years, %</td>
<td>26</td>
<td>27</td>
<td>33</td>
<td>0.525</td>
</tr>
<tr>
<td>Men, %</td>
<td>69</td>
<td>78</td>
<td>61</td>
<td>0.071</td>
</tr>
<tr>
<td>Diabetes, %</td>
<td>23</td>
<td>27</td>
<td>21</td>
<td>0.684</td>
</tr>
<tr>
<td>Smoking*, %</td>
<td>50</td>
<td>61</td>
<td>58</td>
<td>0.163</td>
</tr>
<tr>
<td>HT, %</td>
<td>85 [79-90]</td>
<td>66 [55-76]</td>
<td>87 [76-94]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>HLP, %</td>
<td>78</td>
<td>68</td>
<td>79</td>
<td>0.198</td>
</tr>
<tr>
<td><strong>Lesions, n</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulcerated, %</td>
<td>46</td>
<td>47</td>
<td>39</td>
<td>0.551</td>
</tr>
<tr>
<td>Calcified, %</td>
<td>73 [67-79]</td>
<td>30 [21-41]</td>
<td>55 [43-67]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Thrombotic, %</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>0.090</td>
</tr>
<tr>
<td>Symptomatic, %</td>
<td>24 [18-30]</td>
<td>47 [37-58]</td>
<td>22 [14-33]</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*ex/current [] = 95% CI
**Routine Protected CAS in Hamburg**
01/99–08/07

- Most frequently used stent/EPD combinations

**More Lesion Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>A (Aclk+ES BW)</th>
<th>B (Wall+GW)</th>
<th>C (Aclk+Acnt)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>213</td>
<td>91</td>
<td>81</td>
</tr>
<tr>
<td>Lesion length, mm</td>
<td><strong>15.4 ± 5.7</strong></td>
<td><strong>12.0 ± 5.5</strong></td>
<td><strong>16.0 ± 11.2</strong></td>
</tr>
<tr>
<td>Diameter stenosis, %</td>
<td><strong>85 ± 8</strong></td>
<td><strong>86 ± 8</strong></td>
<td><strong>85 ± 8</strong></td>
</tr>
</tbody>
</table>

- **Procedural Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>A (Aclk+ES BW)</th>
<th>B (Wall+GW)</th>
<th>C (Aclk+Acnt)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>213</td>
<td>91</td>
<td>81</td>
</tr>
<tr>
<td>Procedure duration, min</td>
<td><strong>34 ± 16</strong></td>
<td><strong>54 ± 19</strong></td>
<td><strong>38 ± 23</strong></td>
</tr>
<tr>
<td>Dwell time of EPD, min</td>
<td><strong>5.7 ± 2.1</strong></td>
<td><strong>8.8 ± 3.2</strong></td>
<td><strong>5.8 ± 3.2</strong></td>
</tr>
</tbody>
</table>

*P < 0.001 vs. A, P < 0.001 vs. C*
Routine Protected CAS in Hamburg
Case Presentations of Challenging Lesions

- Rare situations necessitating **proximal embolic protection**:
  - Extreme tortuosity of the distal vessel
  - Thrombus containing lesion

- In our experience, such situations were encountered in less than 5% of cases
Stenosis in ICA with distal loop:
Proximal embolic protection

Blockage of antegrade flow by both balloons

ECA balloon

CCA balloon

P03-0077
**Routine Protected CAS in Hamburg**

01/99–08/07

- Most frequently used stent/EPD combinations
- **Device success** (residual stenosis ≤20%)

![Bar chart showing device success rates for three different stent/EPD combinations: A (n=213) with 100%, B (n=91) with 100%, and C (n=81) with 97.5%.

*Partial success (residual stenosis >20%<50%): n=2
**ROUTINE** Protected CAS in Hamburg
01/99–08/07

- Most frequently used stent/EPD combinations
- 30-day stroke rates (no deaths)

![Diagram showing stent/EPD combinations and 30-day stroke rates](image)

- **Stent/EPD Combos**
  - A: 2.1% (n=4)
  - B: 1.2% (n=1)
  - C: 0%

- **Difference between Rates**
  - A–B: 1.2% (P=0.999)
  - A–C: 2.1% (P=0.575)
  - B–C: 1.2% (P=0.999)

95% CI
Most frequently used vs. miscellaneous stent/EPD combinations

483 patients
539 procedures

Most Frequent Combos
344 patients
385 procedures (71%)
- Combos n = 3
- Stents n = 2
- EPDs n = 3

Miscellaneous Combos
139 patients
154 procedures (29%)
- Combos n = 31
- Stents n = 9
- EPDs n = 11
**ROUTINE** Protected CAS in Hamburg  
01/99–08/07

- Temporal distribution of most frequently used vs. miscellaneous **stent/EPD combinations**

- **Proximal** among misc. EPDs:  
  **n=16**  
  (3% of total, 10% of misc.)
**ROUTINE Protected CAS in Hamburg**

01/99–08/07

- Most frequent vs. miscellaneous stent/EPD combos

<table>
<thead>
<tr>
<th></th>
<th>Combos A, B &amp; C Pooled</th>
<th>Miscellaneous Combos</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients, n</strong></td>
<td>344</td>
<td>139</td>
<td></td>
</tr>
<tr>
<td>Age, yrs</td>
<td>69 ± 9</td>
<td>70 ± 9</td>
<td>0.290</td>
</tr>
<tr>
<td>Age ≥75 years, %</td>
<td>27</td>
<td>32</td>
<td>0.374</td>
</tr>
<tr>
<td>Men, %</td>
<td>70</td>
<td>71</td>
<td>0.743</td>
</tr>
<tr>
<td>Diabetes, %</td>
<td>23</td>
<td>25</td>
<td>0.638</td>
</tr>
<tr>
<td>Smoking*, %</td>
<td>54</td>
<td>49</td>
<td>0.358</td>
</tr>
<tr>
<td>HT, %</td>
<td>81</td>
<td>92</td>
<td>0.0015</td>
</tr>
<tr>
<td>HLP, %</td>
<td>76</td>
<td>79</td>
<td>0.476</td>
</tr>
<tr>
<td><strong>Lesions, n</strong></td>
<td>385</td>
<td>154</td>
<td></td>
</tr>
<tr>
<td>Ulcerated, %</td>
<td>45</td>
<td>43</td>
<td>0.846</td>
</tr>
<tr>
<td>Calcified, %</td>
<td>59</td>
<td>48</td>
<td>0.0188</td>
</tr>
<tr>
<td>Thrombotic, %</td>
<td>2</td>
<td>7</td>
<td>0.0095</td>
</tr>
<tr>
<td>Symptomatic, %</td>
<td>29</td>
<td>29</td>
<td>&gt;0.999</td>
</tr>
</tbody>
</table>

*ex/current
**ROUTINE Protected CAS in Hamburg**

01/99–08/07

- Most frequent vs. miscellaneous stent/EPD combos
- **More Lesion Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Combos A, B &amp; C Pooled</th>
<th>Miscellaneous Combos</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>385</td>
<td>154</td>
<td></td>
</tr>
<tr>
<td>Lesion length, mm</td>
<td>14.7 ± 7.3</td>
<td>14.8 ± 5.0</td>
<td>0.334</td>
</tr>
<tr>
<td>Diameter stenosis, %</td>
<td>85 ± 8</td>
<td>87 ± 7</td>
<td>0.150</td>
</tr>
</tbody>
</table>

- **Procedural Characteristics**

<table>
<thead>
<tr>
<th></th>
<th>Combos A, B &amp; C Pooled</th>
<th>Miscellaneous Combos</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>385</td>
<td>154</td>
<td></td>
</tr>
<tr>
<td>Procedure duration, min</td>
<td>39.5 ± 20.2</td>
<td>45.5 ± 22.4</td>
<td>0.0009</td>
</tr>
<tr>
<td>Dwell time of EPD, min</td>
<td>6.4 ± 2.9</td>
<td>7.6 ± 4.0</td>
<td>0.0024</td>
</tr>
</tbody>
</table>
Routine Protected CAS in Hamburg
01/99–08/07

- Miscellaneous stent/EPD combinations
- **Device success** (residual stenosis ≤20%)

![Bar chart showing device success](chart.png)

- **99.4%**

*Partial success (residual stenosis >20%<50%): n=1*
- Most frequent vs. miscellaneous stent/EPD combos
- 30-day stroke/death rates

![Graph showing stent/EPD combos and 30-day stroke/death rates with 95% CI.](image)
Differentiating CAS Devices
Conclusions I

- In our 9-year experience with emboli-protected CAS, **71% of all routine procedures** were performed with just 3 combinations of **2 stents** and **3 EPDs**. Device success rates were on the order of **100%** and the overall 30-day stroke/death rate was **1.5%**, with no significant differences apparent between stent/EPD combinations.

- Device success rates were as good when using any of the 31 other stent/EPD combinations employed in 29% of our routine CAS procedures, but the 30-day stroke/death rate – although still acceptable at **3.6%** – tended to be higher.
Differentiating CAS Devices

Conclusions II

- There is no such thing as a “lesion-specific carotid stent”

- There is no such thing as a “lesion-specific embolic protection device”
  – except for the rare cases of extreme distal vessel tortuosity or a thrombus-containing lesion, which call for proximal emboli protection
Differentiating CAS Devices

Conclusions III

- Complications such as stroke or death do happen. But there is no evidence to date that their incidence is impacted by stent or EPD design. There is evidence, however, that the stroke/death rate is impacted by **patient characteristics**, such as age and diabetic status.

- To achieve a perfect outcome of a CAS procedure, **operator familiarity with the devices** rather than their design specifications appears to be the most important factor.