Stenting Design Is a Major Determinant of Outcomes in CAS Pro!

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Clinic Louis Pasteur
Essey Les Nancy . France
The determinants of outcomes in CAS

- Good patient selection
- Good patient preparation
- Technical skill and virtuosity to access
- Good selection of the protecting device
- **Good stent selection**
- True and complete post dilatation under protection
- Fast procedure
- Good patient surveillance post procedure
How to choose the most appropriate stent?

Emmanuel Houdart

Department of Interventional Neuroradiology
Hôpital Lariboisière
Paris, France
Personal experience

- 125 Carotid Wall Stent (closed cells stent)  
  1 delayed ischemic stroke due to Clopidogrel resistance

- 40 Nitinol stents (open cells stent) : 2 delayed ischemic complications without Clopidogrel resistance
Mr Rai...left symptomatic stenosis
After nitinol stent implantation under filter deployment (no debris)
Evolution

- Patient was discharged
- Recurrent TIA at day 8
- Echo-Doppler : normal stent patency, no intrastent thrombosis
Failure of plaque exclusion was the suspected mechanism of delayed stroke in our patients

- Delayed embolism could occur if plaque (block of butter) protrudes through stent struts (wire able to cut the butter)
Cell’s definition

- Elementary unit of a stent including the metallic struts and its void surface
Closed cells
interdependent cells

Open cells
independent cells
Scaffolding

Stents are not equal, ...

the CWS cell size is 10 times smaller than the Acculink

Based on Houdart, Cirse 2005.
CAS device selection

A. Cremonesi*

F. Castriota*

* Interventional Cardio-Angiology Unit
Villa Maria Cecilia Hospital
Cotignola (RA) - Italy
Symptomatic left ICA stenosis

- Male 85

- CVRF:
  - diabetes, hypertension

- Symptoms:
  - recurrent TIAs

- Eco-Doppler:
  - Left ICA 75% long lesion, PFV 2.3 m/sec
  - Dishomogeneous plaque, partially ulcerated, with significant soft component

- Medical therapy
  - Beta-blocker
  - Plavix 75 mg
  - Aspirin 100 mg
EPD: Accunet 6.5 concentric filter
Direct stenting: Protégé 7-10/40 mm
Balloon: Maveric 5.0/20 mm @ 7 bars
Final result

Is there a filling defect?
The complication: progressive plaque prolapse
min. 8 after stenting

Patient: asymptomatic
Plaque prolapse treatment
min. 20 after stenting

**EPD: Accunet 6.5**

**“Sandwich technique”:** stent in stent to fix the protruding plaque between the two frames

**Stent: XAct 8/30**

**No post-dilatation**

Patient: asymptomatic
Plaque prolapse treatment
min. 21 after stenting

Patient: symptomatic for worsening right hemi-paresis!
Filter still in place!
The Patient developed a right hemi-paresis, successfully treated in ICU for two days.

Neuro-rehabilitation for 20 days, with complete resolution of neurological deficits.

Echo-Doppler: no evidence of significant plaque protrusion.
### Stenting strategies to prevent peri-procedural complications

<table>
<thead>
<tr>
<th>Carotid lesion / bifurcation issue</th>
<th>Type of stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque covering</td>
<td>Cobalt-alloy braided thread stent</td>
</tr>
<tr>
<td>Long acting plaque prolapse prevention</td>
<td></td>
</tr>
<tr>
<td>In vessel flexibility</td>
<td>Nitinol open cell stents</td>
</tr>
<tr>
<td>Wall/plaque conformability</td>
<td></td>
</tr>
<tr>
<td>Outward radial force</td>
<td>Nitinol closed cell stents</td>
</tr>
<tr>
<td>Resistance to compression</td>
<td></td>
</tr>
</tbody>
</table>
Do device characteristic affect outcome in carotid artery stenting?

M. Bosiers – P. Peeters
Post-procedural phase (M. Bosiers)

ENOVOASCULAR → Plaque containment!

GARBAGE COMPACTOR

Courtesy of M. Makaroun, University of Pittsburgh / Courtesy of K. Balzer, Mulheim
Timing events

2/3 of all complications occurred in the post-procedural phase.

Distribution of Complications Over Time

Complication rate (%)
### “Stent design” based analysis

<table>
<thead>
<tr>
<th>ALL EVENTS</th>
<th>Total population</th>
<th>Symptomatic</th>
<th>Asymptomatic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>%</td>
<td>n/N</td>
</tr>
<tr>
<td>Closed</td>
<td>51/2242</td>
<td>2.3%</td>
<td>21/934</td>
</tr>
<tr>
<td>Open</td>
<td>39/937</td>
<td>4.2%</td>
<td>27/383</td>
</tr>
<tr>
<td>TOTAL</td>
<td>90/3179</td>
<td>2.8%</td>
<td>48/1317</td>
</tr>
</tbody>
</table>
“Free cell area” based analysis

LATE EVENTS

symptomatic population

Odds Ratio  95% C.I.

2.5-5 vs <2.5 mm²
1.553  [0.197-12.261]

5-7.5 vs <2.5 mm²
4.309  [1.705-10.893]

>7.5 vs <2.5 mm²
5.976  [2.733-13.065]
Material and methods. A CAS database of 3179 consecutive CAS patients was retrospectively assessed. The distribution of neurological complications were analysed for association with the different stent types and designs. Events where subdivided into procedural and postprocedural events.

Results. The overall combined rate of TIA, stroke and death was 2.8% at 30 days (late events 1.9%). The post-procedural event rate analyzed for differences stents varied from 1.2% using BSCI Carotid Wallstent to 5.9% using MedtronicExponent. The late event rates varied from 1.2% to 3.4% for free cell areas <2.5 mm$^2$ and >7.5 mm$^2$ respectively ($p < 0.05$). Post-procedural event rate was 1.3% for closed cells and 3.4% for open cells. All these differences were highly pronounced among symptomatic patients ($p < 0.0001$).

Conclusions. After carotid stenting, complication rates vary according to stent type, free cell area and cell design. In the symptomatic population (and also in the total population), post-procedural complication rates are highest for the open cell types and increase with larger free cell area.
Post-procedural phase

- The majority of strokes occur post-procedure (± 70%)
# SPACE Clinical Trial Sub Analysis

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Cell Design</th>
<th>MAE All Patients</th>
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<tbody>
<tr>
<td>Carotid Endarterectomy (CEA)</td>
<td></td>
<td>6.3% (37/584)</td>
</tr>
<tr>
<td>Carotid Artery Stent (CAS)</td>
<td>Closed Cell</td>
<td>6.0% (26/434)</td>
</tr>
<tr>
<td>Carotid Artery Stent (CAS)</td>
<td>Open Cell</td>
<td>11.0% (13/118)</td>
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</table>
“Stent design” based analysis

<table>
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<th>30-day MAE</th>
<th>Symptomatic</th>
<th>n/N</th>
<th>%</th>
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<tr>
<td><strong>BIC</strong></td>
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<td>7.0%</td>
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<tr>
<td><strong>SPACE</strong></td>
<td></td>
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Results confirmed by subanalysis SPACE-trial (Prof. Jansen)

30 day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomised non-inferiority trial

The SPACE Collaborative Group

Summary
Background Carotid endarterectomy is effective in stroke prevention for patients with severe symptomatic carotid-artery stenosis, and carotid-artery stenting has been widely used as alternative treatment. Since equivalence or superiority has not been established, the SPACE trial compared the effects of stent-protected angioplasty versus carotid endarterectomy on periprocedural stroke. The results of this trial do not justify the widespread use of carotid-artery stenting for treatment of carotid-artery stenoses. Results at 6–24 months are awaited.
Closed Cell Concept

Scaffolding

Structure

Radial Force

Stroke Prevention

Confidential Information of Boston Scientific
Closed and Open Cell Geometry
*Inner Lumen Images*

### 25% Lesion
Stent deployed in lumen representative of a vessel with a plaque protrusion infiltrating 25% of the internal diameter

### 70% Lesion
Stent deployed in lumen representative of a vessel with a plaque protrusion infiltrating 70% of the internal diameter
Open cells protruding in the ulcerated niche
“Stent design”: why closed cell?

• Open cell designs in tortuous curvature

PROLAPSE
“Stent design”: why closed cell?

FISH SCALING at the concave surface of the stent

Open-cell struts extending beyond the intima with focal contrast extravasation
Stentboost of an open cell stent at different phases

Bulging toward External carotid

Scale
Chimney!
The open cell stent signature

- External Carotid Bulging with or without teeth
- Scale protruding to the lumen or the wall
First OCT cases
Carotid Arteries Stents

Clinique Louis PASTEUR
Essey-les-Nancy / France
M.Amor – G.Ethevenot
F.Marty – J.P Simon – J Lemoine
Cases

- Target: Control post stenting Wallstent (autoexp. Stent) in internal carotid
- Positions of the struts
- Presence of materiel between the struts post stenting
- Definition of protocol to obtain images
- Case report will be made
Case 1
Case 1

Protrusion of the struts in the ulceration niche.
Case 2
Control post stenting

Floating struts and longer pullback – Protocol to obtain better flush is working.
Surprise Surprise
Black & White
Case 3
Control Post stenting
Visualisation of malposition
Protrusion and material between struts
Future scaffolding solutions???

- Flexible *porous membrane* stent (± 100 µm ~ EPD)
Future scaffolding solutions???

- Flexible *porous membrane* stent

Membrane stent has potential for reducing the late emboli

MembraX – prototype membrane stent (Abbott Vascular)
Pore size 80µm

Closed Cell Concept

Scaffolding

Structure

Stroke Prevention

Radial Force

Lumen
Stent
The relationship of post CAS hypotension to stent type – Dr. Katzen

**Purpose**

- To assess whether there is a significant difference in the incidence of peri-procedural hypotension requiring treatment related to stent type used in the carotid artery for de novo lesions.

**Conclusion**

Nitinol carotid stents exhibit 2x greater risk of peri-procedural hypotension than Carotid Wallstent.

<table>
<thead>
<tr>
<th>Incidence of Hypotension</th>
<th>Nitinol(^1) (n=141)</th>
<th>Carotid Wallstent (n=31)</th>
<th>t-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periprocedural Hypotension</td>
<td>31.0%</td>
<td>12.9%</td>
<td>p=0.045</td>
</tr>
<tr>
<td>All Hypotension</td>
<td>40.4%</td>
<td>19.4%</td>
<td>p=0.014</td>
</tr>
</tbody>
</table>
Outcome of carotid artery stenting at 2 years follow-up: comparison of nitinol open cell versus stainless steel closed cell stent design.

Maleux G, Marrannes J, Heye S, Daenens K, Verhamme P, Thijs V. Department of Radiology, University Hospitals Leuven, Leuven, Belgium


- This was a non-randomized, retrospective study including 123 patients in whom 132 carotid stent-procedures were performed.

- In 72 procedures a closed cell stainless steel stent was implanted, in the remaining 60 procedures an open cell nitinol stent was placed. In 8 patients with a stainless steel stent (11%) and in 6 patients with a nitinol stent (10%) a stroke occurred during the follow-up period (P=0.79).

- CONCLUSIONS: At 2-year follow-up after carotid artery stenting, there is no difference in clinical outcome or in stent patency among patients treated with open versus closed cell design stents. Subsequently the type of carotid stent design does not seem to impact the overall midterm outcome after carotid artery stenting.
Size of the cells Only matters!
Deformation of closed cells
A pocket is a deformable closed cell.