Transcatheter **C**ardiovascular **T**herapeutics **2007**
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Carotid Stents and Embolic Protection Systems: Differentiating the Devices

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TCT2007
TRANSCATHETER CARDIOVASCULAR THERAPEUTICS

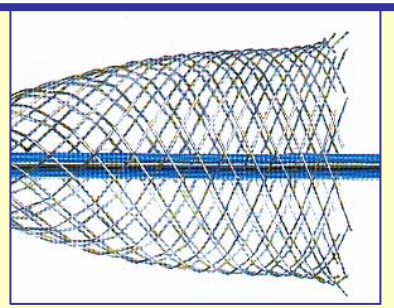
Disclosure Statement of Financial Interest

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.

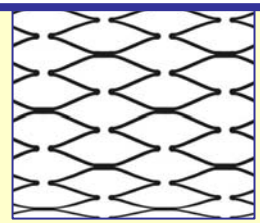
Carotid Stents

Self-expanding

Braided **mesh wire**
(Super Alloy)



Nitinol
(Nickel-Titanium)

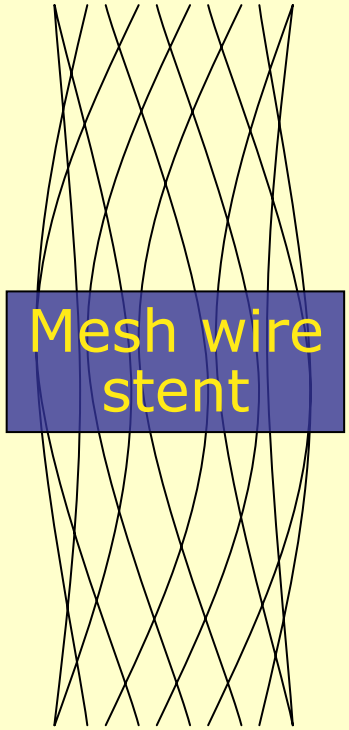


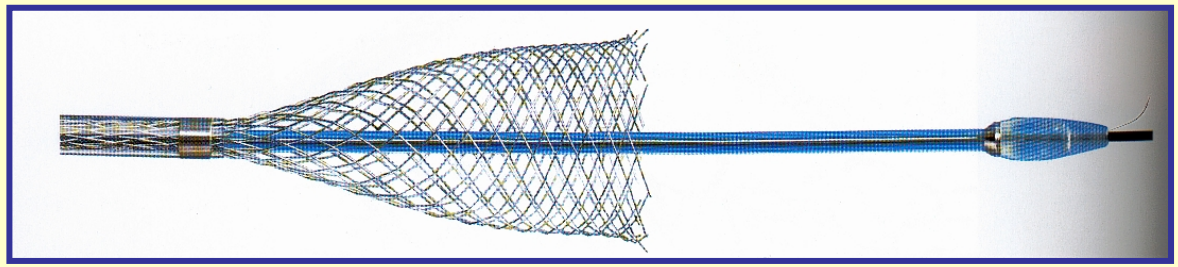
Open-cell design

Closed-cell design

Carotid Stents

Braided Mesh Wire (Super Alloy)



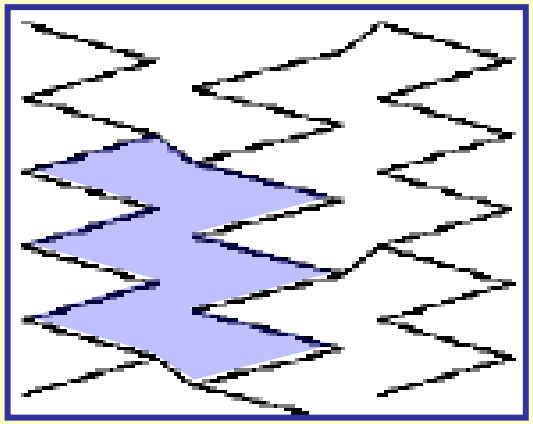


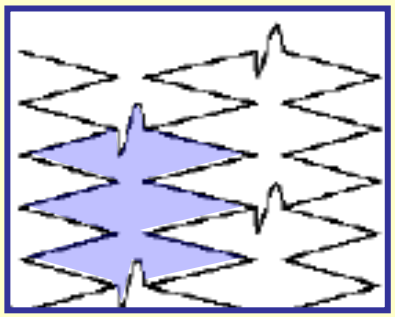
- Super-alloy wires braided to a tubular mesh
- Braided to different diameters
- Spring-like expansion
- "Closed cell"-like

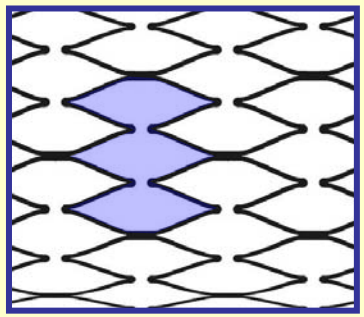
e.g. Carotid Wallstent (Boston Scientific)

Carotid Stent Designs
Nitinol Stents

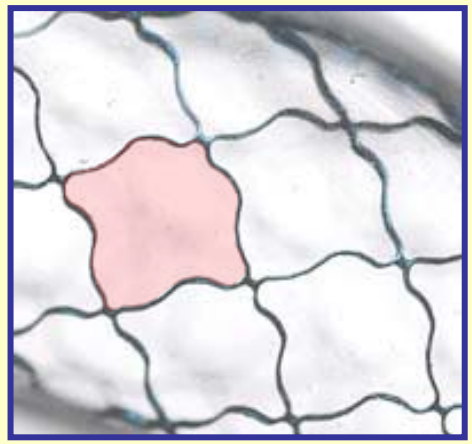
Open-cell design

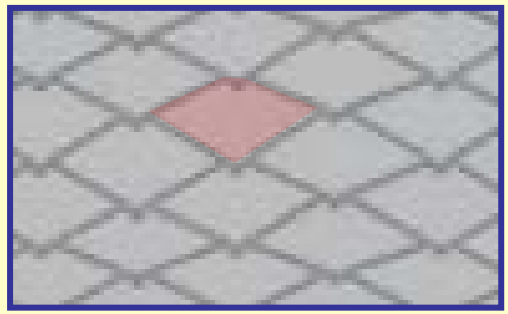






Closed-cell design

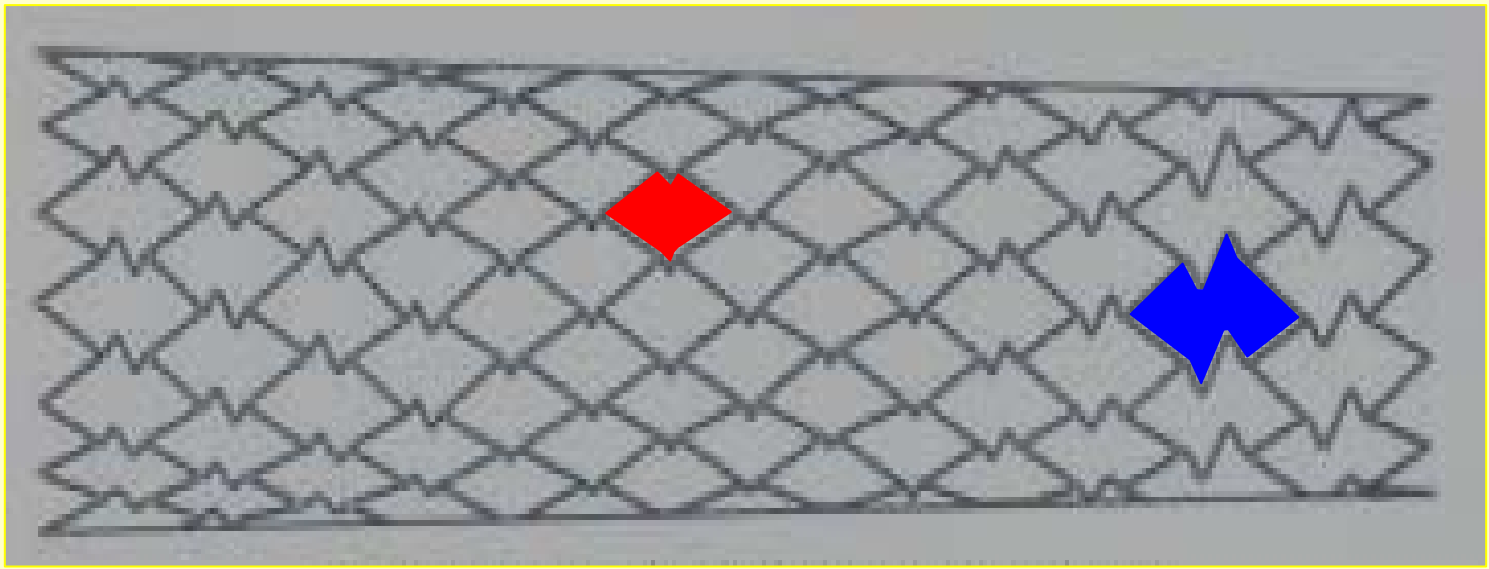




Carotid Stents
Varying-Size Closed-Cell Design

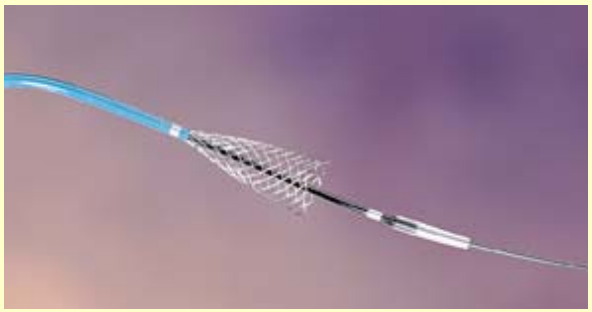
- e.g., Xact Stent (Abbott), Cristallo (Invatec)

Central: smaller cells: increased **coverage**



Edges: larger cells: increased **flexibility**

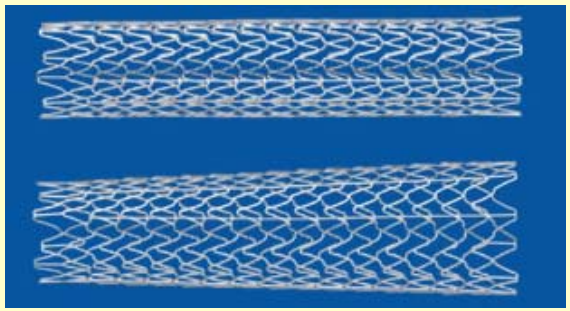
Carotid Stents (Random Selection)



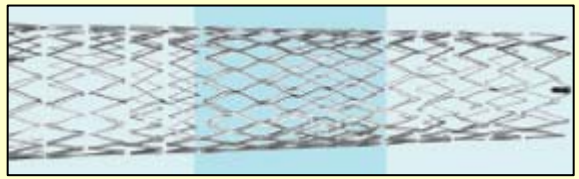
Wallstent (BSCI)

NexStent (Endotex)

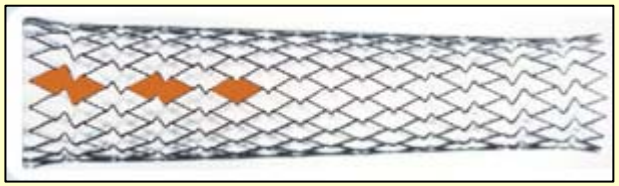
Precise (Cordis)



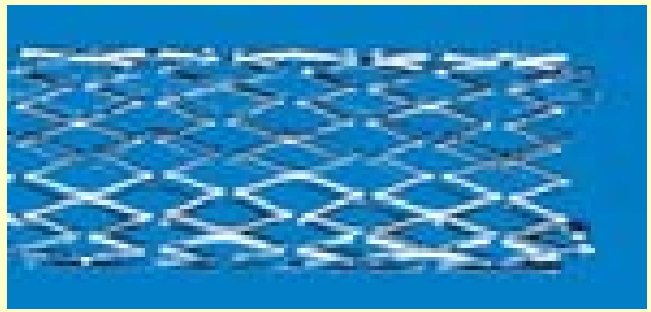
Acculink (Guidant)



Cristallo Ideale (Invatec)



Xact (Abbott)



Protégé (ev3)

Embolic Protection Systems

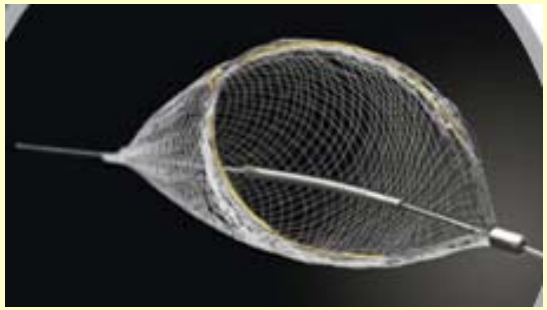
- **Distal balloon-occlusive systems**
- **Distal filter systems**
- **Proximal balloon-occlusive (flow-blockage) systems**

EPDs (Random Selection)

GuardWire
(Medtronic)

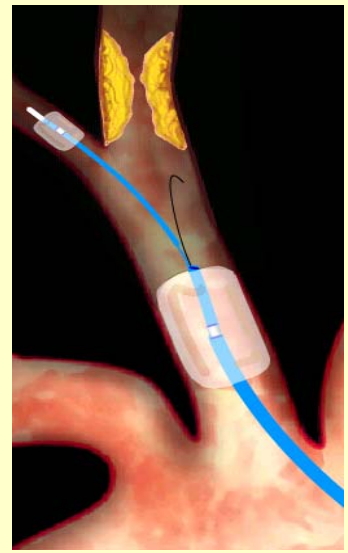
Angioguard
(Cordis)

FilterWire
(Boston Scientific)

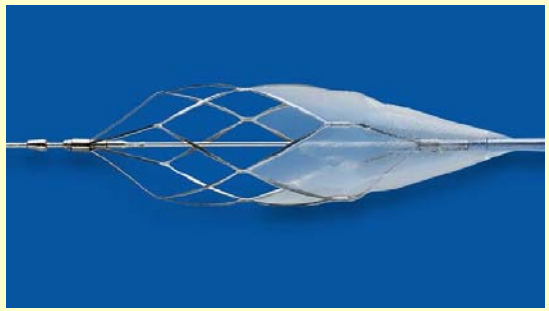


SpiderFX (ev3)

Emboshield BW
(Abbott)



Mo.Ma
(Invatec)



Accunet (Guidant)

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 — n = 1317 (41.4%)
  - Asymptomatic — n = 1862 (58.6%)
  - **EPD use** — n = 3049 (**95.9%**)
    - Filters (n=8) — n = 2831 (92.9%)
    - Proximal balloon (1) — n = 192 (6.4%)
    - Distal balloon (1) — n = 26 (0.8%)

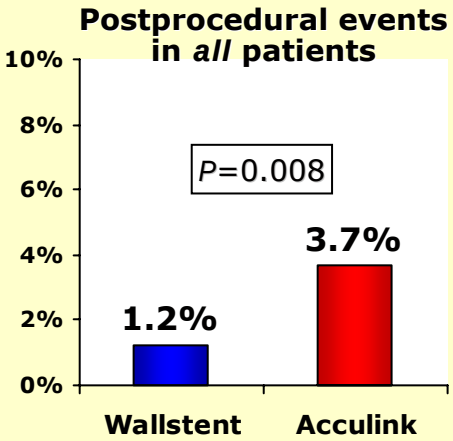
Closed-Cell Stents n = 2242 (70.5%)	**Open-Cell Stents n=937 (29.5%)**
Wallstent (BSCI) [n=**2107**]	Acculink (Abbott) [n=**409**]
Xact (Abbott) [n=105]	Precise (Cordis) [n=293]
NexStent (Endotex) [n=30]	Protégé (ev3) [n=201]
	Exponent (Medtronic) [n=34]

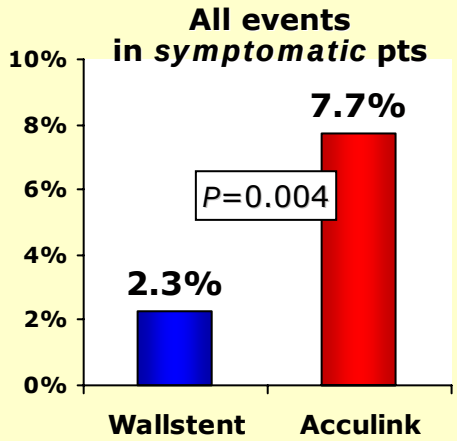
➔ Marked imbalance in numbers of stents used

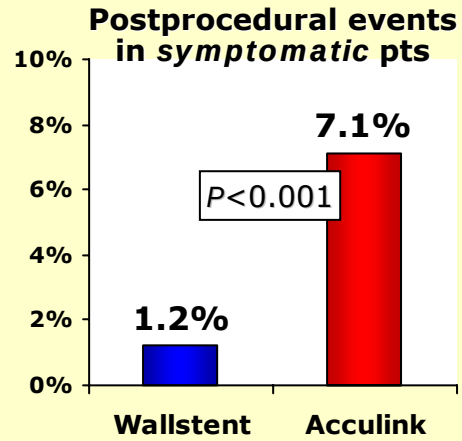
Bosiers M et al., *Eur J Vasc Endovasc Surg* 2007

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

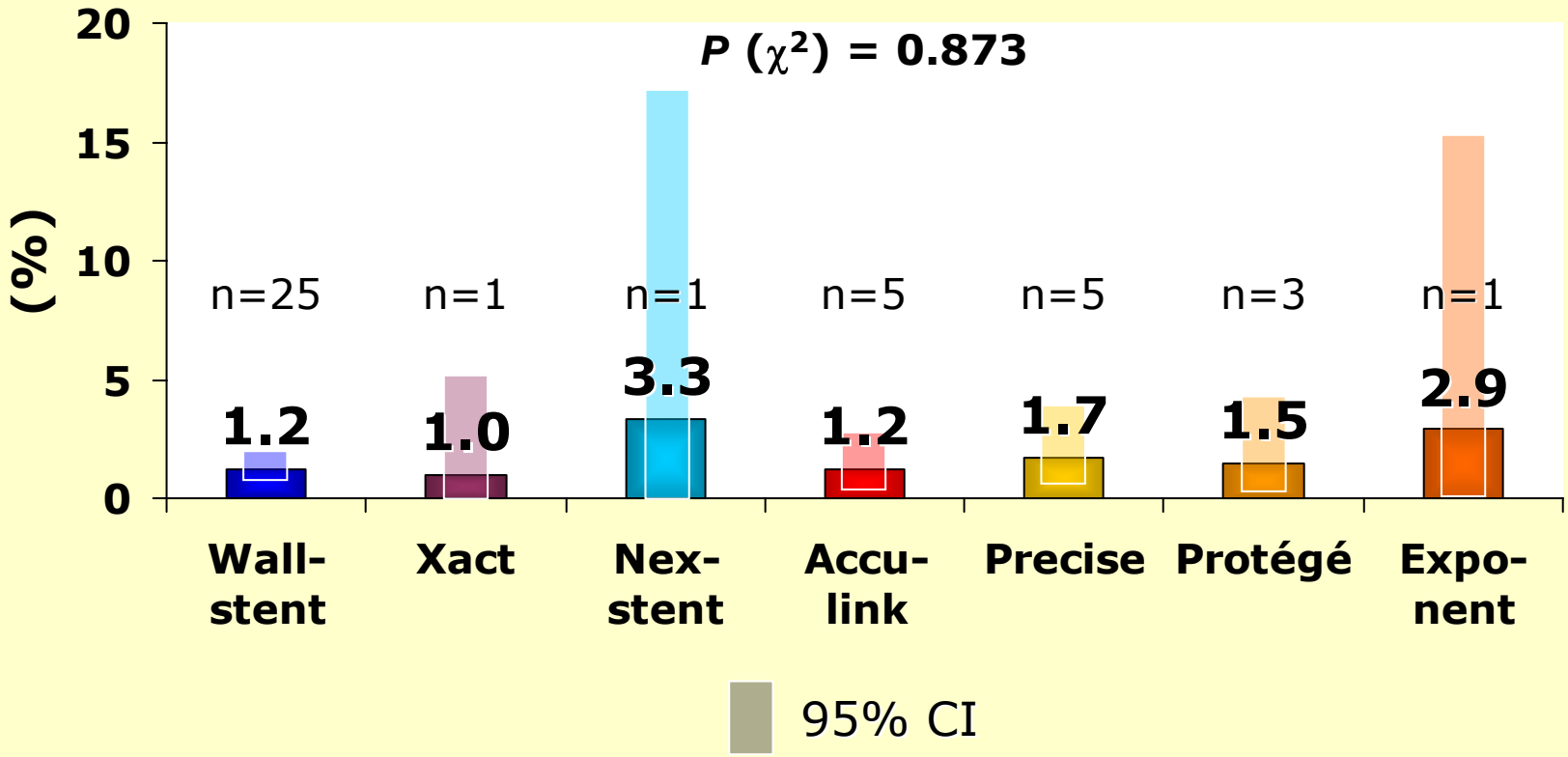
Definition of Neurological Endpoints

- **TIA**
  - New neurological deficit that resolved completely within 24 hours
- **Minor stroke**
  - New neurological deficit that resolved completely ≤30 days *or* increased the NIH Stroke Scale by ≤3
- **Major stroke**
  - New neurological deficit that persisted for more than 30 days *and* increased the NIH Stroke Scale by ≥4

Despite different existing definitions of **stroke**, all agree on the fact that symptoms must last for **>24 hours**

The Belgian-Italian CAS Study

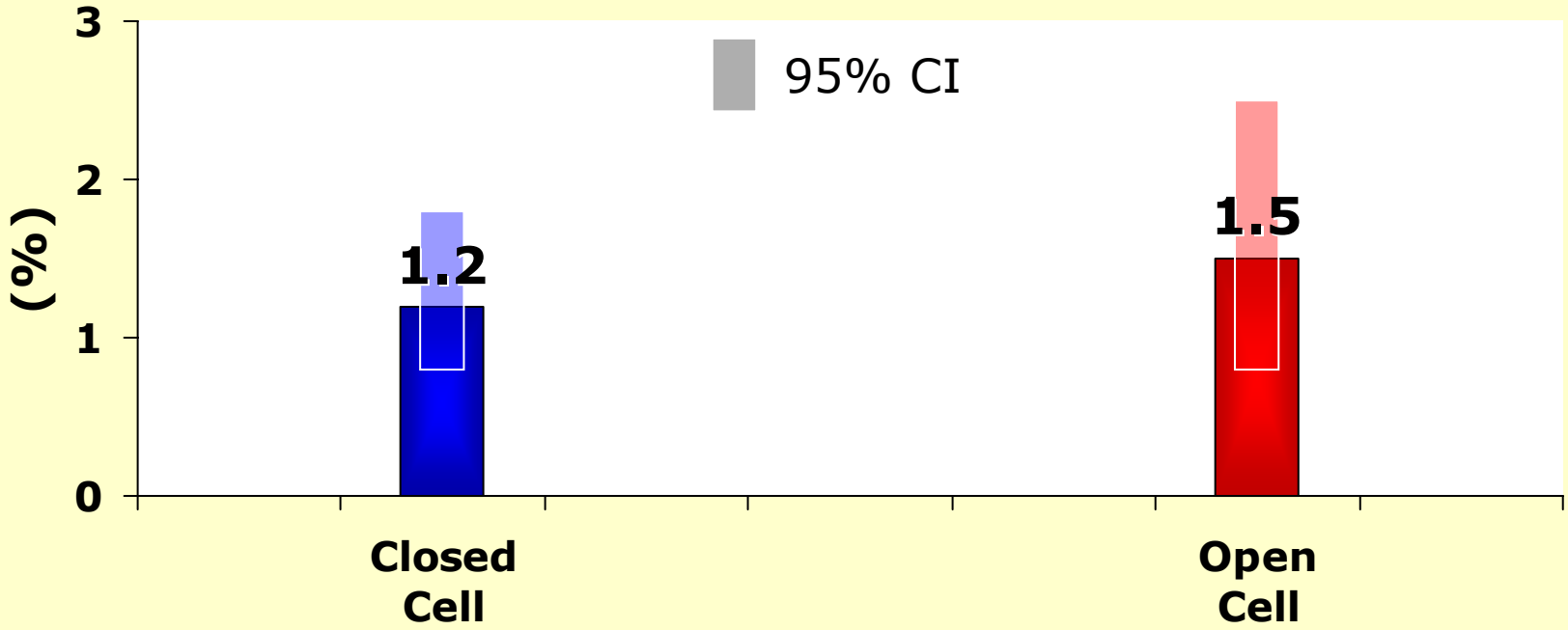
- Retrospective analysis of **3,179 patients**
  - 30-day stroke (as defined by the authors)/death rates



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

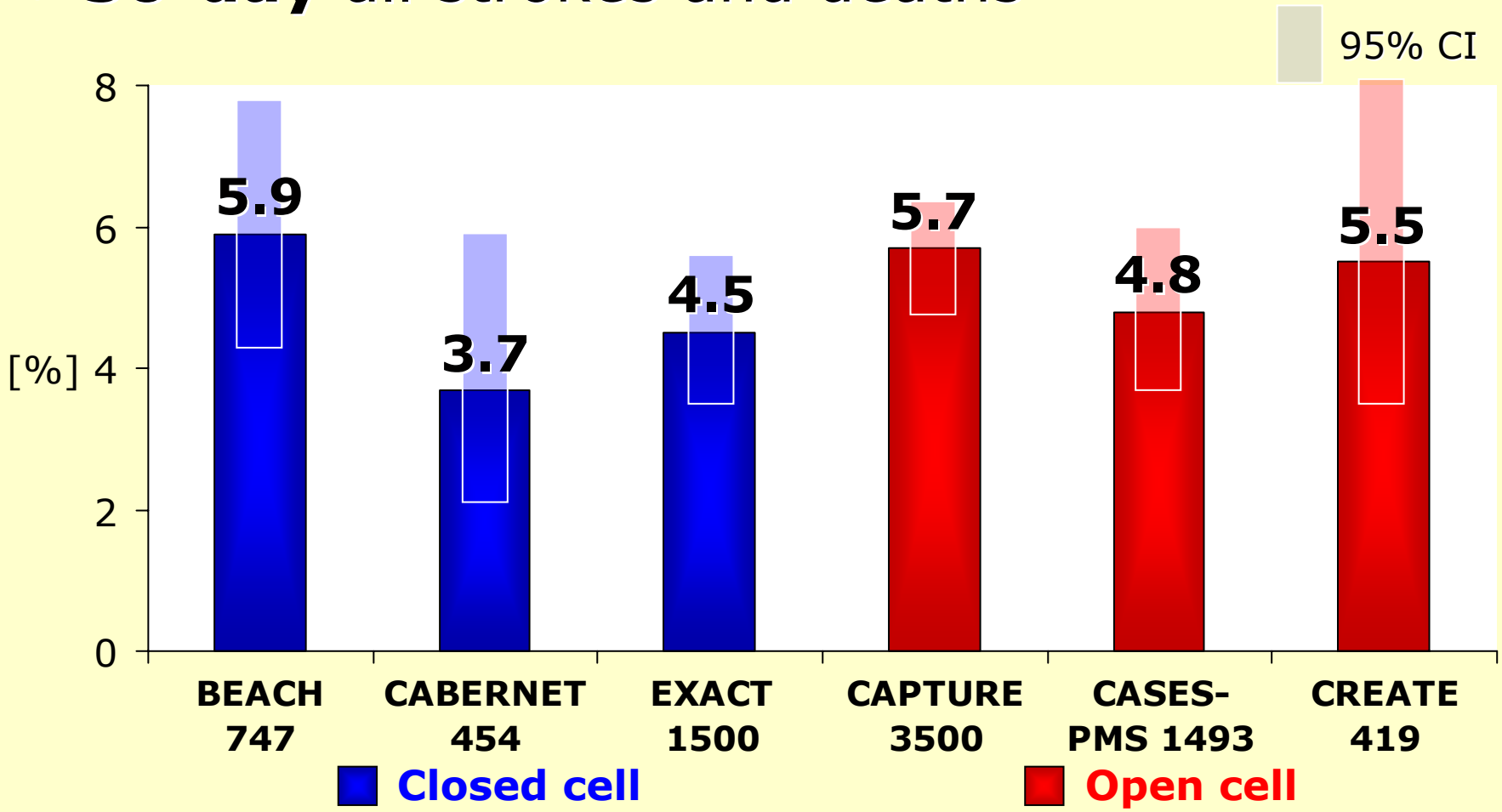


➔ Difference:
0.3% (95% CI -0.5% to 1.4%, ***P*=0.495**)

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

Recent CAS Registries

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



BEACH: White CJ et al., *CCI* 2006; **CABERNET**: BSCI FilterWire EZ™ DFU ©2006;
EXACT: Gray WA. *i2 Summit (ACC)* 2007; **CAPTURE**: Gray WA et al., *CCI* 2007;
CASES-PMS: Katzen BT et al., *CCI* 2007; **CREATE**: Safian RD et al., *JACC* 2006

Is there evidence that

EPD design

impacts the 30-day stroke/death rate?

No!

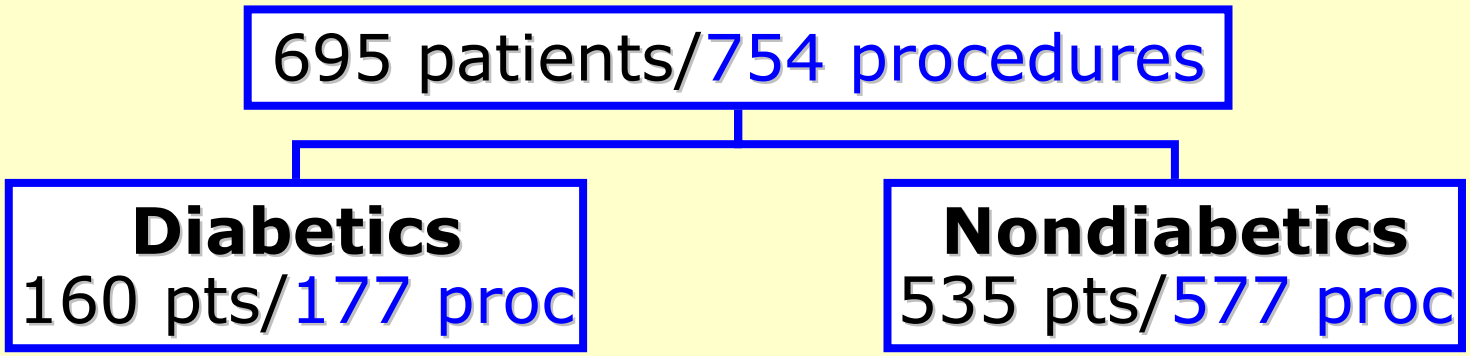
Periprocedural Complications of CAS

- 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



- Stents n = 9 (72% Wallstent)
- EPDs n = 8 (79% filters)

The Italian-German CAS Registry

- **Objective:**

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

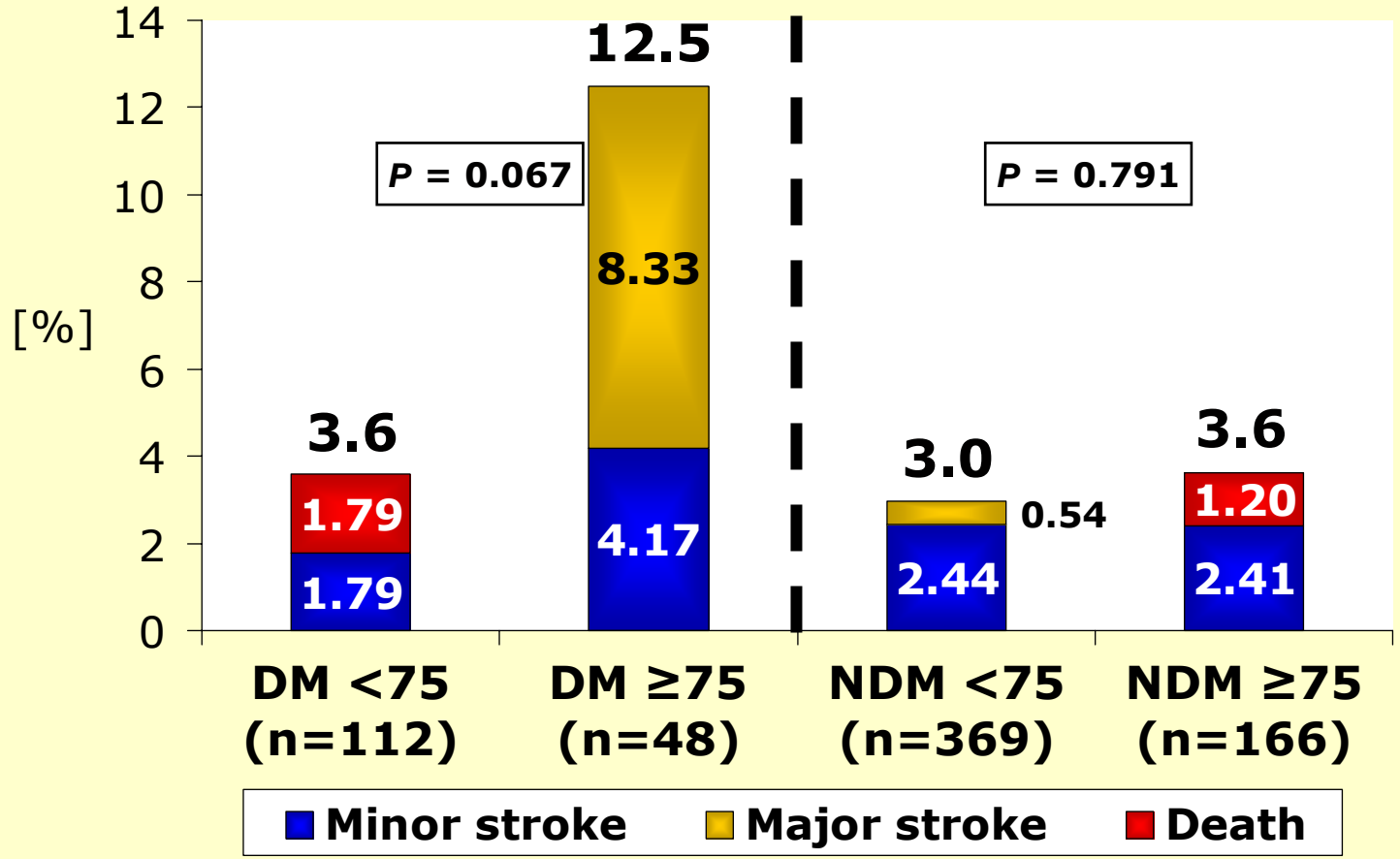
  on the **30-day stroke/death rate**

- **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**



Schlüter M et al., *J Endovasc Ther* 2007

The Italian-German CAS Registry

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

	OR	95% CI	*P*
Diabetes	**2.1**	1.0 – 4.8	**0.068**
Age (1-year increase)	**1.06**	1.01 – 1.12	**0.031**
Diabetes and age <75 years	**1.1**	0.3 – 3.6	1.000
Diabetes and age ≥75 years	**4.3**	1.3 – 12.3	**0.016**

- **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

	OR	95% CI	*P*
Diabetes	**5.9**	1.6 – 21.8	**0.007**
Age (1-year increase)	**1.13**	1.02 – 1.25	**0.018**
Diabetes and age <75 years	**2.4**	0.2 – 17.1	0.557
Diabetes and age ≥75 years	**12.0**	2.1 – 66.5	**0.005**

- **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

ROUTINE Protected CAS in Hamburg 01/99–08/07

- Most frequently used vs. miscellaneous **stent/EPD combinations**

483 patients
539 procedures

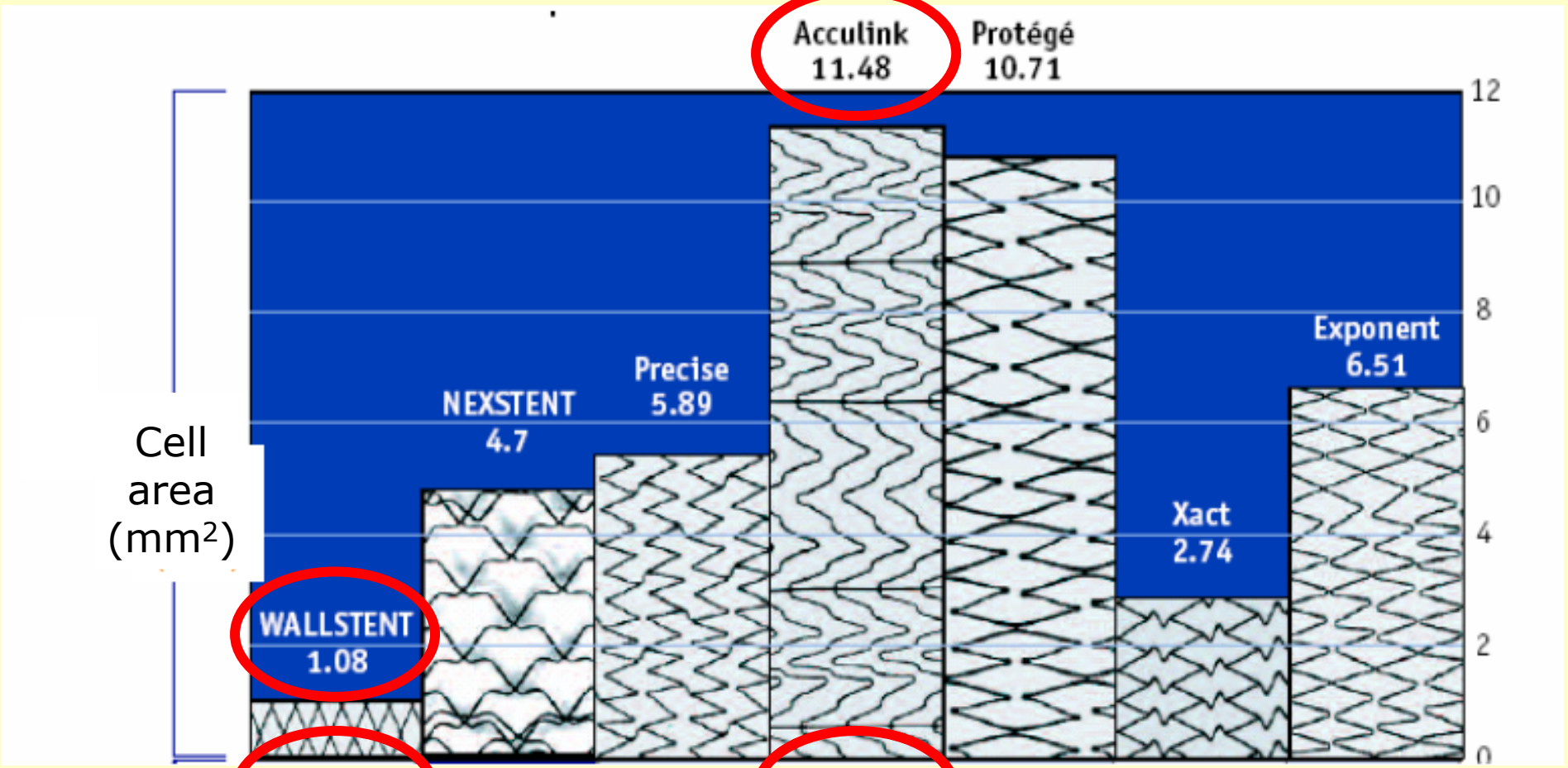
Most Frequent Combos	Miscellaneous Combos
344 patients	**139 patients**
385 procedures (71%)	**154 procedures (29%)**
• Combos n = 3	• Combos n = 31
• Stents n = 2	• Stents n = 9
• EPDs n = 3	• EPDs n = 11

ROUTINE Protected CAS in Hamburg 01/99–08/07

- Most frequently used stent/EPD combinations

A	1/03 –8/07	**Acculink + Emboshield BW** **194 patients** **213 procedures (40%)**
B	1/99 –3/01	**Wall Stent + GuardWire** **83 patients** **91 procedures (17%)**
C	1/03 –5/06	**Acculink + Accunet** **67 patients** **81 procedures (15%)**

Carotid Stents
Stent cell area

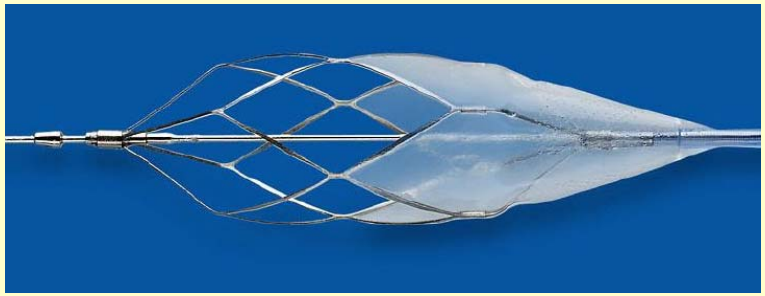


Design: closed closed open open open closed open

Houdart E, *CIRSE* 2006

Most Frequently Used EPDs

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

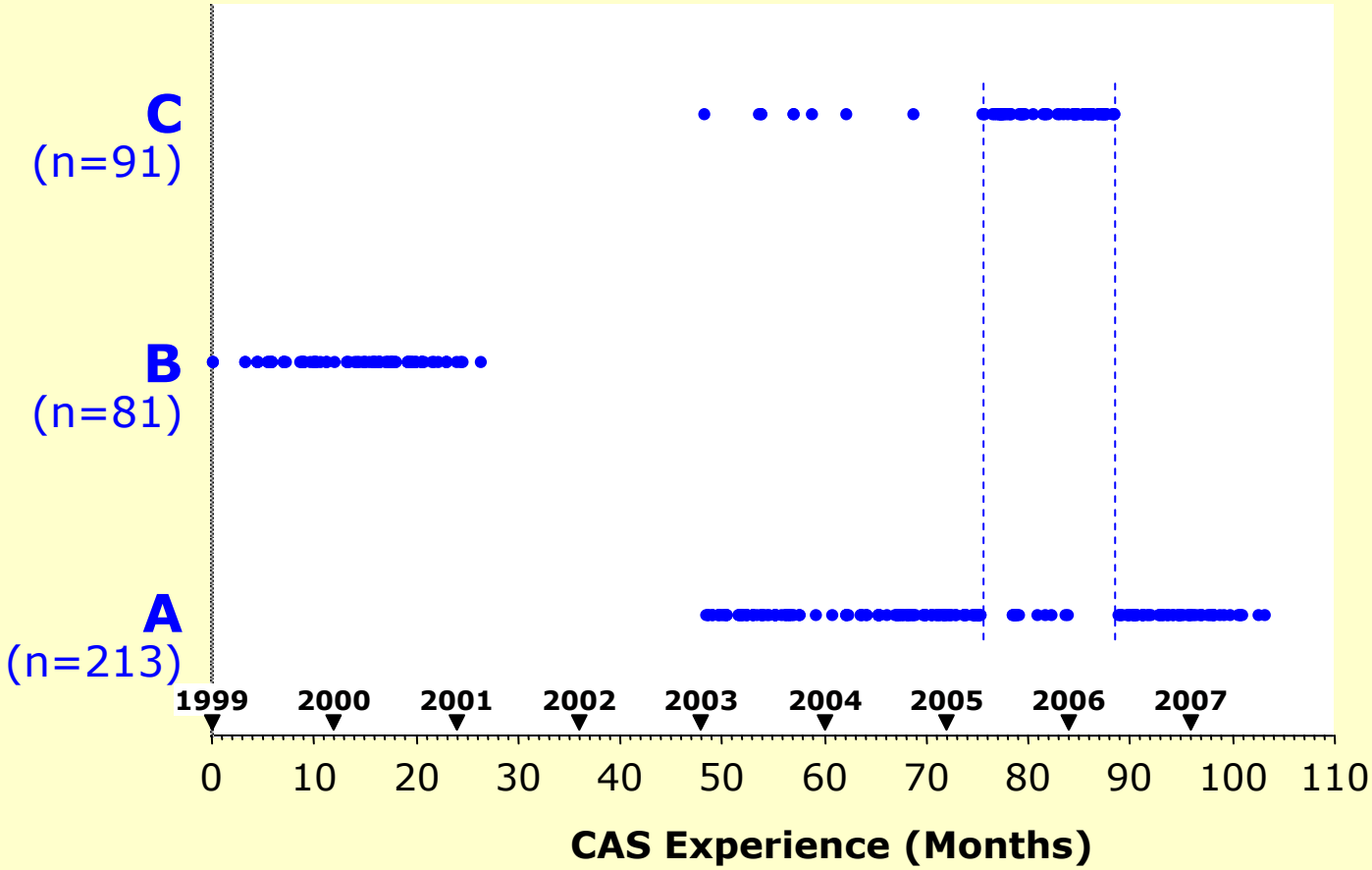


Accunet (Guidant)
- **Fixed-wire filter system**

GuardWire (Medtronic)
- **Distal balloon-occlusive system**

ROUTINE Protected CAS in Hamburg 01/99–08/07

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



ROUTINE Protected CAS in Hamburg 01/99–08/07

- Most frequently used stent/EPD combinations

	A (Aclk+ES BW)	B (Wall+GW)	C (Aclk+Acnt)	*P*
Patients, n	**194**	**83**	**67**	
Age, yrs	69 ± 9	68 ± 9	70 ± 9	
Age ≥75 years, %	26	27	33	0.525
Men, %	69	78	61	0.071
Diabetes, %	23	27	21	0.684
Smoking*, %	50	61	58	0.163
HT, %	85 [79-90]	66 [55-76]	87 [76-94]	<0.001
HLP, %	78	68	79	0.198
Lesions, n	**213**	**91**	**81**	
Ulcerated, %	46	47	39	0.551
Calcified, %	73 [67-79]	30 [21-41]	55 [43-67]	<0.001
Thrombotic, %	1	2	5	0.090
Symptomatic, %	24 [18-30]	47 [37-58]	22 [14-33]	<0.001

*ex/current

[] = 95% CI

ROUTINE Protected CAS in Hamburg 01/99–08/07

- Most frequently used stent/EPD combinations
- **More Lesion Characteristics**

	A (Aclk+ES BW)	B (Wall+GW)	C (Aclk+Acnt)
n	213	91	81
Lesion length, mm	**15.4** ± 5.7	**12.0** ± 5.5*	**16.0** ± 11.2
Diameter stenosis, %	**85** ± 8	**86** ± 8	**85** ± 8

- **Procedural Characteristics**

	A (Aclk+ES BW)	B (Wall+GW)	C (Aclk+Acnt)
n	213	91	81
Procedure duration, min	**34** ± 16	**54** ± 19*	**38** ± 23
Dwell time of EPD, min	**5.7** ± 2.1	**8.8** ± 3.2*	**5.8** ± 3.2

*$P < 0.001$ vs. A, $P < 0.001$ vs. C

ROUTINE Protected CAS in Hamburg
Case Presentations of Challenging Lesions

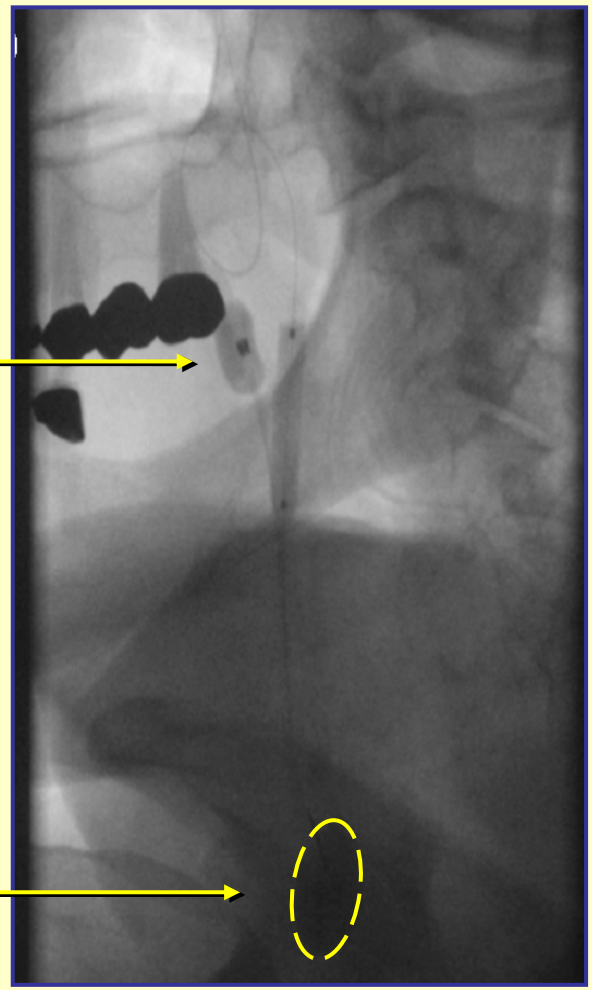
- Rare situations necessitating **proximal embolic protection**:
  - Extreme tortuosity of the distal vessel
  - Thrombus containing lesion
- In our experience, such situations were encountered in less than 5% of cases

ROUTINE Protected CAS in Hamburg
Case Presentations of Challenging Lesions

- **Stenosis in ICA with distal loop: Proximal embolic protection**

Blockage of antegrade flow by both balloons

ECA balloon

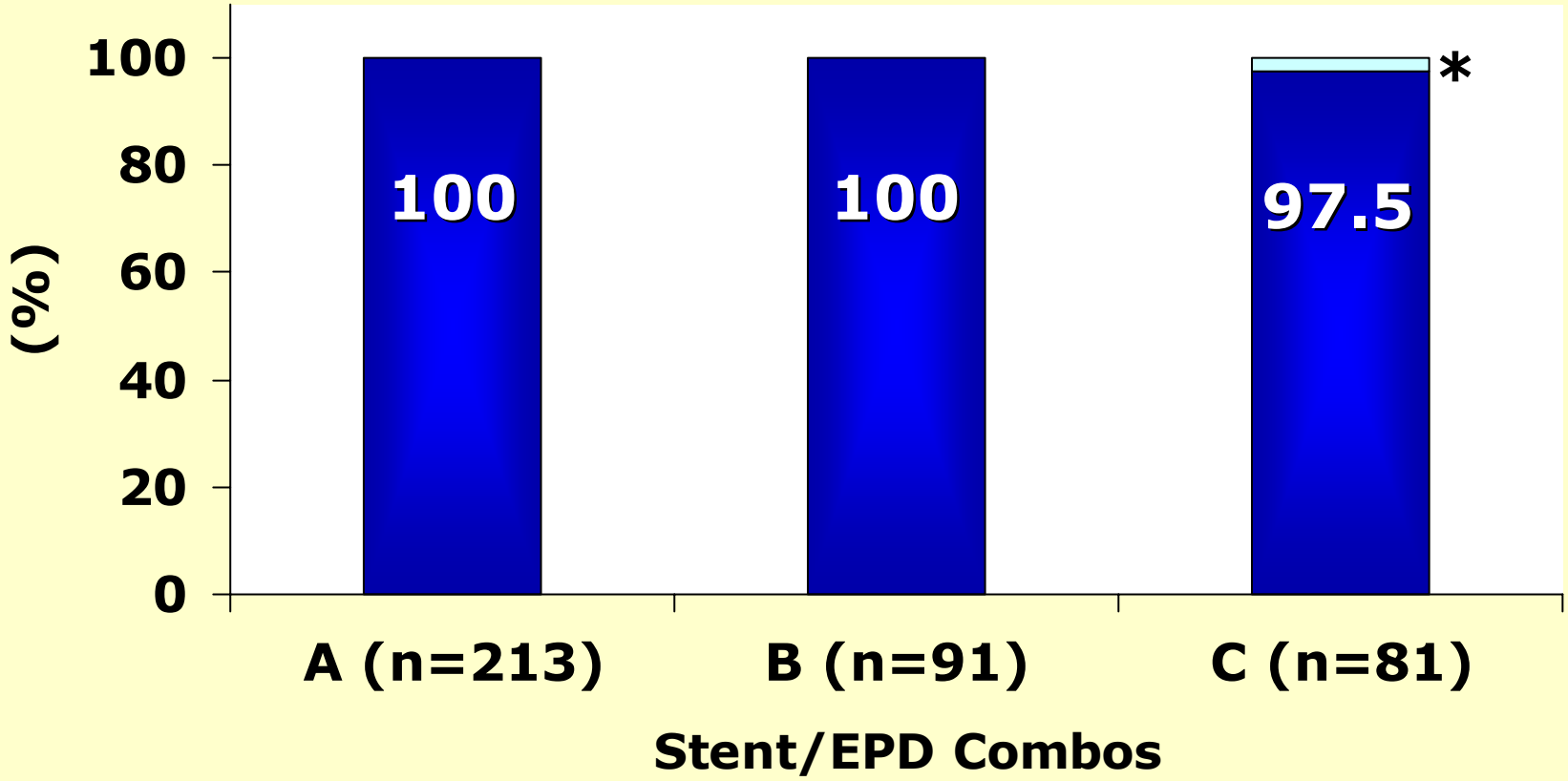


CCA balloon

P03-0077

ROUTINE Protected CAS in Hamburg 01/99–08/07

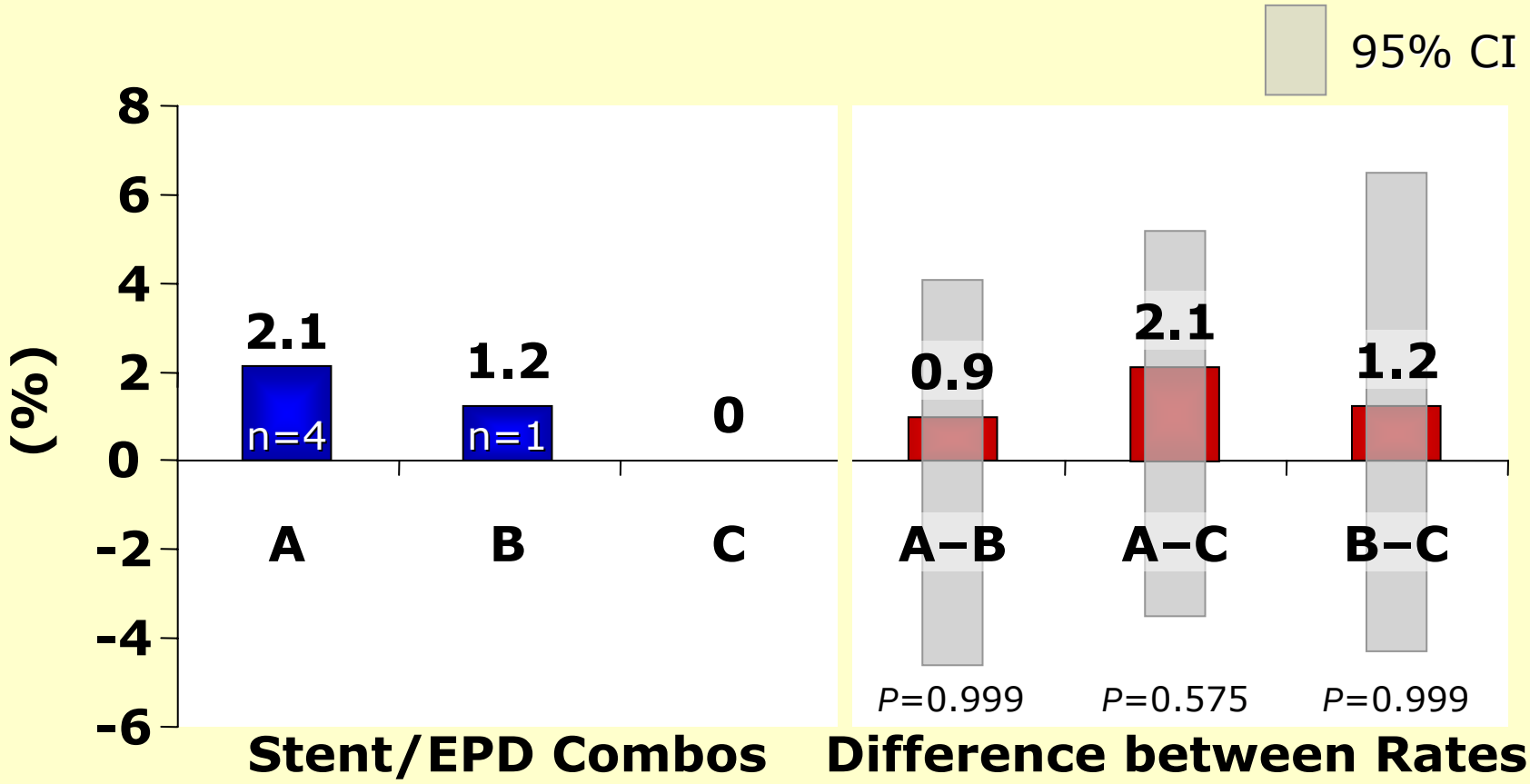
- Most frequently used stent/EPD combinations
- **Device success** (residual stenosis ≤20%)



*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)**



ROUTINE Protected CAS in Hamburg 01/99–08/07

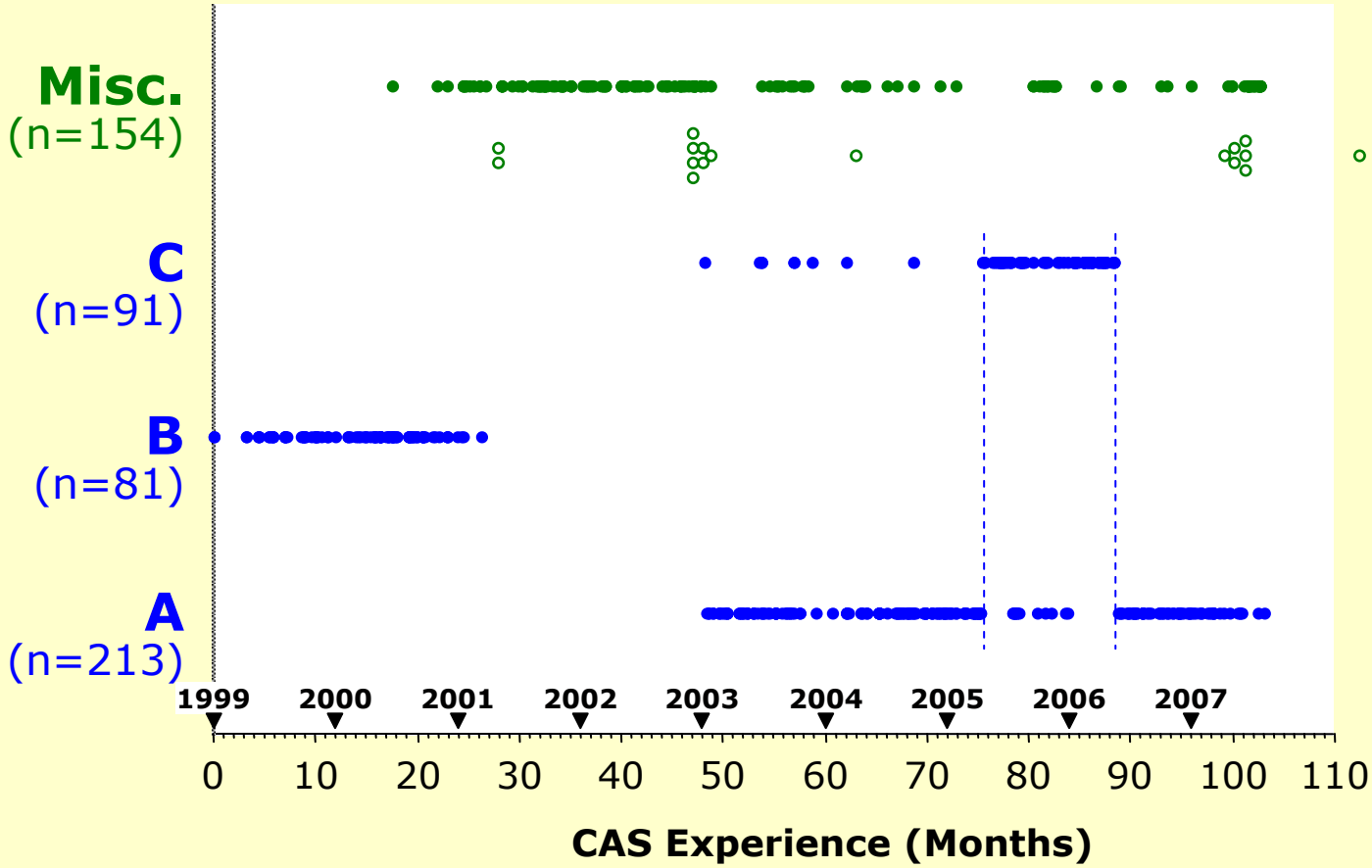
- Most frequently used vs. miscellaneous **stent/EPD combinations**

483 patients
539 procedures

Most Frequent Combos	Miscellaneous Combos
344 patients	**139 patients**
385 procedures (71%)	**154 procedures (29%)**
• Combos n = 3	• Combos n = 31
• Stents n = 2	• Stents n = 9
• EPDs n = 3	• 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.)

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ROUTINE Protected CAS in Hamburg 01/99–08/07

- Most frequent vs. miscellaneous stent/EPD combos

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

*ex/current

ROUTINE Protected CAS in Hamburg 01/99–08/07

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

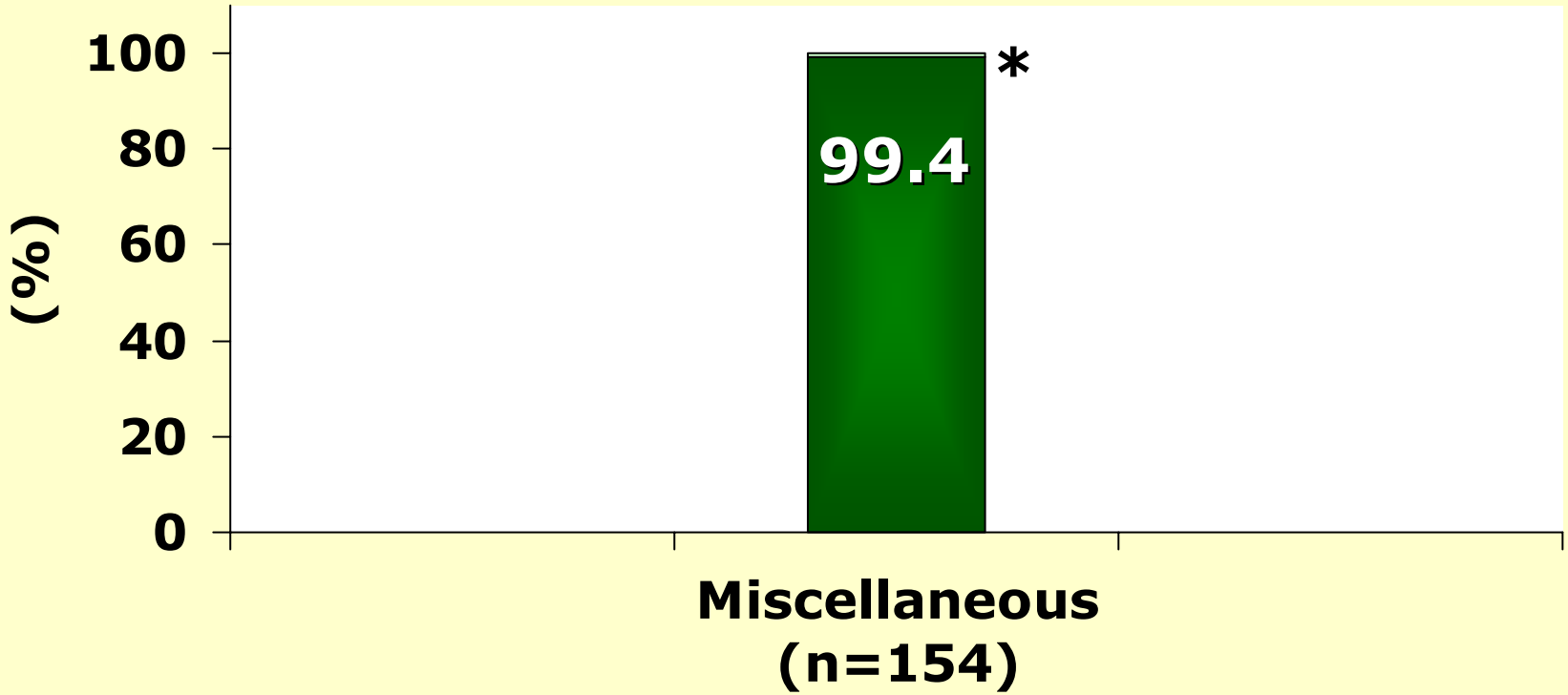
	Combos A, B & C Pooled	Miscellaneous Combos	*P*
n	385	154	
Lesion length, mm	**14.7** ± 7.3	**14.8** ± 5.0	0.334
Diameter stenosis, %	**85** ± 8	**87** ± 7	0.150

- **Procedural Characteristics**

	Combos A, B & C Pooled	Miscellaneous Combos	*P*
n	385	154	
Procedure duration, min	**39.5** ± 20.2	**45.5** ± 22.4	0.0009
Dwell time of EPD, min	**6.4** ± 2.9	**7.6** ± 4.0	0.0024

ROUTINE Protected CAS in Hamburg 01/99–08/07

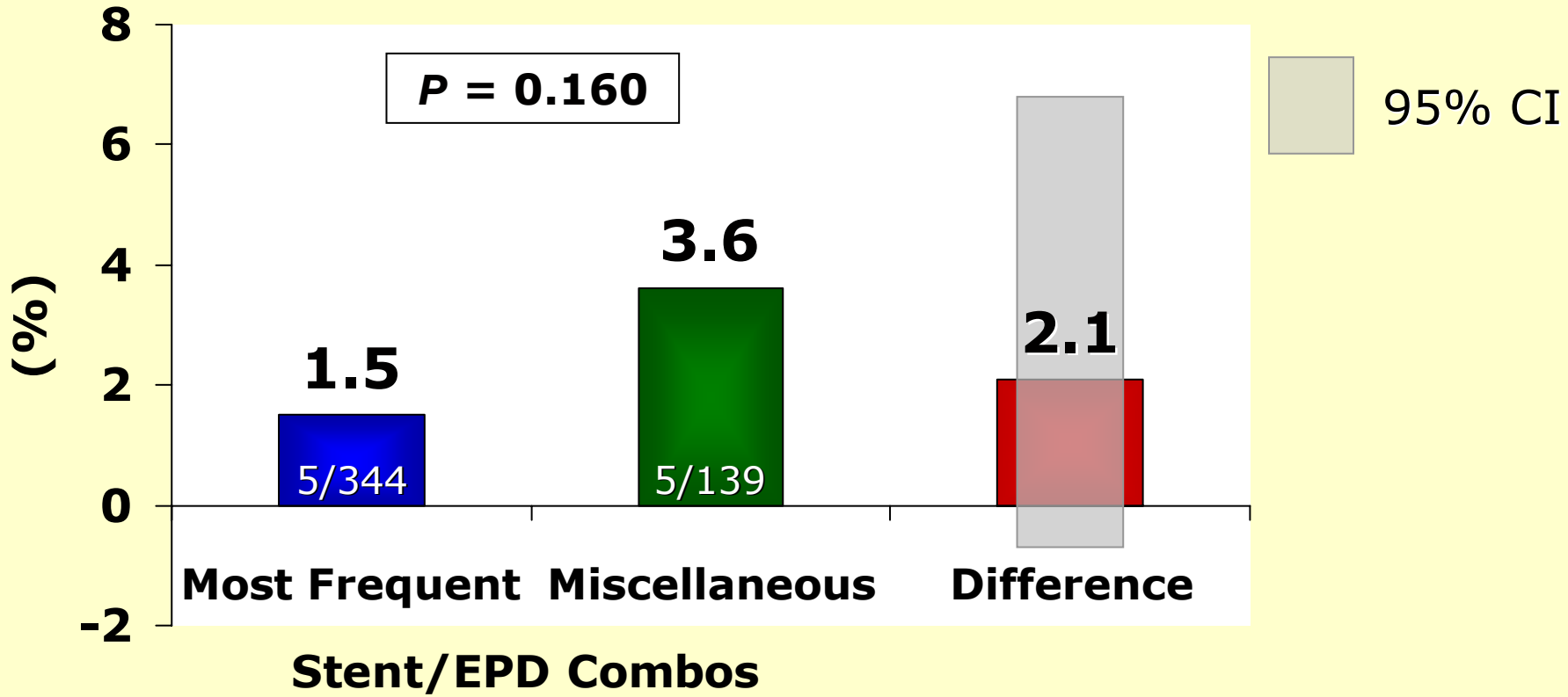
- Miscellaneous stent/EPD combinations
- **Device success** (residual stenosis ≤20%)



*Partial success (residual stenosis >20%<50%): n=1

ROUTINE Protected CAS in Hamburg 01/99–08/07

- Most frequent vs. miscellaneous stent/EPD combos
- **30-day stroke/death rates**



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