Does Carotid Stent Cell Design Matter? Open vs. Closed vs. Micromesh

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Disclosures

Bard Vascular: Research Support Biotronik: Research Support, Consultant Cook Medical: Research Support, Speaker

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Open? Closed? Micromesh? *is there a difference?*

"The question of indications, advantages, and limitations of an open-cell design versus a closed-cell stent has generated significant debate."

> Mark Wholey, MD 2007

Open vs Closed





Closed: All possible points of connection are utilized Open: Some possible points of connection are omitted

Wholey, M. Endovasc Today March 2007:25-34

Closed Cell vs Open Cell

under 1 Newton force









Open vs Closed

- Some series indicated fewer neuro events with closed cell
- Benefit has typically been seen in symptomatic patients
- No difference in DWI defects in symptomatic patients open vs closed

Bosiers, M. Eur J Vasc Endovasc Surg. 2007;33:135-14 Hart, J. J Vasc Surg 2006;44:725-30 Blasel, S. Cardiovasc Intervent Radiol. 2009;32:666-71

Open vs Closed

- CAPTURE postmarket (open) vs EXACT (closed)
 - 3,900 patients
 - No significant difference

Wholey, M. Endovasc Today March 2007:25-34

Open vs Closed *Does It Matter?*

9,751 Patients

Study	No. of patients	Favoring closed cells stents	No difference observed		
Blasel et al ¹³	84		Х		
Bosiers et al ¹⁰	3179	Х			
Hart et al ¹⁴	304	X			
Maleux et al ¹²	123		X		
Schillinger et al ¹¹	1684		X		
Timaran et al ^{17a}	40		X		
Jim et al ¹⁶	4337		Х		

Benefit seen only by Bosiers, Hart in symptomatic patients

Tadros. J Vasc Surg. 2012;56:89-95

Closed Cell Benefit?

Retrospective analysis, majority Wallstent use, Some cases done without embolic protection

Population	Outcome	<i>p</i> -value
Total	All events	0.005
	Post-procedural events	< 0.0001
Symptomatic	All events	< 0.0001
	Post-procedural events	< 0.0001
Asymptomatic	All events	1.00
5 1	Post-procedural events	1.00

Table 10. *P*-values for the test that event rates differ by cell type

Eur J Vasc Endovasc Surg Vol 33, February 2007

TIA was the major contributor to different outcomes

Bosiers, M. Eur J Vasc Endovasc Surg. 2007;33:135-41



Open vs Closed *Comparison of emboli*

- Filters examined from 173 patients
- Open cell vs closed cell: No difference in clinical outcomes
- Particle size and number:

Tadros. J Vasc Surg. 2012;56:89-95

Particle Number and Size Based on Stent Type



Tadros. J Vasc Surg. 2012;56:89-95

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Open vs Closed

too narrow a question

- Overall performance is crucial
 - Profile
 - Trackability
 - Radial support
 - Deployment accuracy
- A big closed cell is more dangerous than a small open cell

Wholey, M. Endovasc Today March 2007:25-34

Micromesh Stents Best of Both Worlds

- Deliverable, conformable
- Large cell frame
- Mesh with exceptionally small cell size



Roadsaver®

- Nitinol double layer micromesh
- Exceptionally small cell size (375-500μm)
- Design goals
 - High flexibility
 - High conformability
 - Avoid plaque protrusion





Case by Max Amor, MD

Plaque Protrusion

- Possible source of intraprocedural complications
- May explain post-procedural stroke

Roadsaver®

Carotid Stent System

- 5 french rapid exchange
- Re-sheathable even after









Case performed by Max Amor, MD

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Roadsaver® Symptomatic LICA Stenosis Proximal Protection (MoMa)



Case performed by Max Amor, MD

Gore Micromesh Stent



Gore Micromesh Stent



Open cell nitinol frame 500µm PTFE closed cell mesh on outside

CGuard Micromesh Stent



CGuard Micromesh Stent



- Nitinol frame
- Single-strand PET mesh
- Cell size 150-180µm
- CARENET trial
 - Low incidence of DWI lesions
 - Low volume of DWI lesions

CARENET: DW-MRI analysis

DW-MRI analysis @ 48 hours*

2015



Piotr Musialek, MD LINC 2015

Summary

- Cell type is only one component of overall stent performance
- Selection of embolic protection may be as or more important
- No convincing superiority of one cell type
- Micromesh design appears superior to conventional stents

Closed Cell Benefit? M. Bosiers et al.

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	Retrospective	analysis	<u>74%</u>	Patients	All Seven Multi	I ISE	All events	Post-procedural events	Patients	All events	Post-procedural events
	i ten copeente	anaryoro,	Open cell Closed cell	937 2242	$39 \\ 51 \\ 29 \\ 32 \\ 32 \\ 32 \\ 32 \\ 32 \\ 32 \\ 32$	383 934	27 21	24 12	554 1308	12 30	8 17
	30-Day Events	Open Cell	Total Cell type Open cell Closed cell Total	3179	90 61 4.2% 3.4% 2.3% Closed	1317 G17e	48 7.0% 2.2% 3.6%	36 6.3% 1.3% 2.73%	1862	42 2.2% 2.3% 2.25%	25 1.4% 1.3% 1.3%
		(N=63)	programs s these session with the spo with extrem	ponsored ons the onsor's c	d by different comparison interventions where levice, except for cases	5 Juring performed presenting	Th sugge are k	e results of our est that especial mown to have	retrospec ly in sym an emb	tive stati ptomatic oligenic free cell	stical analysis patient, who plaque, ²¹ the area resulted
<	Stroke/death	1.6%	stent in tor plaques cor one could the majority	rtuous b nsidered argue th y of the s	ifurcation or closed co as vulneration () So ev nat devise selection w stents where assigned r	ll stent in en though as biased, andomly.	in a sin a	e of a stent with gnificant decrea symptomatic p nt predictor of 002 and post-p rell area lower t	se of the ppulation he numb rocedural han 2.5 m	post-proc free cell er of even events	redural events. area was a sig- nts (all events: p < 0.0001). A ed superiority
	Death	0%	The nature	of mos	Discussion	n patients	for be (<2.5 p = 0. proce also b	oth event types vs. 5–7.5; all 024 and <2.5 dural: $p = 2.8$ 10 e established be	(all and $p = 0.04$ vs. >7.5, ⁻⁶). Signi tween the	post-proce 48 - pc all: p = ficant difference $at stent with the stendard ste$	edural events) st-procedural: = 0.0006; post- ferences could th the smallest
<	Stroke, death, TIA	11.1%	with carotic perfusion of As demo domized tr removing th	d artery f the brai phstrated r als, ^{10—14} he plaqu	stenosis are not related in but have an embolige in multionter prosp carotia endarterector e and the source of em	t to hypo- enic origin. ective ran- ny (CEA), boli, is the	free c the la terms (p = 0) proce	ell area (Wallsto argest free cell of all ever 0.0079) and all dural ($p = 3.6$ 1	ent: 1.08 r area (Ad ts for (p = 0.00) 0^{-5}) ever	nm ²) and cculink: the tota 041) as nts in the	l the one with 11.48 mm ²) in I population well as post- symptomatic
			goiu stanu	aru to	reduce shoke in syl	inpiomatic	popu	lation.			

NOTE: Data from a retrospective dual-center study of patients with significant carotid CAS?: An effective endovascular approach should consebinary categorization of open- or closed- cell stents and closed of stents and closed cell group. procedure as performed now¹⁷ opens the stenosis by dilatation and tries to prevent future embolization and death rates. through the scaffolding of the ruptured plaque

against the vessel wall by means of a stent. Therefore after completion of the procedure the struts of the stent are the only protection against post-procedural 1317 patients: 3.6%). neurological events.18-20

Table 10. P-values for the test that event rates differ by cell type

TIA was the major contributor to different outcomes

All events Asymptomatic

Post-procedural events

1.00

Eur J Vasc Endovasc Surg Vol 33, February 2007

Comparing stents by cell types (open vs. closed) in the total (3.4% vs. 1.3%) and most of all in the symptomatic population (6.3% vs. 1.3%) resulted in a clear reduction of predominantly post-procedural events

Asymptomatic populatic

In the asymptomatic population free cell area or cell type did not influence the event rate. The 30-day stroke and death rate for the asymptomatic group (42 events in 1862 patients: 2.2%) was considerably lower than in the symptomatic patients (48 events in

In contrast with many single high volume centers who have reported low intra- and post-procedural adverse neurologic events after CAS,^{22–25} recent update from randomized multi-center trial suggest higher complications. The EVA-3S²⁶ and SPACE² or CAS in symptomatic

ath rate at 30 days respectively ny different stents have been used. A sub-analysis of these trial results comparing free cell area with event rate could be of

Bosiers, M. Eur J Vasc Endovasc Surg. 2007;33:135-41

Competition

Compa ny	Inspire MD	Terumo/ Micro- vention	W.L. Gore	Boston Scientific	Abbott \	/ascular	Cordis/ Cardinal Health	Invatec/ Medtronic	ev3/ Covidien/ Medtronic
Stent Name	C-Guard	Roadsave r	Gore Carotid Stent	Carotid Wallstent	XACT	Acculink	Precise Pro	Cristallo Ideale	Protégé RX
Micro- mesh	PET knitted	Braided Nitinol	Heparin- coated PTFE	-	-	-	-	-	-
Cell area (mm²)	~ 0.17	0.38	~ 0.51	1.40	1.89	2.36	2.36	3.23	4.93



Different types of protection devices







The Planck-Surger Guard/Wire ^{on} Systems is of approved for size in the U.S. in the promary, combined or parolel concollation

> PercuSurge Export[™] Aspiration Catheter Mounted on GuardWire[™]

Types of protection, what device is optimal?



In-vitro performance of different filters

- 3 filter devices
- Silicone flow model
- Quantification of vessel wall apposition
- Quantification of capture ability

wall apposition capture ability *p*=NS

Finol et al J Endovasc Ther 2008; 15:177-185

Neuro-complications after CAS

- Patients 3160 CAS, 9 protection devices in total
- Clinical/neurological follow-up at 30 days

concentric vs eccentric lesions *p*=NS proximal vs distal protection*p*=NS

Iyer V et al J Vasc Surg 2007; 46: 251-56

Does stent design matter?

- Wallstent
 - Closed cell elgiloy
- Acculink
 - Open cell
- Xact
 - Closed cell nitinol



Plaque coverage



- Very good
- Less coverage
- Good



Cell design on CVA risk

ALL EVENTS	Tota popula	al tion	Sympton	matic	Asymptomatic		
	n/N	%	n/N	%	n/N	%	
Closed	51/2242	2.3%	21/934	2.2%	30/1308	2.3%	
Open	39/937	4.2%	27/383	7.0%	12/554	2.2%	
TOTAL	90/3179	2.8%	48/1317	3.6%	42/1862	<mark>2.6%</mark>	

Closed cell reduced overall risk for CVA primarily in symptomatic patients However never studied-large RCT necessary to discriminate

Bosiers M et al EJVES 2008

Open vs Closed... the question is not so easy...

- Large closed cell vs small open cell
- Other components of overall stent performance
- Other variables:
 - Type of embolic protection filter
 - Proximal vs distal protection
 - Symptomatic vs asymptomatic
 - Other patient variables

CONCLUSIONS

- Distal Embolic Protection has dramatically improved outcomes from stenting
- Distal embolic protection is the standard of care
- Operators must have experience to use DEP in CAS
- Device types, DEP seem similar in all outcomes