i-MEET
NEXT GENERATION
Multidisciplinary European Endovascular Therapy

The stent choice in TCAR Does (not) Matter!

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University of Navarra, Pamplona

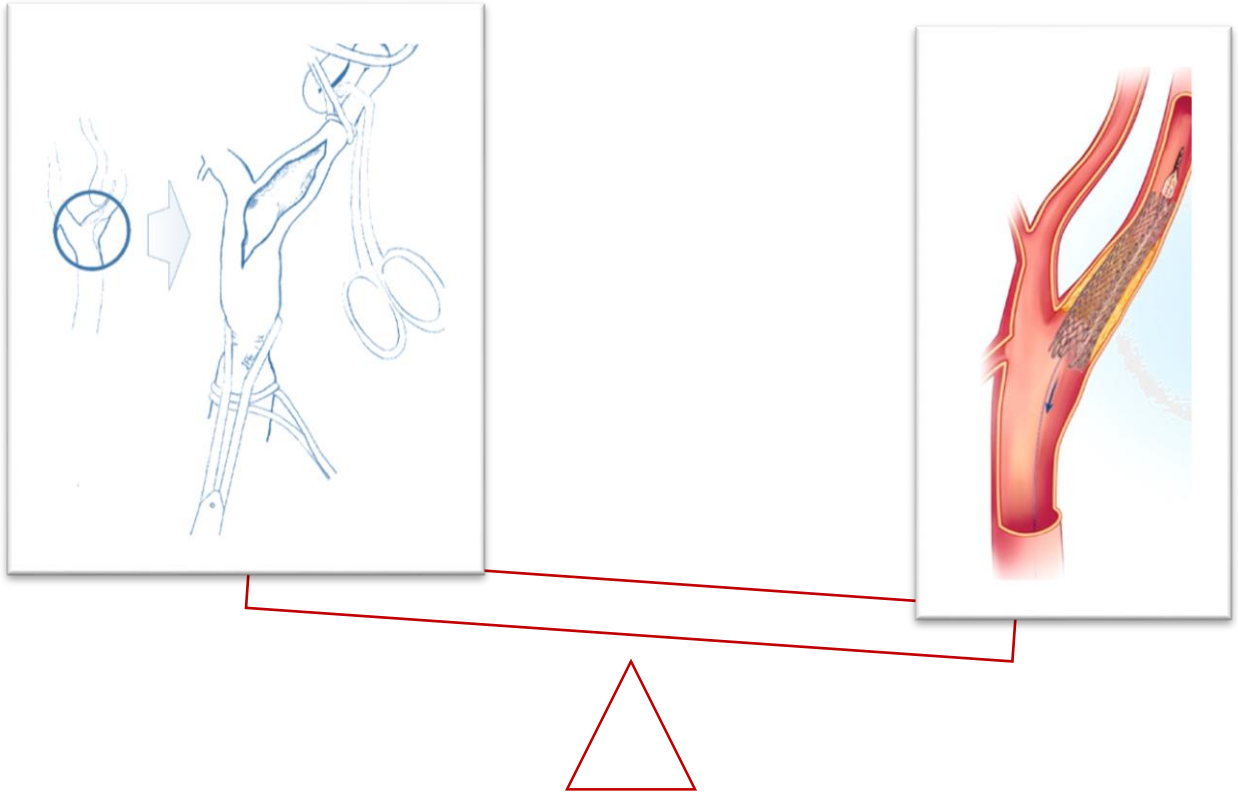
Disclosure of Interest

Disclosure

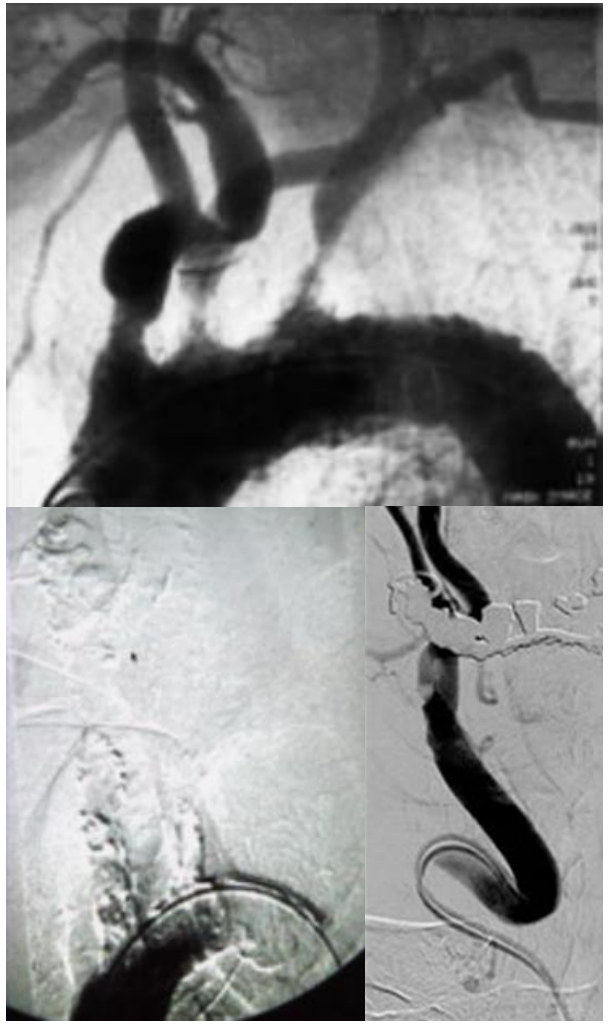
Speaker name: Ignacio Leal

.....

- ☐ I have the following potential conflicts of interest to report:
- ☒ Consulting, SilkRoad Medical.
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)
- ☐ I do not have any potential conflict of interest



These ones are not very easy to stent…



Neither CEA nor CAS are perfect for 100 %

of our patients

TODAY…

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Trans-Femoral Carotid Artery Stenting (TF-CAS)

15 years on Market

HIGH (2X) peri-procedural stroke risk

CREST 30-day All Stroke[1]: 2.3% CEA vs 4.1% TF CAS

[1] CREST Trial: N Engl J Med 2010;363:11-23 [2] Circulation. 2012;125:2256-2264

CAS

TODAY…

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TRANSFEMORAL CAS (and FILTERS)

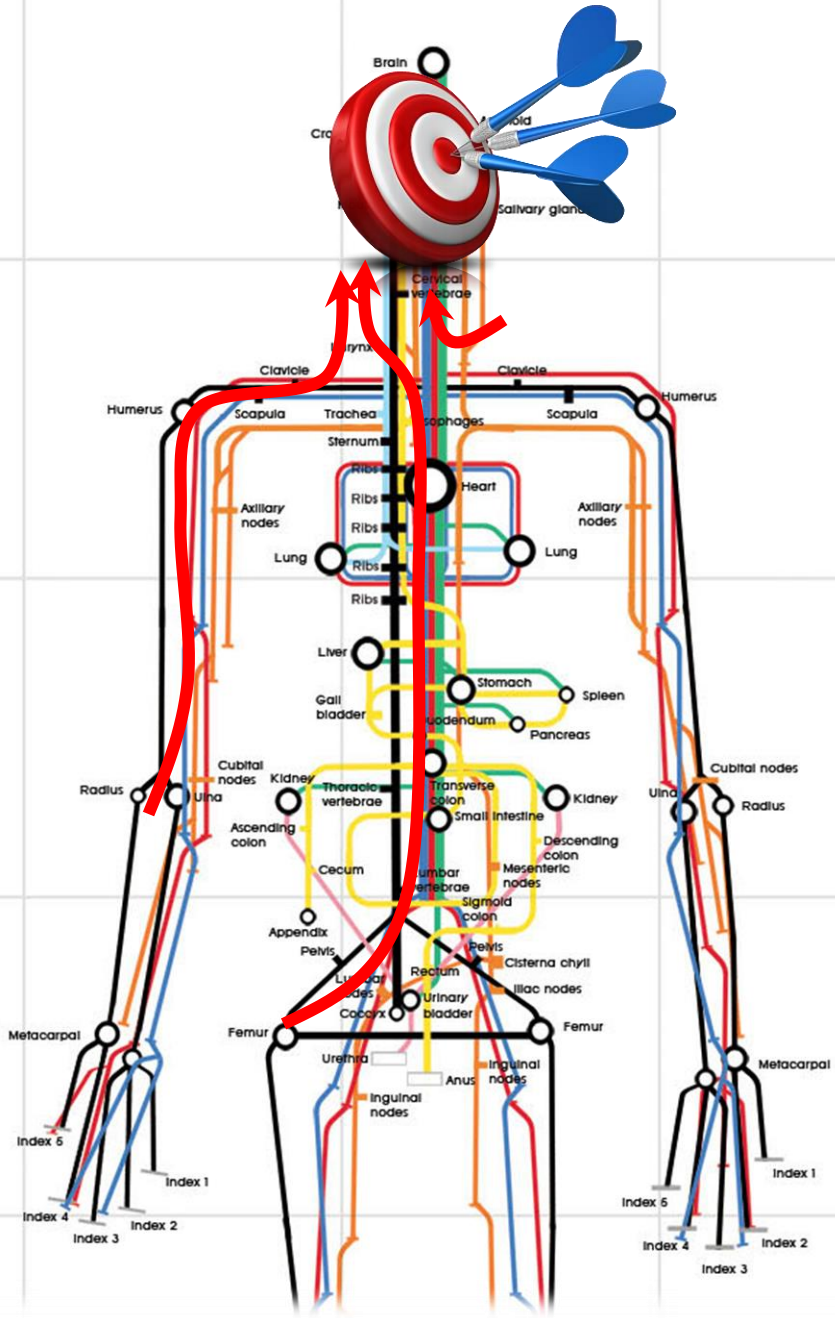
[1] CREST Trial: N Engl J Med 2010;363:11-23 [2] Circulation. 2012;125:2256-2264

The terminology ” CAS” is a source of misunderstandings

- Which EPD ?
- Which stent ?
- Which access route ?

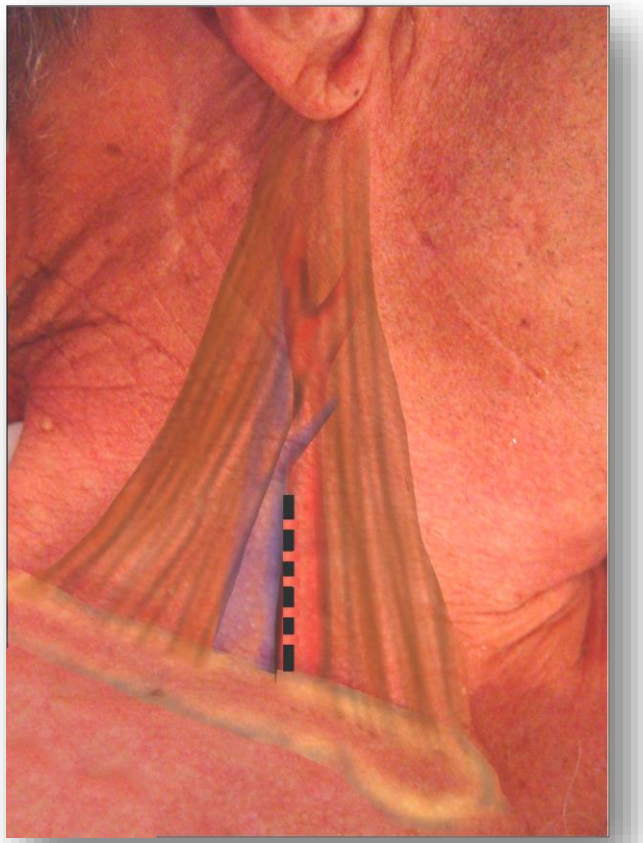
UNDERSKIN

WHY NOT STARTING YOUR RIDE IN THE NEAREST STATION?



Direct TRANSCAROTID ACCESS

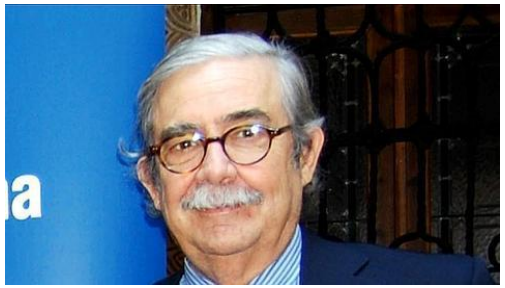
FLOW REVERSAL

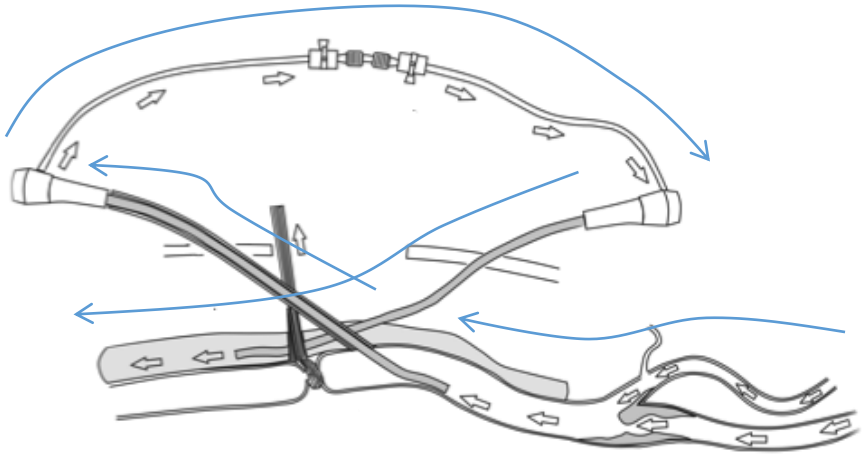


Transcervical Carotid Artery Angioplasty and Stenting with Carotid Flow Reversal: Surgical Technique

Enrique Criado, MD,[1] Manuel Doblas, MD,[2] Juan Fontcuberta, MD,[2] Antonio Orgaz, MD,[2] and Angel Flores, MD,[2] Stony Brook, New York, and Toledo, Spain

Ann Vasc Surg 2004; 18: 257-261

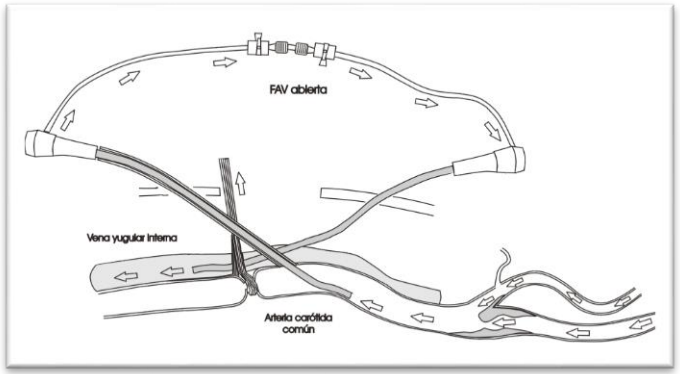




A Prospective Evaluation of Cerebral Infarction following Transcervical Carotid Stenting with Carotid Flow Reversal

J.I. Leal [a], A. Orgaz [a], J. Fontcuberta [a], A. Flores [a], M. Doblas [a], J.M. Garcia-Benassi [b], B. Lane [c], C. Loh [d], E. Criado [e,*]

Eur J Vasc Endovasc Surg (2010) 39, 661–666

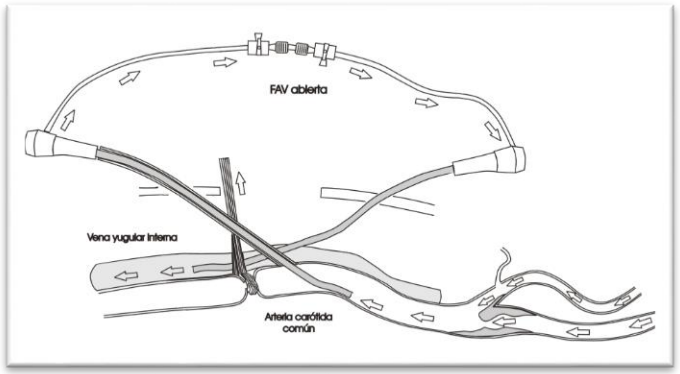


Stent	Embolic Protection	N	Symptom Status	% New Lesions	% New Ipsi Lesions
Wallstent (n=25) Protégé (n=6)	Proximal Flow Reversal	31	Asx=39% Sx=61%	12.5%	12.5%

A diffusion-weighted magnetic resonance imaging-based study of transcervical carotid stenting with flow reversal versus transfemoral filter protection

Ignacio Leal, MD,[a] Antonio Orgaz, MD,[a] Ángel Flores, MD,[a] Jose Gil, MD,[a] Rubén Rodríguez, MD,[a] Javier Peinado, MD,[a] Enrique Criado, MD,[b] and Manuel Doblas, MD,[a] *Toledo, Spain; and Ann Arbor, Mich*

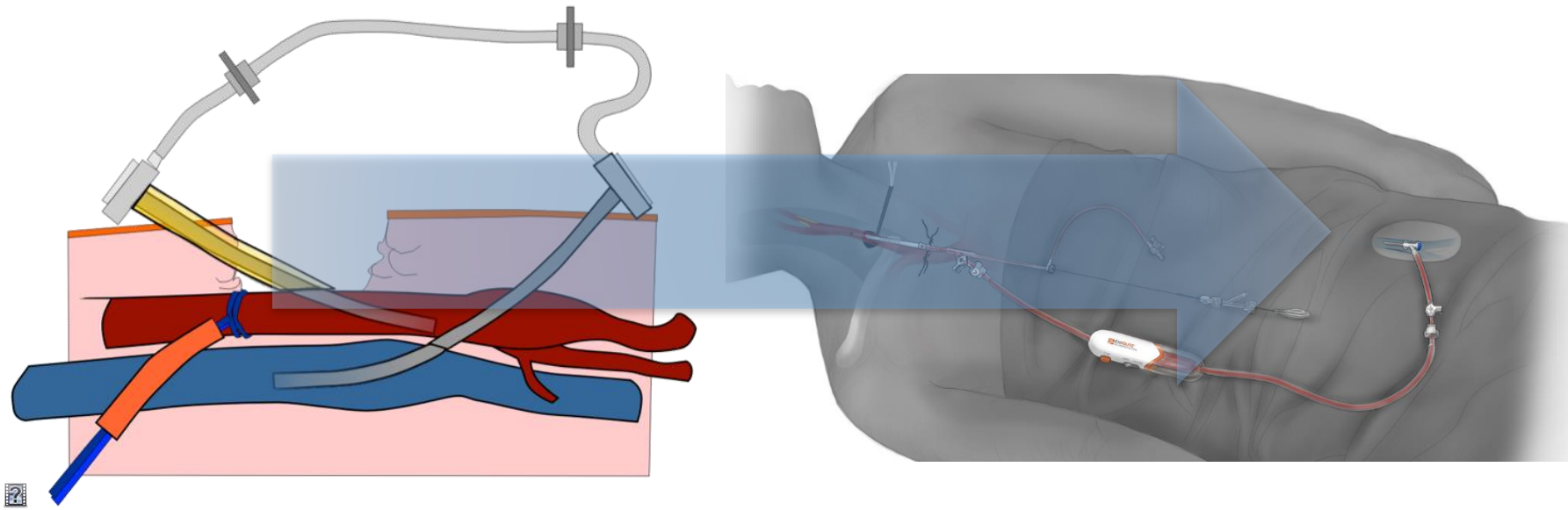
J Vasc Surg 2012;56:1585-90



The lowest reported to date in a CAS experience

	TRANSCERVICAL FLOW REVERSAL	TRANSFEMORAL FILTER	P
Patients with new lesions (n, %)	4 (11,70 %)	11 (33,33 %)	0.04
Number of new lesions	4	13	
Localization of new lesions	Ipsilateral: 4 Contralateral: 0	Ipsilateral: 11 Contralateral: 2	

ICSS[2]	**CEA**	**Clamp, backbleed**	**107**	**17%**



Silk Road Medical @SilkRoadMed · 9 may.

This week we celebrate 10,000 #TCAR procedures performed worldwide. Thanks to all the physicians and patients who have put their trust in us to #preventstroke!

Traducir Tweet

TransCarotid Artery Revascularization

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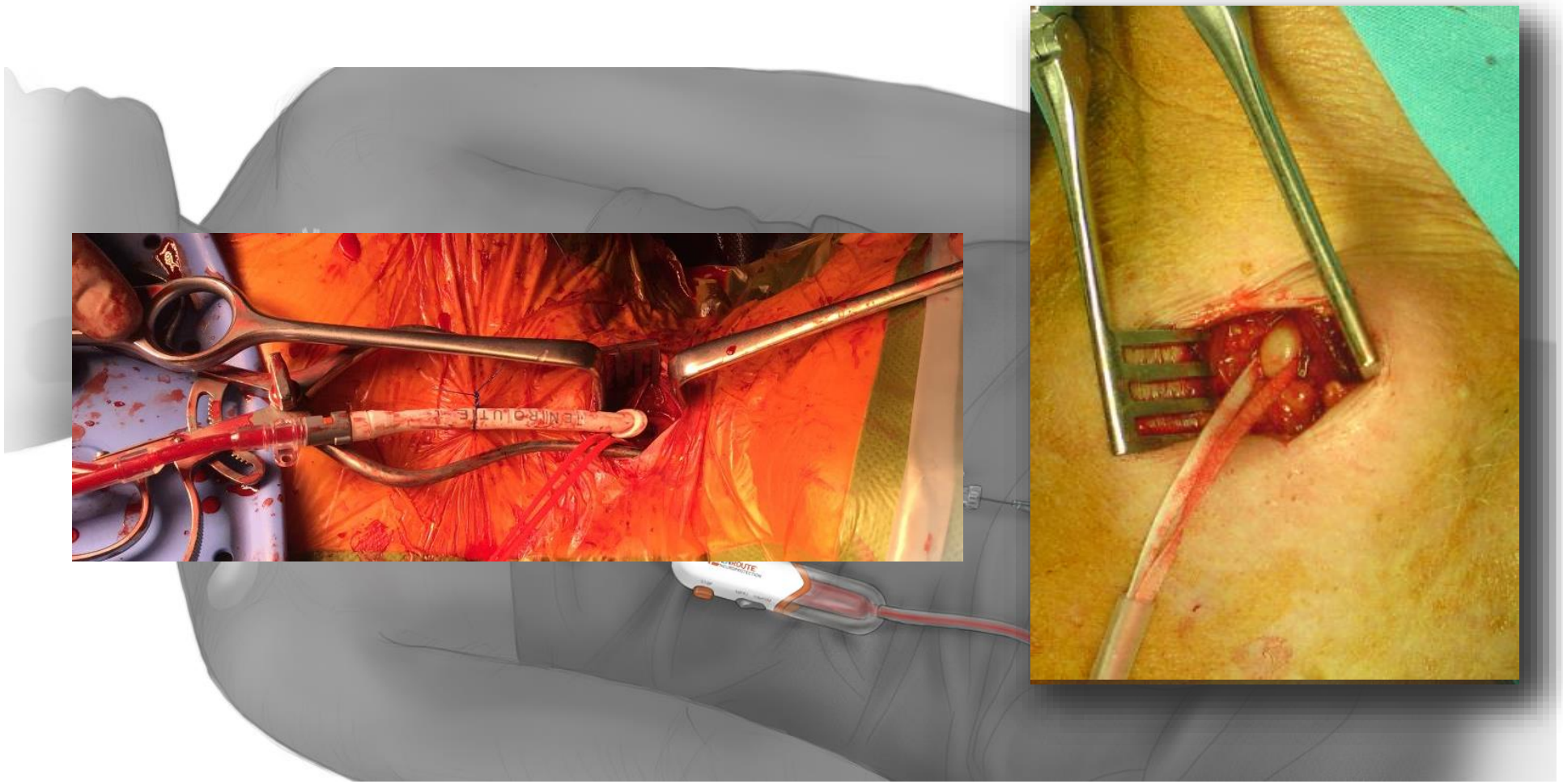
ENROUTE® Transcarotid Neuroprotection System



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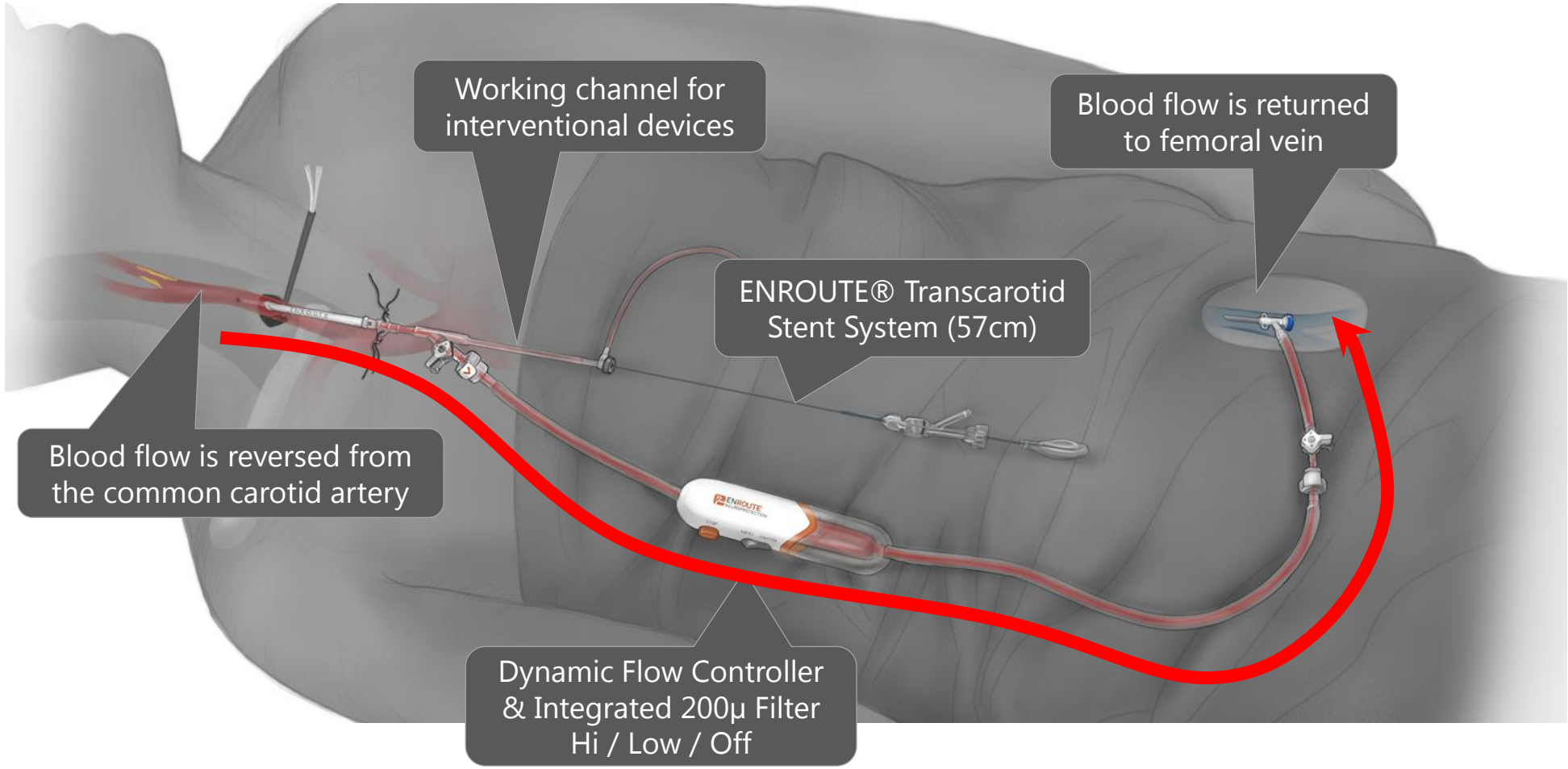

TCAR – Clinical Outcomes

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Results of the ROADSTER multicenter trial of transcarotid stenting with dynamic flow reversal

Christopher J. Kwolek, MD,[a] Michael R. Jaff, DO,[b] J. Ignacio Leal, MD,[c] L. Nelson Hopkins, MD,[d] Rasesh M. Shah, MD,[e] Todd M. Hanover, MD,[f] Sumaira Macdonald, MD,[g] and Richard P. Cambria, MD,[a]
Boston, Mass; Toledo, Spain; Buffalo, NY; Norfolk, Va; Greenville, SC; and Sunnyvale, Calif

J Vasc Surg 2015;62:1227-35.

Conclusions: The results of the ROADSTER trial demonstrate that the use of the ENROUTE Transcarotid NPS is safe and effective at preventing stroke during CAS. The overall stroke rate of 1.4% is the lowest reported to date for any prospective, multicenter clinical trial of CAS. (J Vasc Surg 2015;62:1227-35.)

ROADSTER Study
TCAR Subgroup Outcomes

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TCAR 30-Day All Stroke
ROADSTER* STUDY n=141

1.4%	**All Stroke**
0.0%	**Major Stroke**
0.0%	**>75yrs**
0.0%	**Symptomatic**
0.0%	**Female**

ROADSTER - High Surgical Risk Patients

CEA 30-Day All Stroke
CREST STUDY n=1,240

2.3%	**All Stroke**
0.6%	**Major Stroke[1]**
3.1%	**>75yrs[2]**
3.2%	**Symptomatic[1]**
2.2%	**Female[3]**

CREST - Standard Surgical Risk Patients

*J Vasc Surg 2015;62:227-35 [1] N Engl J Med 2010;363:11-23 [2]Stroke. 2011 Dec;42(12):3484-90
[3]Lancet Neurol. 2011Jun; 10(6): 530-537

TCAR Clinical Results: Real-life patients

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In-Hospital Outcomes of TCAR and CEA in the SVS-VQI TCAR Surveillance Project

Marc Schermerhorn, MD; Patric Liang, MD; Hanaa Dakour Aridi, MD; Vikram Kashyap, MD; Grace Wang, MD; Brian Nolan, MD; Jack Cronenwett, MD; Jens Eldrup-Jorgensen, MD; Mahmoud Malas, MD, MHS – **VEITH Symposium Presentation, November 2018**

Baseline Characteristics	TCAR N=2,545	CEA N=43,114	*P*-value
Age, Mean (SD)	73.1 ± 9.4	70.6 ± 9.6	<.001
Female	36%	39%	<.01
Black	5%	5%	.61
Hypertension	90%	89%	.50
Diabetes Mellitus	37%	36%	.52
Coronary Artery Disease	51%	27%	<.001
CHF	19%	11%	<.001
COPD	29%	23%	<.001
Chronic Kidney Disease (GFR <60)	41%	34%	<.001
Prior CEA/CAS	31%	15%	<.001
Asymptomatic	53%	51%	.37
General Anesthesia	83%	92%	<.001

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Brian Nolan, MD; Jack Cronenwett, MD; Jens Eldrup-Jorgensen, MD; Mahmoud Malas, MD, MHS – **VEITH Symposium Presentation, November 2018**

Unadjusted Outcomes	TCAR N = 2,545	CEA N = 43,114	*P*-value
Stroke/Death	1.8%	1.4%	.09
Stroke/Death/MI	2.1%	1.8%	.17
Stroke	**1.4%**	**1.2%**	**.27**
In-hospital Death	0.5%	0.3%	.04
30-day Death	0.9%	0.6%	.08
Myocardial Infarction	0.4%	0.4%	.71

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Unadjusted Outcomes	TCAR N = 2,545	CEA N = 43,114	*P*-value
Hemodynamic Instability			
Hypertension	12%	20%	<.001
Hypotension	13%	10%	<.001
Bleeding with Intervention	1.4%	1.0%	.05
Reperfusion Syndrome	0.2%	0.2%	.54
CNI	0.2%	2.7%	<.001
Operative Time, Mins, Mean	75 ± 31	116 ± 45	<.001
LOS, Days, Median (IQR)	1 (1-2)	1 (1-2)	.34
LOS >1 day	29%	32%	<.01

Analysis of the ROADSTER pivotal and extended-access cohorts shows excellent 1-year durability of transcarotid stenting with dynamic flow reversal

Mahmoud B. Malas, MD, MHS, FACS,[a] Jose Ignacio Leal Lorenzo, MD,[b] Besma Nejim, MBChB, MPH,[a] Todd M. Hanover, MD,[c] Manish Mehta, MD, MPH,[d] Vikram Kashyap, MD,[e] Christopher J. Kwolek, MD,[f] *and* Richard Cambria, MD,[g] *Baltimore, Md; Toledo, Spain; Greenville, SC; Albany, NY; Cleveland, Ohio; and Boston, Mass*

J Vasc Surg 2019;69:1786-96.

requiring treatment (4.3%), and hostile neck (14.6%). Medical high-risk criteria included two-vessel coronary artery disease (14.0%) and severe left ventricular dysfunction with ejection fraction <30% (1.8%). In general, 43.3% of patients had at least one anatomic high-risk factor, whereas 29.9% of patients had medical high-risk factors. Both subsets of factors were present simultaneously in 26.8% of the cohort. At 1-year follow-up, ipsilateral stroke incidence rate was 0.6%, and seven patients (4.2%) died. None of the deaths were neurologic in origin.

Periprocedural Stroke Rates

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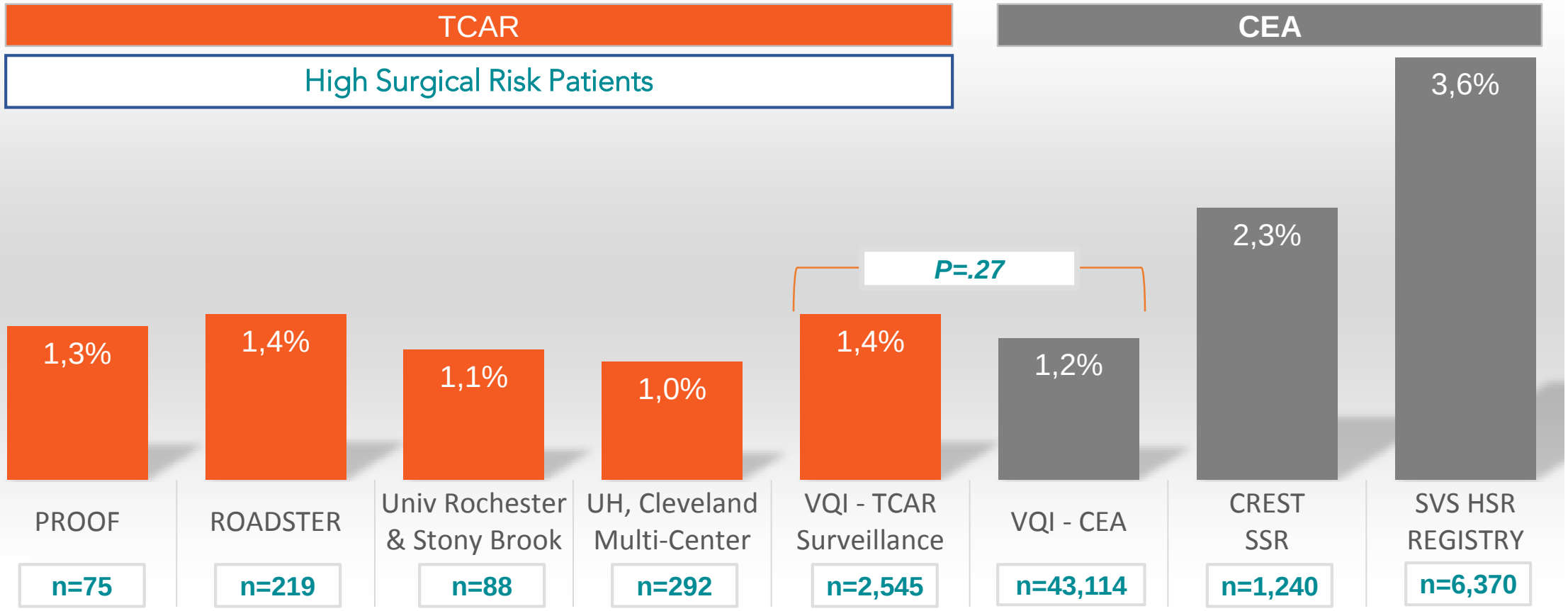


PROOF: J Endovasc Ther. 2017 Apr;24(2):265-270
ROADSTER: J Vasc Surg. 2015 Nov;62(5):1227-34. The Silk Road System for Transcervical Access with Reversal of Flow to Perform TCAR: Results of the ROADSTER Trial - VEITH, 2016
Univ Rochester & Stony Brook: Transcarotid Arterial Revascularization: First Post-Approval Safety & Efficacy Study – VAM, 2018 Poster Presentation
UH Cleveland: A Multi Institutional Analysis of TCAR Compared to CEA – VAM, 2018 Poster Presentation
VQI TCAR + CEA: In-Hospital Outcomes of TCAR & CEA in the SVS-VQI TCAR Surveillance Project – VEITH Symposium 2018 Presentation Unadjusted Outcomes – M. Schermerhorn, MD
CREST Standard Surgical Risk: N Engl J Med. 2016 Mar 17;374(11):1011-20.
SVS Registry: J Vasc Surg. 2013 May;57(5):1318-24.

Can we really improve this numbers ??

Can we really improve this numbers with different stent choices ??

Which stent design is your first choice for most of your CAS patients?

1. Open cell
2. Closed cell
3. Mesh-membrane

Influence of stent design and use of protection devices on outcome of carotid artery stenting: a pooled analysis of individual patient data

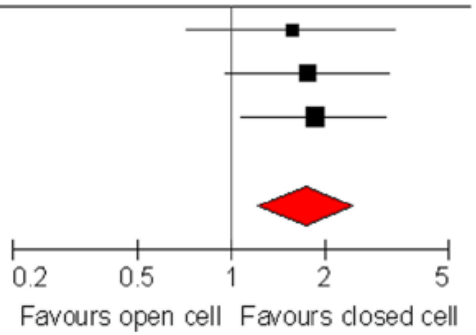
Fritz Wodarg,[1] Elisabeth L Turner,[2] Joanna Dobson,[2] Peter A Ringleb,[3] Willem P Mali,[4] Gustav Fraedrich,[5] Gilles Chatellier,[6] Jean-Pierre Bequemin,[7] Martin M Brown,[8] Ale Algra,[9] Jean-Louis Mas,[10] Olav Jansen,[1] Leo H Bonati,[8,11] On behalf of the Carotid Stenosis Trialists' Collaboration

J NeuroIntervent Surg 2018;**10**:1149–1154

Study	Open cell Events	Total	Closed cell Events	Total	Risk Ratio 95% CI
EVA-3S	12 (11.9)	101	11 (7.6)	145	1.57 (0.72-3.41)
SPACE	14 (11.0)	127	28 (6.3)	446	1.76 (0.95-3.23)
ICSS	35 (9.5)	367	19 (5.1)	371	1.86 (1.09-3.19)
Total	**61 (10.3)**	**595**	**58 (6.0)**	**962**	**1.76 (1.23-2.52)**

Heterogeneity: interaction p=0.938

Test for overall effect: p=0.002



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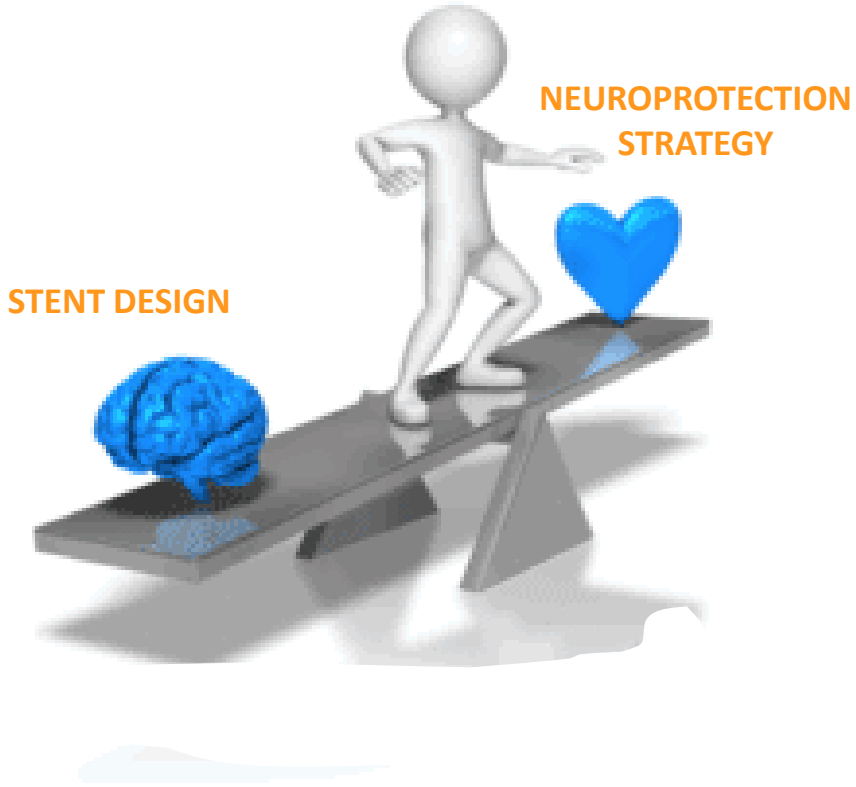
Conclusions In symptomatic carotid stenosis, the use of stents with a closed-cell design is independently associated with a lower risk of procedural stroke or death compared with open-cell stents. Filter-type protection devices do not appear to reduce procedural risk.


NEUROPROTECTION
STRATEGY
STENT DESIGN

…We are talking about a real-life relative weakness of CAS

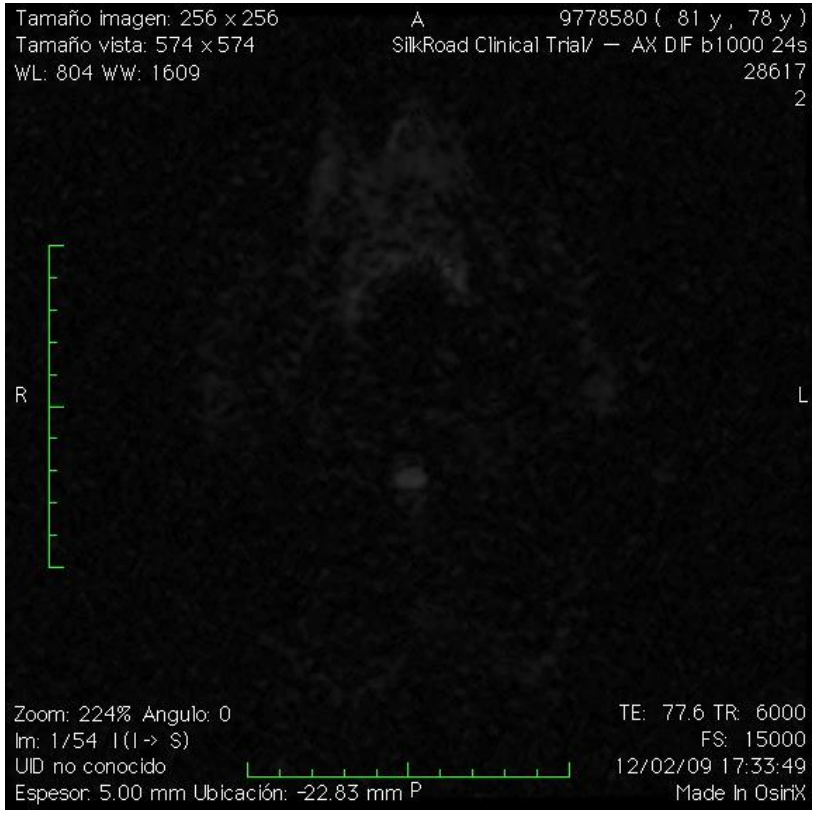
EXCESS OF MICROEMBOLIZATION

Which of the following is the most important for you in terms of embolic protection during CAS?

1. The stent you use
2. The EPD you use

DW-MRI

- Diffusion-weighted magnetic resonance imaging (DW-MRI) has emerged as a highly sensitive (88-100%)[1-3] and specific (95-100%)[4-7] tool in detecting cerebral ischemia



1. Lovblad et al . Am J Neuroradiol 1998;19:201-. 2.Meyer et al. Am J Neuroradiol 2000;21:1821-9. 3. Hammer et al. J Vasc Surg. 2005;42:847-53. 4. Jaeger et al. Am J Neuroradiol. 2002;23:200-7 5. McDonnell et al. Eur J Vasc Endovasc Surg. 2006;32:46-50. 6. Rapp et al. J Vasc Surg. 2007;45:867-72; discussion 872-4. 7. Guidelines for the early management of adults with ischemic stroke. Circulation. 2007;115:e478-534.

DW-MRI: How does it work?

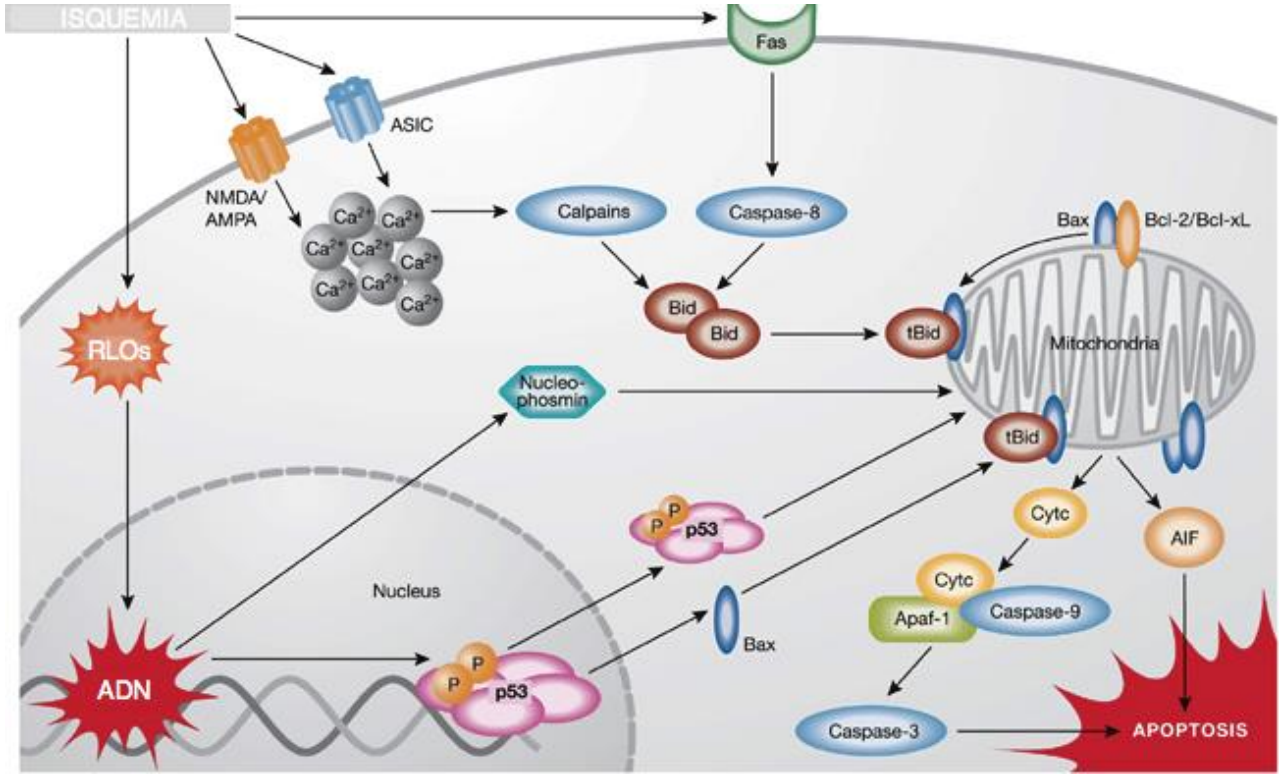
ACUTE ISCHEMIA

↓

MEMBRANE DISFUNCTION

↓

CELLULAR SWELLING



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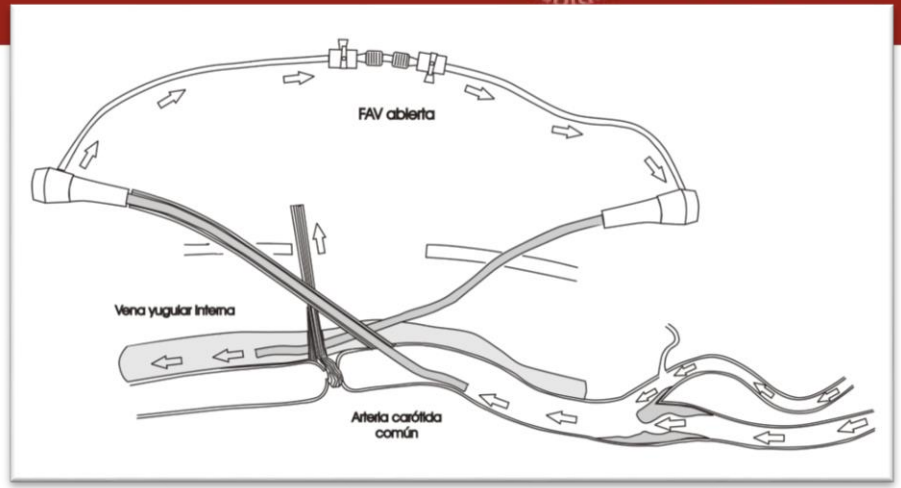

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Number of new lesions	4	13	
Localization of new lesions	Ipsilateral: 4 Contralateral: 0	Ipsilateral: 11 Contralateral: 2	

MULTI VARIATE ANALYSIS **TRANSFEMORAL GROUP**

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TRANSFEMORAL GROUPS	B	E.S.	Wald	gl	P	Exp(B)	CI 95 % Exp (B)	
							Inferior	Superior
Age	1,641	,291	4,312	1	,003	1,122	1,021	1,041
Sex	-2,156	,211	316,621	1	,225	1,024	0,733	1,034
Recent Symptoms	4,109	,537	9,4535	1	,000	4,118	1,740	9,650
Hypertension	,976	,041	5,001	1	,219	1,135	0,697	1,662
Hypercolesterolemia	-2,337	,347	64,423	1	,199	,376	0,265	1,199
Diabetes Mellitus	-4,112	,631	43,494	1	,422	,776	0,239	1,746
Previous Myocardial Infarctation	1,413	,438	10,415	1	,455	4,109	0,742	9,695
Current smokers	,044	,025	31,240	1	,322	1,931	0,521	2,032
Peripherial arterial disease	,131	,482	12,451	1	,349	2,341	,691	4,072
Preop - RANKIN	-2,119	,121	9,121	1	,198	,201	0,118	1,345
Post- RANKIN	2,126	,543	1,288	1	,651	1,534	0,847	1,913
RANKIN difference	-3,222	,128	5,422	1	,112	0,986	0,701	1,475
Plaque morphology	0,912	,315	6,359	1	,285	1,346	0,634	1,542
Predilatation	1,231	,028	2,115	1	,173	1,247	0,618	1,189
Stent (Open cell / closed cell)	2,536	,114	3,331	1	,031	1,991	1,032	3,421
Flow reversal time	-	-	-	-	-	-	-	-
Surgical time	,963	,211	3,322	1	,432	1,293	,888	1,293

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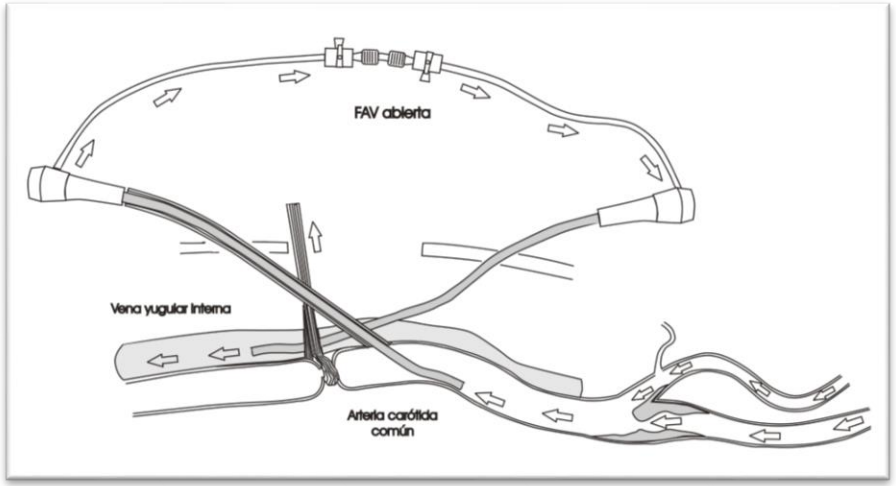
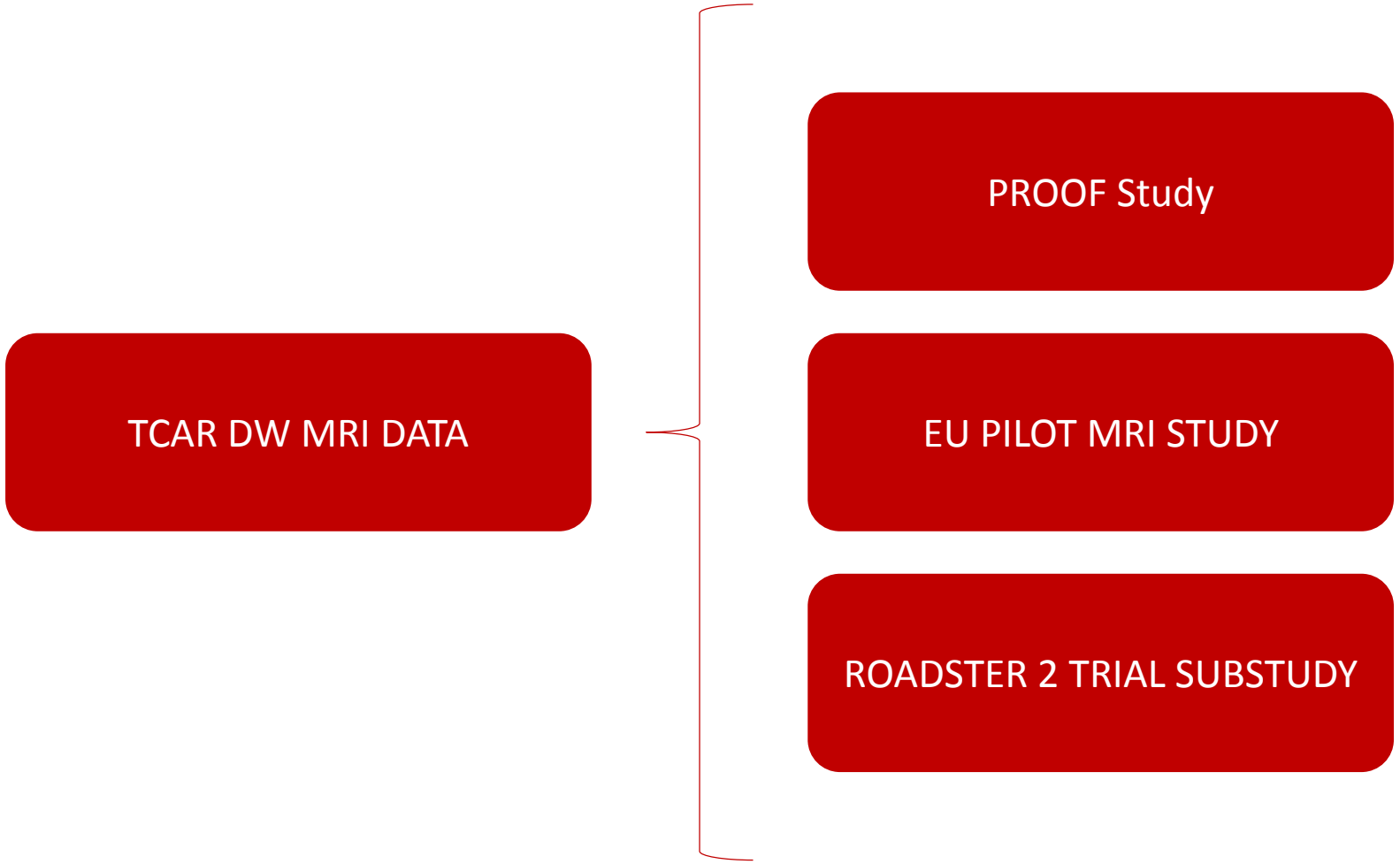
Ignacio Leal, MD,[a] Antonio Orgaz, MD,[a] Ángel Flores, MD,[a] Jose Gil, MD,[a] Rubén Rodríguez, MD,[a] Javier Peinado, MD,[a] Enrique Criado, MD,[b] and Manuel Doblas, MD,[a] *Toledo, Spain; and Ann Arbor, Mich*

J Vasc Surg 2012;56:1585-90



Adjusting analysis by type of treatment, age (relative risk [RR], 1.022, 95% confidence interval [95% CI], 1.021-1.041; $P < .001$), recent symptomatic status (RR, 4.109; 95% CI, 1.74-9.65; $P < .001$), and closed-cell vs open-cell stent type (RR, 0.082; 95% CI, 0.019-0.359; $P < .001$) were independent predictors of embolization in the transfemoral group but not in the transcervical group.


TCAR DW MRI DATA
PROOF Study
EU PILOT MRI STUDY
ROADSTER 2 TRIAL SUBSTUDY

Do you think Mesch-Covered stents will be game-changers?

1. Yes
2. No
3. N/A

Membrane- Mesh – Not sure…

Universidad de Navarra

Peri-procedural brain lesions prevention in CAS (3PCAS): Randomized trial comparing CGuard™ stent vs. Wallstent™☆

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Table 3
Outcomes in 29 CGuard patients and 29 Wallstent patients.

	CGuard	Wallstent	P (OR; 95%CI)
Positive 72 h-DWMRI (n;%)	9 (31%)	7 (24.1%)	0.55 (1.41; 0.44–4.50)
72 h-DWMRI lesion number per pt (mean ± SD; 95%CI)	3.56 ± 2.30 (2.05–5.06)	3.43 ± 1.81 (1.72–5.13)	0.91
72 h-DWMRI lesion diameter	3.87 ± 1.53	3.56 ± 1.07	0.49

Membrane- Mesh – Not sure…

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Study	Procedure	Stent	Embolic Protection	N	Symptom Status	% New Lesions	% New Ipsi Lesions	Avg Lesion Volume
CARENET	TF-CAS	CGuard	Distal Filter[1]	30	Asx=66% Sx=33%	NR	37%	**0.039**
PARADIGM[2]	TF-CAS	CGuard	Proximal (46%) Distal (54%)	101	Asx=45% Sx=55%	NR	NR	NR
CLEAR-ROAD[3]	TF-CAS	Roadsaver	Distal (48%) Proximal (10%) None (32%)	100	Asx=69% Sx=31%	40%	NR	NR
IRON-GUARD	TF-CAS	CGuard	NR	165 Total 61 DW-MRI	NR	19%[4]	30%[4]	NR
Krakow	TCAR	CGuard	Proximal Flow Reversal	11	Asx=45% Sx=55%	9.1%	9.1%	NR
PROOF	TCAR	Wallstent (n=36) Precise (n=13) Other (n=7)	Proximal Flow Reversal	56	Asx=82% Sx=18%	23.4%	17.9%	**0.171**

[1] MOMA was used in one patient; **30-day S/D/MI = 0%**

[2] **30-day S/D/MI = 0.9%**

[3] DW-MRI rate was sub-study performed at some centers- detail not provided; **30-day S/D/MI = 2.1%**

[4] % new lesions was reported for only those that had ipsilateral lesion; bilateral lesions were not included (hence manually calculated); **30-day S/D/MI = 3.0%**

In conclusion…

1. Microembolization is inherent to any carotid stent intervention
2. Both stent design and neuroprotection strategy impact outcomes
3. The choice of the neuroprotection strategy is crutial in terms of clinical and subclinical outcomes
4. TCAR is associated with excellent clinical results, and the stent used shows no impact

i-MEET
NEXT GENERATION
Multidisciplinary European Endovascular Therapy

The stent choice in TCAR Does (not) Matter!

Ignacio Leal, MD PhD RPVI FACS

Co-Director, Department of Vascular Surgery

Associate Professor of Surgery

Clínica Universidad de Navarra, Madrid

University of Navarra, Pamplona

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