Troubleshooting during carotid endarterectomy

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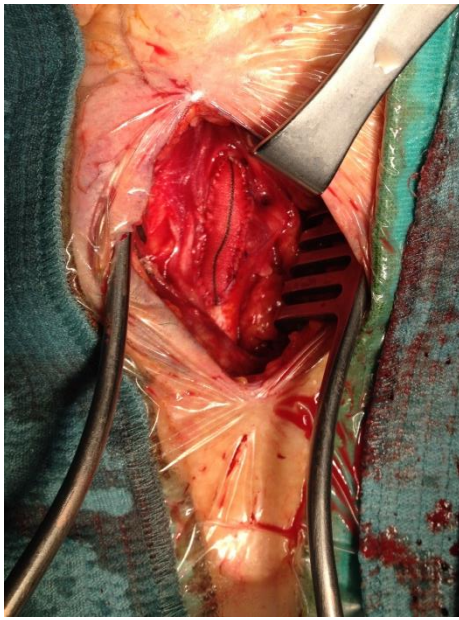
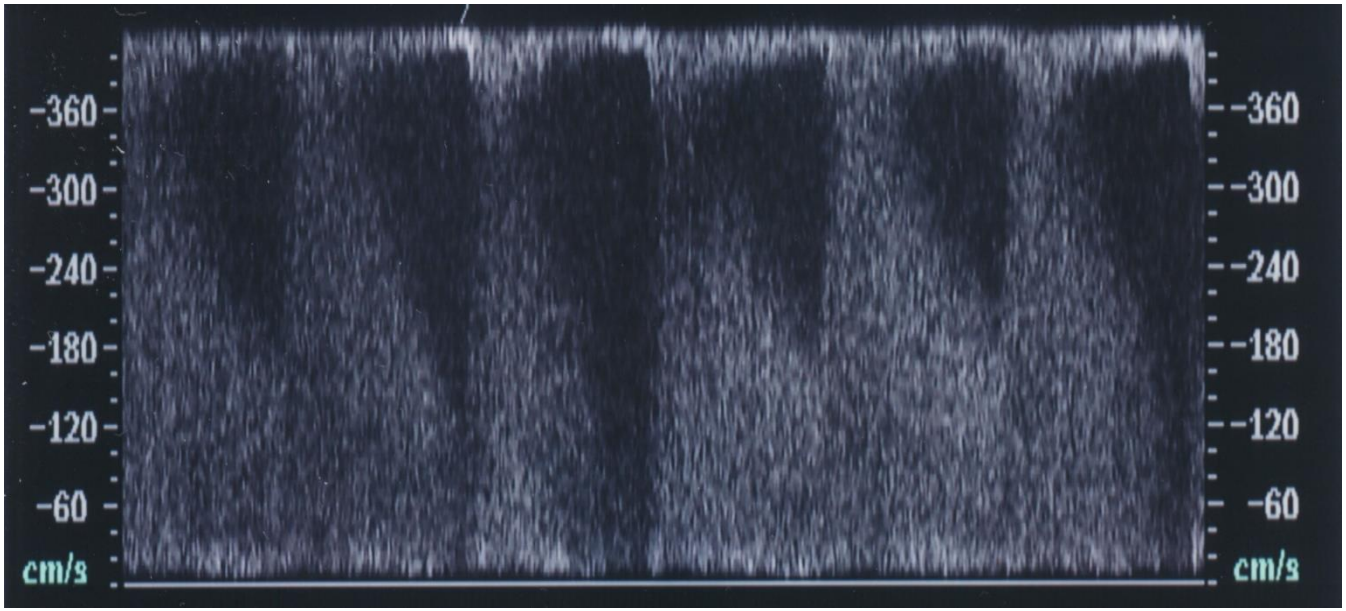
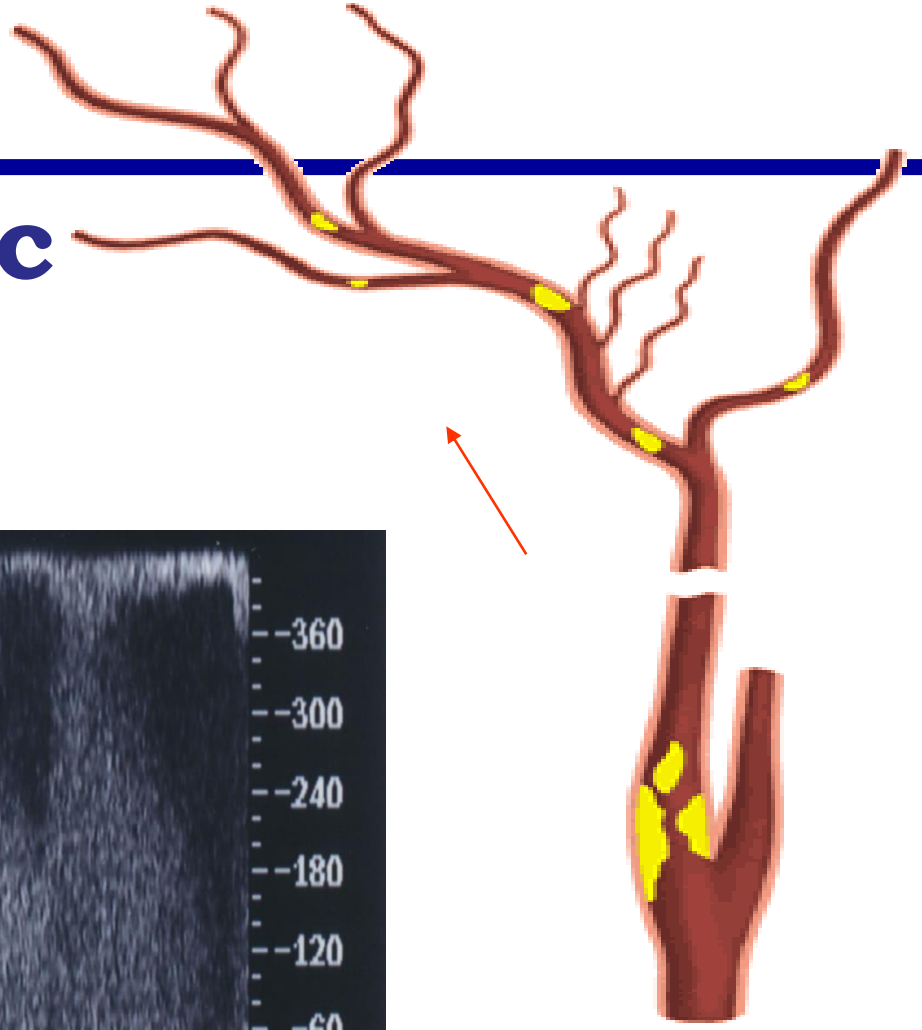


WHO?

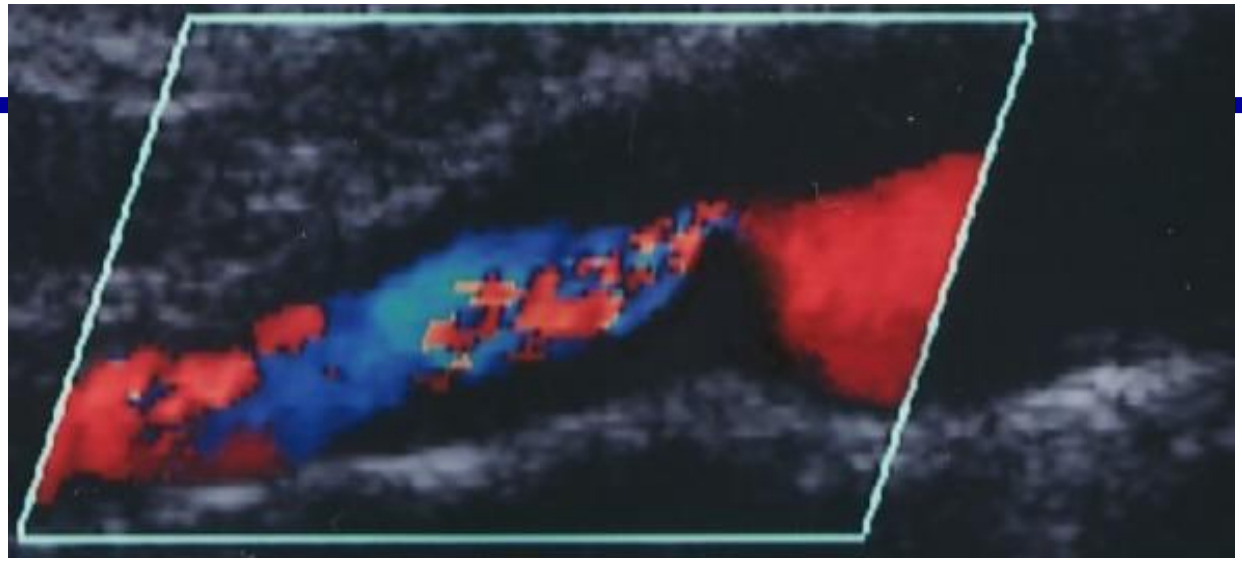
Haemodinamic stenoses

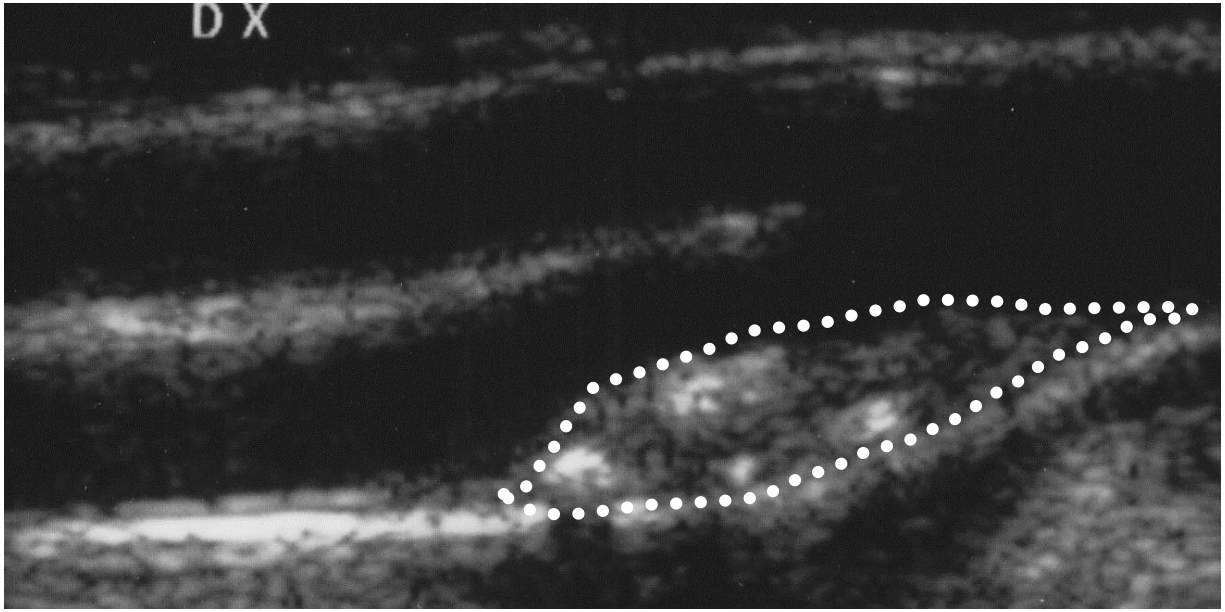




Paque

SOFT Plaque





HARD Plaque

WHY?

Since the first reported successful carotid reconstruction in 1954 by Eastcott and Rob, CEA has been under attack

At first there was a long-standing argument that the benefit of CEA was anecdotal

- *Barnett HJM.* ***CEA: an expression of concern****. Stroke 1984; 15: 941.*
- *Warlow C.* ***CEA: does it work?*** *Stroke 1984; 15: 1068-76.*
- *Hertzer NR.* ***CEA: a crisis in confidence****. J Vasc Surg 1988; 7: 611-9.*

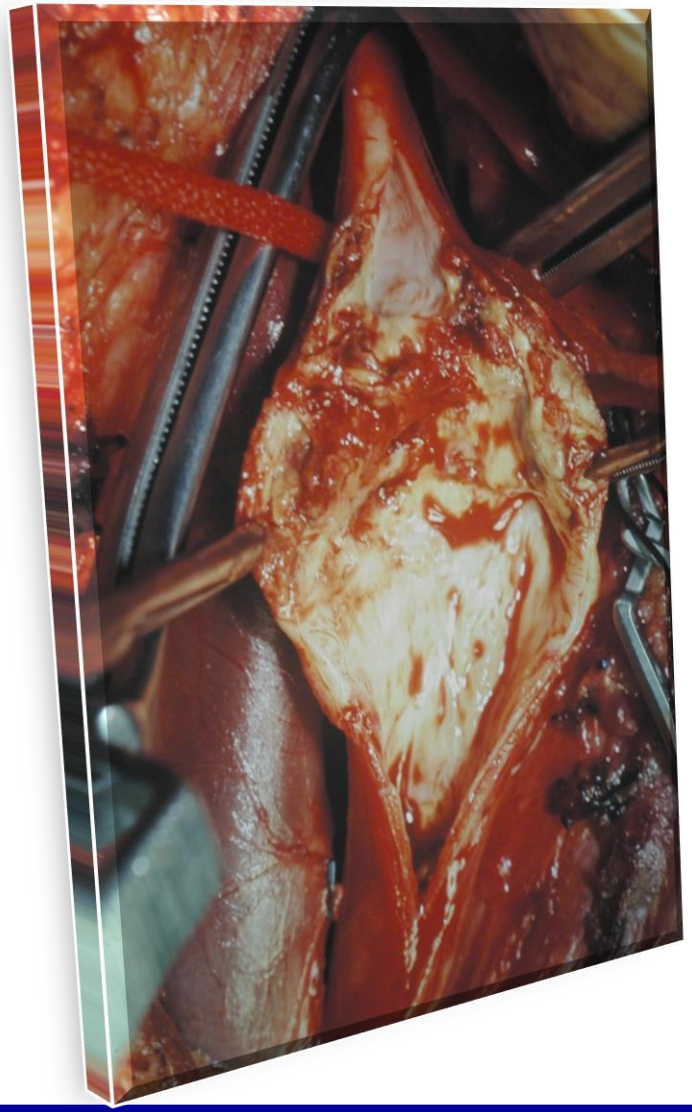
Randomized Trials of CEA Vs BMT

Trial (N)	Stenosis	Follow up	End Point	Medical (%)	CEA (%)	NNT
ECST (3.018)	≥80%	3 yrs	Major stroke / death	26.5	14.9	8.6
NASCET (659)	≥70%	2 yrs	Ipsilateral stroke	26	9	5.9
VA 309 (189)	>50%	1 yr	Ipsilateral stroke/TIA/ surgical death	19.4	7.7	8.5
NASCET (858)	50-69%	5 yr	Ipsilateral stroke	22.2	15.7	15.4
NASCET (1,368)	≤50%	5 yrs	Ipsilateral stroke	18.7	14.9	26.3
ACAS (1,662)*	>60%	5 yrs	Ipsilateral stroke, surgical death	11	5.1	16.9
ACST (3,120)*	≥60%	5 yrs	Any stroke	11.8	6.4	18.5
VA (149)*	≥50%	4 yrs	Ipsilateral stroke	9.4	4.7	21.3

Symptomatic patients
Asymptomatic patients*

Bates et al. J Am Coll Cardiol Jan 2007

Carotid endarterectomy trials



Safe and effective in significant stenosis

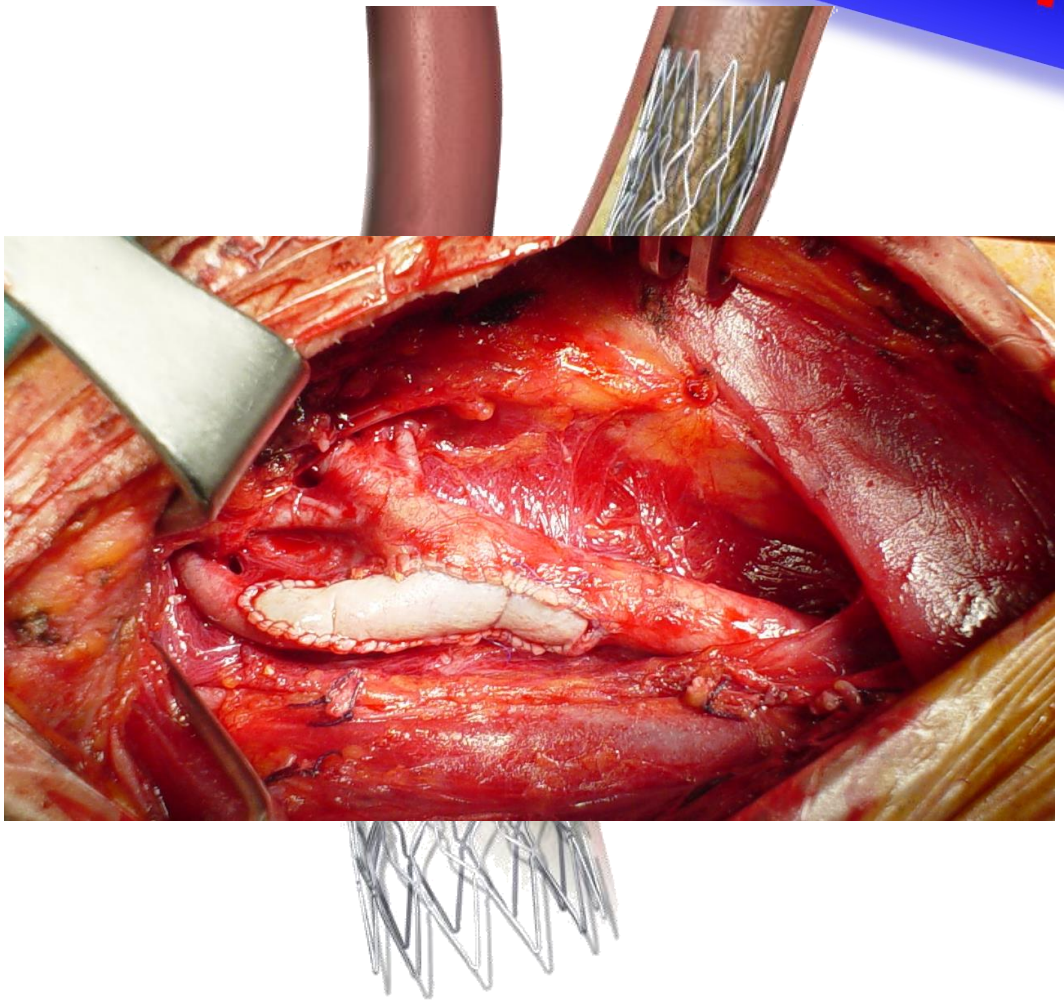
- NASCET ('91)
- ACAS ('95)
- ECST ('95)
- ACST ('03)

All this changed in the early 1990s when a number of important clinical TRIALS were first reported

The trials concluded that there was a clear benefit to CEA in patients with symptomatic and asymptomatic carotid occlusive disease, defining which patient population and which patients what degree of stenosis would benefit from CEA.

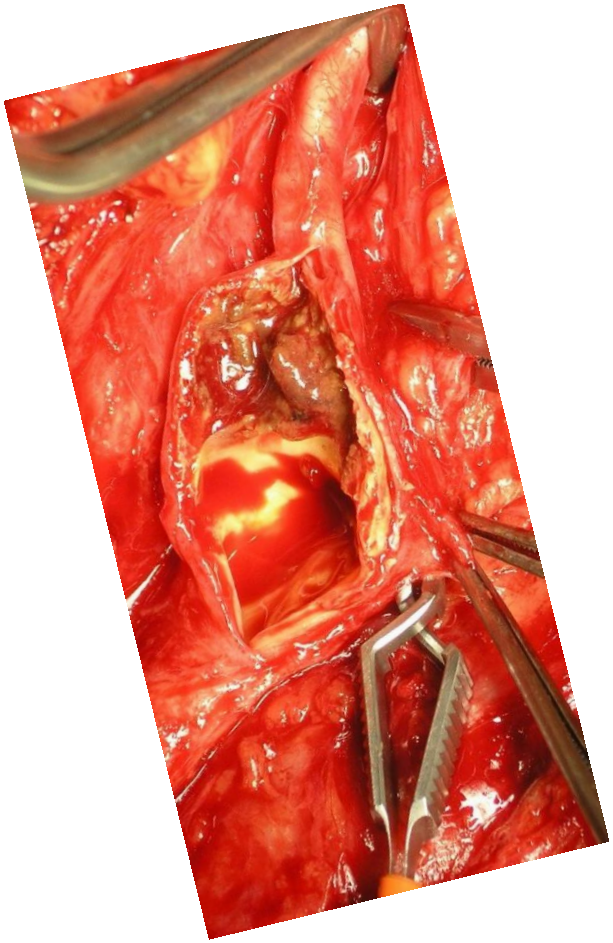
Study	Treatment	Death/stroke
NASCET	1087 CEA	6.7 %
ACAS	825 CEA	2.3 %

HOW?

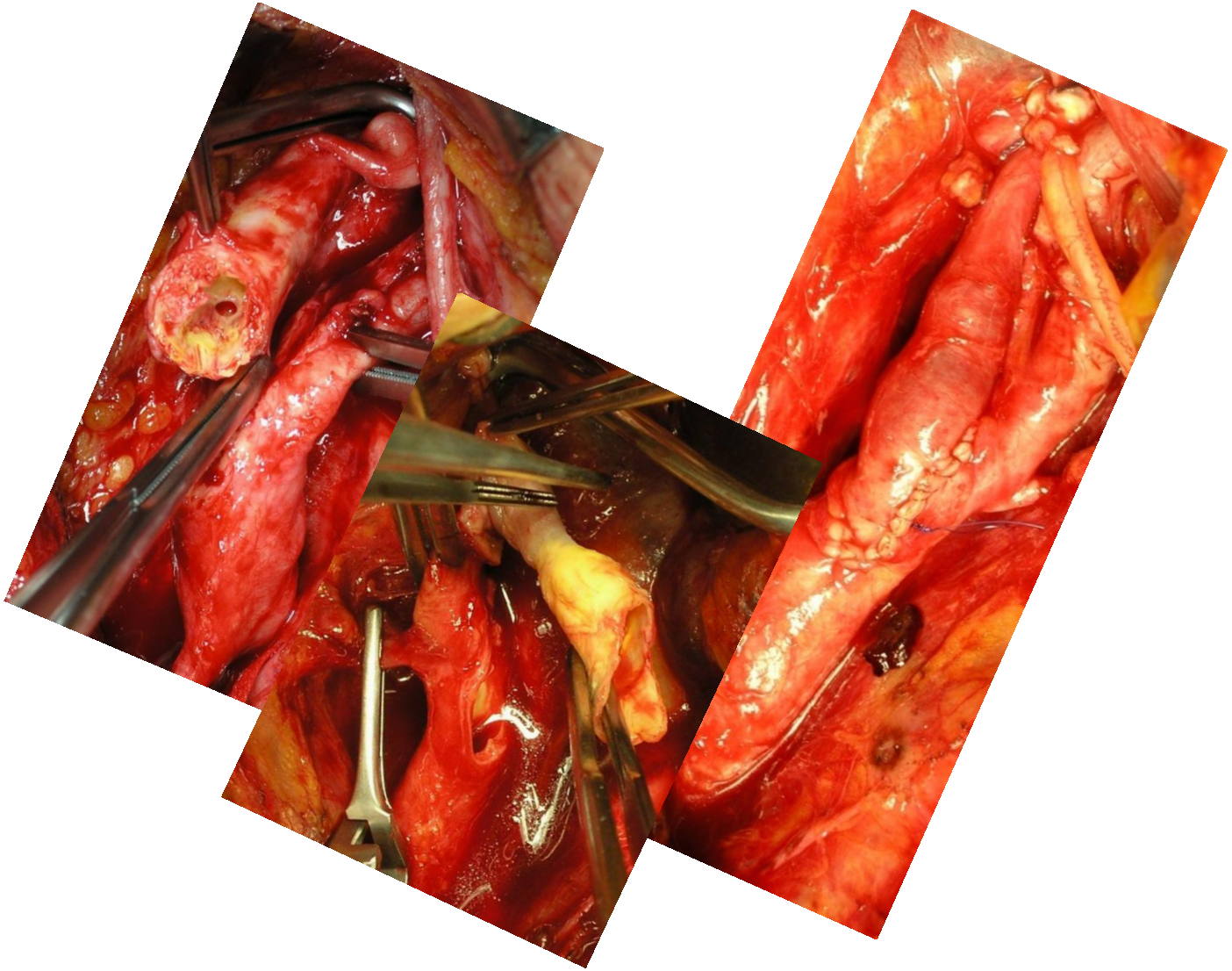


Carotid endarterectomy tecnique

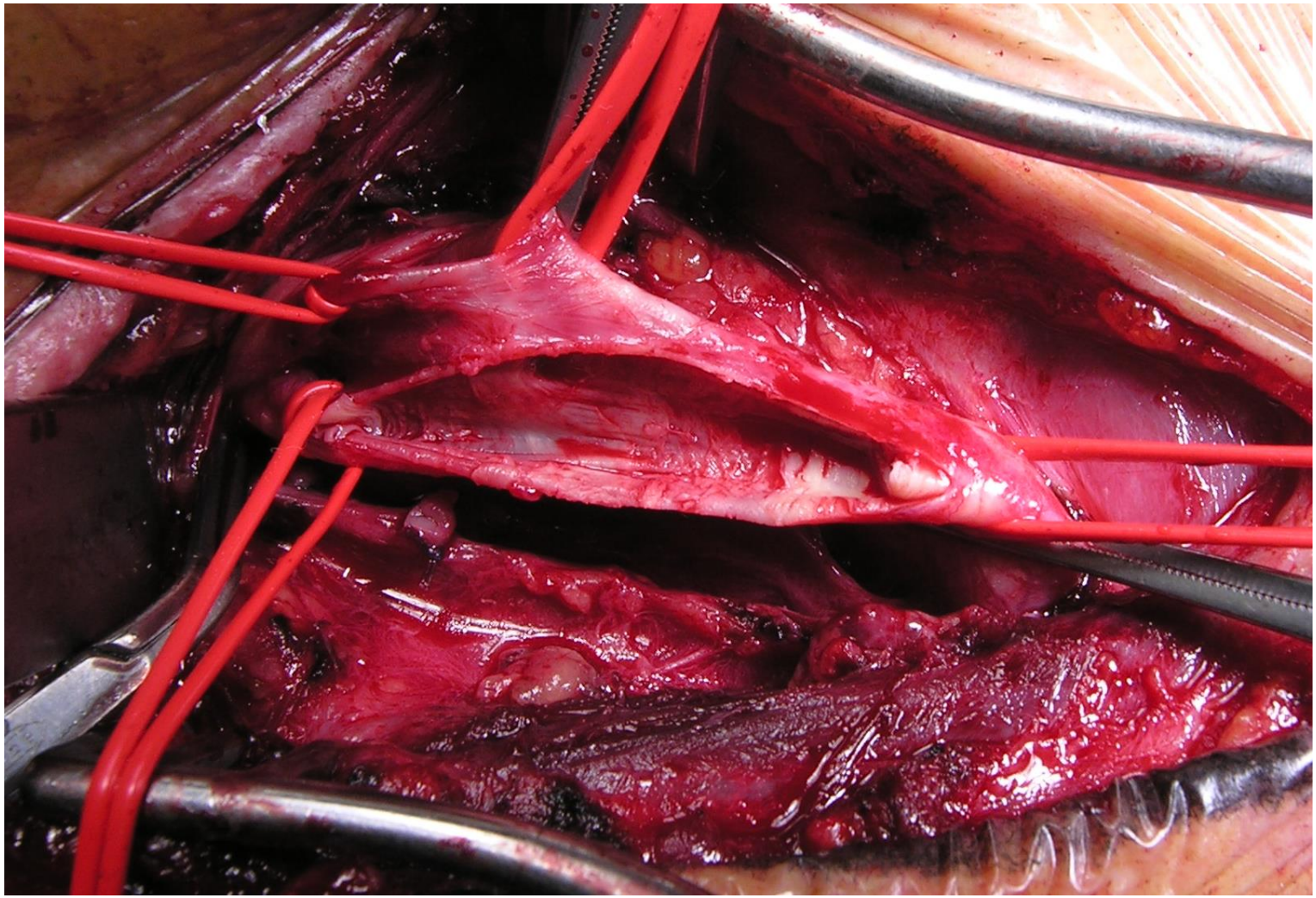
Carotid endarterectomy tecnique



Carotid endarterectomy tecnique



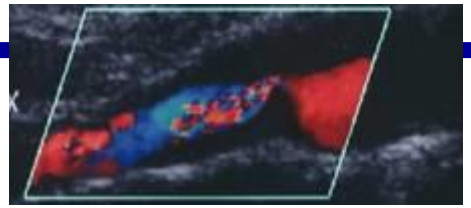
Which are in 2016 the standards of practice of CEA?

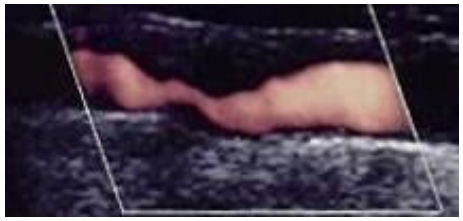


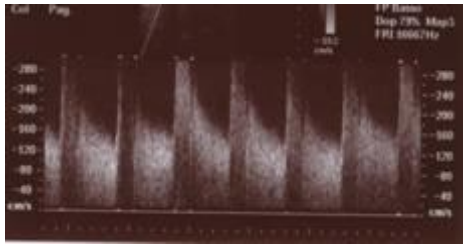
CEA: Our Standards of practice

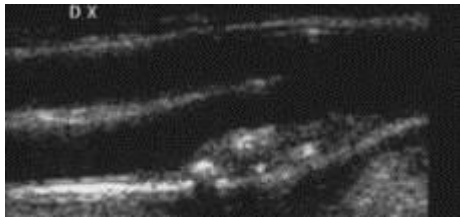
Our standard CEA protocol (5 steps) includes:

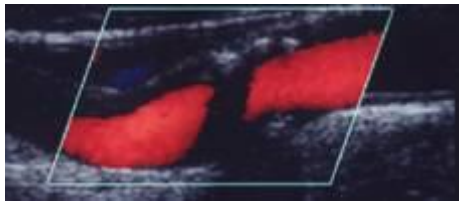
1. duplex ultrasonography as the sole diagnostic preoperative study (neck)
2. cervical block anesthesia
3. selective shunting
4. recovery room (few hours) and transfer to ward
5. discharge the second or third day











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2. cervical block anesthesia
3. selective shunting
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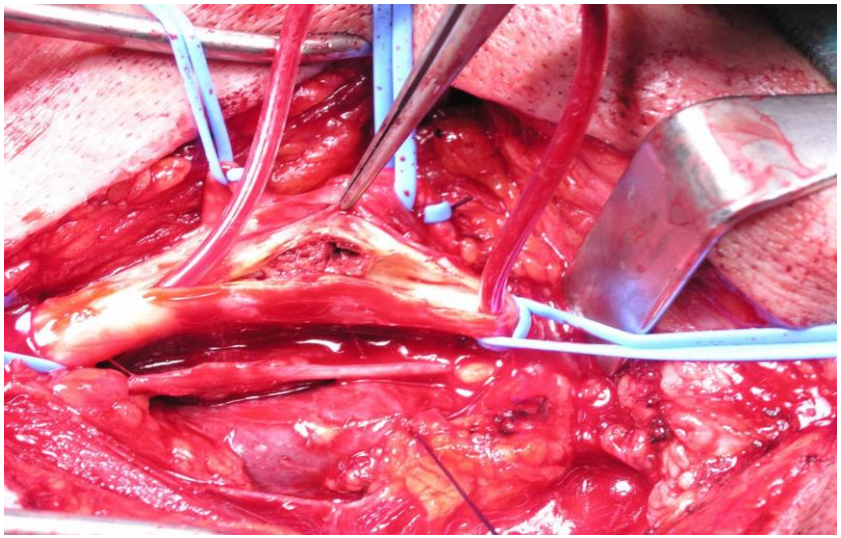
1. duplex ultrasonography
2. cervical block anesthesia
3. selective shunting

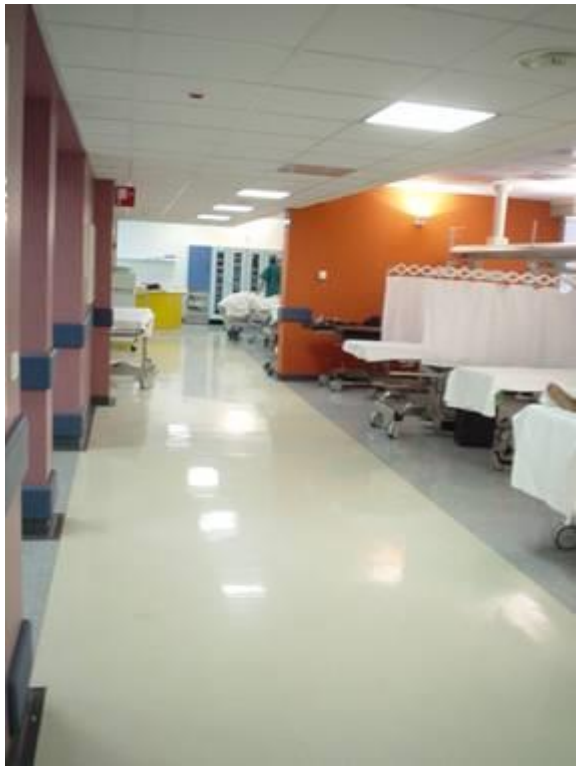


4. recovery room (few hours) and transfer to ward
5. discharge the second or third day

CEA: Our Standards of practice

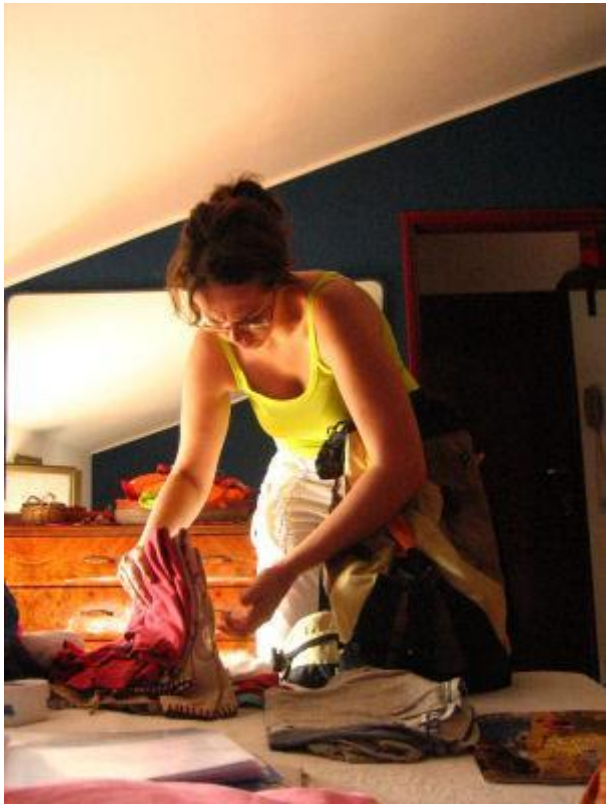
Our standard CEA protocol (5 steps) includes:

1. duplex ultrasonography
2. cervical block anesthesia
3. selective shunting
4. recovery room (few hours) and transfer to ward (without ICU)
5. discharge the second or third day



CEA: Our Standards of practice

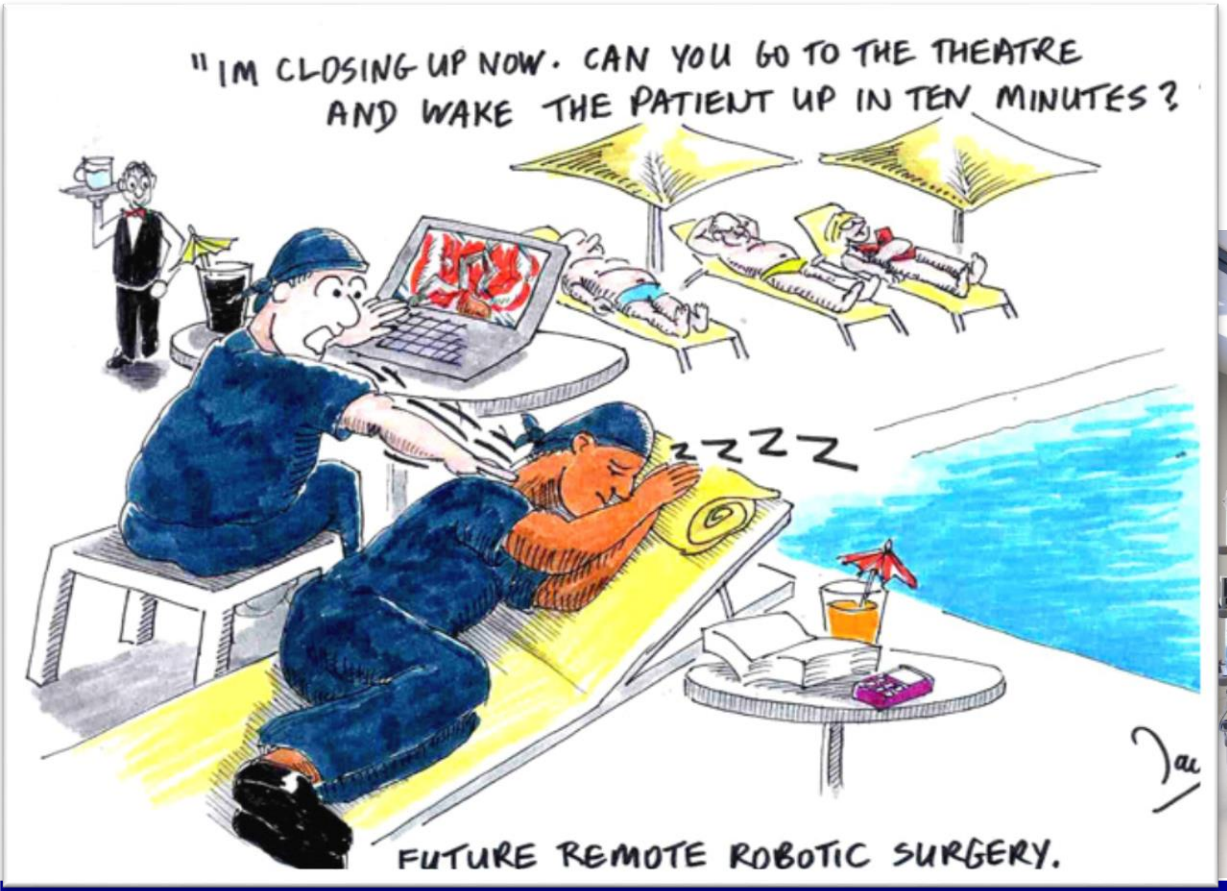
Our standard CEA protocol (5 steps) includes:

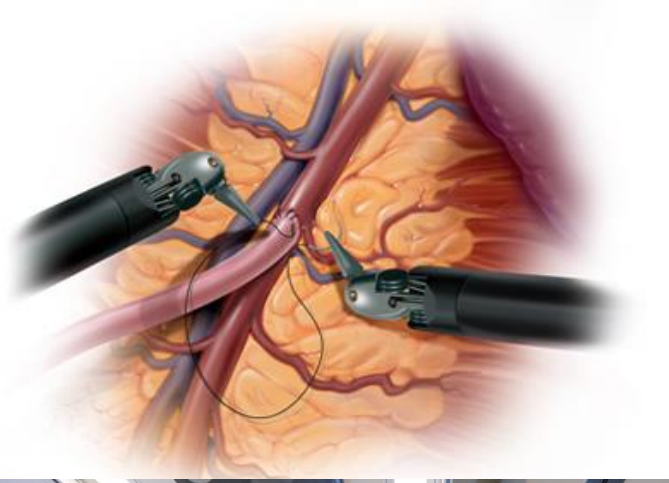


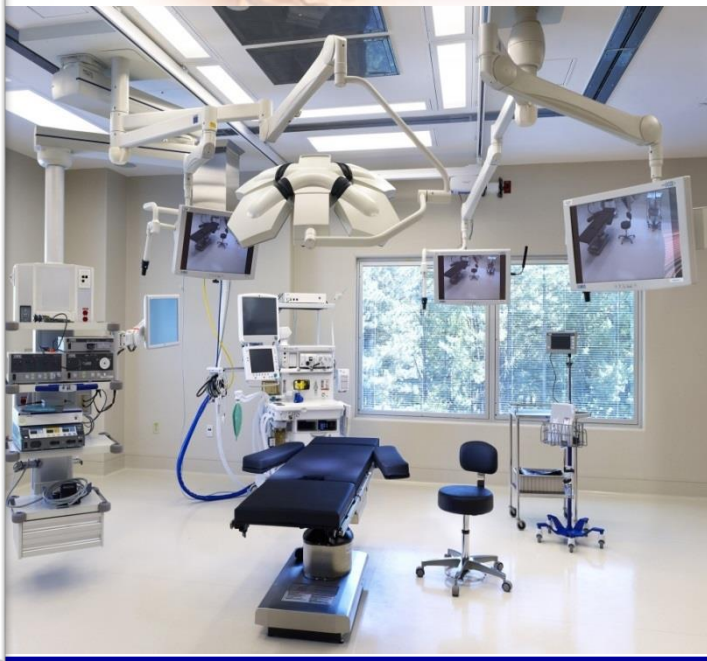
1. duplex ultrasonography
2. cervical block anesthesia
3. selective shunting
4. recovery room (few hours) and transfer to ward
5. discharge the second day

CEA: As regard HOW

MODERN SURGERY IS INCREASINGLY MOVING TOWARDS MININVASIVENESS

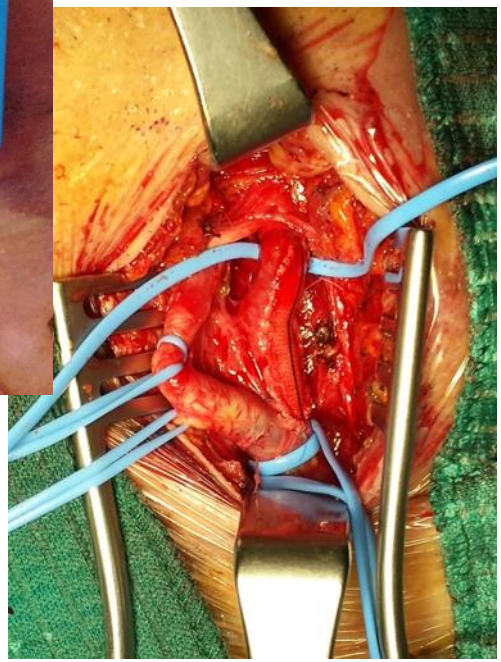






STUDY

MINI INVASIVE INCISION
≈5CM



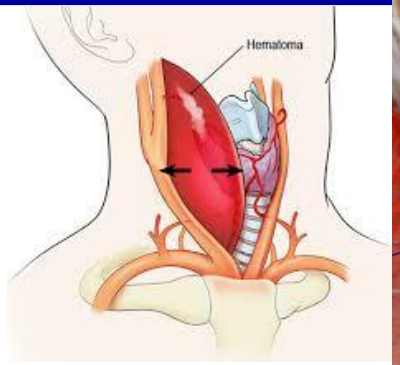
VS

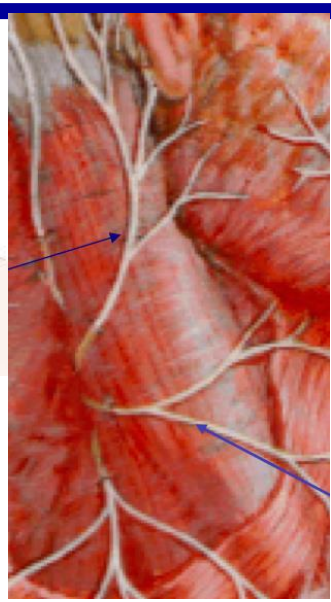
STANDARD ACCESS

OUTCOMES

PRIMARY OUTCOMES

- DEATH
- STROKE
- TIA



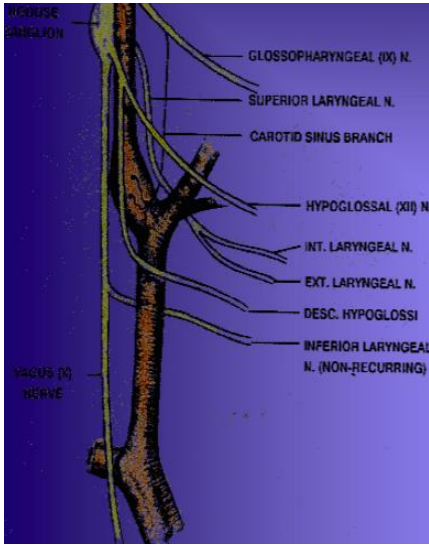


SECONDARY OUTCOMES

- NERVE INJURY
- NECK HEMATOMA

DURING

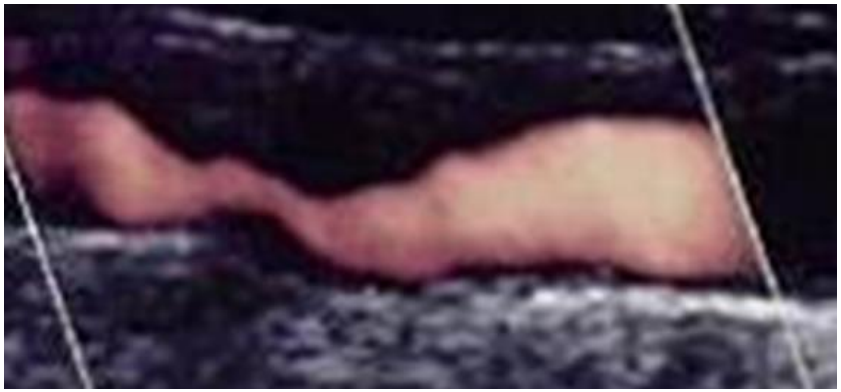
- INTRAOPERATIVE PERIOD
- POST-PROCEDURAL EVENTS AT DISCHARGE
- 30 DAYS
- 3 MONTHS



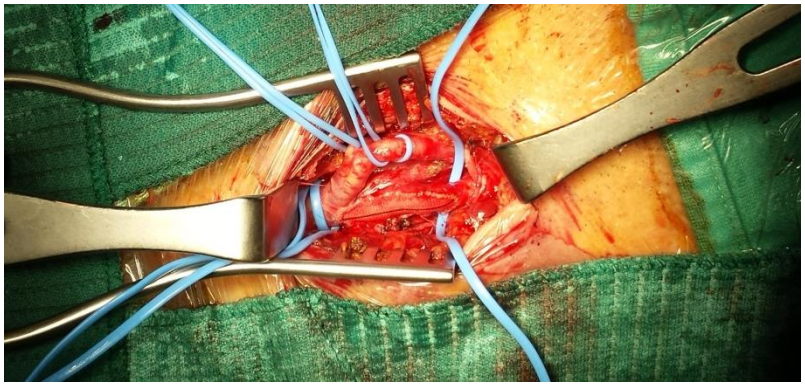
METHODS

1785 CEA

1589 STANDARD ACCESS
SKIN INCISION ≈**12-15cm**
2000-2006



196 WITH MINI SKIN INCISION
SKIN INCISION **≈5 cm**
2012-2014

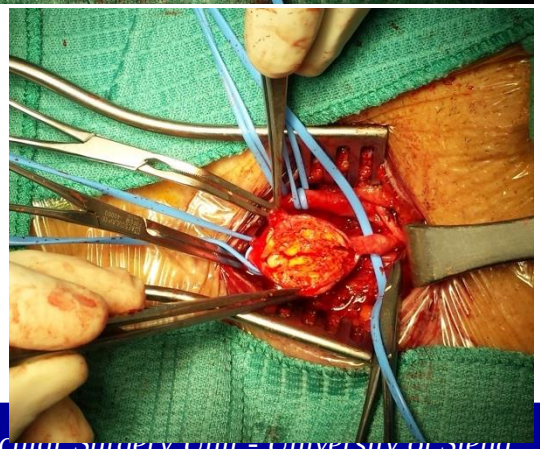


Carotid Artery Stenting in a Single Center: Are Six Years of Experience Enough to Achieve the Standard of Care?

C. Setacci,* E. Chisci, G. de Donato, F. Setacci, P. Sirignano and G. Galzerano

Department of Surgery, Vascular and Endovascular Surgery Unit, University of Siena, Viale Bracci, I-53100 Siena, Italy

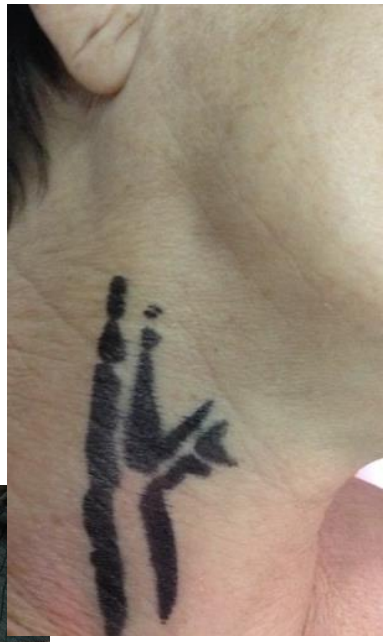
Eur J Vasc Endovasc Surg **34**, 655–662 (2007)

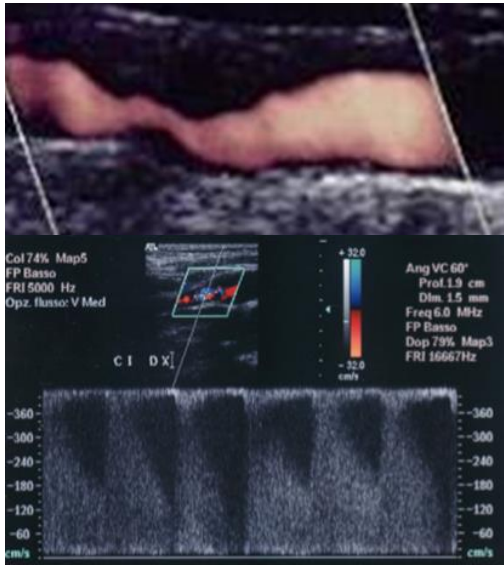


METHODS

DUPLEX US SCANNING

- RELIABLE TO EVALUATE EXTRACRANIAL CAROTID STENOSIS
- LOCATION OF THE CAROTID BIFURCATION ON THE SKIN
- LENGTH OF THE LESION
- DEPTH OF THE ARTERY

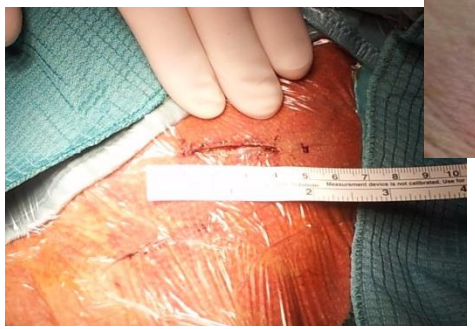


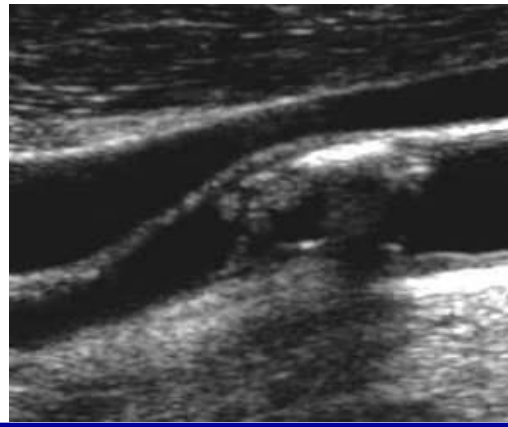


esvs

GUIDELINES

- DIGNOSIS
- TREATMENT
- FOLLOW-UP

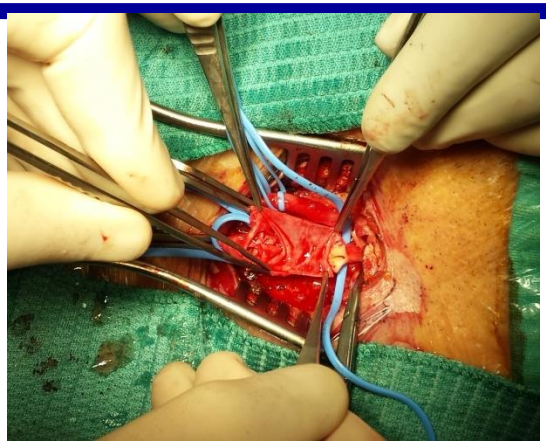




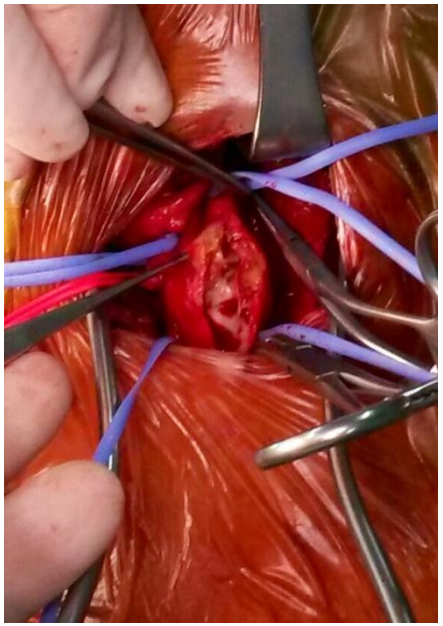
LIMITED SKIN INCISION OVER THE BIFURCATION

RESULTS

3 CASES THE OPERATOR DECIDED TO EXTEND FOR 2CM THE VERTICAL CERVICAL INCISION TO EXPOSE BETTER THE INTERNAL CAROTID ARTERY AND ENSURE A SAFER CLAMPING



18 CASES WE HAD TO PUT THE SHUNT WITHOUT EXTENTION OF THE INCISION



CLINICAL OUTCOME

Mini incision

Events during procedure	
Death (any cause)	0.00%
Major stroke	0.00%
Minor stroke	1.02%
TIA	0.51%
Myocardial infarction	0.00%

Postoperative Events, at discharge	
Death procedure related	0.00%
Death not procedure related	0.00%
Major stroke	0.00%
Minor stroke	0.00%
TIA	0.00%
Myocardial Infarcton	0.51%

Standard access

Events during procedure	
Death (any cause)	0.00%
Major stroke	0.12%
Minor stroke	0.25%
TIA	0.82%
Myocardial infarction	0.00%

Postoperative Events, at discharge	
Death procedure related	0.44%
Death not procedure related	0.12%
Major stroke	0.32%
Minor stroke	0.56%
TIA	0.25%
Myocardial Infarcton	0.44%

CLINICAL OUTCOME

Mini incision

Events between discharge and 30 days	
Death procedure related	0.00%
Death not procedure related	0.00%
Major stroke	0.51%
Minor stroke	0.51%
TIA	0.00%
Myocardial Infarcton at 30 days	0.51%

Events between 30 days and 3 months	
Death procedure related	0.00%
Death not procedure related	0.00%
Major stroke	0.00%
Minor stroke	0.00%
TIA	0.00%

Standard access

Events between discharge and 30 days	
Death procedure related	0.12%
Death not procedure related	0.00%
Major stroke	0.06%
Minor stroke	0.00%
TIA	0.00%
Myocardial Infarcton at 30 days	0.44%

Events between 30 days and 3 months	
Death procedure related	0.23%
Death not procedure related	0.39%
Major stroke	0.15%
Minor stroke	0.23%
TIA	0.54%

SECONDARY COMPLICATIONS

	Mini access		Standard access	
	N°	%	N°	%
Procedures	196		1589	
Neck hematomas	4	2,1%	71	4.46%
Cranial nerves injury	4	2,1%	110	6.92%
Auricular nerve injury	3	1.53%	238	15%

OBSERVATIONS

REDUCTION OF PAIN THERAPY

BETTER AESTHETIC RESULTS

VS

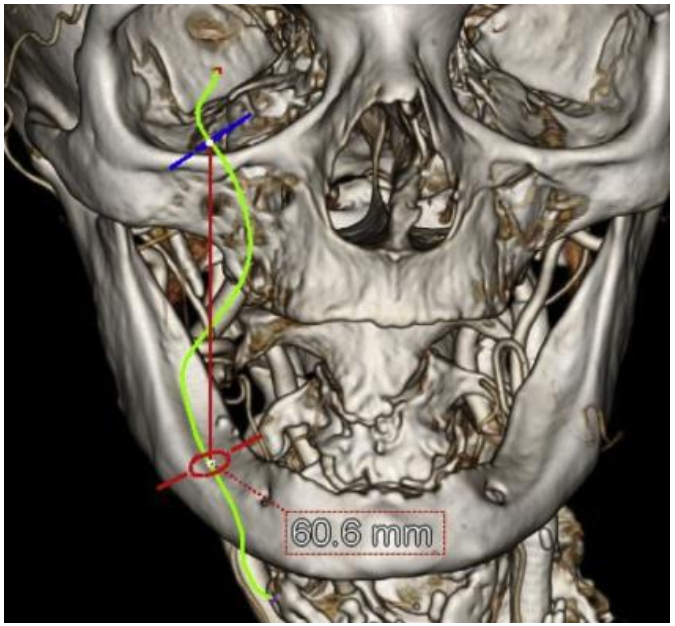
CEA: TIPS AND TRICKS

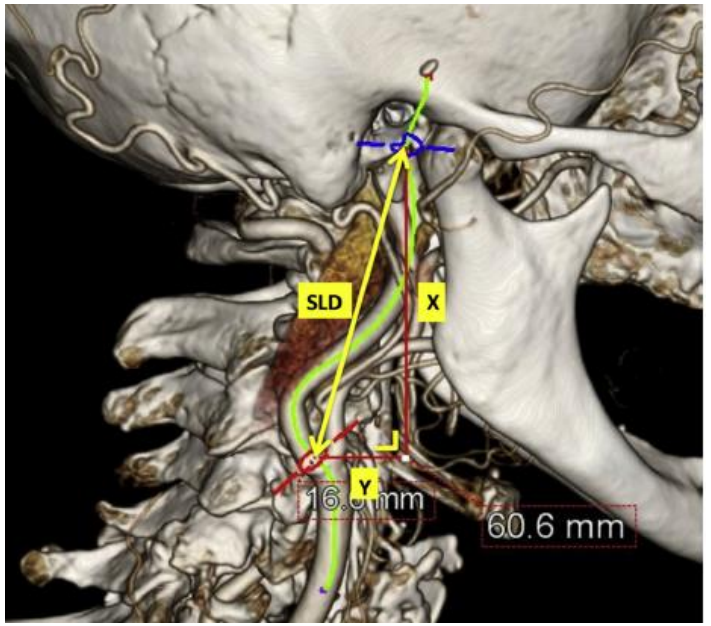
Three-dimensional Computed Tomographic Reconstruction of the Carotid Artery: Identifying High Bifurcation

J.R. McNamara *, G.J. Fulton, B.J. Manning

Department of Surgery, Cork University Hospital, Cork, Ireland

Chakfè et al





McNamara et al

CEA: TIPS AND TRICKS

Surgical Dissection of the Internal Carotid Artery Under Flow Control by Proximal Vessel Clamping Reduces Embolic Infarcts During Carotid Endarterectomy

Kazumichi Yoshida[1], Yoshitaka Kurosaki[2], Takeshi Funaki[1], Takayuki Kikuchi[1], Akira Ishii[1], Jun C. Takahashi[1], Yasushi Takagi[1], Sen Yamagata[2], Susumu Miyamoto[1]

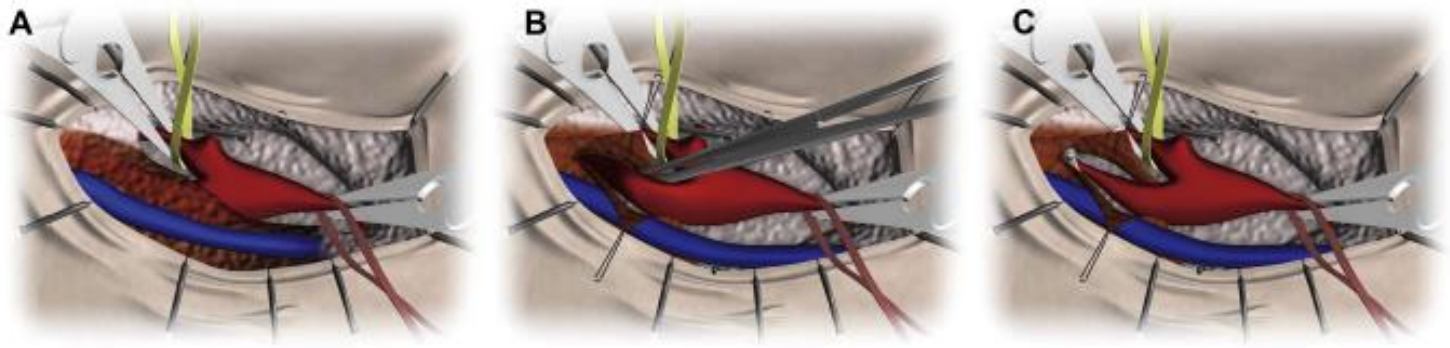


Figure 2. Schematic illustrations of flow-control carotid endarterectomy. (**A**) The common carotid artery, external carotid artery, and superior thyroid artery are isolated and controlled before the plaque-bearing internal carotid artery is dissected. (**B**) The carotid sheath over the internal carotid artery is dissected under flow control by clamping proximal vessels while somatosensory-evoked potential and near infrared spectroscopy changes are carefully monitored. (**C**) After exposure and isolation of the distal internal carotid artery are completed, standard longitudinal endarterectomy is then begun.

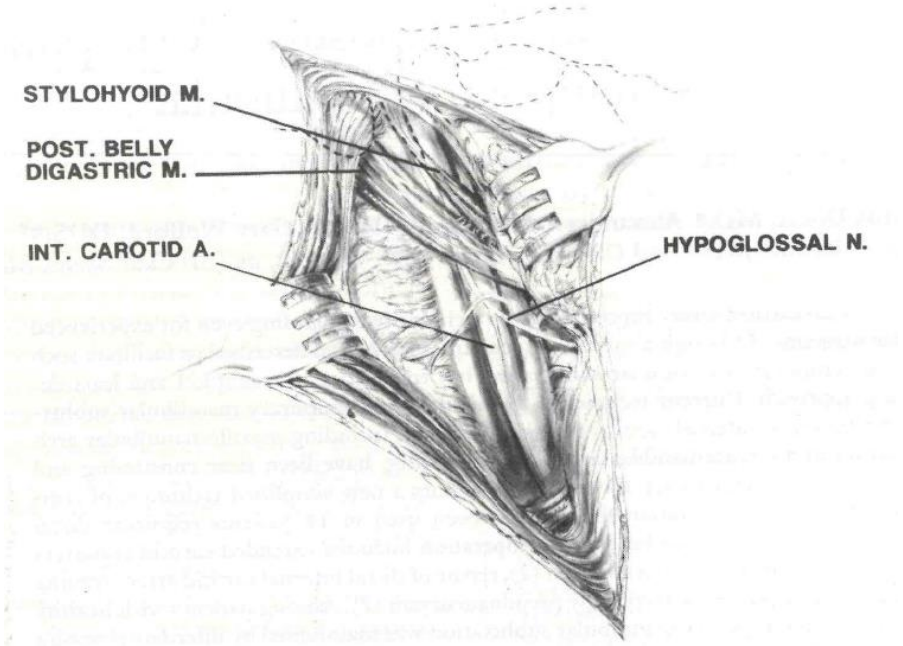
RESULTS: New postoperative DWI lesions were observed in 7 of 67 patients (10.4%), and none of them was symptomatic. With respect to operative technique, the incidence rate of DWI spots was significantly lower in the flow-control group (2.6%) than in the conventional group (20.7%), odds ratio: 0.069; 95% confidence interval: 0.006–0.779; $P = 0.031$). On multiple logistic regression analysis, age, side of ICA stenosis, high-grade stenosis, symptoms, and the use of internal shunting did not have significant effects on new postoperative DWI lesions, whereas technique did have an effect.

CEA: TIPS AND TRICKS

An aid to accessing the distal internal carotid artery

A. Ross Naylor, MD, FRCS,[a] and Andrew Moir, FRCS,[b] *Leicester, United Kingdom*

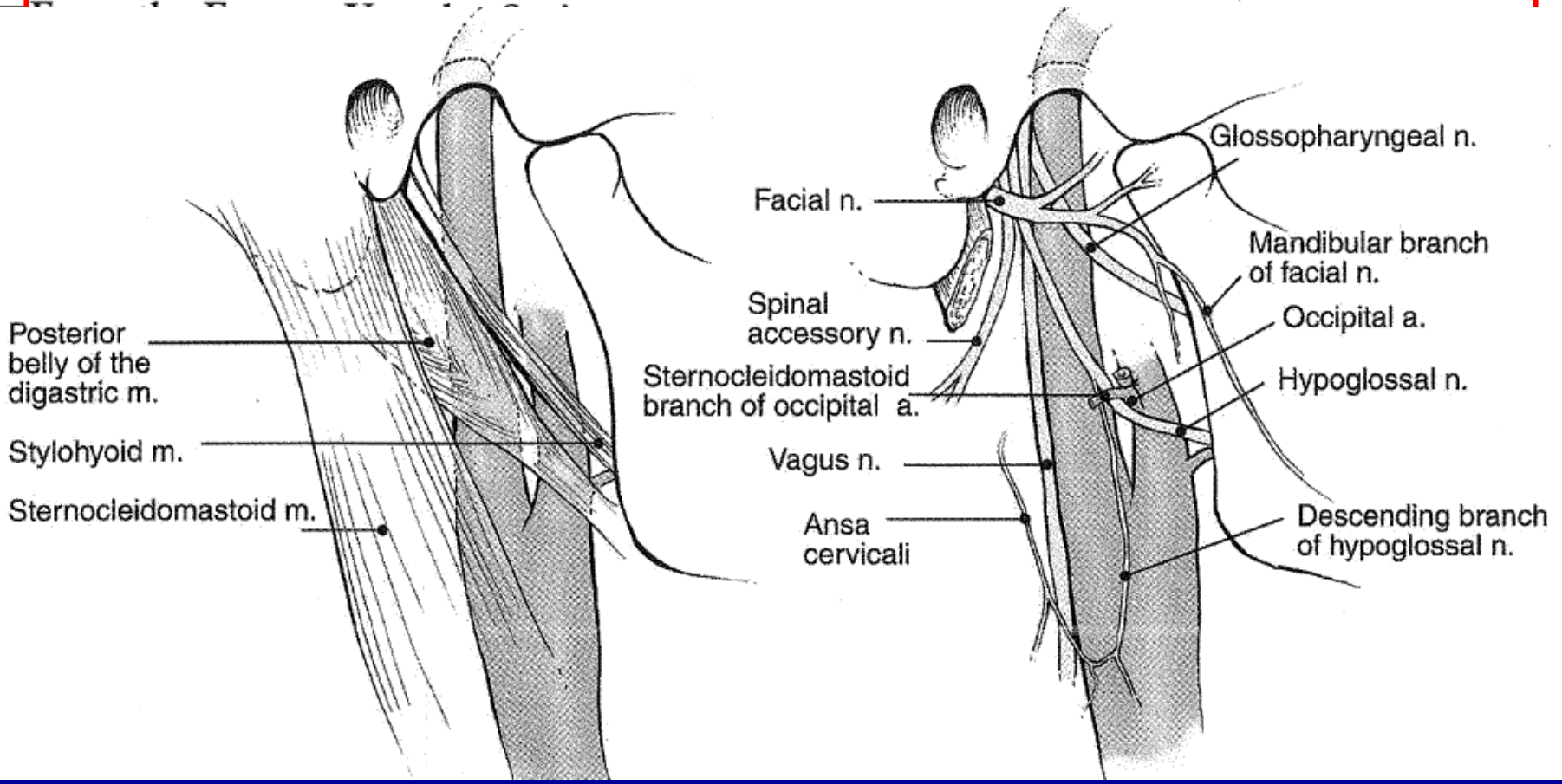
- Temporomandibular subluxation
- Nasolaryngeal intubation
- Styloidectomy
- Mandibulotomy
- Division of the posterior belly of the digastric muscle



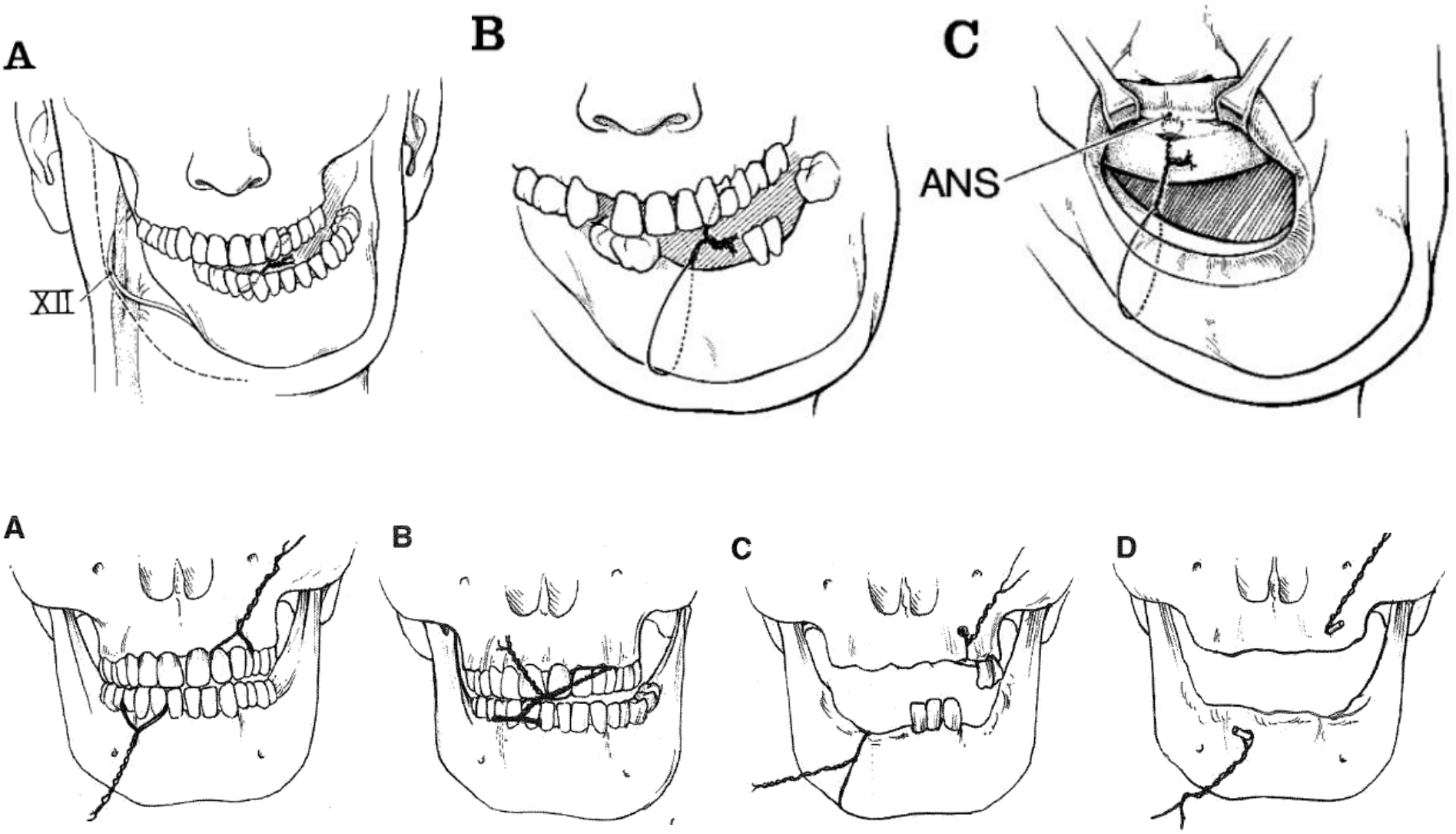
Dossa et al

CEA: TIPS AND TRICKS

Mandibular subluxation as an adjunct to exposure of the distal internal carotid artery in endarterectomy surgery



Mandibular subluxation for high bifurcation



Post- CEA carotid restenosis

Recurrent Carotid Stenosis after CEA and CAS: Diagnosis and Management

Brajesh K. Lal, MD

Early Postsurgical Carotid Restenosis: Redo Surgery Versus Angioplasty/Stenting

Ali F. AbuRahma, MD; Mark C. Bates, MD; John T. Wulu, PhD*; and Patrick A. Stone, MD

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Redo Surgery or Carotid Stenting for Restenosis after Carotid Endarterectomy: Results of Two Different Treatment Strategies

Nicolas Attigah,[1] Sonja Külkens,[2] Claudia Deyle,[1] Peter Ringleb,[2] Marius Hartmann,[3] Philipp Geisbüsch,[1] and Dittmar Böckler,[1] Heidelberg, Germany

- Incidence: 10%-34%
- Necessity of reoperation: 1%-8%
- Early restenosis (within 24 months) : Myointimal Hyperplasia, clamp trauma, intimal and medial flaps, strictures at the distal end of the arteriotomy, inadequate resection of an ICA
- Late restenosis (>24 months): atherosclerosis

Post- CEA carotid restenosis

Comparison of Open and Endovascular Treatments of Post-carotid Endarterectomy Restenosis

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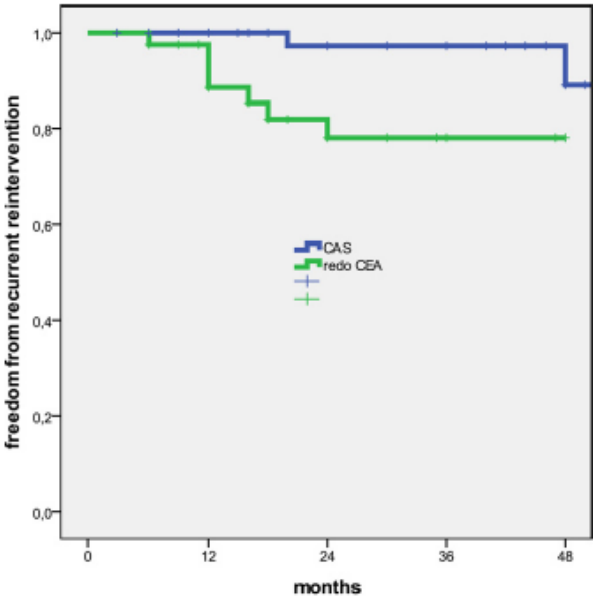


Months	0	12	24	48	S.E.
Group 1 – redo CEA (n. at risk)	39	32	20	3	7,5
Group 2 – CAS (n. at risk)	57	55	34	11	8,2

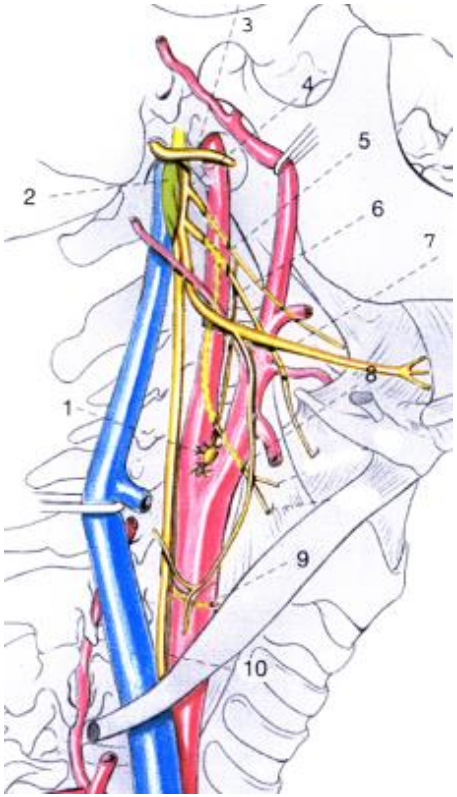
Redo surgery vs Balloon Angioplasty/Stenting

- Stroke and deaths rates are comparable
- Redo surgery is associated with cranial nerve injuries (transient)
- Patients with BA/S have a higher incidence of recurrent restenosis

RECURRENT CAROTID DISEASE: REDO SURGERY

Redo open carotid surgery is technically more complex

- scar tissue
- risk of cranial nerve injury
- control of the distal ICA



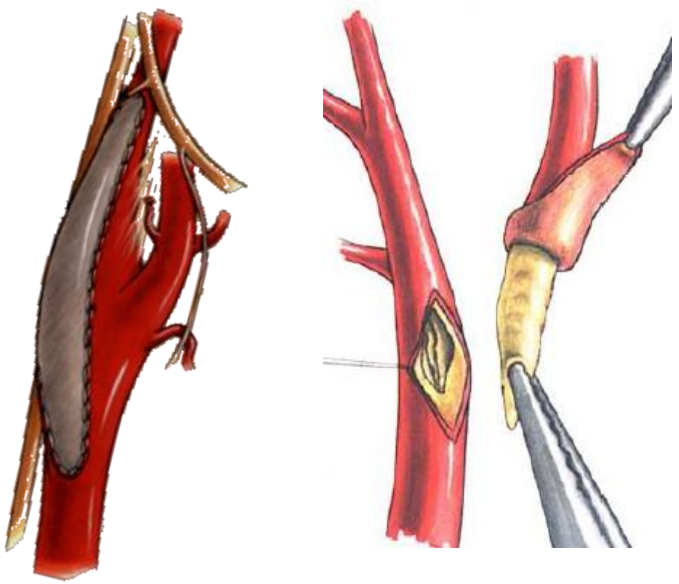
RECURRENT CAROTID DISEASE: REDO SURGERY

Recurrent Carotid Disease: Optimum Technique for Redo Surgery

Dieter Raithel, MD
Department of Vascular Surgery, Nuremberg Hospital, Nuremberg, Germany

Safety and Efficacy of Eversion Carotid Endarterectomy for the Treatment of Recurrent Stenosis: 20-Year Experience

Manish Mehta, MD, MPH, Sean P. Roddy, MD, R. Clement Darling III, MD, Philip S.K. Paty, MD, Paul B. Kreienberg, MD, Kathleen J. Ozsvath, MD, Benjamin B. Chang, MD, and Dhiraj M. Shah, MD, Albany, New York



Eversion Cea is a feasible option for the treatment of many Recurrent Carotid Restenosis (RCCs) and can be performed with a low rate of cranial nerve iniury, reduced clamp time (vs standard CEA), recurrent stenosis, stroke and death

IN-STENT RESTENOSIS (IRS)

IN-STENT RESTENOSIS

While redo endovascular therapy has been the most common treatment for *ISR*, a wide range of surgical options have been reported.

RESTENOSIS AFTER CAS

Journal of Vascular Surgery

Carotid endarterectomy for treatment of in-stent restenosis

Alberto Gonzalez, MD,[a] Michael Drummond, MD,[b] Scott McCord, MD,[b] and H. Edward Garrett Jr, MD,[a] *Memphis, Tenn; and Birmingham, Ala*

In-stent restenosis (ISR) after carotid angioplasty and stenting is becoming evident as more patients undergo carotid stenting and duplex scan surveillance. While redo endovascular therapy has been immediately successful, recurrent stenosis remains a problem. The ideal management of ISR has not been determined. Three cases of symptomatic ISR that were successfully treated by standard carotid endarterectomy (CEA) with removal of the stent are reported herein. Current options for management of ISR are reviewed from the literature. (J Vasc Surg 2011;54:1167-9.)

RESTENOSIS AFTER CAS

J Vasc Surg. 2011 Jul;54(1):87-92. Epub 2011 Feb 11.

Carotid endarterectomy for treatment of in-stent restenosis after carotid angioplasty and stenting.

Reichmann BL, van Laanen JH, de Vries JP, Hendriks JM, Verhagen HJ, Moll FL, de Borst GJ.

Department of Vascular Surgery, University Medical Center Utrecht, Utrecht, The Netherlands.

RESULTS: Standard CEA with stent removal was performed in all 15 patients. A Javid shunt was used in two procedures. One patient sustained an intraoperative minor ischemic stroke, with complete recovery during the first postoperative days. No neurologic complications occurred in the other 14 patients. Two patients required a reoperation to evacuate a neck hematoma. There were no peripheral nerve complications. After a median follow-up of 21 months (range, 3-100 months), all 15 patients remained asymptomatic and without recurrent restenosis (≥50%) on duplex ultrasound imaging.

CONCLUSION: CEA with stent explantation for ISR after CAS seems an effective and durable therapeutic option, albeit with potential cerebral and bleeding complications, as in this study. The optimal treatment for carotid ISR, however, has yet to be defined.

CAROTID ARTERY STENTING

AS AN ENDOVASCULAR ORIENTED VASCULAR SURGEON I BELIEVE IN THE RENAISSANCE OF CAS

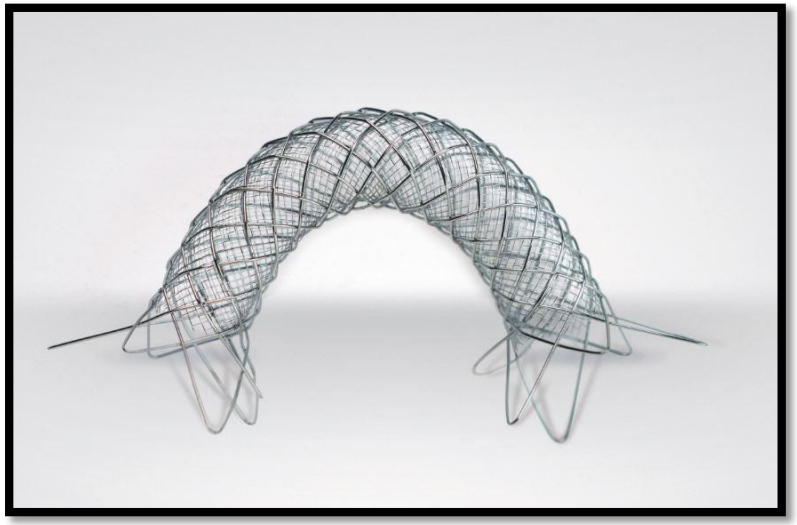
IDEAL STENT - OCT ANSWER

- **Stent malapposition is more frequent with closed cell stent**
- **Plaque prolapse is more common with open cell stents**

We need new stent design

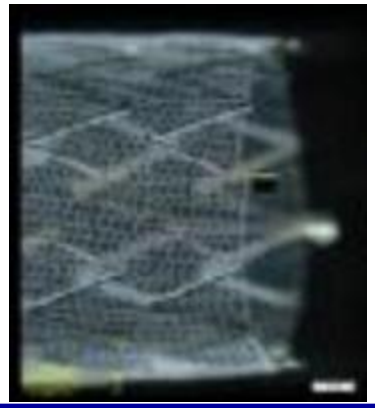
We need MESH-STENT

NEW CAROTID STENT DESIGN



Terumo - Roadsaver

Gore – Mesh carotid stent



Inspire – C-Guard

IMPACT OF NEW STENT DESIGN

TERUMO

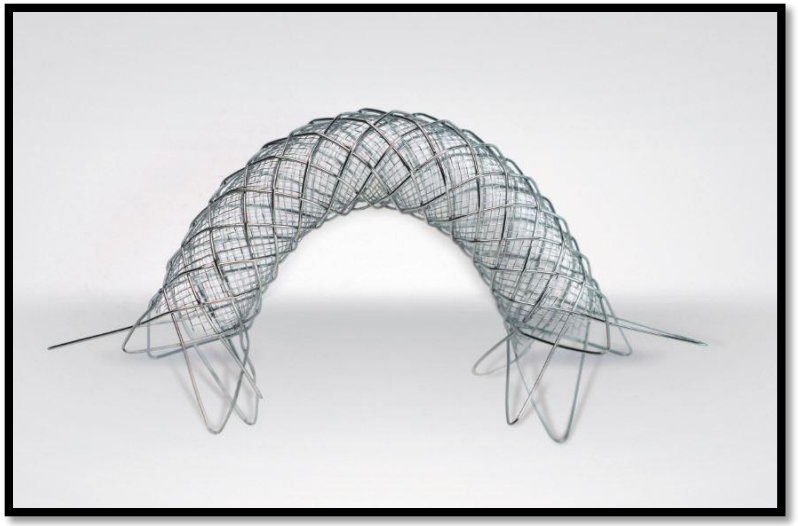
Roadsaver®

A novel carotid stent for sustained embolic protection

Sustained embolic protection

- Double layer micromesh nitinol design
- Smallest cell stent size preventing embolic release
- Double layer micromesh design

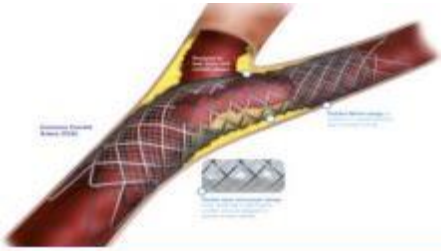
-- Chronic embolic protection



Lesion specific scaffolding:

- Extremely high plaque coverage
- Superior in vessel flexibility
- Excellent wall apposition: the two mash layers enable a flexible scaffold

SUMMARY OF THE MAIN CHARACTERISTICS OF ROADSAVER

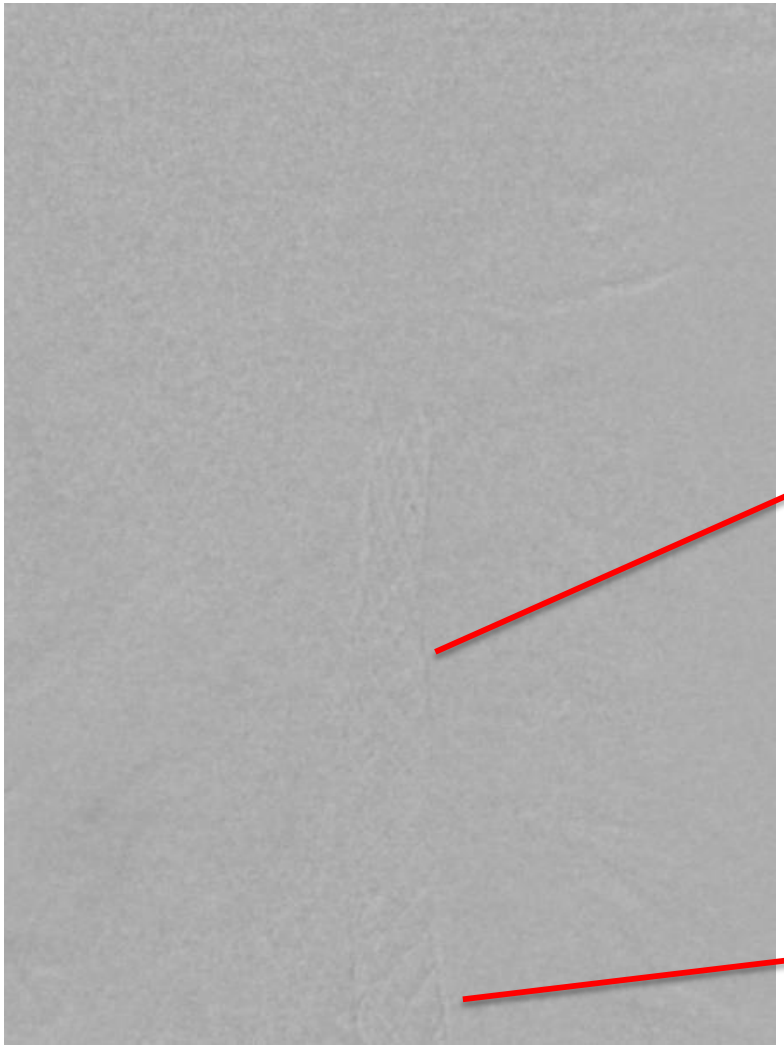


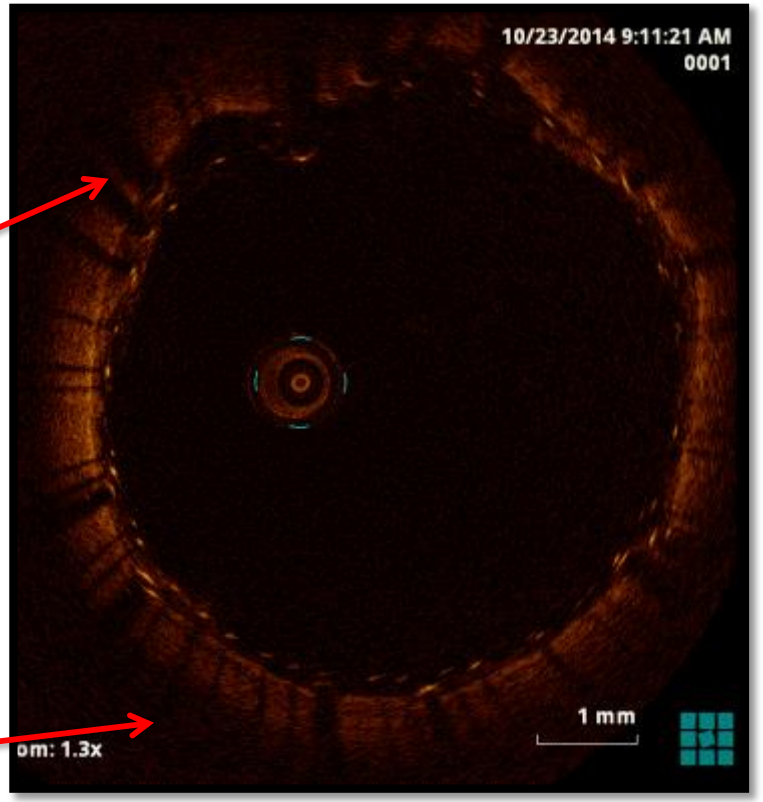
Roadsaver

Roadsaver Stent Platform	
Design	Double layer, micromesh
Construction	Braided mesh
Material	Nitinol®
Stent Delivery System	
Guide wire compatibility	0.014" (0.36mm)
Introducer sheath compatibility	5Fr. (I.D.> 0.074")
Delivery system construction	Rapid Exchange (RX), RX segment length 25cm

Company	Microvention /Terumo
Material (Stent/Micromesh)	Nitinol /**Nitinol**
Size of delivery	**5F**
Size of Pores µ	**375-500**
Flared tips	**yes**
Retrievable/Repositionable	**yes**
Accuracy	++
Conformability	+++
Crossability	+++
ECA preservation	yes
EPD compatibility	All

IMPACT OF NEW STENT DESIGN





ITALIAN REGISTRY - ROADSAVER

Torino: Dr. C.Rabbia
Radiologist

Cotignola: Dr. A.Cremonesi
Cardiologist

3 Italian Vascular Centers

Siena: Prof. C. Setacci
Vascular Surgeon

PRELIMINARY RESULTS

3 ITALIAN CENTRES

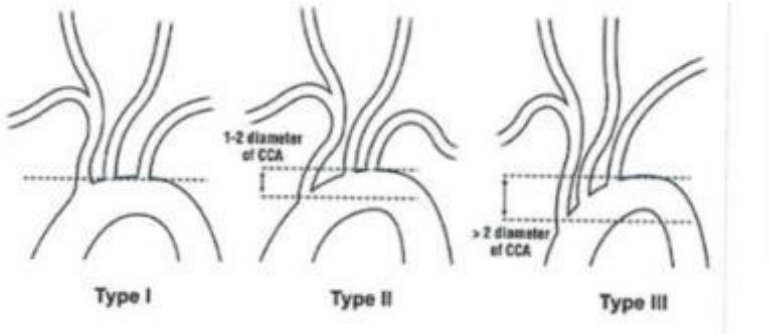
Cotignola	n= 82
Siena	n= 52
Torino	n= 16
	150

Under review
Eurointervention

PATIENT'S CHARACTERISTICS

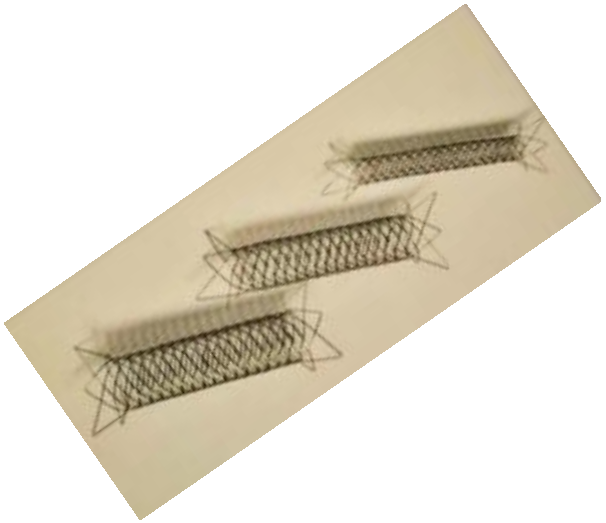
Age (years)	74±8
Male sex (%)	113 (75)
Symptomatic carotid artery disease (%)	43 (29)
Hypertension (%)	124 (83)
Dyslipidemia (%)	106 (71)
Diabetes mellitus (%)	41 (27)
Current or prior cigarette smoking (%)	83 (55)
Prior myocardial infarction (%)	27 (18)
Previous CABG (%)	15 (10)
Previous TEA (%)	15 (10)

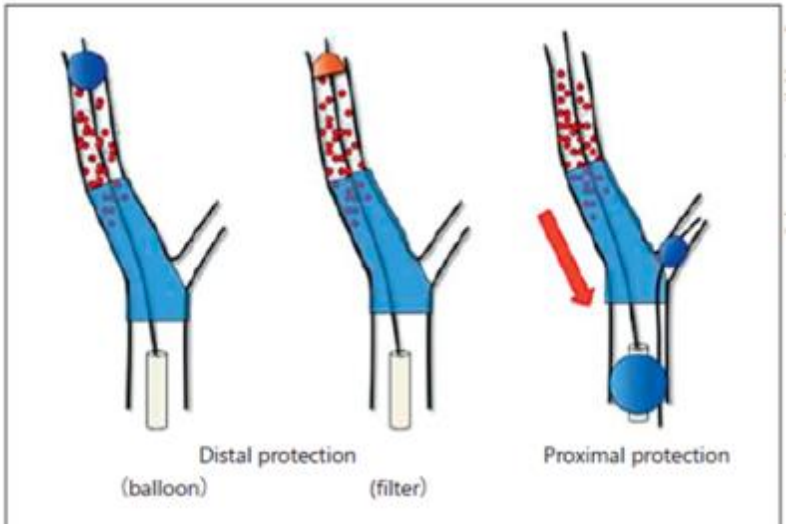
Bilateral carotid artery disease (%)		47 (31)
Aortic Arch (elongation variant)		
	Type I , %	71%
	Type II, %	18%
	Type III, %	11%
Bovine arch, %		21%
Target lesion severity, %		80.8±7.5
Doppler velocity flow (m/sec)		2.7±0.7
Severe tortuosity (%)		16 (11)
Severe calcification (%)		13 (9)
Ulcerated plaque (%)		13 (9)
Dissection (%)		4 (3)



PROCEDURE FINDINGS

Target vessel	
Left ICA (%)	70 (47)
Right ICA (%)	80 (53)
Protection used	
Distal filter (%)	88 (59)
Proximal balloon (%)	62 (41)
Access site	
Femoral (%)	140 (93)
Radial (%)	9 (7)
Brachial (%)	1 (0)



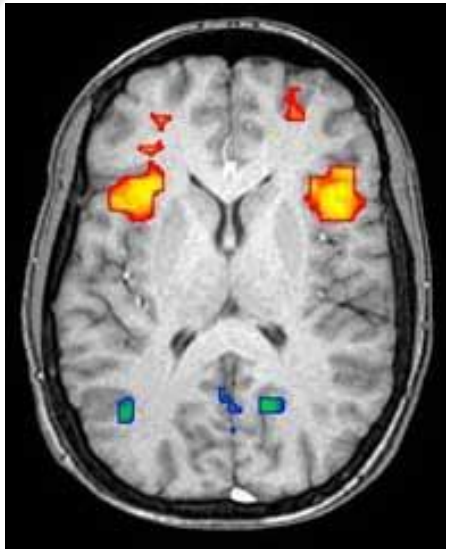


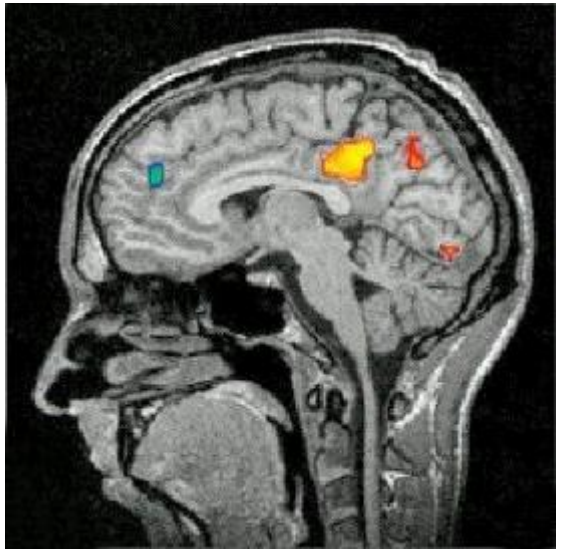
Predilatation (%)	11 (7)
Postdilatation (%)	150 (100)
Stent deployed (%)	150 (100)
Procedure success (%)	150 (100)
Stent diameter (mm)	8.6±0.8
Stent length (mm)	25.0±4.5
TIMI III flow in ECA (%)	150 (100)

ITALIAN REGISTRY - ROADSAVER

Subgroup analysis_MR

- Magnetic Resonance evaluation of cerebral parenchyma before and 24 hours post-op

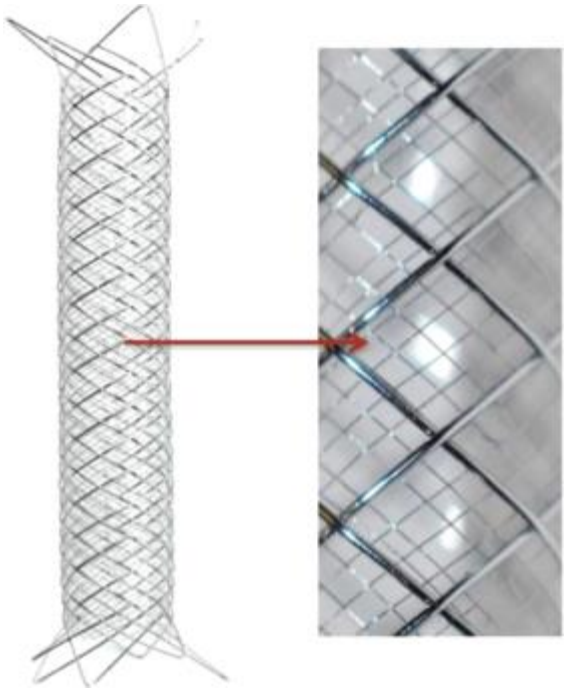


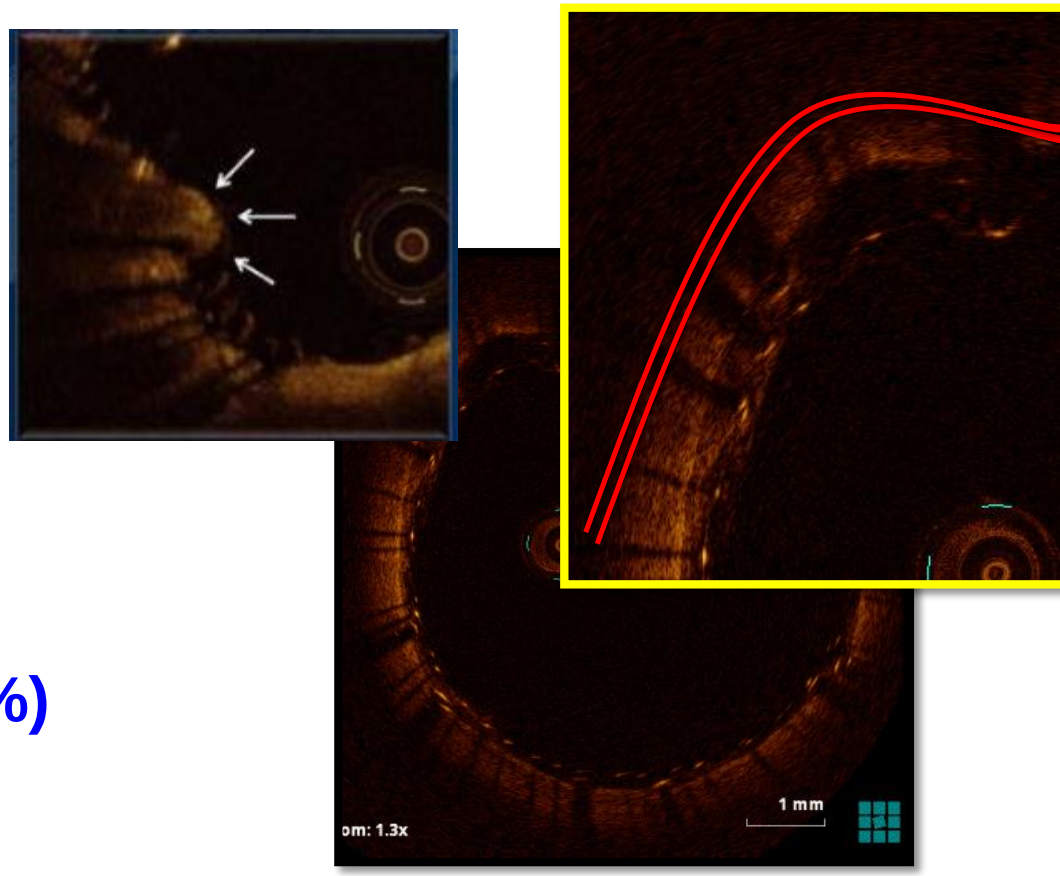


New lesions in **1 case** @ 24 hrs
(n=3 in the ipsilateral and
n=2 in controlateral hemisphere

ITALIAN REGISTRY - ROADSAVER

Subgroup analysis_OCT 36 patients





Plaque prolapse 2/36 (5.5%)

PRELIMINARY RESULTS

30 DAYS:

- 0% STROKE AND DEATH
- 0% TIA
- 0% MI

CLEAR ROAD - PROSPECTIVE INTERNATIONAL TRIAL

CLEAR ROAD – participating centers

- PI: Dr. Bosiers, AZ Sint-Blasius, Dendermonde, Belgium

- Participating centers:
  - 5 Belgian centers
  - 4 German centers
  - 3 Italian centers

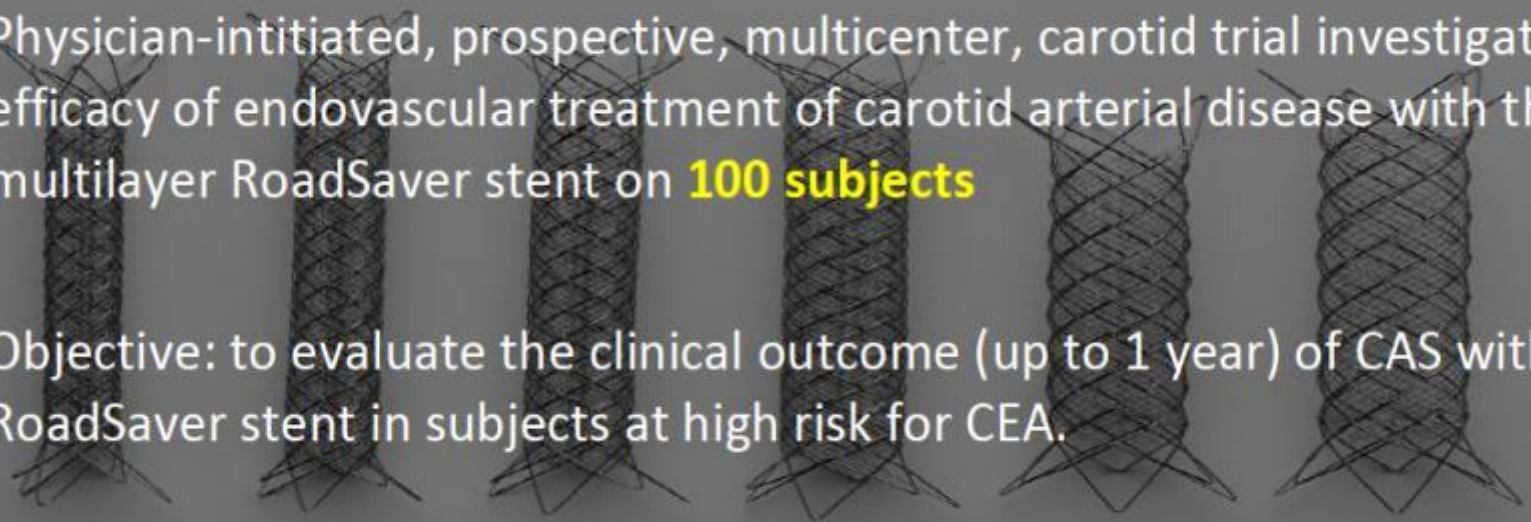
CLEAR ROAD - PROSPECTIVE INTERNATIONAL TRIAL

Sustained embolic protection device....

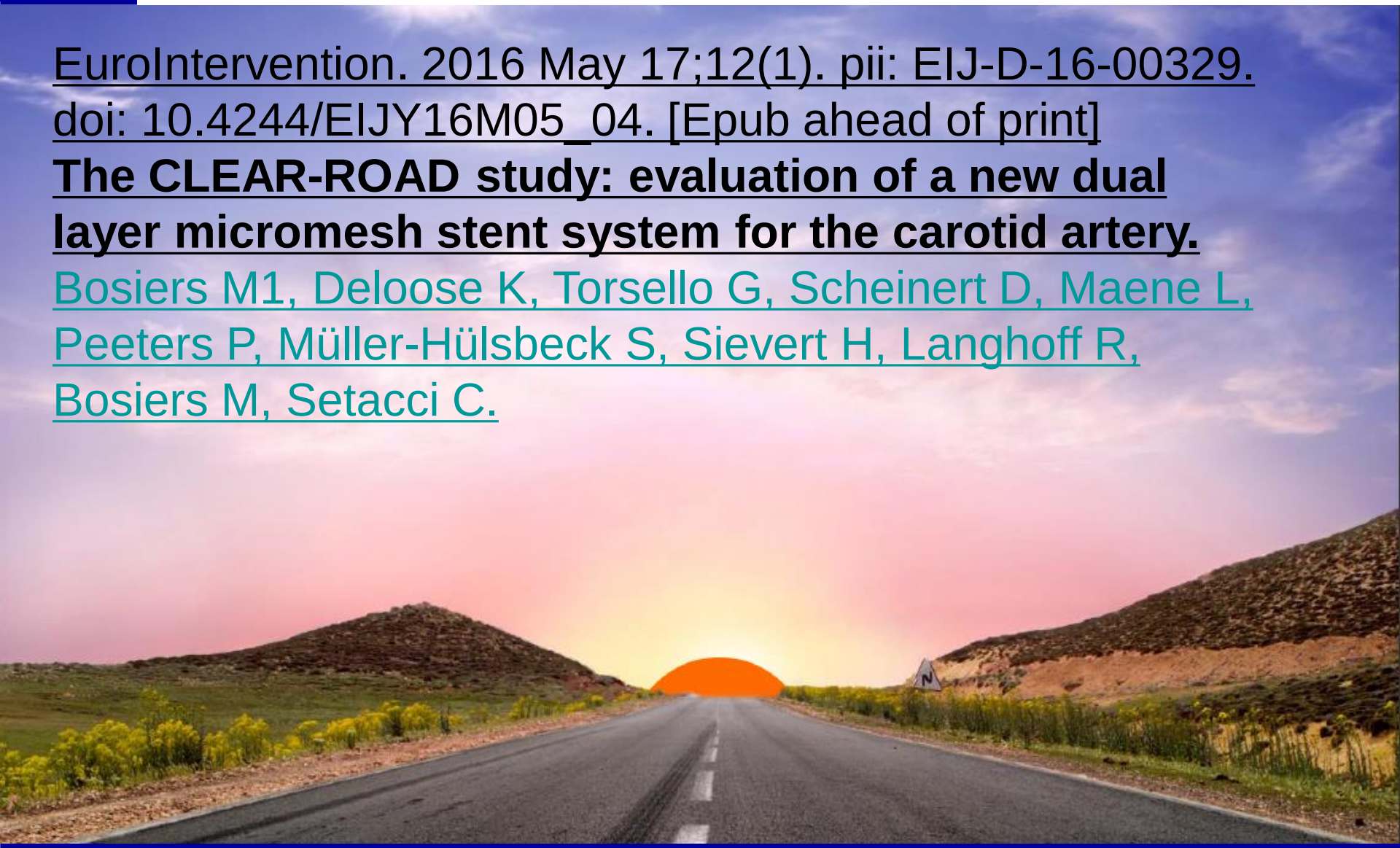
CLEAR ROAD TRIAL

- Physician-intitiated, prospective, multicenter, carotid trial investigating the efficacy of endovascular treatment of carotid arterial disease with the multilayer RoadSaver stent on **100 subjects**

- Objective: to evaluate the clinical outcome (up to 1 year) of CAS with the RoadSaver stent in subjects at high risk for CEA.



CLEAR ROAD TRIAL



EuroIntervention. 2016 May 17;12(1). pii: EIJ-D-16-00329. doi: 10.4244/EIJY16M05_04. [Epub ahead of print]

The CLEAR-ROAD study: evaluation of a new dual layer micromesh stent system for the carotid artery.

Bosiers M1, Deloose K, Torsello G, Scheinert D, Maene L, Peeters P, Müller-Hülsbeck S, Sievert H, Langhoff R, Bosiers M, Setacci C.

Registry

European Society for Vascular Medicine

Iron Guard

Physician-initiated prospective **I**talian **R**egistry **o**f carotid ste**n**ting with the C-**Guard** mesh-stent.

UNIVERSITÀ DI SIENA 1240

SAPIENZA UNIVERSITÀ DI ROMA

Registry

European Society for Vascular Medicine

2. OBJECTIVES

The objective of this clinical investigation is to evaluate the clinical outcome (up to 12 months) of treatment by means of stenting with the C-Guard (InspireMD) in subjects requiring carotid revascularization due to significant extra-cranial carotid artery stenosis.

Registry

6 ENDPOINTS

6.1 Primary Endpoint

The primary endpoint of this study is the 30-day rate of major adverse events (MAE), defined as the cumulative incidence of any peri-procedural (≤ 30 days post-procedure) death, stroke or myocardial infarction (MI).

6.2 Secondary Endpoints

1. Late ipsilateral stroke (31 through 365 days)
2. System Technical Success
3. Device malfunctions.
4. Major Adverse Events (MAEs)
5. Serious device-related and procedure-related Adverse Events (SAEs) as defined per ISO 14155-1:2011.
6. Target Lesion Revascularization (TLR).
7. In-Stent Restenosis (ISR).

Preliminary results

From April 2015 to February 2016
165 patients included

Technical success was achieved in 98.8%

in two patients one single stent was unable to cover the whole length of plaque so that a second stent was implanted

61 on 165 patients underwent DWMRI pre and postoperatively

Preliminary results

Neurological events 30 days :

- 5 minor strokes
- 2 additional TIA
- 2 mental confusions
- 2 bradicardia lasting more than 24 hours

Preliminary results

Reinterventions:

- Redo CAS for restenosis
- stent explanted for partial thrombosis

Preliminary results

DWMRI results:

New postoperative DWMRI lesions were detected in 12 patients (19.6%): among them 7 presented with contralateral or bilateral microembolic lesions

THANKS FOR YOUR ATTENTION