



# MA PERSPECTIVE DE PROTECTION PAR REVERSE FLOW LA PLUS PROMETTEUSE



A. Cardon  
CHU RENNES



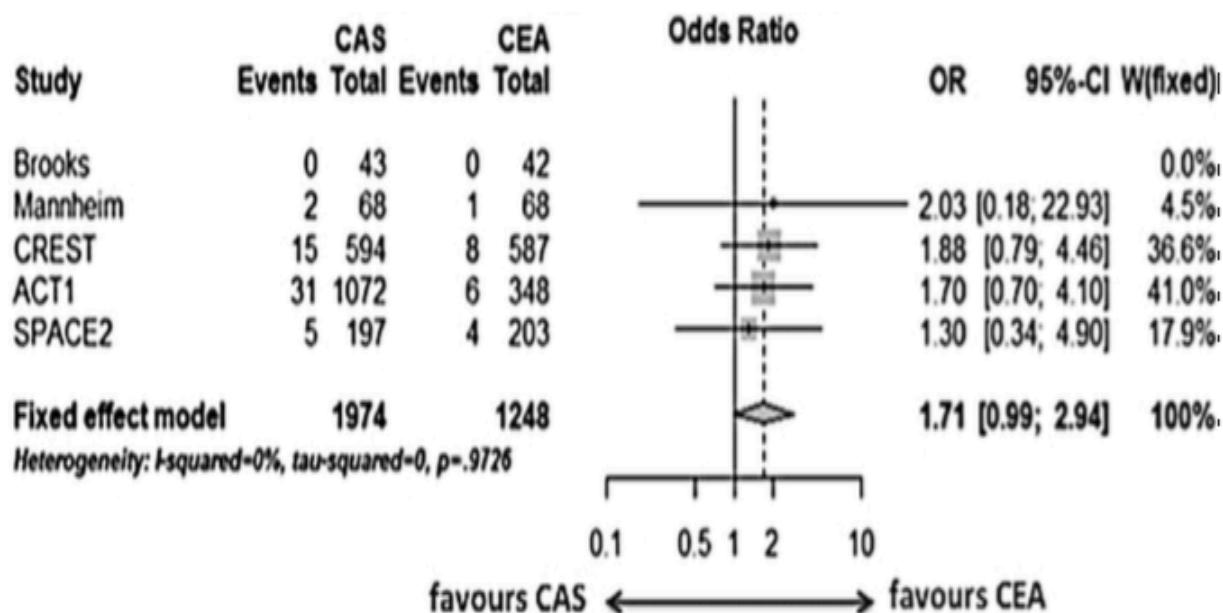
# Conflits d'intérêt

- Aucun conflit d'intérêt pour cette présentation



## Management of Atherosclerotic Carotid and Vertebral Artery Disease: 2017 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS)

Writing Group <sup>a</sup>, A.R. Naylor, J.-B. Ricco, G.J. de Borst, S. Debus, J. de Haro, A. Halliday, G. Hamilton, J. Kakisis, S. Kakkos, S. Lepidi, H.S. Markus, D.J. McCabe, J. Roy, H. Sillesen, J.C. van den Berg, F. Vermassen, ESVS Guidelines Committee <sup>b</sup>, P. Kolh, N. Chakfe, R.J. Hinchliffe, I. Koncar, J.S. Lindholt, M. Vega de Ceniga, F. Verzini, ESVS Guideline Reviewers <sup>c</sup>, J. Archie, S. Bellmunt, A. Chaudhuri, M. Koelemay, A.-K. Lindahl, F. Padberg, M. Venermo



**Figure 4.** Forest Plot comparing 30-day death/stroke in four randomised trials comparing carotid endarterectomy and carotid artery stenting in asymptomatic patients.

# RISQUE ANATOMIQUE: infarctus silencieux

ICSS sub study :

124 CAS Transfemoral+filtre distal

vs 107 CEA avec IRM pré/post

73% nouvelles lésions CAS vs 17% CEA  
( $P<0001$ )

*Bonati LH Lancet Neuro 2010*



# DW MRI

## Prospective Studies

| <i>Study</i>         | <i>Procedure</i>  | <i>Embolic Protection</i>  | <i># subjects</i> | <i>% w/ New DWI Lesions</i> |
|----------------------|-------------------|----------------------------|-------------------|-----------------------------|
| PROFI <sup>1</sup>   | Transfemoral CAS  | Distal filter (Emboshield) | 31                | 87%                         |
| ICSS <sup>2</sup>    | Transfemoral CAS  | Distal filter (various)    | 51                | 73%                         |
| PROFI <sup>1</sup>   | Transfemoral CAS  | Proximal occlusion (MO.MA) | 31                | 45%                         |
| DESERVE <sup>3</sup> | Transfemoral CAS  | Proximal occlusion (MO.MA) | 127               | 30%                         |
| PROOF                | Transcervical CAS | Roadster                   | 57                | 19%                         |
| ICSS <sup>2</sup>    | CEA               | Clamp, backbleed           | 107               | 17%                         |

# RISQUE ANATOMIQUE

- Shaudigel S: Stroke 2008 : Review
  - CAS 37% vs CEA 10% nouvelles lésions  
IRM (P<0,01)
  - 16% controlatérales CAS vs 0,01% CEA



# Risque anatomique

Grossetti : acta chir belg 2011

50 CAS: pas de prédilatation ;filtre distal

- Minor stroke : 4%
- hits per op : 100%
- Nouvelles lésions ischémiques : 44%
- Diminution capacités cognitives : 36%



VIEWPOINT

## The Problem With Asymptomatic Cerebral Embolic Complications in Vascular Procedures

What If They Are Not Asymptomatic?

**Table 1** Estimated Annual U.S. Patients With New Brain Lesions

| Procedures                         | No. of Annual U.S. Patients | Incidence of New Brain Lesions, % | No. of Annual U.S. Patients With New Brain Lesions |
|------------------------------------|-----------------------------|-----------------------------------|--|
| Coronary angiography               | 1,072,000                   | 11–17                             | 118,000–182,000                                    |
| Percutaneous coronary intervention | 596,000                     | 11–17                             | 66,000–101,000                                     |
| Coronary artery bypass graft       | 242,000                     | 16–51                             | 39,000–123,000                                     |
| Surgical aortic valve replacement  | 90,000                      | 38–47                             | 34,000–42,000                                      |

*Although the fundamental issues of the nature of the embolic particles, precise mechanisms of cerebral injury, and effective prevention remain debated and unclear, recent reports have provided substantial evidence of memory loss, cognitive decline, and dementia related to these so-called silent infarcts.*

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## STATE-OF-THE-ART PAPER

### Silent Brain Injury After Cardiac Surgery: A Review

Cognitive Dysfunction and Magnetic Resonance Imaging  
Diffusion-Weighted Imaging Findings

Xiumei Sun, MD, Joseph Lindsay, MD, Lee H. Monsein, MD, Peter C. Hill, MD, Paul J. Corso, MD  
*Washington, DC*

The appearance of cognitive dysfunction after cardiac surgery in the absence of focal neurologic signs, a poorly

*In population-based studies, a strong association has been found between MRI lesions and prevalent cognitive dysfunction and dementia.*

that post-operative appearance of MRI lesions may serve as a more objective marker of brain injury in research efforts. If MRI examination can be used in this way, then 2 vitally important questions can be addressed.

*The more extensive the MRI lesions, the more severe is the observed cognitive impairment.*

(J Am Coll Cardiol 2012;60:791–7) © 2012 by the American College of Cardiology Foundation

Clinical Significance of White Lesions

Suppl X, JACC 2012;60:791–7.

# Flow reverse est la solution

Par abord trans cervical tous les problèmes sont réglés:

comme CAS : risque coronaire minimal

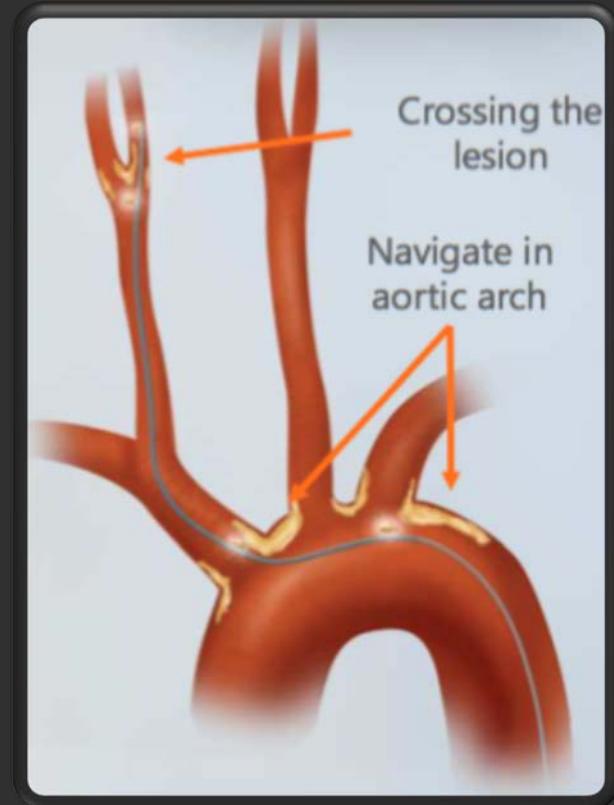
comme CEA: risque cérébral minimal



# Accès cervical vs. voie fémorale

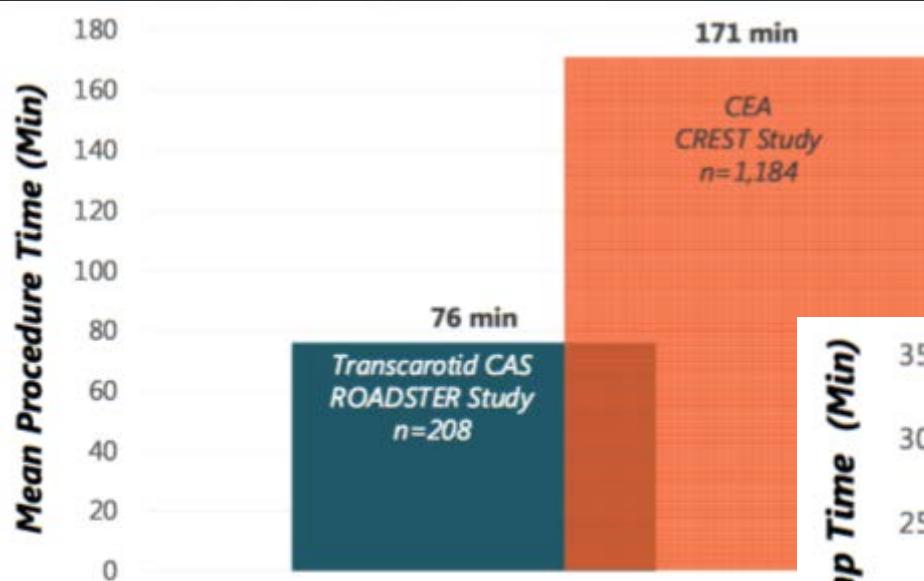
- ↘ risque embolique :

- Pas de navigation dans la crosse aortique
- Pas de passage de la lésion carotidienne avant mise en place du système de protection cérébrale



# Avantages du reverse flow

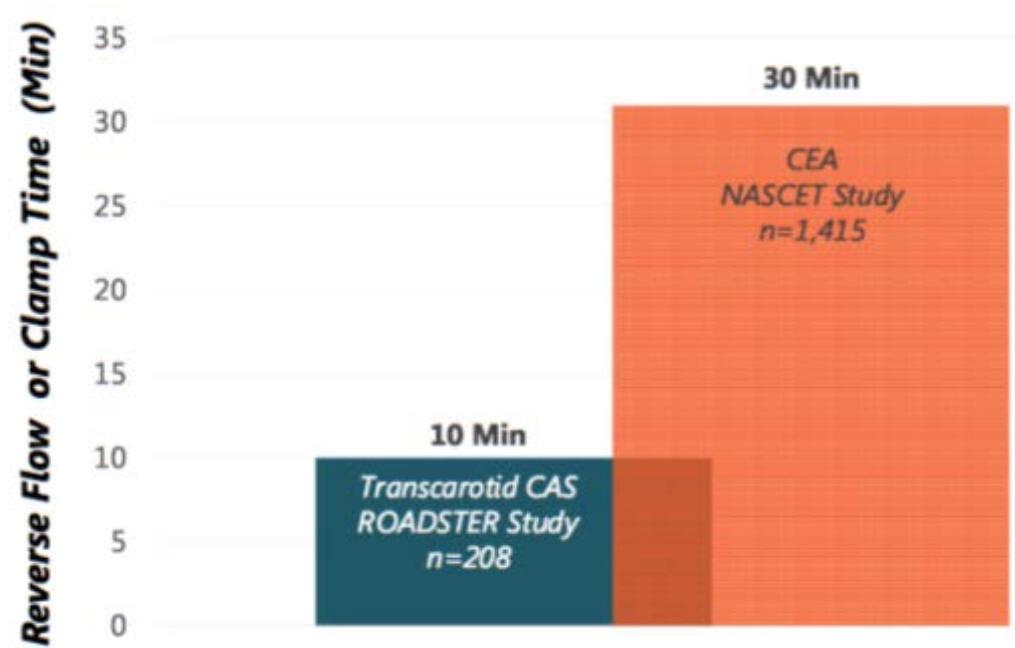
Durée de la procédure  
< 1/2 de celle de CEA



1. ROADSTER Presentation – Late Breaking Trials, VIVA 2014, C. Kwolek, MD  
2. Stroke. 2012;43:00-00.

■ Transcarotid CAS  
■ CEA

Durée d'inversion de flux  
= 1/3 de la durée de  
clampage pour CEA



# TRANSCERVICAL CAS

## Vs. TRANSFEMORAL CAS

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

Ignacio Leal, MD,<sup>a</sup> Antonio Orgaz, MD,<sup>a</sup> Ángel Flores, MD,<sup>a</sup> José Gil, MD,<sup>a</sup> Rubén Rodríguez, MD,<sup>a</sup> Javier Peinado, MD,<sup>a</sup> Enrique Criado, MD,<sup>b</sup> and Manuel Doblas, MD,<sup>a</sup> Toledo, Spain; and Ann Arbor, Mich

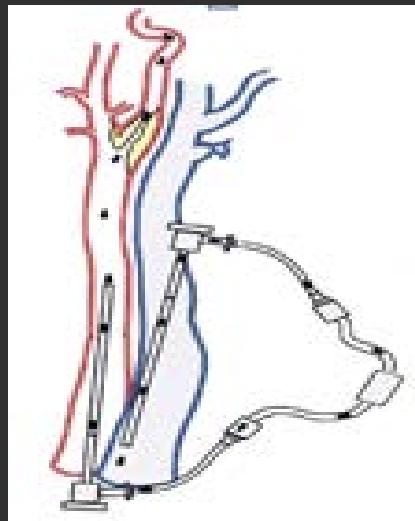
“The low 12.9% incidence in the transcervical group is comparable to the best series of CEA and a great improvement over the results of CAS with distal filters.”

| Variable                    | Transcervical<br>(n = 31)<br>No. (%) | Transfemoral<br>(n = 33)<br>No. (%) | P   |
|-----------------------------|--------------------------------------|-------------------------------------|-----|
| Patients with new lesions   | 4 (12.90)                            | 11 (33.33)                          | .03 |
| No. of new lesions          | 4                                    | 13                                  | .02 |
| Localization of new lesions |                                      |                                     |     |
| Ipsilateral                 | 4                                    | 11                                  | .03 |
| Contralateral               | 0                                    | 2                                   | .16 |

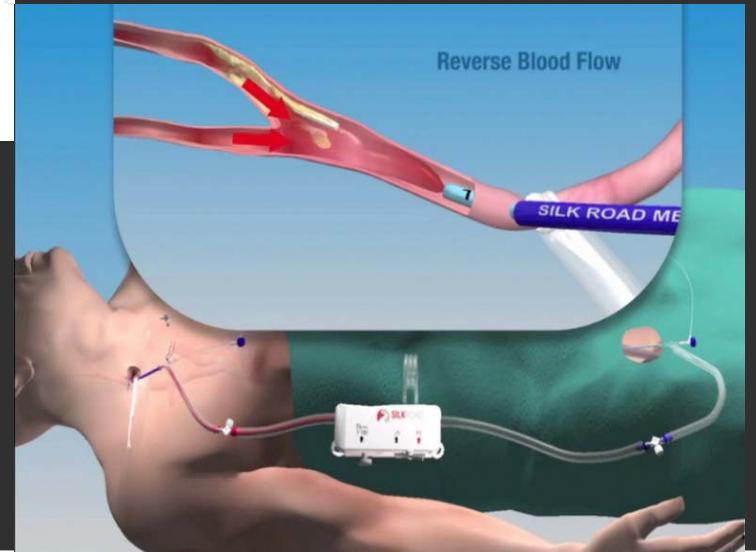
*“The results of CAS are clearly influenced by the access route and cerebral protection methods.....The risk of embolic complications with transfemoral carotid stenting is related to instrumentation of the arch and proximal supra-aortic trunks, crossing of the carotid lesion without protection, and use of distal filter protection devices of questionable benefit.”*

# 2 techniques de reverse flow

- Home made



- ENROUTE( silk road )



# Home made

- Avantages

Pas de navigation

Pas de franchissement de  
la lésion sans protection

cousts

disponible

- Inconvénients

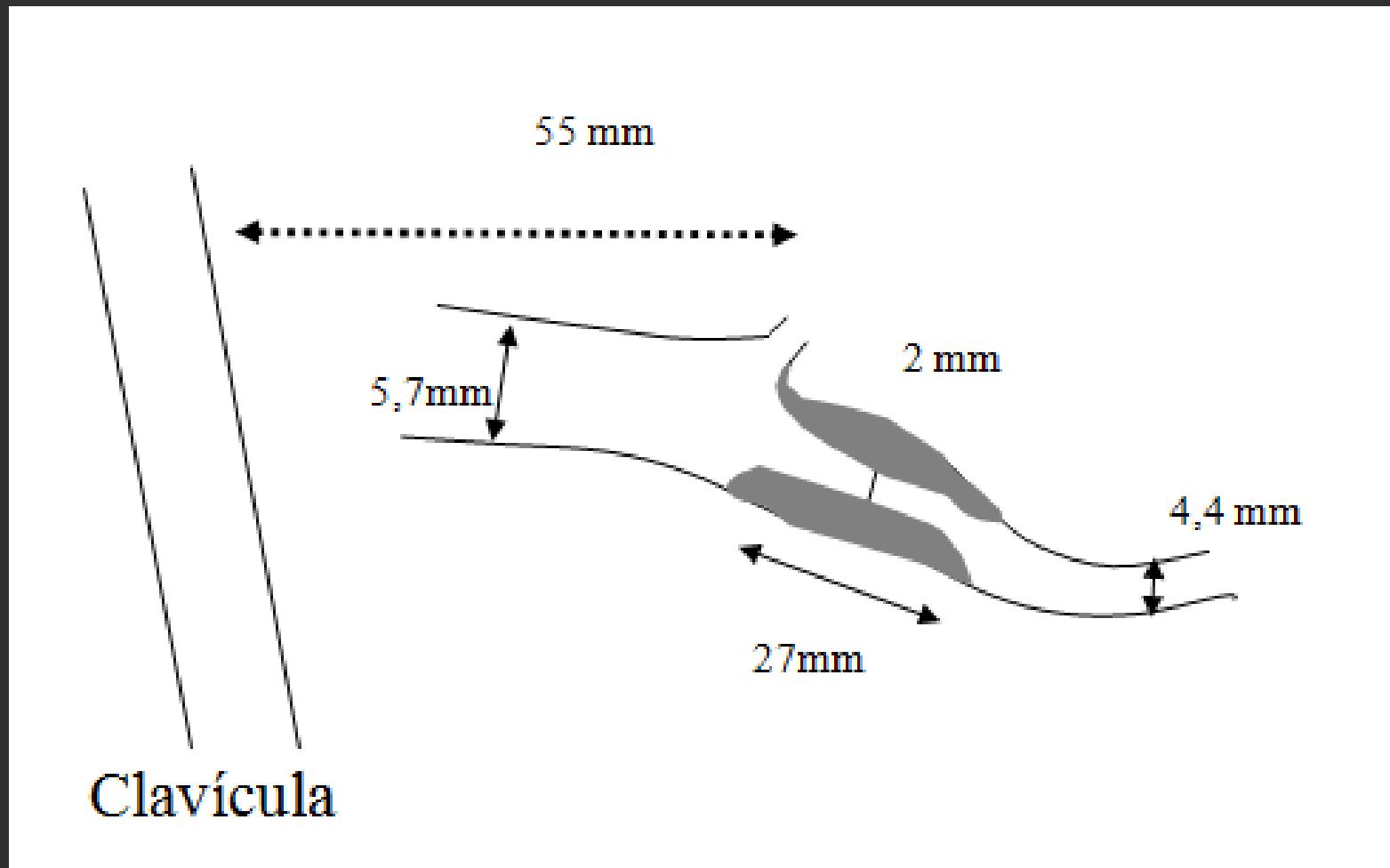
Hémodétournement  
cérébral

CI si calcification CP

Exposition des mains

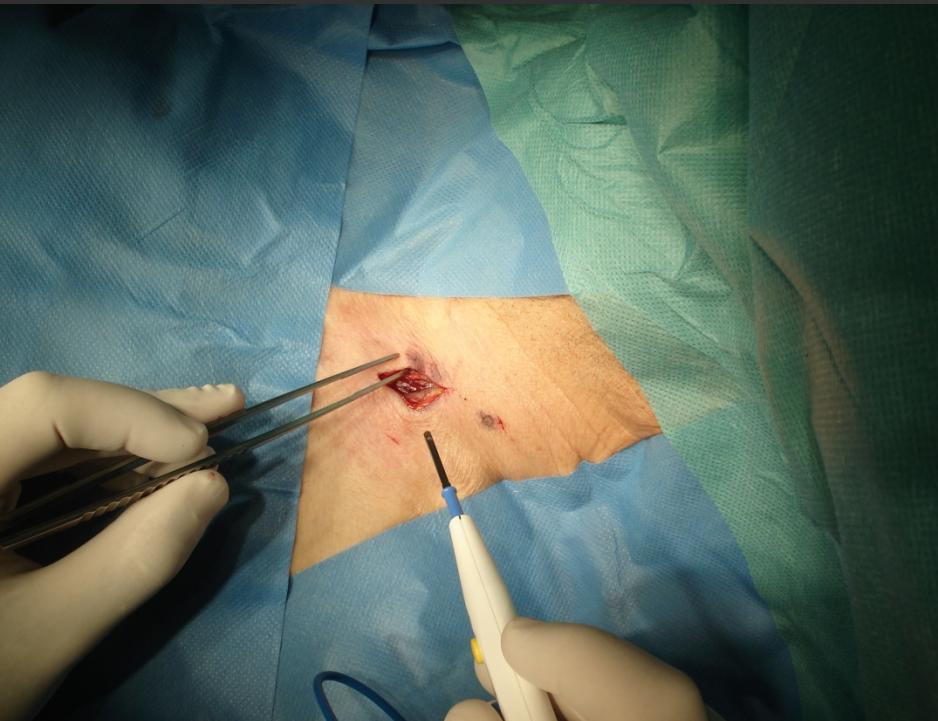
# TECHNIQUE

## ECHOGRAPHIE PRÉOPÉRATOIRE:



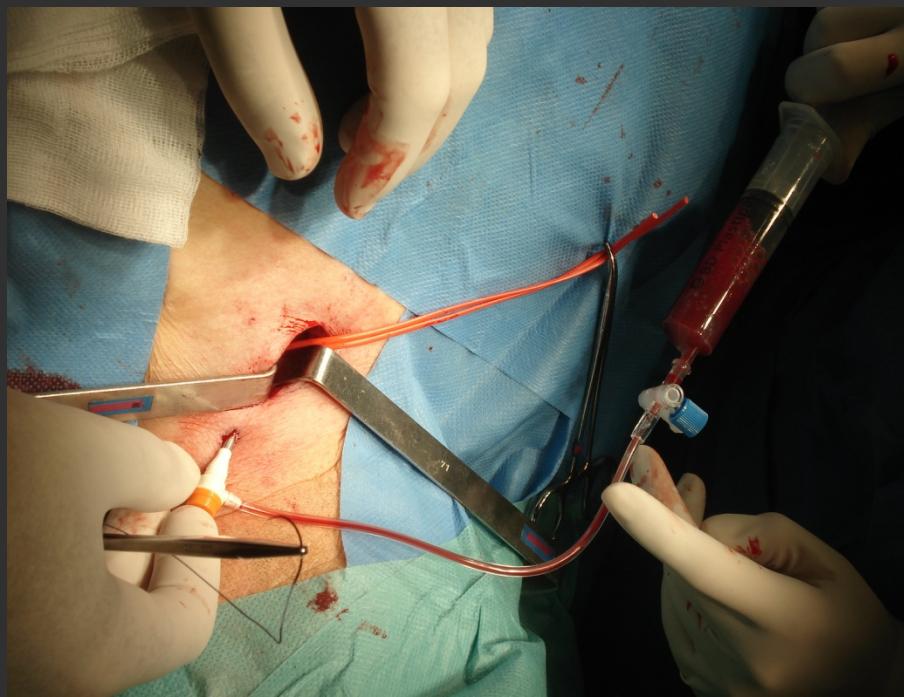
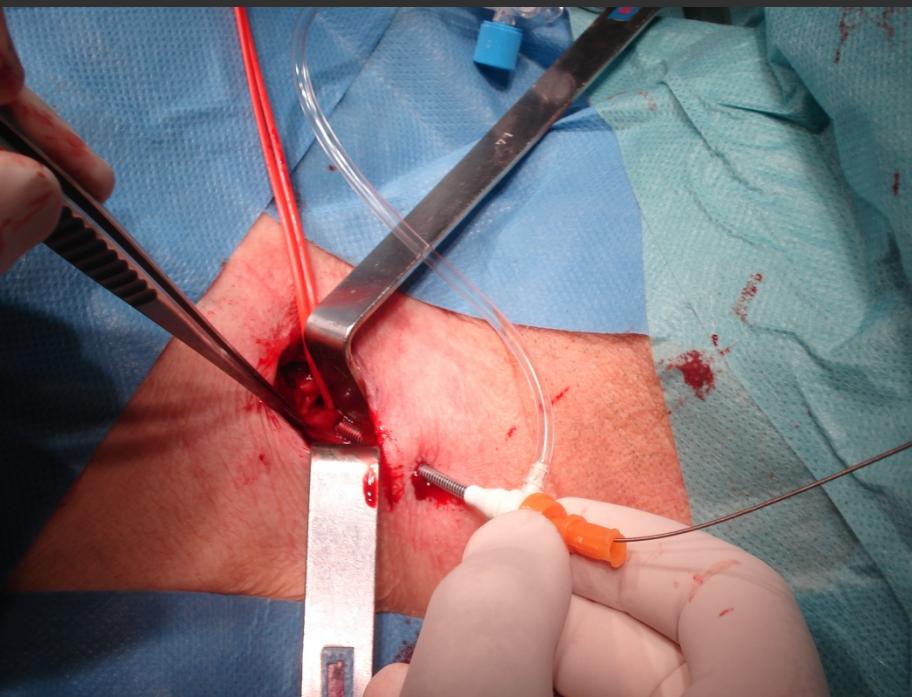
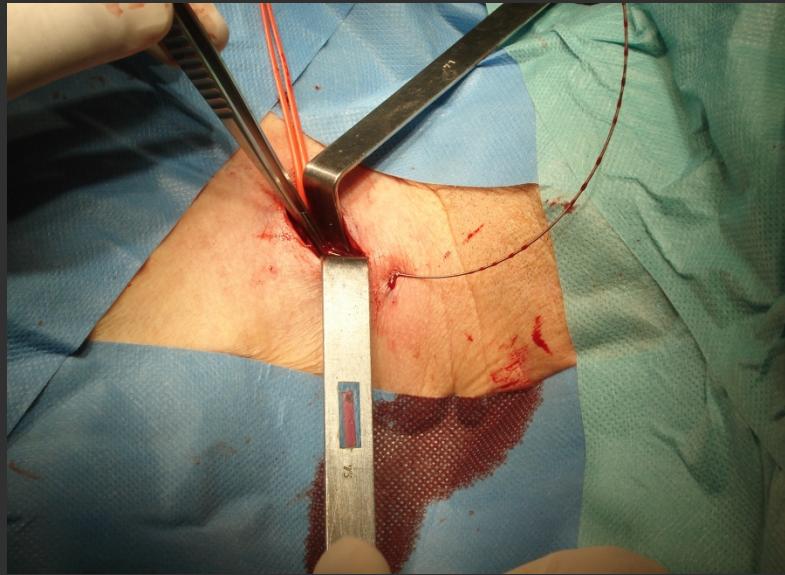
# TECHNIQUE

## DISSECTION VEINEUSE ET ARTÉRIELLE:



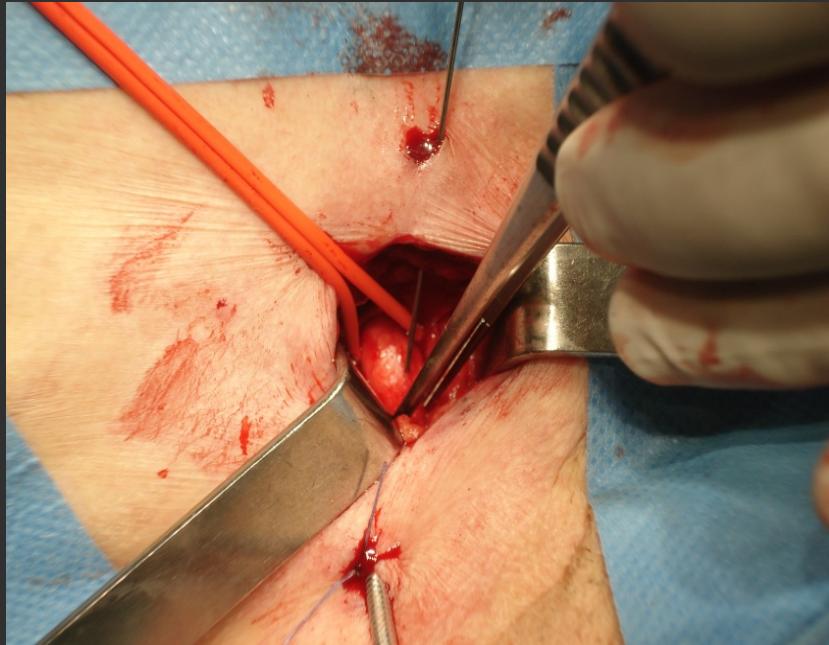
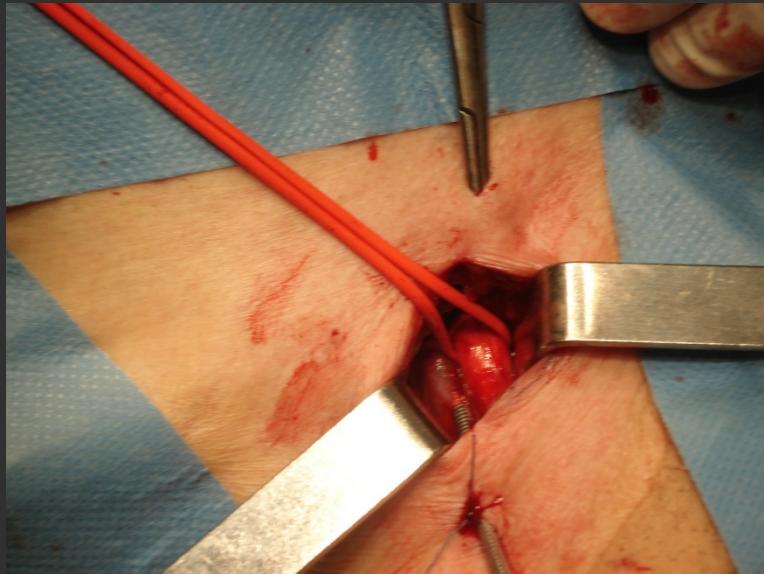
# TECHNIQUE

PONCTION VEINEUSE:  
homo ou controlatérale



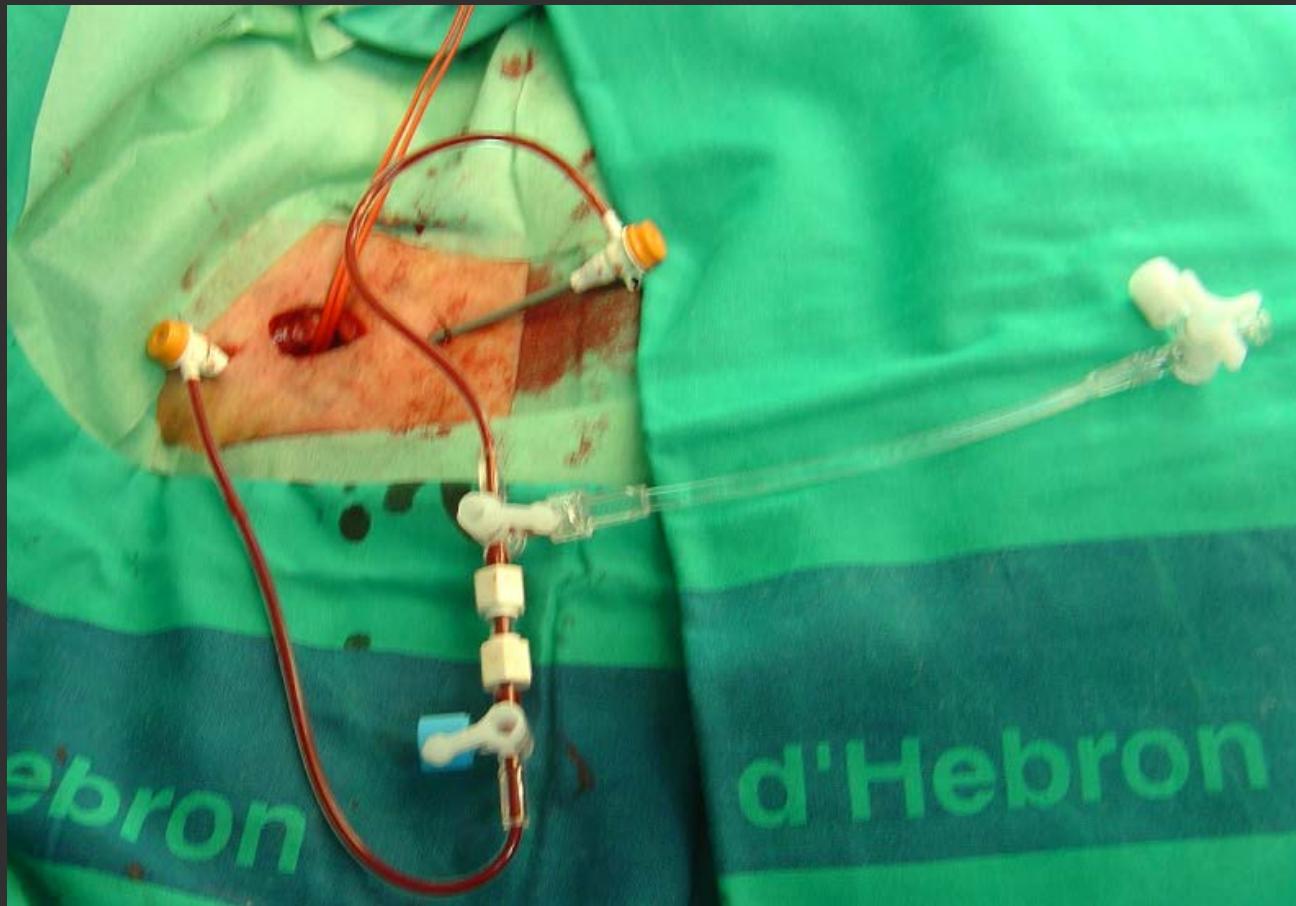
# TECHNIQUE

Bourse artérielle  
Kite de ponction radial  
Guide carotide externe  
Attention à la dissection  
Clampage par loop ou clamp



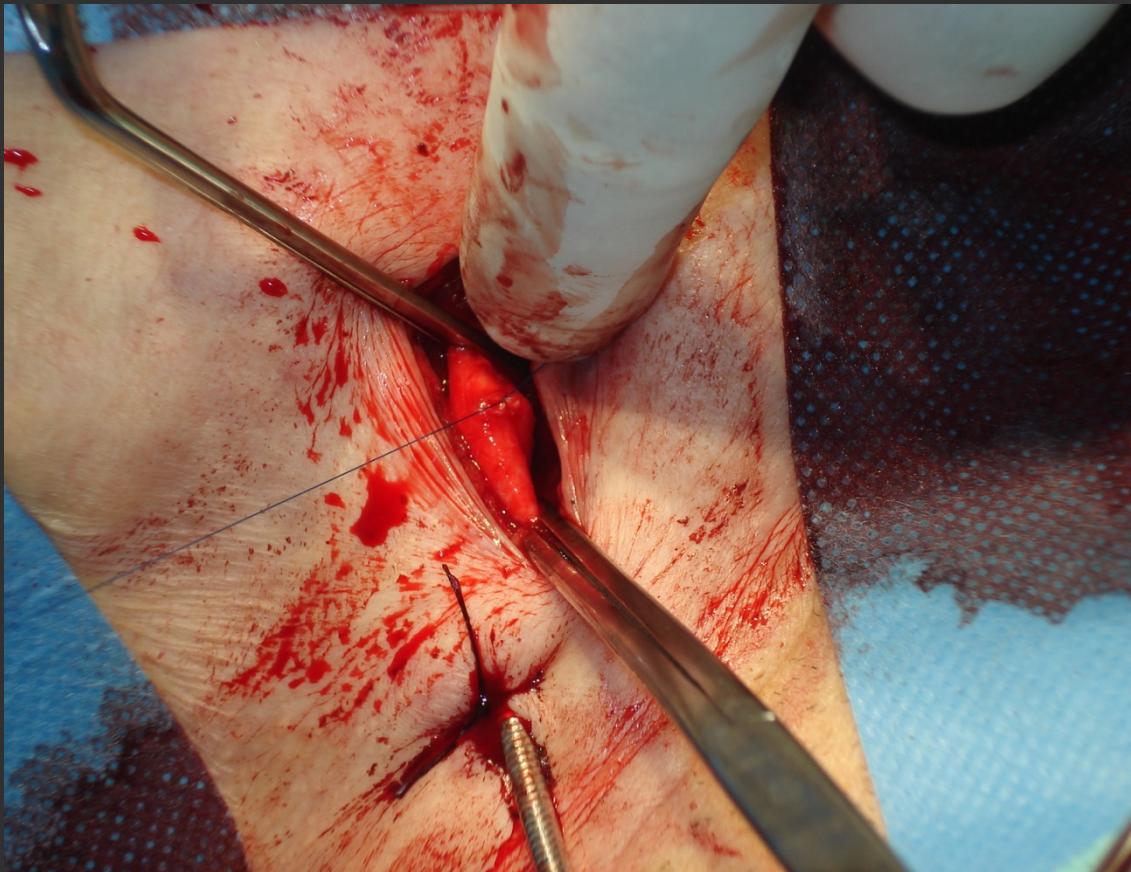
# TECHNIQUE

CONNEXION:



# TECHNIQUE

SUTURE DE L'ARTÉRIOTOMIE APRES PURGE :

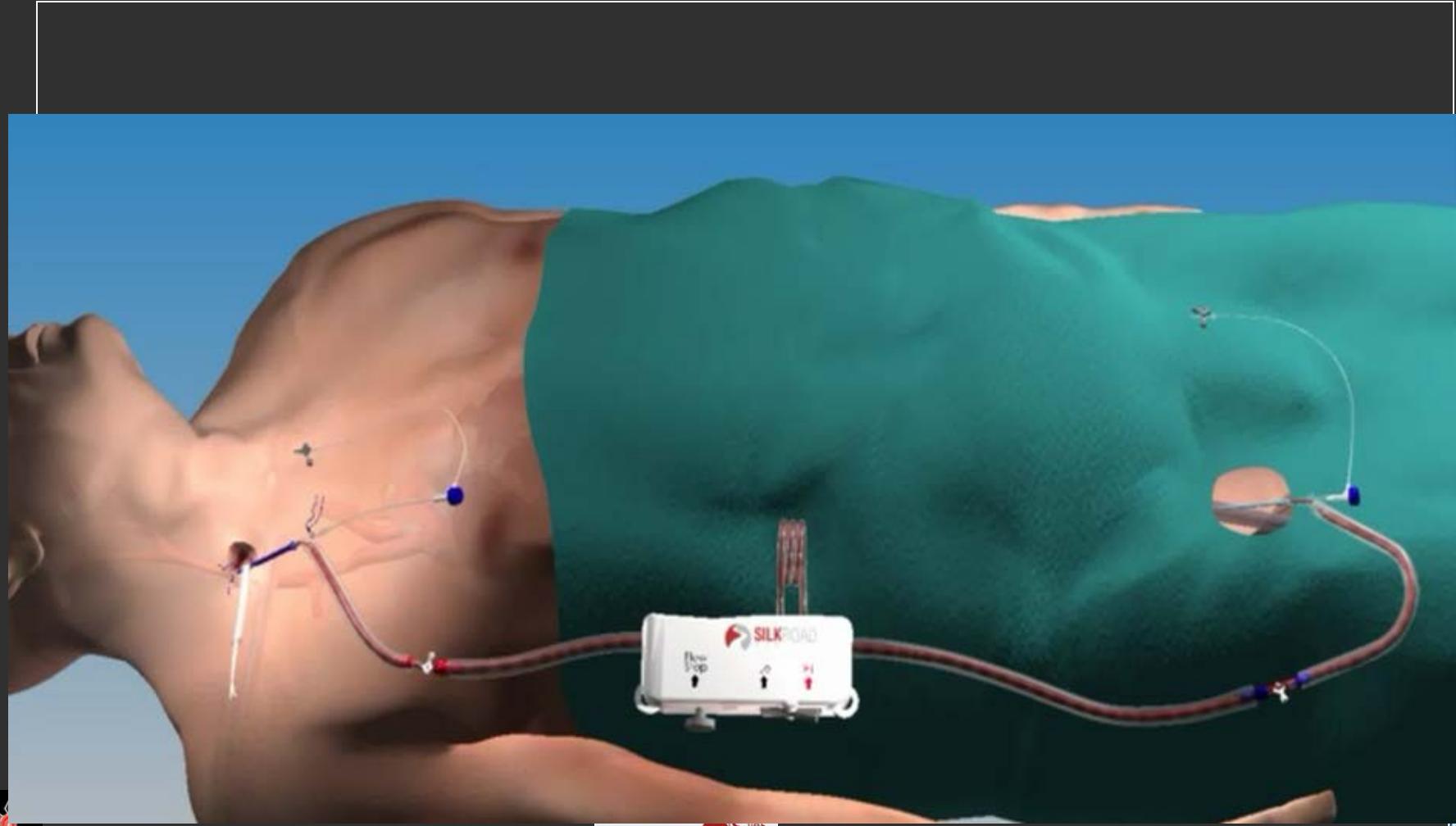


# Résultats home made

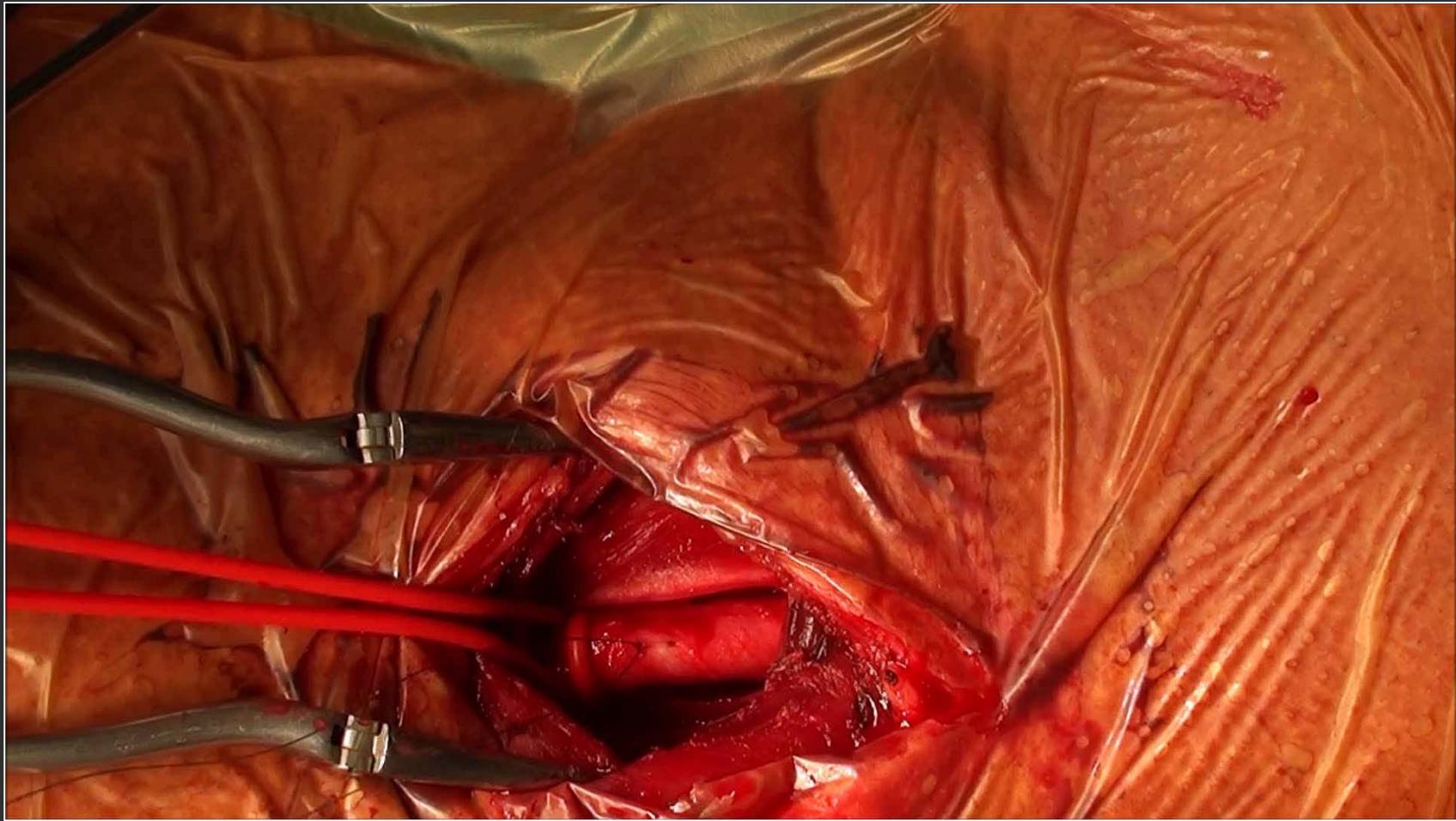
- Pipinos II: Vascular 2006
- 38 patients :
  - dc avc =0
  - Temps reverse flow : 26 mm
  - Intolerance : 3%

# Silk road

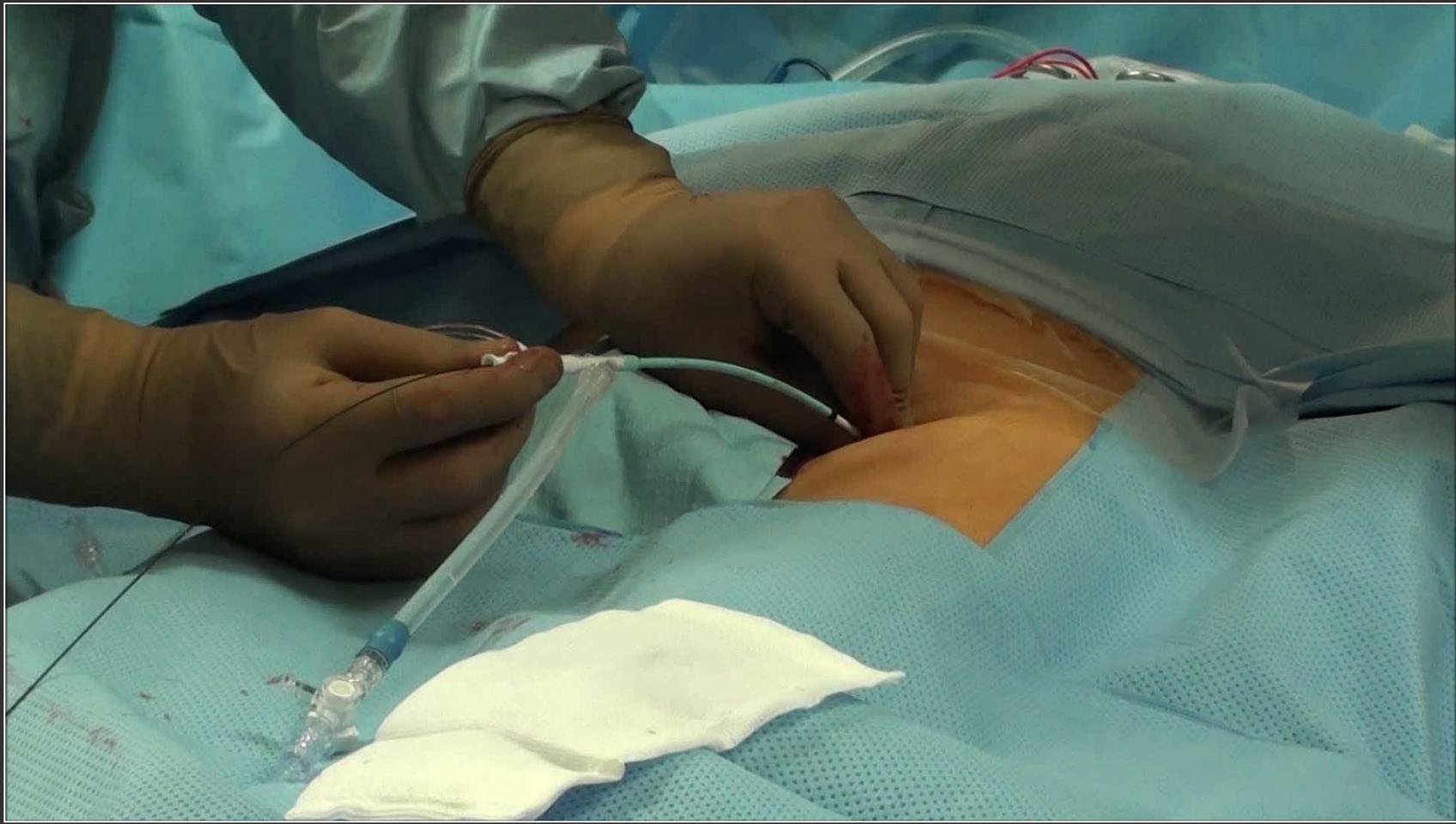
- 8F Transcervical Arterial Sheath
- 8F Venous Return Sheath
- Large bore flow reversal circuit
- Flow controller with stop, HI and LO flow



# TECHNIQUE ( Pr E. Ducasse )

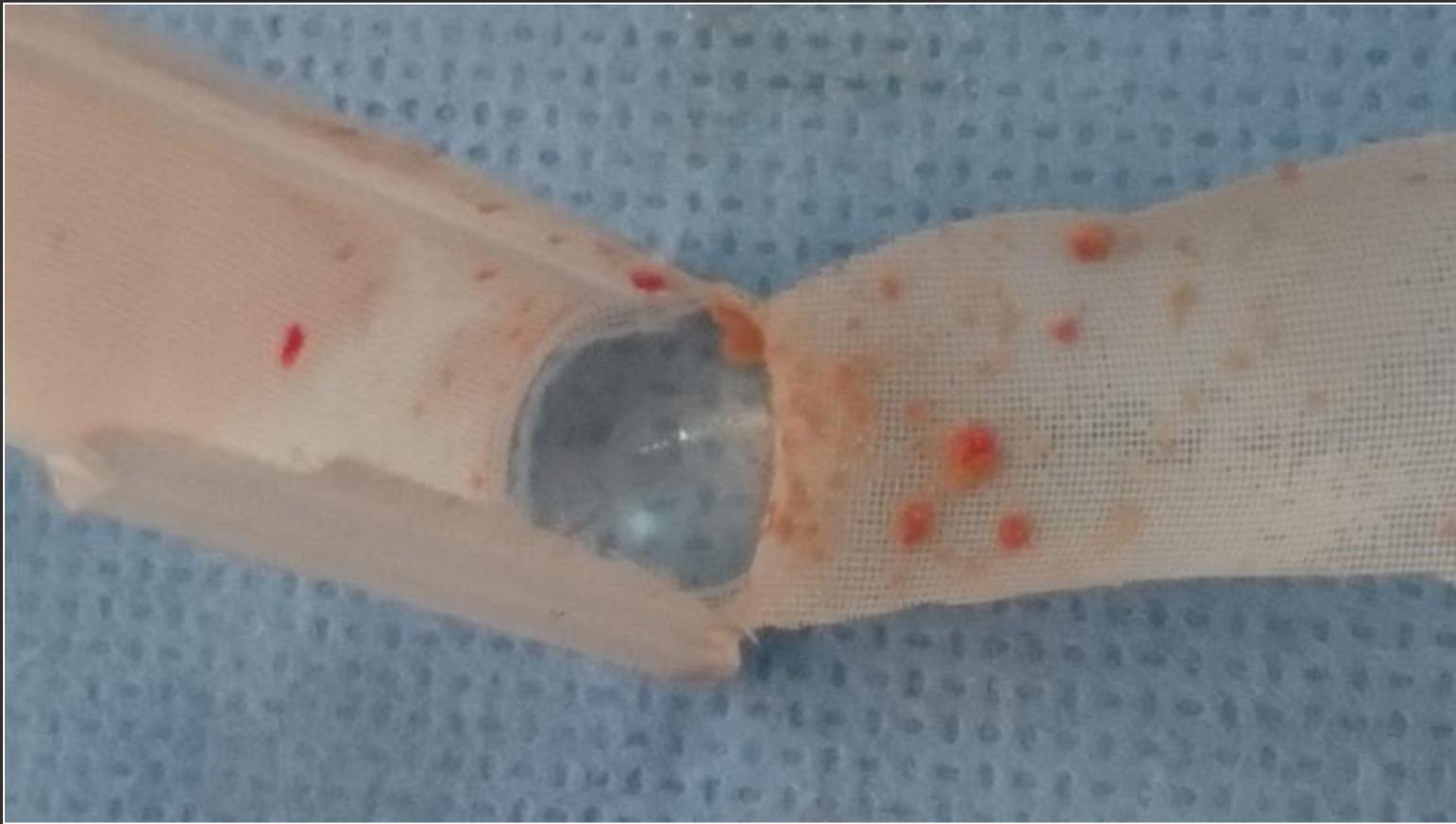








# Les preuves sont dans le filtre



# Intolerance Management

- In the PROOF study, 5 of 65 (7.7%)
- In the ROASTER study 1 (0,7%)
- All patients successfully received a stent and intolerance resolved without clinical sequelae.
- Intolerance was not associated with post-procedure DWI lesions
- Intolerance can be managed. There are many options:
  1. Supplemental O<sub>2</sub>
  2. Increase blood pressure
  3. Manage flow: intermittently switch to lo flow or stop flow

# proof study :

Pinter l ;JVS 2011

| Safety Results <sup>1,2</sup>  |             |
|--|-------------|
| Primary Endpoint:<br>Major stroke, MI, and death through 30 days                             | 0/71 (0%)   |
| Minor stroke<br>Minor contralateral stroke adjudicated as not device<br>or procedure-related | 1/71 (1.3%) |

**Mesure des micro-embolies PAR DW-MRI: 19%**



# Tesla study

| TESLA - DEMOGRAPHICS & RESULTS  |                      | Value (n=58) |
|---|----------------------|--------------|
| Neurological Status   |                      |              |
|   | Symptomatic          | 38 (65.5%)   |
|   | Asymptomatic         | 20 (34.5%)   |
| Outcomes  |                      |              |
|   | Procedural Success   | 57 (98.3%)   |
| Major Adverse Event Rate – Day 0<br>(Stroke, Death and Myocardial Infarction) |                      | 0 (0%)       |
|   | Cranial Nerve Injury | 0 (0%)       |

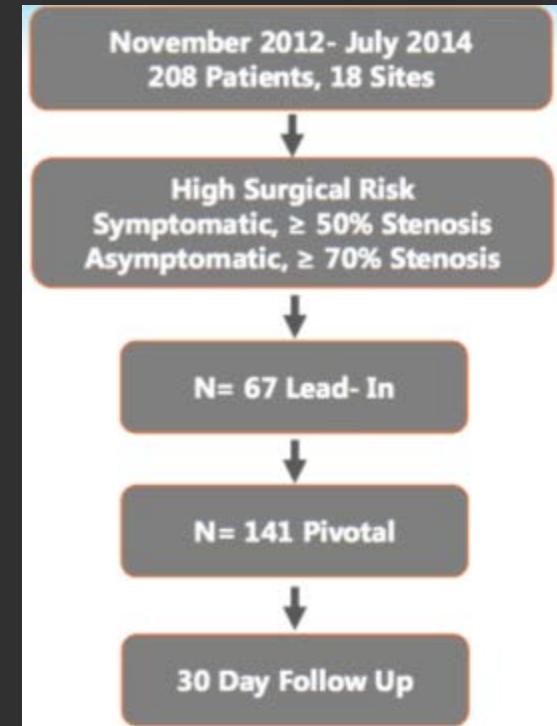


# Roadster study

kwolek JVS 2012

- Objectif primaire : critère composite AVC/decès/IDM à 30-jours
- Objectifs secondaires : atteinte des nerfs craniens, AVC, décès, succès technique

| High Surgical Risk                  |  | Pivotal Group<br>(N=141) |
|-------------------------------------|--|--------------------------|
| Age                                 |  | 72.9 ±9 (40,90)          |
| Age ≥75                             |  | 47%                      |
| Age ≥ 80                            |  | 28%                      |
| Female                              |  | 35%                      |
| Symptomatic                         |  | 26%                      |
| Physiologic Risk Factors            |  | 56%                      |
| Anatomic Risk Factors               |  |                          |
| Hostile Neck                        |  | 16%                      |
| Restenosis post CEA                 |  | 21%                      |
| Physiologic & Anatomic Risk Factors |  | 40%                      |



# Roadster study

| High Surgical Risk         | Pivotal Group, ITT<br>(N=141) | Pivotal Group, PP<br>(N=136) |
|----------------------------|-------------------------------|------------------------------|
| S/D/MI*                    | 5<br>3.5%                     | 4<br>2.9%                    |
| Major Stroke               | 0<br>0%                       | 0<br>0%                      |
| Minor Stroke               | 2<br>1.4%                     | 1<br>0.7%                    |
| Death                      | 2<br>1.4%                     | 2<br>1.5%                    |
| MI                         | 1<br>0.7%                     | 1<br>0.7%                    |
| Stroke & Death             | 4<br>2.8%                     | 3<br>2.2%                    |
| Cranial Nerve Injury (CNI) | 1<br>0.7%                     | 1<br>0.7%                    |
| CNI Unresolved at 6 Mo     | 0<br>0%                       | 0<br>0%                      |



# Roadster study

| <b>High Surgical Risk<br/>Pivotal Intention to Treat</b> | <b>Age <math>\geq 75</math></b> | <b>Symptomatic</b> |
|--|---------------------------------|--------------------|
| N  | N=66 (47%)                      | N=36 (26%)         |
| S/D/MI   | 3 (4.5%)                        | 1 (2.8%)           |
| Major Stroke   | 0%                              | 0%                 |
| Minor Stroke   | 0%                              | 0%                 |
| Death  | 3.0%                            | 2.8%               |
| MI   | 1.5%                            | 0%                 |
| Stroke & Death   | 3.0%                            | 2.8%               |



# Conclusion

- Utile si indication CAS
  - en cas d'anatomie défavorable de la crosse ou des accès iliaques
  - Patients symptomatiques  
Ou à risque embolique++



# CONCLUSION

- IL EXISTE UN RISQUE CLINIQUE ET ANATOMIQUE AU CAS F > CEA
- MEME SI PAS D'AVC :DIMINUTION DES FONCTIONS COGNITIVES PAR AUGMENTATION DES ZONES ISCHEMIQUES A L'IRM
- REVERSE FLOW: RISQUE NEURO EQUIVALENT CEA SANS RISQUE CORONARIEN SANS RISQUE NEURO PERIPHERIQUE

