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New Road for Carotid Intervention:

Transradial and Transcervical Access

With Flow Reversal

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Potential conflicts of interest

Piotr Pieniazek, MD, Ph.D.

- **I have the following potential conflict of interests to be reported.**

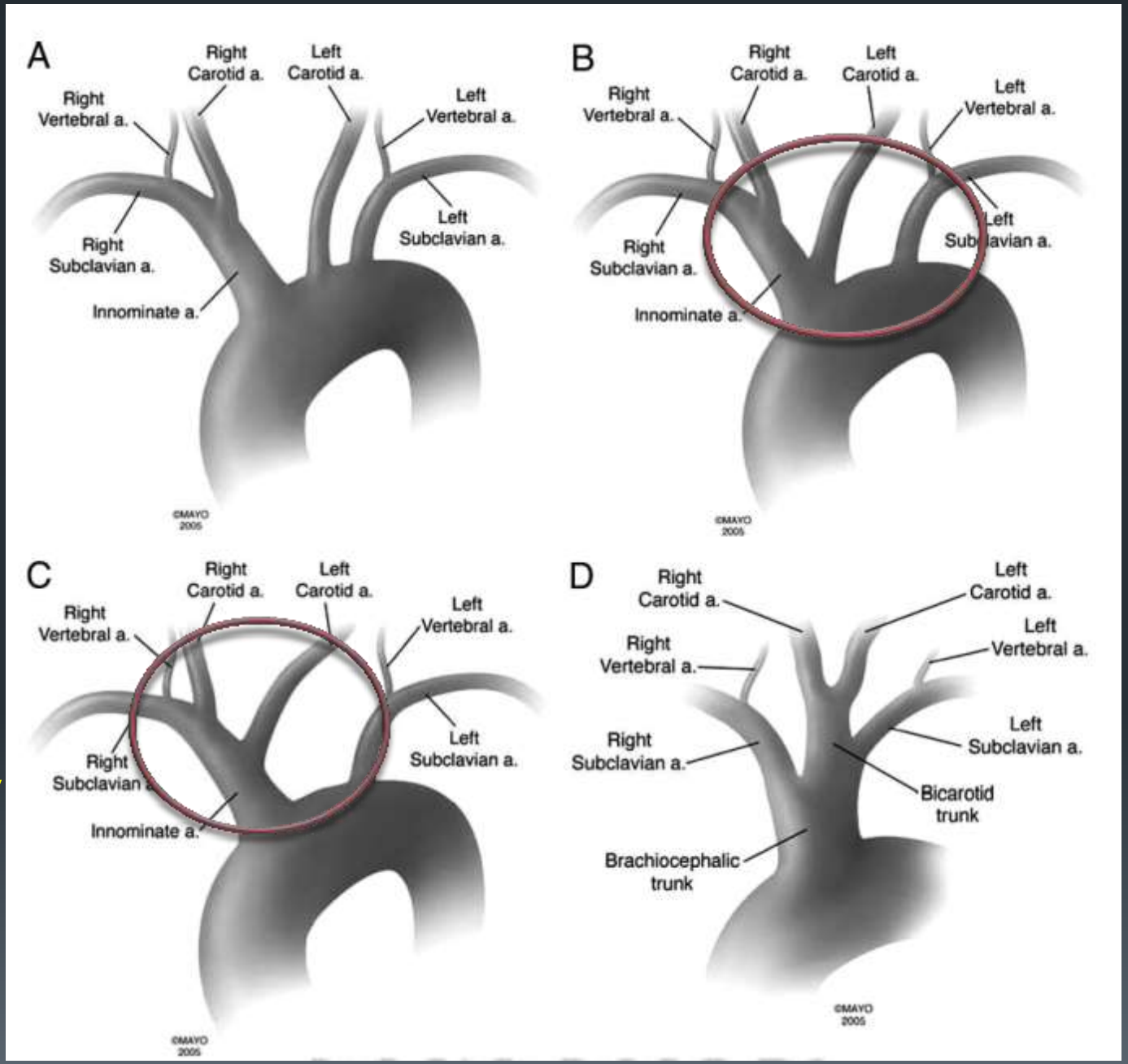
Consulting; Study Honoraria; Travel Expenses; Trials Involvement:

- **Boston Scientific**
- **Abbott**
- **Medtronic**
- **Terumo**
- **Balton**
- **Astra Zeneca**

Target ICA access anatomy:

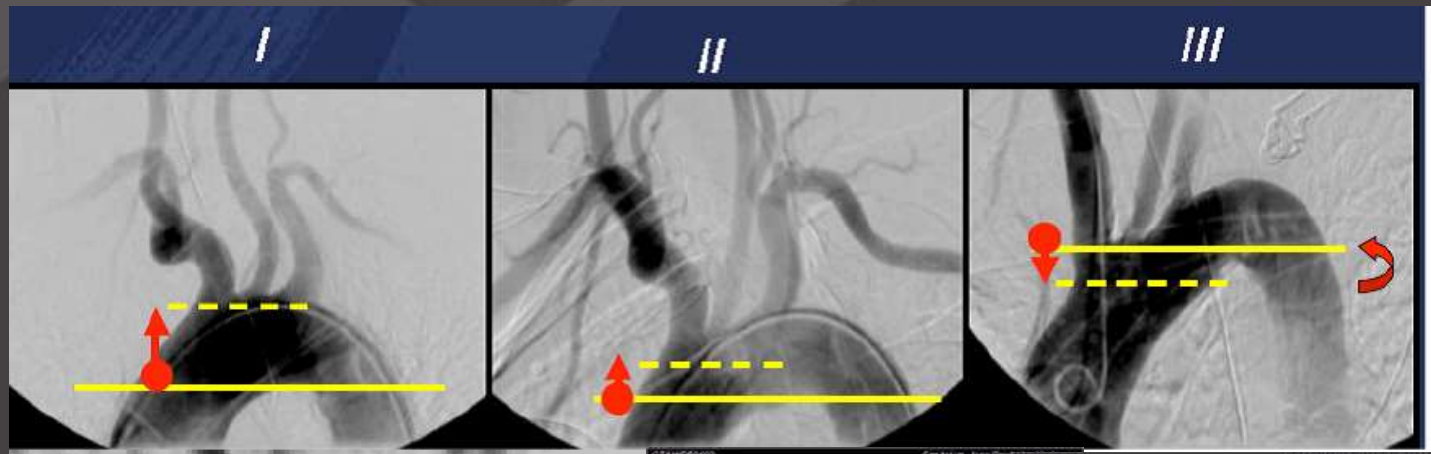
…can be crucial in determining CAS feasibility & safety

⇒ less contrast use / less time / less risk when access anatomy is defined prior to CAS!

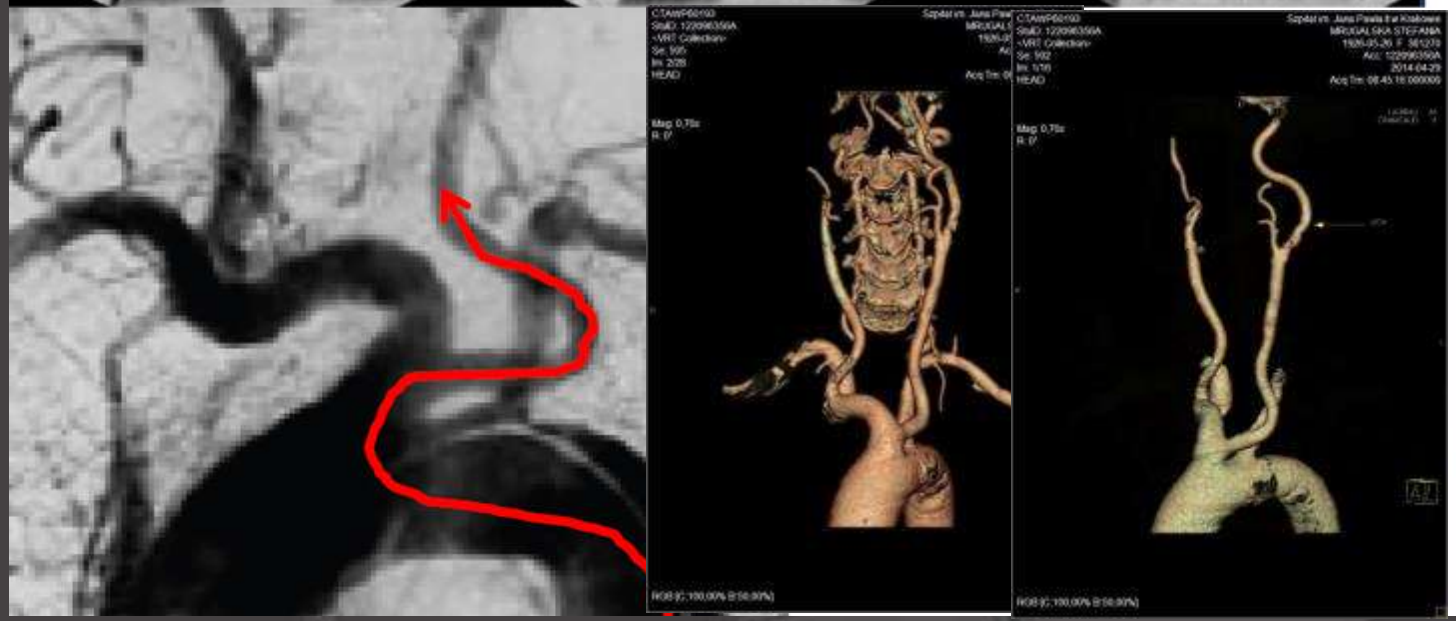


Access Site Complications:

Most technical failures are related to complex arch !!!



Aortic arch

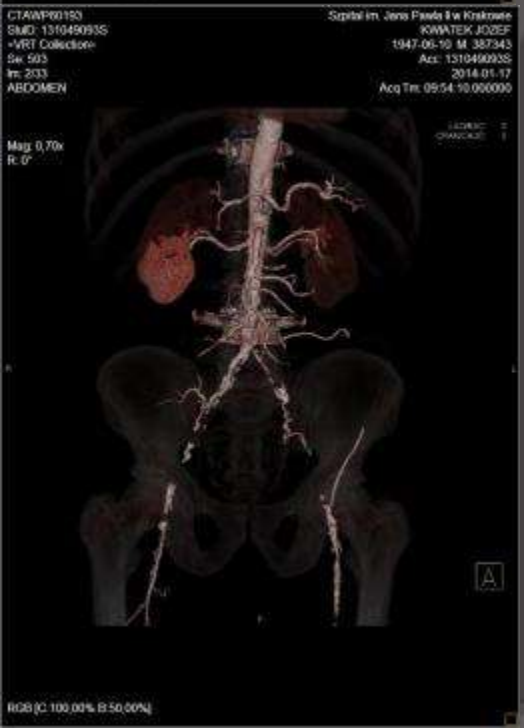


Bovine arch

Cannulation difficulties of CCA during CAS

Final Consideration: Physician training requirements

Addressing challenges		CAS experience (no.)		
		<100	100-200	>200
Aortic arch:	III	No	No	Yes
Lesion anatomy:	angled	No	Yes	Yes
Vessel anatomy:	severely tortuous	No	No	Yes
Lesion characteristics:	angled, severely calcified, high grade, sub-occlusive	No	Yes	Yes
Plaque composition:	dis-homogeneous, soft, ulcerated	No	Yes	Yes



Why Do We Need to Develop CAS via Radial Access ????

Femoral Approach Limitations !!!

Aortoiliac disease or occlusion
(Lerishe's Syndrom)

Previous surgical bypass of peripheral arteries

Severe aortic arch angulation incl. bovine arch

History of stent graft implantation

Significant overweight

Large hernia

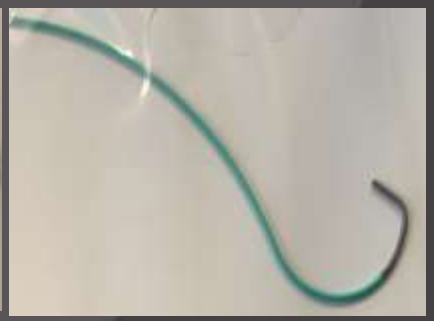
Spine disease causing intolerance of lying after CAS

Hematological disease or warfarin therapy

Unique solution for transradial access interventions!! Glidesheath SLENDER !

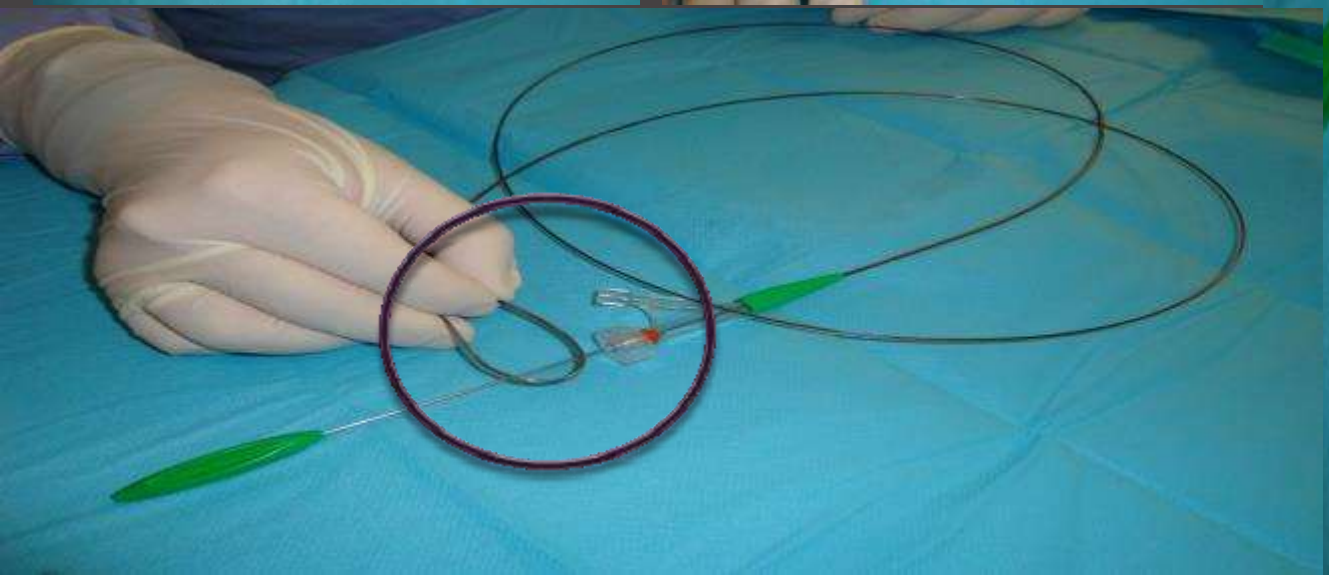
Save radial and ulnar artery for the next intervention

Special devices are crucial for radial access CAS



Specially dedicated diagnostic cath.(Cobra 1&2&3 5F.),
DuraGlide Jindo or Glidewire Advantage,
Independent Filter (Spider RX or Wirion)

Roadsaver - the most flexible carotid stent on market

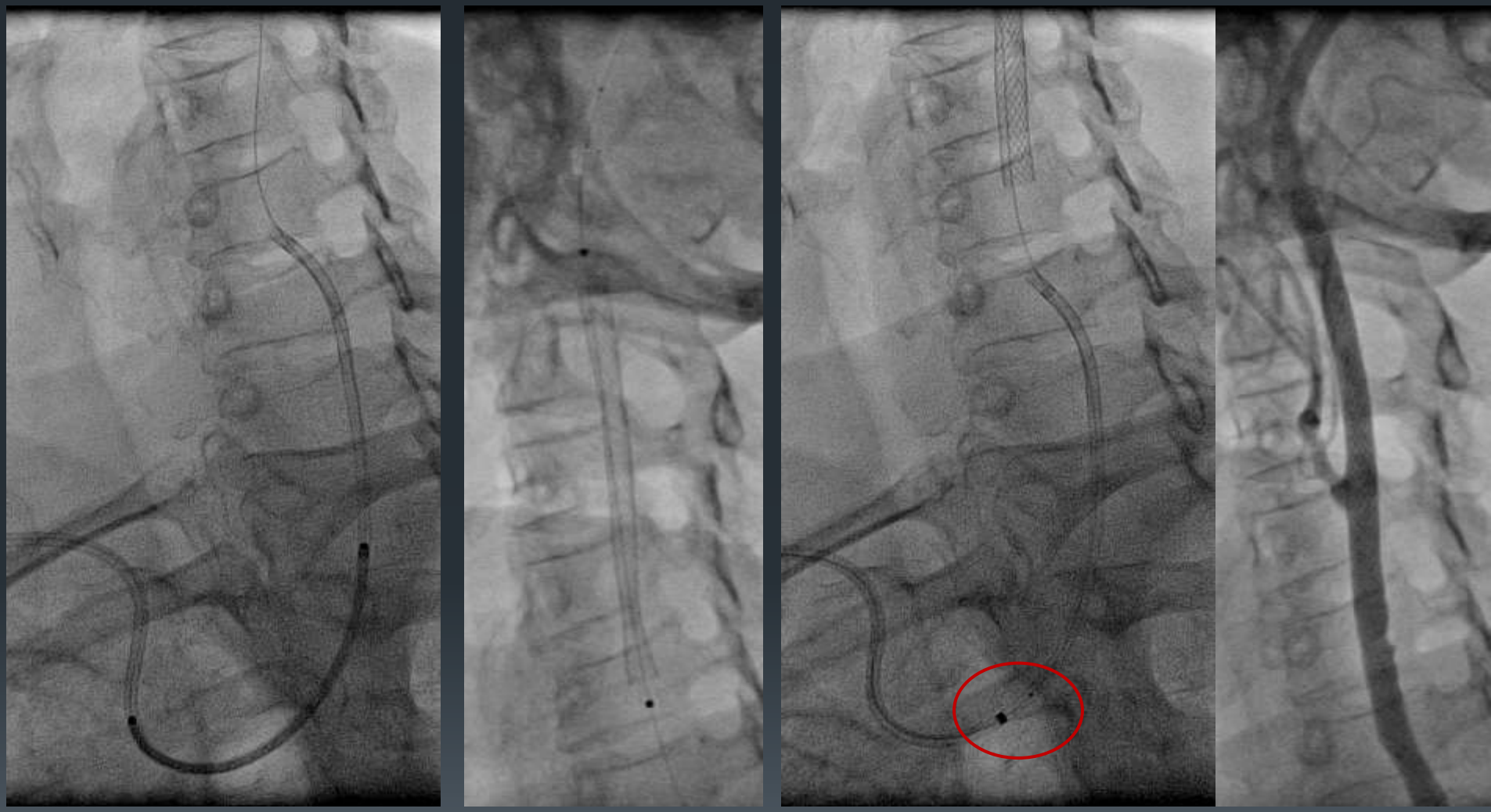


Restenosis 6 Months After Surgical Carotid Endarterectomy

Pt. selected for CEA due to difficult access to LCCA from femoral approach

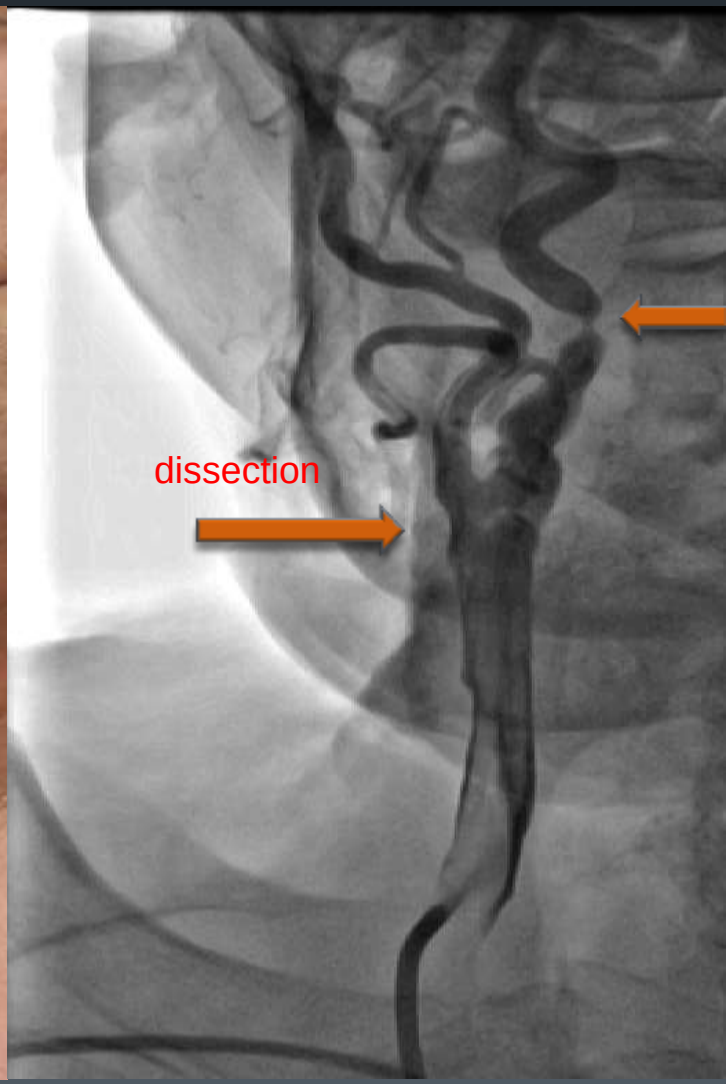
Bovine arch - one of the main indications for radial approach to CAS

Multilevel restenosis after CEA requiring stent with high radial force



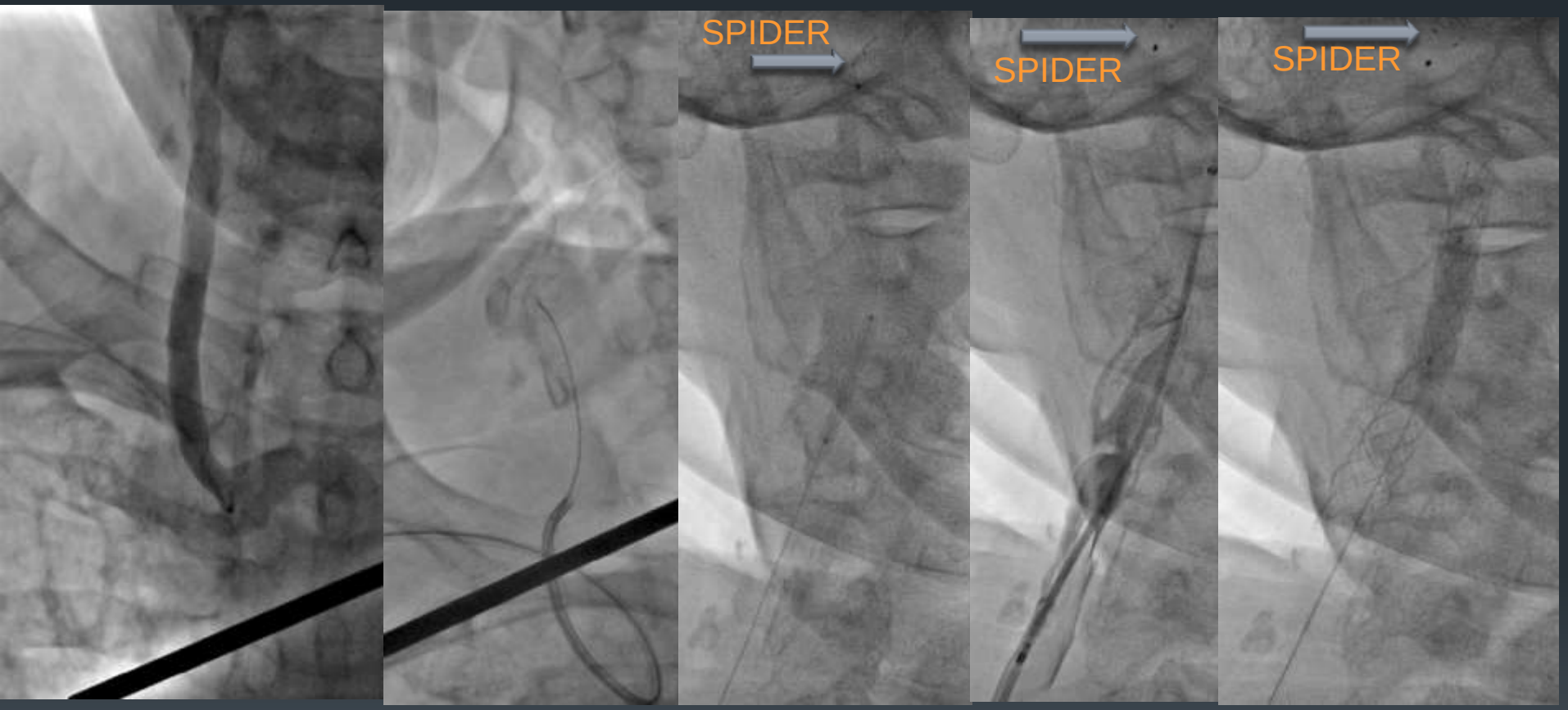
Most important in radial technique is stent and retrieval device delivery
Corotid Wallstent and WIRION filter have been used

Case # 3286!! 62 y.o. patient after neck surgery and radiation with severe PAD. Symptomatic RICA lesion !! CAS from radial access was the only option !!!!



62 y.o. patient after neck surgery and radiation with severe PAD Symptomatic RICA lesion! CAS from radial access was the only option!!!

Case # 3286!! 62 y.o. patient after neck surgery and radiation with severe PAD. Symptomatic RICA lesion !! CAS from radial access was the only option !!!!



Cobra diagnostic cath, Advantage 0.035”, Guider Softip XF and SPIDER FX our routine practice. (predilatation – optional)
RoadSaver stent is no. 1 indication in this particular situation.
Some aggressive postdilatation.

Case # 3286!! 62 y.o. patient after neck surgery and radiation with severe PAD. Symptomatic RICA lesion !! CAS from radial access was the only option !!!!

Right haemisphere before CAS

Final angio !!

Right haemisphere after CAS

Advantages of CAS from radial access:

Importance of early ambulations

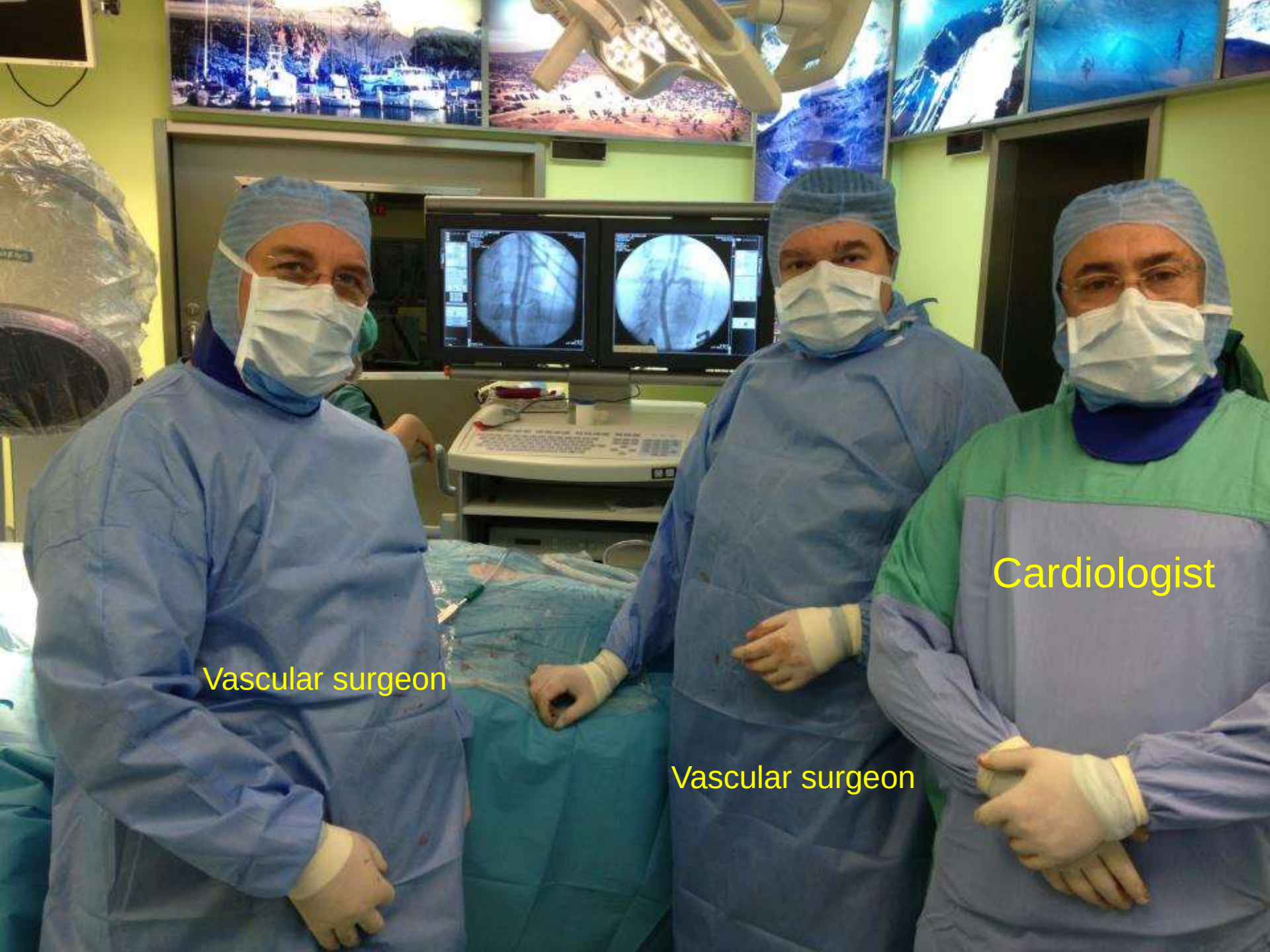
Patient’s comfort and satisfaction

Reducing nursing cost

Reducing vagal reaction

Reducing hypotensive response

Reducing bleeding complication


Cardiologist
Vascular surgeon
Vascular surgeon

Introducing *TCAR*

Trans**C**arotid **A**rtery **R**evascularization

The Clinically Proven,
Less Invasive Alternative to CEA

Combines **direct carotid access** with **robust flow reversal** during Transcarotid stent placement

Why do we need new access for carotid stenting e.g

Direct common carotid access.

No femoral (Lerishe's syndrom)
or radial access (many PCI intervention)

We need proximal protection in high risk patients with no femoral access

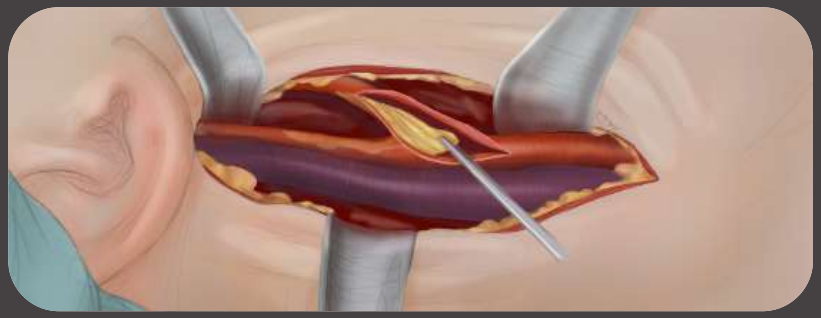
CAS done by vascular surgeons can be more save with direct access than with endovascular technique.

TCAR is promising technique for high risk patient with difficult femoral and radial access.

Carotid Revascularization Options

Gold Standard
Carotid Endarterectomy

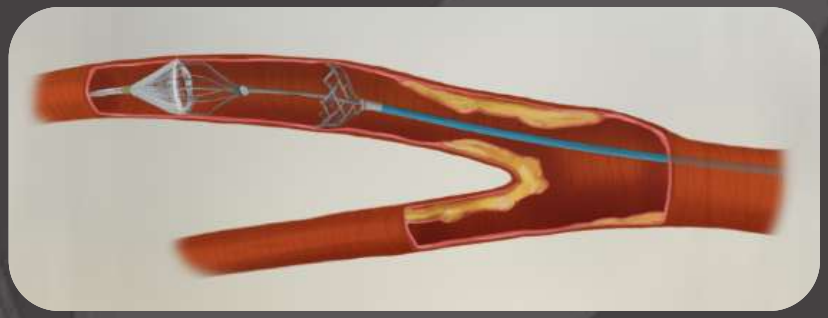
- Low stroke risk[1], but…
- Invasive; risk of surgical complications
  - Risk of cranial nerve injury[2]
  - MI rates 2X that of TF-CAS[1]



CREST CNI Rates: 2.1% CNI unresolved at 6 months (80% motor)
CREST MI Rates: 2.3% CEA vs 1.1% TF CAS

Less Invasive Alternative
Transfemoral, Filter Protected CAS CAS

- Patient friendly, long-term durability[1], **but…**
- Excess procedural stroke risk[1]
  - Unprotected arch and disease navigation; lower embolic capture rate from misaligned filters



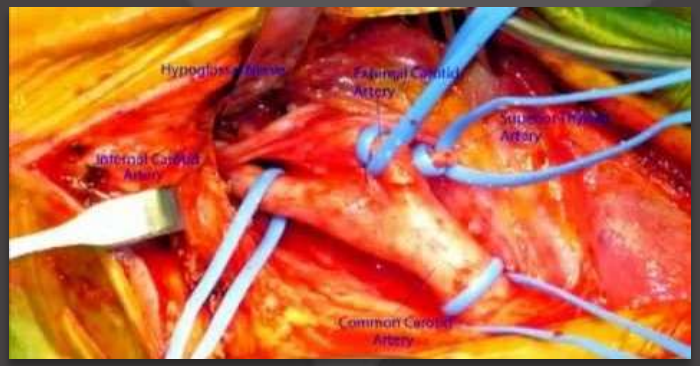
CREST 30-day All Stroke Rates: 2.3% CEA vs 4.1% TF CAS

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

TCAR – A Surgically Inspired Less Invasive Alternative to CEA

CEA

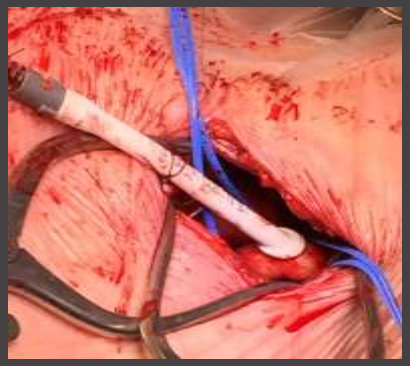
Direct Carotid Access
CCA Clamp & Loop Control



Back-bleeding to Clear Debris

TCAR

Direct Carotid Access (avoid arch)
CCA Clamp & Loop Control



Flow Reversal to Clear Debris

TCAR Procedure
Transcarotid Artery Revascularization
Direct Carotid Access

TW, man 69 y.o. (Case #1) 12 Jan 2016
critical LICA stenosis, post-stroke

First-in-Poland John Paul II Hospital **direct carotid access CAS (TCAR)**
Under En Route (SilkRoad Medical) Flow Reversal

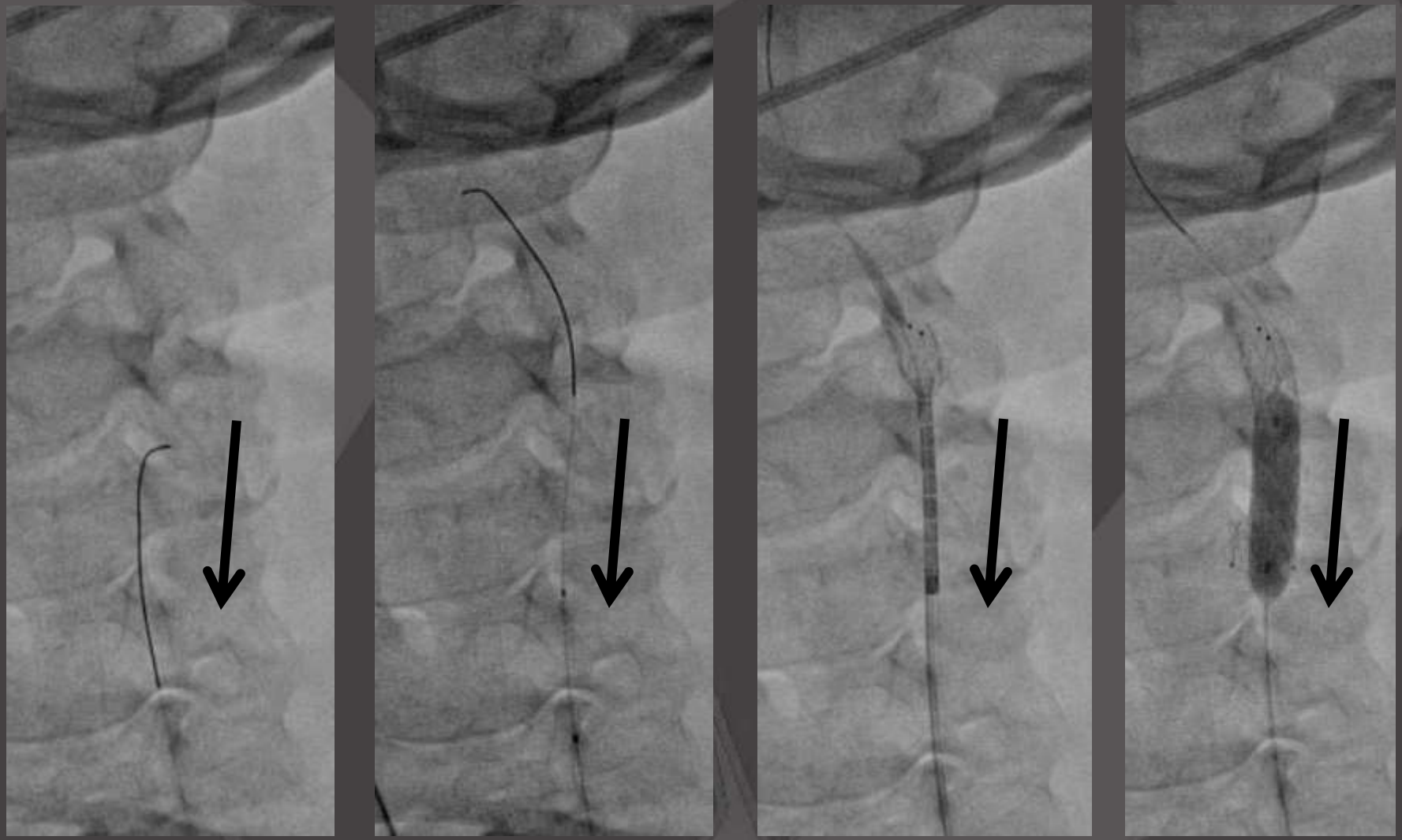
Courtesy : P Musialek

TW, man 69 y.o. (Case #1) 12 Jan 2016
critical LICA stenosis, post-stroke

movie movie

Courtesy; P Musialek

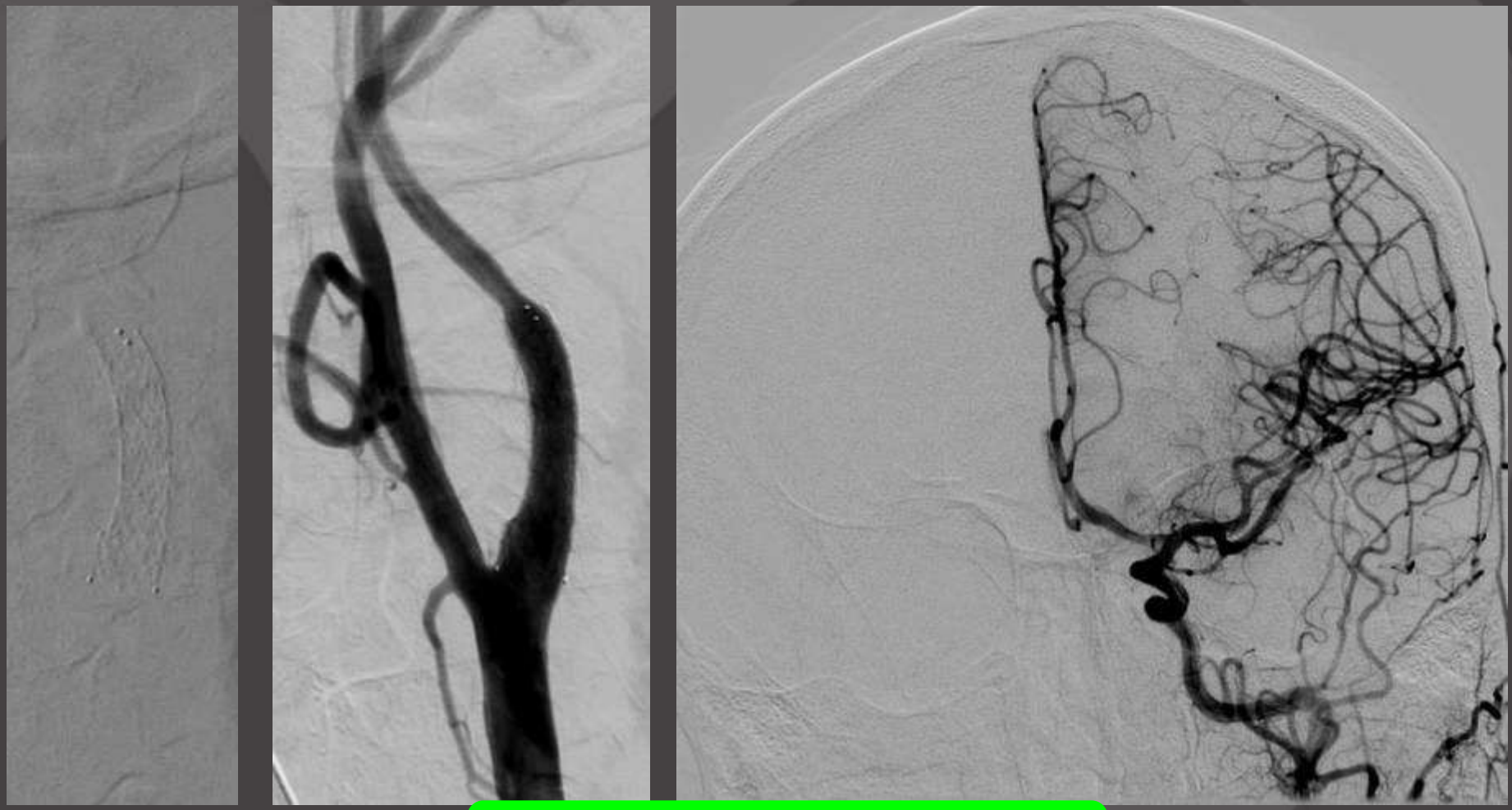
TW, man 69 y.o. (Case #1) 12 Jan 2016
critical LICA stenosis, post-stroke



lesion crossing, predil, CGuard stent implantation and postdil under En Route (SilkRoad Medical) Flow Reversal

Courtesy :P Musialek

TW, man 69 y.o. (Case #1) 12 Jan 2016
critical LICA stenosis, post-stroke

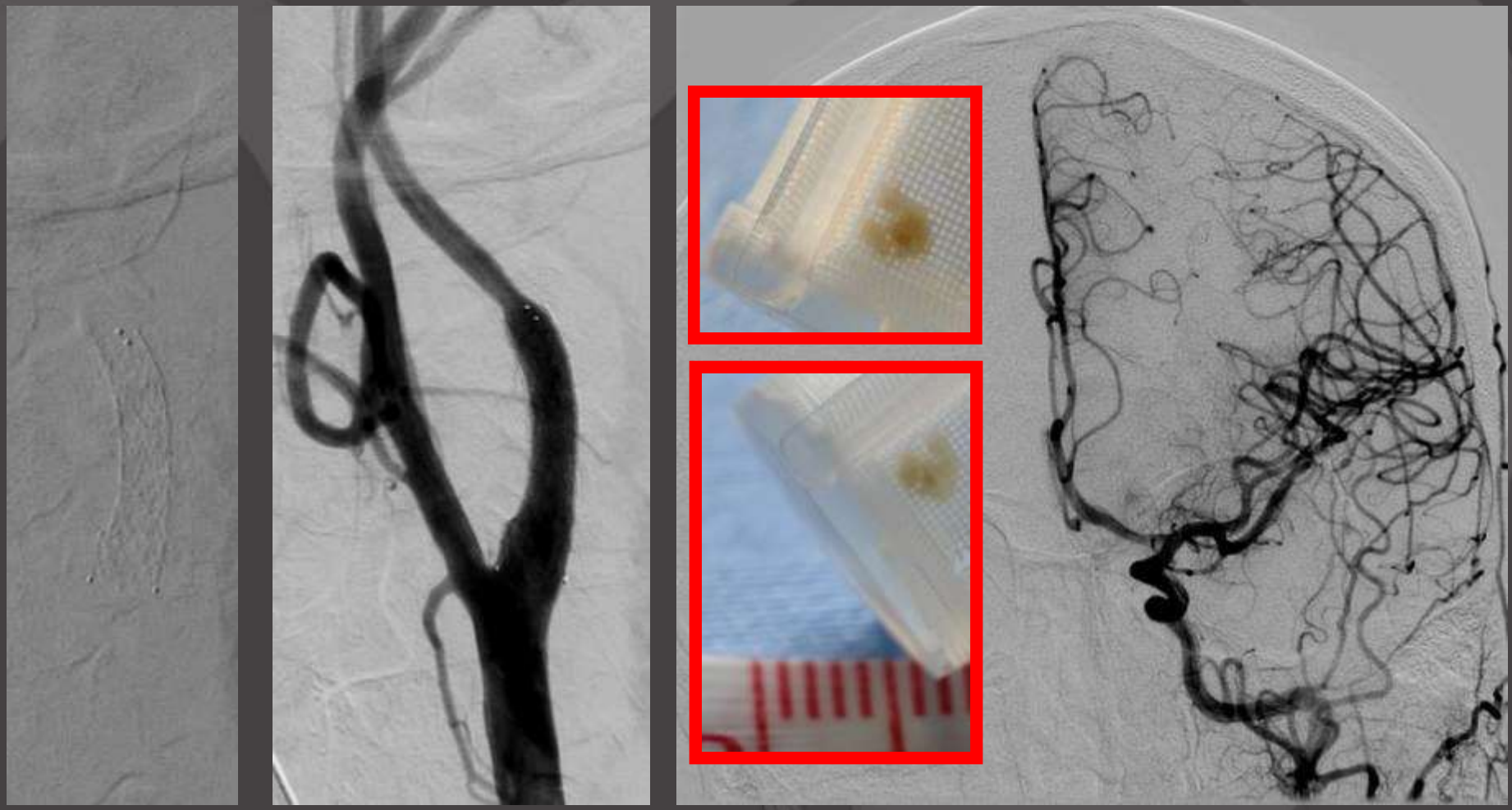


CGuard 7.0 x 30mm full endovascular reconstruction

First-in-Poland **direct carotid access CAS under En Route (SilkRoad Medical) Flow Reversal**

Courtesy:P Musialek

TW, man 69 y.o. (Case #1) 12 Jan 2016
critical LICA stenosis, post-stroke



CGuard 7.0x30mm full endovascular reconstruction

First-in-Poland direct carotid access CAS under
En Route (SilkRoad Medical) Flow Reversal

Courtesy: P Musialek

J Vasc Surg. 2015 Nov;62(5):1227-34. doi: 10.1016/j.jvs.2015.04.460.

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

Kwolek CJ[1], Jaff MR[2], Leal JI[3], Hopkins LN[4], Shah RM[5], Hanover TM[6], Macdonald S[7], Cambria RP[8].

Author information

Abstract

OBJECTIVE: This report presents the 30-day results of the Safety and Efficacy Study for Reverse Flow Used During Carotid Artery Stenting Procedure (ROADSTER) multicenter trial and evaluates the safety and efficacy of ENROUTE Transcarotid NPS (Silk Road Medical Inc, Sunnyvale, Calif), a novel transcarotid neuroprotection system that provides direct surgical common carotid access and cerebral embolic protection via high-rate flow reversal during carotid artery stenting (CAS).

METHODS: A prospective, single-arm, multicenter clinical trial was performed to evaluate the use of the ENROUTE Transcarotid NPS during CAS procedures performed in patients considered to be at high risk for complications from carotid endarterectomy. Symptomatic patients with ≥50% stenosis and asymptomatic patients with ≥70% stenosis were eligible to be treated with any U.S. Food and Drug Administration-approved carotid artery stent. The primary end point was the composite of all stroke, myocardial infarction (MI), and death at 30 days postprocedure as defined in the Food and Drug Administration-approved study protocol. Secondary end points included cranial nerve injury; 30-day stroke, death, stroke/death, and MI; acute device, technical, and procedural success; and access site complications. All major adverse events were adjudicated by an independent clinical events committee.

RESULTS: Between November 2012 and July 2014, 208 patients were enrolled at 18 sites. Sixty-seven patients were enrolled as lead-in cases, and 141 were enrolled in the pivotal phase. In the pivotal cohort, 26% were symptomatic and 75% were asymptomatic. Acute device and technical success were 99% (140 of 141). By hierarchical analysis, the all-stroke rate in the pivotal group was 1.4% (2 of 141), stroke and death was 2.8% (4 of 141), and stroke, death and MI was 3.5% (5 of 141). One patient (0.7%) experienced postoperative hoarseness from potential Xth cranial nerve injury, which completely resolved at the 6-month follow-up visit.

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.

TRIAL REGISTRATION: ClinicalTrials.gov NCT01685567.

TCAR - Clinically proven less invasive alternative to CEA

- Clinically Proven, Surgically Inspired ***Neuroprotection***
  - **Low 1.4% 30-day all stroke rate**
  - Direct carotid access with CCA clamp & vessel control
  - Robust flow reversal akin to CEA backbleeding
- Less Invasive, Patient-Friendly Procedure
  - Reduced rates of MI & cranial nerve injury
  - Cosmetic result of a less invasive procedure
  - Local anesthesia can improve recovery time

ROADSTER 2 Post-Approval Study is Currently Enrolling

Conclusion:

Carotid artery stenting with EPD can be perform safely and effectively using radial access

In severe PAD or difficult aortic arch anatomy transradial CAS can be more save then transfemoral access.

Thanks to New generation of DC, GC, Sheaths, GW, Filters and Stents CAS procedure is fast and safe.

TCAR is a new and very promising therapeutic option for CAS

All centers performing CAS should know the radial access technique and VS should start to use EnRoute(Silkroad Medical) device in particular patients


Thank you


John Paul II Hospital Krakow PL