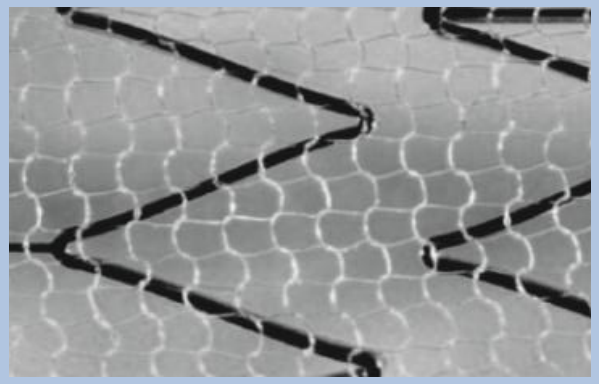


OPTIMAl endovascular sequestration of high-risk carotid plaque using the CGuard™ MicroNET–covered embolic prevention stent system in consecutive patients with sym--ptoms or signs of carotid stenosis-related brain injury: An intravascular ultrasound – controlled investigator-initiated multcentric multi-specialty study

CGuard™ OPTIMA

P. Musialek

on behalf of OPTIMA Investigators
(list follows)

Disclosure

Speaker name: Piotr Musialek

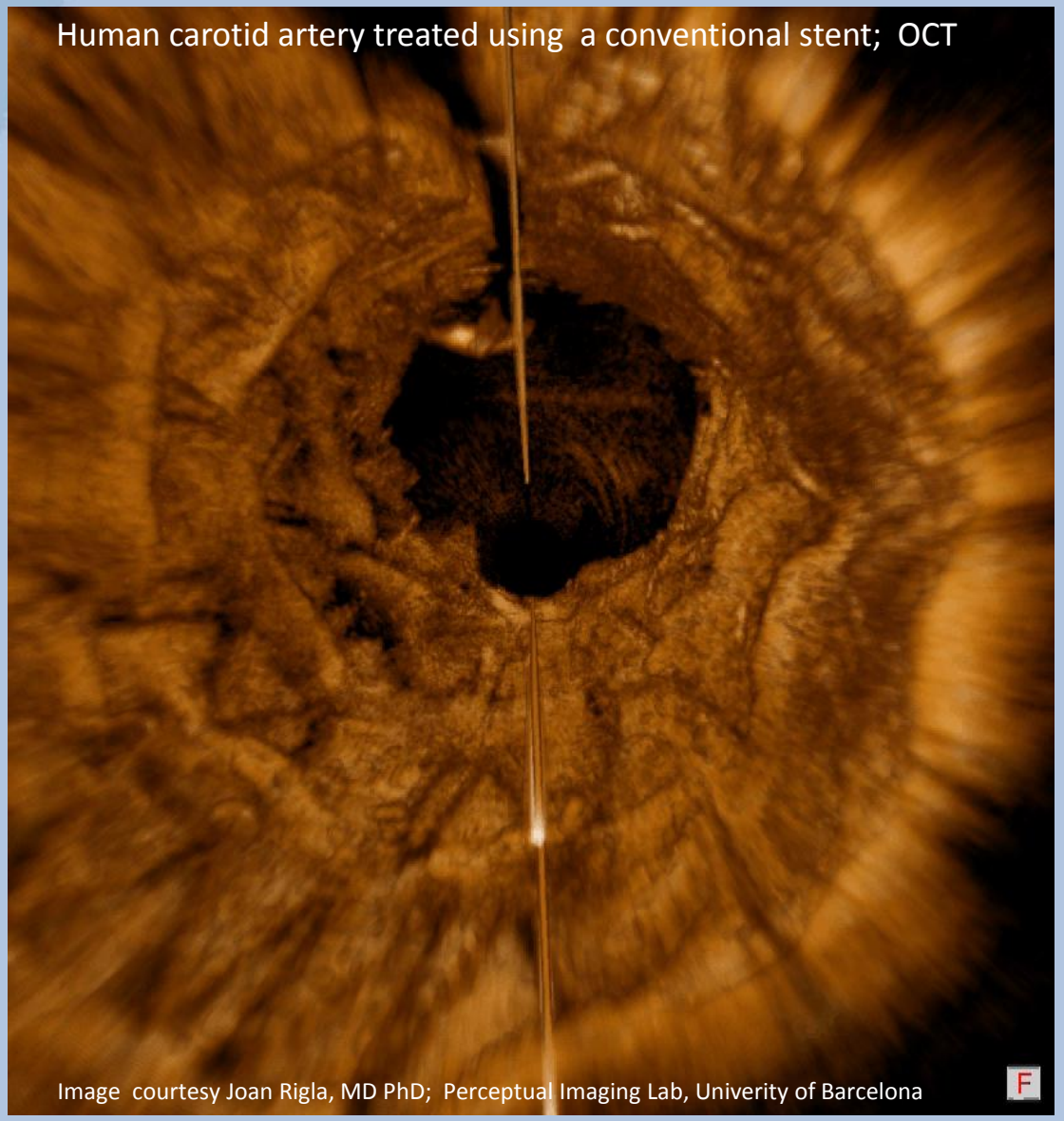
I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

CGuard OPTIMA is an Investigator-initiated, academic, non-commercial study

The Problem


Human carotid artery treated using a conventional stent; OCT
Image courtesy Joan Rigla, MD PhD; Perceptual Imaging Lab, Univerity of Barcelona

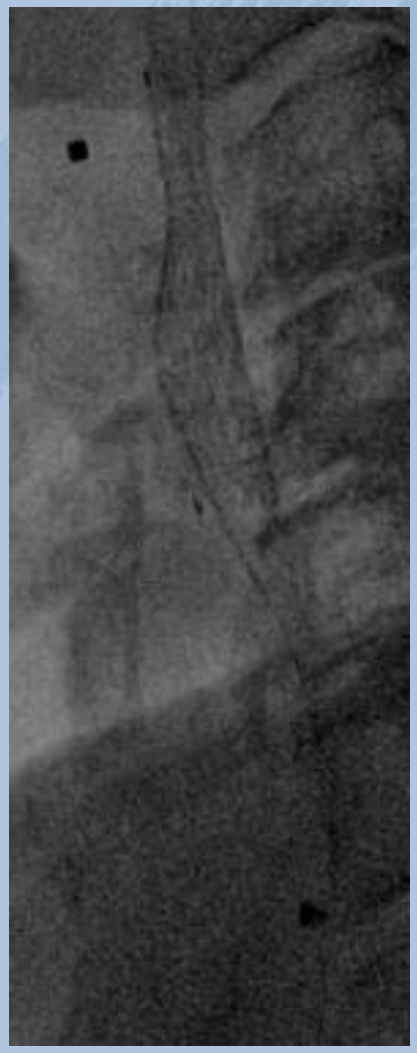
The Problem

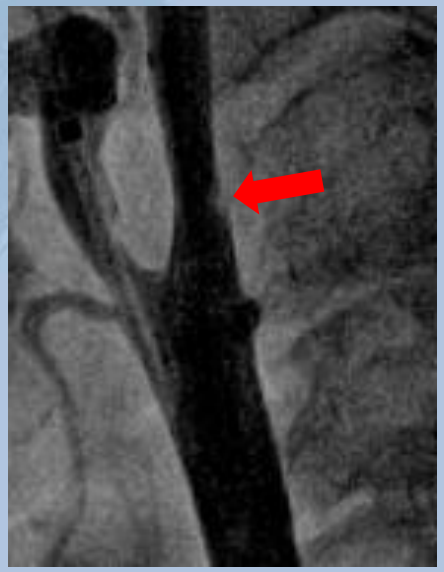
This translates into post-procedural minor strokes during the stent healing (≈30days)

(CREST, CAPTURE, ICSS)
≈ 50% 30d-strokes are post-procedural

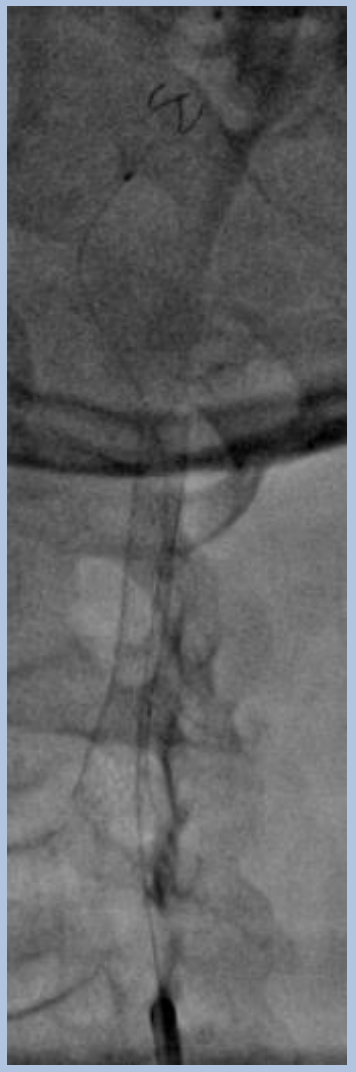
Image courtesy Joan Rigla, MD PhD; Perceptual Imaging Lab, Univerity of Barcelona

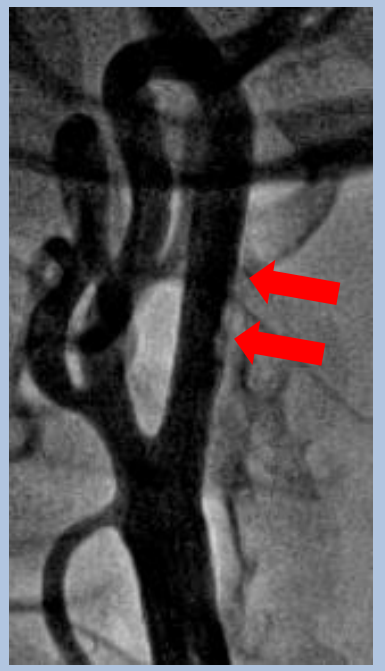
conventional best-in-class
Open-cell stent



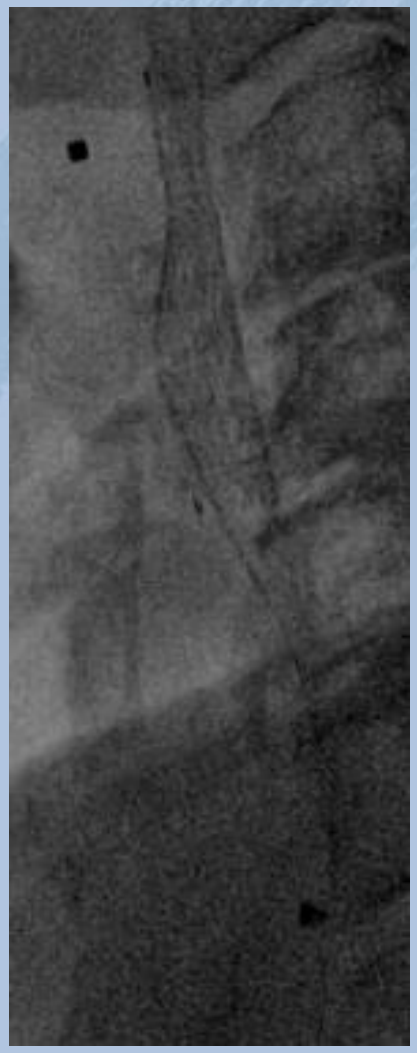


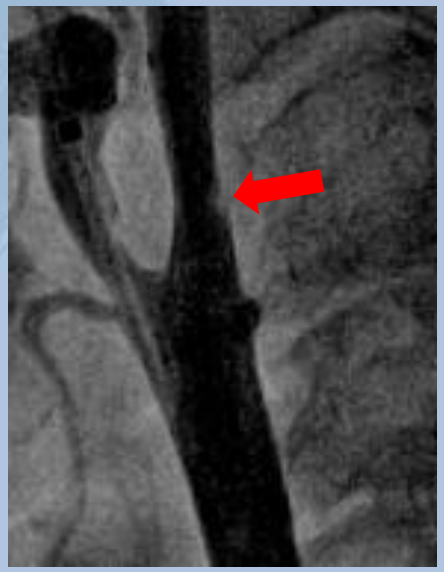
conventional best-in-class
Closed-cell stent



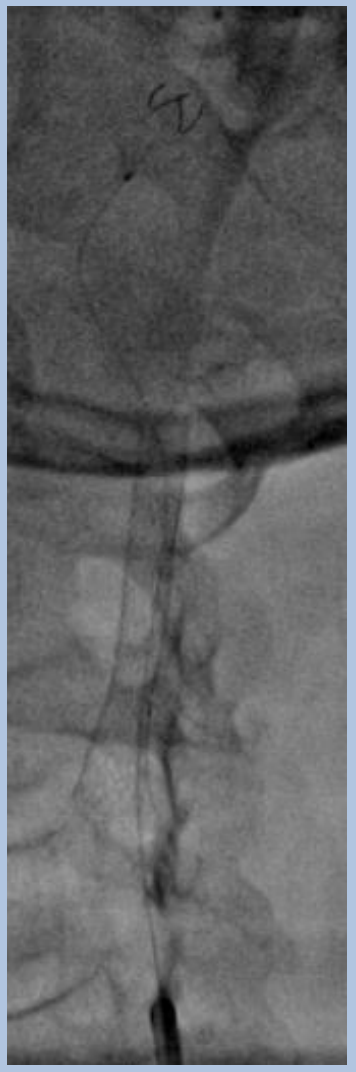


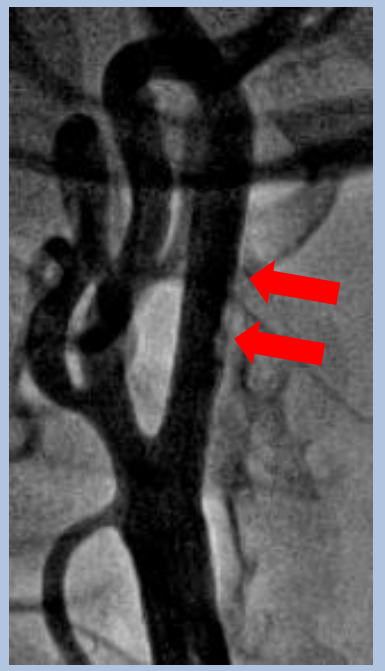
conventional best-in-class
Open-cell stent



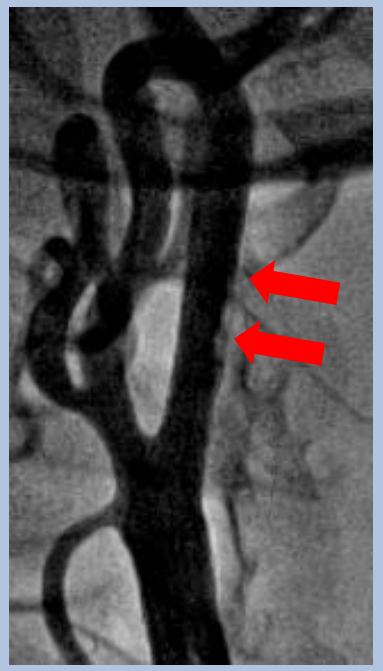


conventional best-in-class
Closed-cell stent





l best-in-class
cell stent



Carotid Artery Stenting

Investigation of Plaque Protrusion Incidence and Prognosis

Masashi Kotsugi, MD,[a] Katsutoshi Takayama, MD,[b] Kaoru Myouchin, MD,[b] Takeshi Wada, MD,[c] Ichiro Nakagawa, MD,[d] Hiroyuki Nakagawa, MD,[c] Toshiaki Taoka, MD,[c] Shinichiro Kurokawa, MD,[a] Hiroyuki Nakase, MD,[d] Kimihiko Kichikawa, MD[c]

METHODS A total of 354 consecutive carotid atherosclerotic stenoses in 328 patients (285 men, 43 women; age range 51 to 97 years [mean age 73.6 years]; 158 symptomatic cases; stenosis rate, 50% to 99% [mean 81.0%]) who underwent CAS under IVUS between October 2007 and March 2016 were retrospectively analyzed. PP was defined as plaque seen inside the stent lumen on both digital subtraction angiography and IVUS. The incidence and prognosis (rate of stroke within 30 post-operative days) of PP and the rate of ischemic lesions on the treated side on diffusion-weighted imaging performed within 48 post-operative hours within the PP group were investigated.

RESULTS PP was observed in 9 cases (2.6%). Ischemic stroke occurred in 6 of 9 PP cases (66.7%; 1 major, 5 minor). Ischemic lesions were observed on diffusion-weighted imaging in 8 of 9 cases (88.9%). PP was strongly associated with perioperative ischemic stroke. A significant increase in PP susceptibility was observed with open-cell stent use and unstable plaque.

CONCLUSIONS The incidence of PP in CAS was 2.6%, with a high risk of ischemic complications if PP was observed. The present findings indicate the necessity of appropriate device selection to avoid PP.

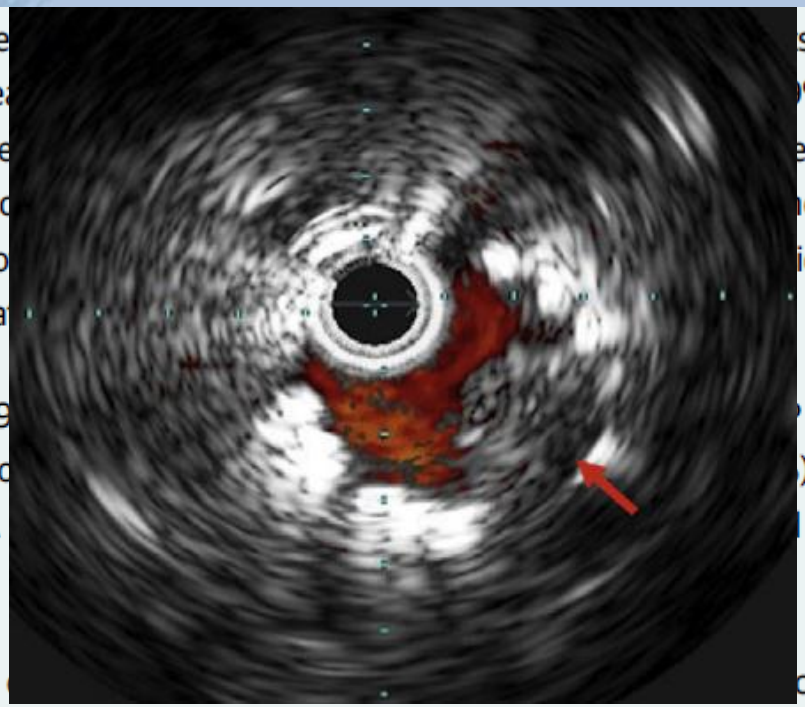
(J Am Coll Cardiol Intv 2017;10:824–31)

Carotid Artery Stenting

Investigation of Plaque Protrusion Incidence and Prognosis

Masashi Kotsugi, MD,[a] Katsutoshi Takayama, MD,[b] Kaoru Myouchin, MD,[b] Takeshi Wada, MD,[c] Ichiro Nakagawa, MD,[d] Hiroyuki Nakagawa, MD,[c] Toshiaki Taoka, MD,[c] Shinichiro Kurokawa, MD,[a] Hiroyuki Nakase, MD,[d] Kimihiko Kichikawa, MD[c]

METHODS A total of 354 conse s (285 men, 43 women; age range 51 to 97 years [mean age 73.6 ye % [mean 81.0%]) who underwent CAS under IVUS between Octobe ed. PP was defined as plaque seen inside the stent lumen on both c nce and prognosis (rate of stroke within 30 post-operative days) o ide on diffusion-weighted imaging performed within 48 post-opera



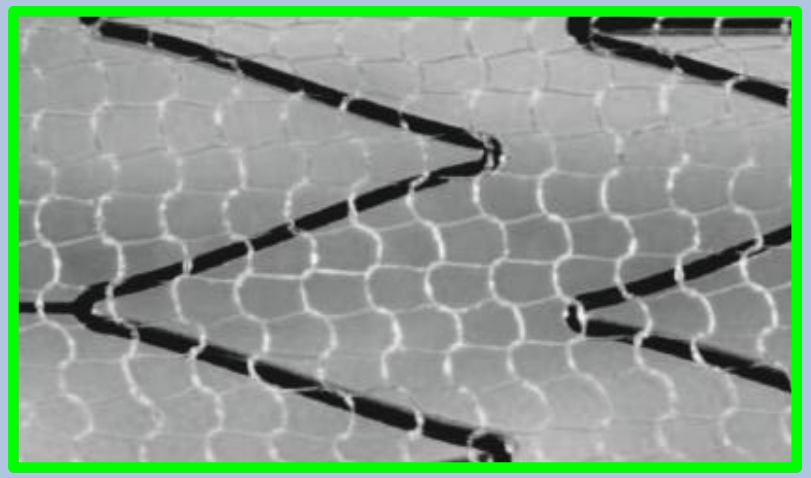
RESULTS PP was observed in 9 cases (66.7%; 1 major, 5 minor). Ischemic lesions were observed c). PP was strongly associated with perioperative ischemic stroke. A with open-cell stent use and unstable plaque.

CONCLUSIONS The incidence complications if PP was observed. The present findings indicate the necessity of appropriate device selection to avoid PP.

(J Am Coll Cardiol Intv 2017;10:824–31)

- CEA excludes the plaque
- In CAS, the stent should exclude the plaque too

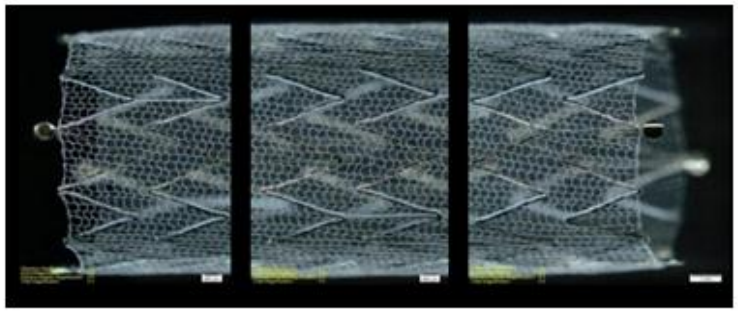
- CEA excludes the plaque
- In CAS, the stent should exclude the plaque too



CGuard™– Carotid Embolic Prevention System

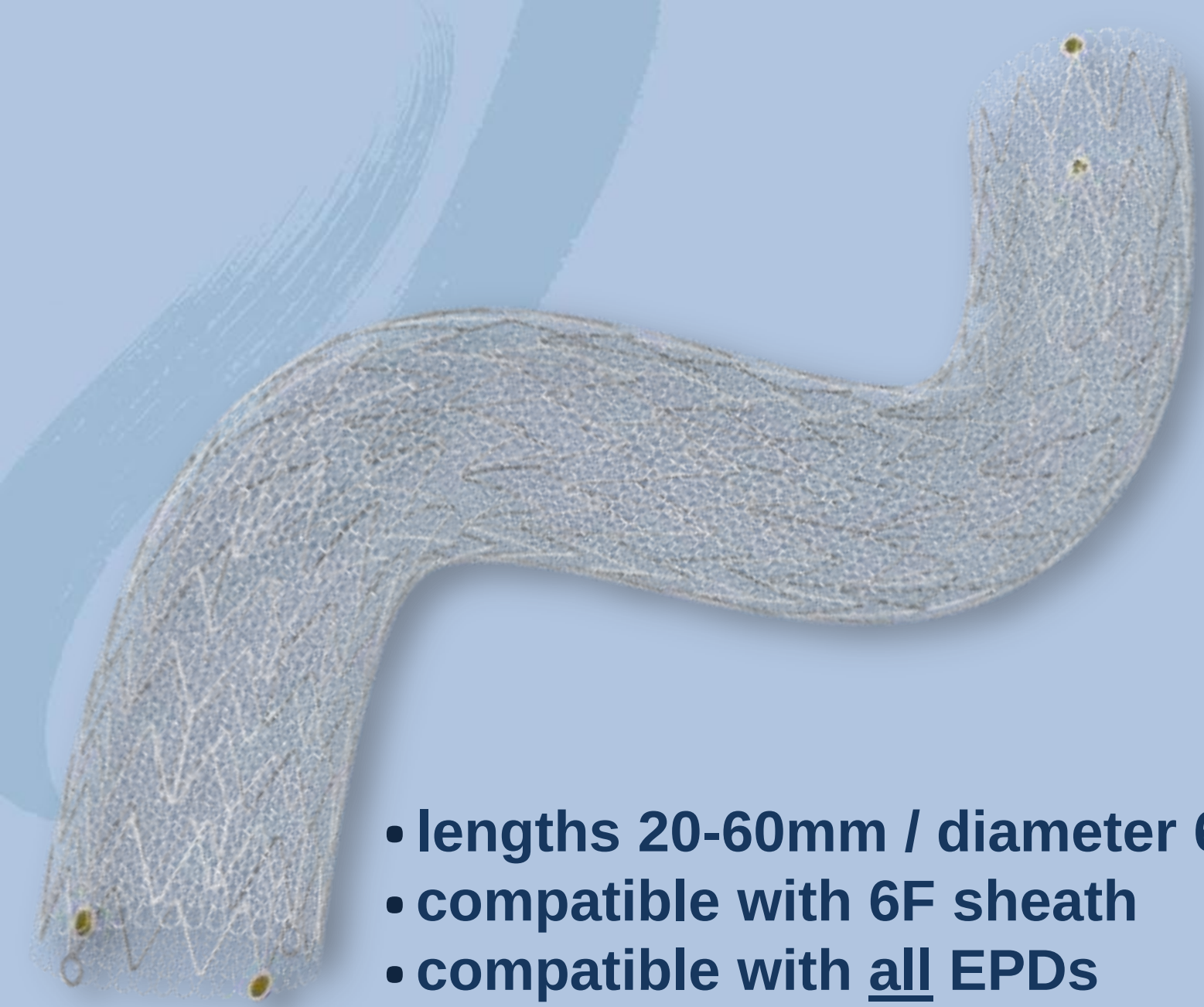
System specifications	
Stent type	Nitinol – self expanding
Micronet aperture size	150-180 µm
Guidewire	0.014”
Sizes - Diameter - Length	 6-10mm 20-60mm

CE Mark – March 2014



- Nitinol frame open-cell area ≈ 21 mm
- MicroNet closed-cell area ≈ 0.3mm

LARGEST √
SMALEST √



- **lengths 20-60mm / diameter 6-10mm**
- **compatible with 6F sheath**
- **compatible with <u>all</u> EPDs (MoMa, EnRouteFR, all filter types)**

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Investigator-Initiated, academic, non-commercial study

Condition or disease	Intervention/treatment
Carotid Artery Diseases	Diagnostic Test: Intravascular Utrasound (IVUS) of Carotid Artery after implantation of CGuard stent

NCT04234854

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Investigator-Initiated, academic, non-commercial study

Condition or disease	Intervention/treatment
Carotid Artery Diseases	Diagnostic Test: Intravascular Utrasound (IVUS) of Carotid Artery after implantation of CGuard stent

CGuard™ OPTIMA – Protocol Synopsis

Title:	**OPTIMA**l endovascular exclusion of high-risk carotid plaque using the CGuard™ MicroNET–covered embolic prevention stent system in consecutive patients with symptoms or signs of carotid stenosis-related brain injury: An intravascular ultrasound – controlled investigator initiated multcentric multi-specialty study.
Short title:	CGuard™ **OPTIMA**
Study device description	CGuard™ MicroNET–covered embolic prevention stent system is a self-expandable laser-cut nitinol stent wrapped in a single-fiber knitted PET-MicroNet sleeve.
Study design	Prospective, multicentric, multispecialty, international, open-label, non-randomized study using per-protocol intravascular ultrasound [IVUS, 20MHz electronic phase-array transducer] to document the procedure result of an effective plaque exclusion from the vessel lumen.

NCT04234854

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Investigator-Initiated, academic, non-commercial study

Condition or disease	Intervention/treatment
Carotid Artery Diseases	Diagnostic Test: Intravascular Utrasound (IVUS) of Carotid Artery after implantation of CGuard stent

CGuard™ OPTIMA – Protocol Synopsis

Primary aim	To evaluate the efficacy of CGuard™ MicroNET–covered embolic prevention stent system in high-risk carotid plaque sequestration in consecutive patients with atherosclerotic high-risk carotid artery stenosis by determining the incidence of plaque prolapse (on a per-patient and per [IVUS]-frame basis).
Secondary aims	To evaluate the endovascular reconstruction of the diseased artery segment by using the study device, assessing the internal (ICA) and common carotid artery (CCA) stent apposition, and the ICA minimal lumen area in relation to the ICA reference area.

NCT04234854

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Investigator-Initiated, academic, non-commercial study

Condition or disease	Intervention/treatment
Carotid Artery Diseases	Diagnostic Test: Intravascular Utrasound (IVUS) of Carotid Artery after implantation of CGuard stent

CGuard™ OPTIMA – Protocol Synopsis

Study population	Consecutive clinically-symptomatic patients (ipsilateral cerebral or retinal stroke or TIA with the preceding 6 months) with atherosclerotic *de novo* carotid artery stenosis causing at least 50% lumen reduction by quantitative carotid catheter angiography (QCA) *or* carotid stenosis of at least 50% lumen reduction by QCA in relation to documented ipsilateral ischaemic brain lesions/infarct on CT or MRI.
Patient sample	111 consecutive patients will be enrolled in at least 5 centres in the world. Maximal aceceptable drop-out rate by 12 months is determined at 10% (11 subjects), leaving at least 100 subjects evaluable at 12 months.

NCT04234854

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Investigator-Initiated, academic, non-commercial study

Condition or disease	Intervention/treatment
Carotid Artery Diseases	Diagnostic Test: Intravascular Utrasound (IVUS) of Carotid Artery after implantation of CGuard stent

CGuard™ OPTIMA – Protocol Synopsis

Procedure	Neuropotected CAS as per the operator and center standard practice, consistent with the study device IFU, as per the center routine, with final result IVUS imaging added as the procedure quality control. The use of proximal neuroprotection such as MoMa 9F with transient flow reversal preferrable to transient flow caessation is encouraged in this study increased-risk population. Vascular access choice is at the operator's discretion (femoral, radial, or trans-carotid).
IVUS imaging	Study device optimization is encouraged as in the PARADIGM study (Musialek 2016); large balloons/high pressures use for optimal endovascular reconstruction of the diseased artery segment.

NCT04234854

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Investigator-Initiated, academic, non-commercial study

Condition or disease	Intervention/treatment
Carotid Artery Diseases	Diagnostic Test: Intravascular Utrasound (IVUS) of Carotid Artery after implantation of CGuard stent

CGuard™ OPTIMA – Protocol Synopsis

Primary endpoint	Freedom from plaque prolapse defined as observation of plaque inside the stent lumen after completion of the CAS procedure by IVUS assessment (Kotsugi 2017).
Secondary endopoints	1) Procedural success (stent delivery and implantation in absence of an intra-procedural clinical major adverse event, with no more than 30% residual diameter stenosis by on-site QCA, and successful withdrawal of the stent delivery and neuroprotection system). 2) IVUS interrogation success (IVUS interrogation with an effective IVUS probe removal in absence of any clinical complications). 3) Endovascular lumen reconstruction defined as freedom from plaque prolapse plus minimal in-stent area >50% ICA reference area. 4) Peri-procedural (up to 24h from intervention or discharge if discharge before 24h, whichever first) MACCE (death, stroke, MI). 5) 30-day MACCE (death, stroke, MI). 6) Any peri-procedural (up to 24h or discharge, whichever first) complications. 7) Ipsilateral stroke between 31 days and 12 months after the procedure. 8) Peak Systolic Velocity (PSV) and End Diastolic Velocity (EDV) recorded by Duplex Doppler at 30±5 days and 12±1 months after the procedure. NB. Neuro exam, including NIH-SS assessment, will be performed by a local neurologist or trained physician at 24-48h or discharge (whichever first), and at 30±5 days and 12±1 months.

CGuard™ OPTIMA – Participating Centres

Alvarez, Alejandro	IC	Bahia Blanca	Argentina
Amor, Max	IC	Nancy	France
Karpenko, Andrey	VS	Novosybirsk	Russia
Klecha, Artur / Kowalczyk ST	IC	Nowy Targ	Poland
Micari, Antonio / Castriota F	IC	Bergamo	Italy
Miszczuk, Jan	VS	Kielce	Poland
Montorsi, Piero	IC	Milan	Italy
Musialek, Piotr / Mazurek A	A/IC	Krakow	Poland (PI)
Trystula Mariusz	VS		
Petrov, Ivo	IC	Sofia	Bulgaria
Ruffino, Maria Antonella	IR	Torino	Italy
Ruzsa, Zoltan	IC	Budapest/Bacs-K	Hungary
Saugnet, Antoine / Honton B	IC	Tolouse	France
Schmidt, Andrej	A/IC	Leipzig	Germany
Schofer, Joachim	IC	Hamburg	Germany
Setacci, Carlo / De Donato G	VS	Siena	Italy
Stabile, Eugenio	IC	Naples	Italy
Speziale, F / Sirignano P	VS	Rome	Italy
Wissgott, Christian	IR	Rendsburg	Germany

CONFIRMED CENTRES

CGuard™ OPTIMA – Participating Centres

YOU ARE WELCOME TO JOIN

pmusialek@szpitaljp2.krakow.pl
mazurekadam@yahoo.pl

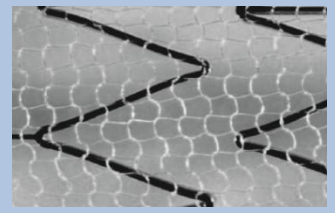
OPEN TO OTHER INVESTIGATORS & CENTRES

Image credit to: https://bernard25.wordpress.com/2015/06/08

CGuard OPTIMA

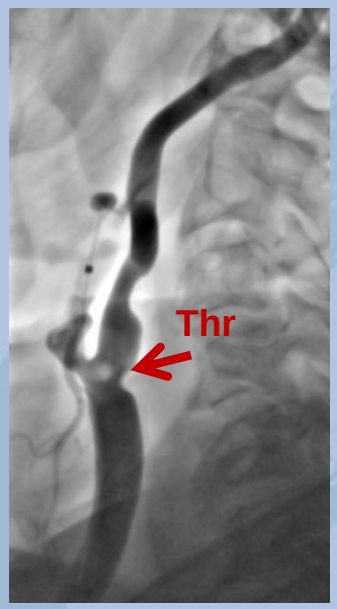
FPI 07 JAN 2020 (Krakow, PL)

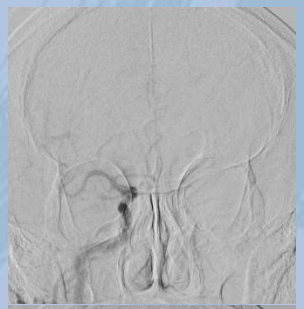
A 58-year-old man with recurrent amaurosis fugax progressing to acute, non-resolving total R eye blindness (retinal stroke)

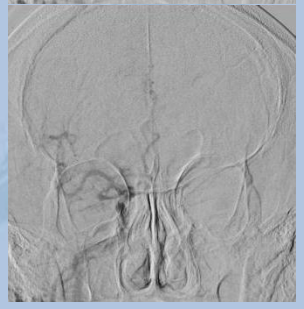


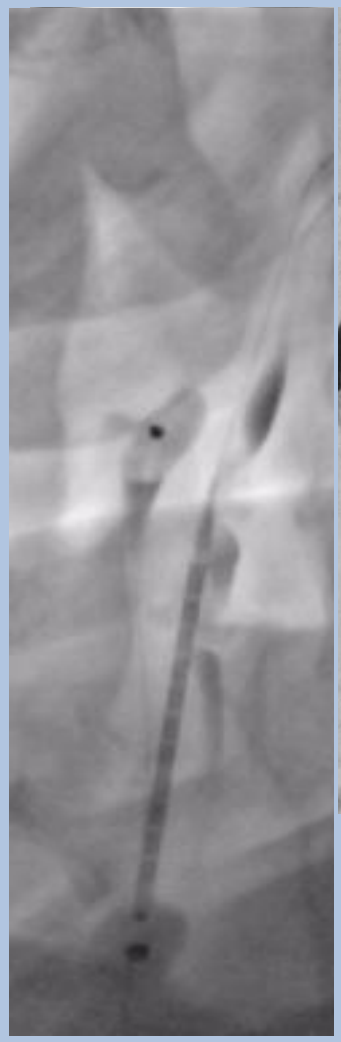
CGuard OPTIMA

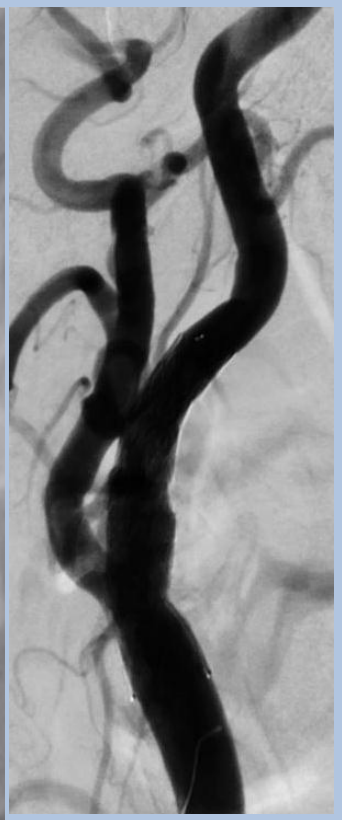
JP II Hosp. / Krakow

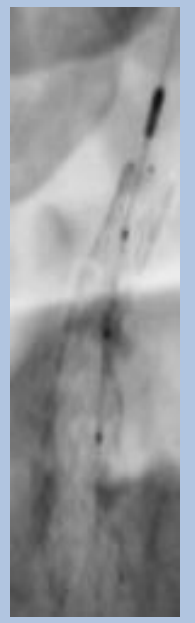


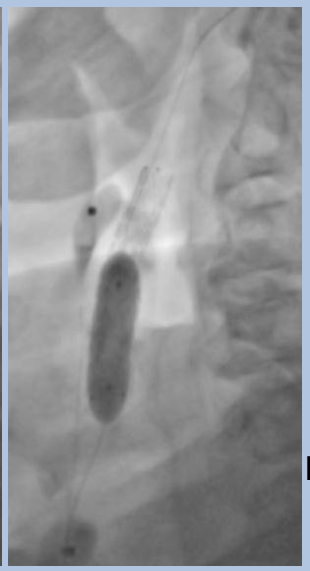




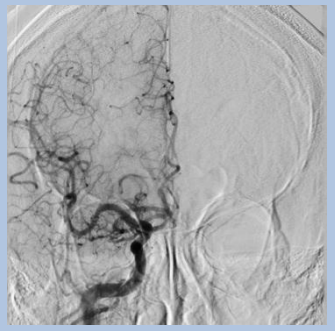


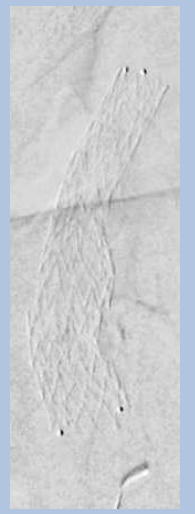




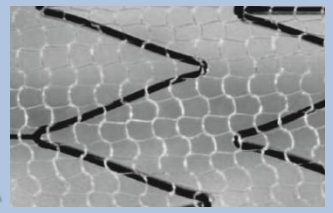


Lesion crossing and CGuard direct stenting under transient flow reversal using MoMa



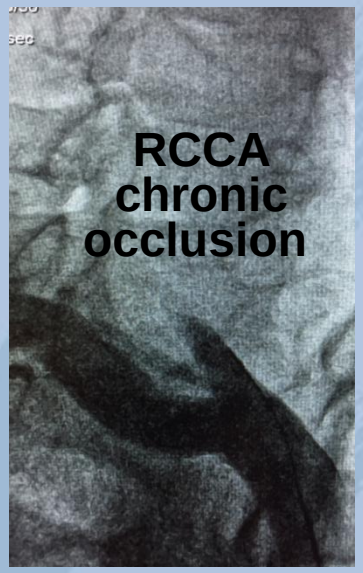


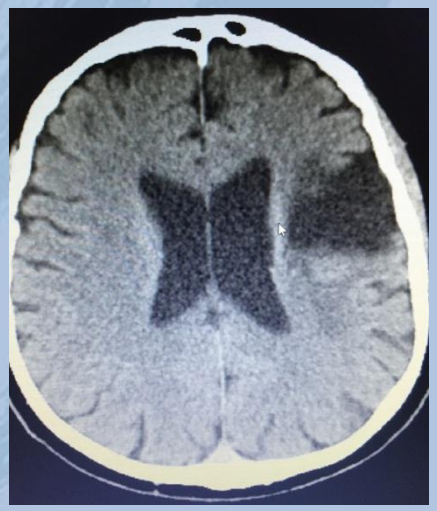
A 54-year-old man with chronic RICA occlusion, history of L-haemispheric stroke in association with (then judged) ”insignificant” LICA stenosis… now in evolving *re*-stroke in absence of on-site vascular surgery



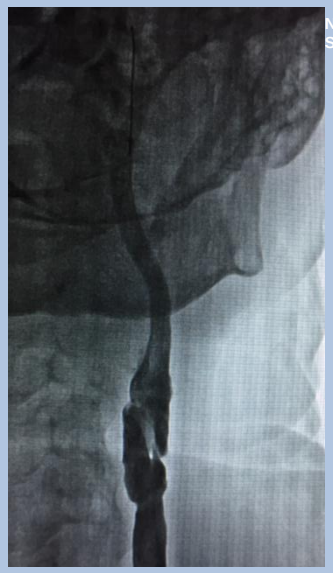
CGuard OPTIMA

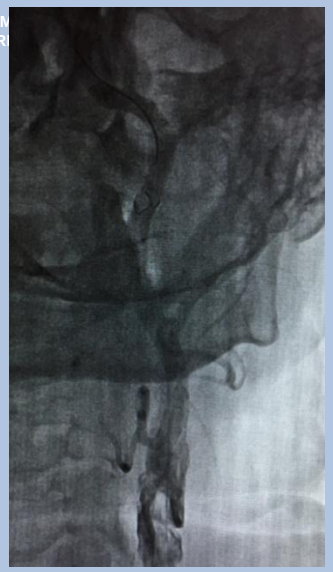
Regional Hosp. / N. Targ

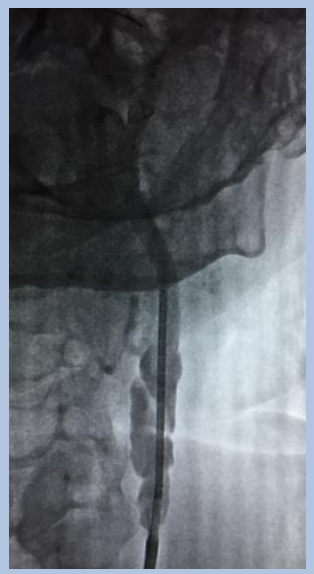


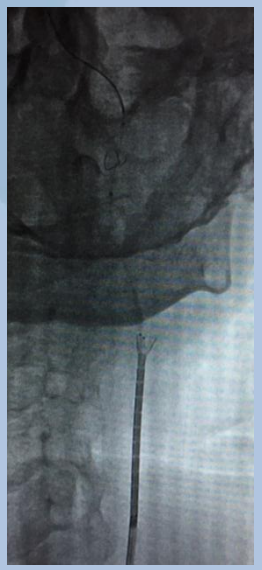


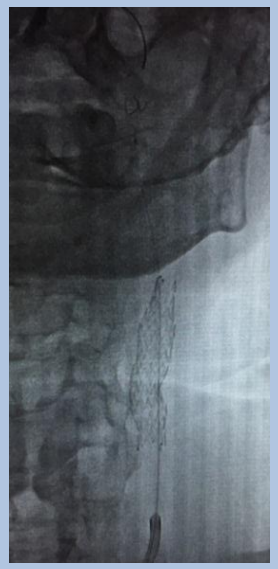
”old” left haemispheric stroke

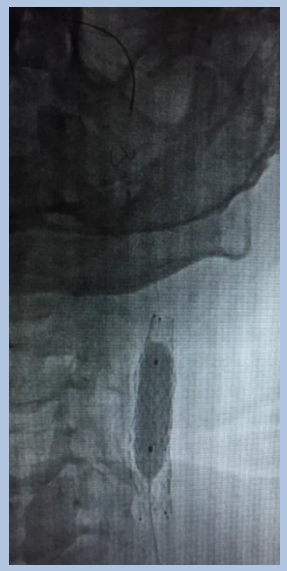


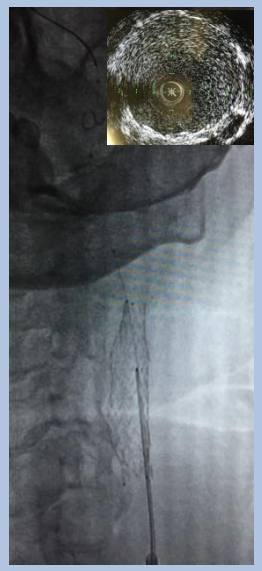


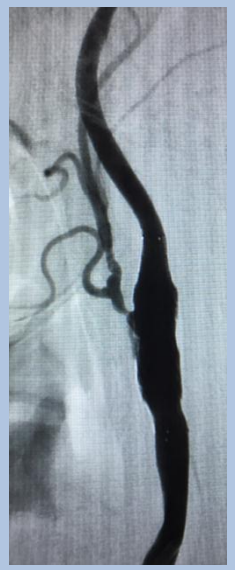


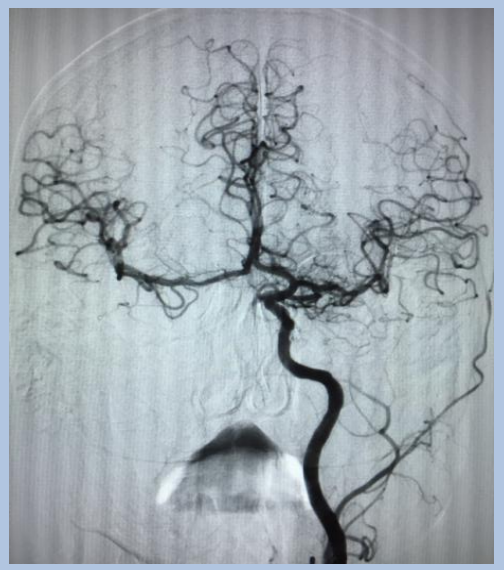


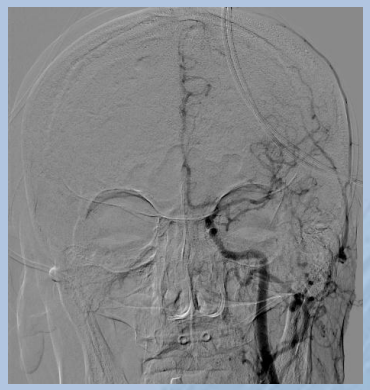
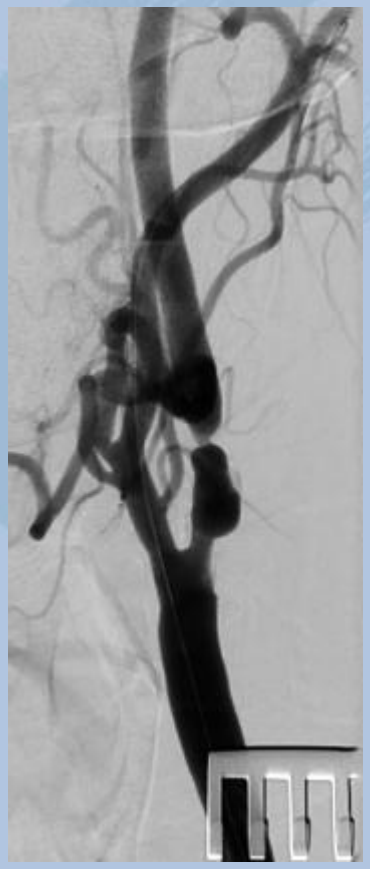
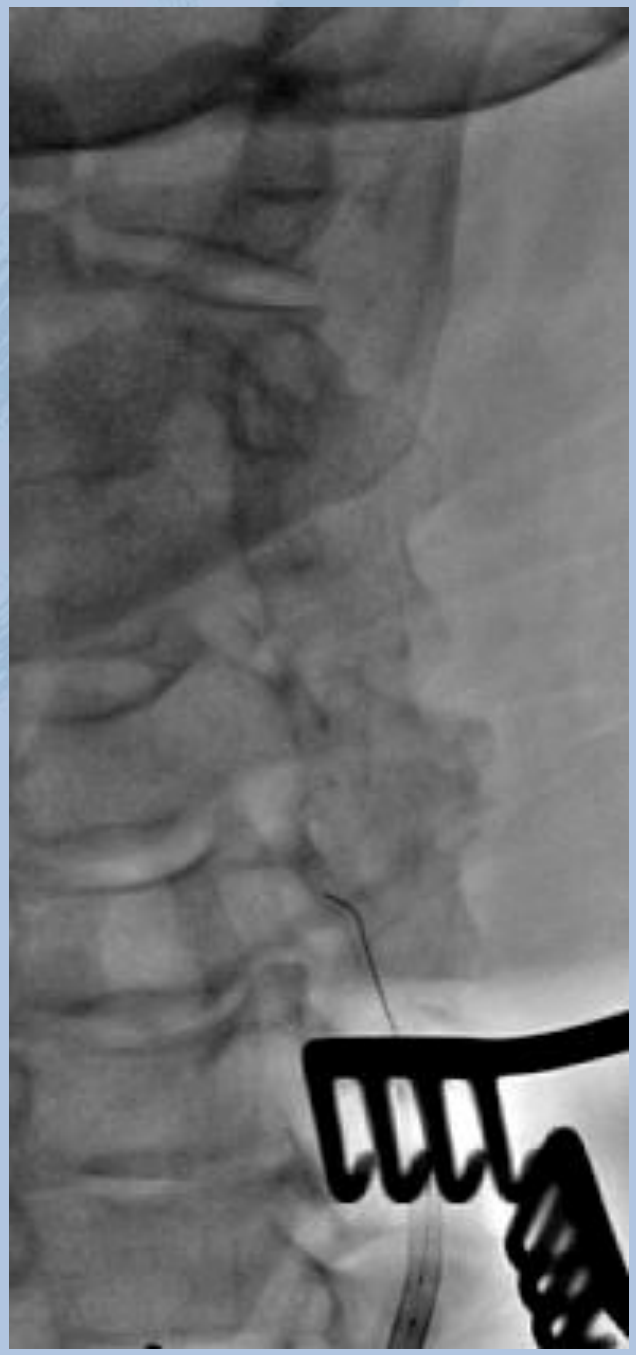
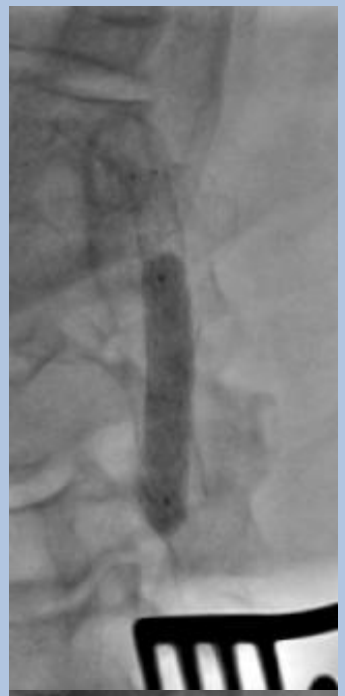
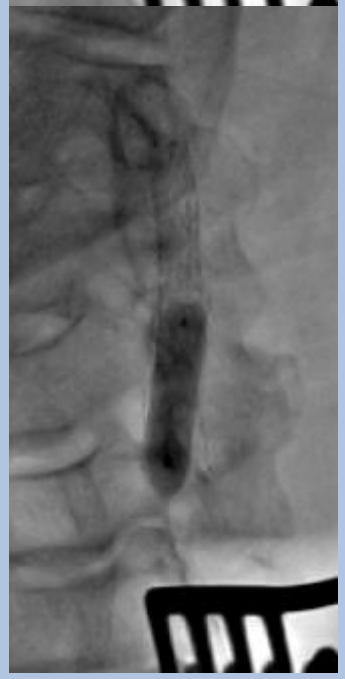
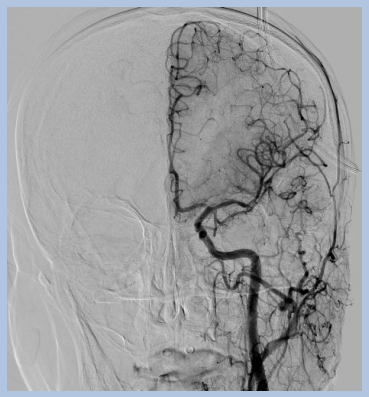
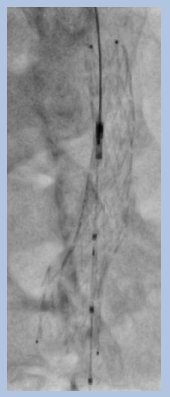
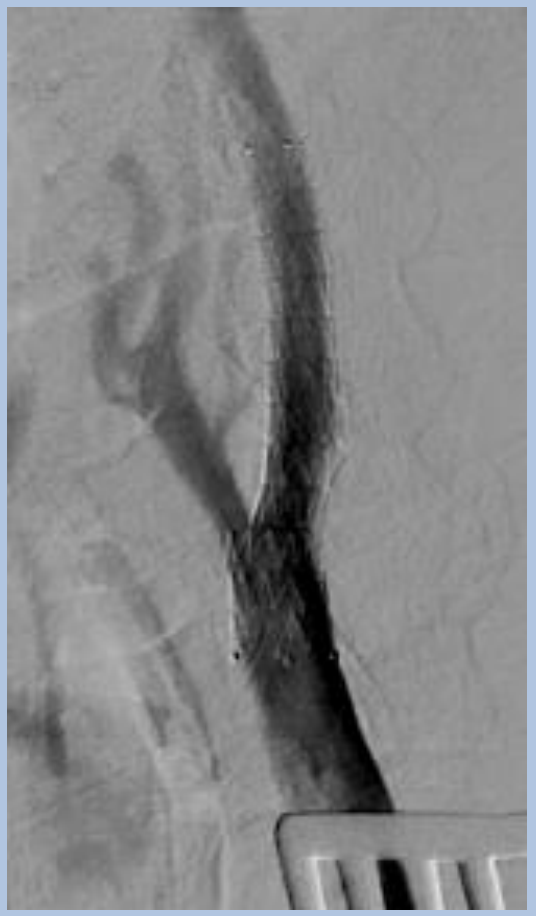




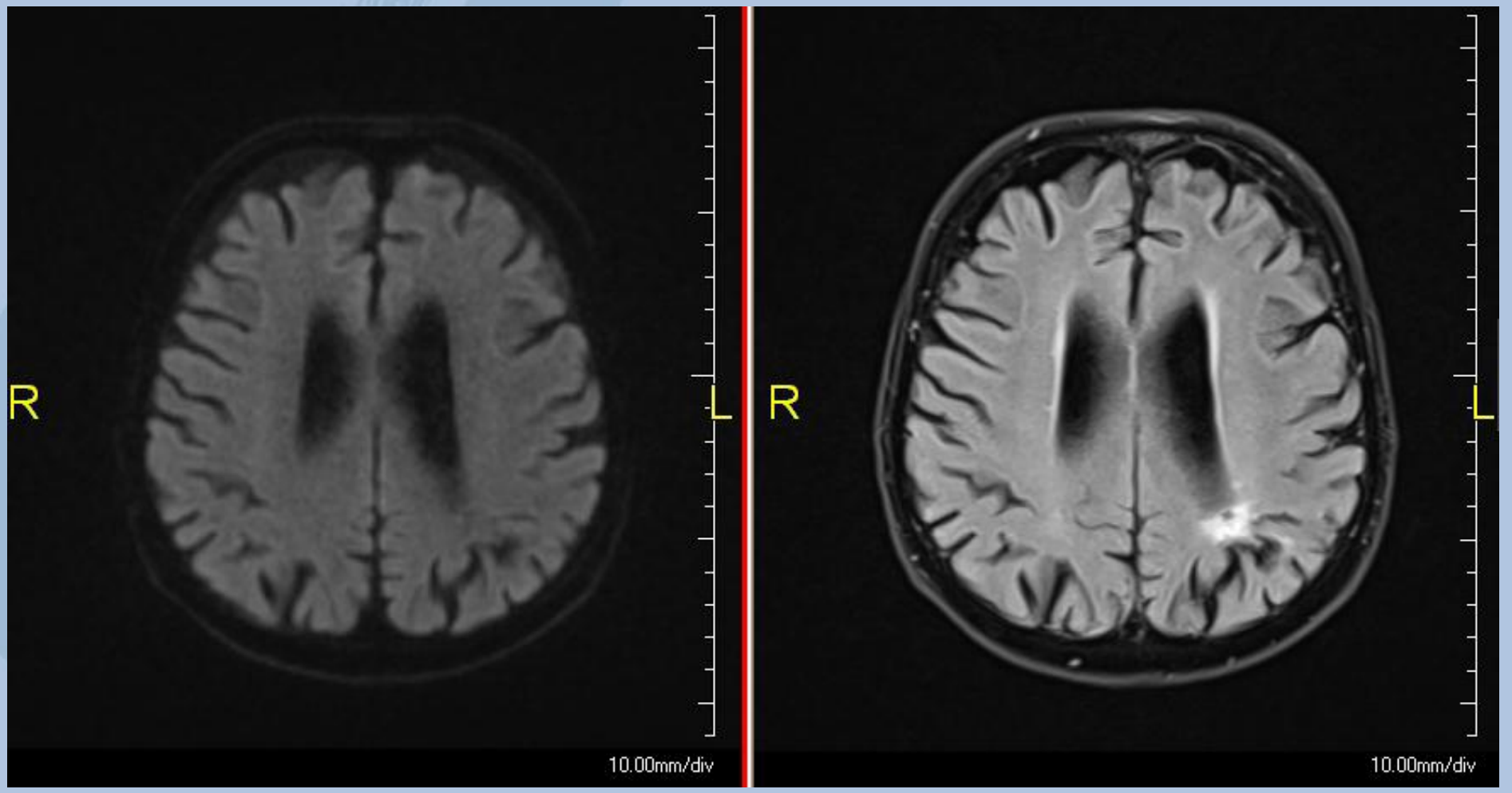






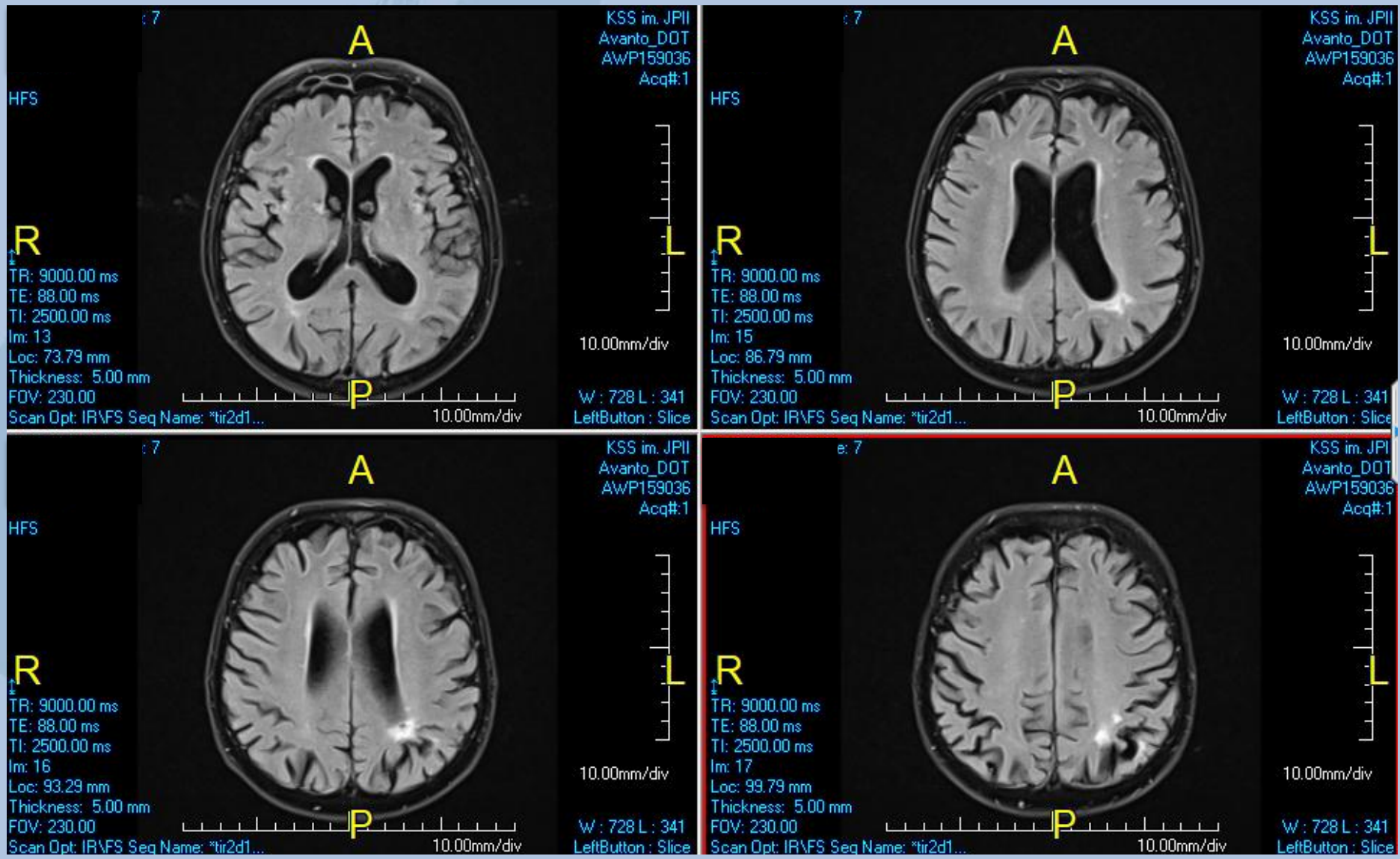









Baseline MRI (morning of the procedure day)



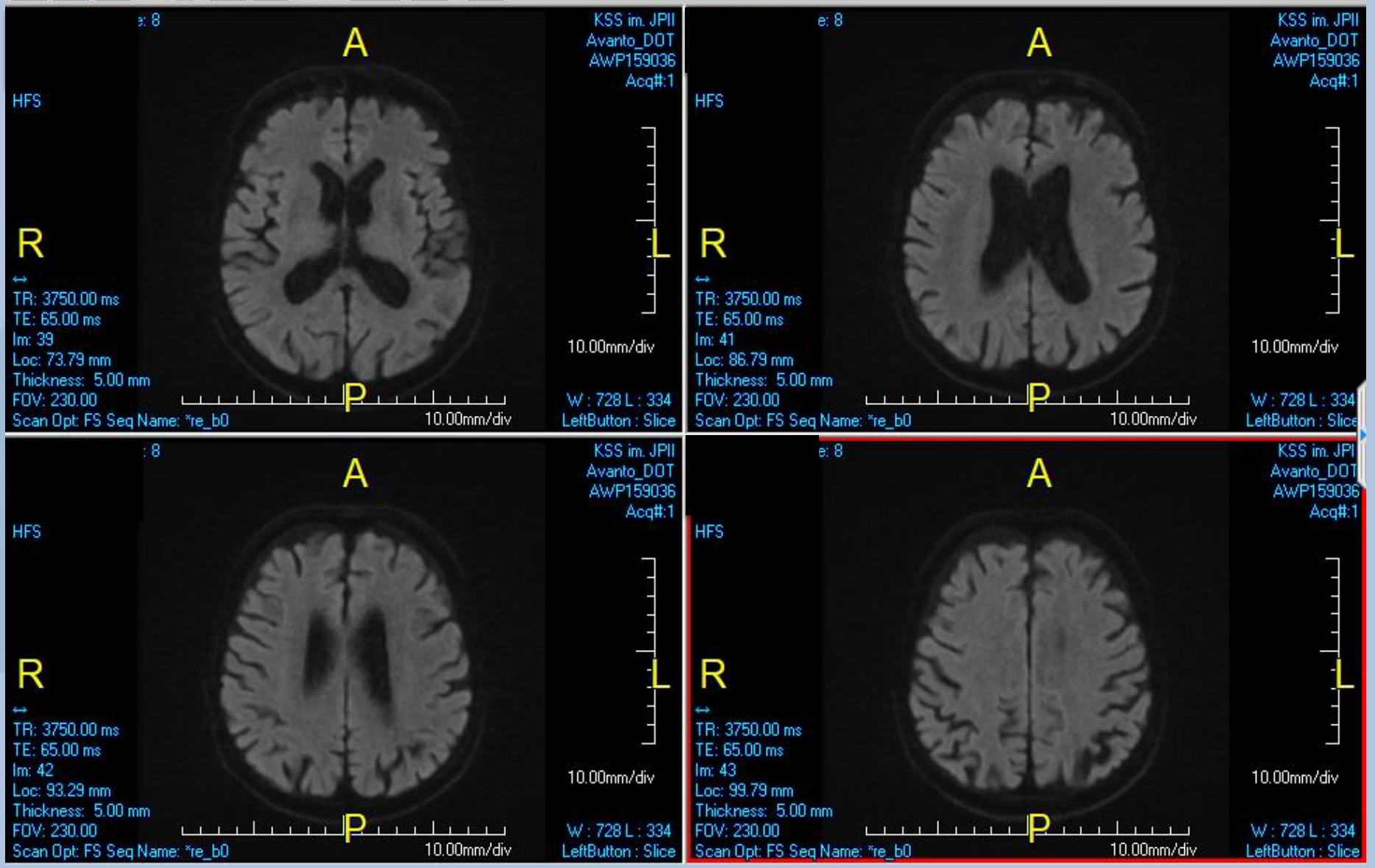
M Urbanczyk & RP Banys, JP2 Hosp. Krakow

FLAIR before



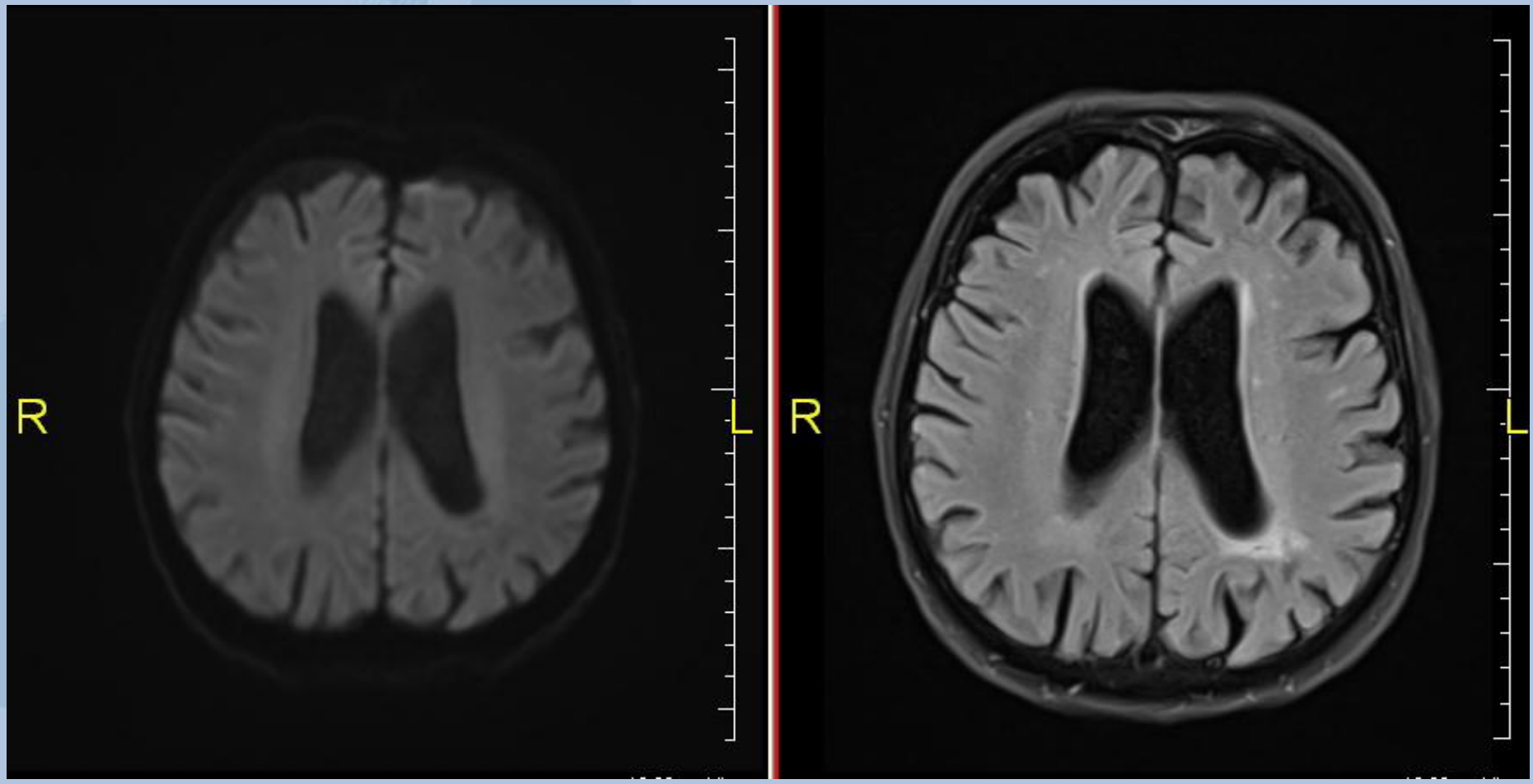
M Urbanczyk & RP Banys, JP2 Hosp. Krakow

DWI before



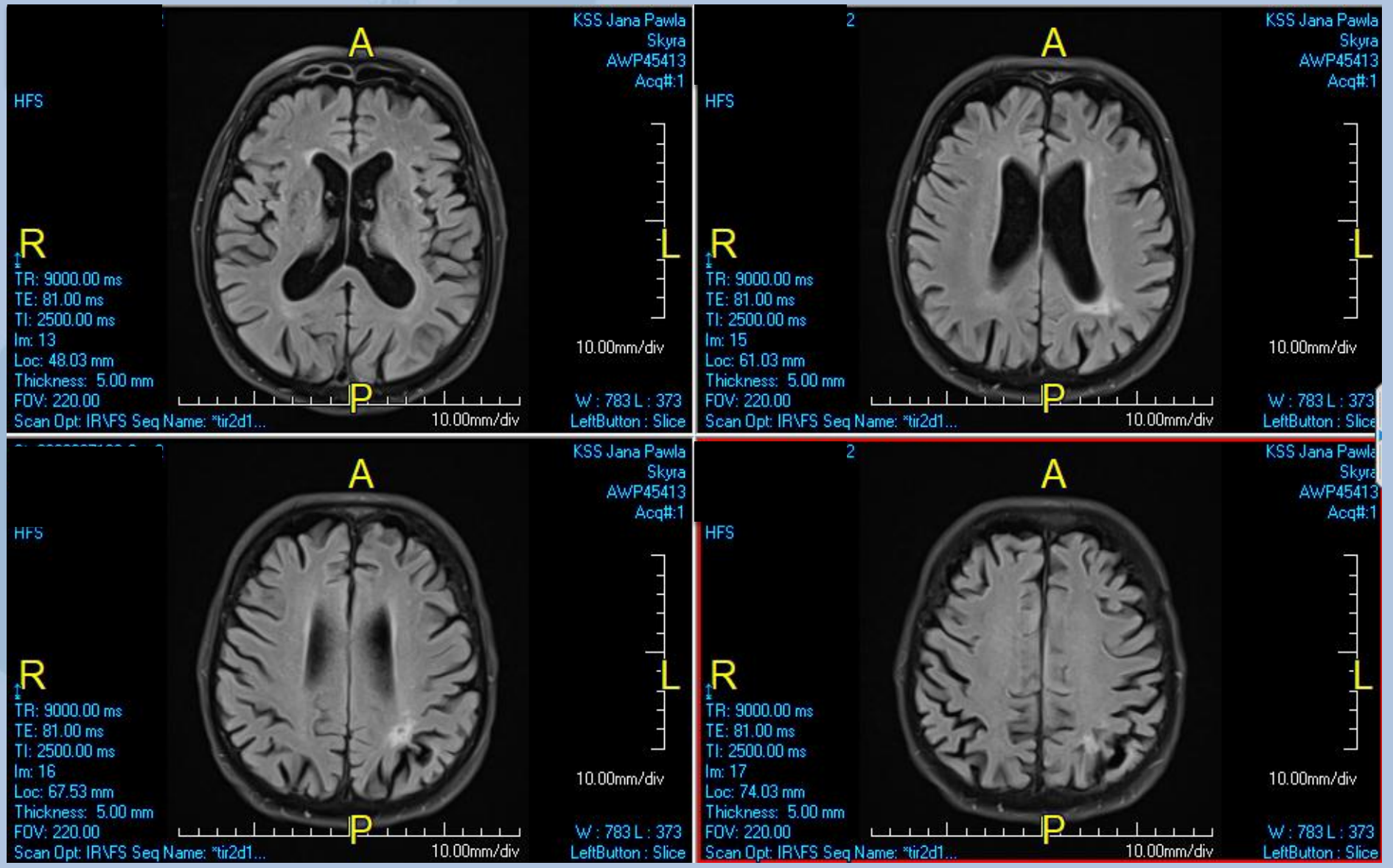
M Urbanczyk & RP Banys, JP2 Hosp. Krakow

MRI @**24h**



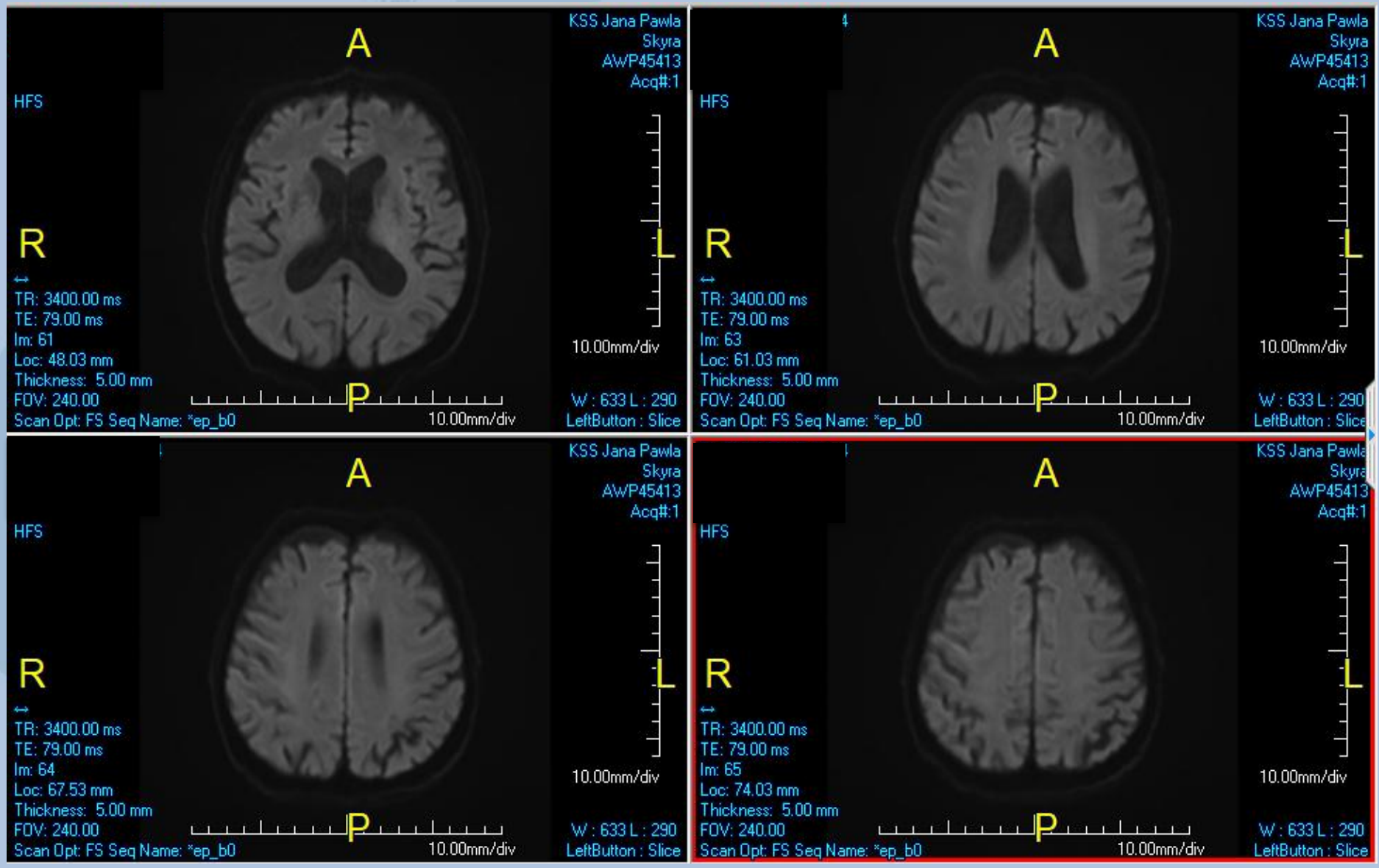
M Urbanczyk & RP Banys, JP2 Hosp. Krakow

FLAIR @**24h**



M Urbanczyk & RP Banys, JP2 Hosp. Krakow

DWI @**24h**



M Urbanczyk & RP Banys, JP2 Hosp. Krakow

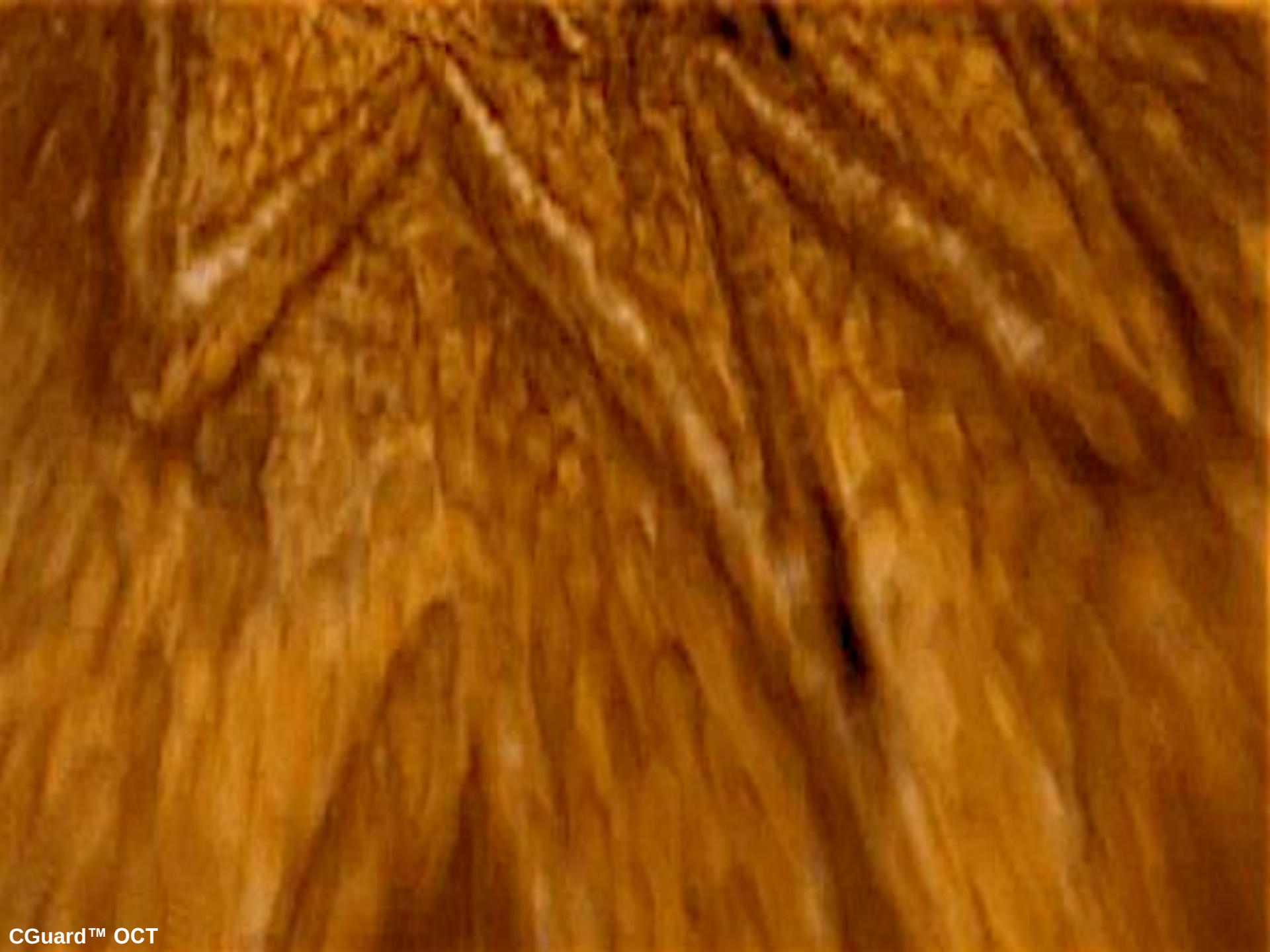
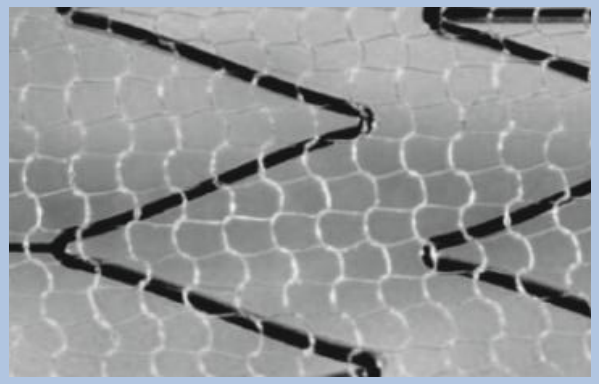

CGuard™ OCT

Image credit to: https://bernard25.wordpress.com/2015/06/08



OPTIMAl endovascular sequestration of high-risk carotid plaque using the CGuard™ MicroNET–covered embolic prevention stent system in consecutive patients with sym--ptoms or signs of carotid stenosis-related brain injury: An intravascular ultrasound – controlled investigator-initiated multcentric multi-specialty study

CGuard™ OPTIMA

P. Musialek

on behalf of OPTIMA Investigators
(list follows)