



CardioPaTh

Cardiovascular Pathophysiology & Therapeutics

Novel therapeutic strategies to peripheral vascular diseases

T. Tesorio, MD

Director of Invasive Cardiology

Clinica Montevergine, Mercogliano, IT



- In 1968 a team of young cardiologists decided to join their efforts and founded the Clinic dedicated to Cardiopulmonary disease
- In their pioneristic plans it was already clear that this institution should be focused on patient care, clinical research and technological improvements





Invasive cardiology

- In 1985 Paolo Rubino, MD in collaboration with Salvatore Battaglia ,MD constituted the Cardiac Cath Lab
- In 1996 Paolo Rubino MD and his collaborators (Luigi Salemmme MD, Tullio Tesorio MD and Angelo Cioppa MD) started a NHS supported program of Cardiovascular Interventions



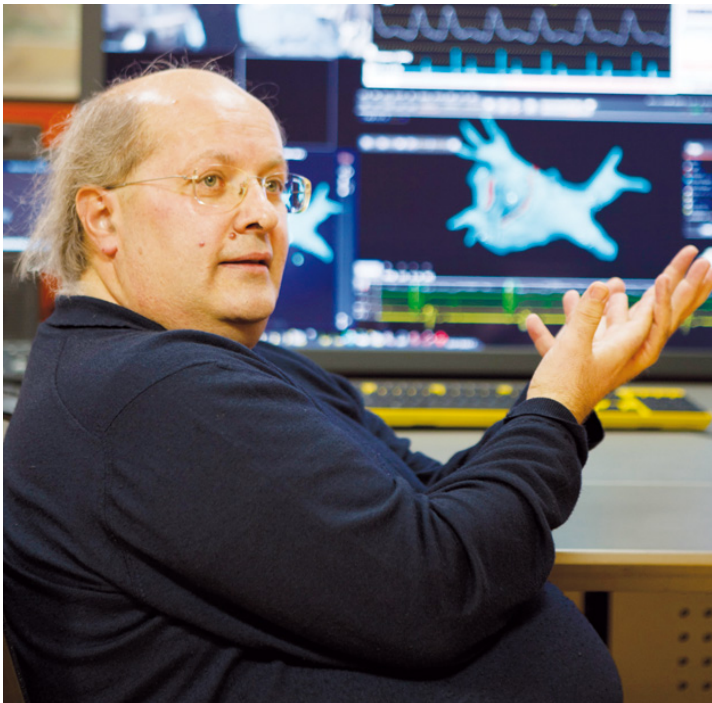
Cardiac Surgery

- 1992: the first CABG was performed
- 1996: Prof. Lucio Parenzan, in collaboration with a cardiac surgeon (Michele Portoghese, MD) and a cardiac anesthesiologist (Luca Lorini, MD), set up an on site division of Cardiac Surgery, NHS supported



Electrophysiology

In 1996 Carlo Pappone, MD created the division of Electrophysiology in collaboration with a Young Cardiologist (Francesco Solimene, MD) who is now the section director





Over the time the Institution increases its activities in terms of patient care, continuing physician education and clinical research...

thanks to the help of several mentors...



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«*Best Practice in Complex Lesions*»

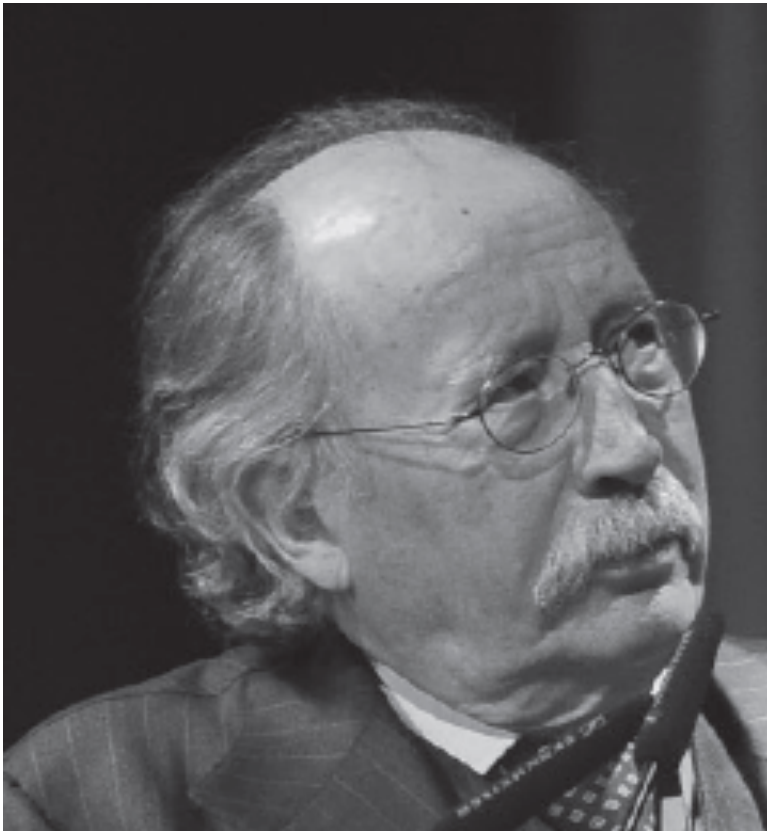


> 600 physicians
attended over 8 years





«Endoschool»

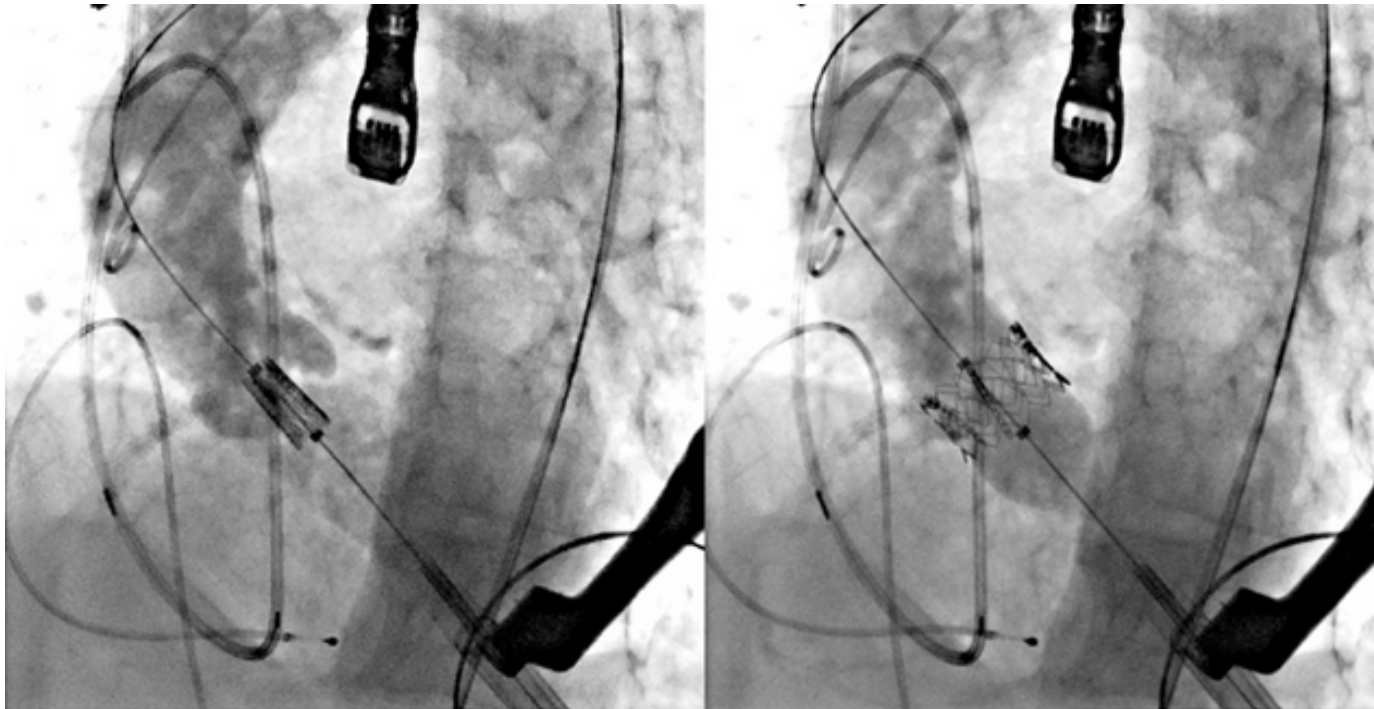


> 200 physicians attended
over 2 yeras





«TAVI program»



First transapical
TAVI in Italy
(2008)



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- Last 12 months activity (*total admissions: 6951*)

Interventional Cardiology	
Coronary	
Coronary angiographies	3064
PCI	1098
Peripheral PTA	281
CAS	223
Structural	
VHD	72
GUCH	29
EVAR/TEVAR	28

Electrophysiology	
Electrostimulation	
PM	379
ICD/CRT-D	394
Loop recorder	12
Extractions	82
Electrophysiology	
EPS/ablations	1029

Cardiac Surgery	
CABG	273
VHD	257



Late Breaking trials

- Transcather Cardiovascular Therapeutics: CIAO, SAT-TAVI, ODS-CAS
- EuroPCR: DESERVE
- LINC: ERCAS

Live Cases Transmission

- LINC and CRT

The CIAO (Coronary Interventions Antiplatelet-based Only) Study

A Randomized Study Comparing Standard Anticoagulation Regimen to Absence of Anticoagulation for Elective Percutaneous Coronary Intervention

Acute left main obstructions following TAVI

Proximal Endovascular Occlusion for Carotid Artery Stenting

Results From a Prospective Registry of 1,300 Patients

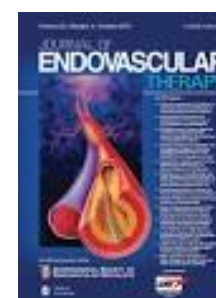
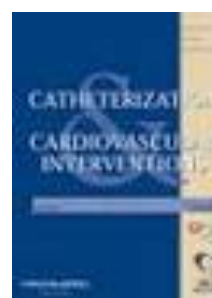
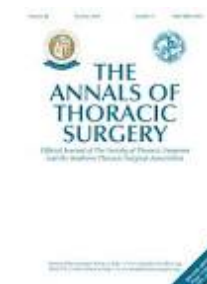
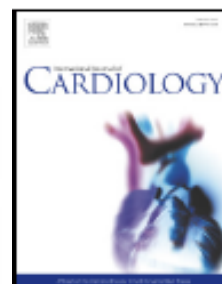
SAT-TAVI (single antiplatelet therapy for TAVI) study: A pilot randomized study comparing double to single antiplatelet therapy for transcatheter aortic valve implantation

The DESERVE study: Diffusion weighted-MRI based evaluation of the effectiveness of endovascular clamping during carotid artery stenting with the Mo.Ma device ☆

Valvular Heart Disease

One-Year Outcomes of Cohort 1 in the Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) Registry

The European Registry of Transcatheter Aortic Valve Implantation Using the Edwards SAPIEN Valve





Actual perspectives

- We are proud to be part of the Cardiopath PhD Program
- We are eager to contribute to the education of the students



Hot issues in peripheral artery interventions

- **How to improve immediate and long term results in complex femoropopliteal interventions**
- How to identify the asymptomatic carotid artery stenosis requiring treatment
- How to improve CAS results

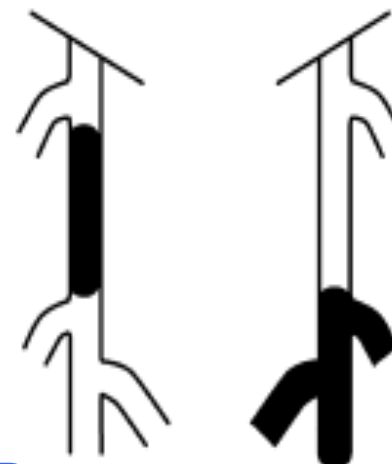


How to treat Complex SFA lesions?



TASC Type C :

- Multiple stenoses or occlusions totaling **>15 cm** with or without heavy calcification
- Recurrent stenosis or occlusions that need treatment after **two** endovascular interventions



TASC Type D :

- Chronic total occlusions of CFA or SFA (>20 cm, involving the popliteal artery)
- Chronic total occlusion of popliteal artery and proximal trifurcation vessels



Clinical and procedural issues related to complex femoropopliteal lesions

- ✓ How to cross total occlusions?
- ✓ How to prevent restenoses?



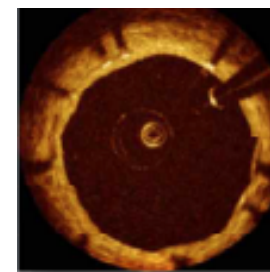
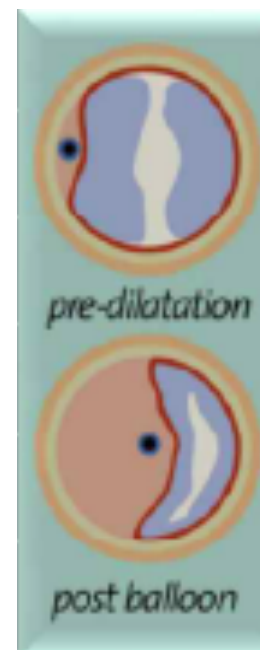
Two strategies for CTOs crossing

Subintimal Navigation (STAR)

- Well characterized, historical technique
- Often as bail-out with re-entry devices necessary
- Limits choices for adjunctive devices

Central Lumen Navigation

- Clinically preferred strategy
- Maximizes therapeutic options
- All adjunctive devices designed to operate in the arterial lumen

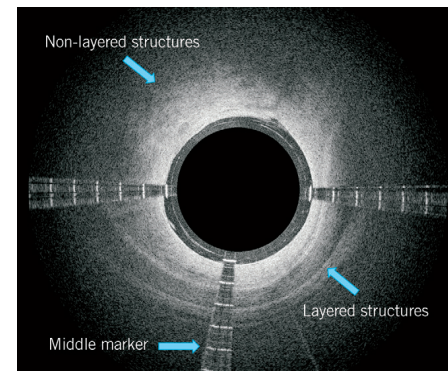




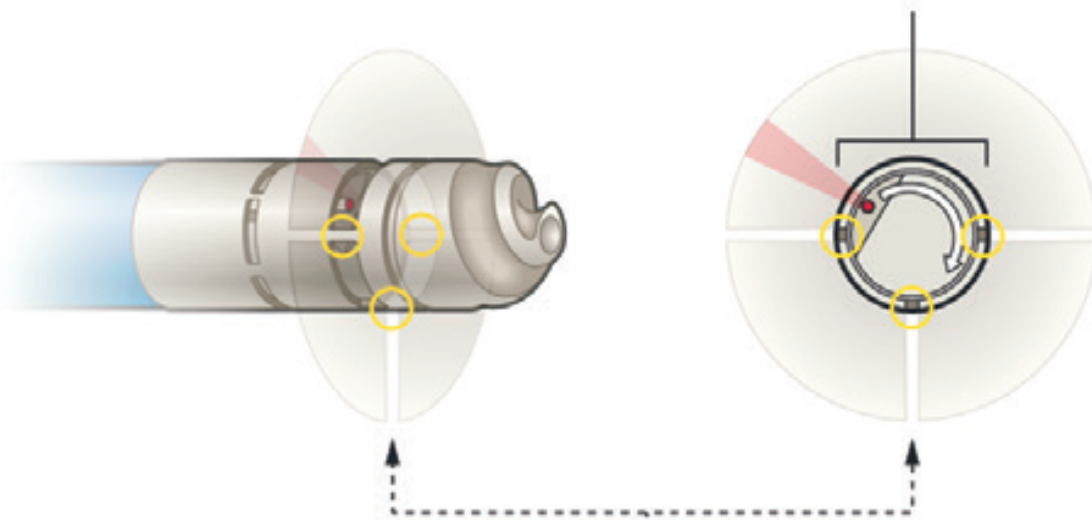
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OCT Guided SFA recanalization



Cross-section view of OCELOT

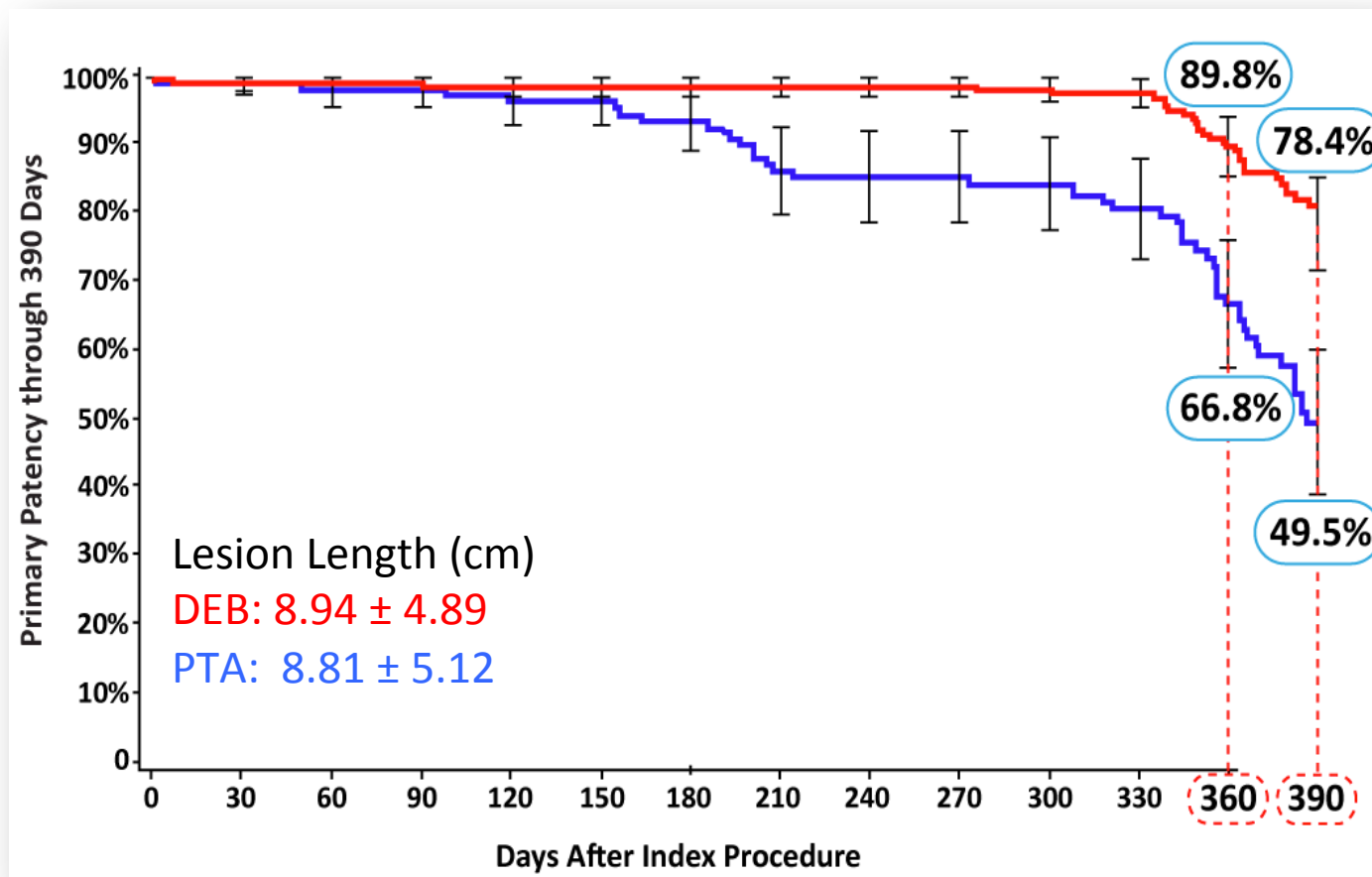


- Imaging
- Scaffolds/Markers

Middle markers



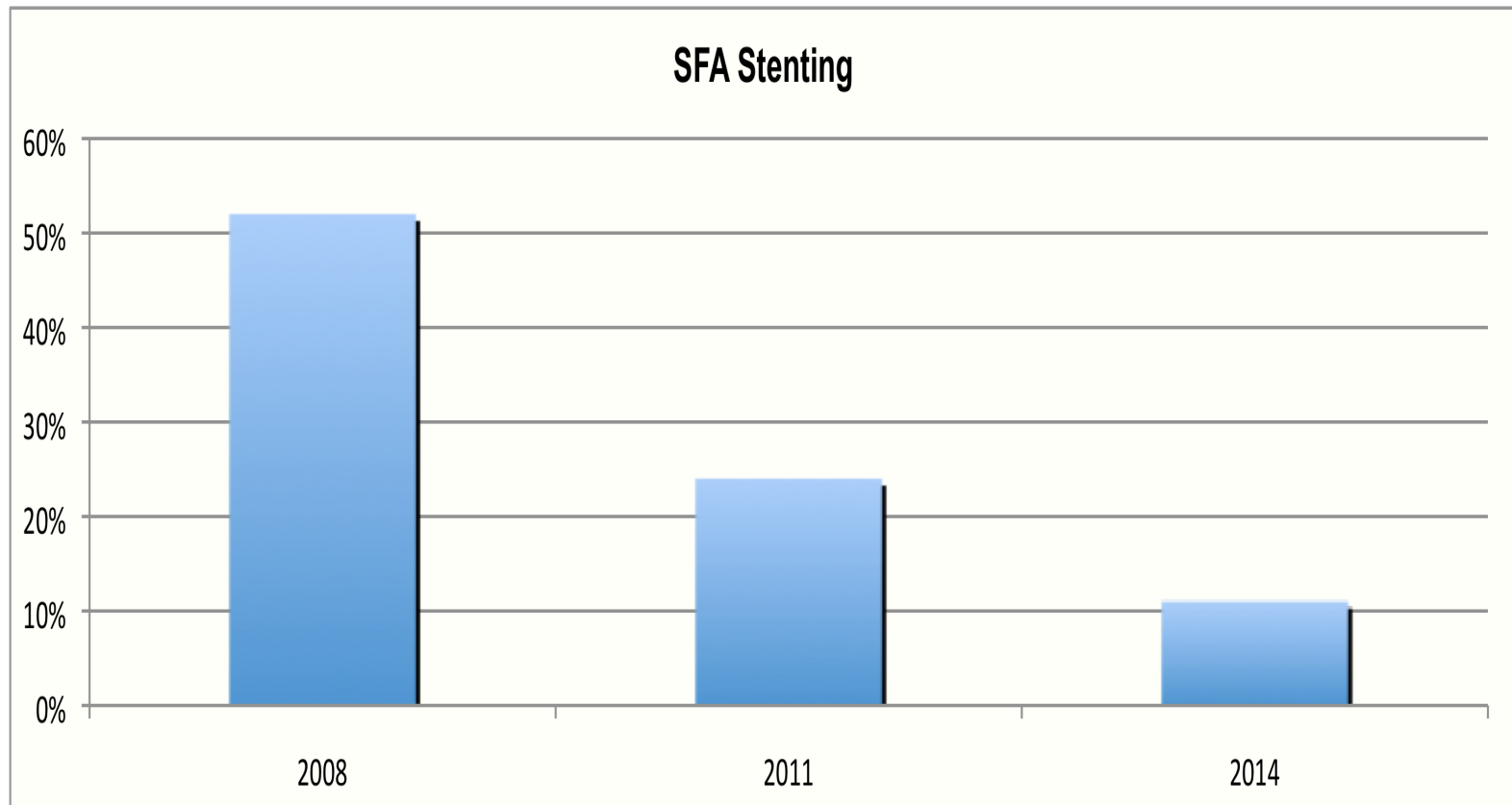
Primary patency in the In.Pact SFA trial



Primary patency is defined as freedom from clinically-driven TLR and freedom from restenosis as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) ≤ 2.4



DEB limited stents use to a minimum!



The systematic use of drug eluting balloons has reduced the need of SFA stenting in our daily practice to less than 15 % of the cases.



How to treat complex fem-pop lesions?

- ***Lesions characteristics***
 - a. Long lesions/occlusions***
 - b. Calcific lesions***
 - c. ISRS***

- ***Anatomic settings***
 - a. Common femoral artery***
 - b. Popliteal artery***



***In case of long lesions (> 15 mm)...
ISRS rate at 12 months is more than 30%!***

		Mean Lesion Length	PP (1 year)	Stent fractures
Vibrant ¹	Gore Viabahn	19 cm	53 %	2.0 %
	Nitinol stent	18 cm	58 %	31.8 %
SuperSL ²	SMART	13 cm	65.8 %	22.4 %
	LUMINEXX	12 cm	55.8 %	31.4 %

¹ Ansel GM: presented @ LINC 2010

² Duda SH: presented @ LINC 2009



In.Pact long SFA lesion

Prospective



Multicenter



Randomized



Corelab



Peer-reviewed Published

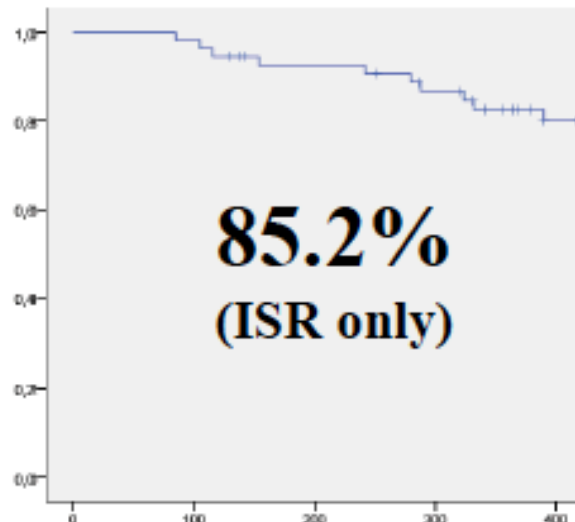
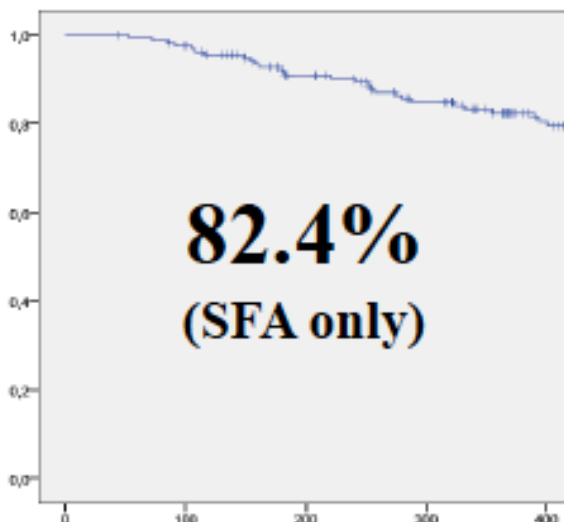
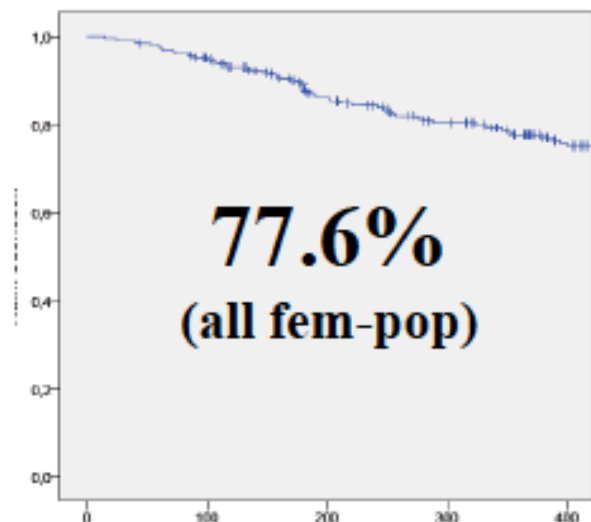


Real world 260-Patient Registry

- High Primary Patency rates achieved overall in the full cohort and subsets
- 23.3% provisional Stent rate

Lesions ~24 cm

1-year freedom from loss of Primary Patency (PSVR < 2.4)





What about calcific lesions?

Combined treatment of heavy calcified femoro-popliteal lesions using directional atherectomy and a paclitaxel coated balloon: One-year single centre clinical results[☆]

Angelo Cioppa^{*}, Eugenio Stabile, Grigore Popusoi, Luigi Salemme, Linda Cota, Armando Pucciarelli, Vittorio Ambrosini, Giovanni Sorropago, Tullio Tesorio, Alessia Agresta, Giancarlo Biamino, Paolo Rubino

Division of Invasive Cardiology, "Montevergine" Clinic, 83013 Mercogliano(Avellino), Italy

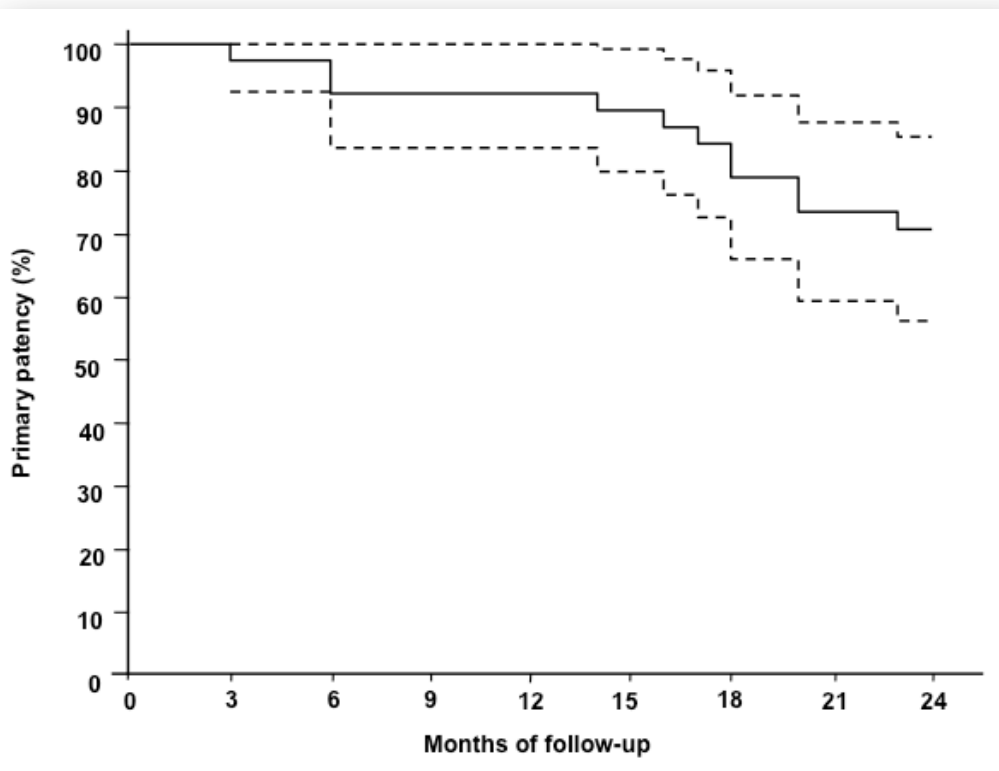
Table 3

Clinical results at one-year follow-up in patients treated with DA and DCB.

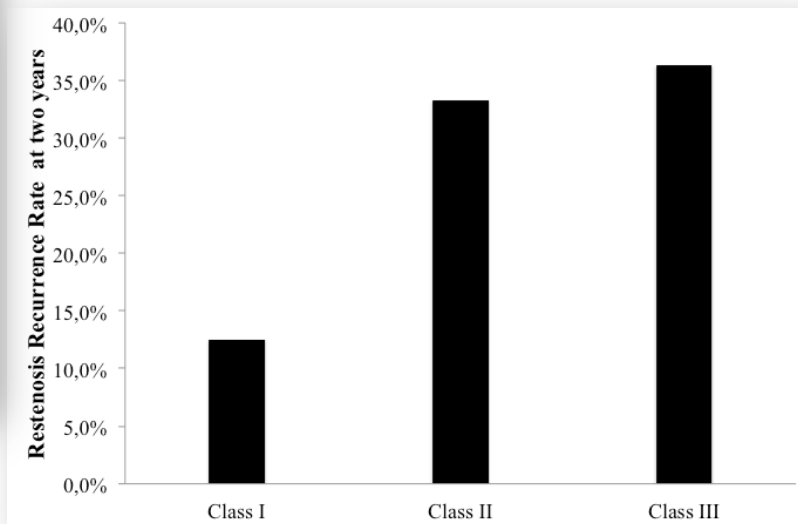
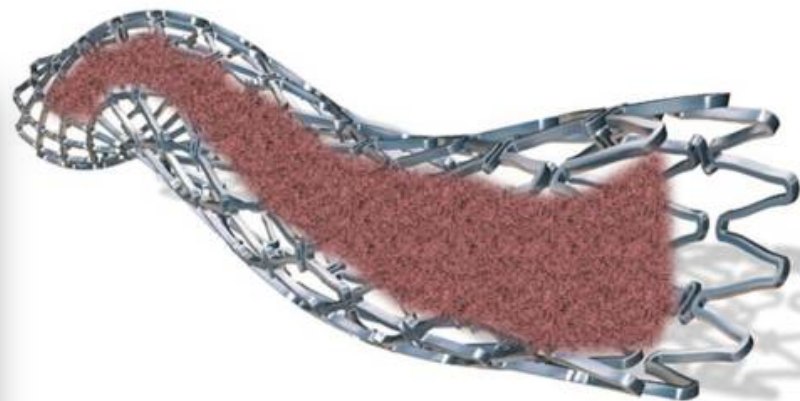
No. of patients	30
Follow-up completion	30 (100 %)
Clinical follow-up duration (days)	371 ± 115
Major amputations (above the ankle) in CLI patients	0
Minor amputations (below the ankle) in CLI patients	3
Limb salvage rate (CLI patients)	12/12 (100%)
Re-hospitalizations (any cause)	4 (13%)
Repeat percutaneous transluminal angioplasty	3 (10%)
Primary Patency at 1 year	27 (90%)
Secondary patency at 1 year	30 (100%)



Drug-Eluting Balloon for Treatment of Superficial Femoral Artery In-Stent Restenosis



70.3 % Primary Patency rate at 2 yrs

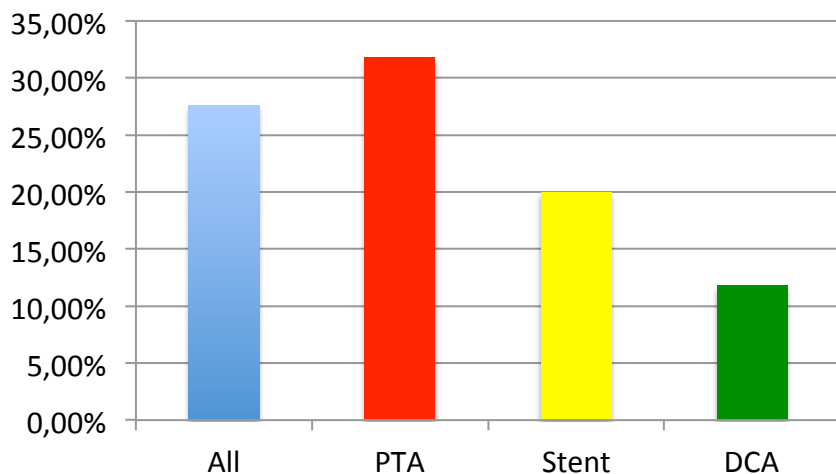




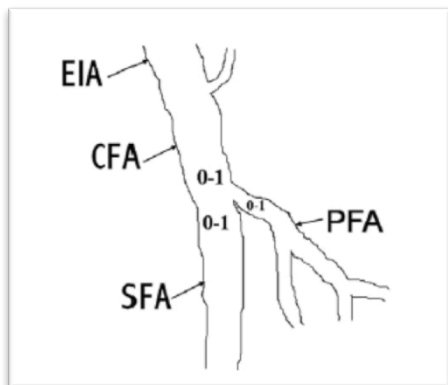
Endovascular Treatment of Common Femoral Artery Disease

Medium-Term Outcomes of 360 Consecutive Procedures

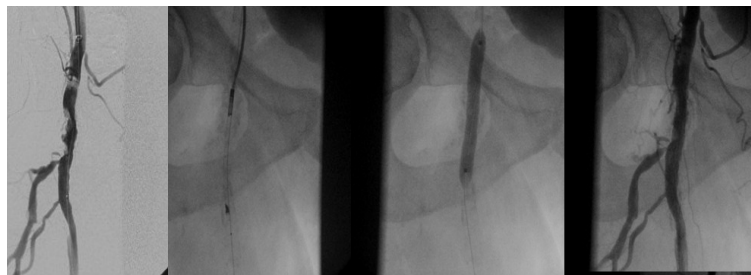
1 year TLR



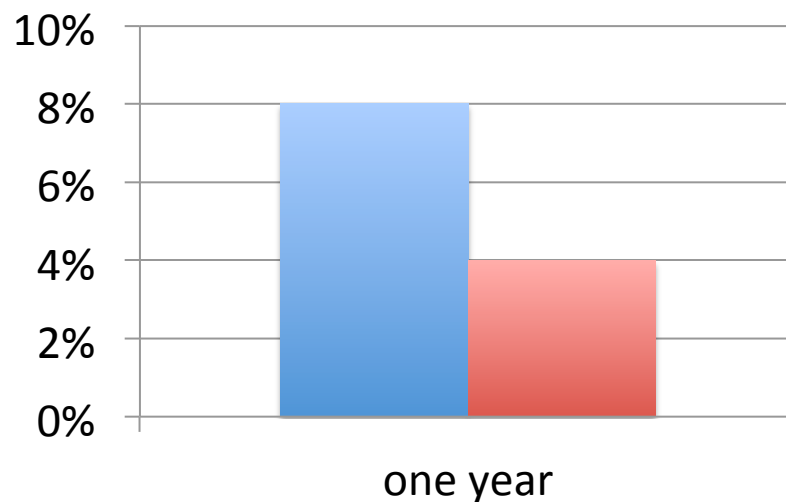
Bonvini et al. JACC 2011



What about DEB and DCA?



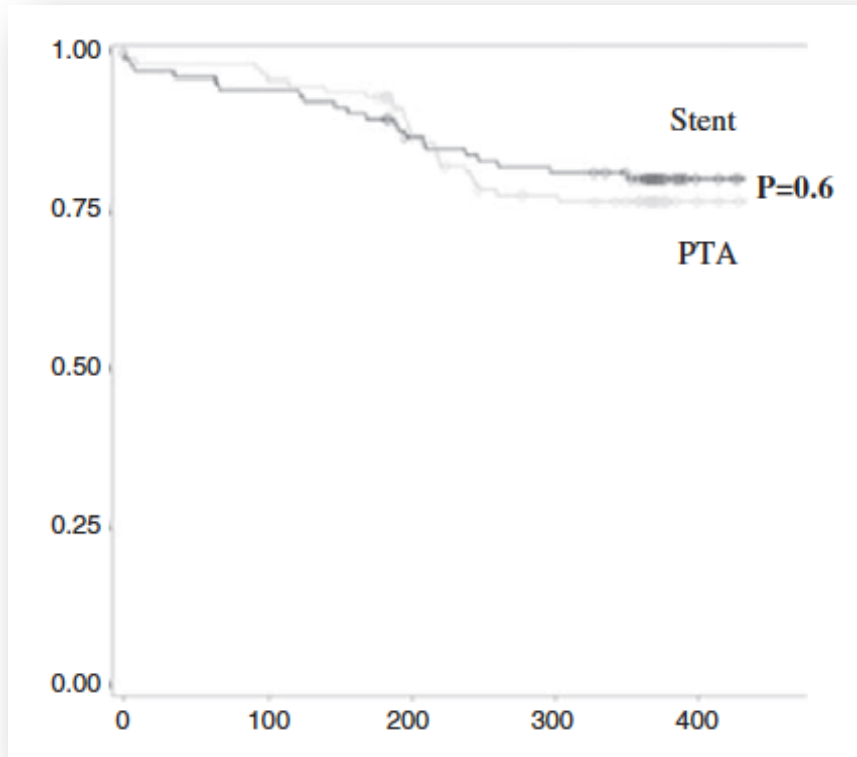
■ Binary restenosis ■ TLR



Cioppa A et al. EuroPCR 2013



Stent for popliteal lesions?



“...optimal percutaneous transluminal angioplasty with provisional stent placement, if indicated, resulted in comparable technical and clinical 1-year outcomes...

The results presented contradict the generally accepted opinion that stent placement in the popliteal artery bed might lead to unfavorable technical and clinical outcomes...”



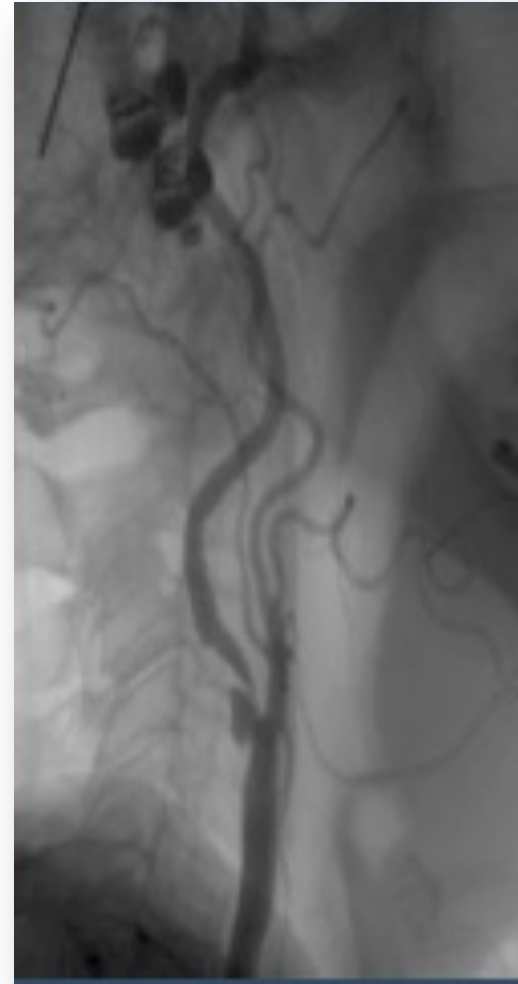
Hot issues in peripheral artery interventions

- How to improve immediate and long term results in complex femoropopliteal interventions
- **How to identify the asymptomatic carotid artery stenosis that requiring treatment**
- How to improve CAS results



Patients with a stroke or TIA
secondary to a carotid stenosis
benefit from revascularization
through reduced future risk of stroke

The role for revascularization in
asymptomatic carotid disease is less
clear and very controversial

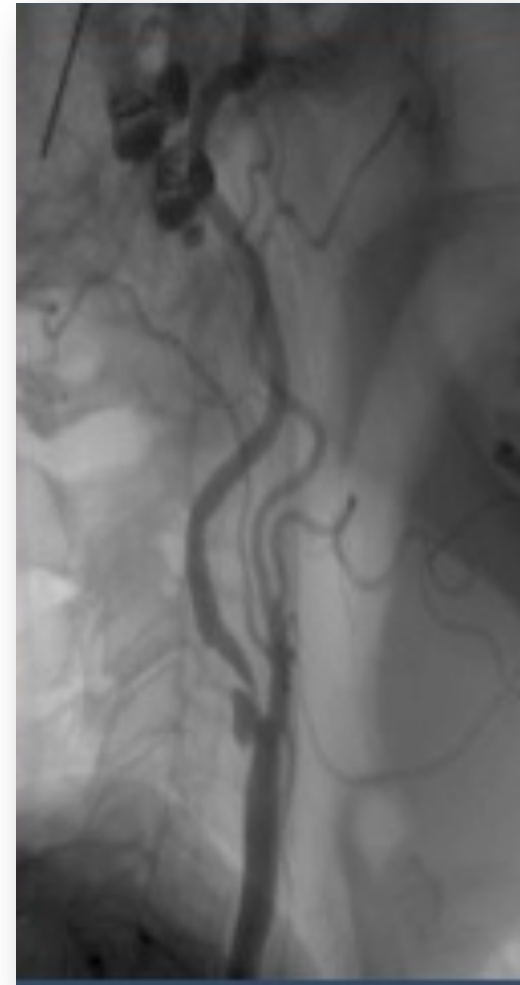




Although intensive MT now reduces the overall risk of stroke ($<1\%/y$), some patients with ACS may go on to have a stroke.

It is therefore important to identify specific subgroups of ACS patients who despite MT are still at increased risk ($>2\%/y$) and may require a carotid intervention.

Identification of these *high-risk ACS patients* is crucial to target carotid revascularization procedures appropriately and to avoid excessive use of unnecessary interventions.

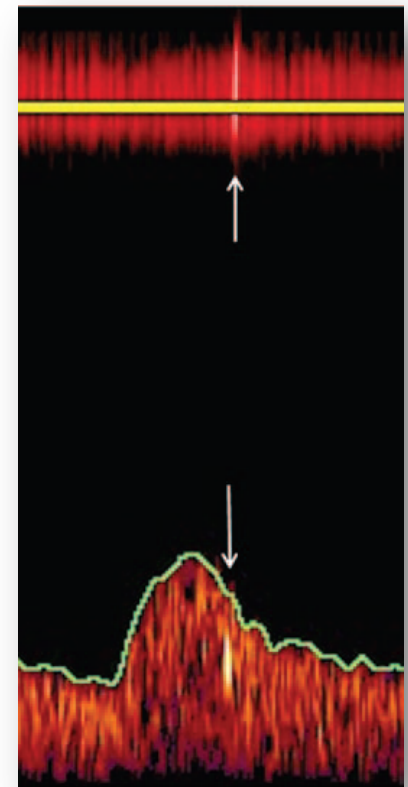
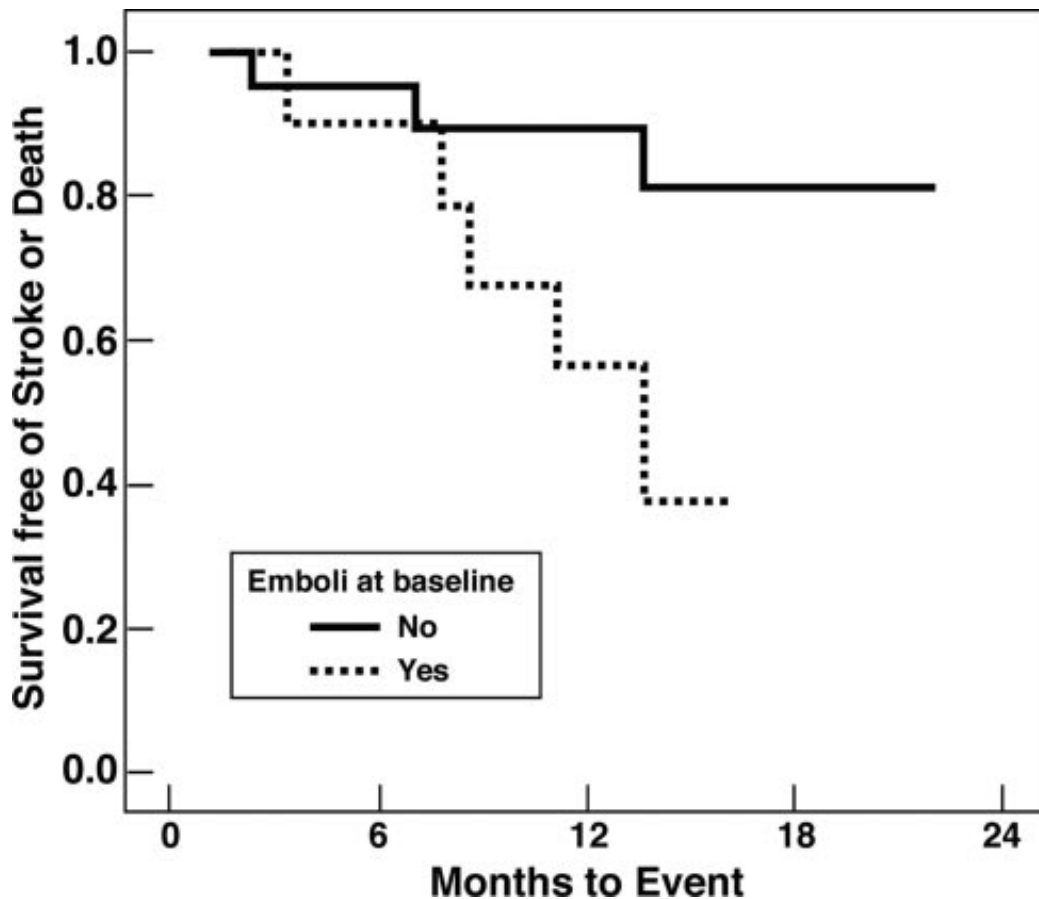




Methods proposed to identify high risk ACS patients

- the detection of microemboli (MES) by TCD
- identification of the unstable carotid plaque using ultrasound
- reduced cerebral blood flow reserve
- Intraplaque hemorrhage using MRI scans
- silent embolic infarcts on brain CT of MRI
- progression in the severity of CAP

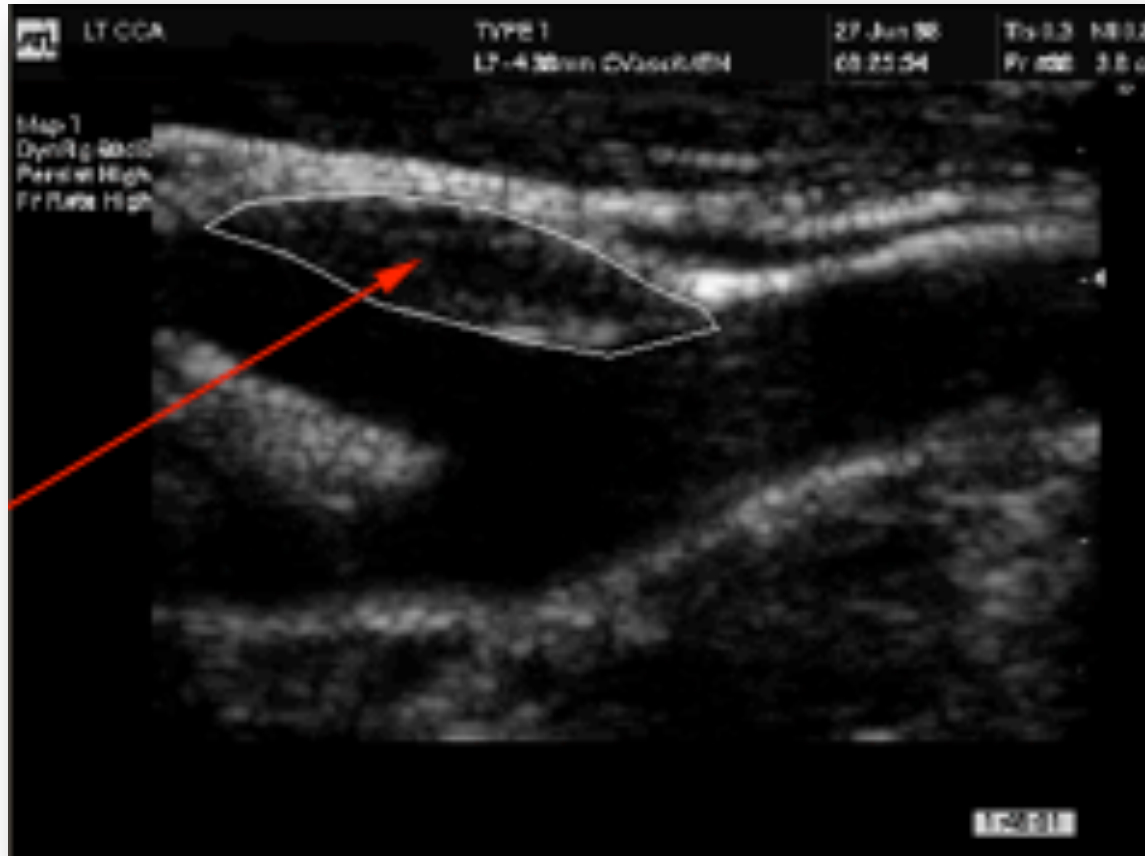
Transcranial Doppler embolus detection could identify the proportion of patients who would be at high enough risk to benefit CEA/CAS



Spence JD et al. Stroke. 2005

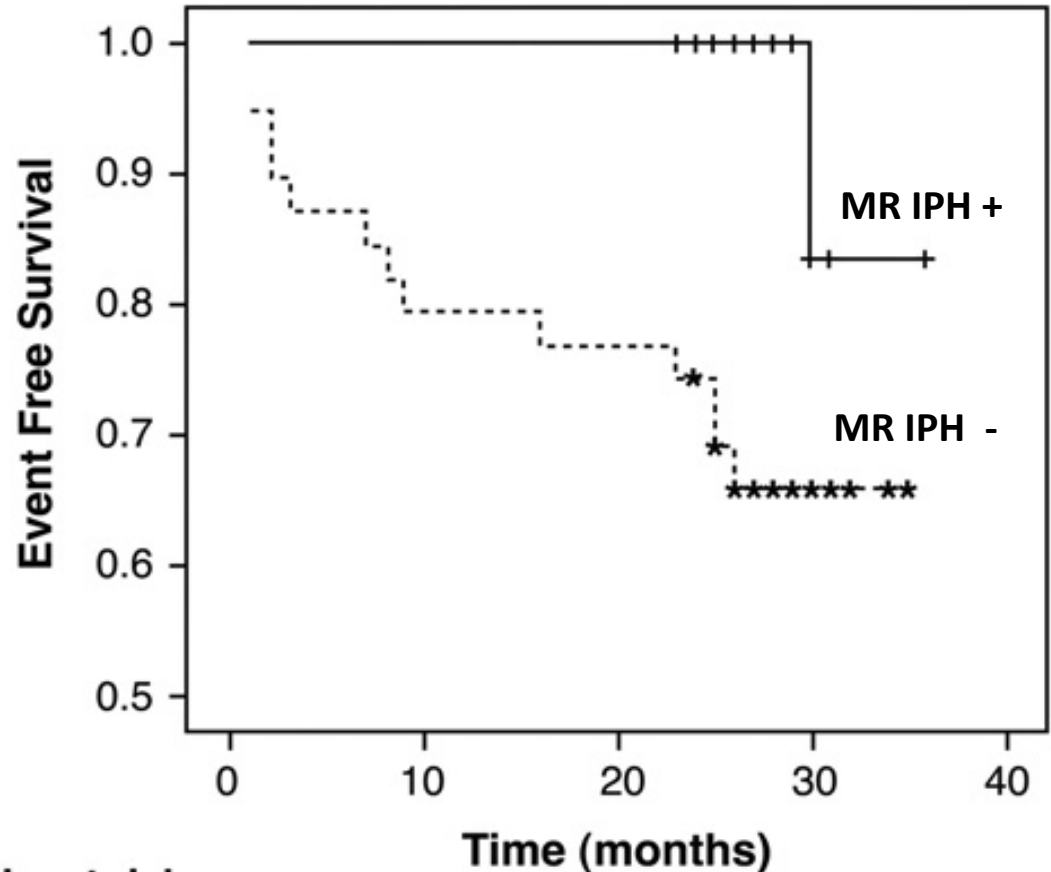
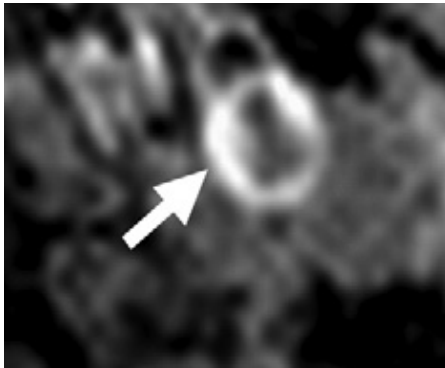
Identification of the Unstable Carotid Plaque Using Ultrasound

The presence of a *juxtaluminal black area of $> 8 \text{ mm}^2$* in a plaque (CAP), without a visible echogenic cap, identified a group of patients (21%) that had an average annual stroke rate of **4.1%**.



Identification of Intraplaque Hemorrhage Using MRI

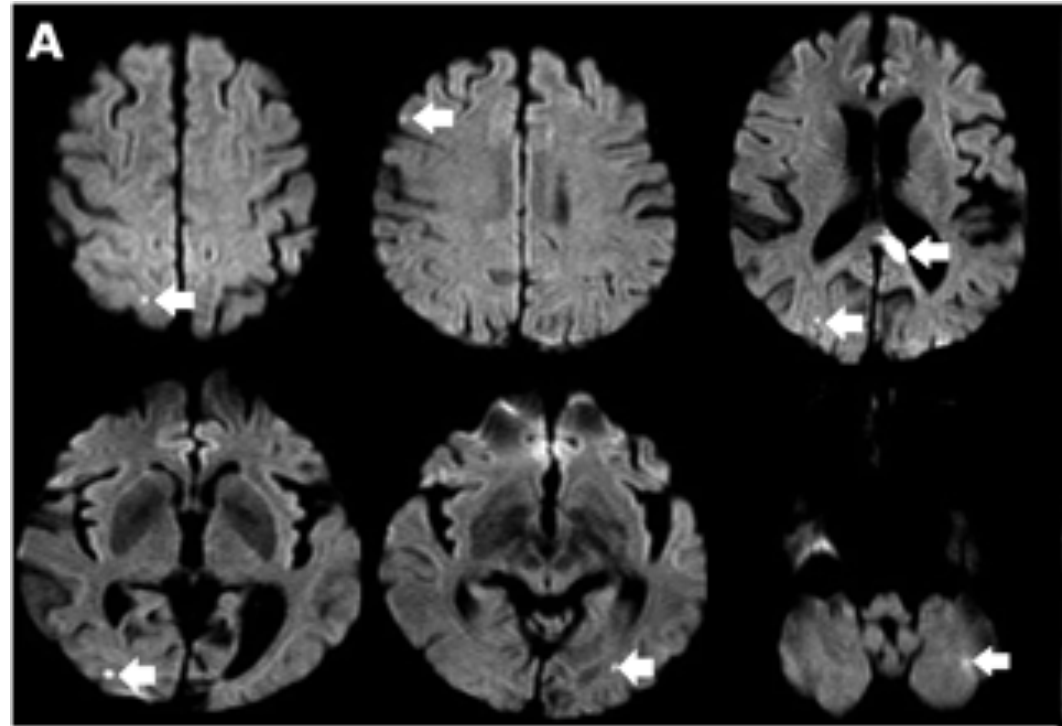
Intraplaque hemorrhage increases necrotic core size and plaque volume and can be considered as a marker of plaque instability



Silent Embolic Infarcts on Brain CT or MRI

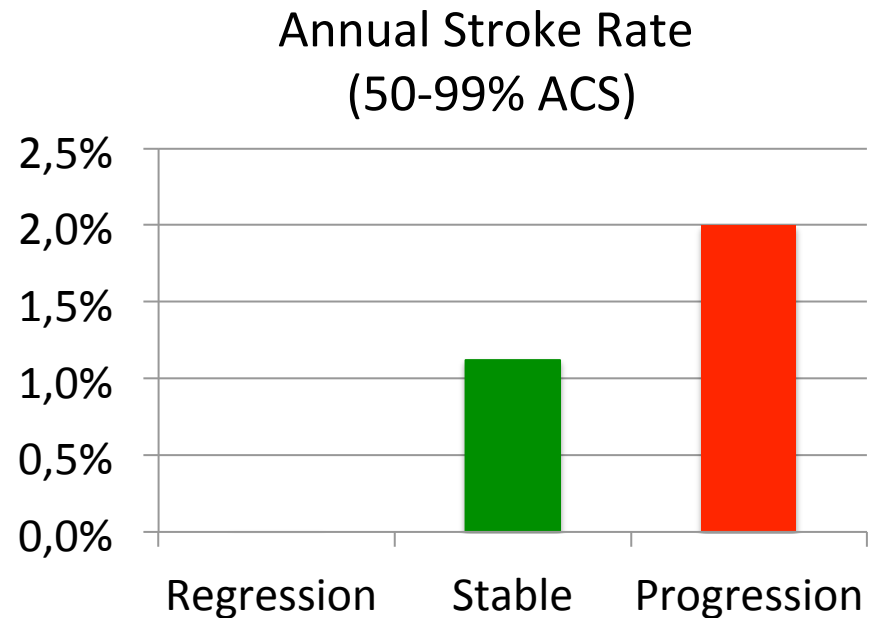
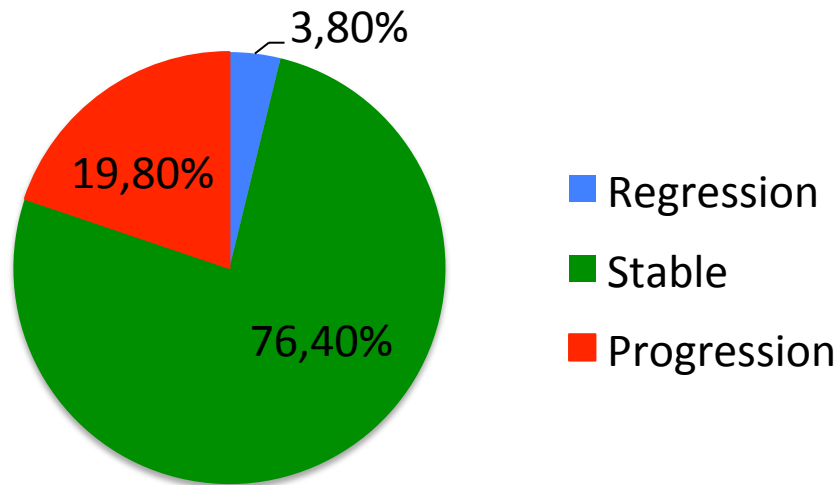
Embolic infarcts were present in 9.6% of the patients with ACS.

This high-risk group has an average annual stroke rate of **3.5%**, thus suggesting that ACS patients found to have prior brain infarcts should be referred for revascularization





Progression in the severity of ACS



For patients with 80% to 99% baseline stenosis, the annual stroke rate was 1.7% in the absence and 3.1% in the presence of progression.

In this study the incidence of plaque progression was inversely proportional to the severity of baseline stenosis and that both baseline stenosis and progression were independent predictors of stroke risk.



Combination of Methods

- The combination of multiple risk stratification parameters, which are independent predictors is better than single parameters when it comes to stroke risk stratification
- The goal of our research on carotid disease is to identify the better parameter combination to identify those ACS patients who will benefit from an intervention



Hot issues in peripheral artery interventions

- How to improve immediate and long term results in complex femoropopliteal interventions
- **How to identify the asymptomatic carotid artery stenosis that requiring treatment**
- **How to improve CAS results**



European Registry of Carotid Artery Stenting: Results from a Prospective Registry of Eight High Volume EUROPEAN Institutions

Eugenio Stabile,^{1*} MD, Pallav Garg,² MD, Alberto Cremonesi,³ MD, Marc Bosiers,⁴ MD, Bernhard Reimers,⁵ MD, Carlo Setacci,⁶ MD, Piergiorgio Cao,⁷ MD, Andrej Schmidt,⁸ MD, Horst Sievert,⁹ MD, Patrick Peeters,⁴ MD, Dimitry Nikas,⁵ MD, Martin Werner,⁸ MD, Gianmarco de Donato,⁶ MD, Giambattista Parlani,⁷ MD, Fausto Castriota,³ MD, Marius Hornung,⁹ MD, Laura Mauri,¹⁰ MD, and Paolo Rubino,¹ MD

TABLE II. Operators Case Load in 2007

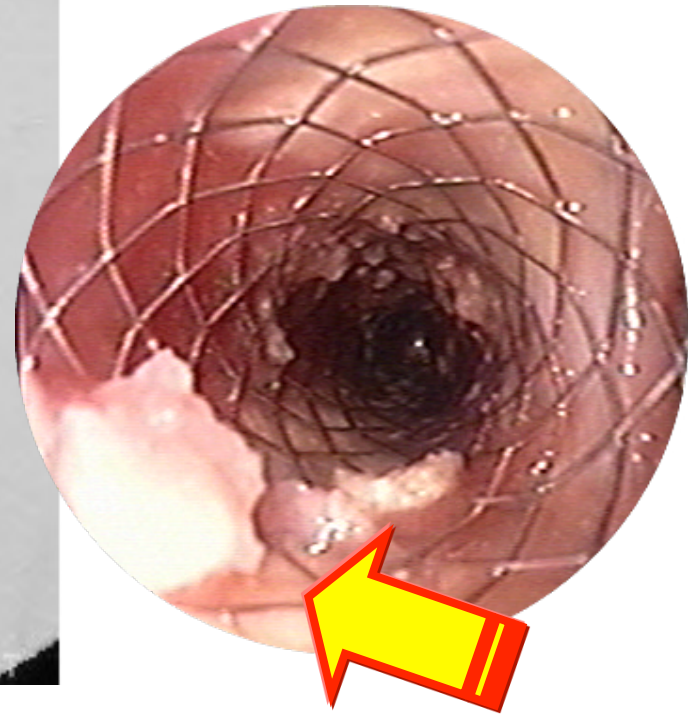
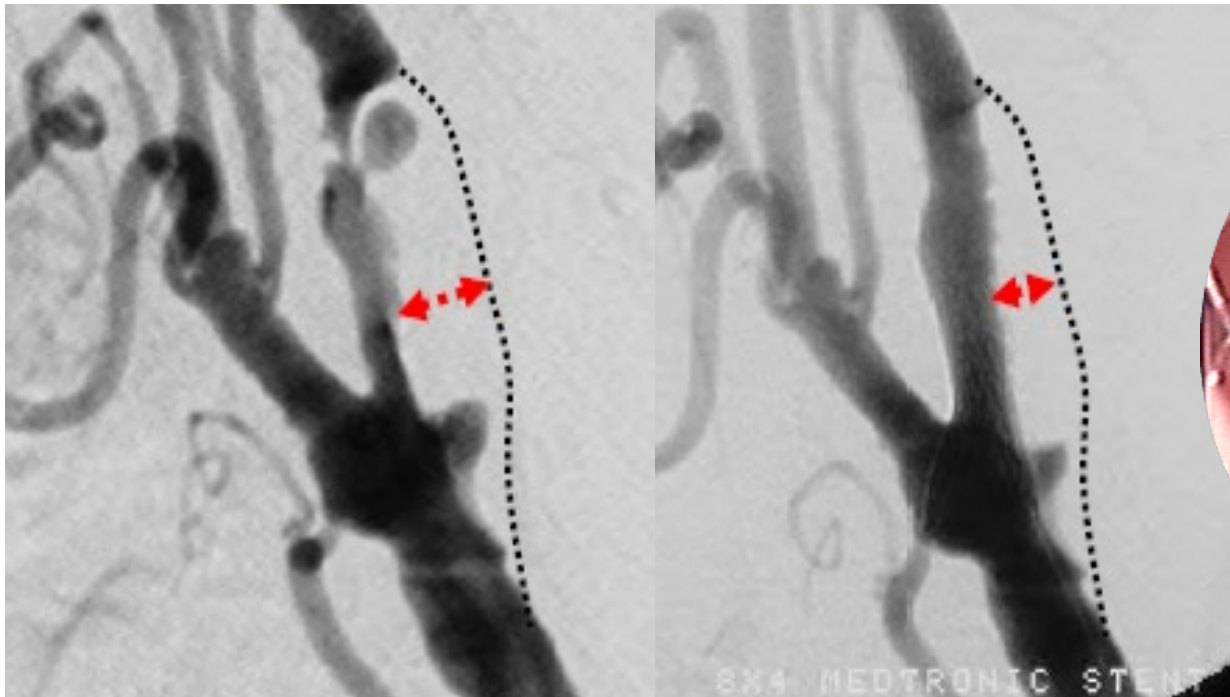
Institution	Enrolled Patients	Operators	Patients/ operator per year
Dendermonde	176	2	88
Cotignola	257	3	85.7
Frankfurt	80	1	80
Liepzig	188	3	62.7
Mercogliano	309	3	103
Mirano	143	3	47.7
Perugia	254	3	84.7
Siena	204	4	51

TABLE IV. Neurological Complications and Deaths within 30 days after CAS

	In-hospital	0–30 days	Overall
Death	1 (0.06)	3 (0.19)	4 (0.25)
Any stroke	8 (0.5)	11 (0.68)	19 (1.12)
Death + any stroke	9 (0.56)	13 (0.81)	22 (1.37)
Major stroke	6 (0.37)	3 (0.18)	9 (0.56)
Minor stroke	2 (0.12)	8 (0.50)	10 (0.62)



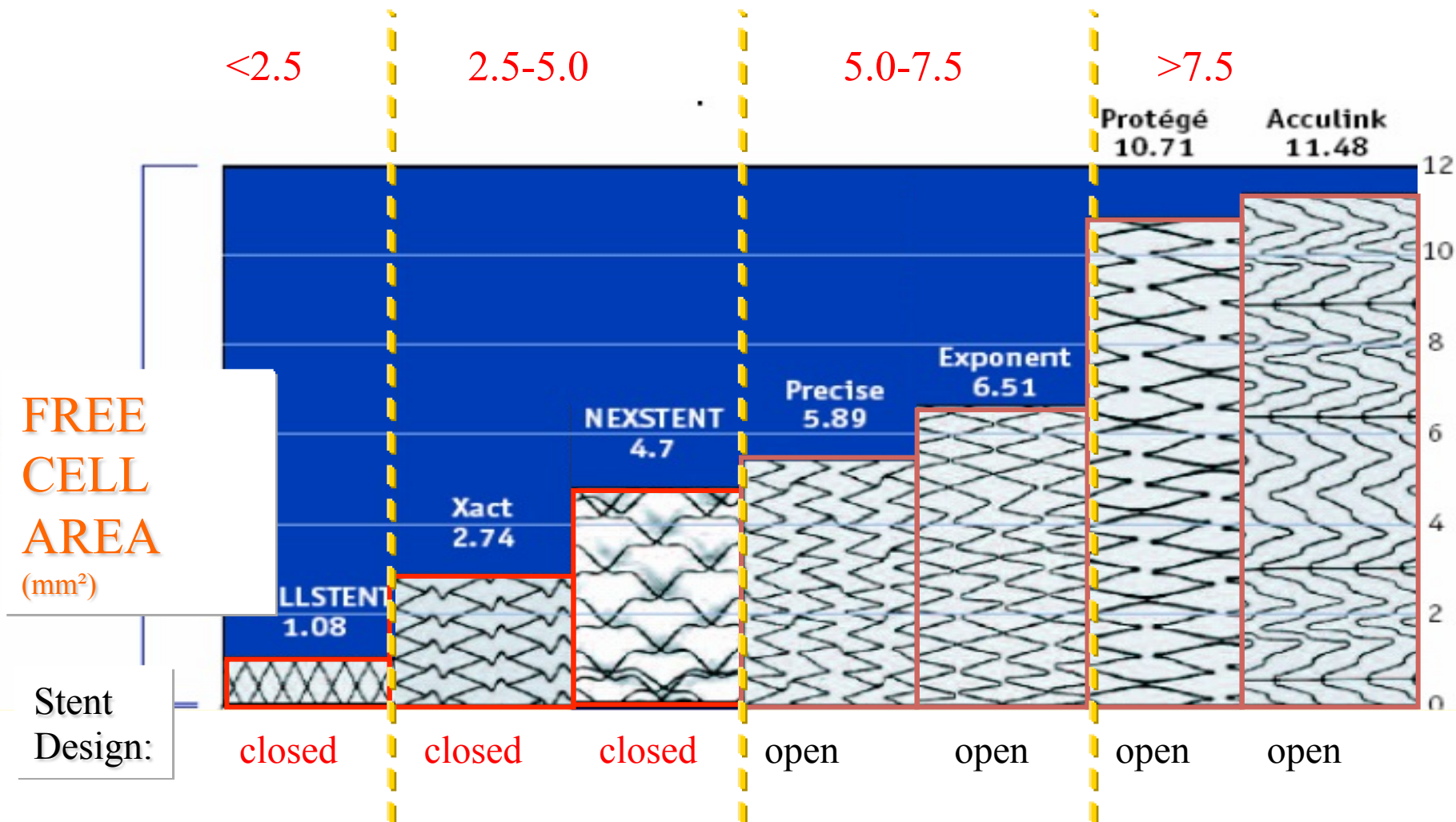
Stent design influence plaque containment, vessel recoil and geometry



Courtesy of M. Makaroun, University of Pittsburg. Courtesy of K. Balzer, Mulheim

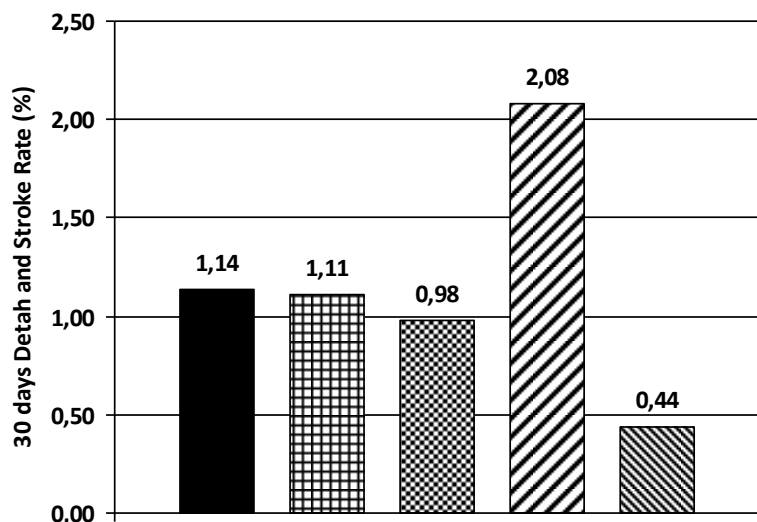


"Free cell area" based analysis

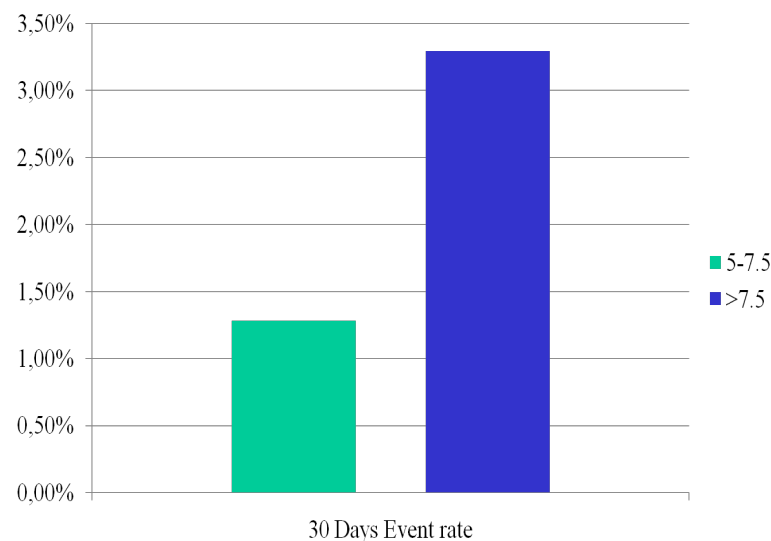




European multicenter **r**etrospective **R**egistry evaluating the outcomes at 30 days of **CAS** procedures in 8 different centers (**ERCAS**) (N=1611)



■ Stainless Steel ■ Nitinol ■ Nitinol Closed cell ■ Nitinol Open Cell ■ Nitinol Hybrid Cell



Thanks for your attention!



Montevergine Panorama