Left Main Revascularization: PCI vs. CABG The US Perspective

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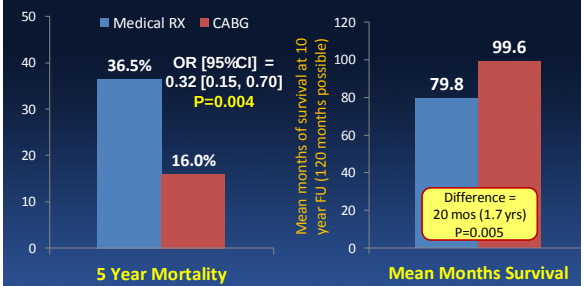
Conflict of Interest Disclosure

- Ajay J. Kirtane
  - None
  - Off-label use will be discussed

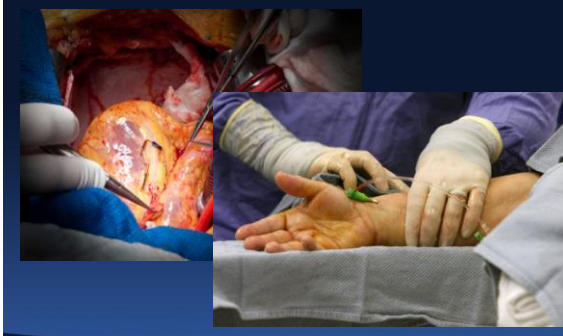
CABG vs. Medical Therapy in LM Ds.

150 pts with left main disease were randomized to CABG vs. medical therapy in 2 studies (VA and EU)



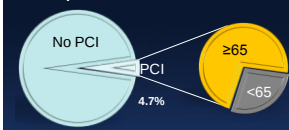
Yusuf S et al. Lancet 1994;344:563-70

Two Very Different Procedures…



Unprotected LM PCI in the USA
NCDR CathPCI, 2004 - 2008

Unprotected Left Main Disease

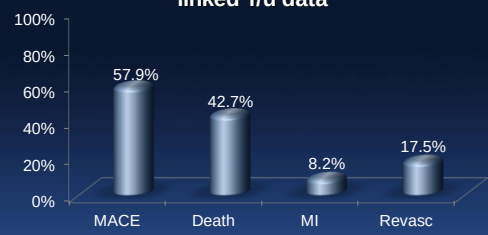


ULMCA PCI Cases/year	<6	6-15	>15
Centers (n)	660	25	8

	PCI (5,627)	No PCI (125,377)
Age	72 yrs	69 yrs
Female	41%	30%
Prior MI	33%	20%
CHF	81%	69%
Stroke	21%	15%
COPD	27%	19%
CKD	13%	8%
STEMI	13%	9%
Shock	16%	4%

J.M. Brennan et al, JACC 2012 and TCT 2012

Unprotected LM PCI: NCDR CathPCI
30-month Outcomes in 2765 pts with linked f/u data



<20% IVUS Use
Single stent in 40% of cases

J.M. Brennan et al, JACC 2012 and TCT 2012

Surgical Candidacy and Selection Bias in National Observational Registries: Case Study Using LMCA PCI

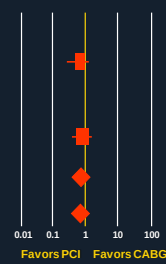
"Surgical ineligibility" independently conferred a 5-fold higher risk of mortality not accounted for by:

- *NCDR risk score*
- *STS risk score*
- *Euroscore*

McNulty et al. JACC CV Intv 2011

PCI vs. CABG for Left Main Disease Meta-analysis of 4 RCTs, 1,611 Patients
1-Year Death, MI or Stroke

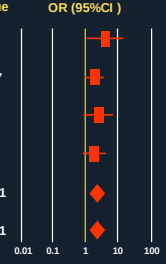
	PCI	CABG	OR (95%CI)	p-Value
LEMANS				
SYNTAX left main	25/355	31/336	0.75 (0.43-1.29)	0.29
Boudriot et al.				
PRECOMBAT	10/300	12/300	0.83 (0.35-1.95)	0.66
Fixed effects estiamate	5.3% (35/655)	6.8% (43/636)	0.77 (0.48-1.22)	0.26
Random effects estimate			0.77 (0.48-1.22)	0.26
I^2=0%				



Capodanno et al, JACC 2011;58:1426-32

PCI vs. CABG for Left Main Disease Meta-analysis of 4 RCTs, 1,611 Patients
1-Year Repeat Revascularization

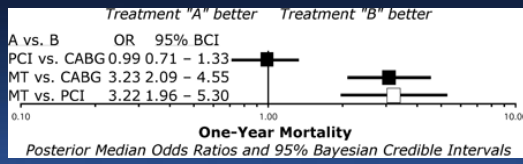
	PCI	CABG	OR (95%CI)	p-Value
LEMANS	15/52	5/53	3.89 (1.30-11.68)	0.02
SYNTAX left main	45/355	22/336	2.07 (1.22-3.53)	0.007
Boudriot et al.	14/100	6/101	2.58 (0.95-7.01)	0.06
PRECOMBAT	18/300	10/300	1.85 (0.84-4.08)	0.13
Fixed effects estiamate	11.4% (92/807)	5.4% (43/790)	2.25 (1.54-3.28)	<0.001
Random effects estimate			2.25 (1.54-3.28)	<0.001
I^2=0%				



Capodanno et al, JACC 2011;58:1426-32

Bayesian Cross-Design and Network Meta-Analysis of LMCA Revascularization

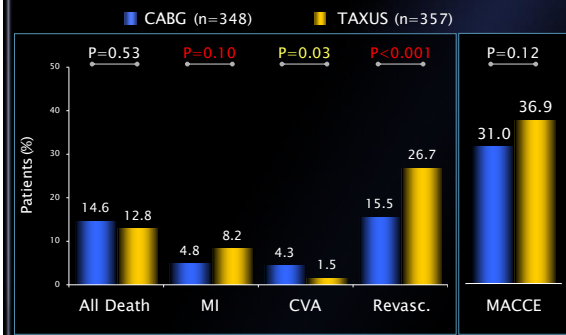
- 12 studies (4 RCTs, 4 observational matched studies and 4 other cohort studies) comparing CABG with PCI (N=4,574)
- 7 studies (2 RCTs and 5 observational studies) comparing CABG with MT (N=3,224)



J. Bittl et al, Circulation 2013

Left Main Disease
5-year Outcomes (N=705)

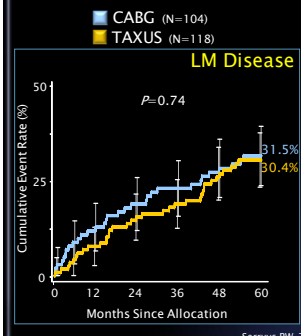
SYNTAX



Mohr FW et al. Lancet 2013;381:629-38

MACCE to 5 Years by SYNTAX Score Tercile
***LM Subset** Low Scores 0-22*

SYNTAX

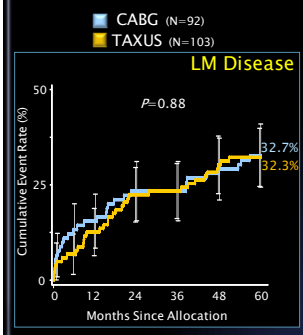


	CABG	PCI	*P* value
Death	11.3%	7.0%	0.28
CVA	4.1%	1.8%	0.28
MI	3.1%	6.2%	0.32
Death, CVA or MI	15.2%	13.9%	0.71
Revasc.	20.3%	23.0%	0.65

Serruys PW. TCT2012

MACCE to 5 Years by SYNTAX Score Tercile

LM Subset Intermediate Scores 23–32

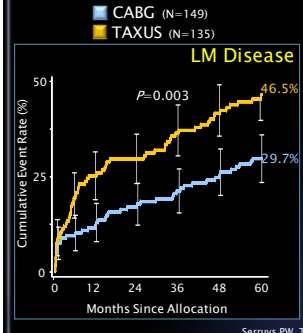


	CABG	PCI	*P* value
Death	19.3%	8.9%	0.04
CVA	3.6%	1.0%	0.23
MI	4.6%	6.0%	0.71
Death, CVA or MI	24.9%	15.7%	0.11
Revasc.	16.6%	22.2%	0.40

Serruys PW. TCT2012

MACCE to 5 Years by SYNTAX Score Tercile

LM Subset High Scores ≥33

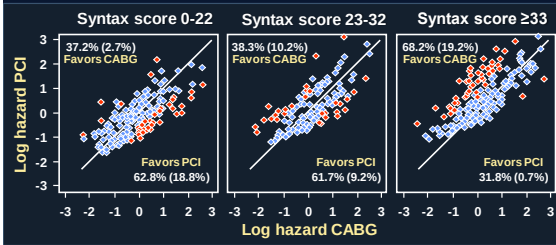


	CABG	PCI	*P* value
Death	14.1%	20.9%	0.11
CVA	4.9%	1.6%	0.13
MI	6.1%	11.7%	0.13
Death, CVA or MI	22.1%	26.1%	0.40
Revasc.	11.6%	34.1%	<0.001

Serruys PW. TCT2012

SYNTAX Score I vs II: The SYNTAX Trial

LM pts: Risk Predictions by Tertiles of the SYNTAX Score



PCI favored	PCI favored	PCI favored
Overall 62.8%	Overall 61.7%	Overall 31.8%
>95%CI 18.8%	>95%CI 9.2%	>95%CI 0.7%

Farooq V et al. Lancet 2013;381:639–50

ST and GO in Prespecified Patient Subsets at 5 years

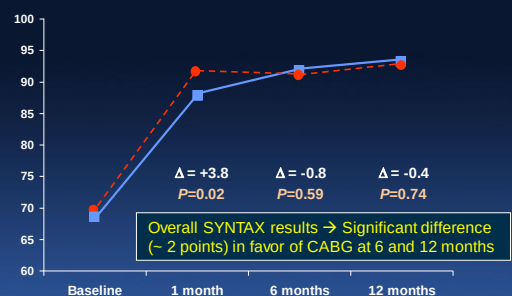
CABG Arm	3-vessel Disease (n=549)	Left Main Disease (n=348)	Diabetes (n=221)
Graft Occlusion	3.7% (n=18)	4.4% (n=14)	4.3% (n=8)

PCI Arm	3-vessel Disease (n=546)	Left Main Disease (n=357)	Diabetes (n=231)
Stent Thrombosis	5.8% (n=30)	5.1% (n=17)	5.3% (n=11)

Per Protocol KM Event Rate

RCT ITT pts; site-reported data

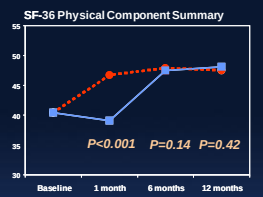
LM Subset – Primary QOL Endpoint: SAQ – Angina Frequency

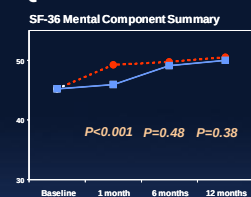


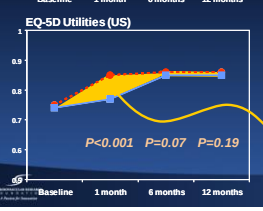
Overall SYNTAX results → Significant difference (~ 2 points) in favor of CABG at 6 and 12 months

Cohen DJ. LM Summit NYC Feb. 2011.

LM Subset – Generic QOL and Utilities



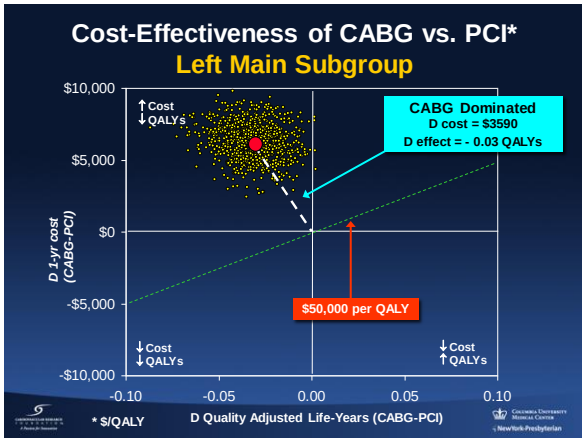


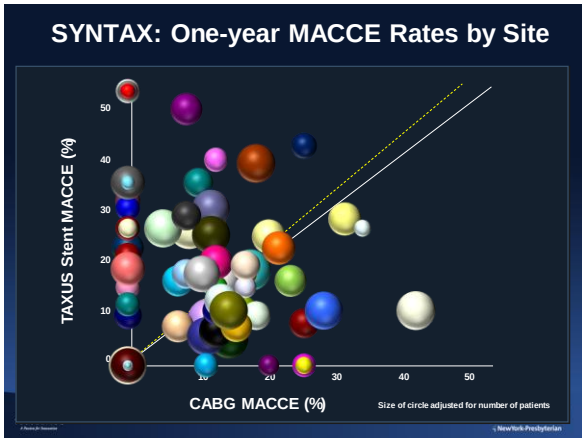


PCI

CABG

Quality Adjusted Life Years
Δ = 0.03 (P<0.01)





2012 SIHD / 2011 PCI Guidelines: Heart Team Approaches to Revascularization Decisions

I IIa IIb III
C

A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD.

I IIa IIb III
B

Calculation of the STS and SYNTAX scores is reasonable in patients with unprotected left main and complex CAD.

Helping Cardiovascular Professionals Learn. Advance. Heal.

American Heart Association.

2012 SIHD / 2011 PCI Guidelines: Left Main CAD Revascularization

CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main coronary artery stenosis.

PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) ULMCA with **both**:

- Anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left main CAD)
- Clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality 5%).

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2012 SIHD / 2011 PCI Guidelines: Left Main CAD Revascularization

PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) ULMCA with **both**:

- Anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low–intermediate SYNTAX score of <33, bifurcation left main CAD)
- Clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate–severe COPD, disability from previous stroke, or previous cardiac surgery; STS-predicted risk of operative mortality >2%).

Helping Cardiovascular Professionals Learn. Advance. Heal.

American Heart Association.

2012 SIHD / 2011 PCI Guidelines: Left Main CAD Revascularization

Harm

PCI to improve survival should not be performed in stable patients with significant (≥50% diameter stenosis) unprotected left main CAD who have unfavorable anatomy for PCI and who are good candidates for CABG.

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American Heart Association.

2012 SIHD / 2011 PCI Guidelines: Left Main CAD Revascularization

PCI to improve survival is reasonable in patients with UA/NSTEMI when an unprotected left main coronary artery is the culprit lesion and the patient is not a candidate for CABG.

PCI to improve survival is reasonable in patients with acute STEMI when an unprotected left main coronary artery is the culprit lesion, distal coronary flow is less than TIMI grade 3, and PCI can be performed more rapidly and safely than CABG.

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American Heart Association.

2012 AUC for Coronary Revascularization Focused Update

	CABG	PCI
Two-vessel CAD with proximal LAD stenosis	A	A
Three-vessel CAD with low CAD burden (i.e., three focal stenosis, low SYNTAX score)	A	A
Three-vessel CAD with intermediate to high CAD burden (i.e., multiple diffuse lesions, presence of CTO, or high SYNTAX score)	A	U
Isolated left main stenosis	A	U
Left main stenosis and additional CAD with low CAD burden (i.e., one to two vessel additional involvement, low SYNTAX score)	A	U
Left main stenosis and additional CAD with intermediate to high CAD burden (i.e., three vessel involvement, presence of CTO, or high SYNTAX score)	A	I

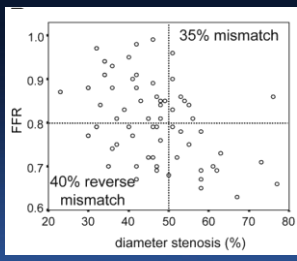
Both previously "Inappropriate"

M. Patel et al, JACC 2012

PCI is Better Now than it Was in SYNTAX and FREEDOM!

Visual-Functional Mismatch in LMCA Lesions: FFR vs. QCA

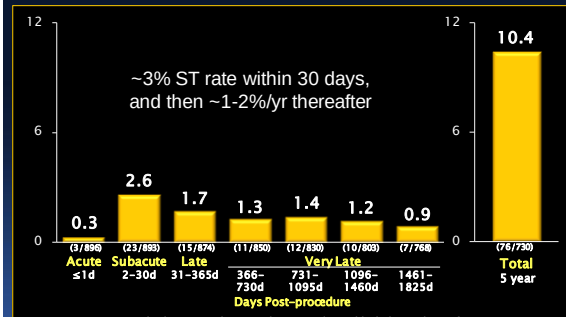
63 LMCA lesions included in overall analyses



- LMCA lesions had a greater frequency of reverse mismatch (underestimation), but lower mismatch (overestimation)
- The presence of plaque rupture influenced the assessment of mismatches

S-J Park et al, JACC CV Intv 2012

SYNTAX: Definite/Probable ARC Stent Thrombosis to 5 Years *(Per Patient)*



Rate was ~ same in the LM and 3VD cohorts, and roughly independent of Syntax Score

Serruys PW. TCT2012

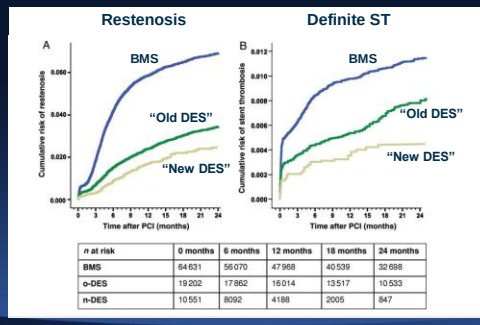
SYNTAX: Location of Stent Thrombosis *(Per Vessel)*

87.2% of 1st ST occurred in vessels treated at the index procedure

Note: Some ST in multiple vessels

Serruys PW. TCT2012

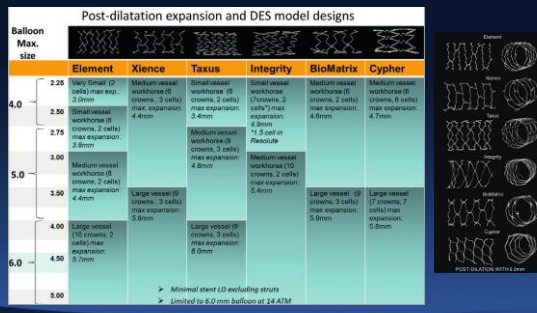
SCAAR Registry (94,384 pts)
Adjusted Risks of Adverse Events at 2 yrs



n at risk	0 months	6 months	12 months	18 months	24 months
BMS	64 631	56 070	47 968	40 539	32 698
o-DES	19 202	17 862	16 014	13 517	10 533
n-DES	10 551	8092	4188	2005	847

Sarno et al, Eur Heart J 2012

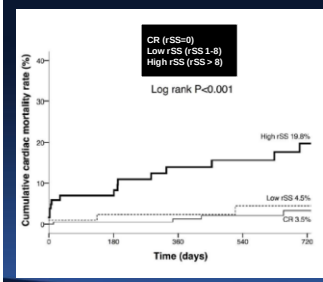
Maximal Stent Expansion Evaluation *in vitro* by MicroCT (6.0 mm at 14 atm)



N. Foin et al, Eurointervention 2012

Association of Residual SYNTAX Score with Outcomes after LMCA PCI

CUSTOMIZE Registry: 400 pts undergoing LM PCI



- Residual SYNTAX score had better calibration with outcomes than baseline SYNTAX score
- Use of both scores likely performs best

Capodanno et al, CCI 2012

How to Improve Left Main PCI Outcomes

- Use best in class DES
- Optimal pharmacotherapy
  - Thienopyridine pre-loading
  - Statin pre-loading
  - Bivalirudin anticoagulation
- IVUS/FFR to assess the intermediate LM lesion
- FFR to avoid unnecessary stenting, but also for ischemia-based optimal/ complete revascularization
- IVUS guided LM stenting
- Optimal LM stent technique
  - 1- vs 2-stent techniques
  - Debulking
  - Hemodynamic support
  - Staging
  - ?Angiographic FU

Adapted from G. Stone

EXCEL: Study Design

3600 pts with unprotected left main disease

@ 165 international sites

SYNTAX score ≤32
Consensus agreement by heart team

No (N=1000) → **Enrollment registry**

Yes (N=2600) → R

- **PCI (Xience Prime) (N=1300)**
- **CABG (N=1300)**

Clinical follow-up: 1 mo, 6 mo and yearly through 5 years

NOBLE

Nordic-Baltic-British Left Main Revascularization Study

1200 pts with left main disease and ≤3 'non-complex' additional lesions

Randomize

- **PCI (recommended Biomatrix)**
- **CABG**

Primary Endpoint: Death, stroke, non-index MI, or new revascularization at 2 years (follow-up to 5 years)

VAD for Left Main interventions

CASE REPORT

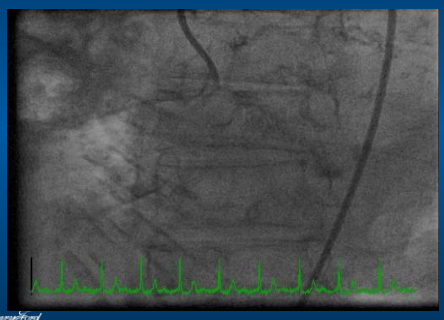
William W. O'Neill, MD
Henry Ford Health System
Medical Director
Center for Structural Heart Disease

Clinical History

- 93 y.o. w, female with class IV dyspnea. Evaluated for TAVR
- Diagnostic cath reveals complex distal LMCA calcified lesion
- Patient scheduled for Impella support ROTO – STENT of LMCA

Cath 4.22 # 12 LMCA

Cath 4.22 # 15 RCA

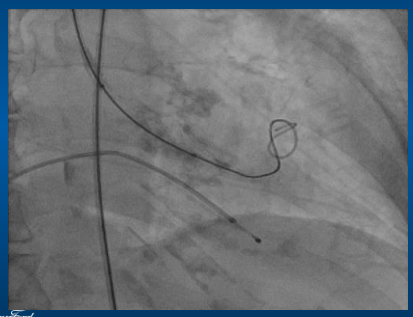


CENTER FOR STRUCTURAL HEART DISEASE - HENRY FORD HOSPITAL

ROTO STENT LMCA 4.24 # 2

CENTER FOR STRUCTURAL HEART DISEASE - HENRY FORD HOSPITAL

ROTO STENT LMCA 4.24 # 6



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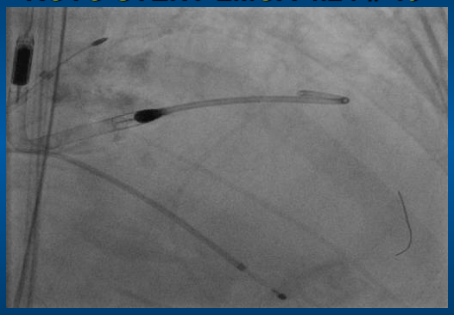
ROTO STENT LMCA 4.24 # 10



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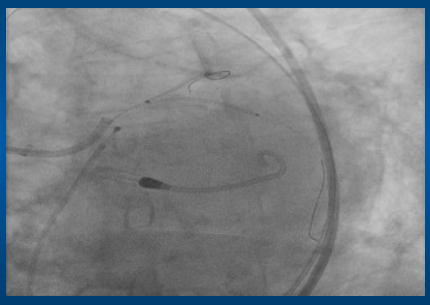
ROTO STENT LMCA 4.24 # 22



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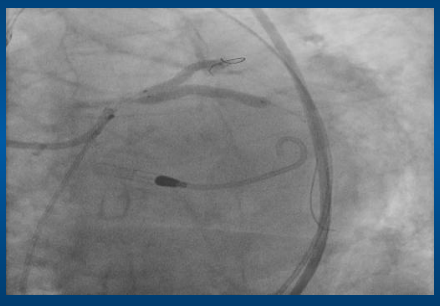
ROTO STENT LMCA 4.24 # 24



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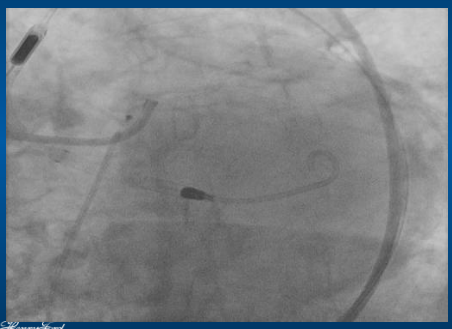

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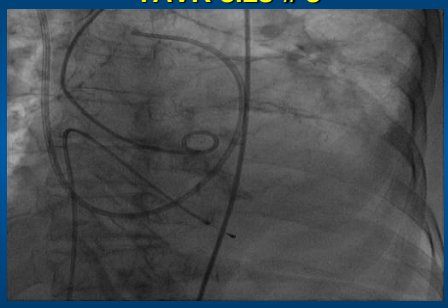
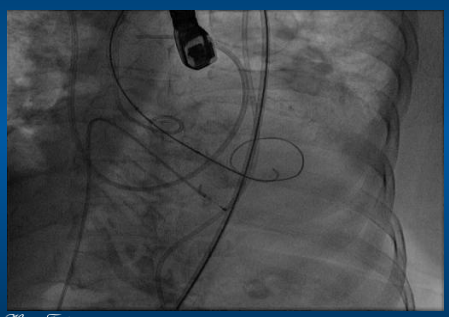
TAVR 5.23 # 5



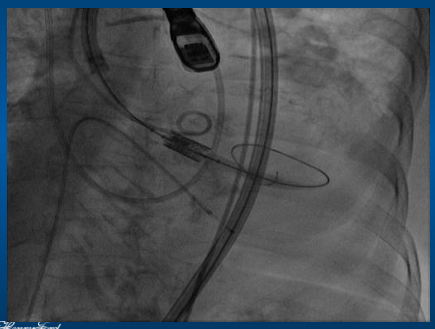
CENTER FOR STRUCTURAL HEART DISEASE - HENRY FORD HOSPITAL

TAVR 5.23 # 7



CENTER FOR STRUCTURAL HEART DISEASE - HENRY FORD HOSPITAL

TAVR 5.23 # 10



CENTER FOR STRUCTURAL HEART DISEASE - HENRY FORD HOSPITAL

TAVR 5.23 # 24

CENTER FOR STRUCTURAL HEART DISEASE - HENRY FORD HOSPITAL

Left Main PCI via Radial

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Disclosure Statement of Financial Interest

I, ***Philippe Généreux*** **DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.**

LM PCI via radial is possible and safe

Transradial Versus Transfemoral Method of Percutaneous Coronary Revascularization for Unprotected Left Main Coronary Artery Disease: Comparison of Procedural and Late-Term Outcomes

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Beijing, China; and Atlanta, Georgia

J Am Coll Cardiol Intv 2010;3:1035– 42

LM PCI via radial is possible and safe

17 months

Table 3. In-Hospital and Late Clinical Outcomes

	Transradial (n = 353)	Transfemoral (n = 468)	p Value
Late clinical outcomes			
MACE (%)	36 (10.2)	43 (9.2)	0.63
Cardiac death (%)	5 (1.4)	8 (1.7)	0.74
Nonfatal MI (%)	14 (4.0)	12 (2.6)	0.26
Fatal MI	1 (0.3)	5 (1.1)	0.24
Overall TVR (%)	28 (7.9)	35 (7.5)	0.89
LM-specific TVR (%)	20 (5.7)	27 (5.8)	0.95
Stent thrombosis (%)	4 (1.1)	12 (2.6)	0.13
Early (%)	1 (0.3)	3 (0.6)	0.64
Late (%)	2 (0.6)	5 (1.1)	0.71
Very late (%)	1 (0.3)	4 (0.9)	0.40

TIMI major and minor bleeding
TR=0.6% vs. TF= 2.8%, p=0.02

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LM PCI via radial is possible and safe

Table 1. Baseline Clinical and Angiographic Characteristics

	Transradial (n = 353)	Transfemoral (n = 468)	p Value
Lesion location			0.56
Isolated UPLM	78 (22)	89 (19)	
UPLM with 1 vessel	71 (20)	108 (23)	
LM with 2 vessel	120 (34)	168 (36)	
LM with 3 vessel	84 (24)	103 (22)	
UPLM lesion distribution			<0.01
Ostium	71 (20)	56 (12)	
Shaft	85 (24)	98 (21)	
Bifurcation	197 (56)	314 (67)	

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LM PCI via radial is possible and safe

Table 2. Procedural Characteristics and Outcomes

	Transradial (n = 353)	Transfemoral (n = 468)	p Value
UPLM treatment characteristics			
LM PCI technique (%)			<0.01
Single stent	256 (81)	290 (62)	
Bifurcation stenting	67 (19)	178 (38)	
DES type			0.11
Sirolimus-eluting	280 (79)	349 (75)	
Paclitaxel-eluting	73 (21)	119 (25)	
Guiding catheter size, F	6.1 ± 0.4	6.9 ± 0.8	<0.01
Final kissing balloon (%)	176 (50)	346 (74)	<0.01
Procedural outcomes			
UPLM angiographic success (%)	350 (99)	463 (99)	1.00
Procedural success (%)	342 (97)	450 (96)	0.57
Procedure time, min	61.6 ± 10.9	62.7 ± 10.2	0.13
Fluoroscopy time, min	25.0 ± 8.7	26.1 ± 8.5	0.08
Contrast volume, ml	311 ± 51	320 ± 65	0.02

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Case #1; Clinical history

- 64 yold female 70 kg 5'5''
- Severe COPD on steroids
- Rest angina for 3 weeks on/off
- Presented with dyspnea NYHA ¾
- Troponin 3.8
- No EKG changes

Clinical history

- Angiogram July 15 2013
  - Right radial
  - 6 F diagnostic
- Ostial left main 90%
- Heavily calcified
- SYNTAX score: 13
- EF 55%

Clinical history

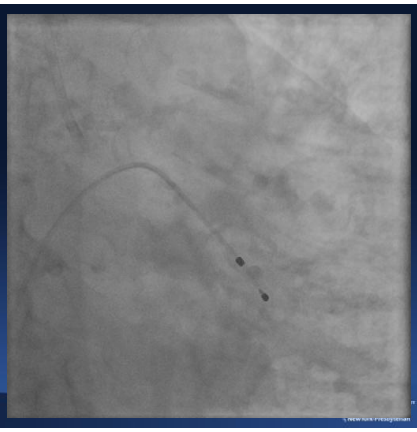
- Sent to CCU
- Discussion with patient: ***EXCEL trial proposed***
- Evaluation by heart team: deemed good surgical candidate
- Patient refused surgery and want PCI
- Bring to cath lab July 18th for PCI LM

Strategy

- Right radial
- 6 F →7 F chosen because of Rotablation using burr 1.75
- 4 F right femoral artery (back up)
- 6 F right femoral vein (temporary pace maker)
- Heparin/ASA/clopidogrel

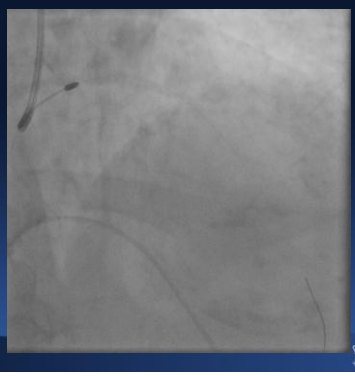
JL-3.5 7F

Heparin 8,000 U

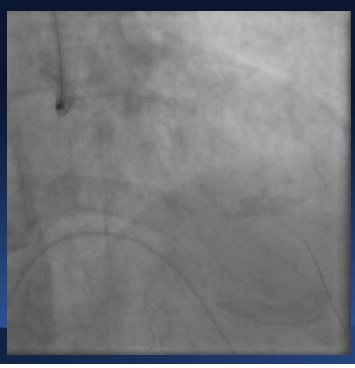


Rota Stiff wire

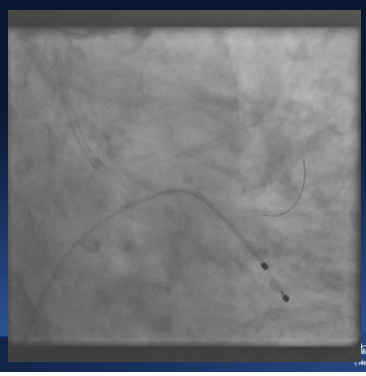
Burr 1.75 x 160 000 RPM x 2



Post Rotablation



Post Rota

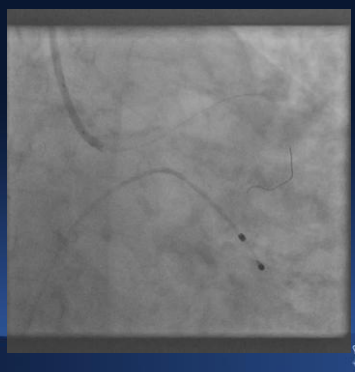


NC 3.0 ad 20 atm

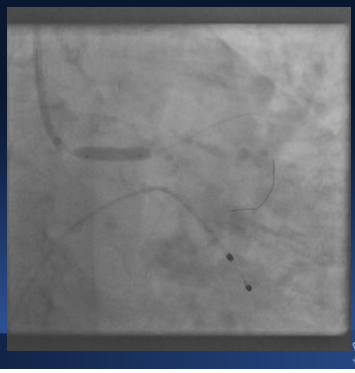
Post pre-dilatation

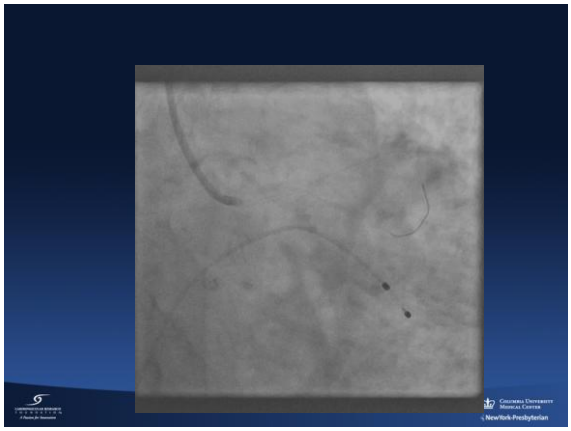
Xience 3.5 x 18 mm 16 atm

Post Xience 3.5 x 18 mm

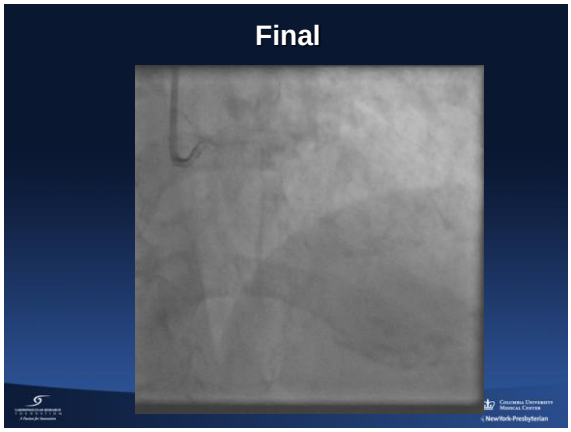


NC 4.0 ad 18 atm





Final



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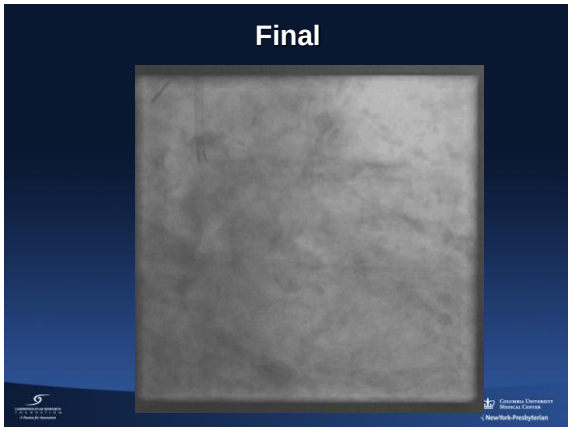
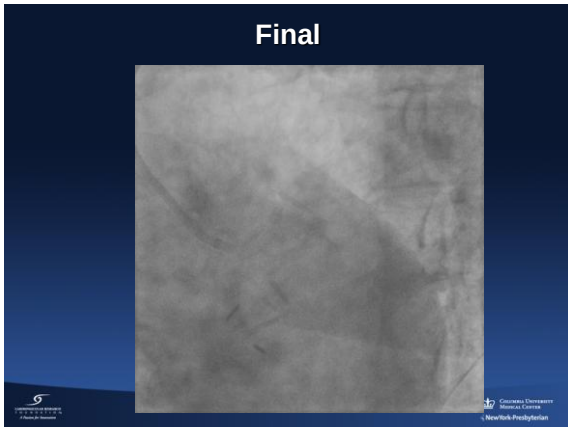
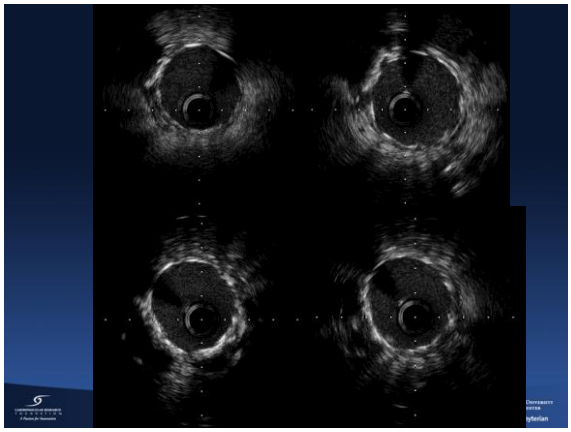
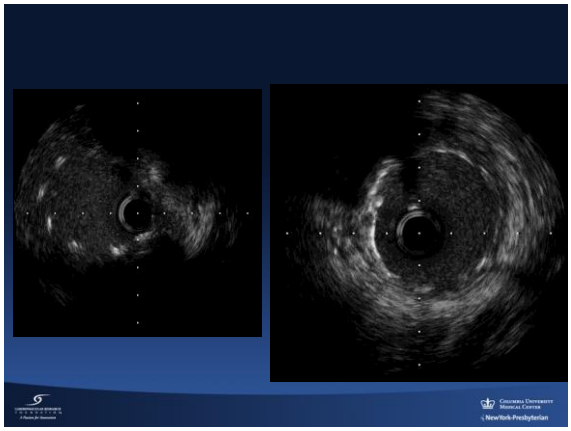
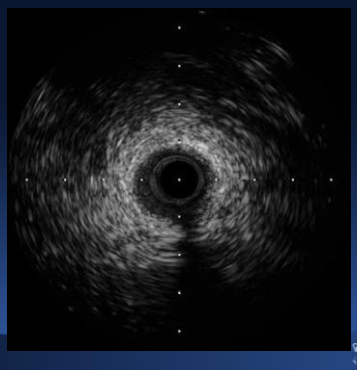



Final





Final IVUS



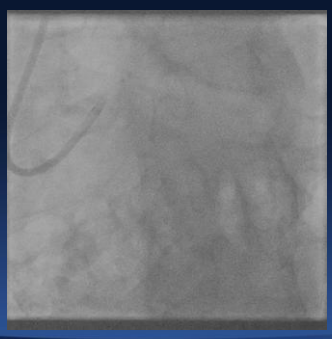
Key points

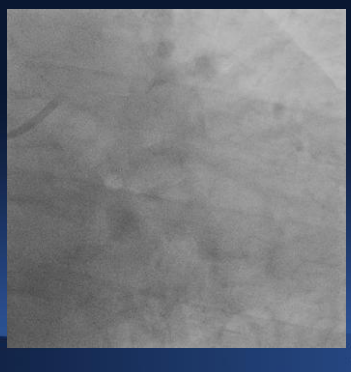
- LM radial PCI is possible and safe
- Most of the PCI could be achieve using 6 F; 7 F is possible in most of the patients
- *Advantages:*
  - if IABP or other hemodynamic support modalities needed, save 1 femoral artery stick
  - Decrease access site related bleeding

Case # 2

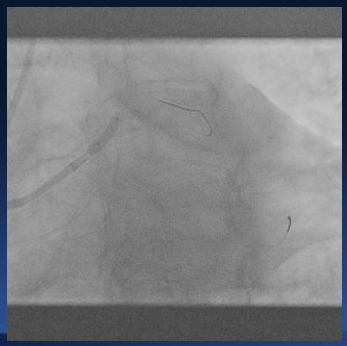
- 78 yo M
- HBP
- NSTEMI
- LM 1-1-1, LAD prox-mid diffuse-D1 1-1-1
- Patient refused surgery

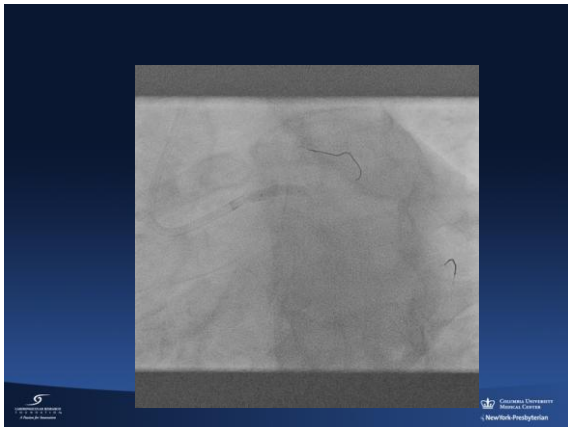
EBU 3.5 6F right Radial

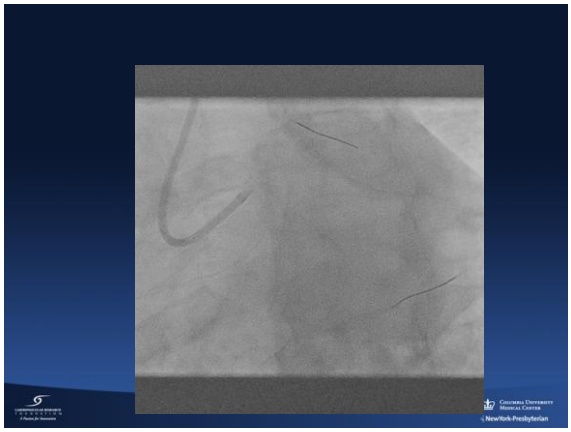


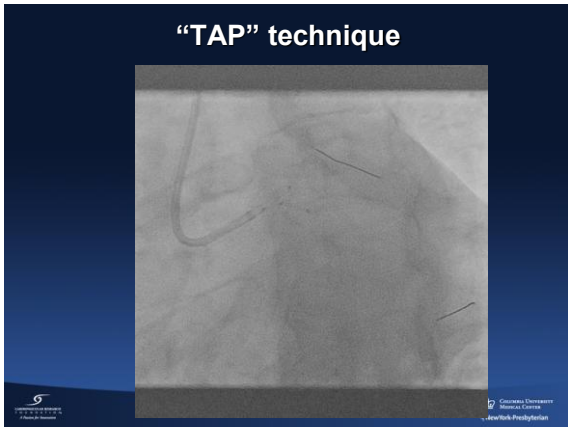


2 BMW 0.014/ Balloon 3.0 LAD

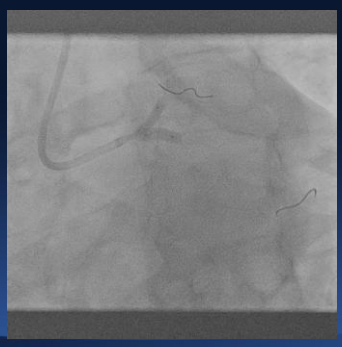


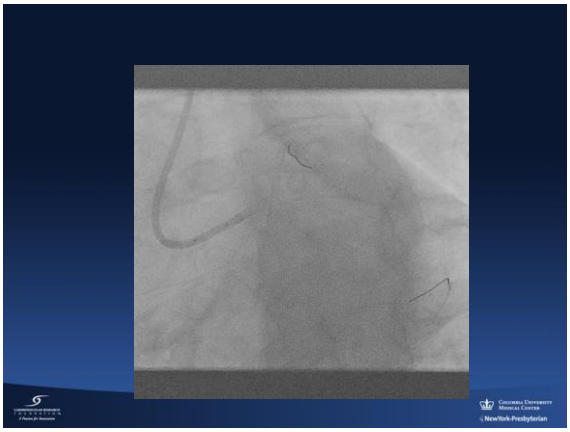




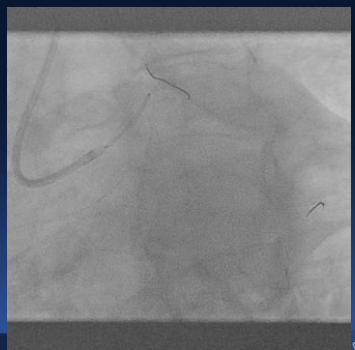

“TAP” technique

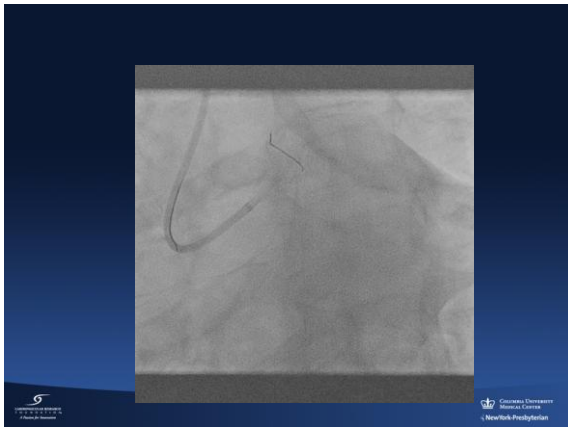
Xience 3.0x 12 mm LCx

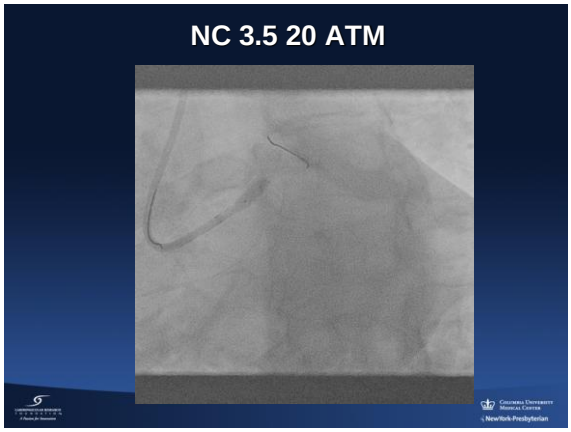


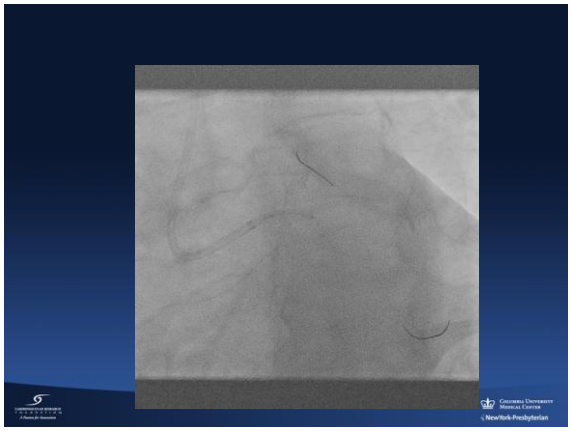


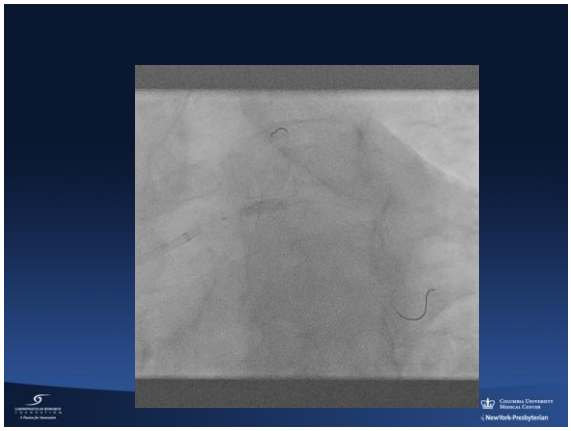
Xience 3.5x23 mm

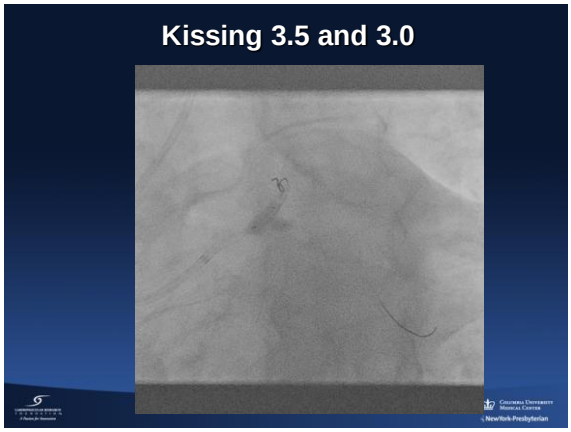


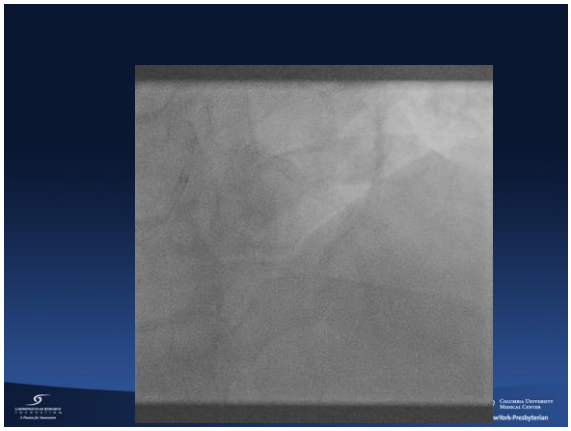


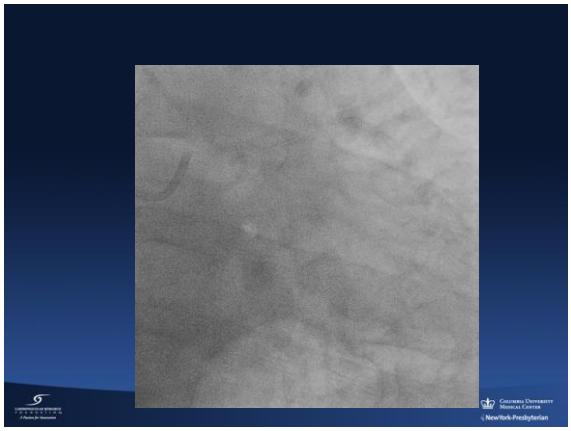

NC 3.5 20 ATM

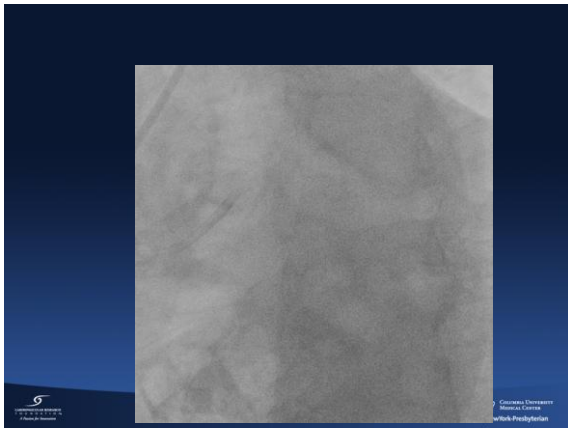





Kissing 3.5 and 3.0







With 6F you can do

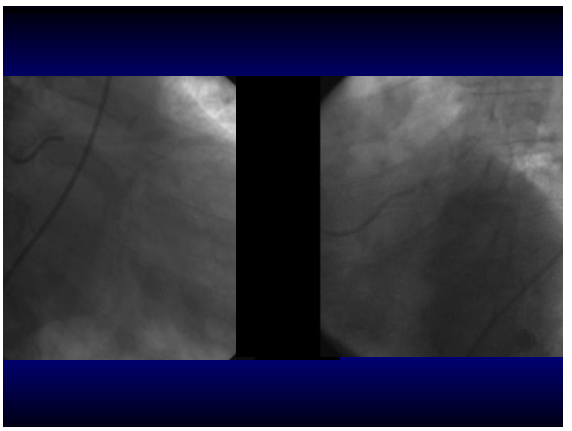
- 3 wires and 1 balloon
- 2 balloons
- 1 stent 1 balloon
  - Stent always advanced first (out of the guide, to leave only stent shaft)
- IVUS
- Anchoring balloon technique

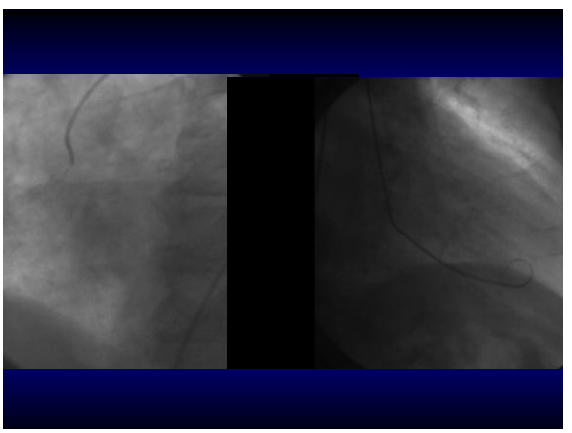
With 6F you cannot do

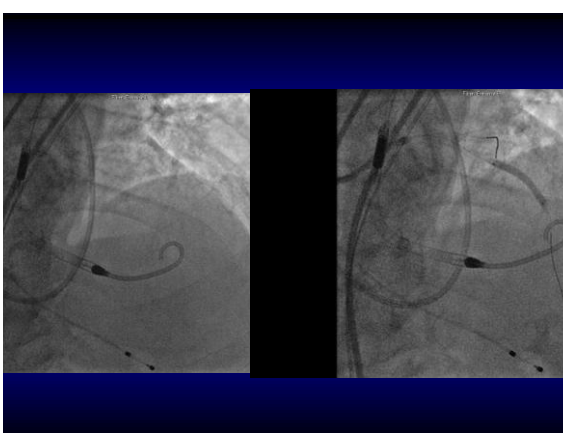
- Implantation of 2 stents at the same time (SKS)

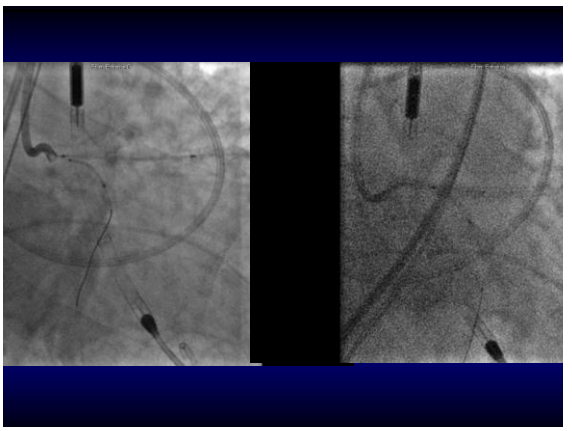
However

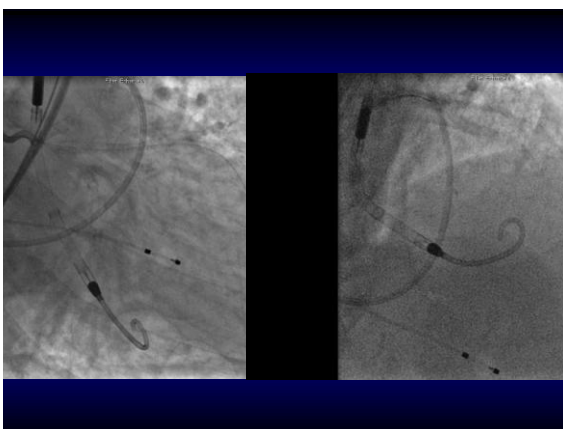
- Sequential SKS is possible
  - First stent delivered with balloon on the other side
  - Second stent delivered with balloon in the previously deployed stent
  - Final kissing balloon inflation

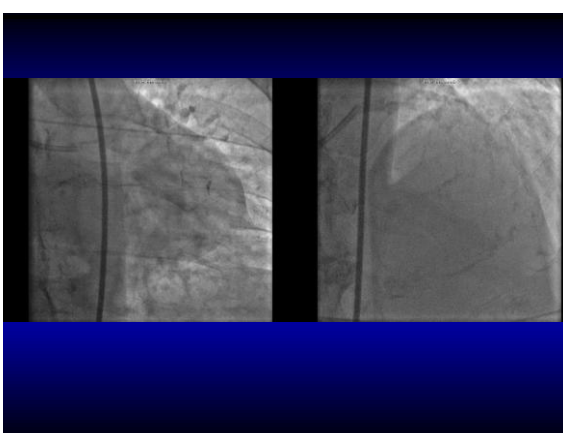


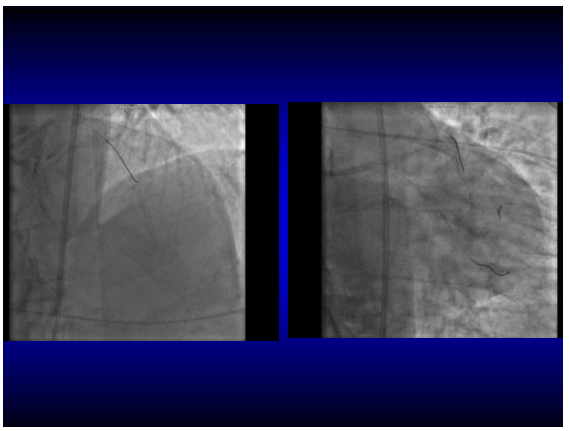


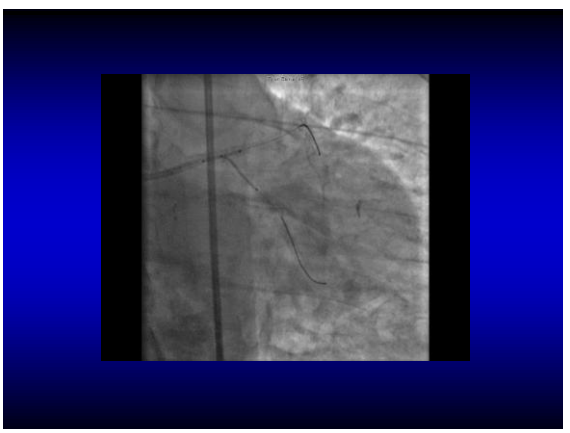


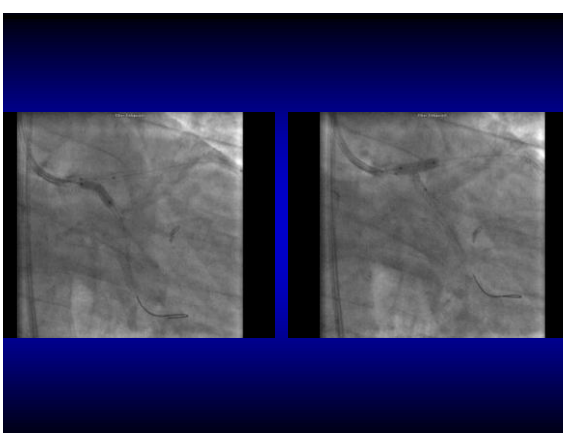


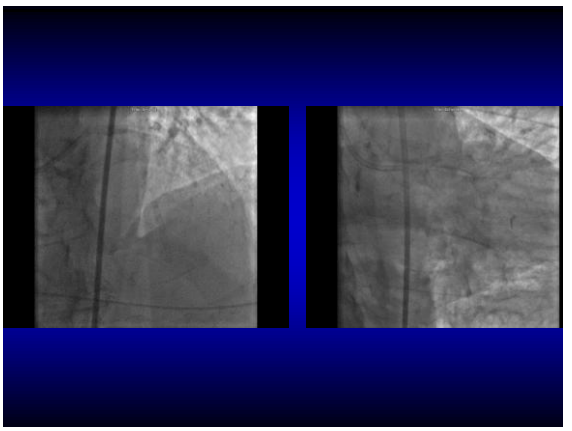












Thank You!