



Vascular Access Complications: Screening And Treatment

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial Interest /arrangement or affiliation with the organization(s) listed below

Affiliation/Financial Relationship

Company

Grant/ Research Support:

Consulting Fees/Honoraria:

**Edwards Lifesciences
(consultant & proctor)**

Major Stock Shareholder/Equity Interest:

Royalty Income:

Ownership/Founder:

Salary:

Intellectual Property Rights:

Other Financial Benefit:

Vascular Complications...

A potential disaster of TAVR

- Vascular complications is common after TAVR

- Main contributors

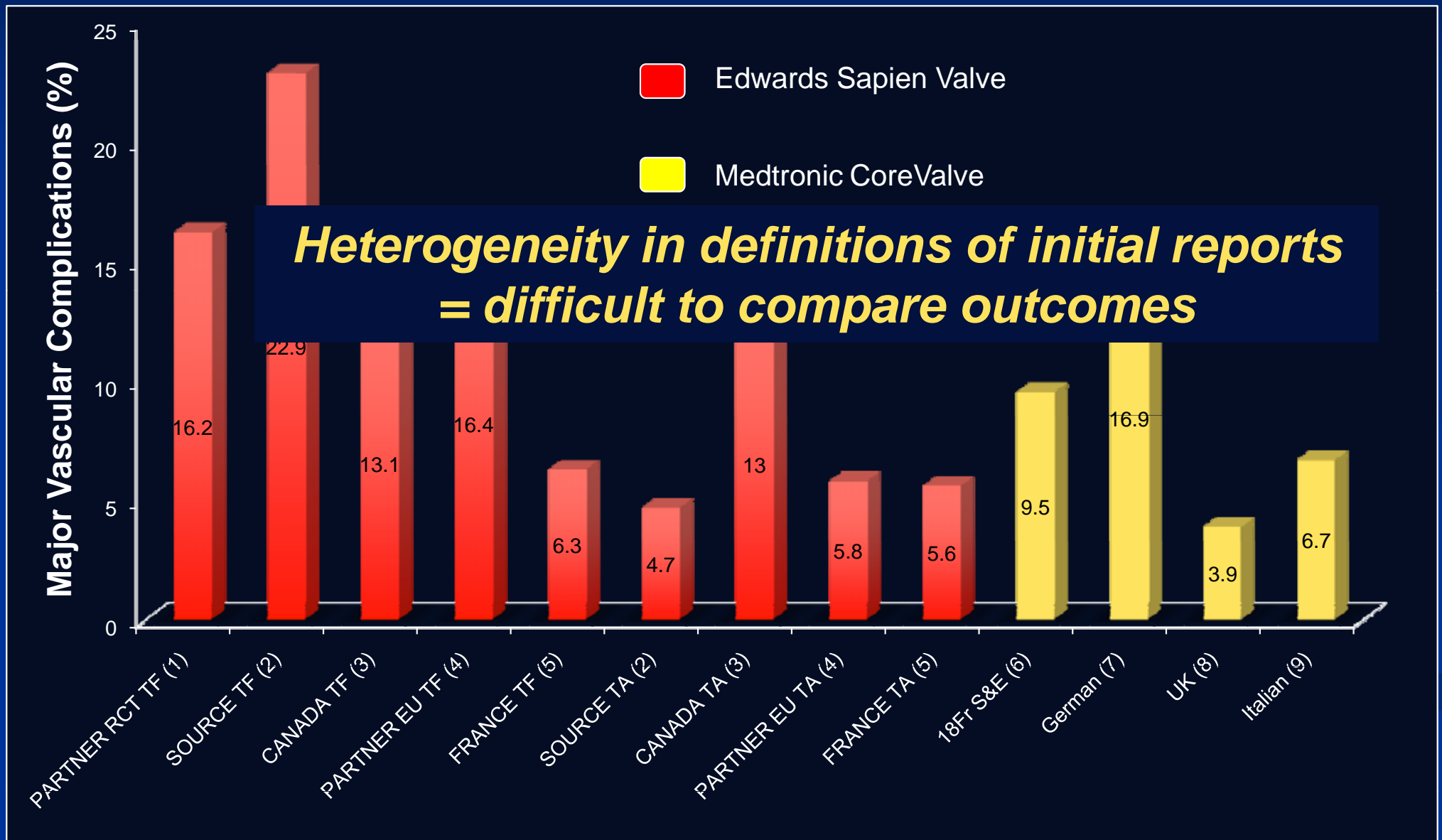
- Large sheaths
- Bulky devices
- Risky patient cohort

- Assoc with catastrophic consequences



HOW COMMON IS IT?

Incidence of Vascular Complications (before VARC definitions publication)



VARC – Major Vascular Complications

- Any thoracic aortic dissection
- Access site or access-related injury leading to:
 - Death
 - Need for significant blood transfusion $\geq 4U$
 - Irreversible end-organ damage
 - Unplanned percutaneous or surgical intervention
- Distal embolisation from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage

TAVR Outcomes - VARC Meta-Analysis

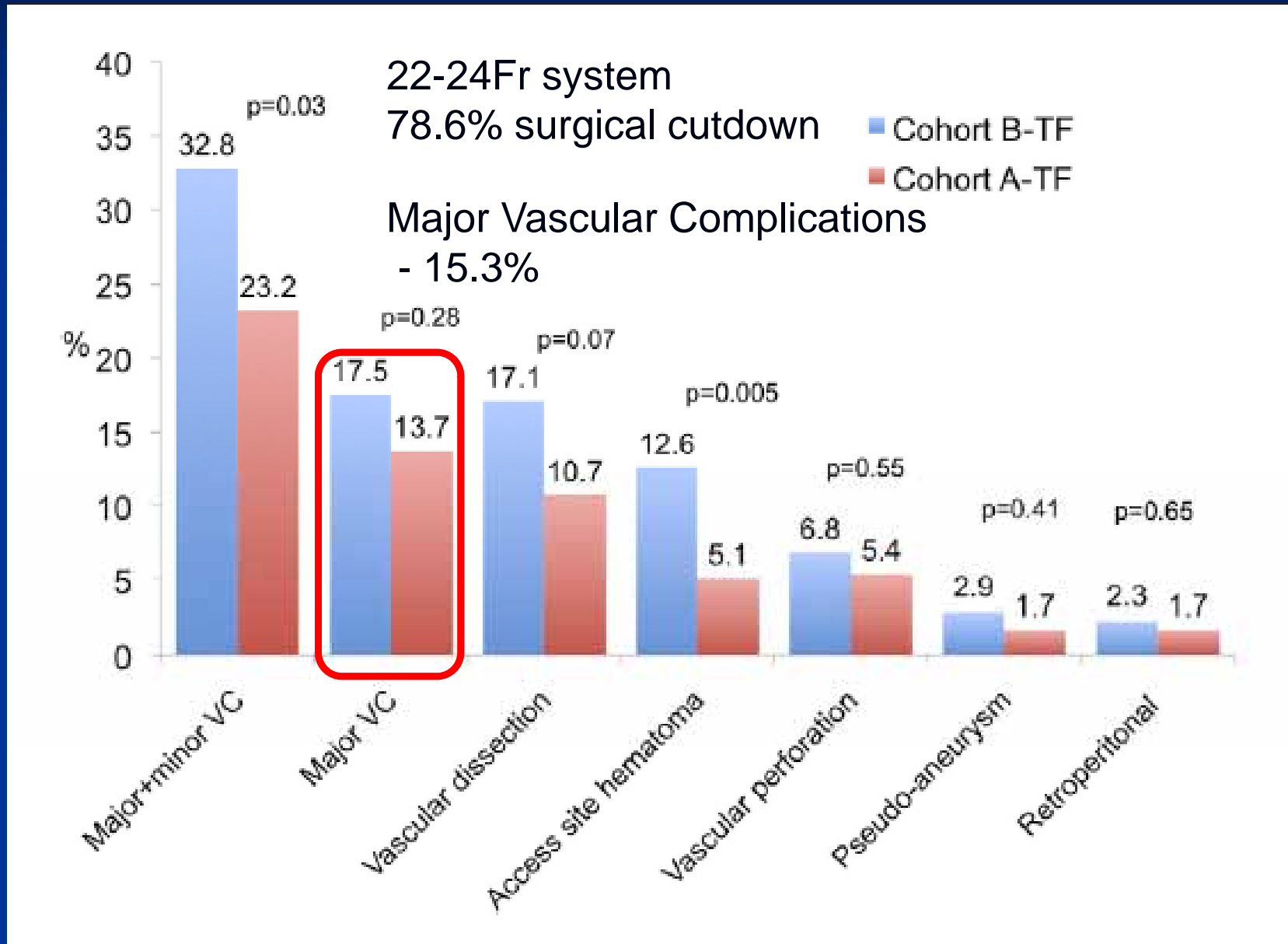
- 16 studies published Jan 2011 – Oct 2011
- 3,519 patients

<i>Endpoint</i>	<i>Pooled Estimate (%)</i>	<i>[95% CI]</i>
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Vascular events @ 30 days

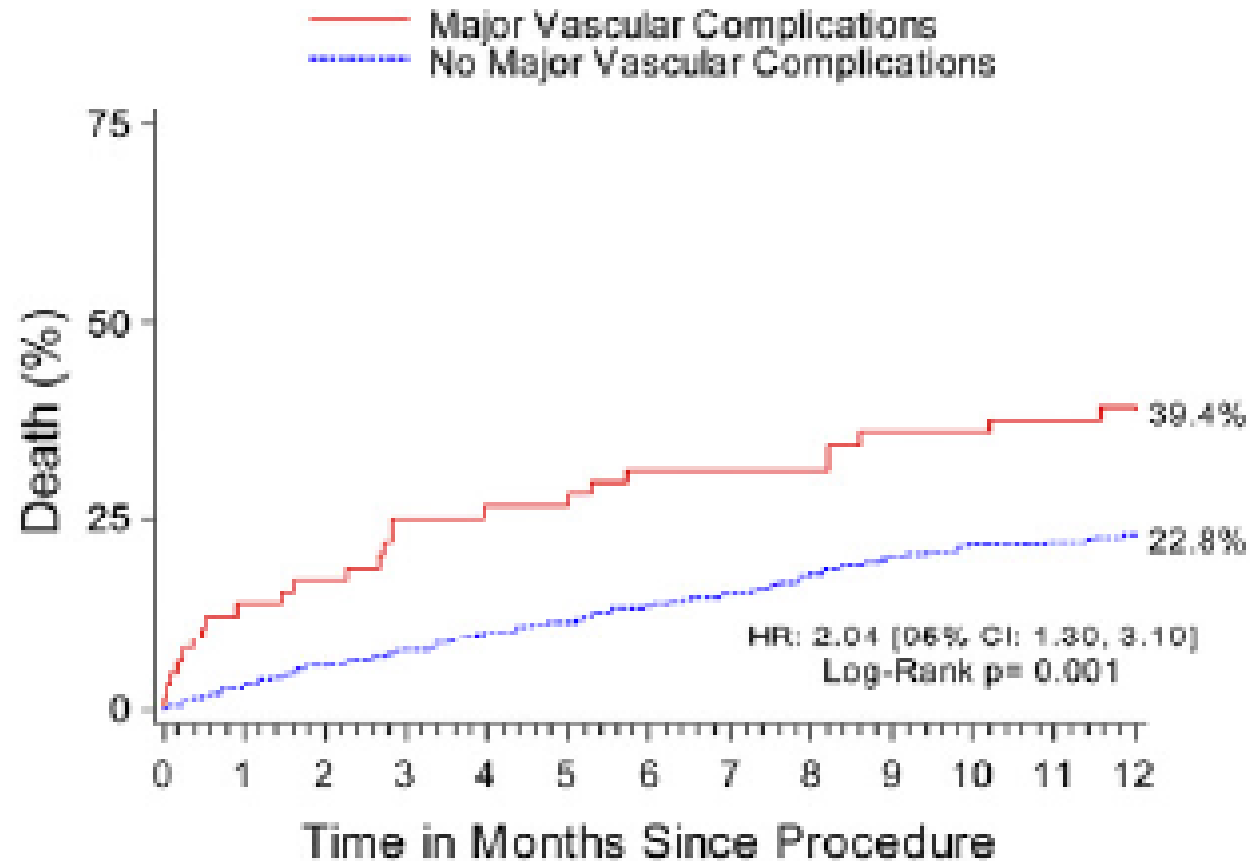
Major	11.9	[8.6, 16.4]
Minor	9.7	[6.7, 14.0]
All	18.8	[14.5, 24.3]

Vascular Complications in TF Cohorts of PARTNER Trial



Vascular Complications associated with Increased Mortality

A



Number at risk

Major VC	64	47	43	37
No Major VC	355	318	291	273

**CAN WE REDUCE VASCULAR
COMPLICATIONS?**

Predictors of Major Vascular Complications

	Hayashida	Van Miegheem	Genereux	Toggweiler
Female Gender		✓	✓	
Peripheral vascular disease				✓
High Sheath:Femoral Artery Ratio; Minimal artery diameter < sheath OD	✓			✓
Femoral Calcification on CT	✓			✓
Early experience	✓			

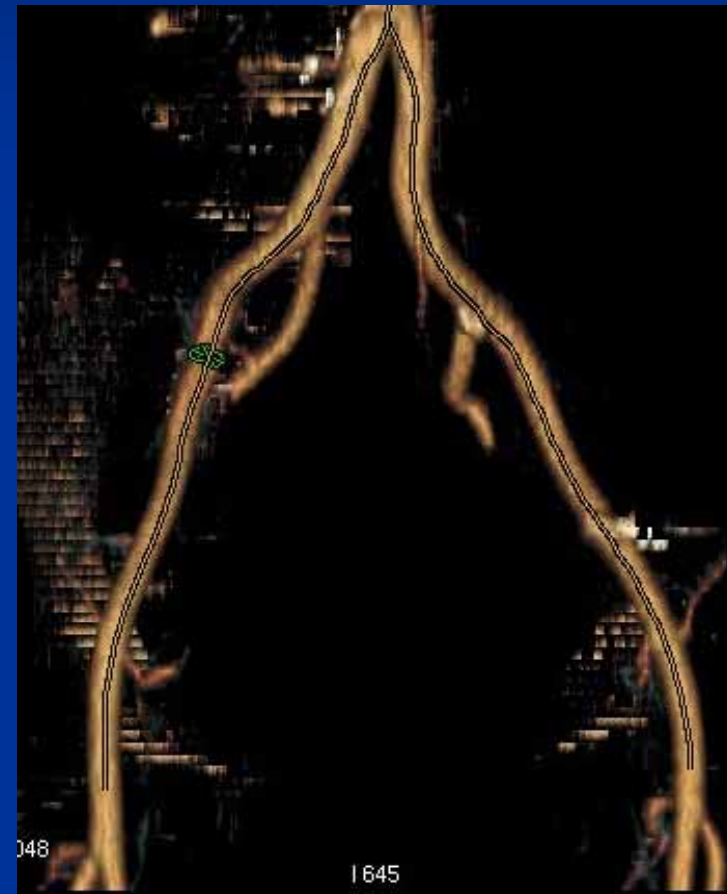
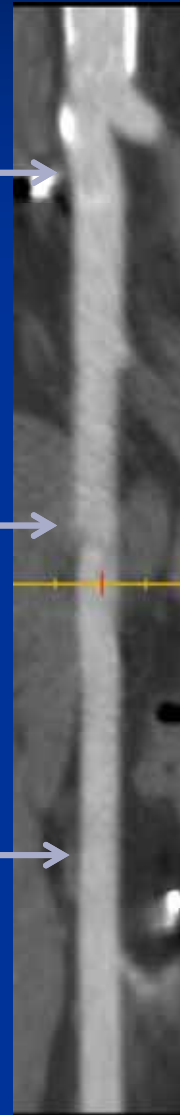
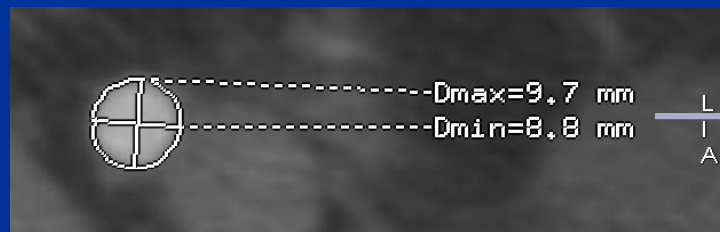
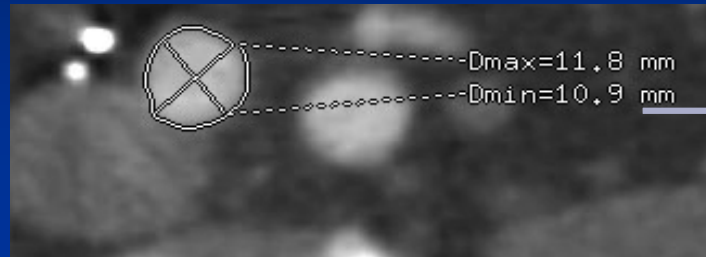
Genereux, P., et al. *J Am Coll Cardiol.* 2012;60:1043-52

Hayashida, K., et al. *JACC Cardiovasc Interv.* 2011;4:851-8

Toggweiler, S., et al. *J Am Coll Cardiol.* 2012;59:113-8

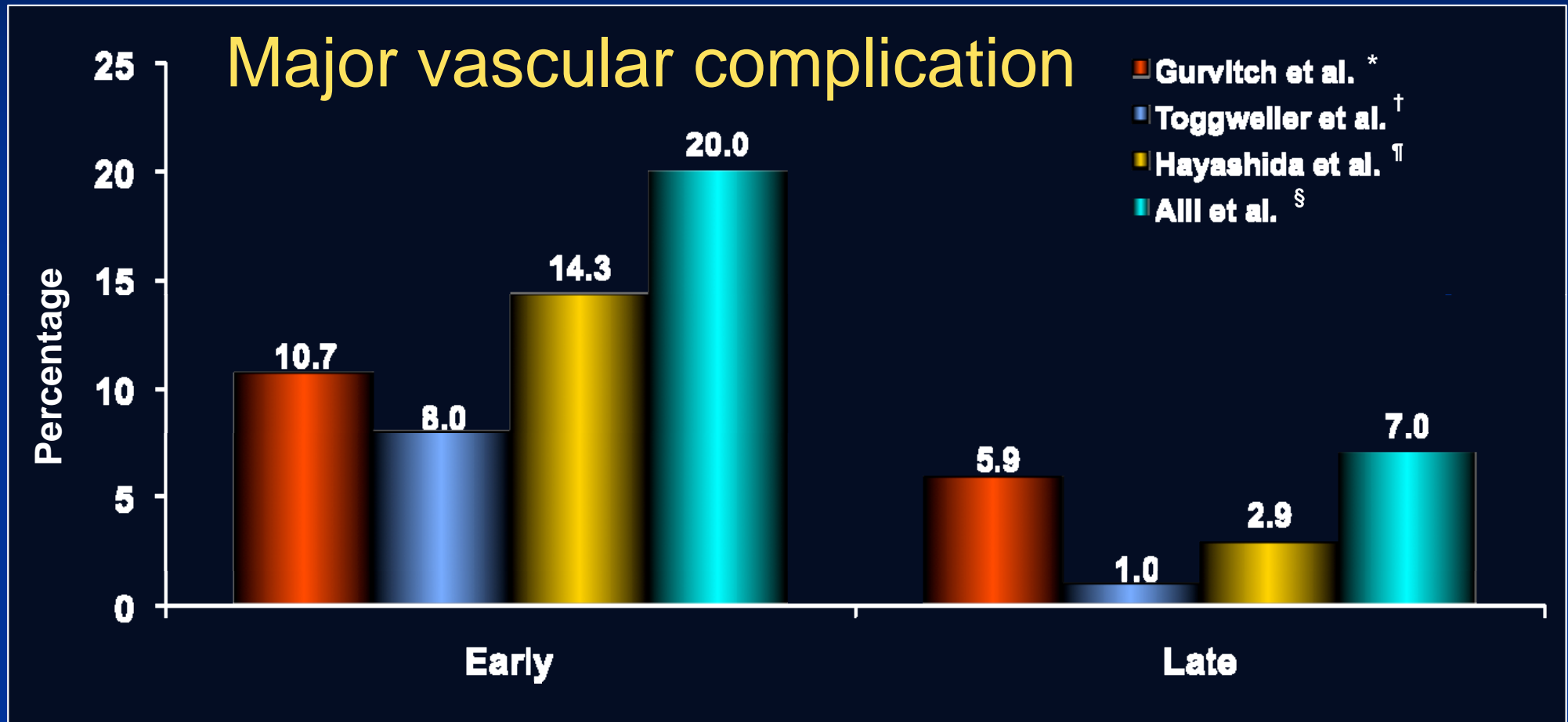
Van Miegheem, N. M., et al. *Am J Cardiol.* 2012;110:1361-7

Vascular Screening have improved...



Operator Experience is Improving...

Learning Curve



* 169 TF patients/ first half vs. second half

† 137 full percutaneous TF/ first 50 vs. 87 last

†† 140 full percutaneous TF/ first 70 vs. 70 last

§ 44 TF patients/ first 30 vs. 14 last

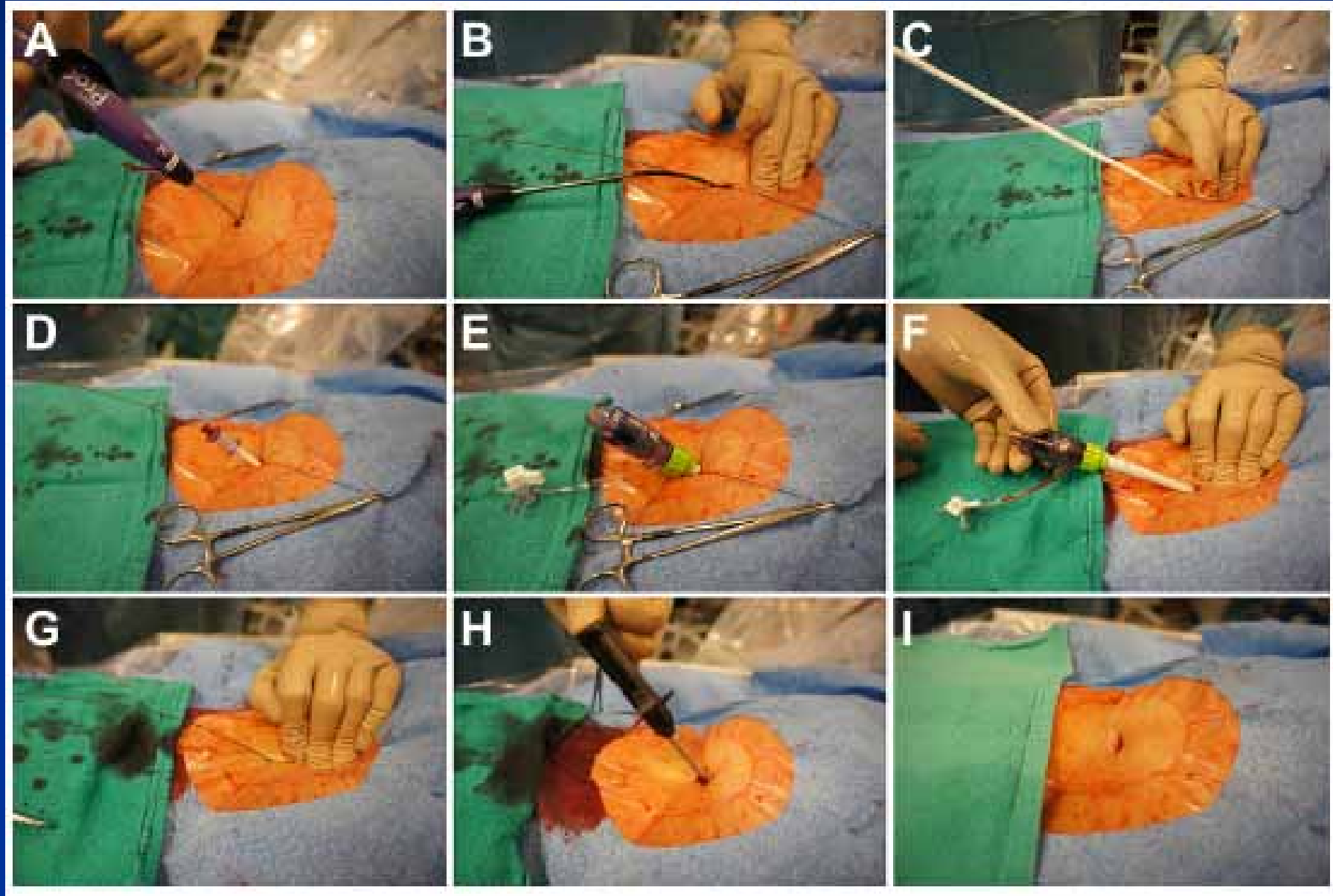
Gurvitch R et al. *Catheter Cardiovasc Inter*;2011;78:977-84

Toggweiler S et al. *J Am Coll Cardiol*;2012;59:113-8

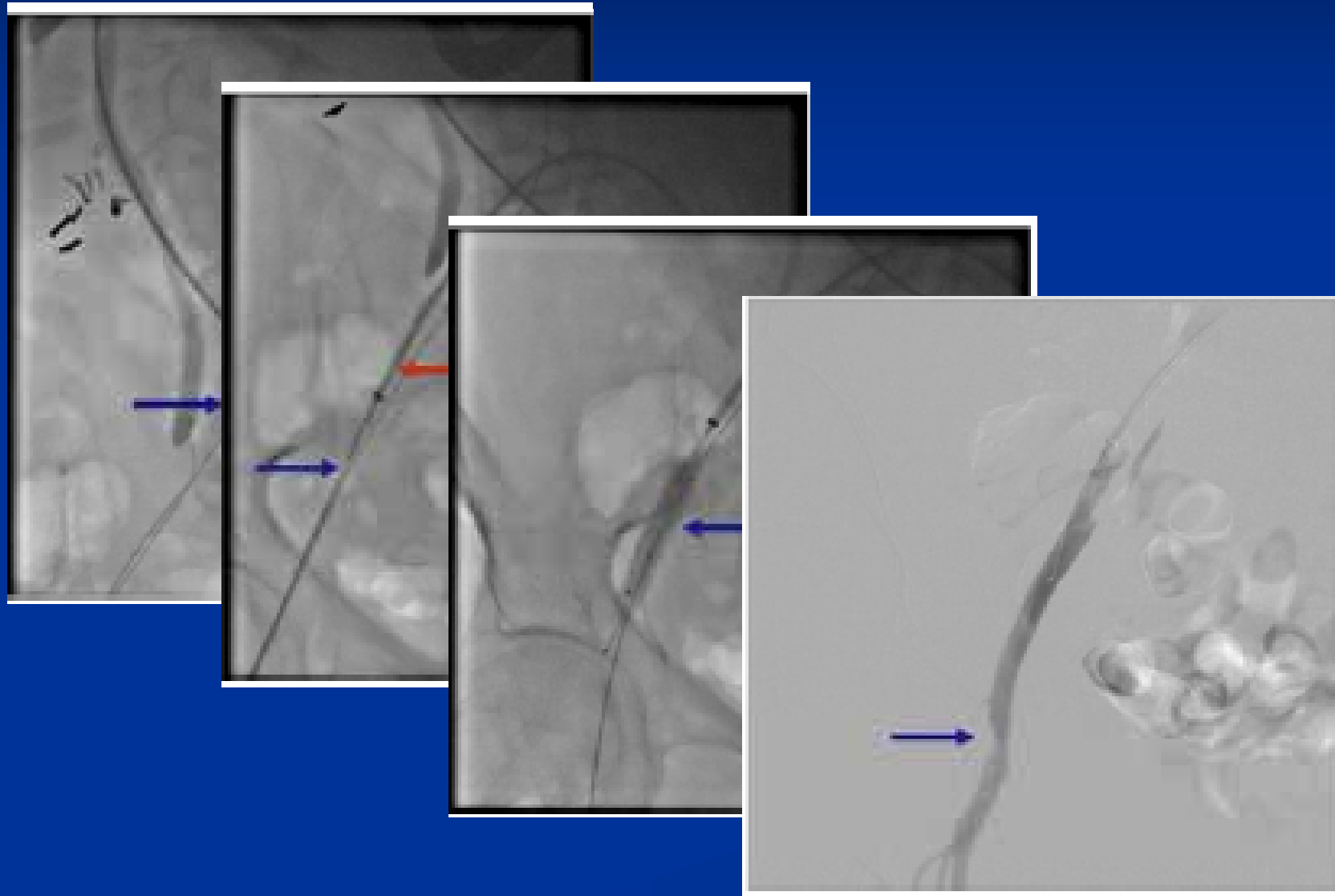
Hayashida K et al. *J Am Coll Cardiol Interv*;2012;5:207-214

Alli O et al. *J Am Coll Cardiol Interv*; 2012;5:72-9

Technique is Improving... Totally Percutaneous Procedure



Crossover Balloon Occlusion Technique (CBOT)



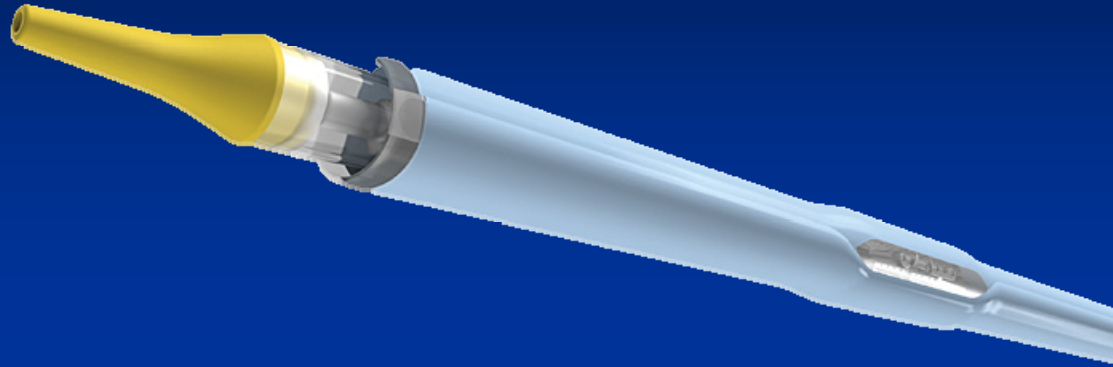
Technology is Improving...

Reduction in size of sheath



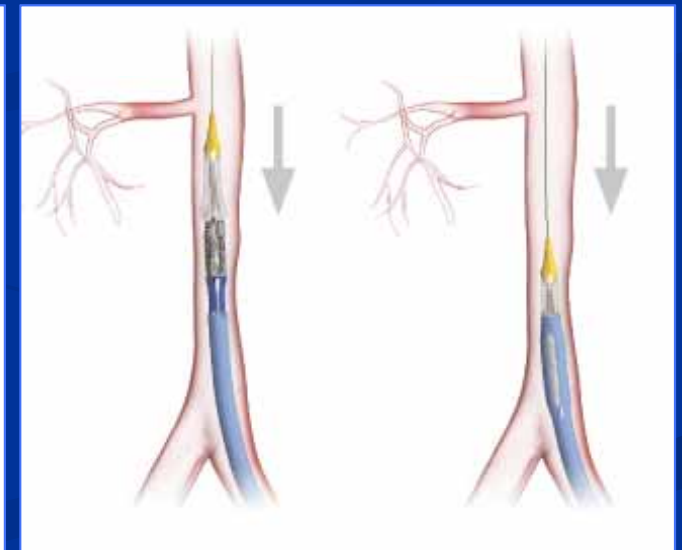
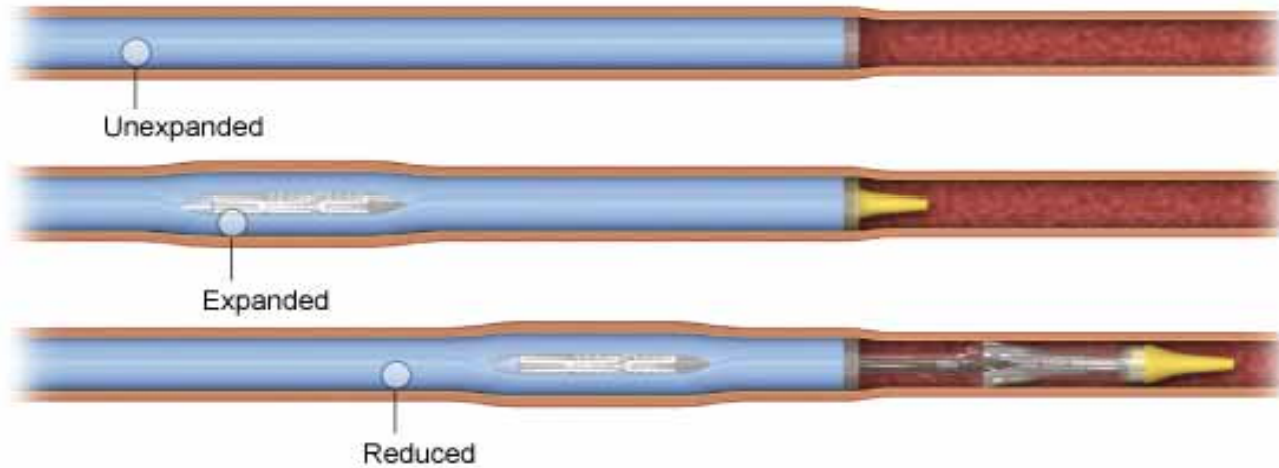
Edwards eSheath - Available

Expandable Introducer Sheath



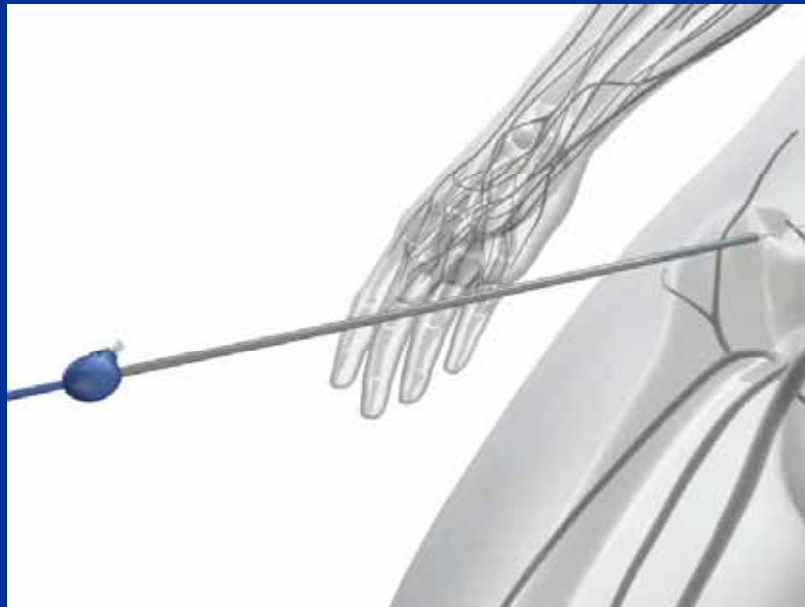
DEM: Dynamic Expansion mechanism

Allows for retrievability



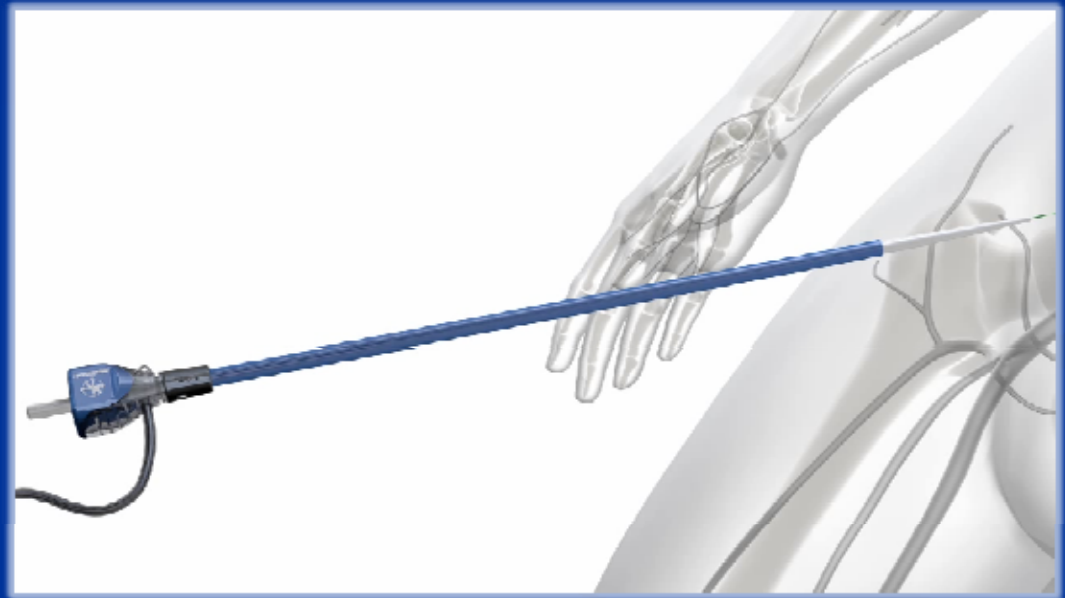
New Medtronic CoreValve Sheath – coming...

InLine Sheath



- 14F equivalent system

Profile Adaptive Sheath



- 13F equivalent
- Nitinol reinforced – expands to 18Fr ID and self-contracts to 13Fr ID

The PARTNER II Inoperable Cohort Study Design



Symptomatic Severe Aortic Stenosis

ASSESSMENT by Heart Valve Team

Inoperable

ASSESSMENT: Transfemoral Access

1:1 Randomization

**n = 560
Randomized
Patients**

**TF TAVR
SAPIEN XT**

VS

**TF TAVR
SAPIEN**

**Primary Endpoint: All-Cause Mortality + Disabling
Stroke + Repeat Hospitalization at One Year
(Non-inferiority)**

Vascular and Bleeding Events: At 30 Days (AT)



Events	SAPIEN (n=271)		SAPIEN XT (n=282)		p-value
	n	%	n	%	
Vascular:					
Major	42	15.5	27	9.6	0.04
Minor	20	7.4	14	5.0	0.23
Bleeding:					
Disabling	34	12.6	22	7.8	0.06
Major	44	16.4	44	15.7	0.84
Patients with Transfusions	6	2.2	7	2.5	0.84

TAVI Vascular Complications: Contemporary Results

	VARC meta- analysis	ADVANCE CoreValve	SOURCE-XT	Euro-Sentinel Registry
N & Valve type	3,619 SAPIEN / XT & CoreValve	1,015 CoreValve	2,700 SAPIEN XT	4,571 SAPIEN XT & CoreValve
Time Period	Publications Jan 2011-Oct 2011	Mar 2010 – Jul 2011	Jun 2010 - Oct 2011	Jan 2011 -Jun 2012
Major Vascular Cx	11.9	10.2%	6.3%	3.1%

VASCULAR SCREENING

Peripheral vessel assessment

- Assess from aorta to common femoral arteries
- Calibre
- Calcification
- Tortuosity

Sheath Outer Diameters

	16Fr	18Fr	19Fr	20Fr	22Fr	24Fr
RF3 Sheath					8.4	9.2
NF Sheath		7.2	7.5			
E-Sheath - Unexpanded	6.7	7.2		8.0		
- Expanded	8.9	8.9		9.9		
Cook		7.2				
St Jude		6.8		7.6	8.2	
Gore	6.2	6.8		7.5		
Terumo Solopath						

Acceptable Minimal Iliofemoral Diameters

- **Edwards Sapien**

- 23 mm (22Fr RF sheath) - 7 mm
- 26 mm (24Fr RF sheath) - 8 mm

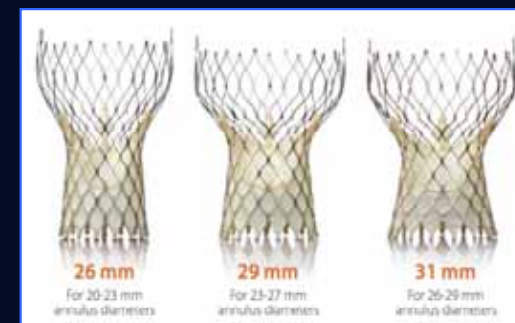
- **Edwards Sapien XT**

- 23 mm (18Fr NF or 16Fr ES sheath): 6 mm
- 26 mm (19Fr NR or 17Fr ES sheath): 6.5 mm
- 29 mm (20Fr ES sheath): 7 mm

- **Medtronic Corevalve**

- 26, 29 and 31 mm (18Fr sheath): 6 mm

If calcification: Add 1 mm



Vascular Screening Modalities

- Invasive aortogram – bifemoral angiogram
- CT angiogram
 - Ideally with contrast
 - Non-contrast also useful for assessing calcification
- Intravascular ultrasound

Image size: 512 x 512
View size: 1222 x 1222
WL: 118 WW: 162

J2158835 (81 y , 80 y)
Coro D200 -- Coro D200
RHC
0

Zoom: 239% 0 0.1

Im: 29 / 109

JPEGLossless:Non-hierarchical-1stOrderPrediction

8/03/13 3:47:11 PM

Position: HFS

Made In OsiriX

Image size: 512 x 512

J2158835 (80 y , 80 y)

View size: 1224 x 1223

Coro D200 -- Coro D200

WL: 118 WW: 162

RHC

0



Zoom: 239% 0 0.1

Im: 45 / 109

JPEGLossless:Non-hierarchical-1stOrderPrediction

8/03/13 3:47:11 PM

Position: HFS

Made In OsiriX

Aortibifemoral Angiography

Marker pigtail for calibration

ADVANTAGES

- Good spacial resolution
- Done same time as coronary angiography
- Lower contrast load than CT
- Assess tortuous vessel response to stiff wire for straightening

DISADVANTAGES

- Limited in identification of calcification and atherosclerotic burden
- Can't identify full 3D feature of tortuosity
- Can't identify eccentric severe stenoses in one view

Tortuosity

Image size: 512 x 512
View size: 1220 x 1220
WL: 118 WW: 162

F6131691 (93 y , 90 y)
Coro -- Coro
VPL
4

Image size: 512 x 512
View size: 1220 x 1220
WL: 118 WW: 162
F6131691 (93 y , 90 y)
Coro -- Coro
CCT
2



Zoom: 238% Angle: 0

Im: 1/64

JPEGLossless:Non-hierarchical-1stOrderPrediction

12/02/10 2:50:03 PM

Position: HFS

Made In OsiriX



Zoom: 238% Angle: 0

Im: 1/46

JPEGLossless:Non-hierarchical-1stOrderPrediction

16/12/09 3:32:09 PM

Position: HFS

Made In OsiriX

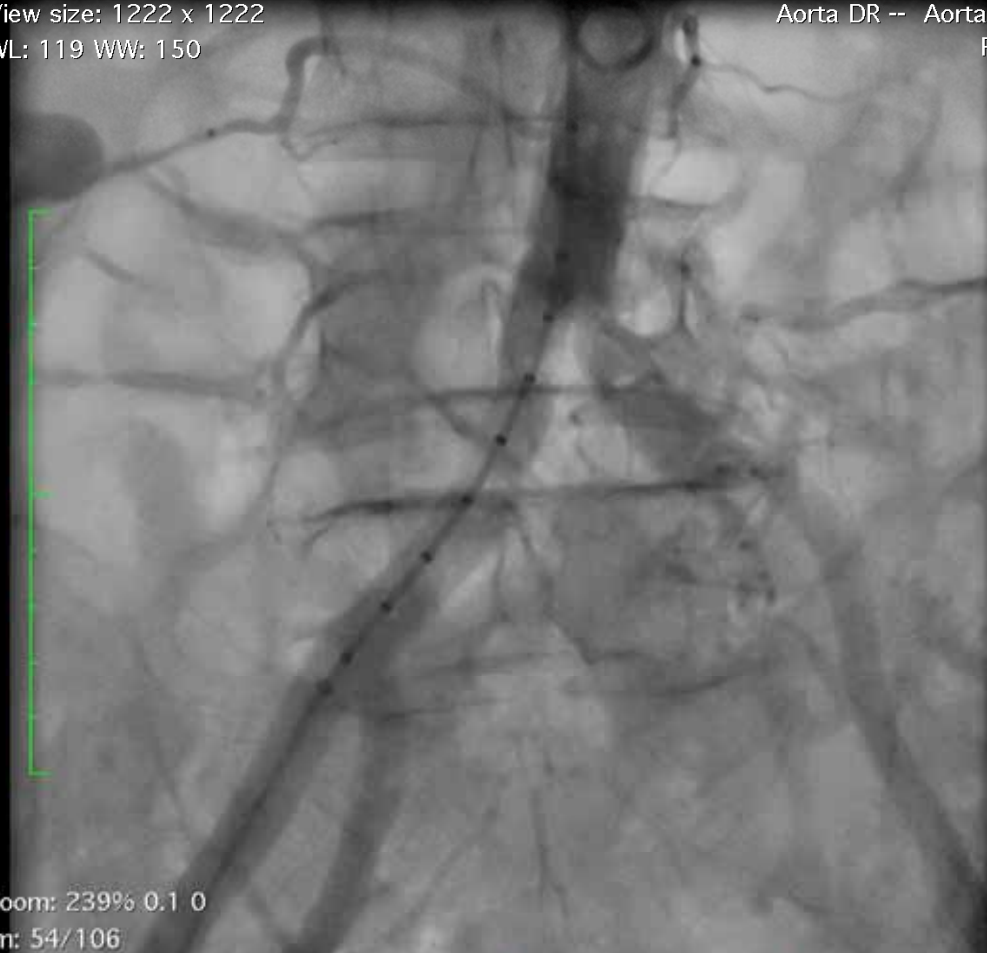
Tortuous right femoral artery

With 0.035" Lunderquist wire

Eccentric lesion

Image size: 512 x 512
View size: 1222 x 1222
WL: 119 WW: 150

G0080460 (88 y , 87 y)
Aorta DR -- Aorta DR
RHC
0



Zoom: 239% 0.1 0

Im: 54/106

JPEGLossless:Non-hierarchical-1stOrderPrediction

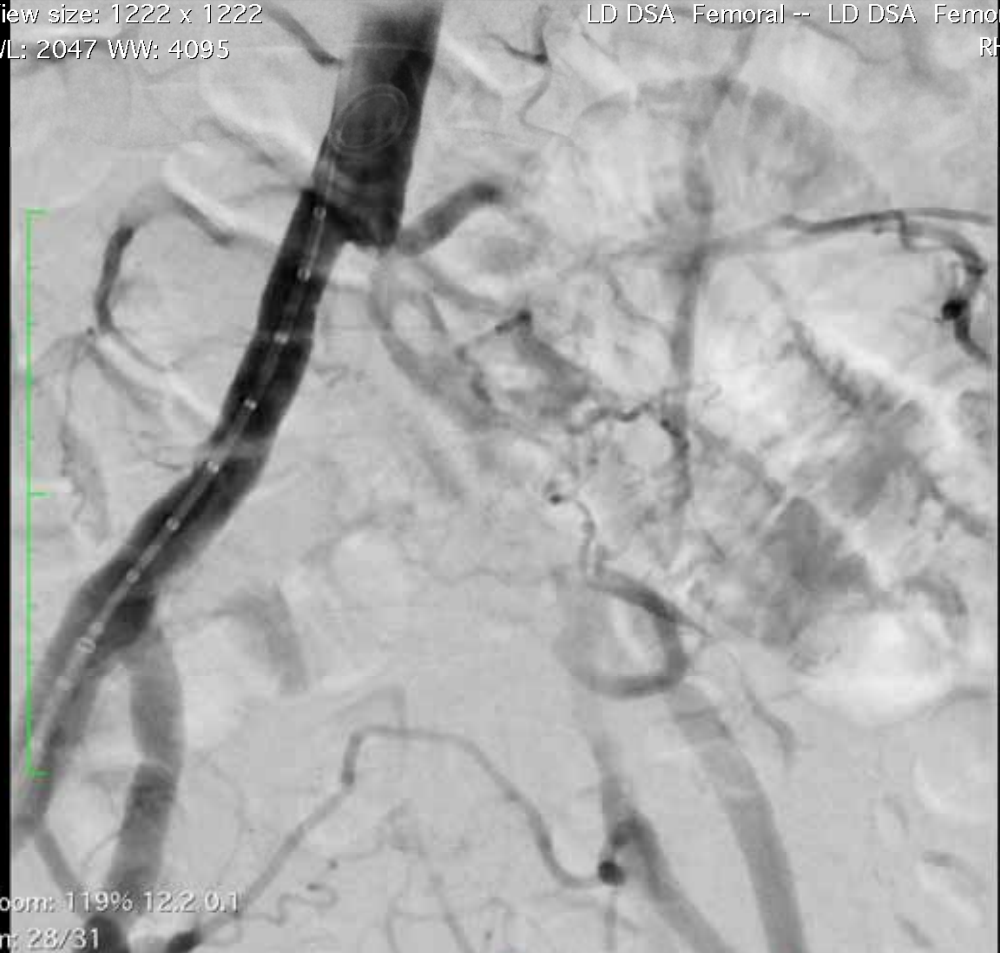
Position: HFS

14/03/13 3:16:07 PM

Made In OsiriX

Image size: 1024 x 1024
View size: 1222 x 1222
WL: 2047 WW: 4095

G0080460 (88 y , 87 y)
LD DSA Femoral -- LD DSA Femoral
RHC
0



Zoom: 119% 12.2 0.1

Im: 28/31

JPEGLossless:Non-hierarchical-1stOrderPrediction

Position: HFS

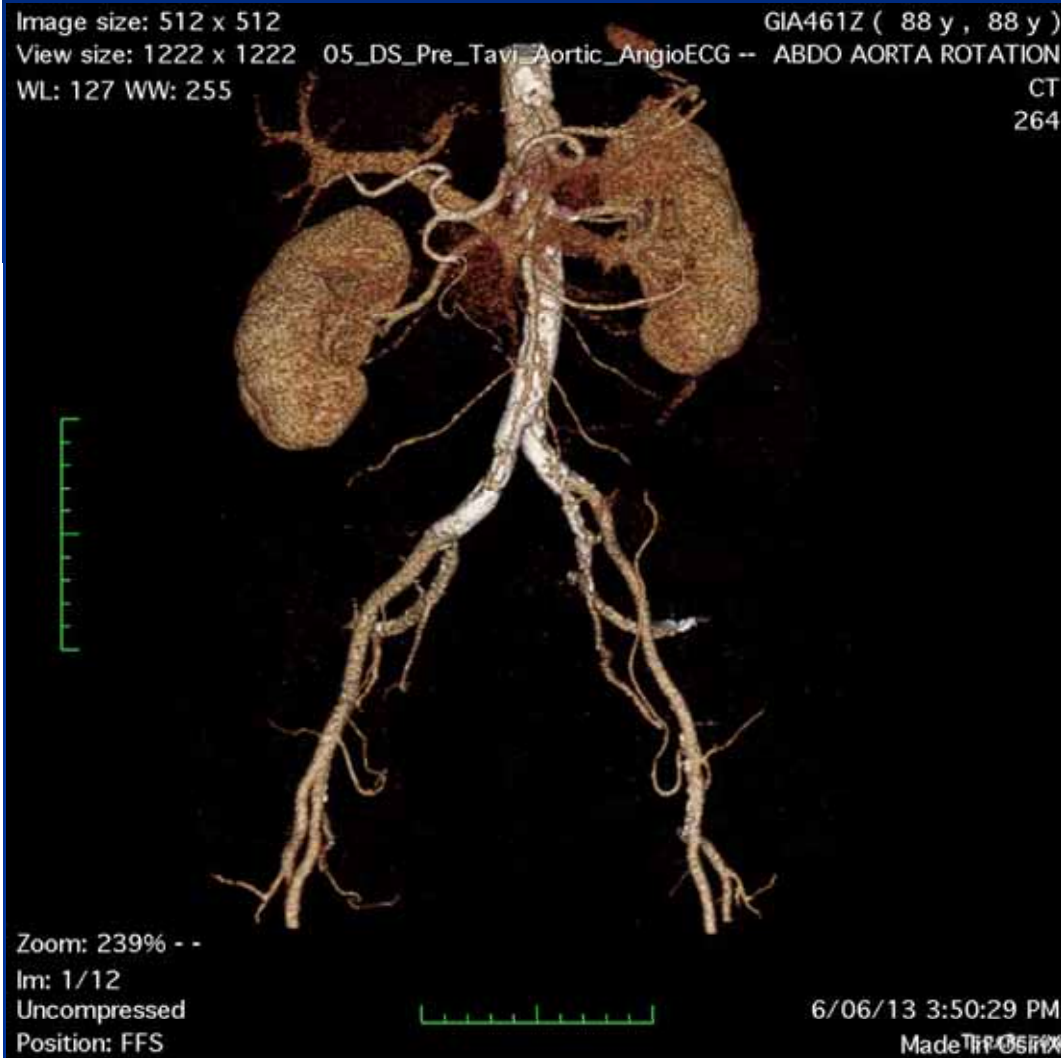
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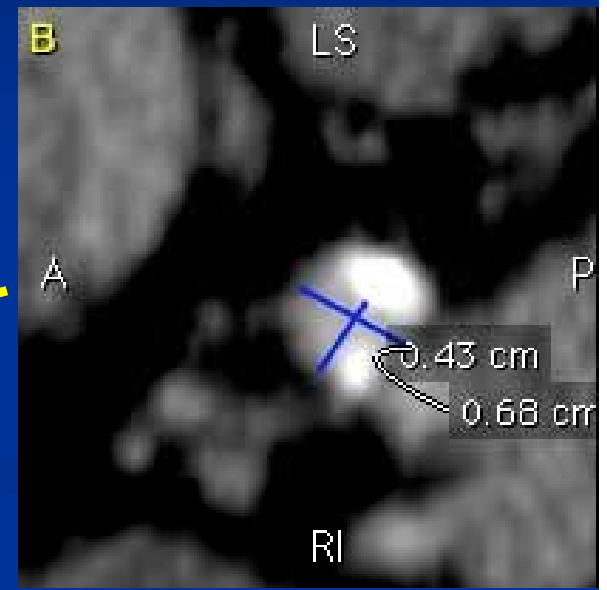
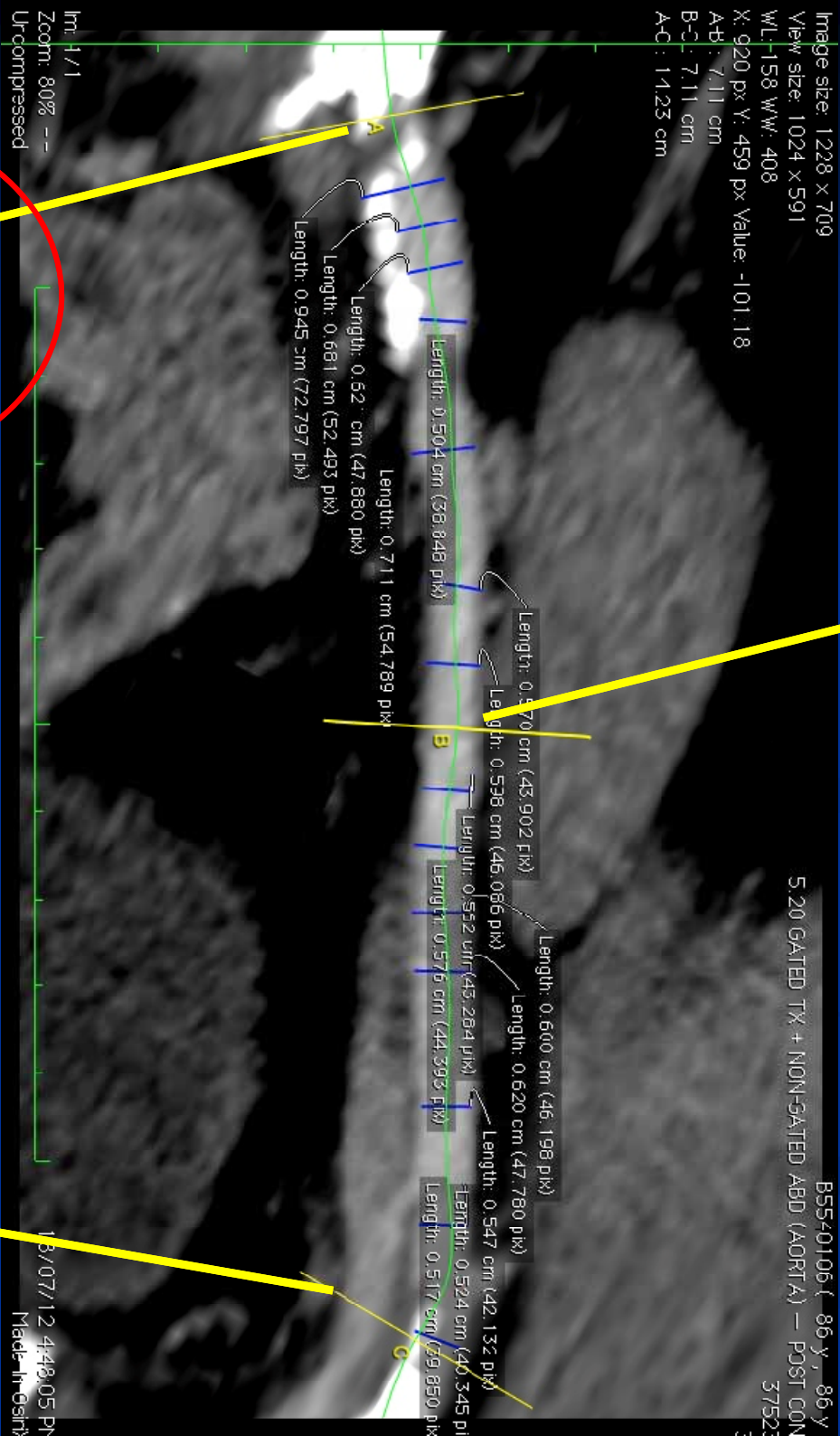
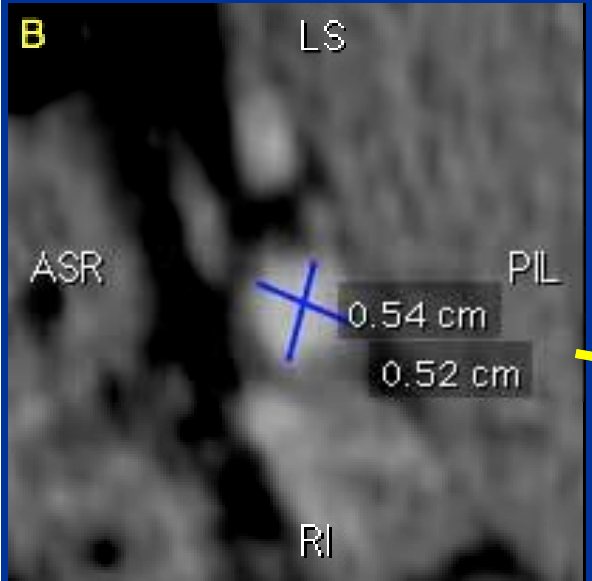
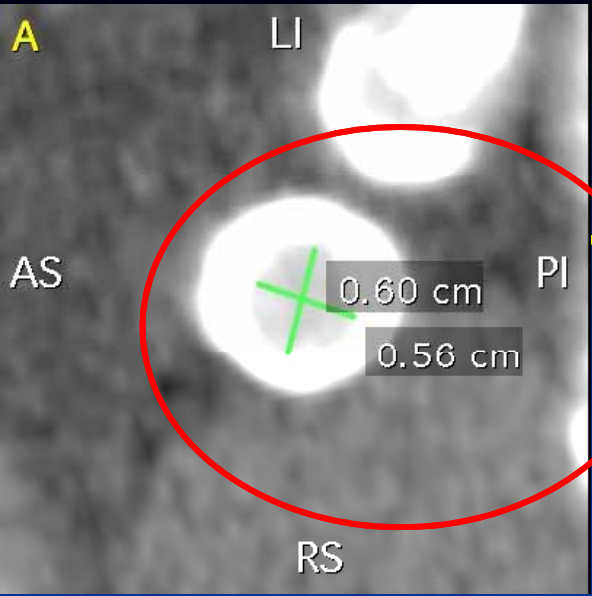
AP VIEW

LAO VIEW

CT Aortogram



- Better appreciation of calcium and atherosclerotic burden
- Appreciate tortuosity in 3D
- Centre-line multiplanar reformat allows measurement of true orthogonal dimensions and CA of vessel
- Uses more contrast generally than invasive angiography
- Lower spacial resolution than invasive angiography



MANAGEMENT OF VASCULAR COMPLICATIONS

Bailout Equipments

- Stiff wires
- Occlusion balloon
 - CODA balloon
 - Reliant balloon
- Peripheral balloons
- Peripheral stents
 - Covered stents – self expanding and balloon expanding
- Cross-over sheath – Ansel

Iliac Rupture



- Hypotension upon sheath removal post CoreValve

Image size: 512 x 512
View size: 1222 x 1222
WL: 106 WW: 150

A0276111 (86 y , 83 y)
Acq Card -- Acq Card
OTH
0



Zoom: 239% 0 0
Im: 1/151
JPEG Lossless; Non-hierarchical-1stOrderPrediction
Position: HFS
5/05/10 3:32:22 PM
Made In OsiriX

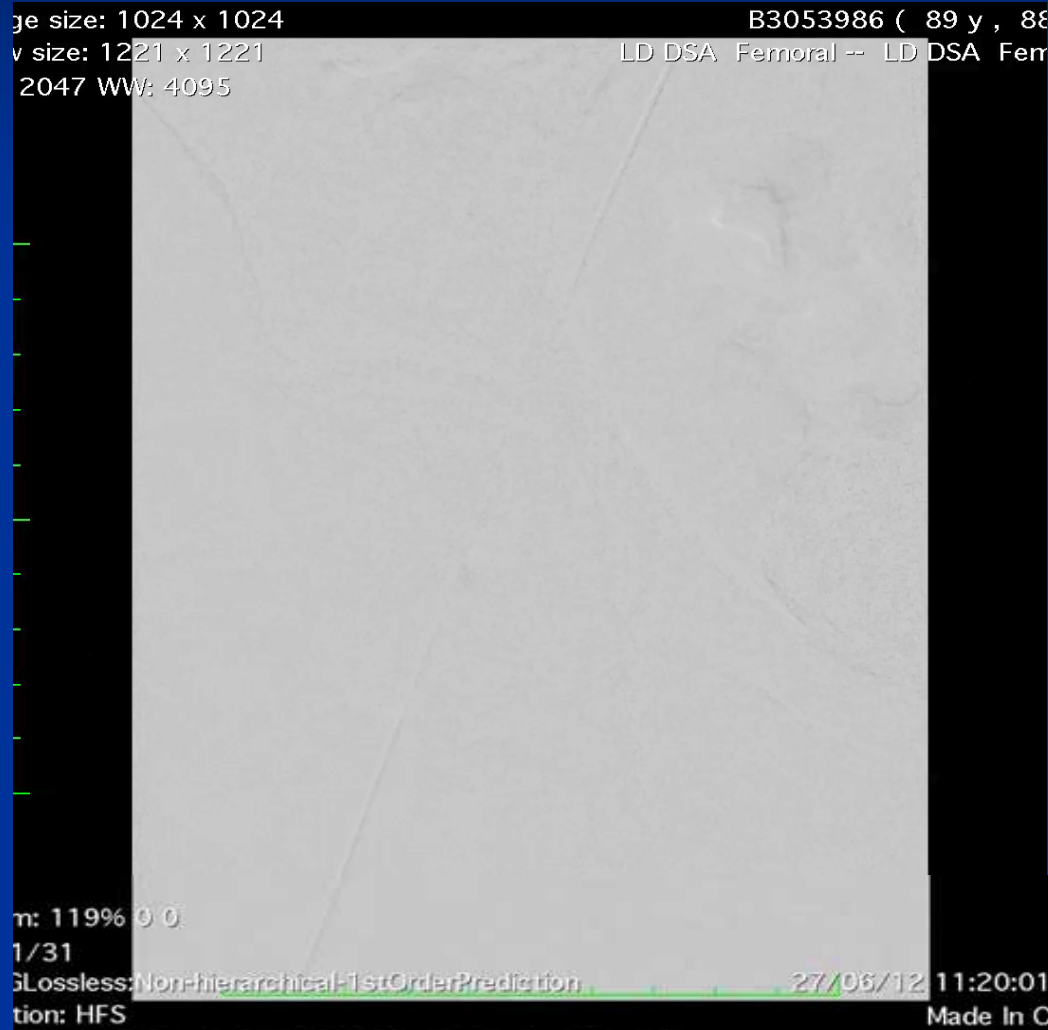
Image size: 512 x 512
View size: 1222 x 1222
WL: 106 WW: 150

A0276111 (86 y , 83 y)
Acq Card -- Acq Card
OTH
0

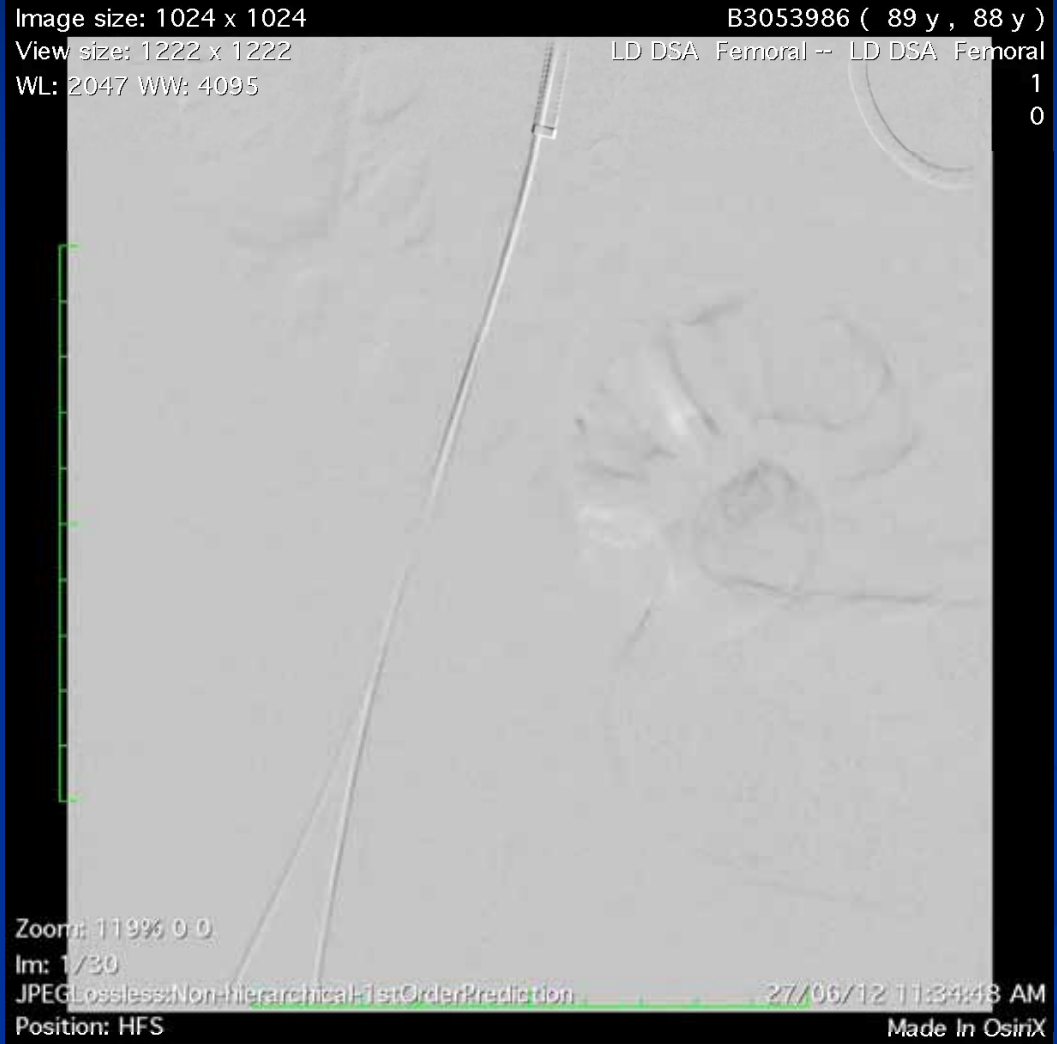


Zoom: 239% -33.7 -0.1
Im: 1/80
JPEG Lossless; Non-hierarchical-1stOrderPrediction
Position: HFS
5/05/10 3:36:49 PM
Made In OsiriX

Occlusive Dissection



- Post TAVR with SAPIEN XT 23mm valve (18Fr sheath)
- Primary failure of pre-closure
- Successful primary closure with Prostar



Gentle balloon dilatation...

Image size: 1024 x 1024

View size: 1222 x 1222

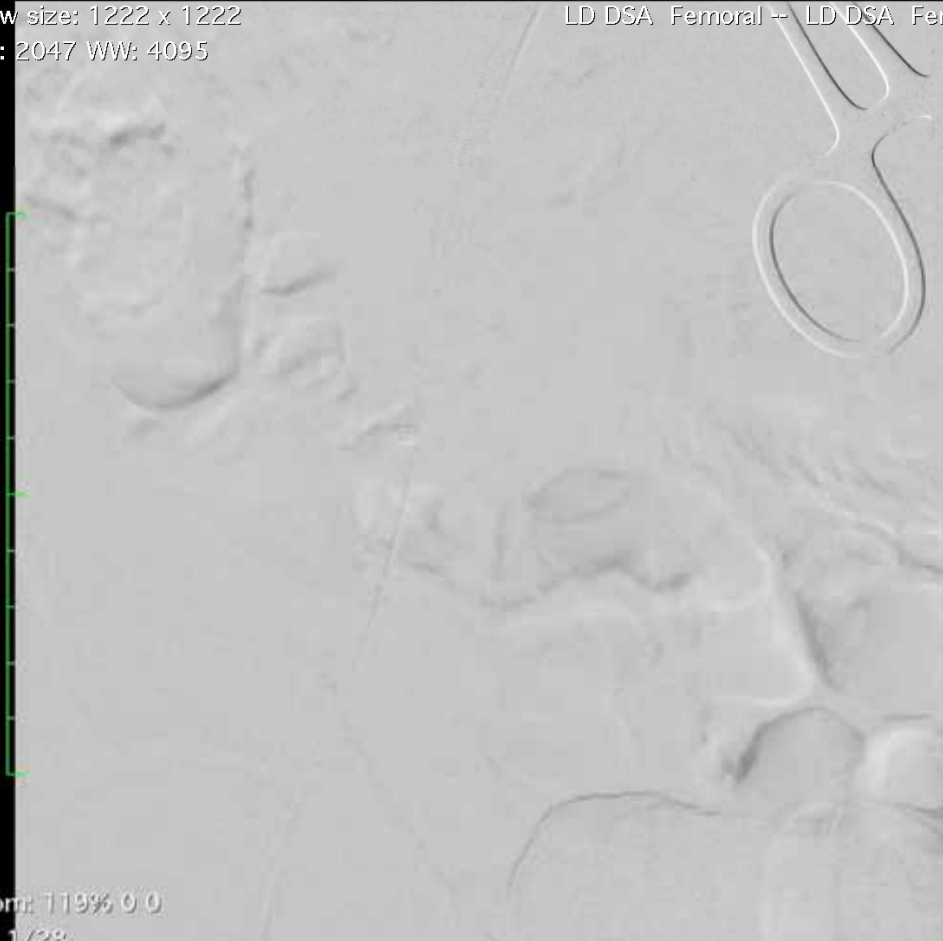
WL: 2047 WW: 4095

B3053986 (89 y , 88 y)

LD DSA Femoral -- LD DSA Femoral

1

0



Zoom: 119% 0 0

Im: 1/28

JPEGLossless:Non-hierarchical-1stOrderPrediction

27/06/12 11:44:06 AM

Position: HFS

Made In OsiriX

Image size: 1024 x 1024

View size: 1222 x 1222

WL: 2047 WW: 4095

B3053986 (89 y , 88 y)

LD DSA Femoral -- LD DSA Femoral

1

0



Zoom: 119% 0 0

Im: 1/33

JPEGLossless:Non-hierarchical-1stOrderPrediction

27/06/12 11:51:27 AM

Position: HFS

Made In OsiriX

Conclusion

- Vascular complication is a common adverse event post-TAVR, and is associated with increased mortality
- Incidence reduced to $\sim 3-10\%$ with improvements
 - Screening technique
 - Operator experience and techniques

Conclusion

- Careful pre-procedural screening and meticulous procedural technique **MANDATORY** to maintain low vascular complications
- Prepared to handle complications
 - Well-planned techniques
 - Bail-out equipments
 - Vascular surgical back-up
- Understand limits
 - Alternatives available – TA, TAO, Transubclavian
 - Prepared to take consequences if pushing limit

