IN.PACT Global Sub-Analysis on Asian Population

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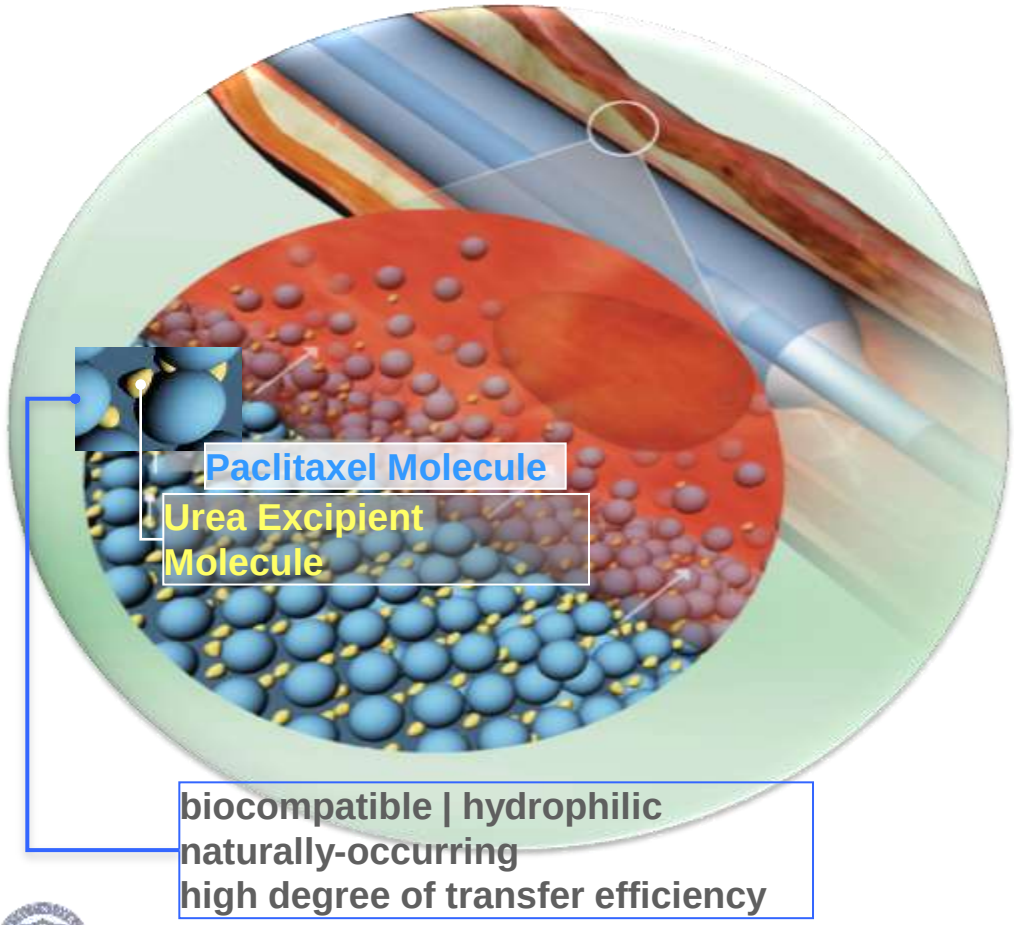
Disclosure

Received research funding from

- Medtronic
- Cordis
- Cook

IN.PACT™ DEB with FreePac™ Coating Technology



IN.PACT™

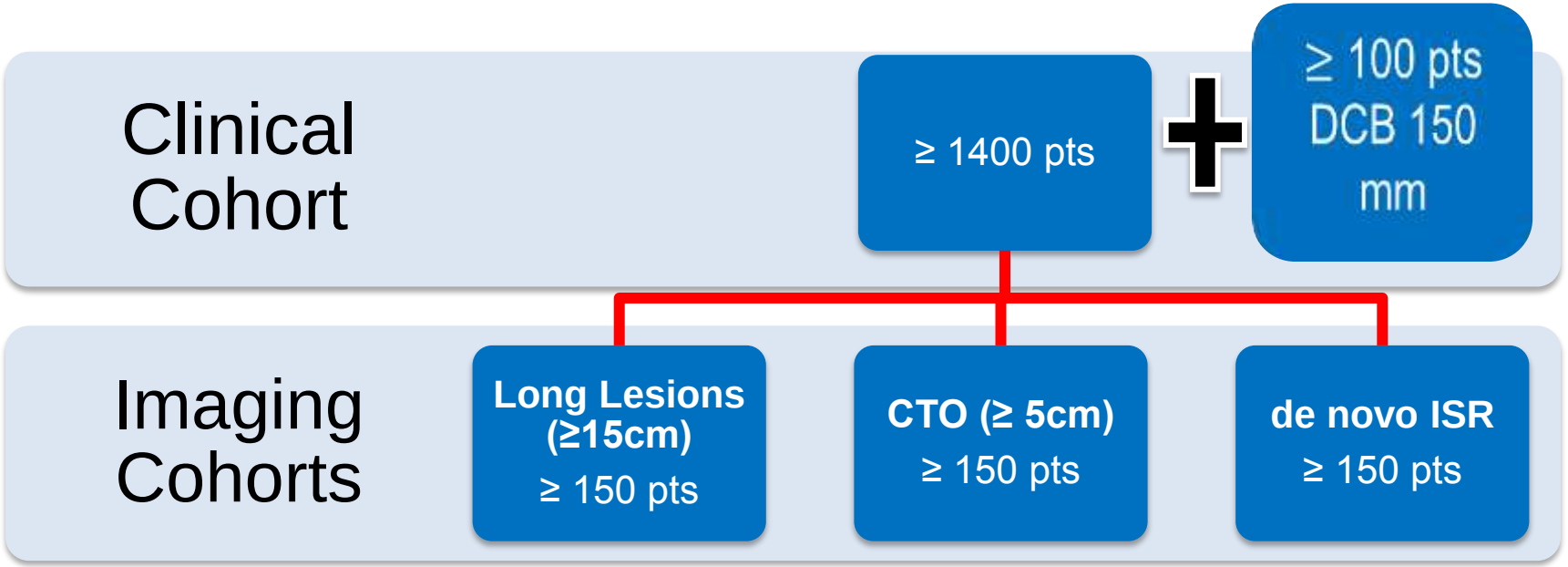
- Medtronic-Invatec DEB balloon line

FreePac™

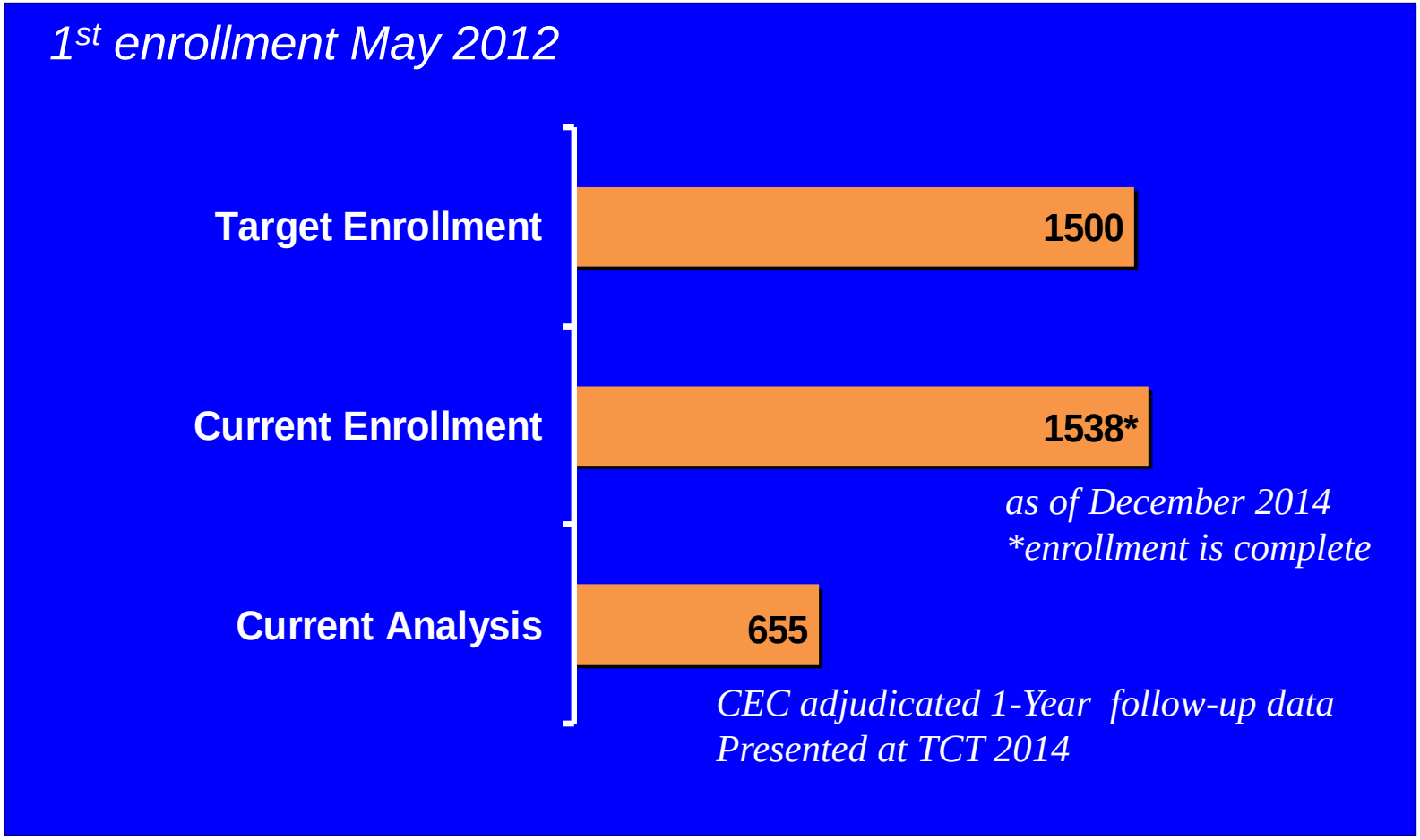
- Proprietary hydrophilic coating formulation
  - Urea separates Paclitaxel molecules
  - Increased drug solubility and optimal diffusion into vessel wall
  - Urea facilitates Paclitaxel absorption into the vessel wall

IN.PACT Global Patient Cohorts

Challenging Lesions Included



IN.PACT Global: Enrollment Status



IN.PACT Global Study in Asia

Patient enrollment in Korea by Nov 2013

Site Name	PI	Enrollment
Severance Hospital	Choi, Dong Hoon	29
Korea Univ. Guro Hospital	Rha, Seung Woon	27
Ajou Univ. Hospital	Won, Jae Whan	20
Samsung Medical Center	Do, Young Soo	16
Asan Medical Center	Lee, Seung Whan	13
	Total	*105*

Preliminary analysis for 1 yr follow-up

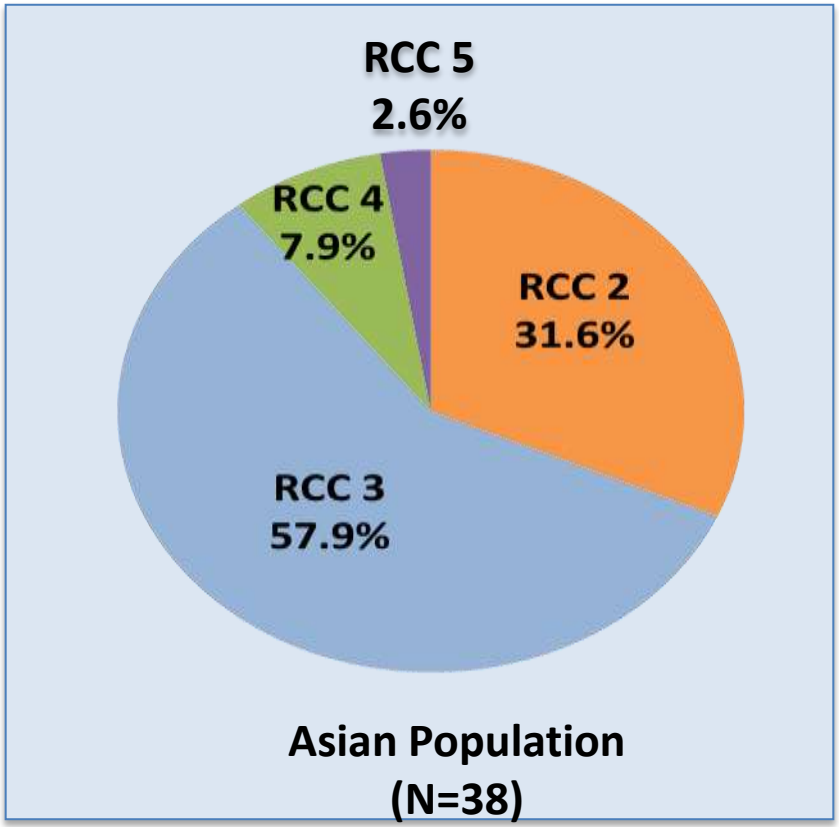
Site	# of subjects
Severance Hospital South Korea	15
Korean University Guro Hospital South Korea	8
Changi General Hospital Singapore	6
Samsung Medical Center South Korea	5
Ajou University Hospital South Korea	4
Total	**38***

Baseline Patient Characteristics

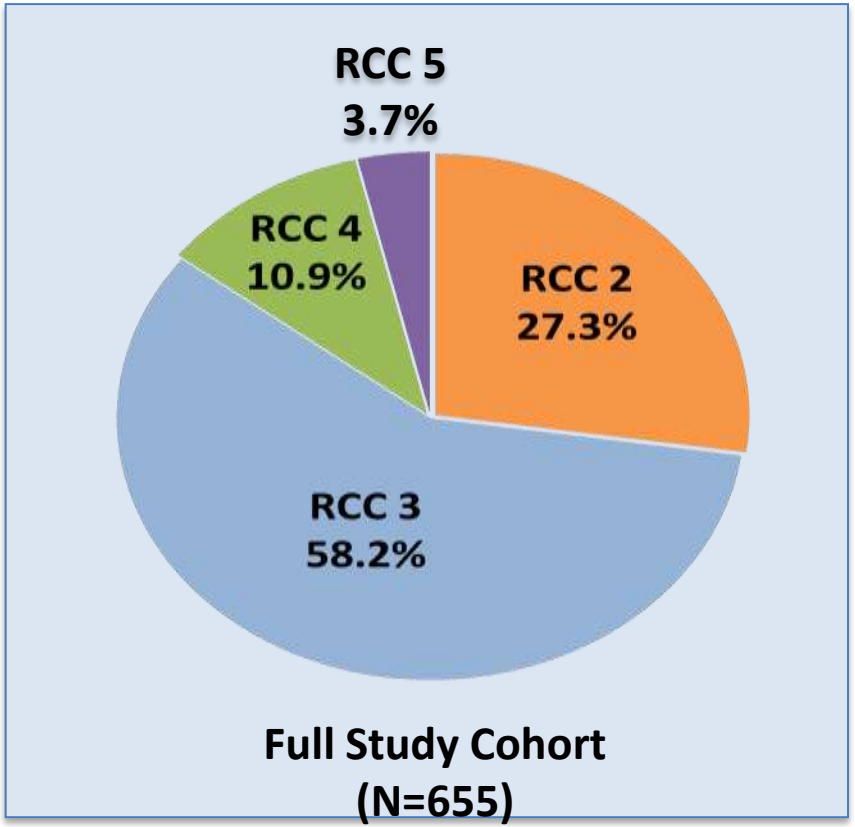
Characteristic	Asian Population (N=38)	Full Study Cohort (N=655)
Age (Y)	69.1 ± 9.3	69.2 ± 10.2
Male Gender (%)	**89.5% (34/38)**	**67.2% (440/655)**
Diabetes (%)	**52.6% (20/38)**	**41.2% (269/653)**
Hypertension (%)	78.9%% (30/38)	83.6% (546/653)
Hyperlipidemia (%)	**50.0% (19/38)**	**73.1% (470/643)**
Current Smoker (%)	36.8% (14/38)	33.6% (220/655)
Obesity (BMI ≥ 30 kg/m²) (%)	**2.6% (1/38)**	**20.6% (134/649)**
Coronary Artery Disease (%)	42.1% (16/38)	43.3% (270/624)
Carotid Artery Disease (%)	13.5% (5/37)	21.5% (122/568)
Renal Insufficiency [1] (%)	18.4% (7/38)	11.8% (70/595)
Previous Peripheral Revasc. (%)	65.8% (25/38)	57.3% (375/655)
Concomitant BTK Disease (%)	34.2% (13/38)	45.7% (283/619)
ABI	0.609± 0.195	0.675 ± 0.233

Baseline Rutherford Classification

Asian Population Similar to Full Cohort



Asian Population
(N=38)



Full Study Cohort
(N=655)

Baseline Lesion Characteristics

Longer lesions and more occlusions in Asian Population

Characteristic	Asian Population (N=38)	Full Study Cohort (N=655)
Lesions (N)	42	763
Lesions per Patient (N)	1.11	1.16
Lesion Type: de novo restenotic (no ISR) ISR	 69.0% (29/42) 0.0% (0/42) **31.0% (13/42)**	 70.6% (539/763) 8.0% (61/763) **21.4% (163/763)**
Lesion Length	**17.97 ±12.57 cm**	**12.23 ± 9.59 cm**
Total Occlusions	**57.1% (24/42)**	**35.8% (273/763)**
Severe Calcification	4.8% (2/42)	10.4% (79/761)
RVD (mm)	5.514 ± 0.976	5.164 ± 0.684
Diameter Stenosis (pre-treatment)	88.8% ± 15.5	88.7% ± 12.2

Procedure Outcomes

Low Incidence of Provisional Stenting

Outcome	Asian Population (N=38)	Full Study Cohort (N=655)
Pre-dilatation	89.5% (34/38)	75.4% (494/655)
Post-dilatation	28.9% (11/38)	31.0% (201/648)
Device Success [1]	**100% (99/99)**	**99.4% (1264/1271)**
Procedure Success [2]	100% (38/38)	99.8% (646/647)
Clinical Success [3]	100% (38/38)	99.5% (644/647)
Provisional Stent	**5.3% (2/38)**	**24.7% (160/648)**
Dissections: 0 **A-C** **D-F**	42.9% (18/42) 40.4% (17/42) 16.7% (7/42)	60.2% (459/762) 33.9% (258/762) 5.9% (45/762)

[1] Device success: successful delivery, inflation, deflation and retrieval of the intact study balloon device without burst below the RBP
[2] Procedure success: residual stenosis of ≤ 50% (non-stented subjects) or ≤ 30% (stented subjects) by core lab (if core lab was not available then the site reported estimate was used)
[3] Clinical success: procedural success without procedural complications (death, major target limb amputation, thrombosis of the target lesion, or TVR) prior to discharge)

12-month Outcomes

Very low incidence of CD-TLR in Asian Population

Characteristic	Asian Population (N=38)	Full Study Cohort (N=655)
Clinically-driven TLR [1]	**3.1% (1/32)**	**8.7% (50/577)**
Primary Safety Endpoint [2]	96.9% (31/32)	89.6% (517/577)
Major Adverse Events [3]	12.5% (4/32)	13.5% (78/577)
Death (all-cause)	9.4% (3/32)	3.3% (19/577)
Major Target Limb Amputation	0.0% (0/32)	0.3% (2/577)
Thrombosis	0.0% (0/32)	3.8% (22/577)
Any TLR	3.1% (1/32)	9.0% (52/577)
Any TVR	3.1% (1/32)	9.9% (57/577)

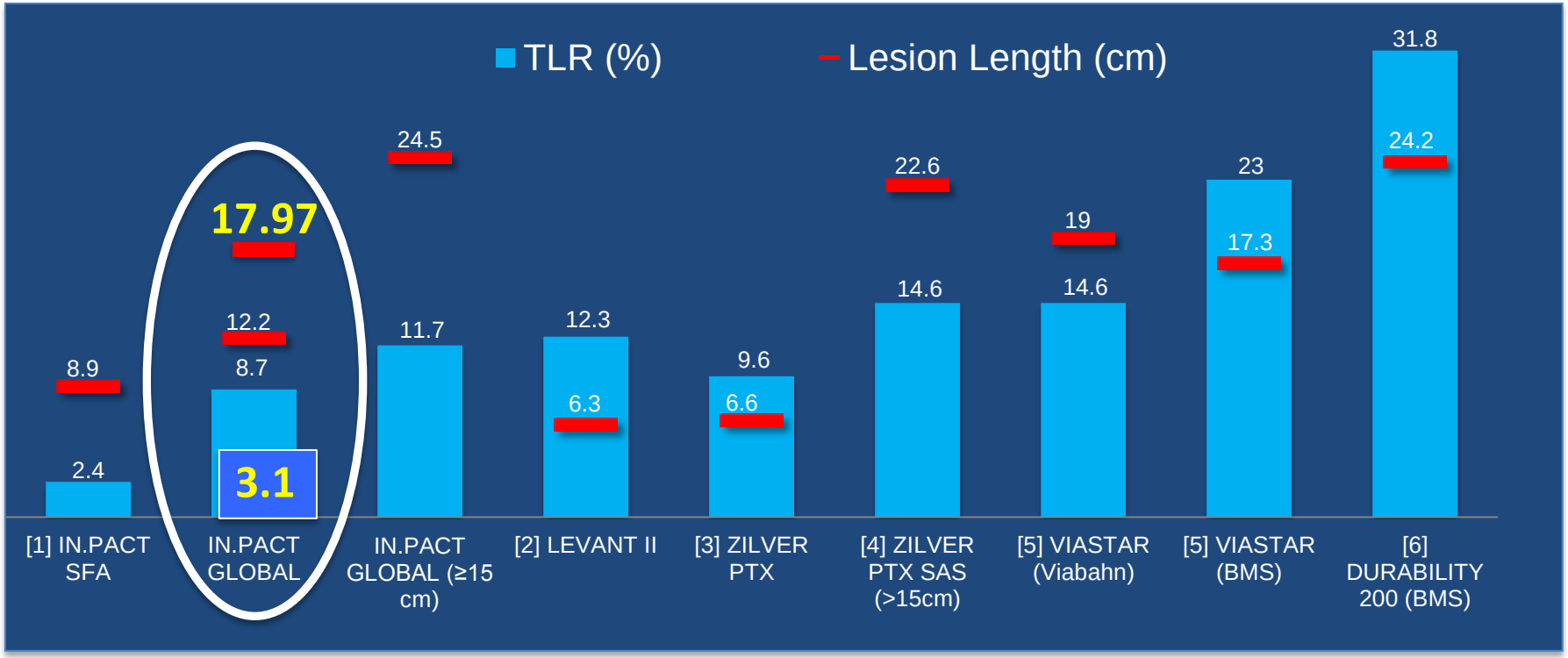
[1] Any re-intervention within the target lesion(s) due to symptoms or drop of ABI of ≥ 20% or > 0.15 when compared to post-index procedure baseline ABI

[2] Composite of 30-day freedom from device- and procedure-related mortality and 12-month freedom from major target limb amputation and clinically-driven TVR

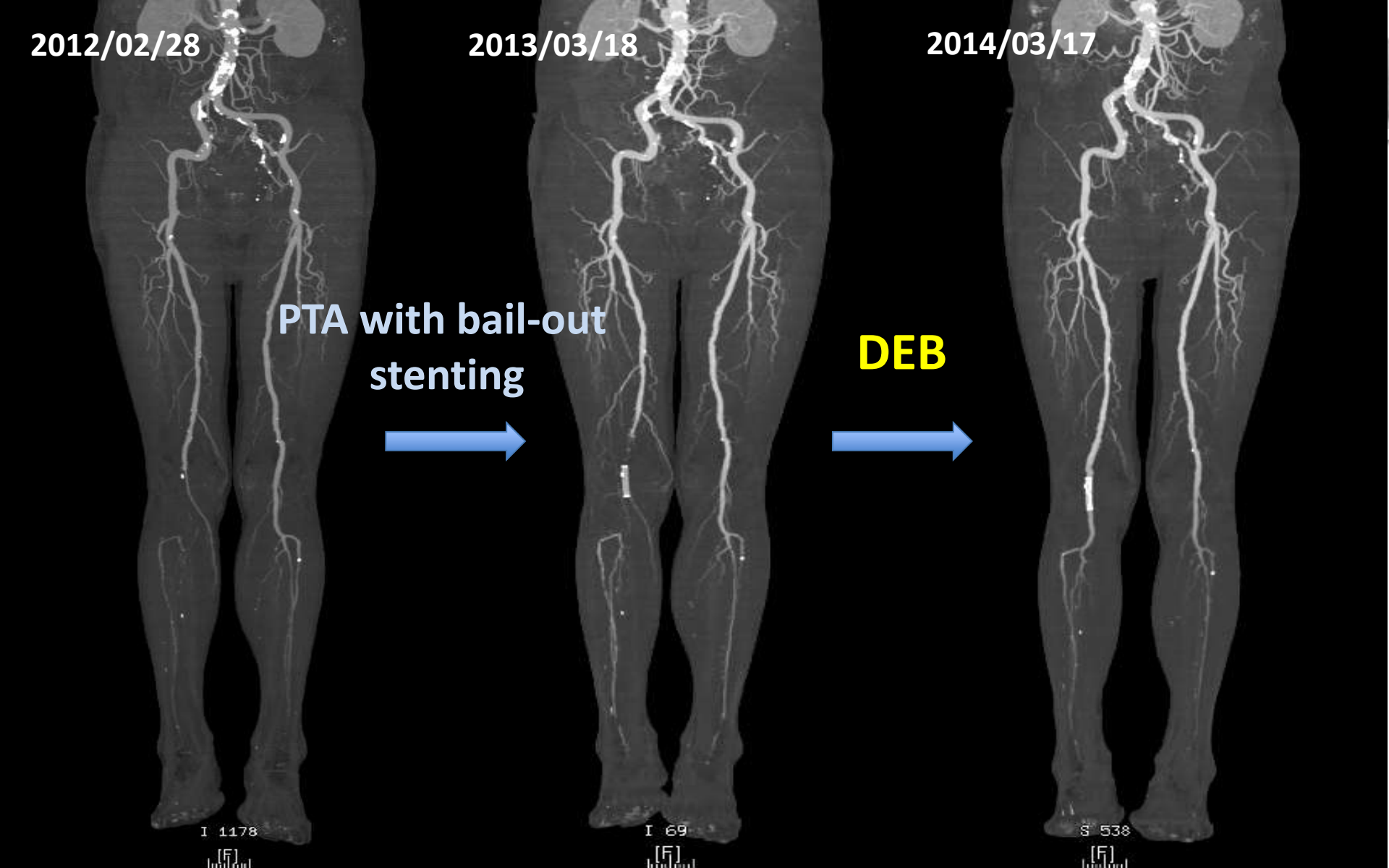
[3] Major Adverse Events: Composite of death, major target limb amputation, clinically-driven TVR, and thrombosis

SFA Trial Comparison

How does the Asian population compare?



[1] Circulation. 2014 Dec 3 [Epub]; [2] Lutonix FDA Panel Presentation; June 12 2014; [3] Circ Cardiovasc Interv. 2011;4:495-504; [4] J Cardiovasc Surg (Torino). 2013 Feb;54(1):115-22; [5] J Am Coll Cardiol. 2013 Oct 8;62(15):1320-7; [6]J Vasc Surg 2011 Oct;54(4):1042-50


2012/02/28
2013/03/18
2014/03/17
PTA with bail-out stenting
DEB
I 1178
I 69
S 538

M/59 (KGS, #5427230)

Rutherford 3
Bilateral SFA CTO

↓

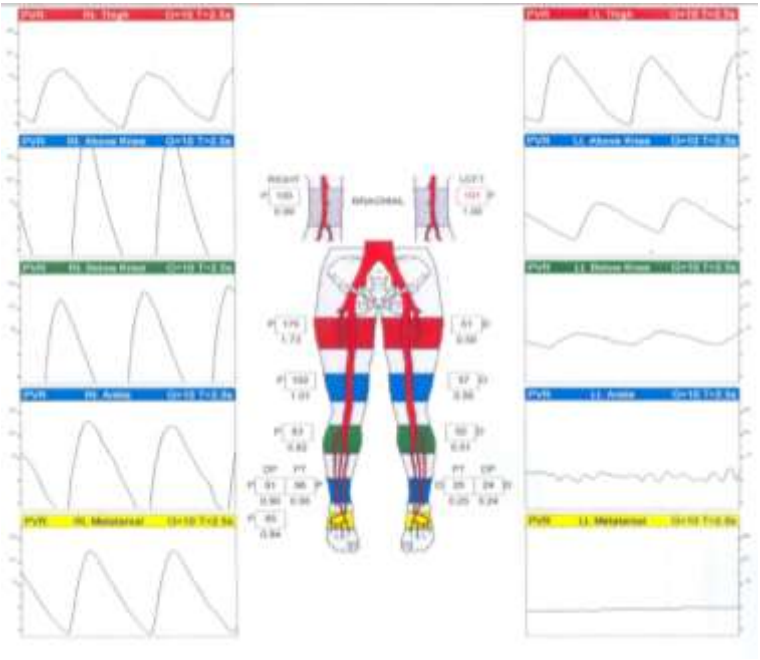
PTA with stenting
for both SFA

↓

ISR, bilateral

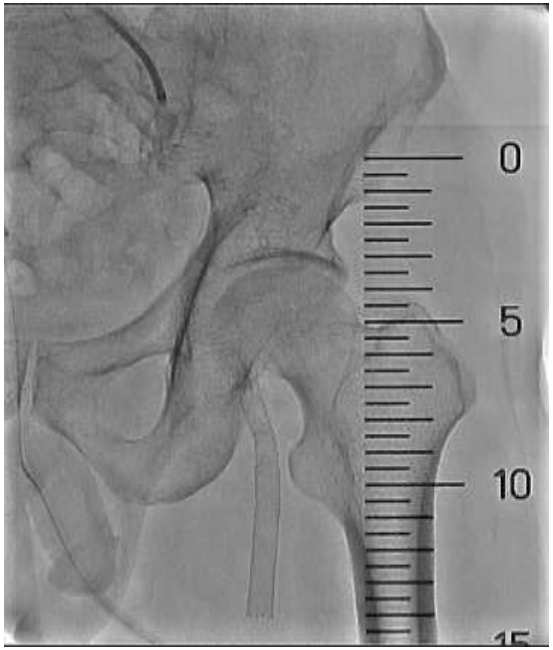
↓

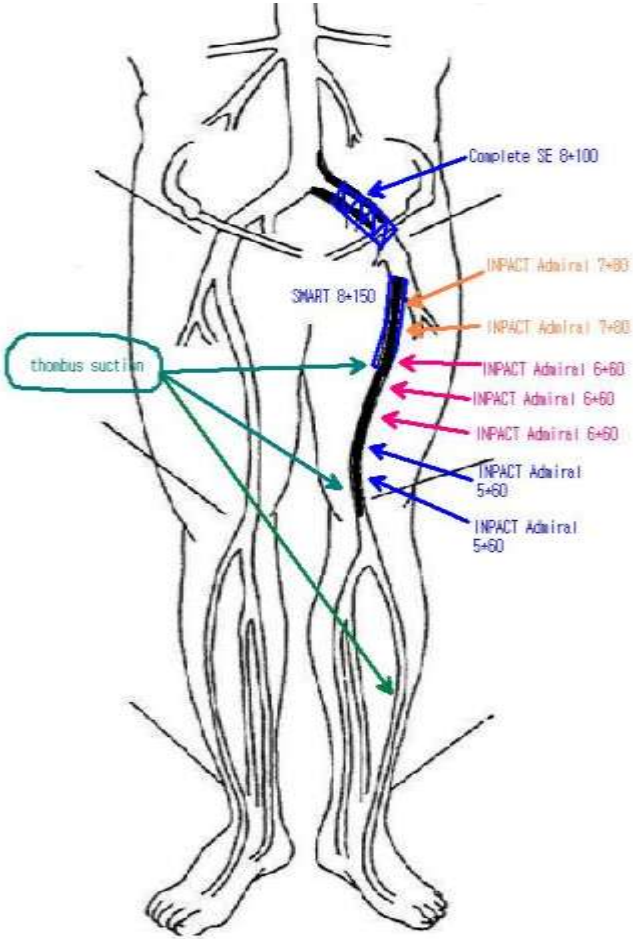
2012/2/10
Fem to pop with
hemashield 8mm
for Rt. SFA

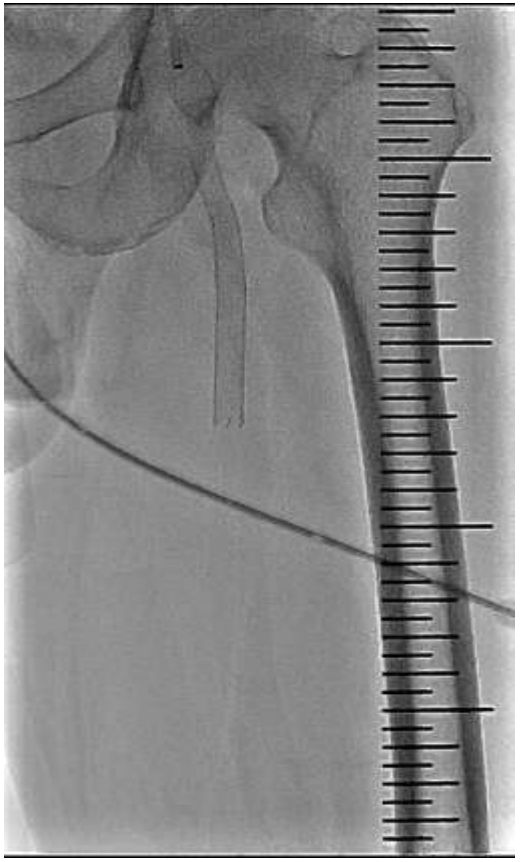


ABI 0.95/0.25

Treatment with DEB (2013/4/18)

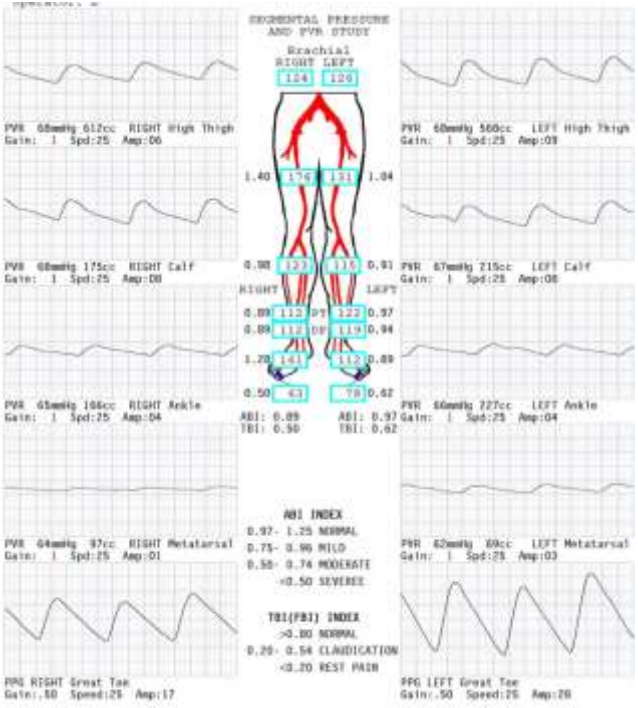






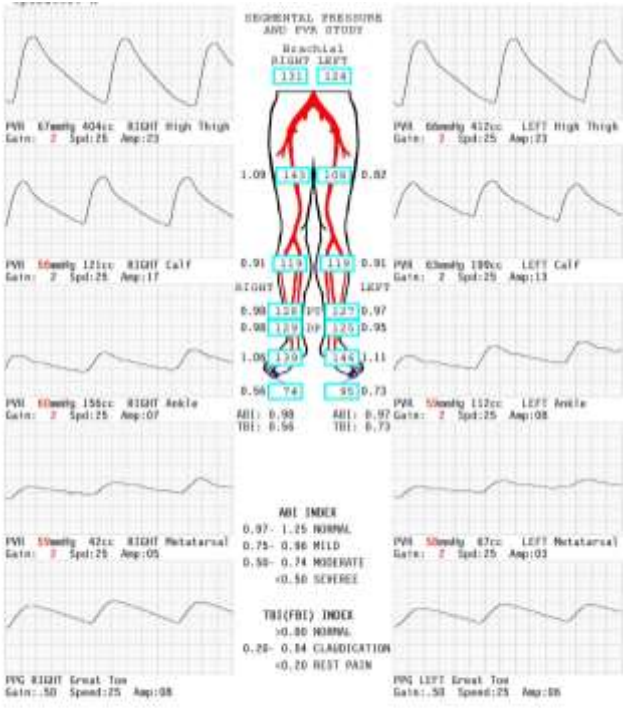
Follow-Up after DEB

At 1 year



ABI 0.89/0.97

At 2 years



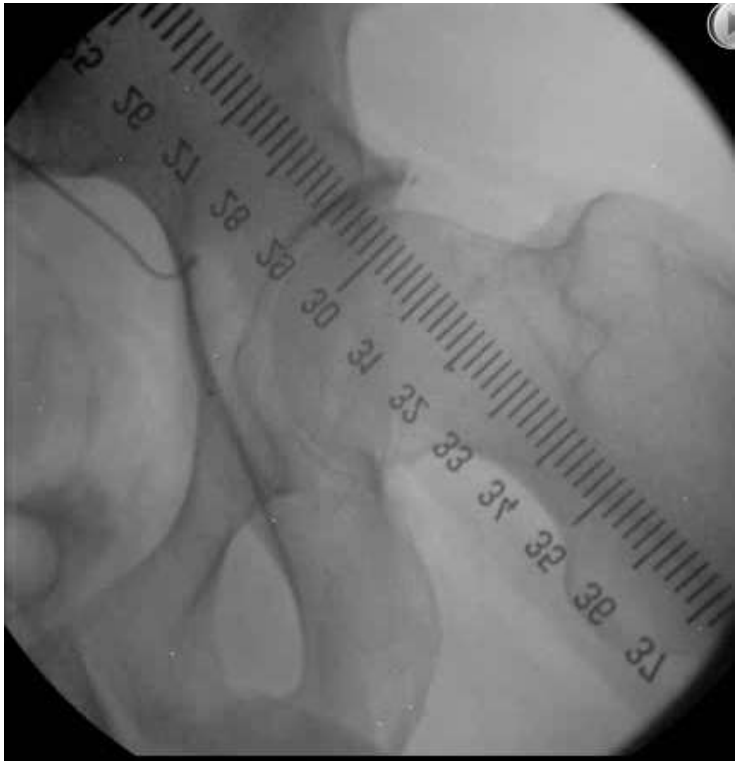
ABI 0.98/0.97

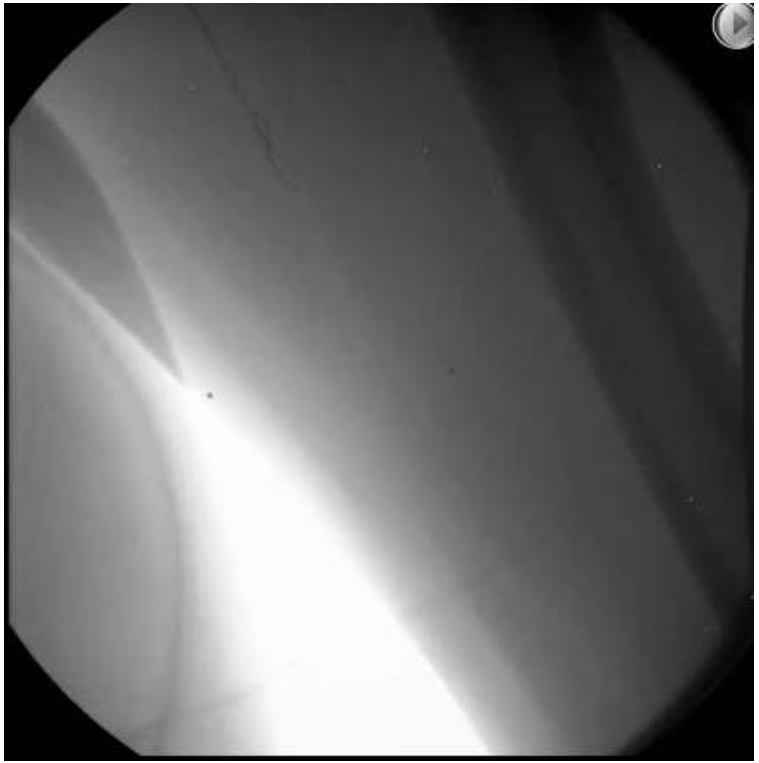
M/57 (LDW, #1749267)

- Left leg claudication at 100M (Rutherford 3)
- Risk factors: DM, HTN, smoker
- PHx:
  - 1992 AMI
  - 2004 Stroke

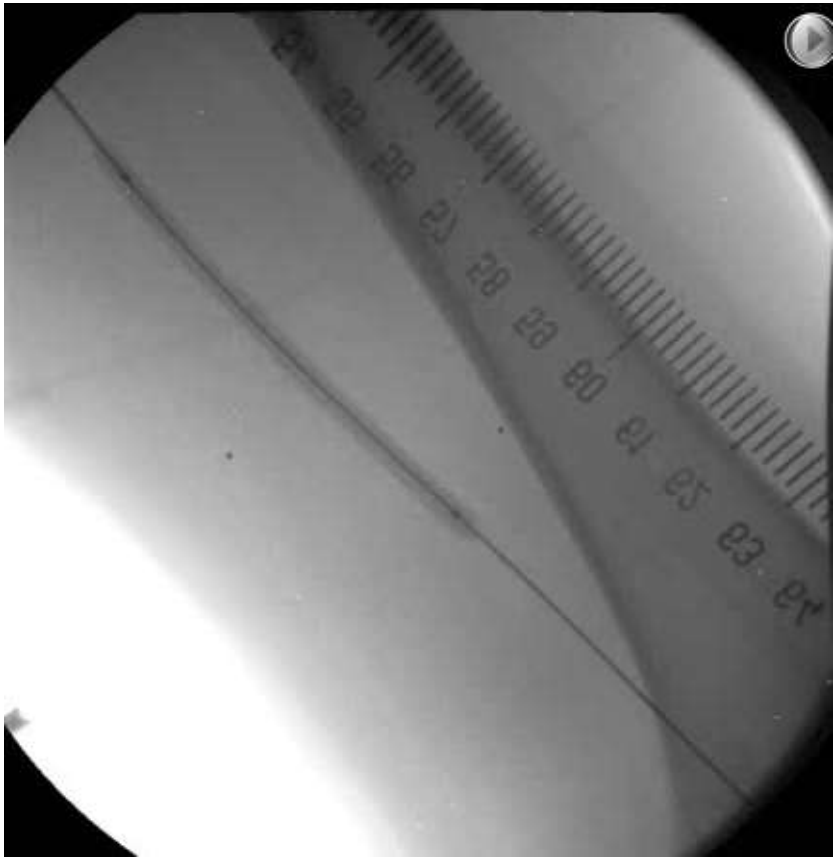
1st Treatment: Subintimal Angioplasty

2009/2/9



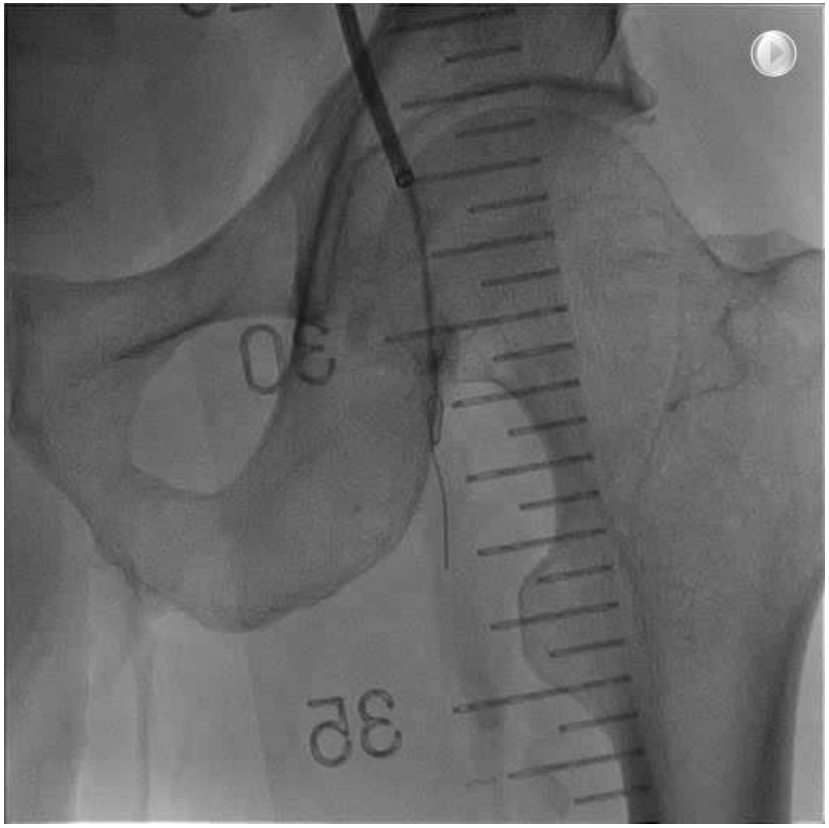


Subintimal Angioplasty

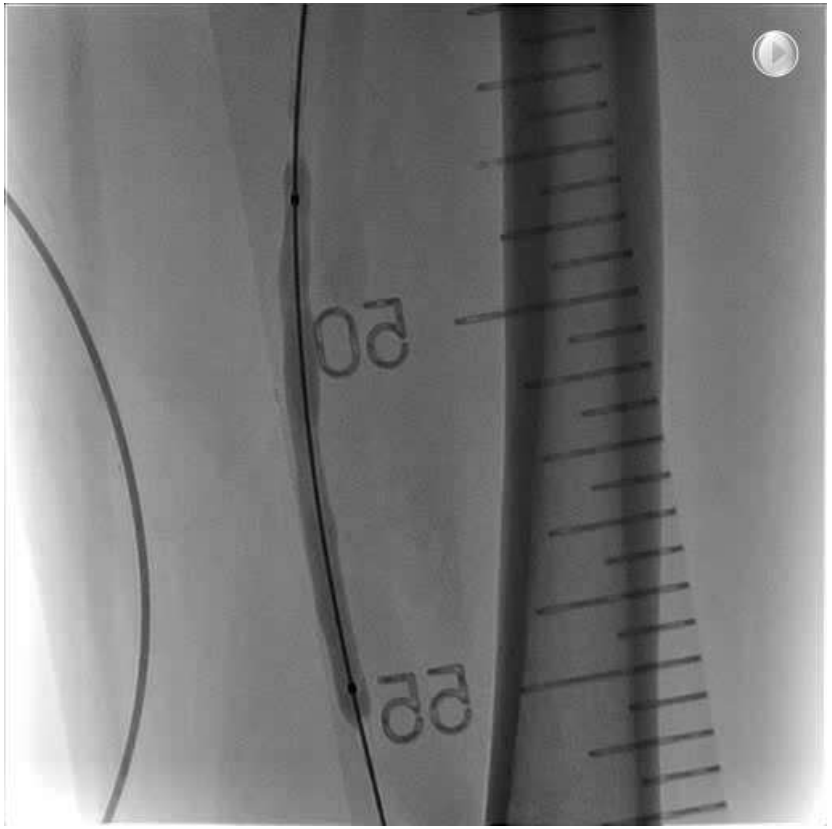


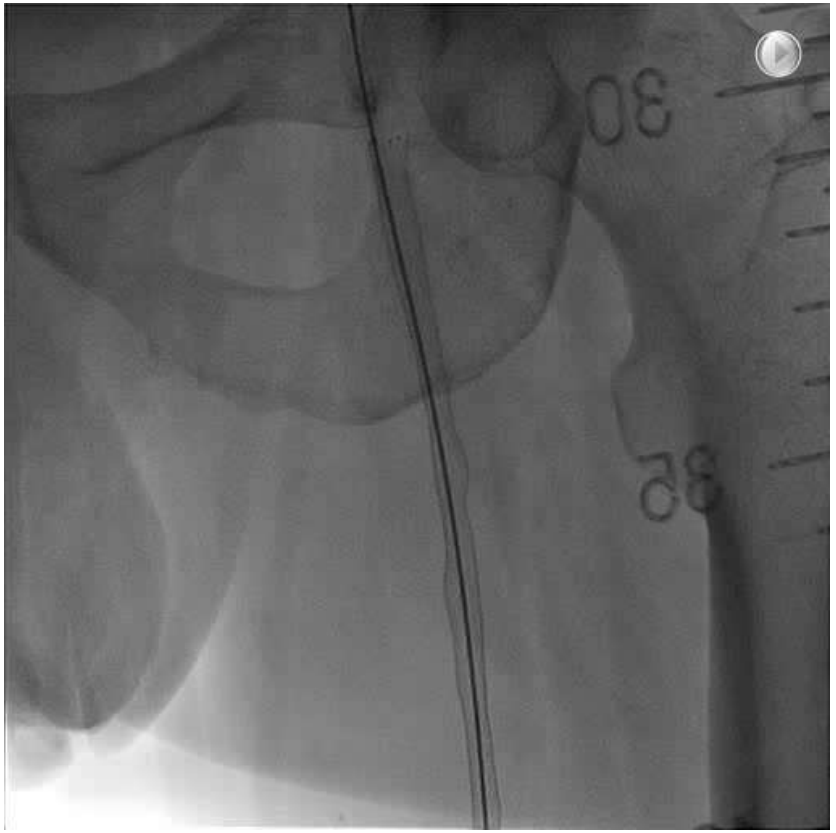
2nd Treatment

(2010/5/27)



2nd Treatment: SIA & Stent





3rd Treatment: Balloon & Stent

2012/8/26

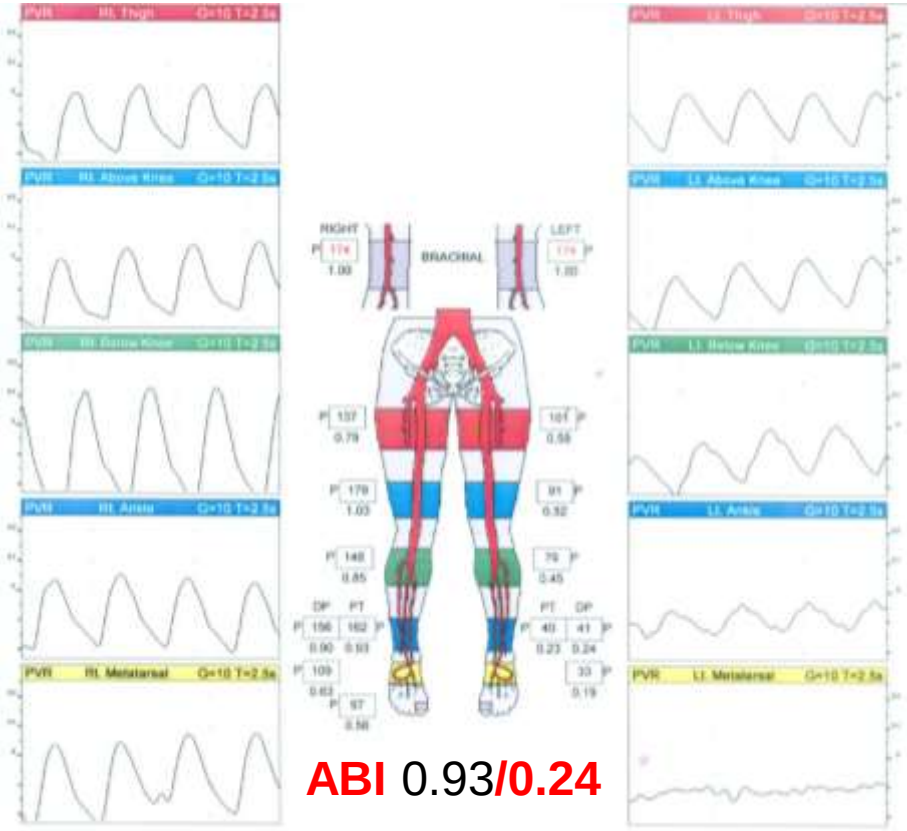
2012/8/28
Balloon angioplasty
& stenting

2012/8/29

Recurrence of Sx

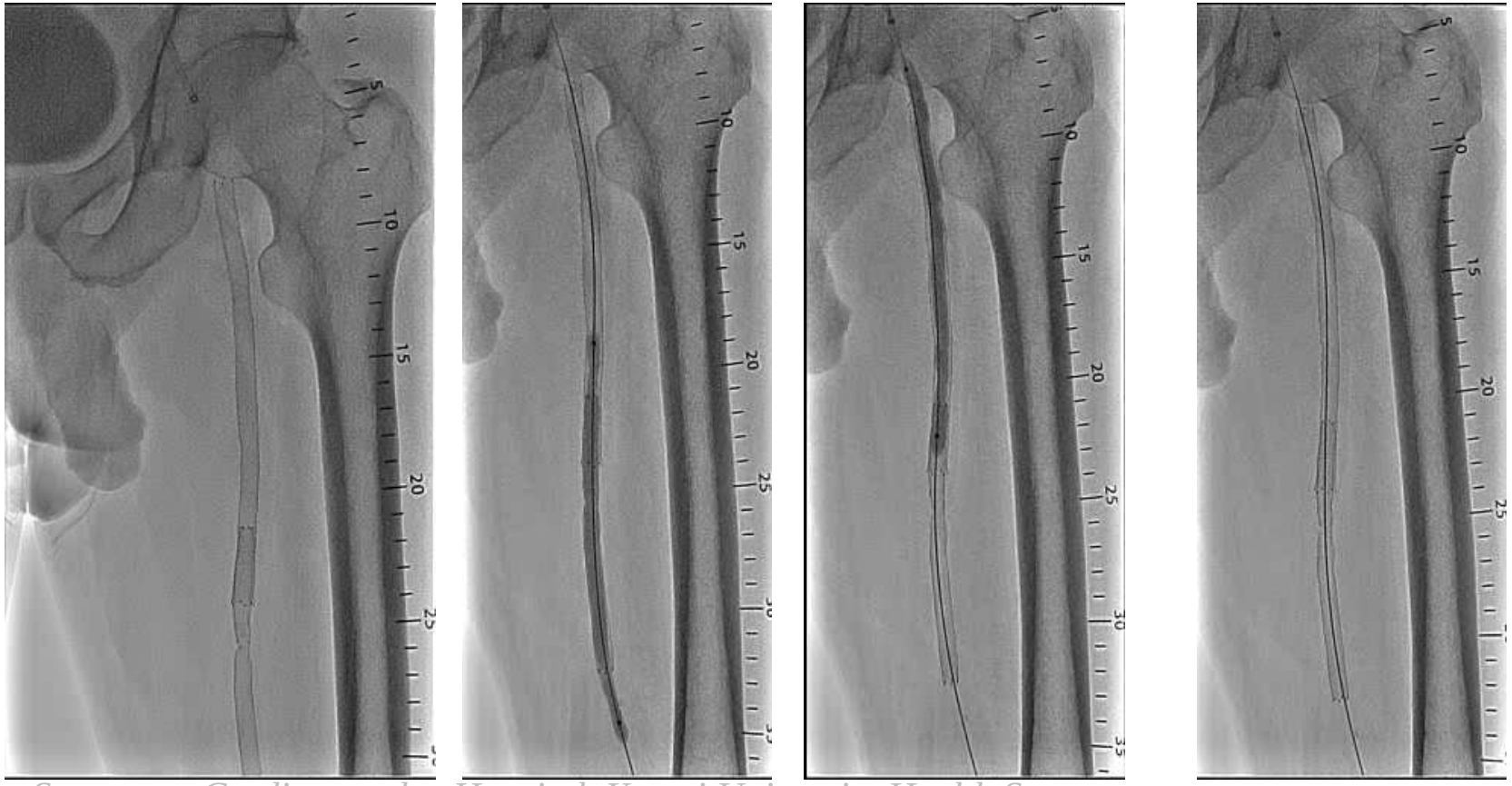
2013/6

Sx:
Claudication at 50 M, left leg



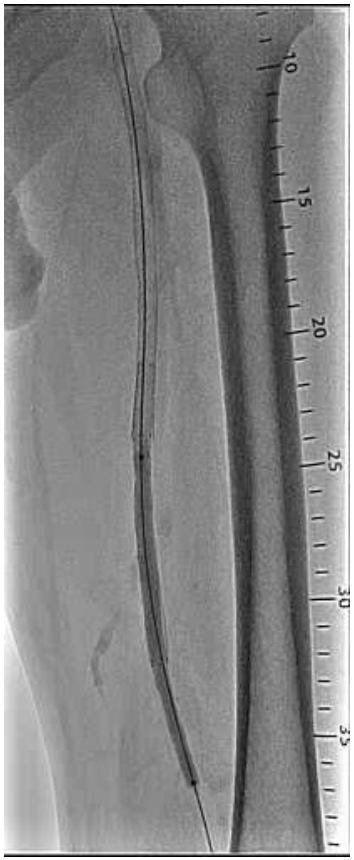
4th Treatment:

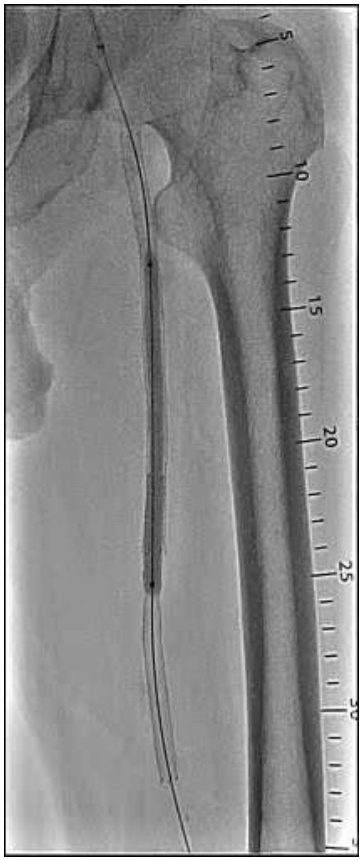
(2013/6/4)



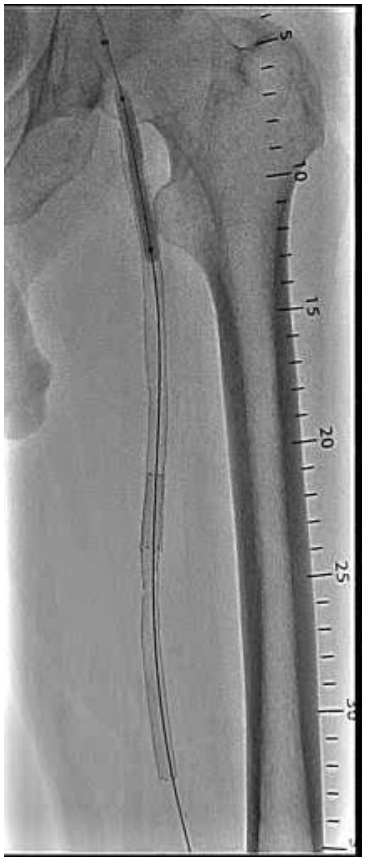
DEB

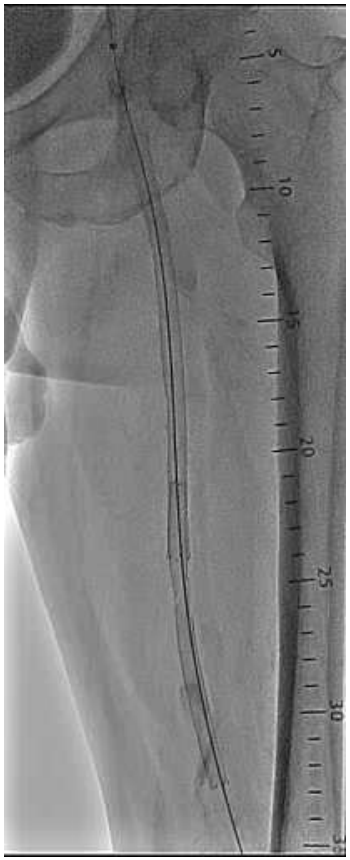
Admiral InPACT 6 x 120 * 2





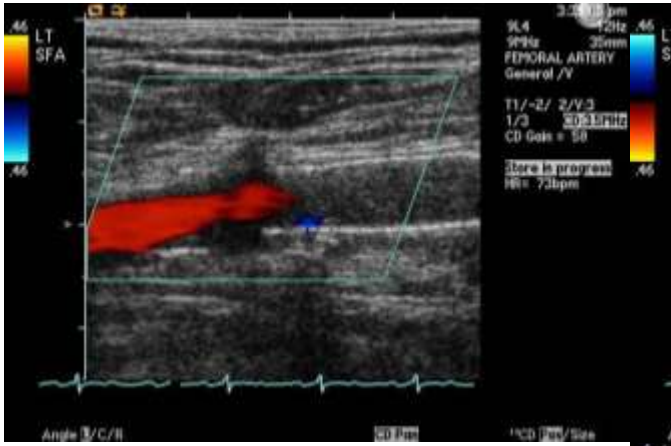
InPACT 6 x 60



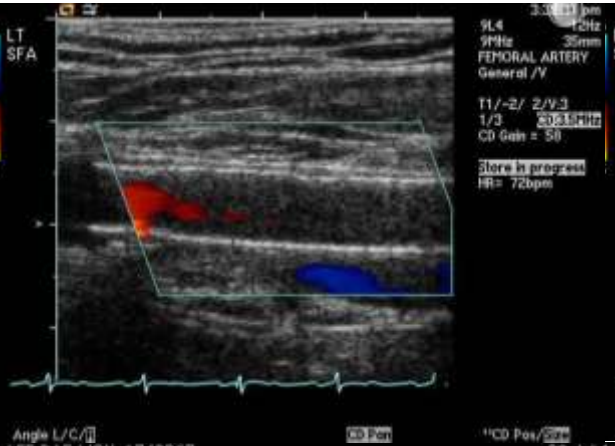


Duplex US Follow-up at 1 year

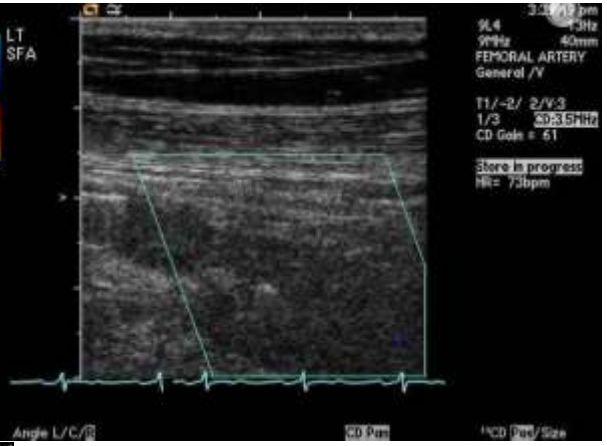
Proximal

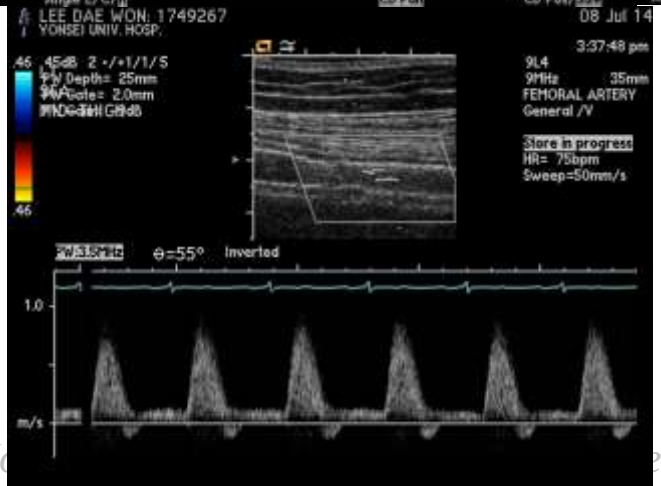


Within stent



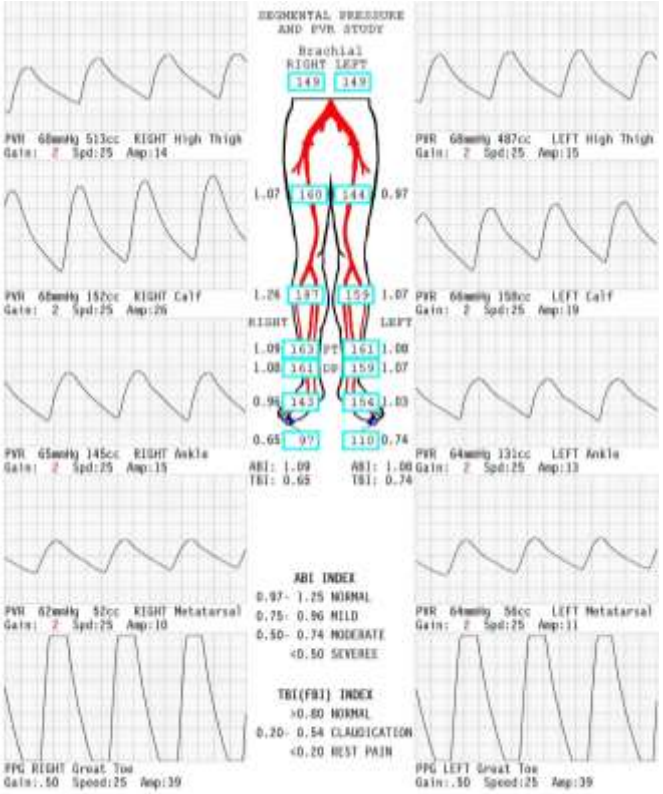
Distal to stent





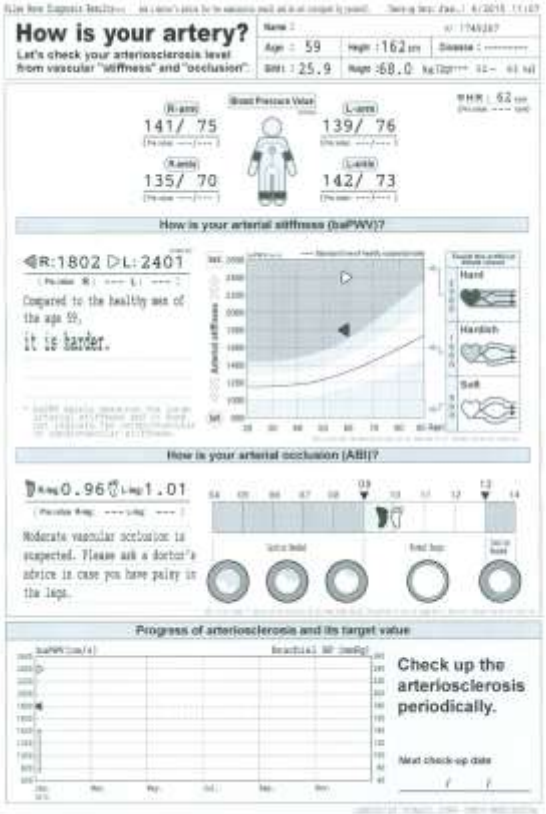
ABI Follow-up

At 12 months



ABI 1.09/**1.08**

At 18 months

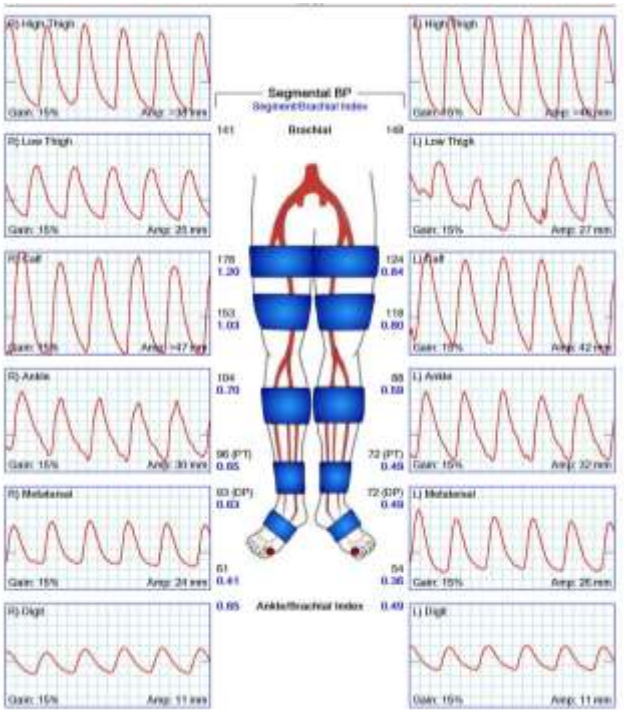


ABI 0.96/**1.01**

M/71 (LWS, M/3275132)

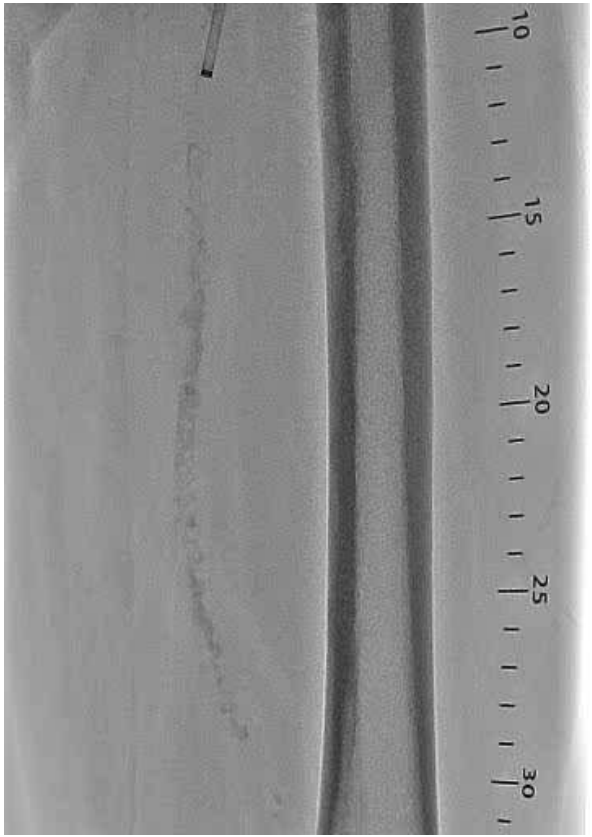
Sx: Claudication: Lt > Rt
(Rutherford 3)

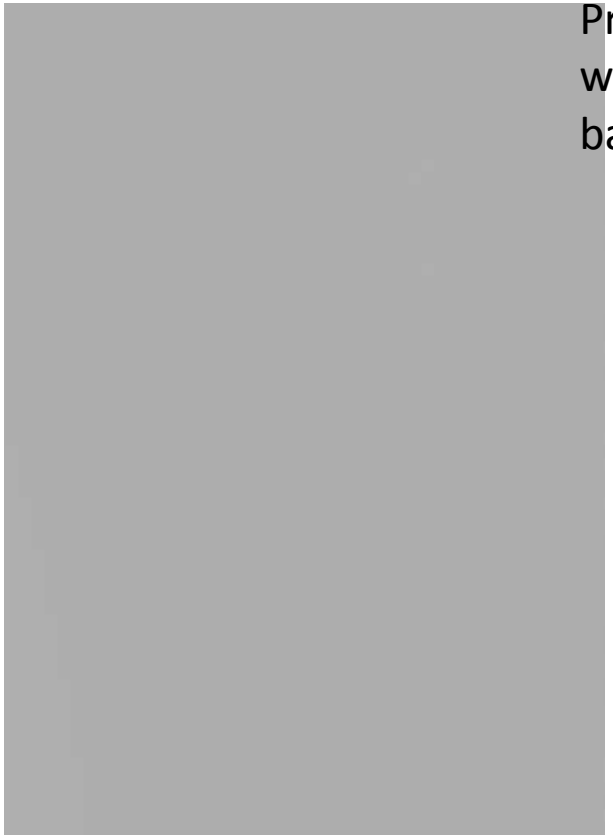
PHx:
- DM, HTN
- CAD (LN & 3VD)
- S/P PCI with stents (2003/3)



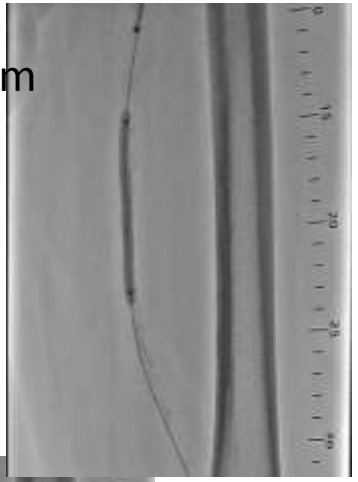
ABI 0.65/0.45

Lt. SFA



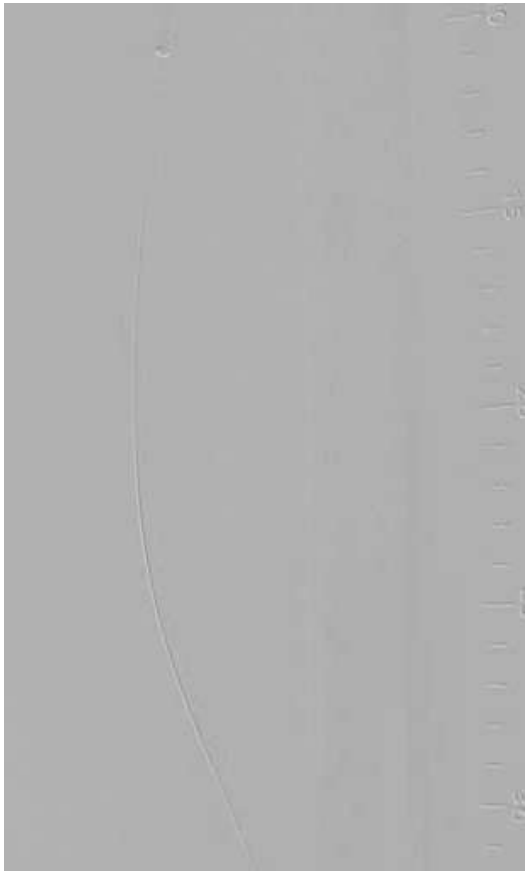


Predilation with a 5x80 mm balloon

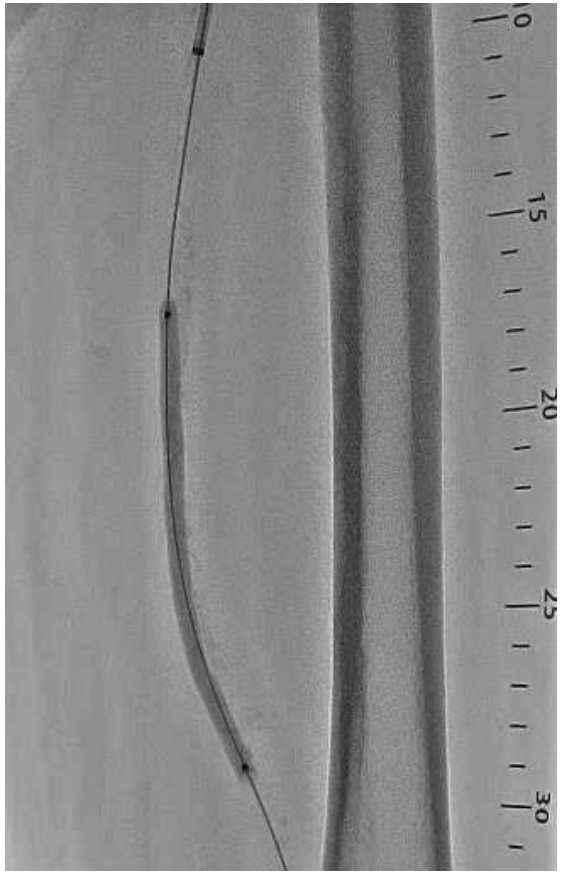


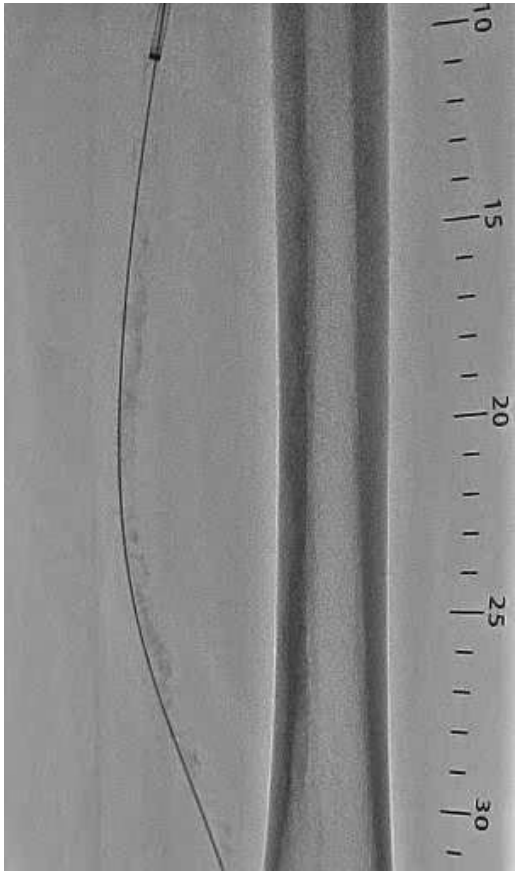
DEB

After predilation



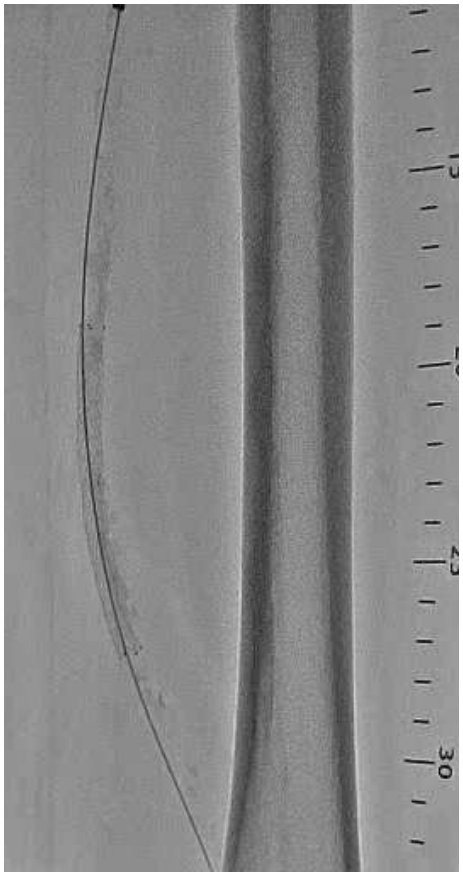
IN.PACT Admiral 5 x 120 mm & 5 x 40 mm



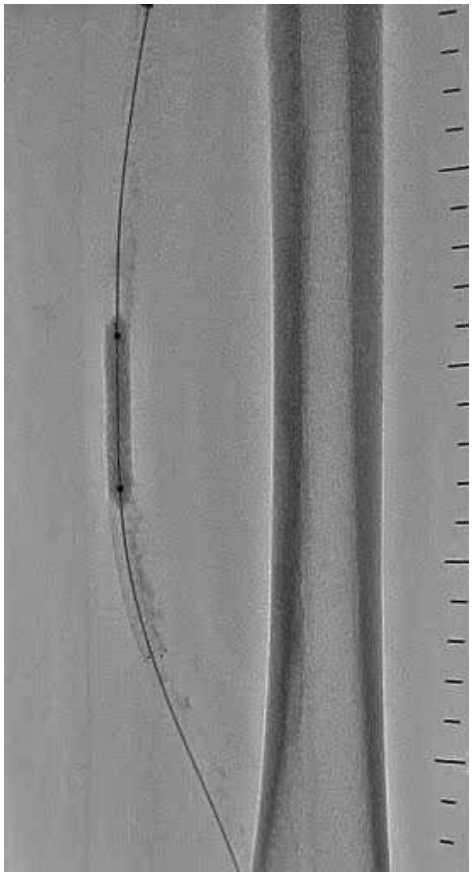


Bail-out Stenting

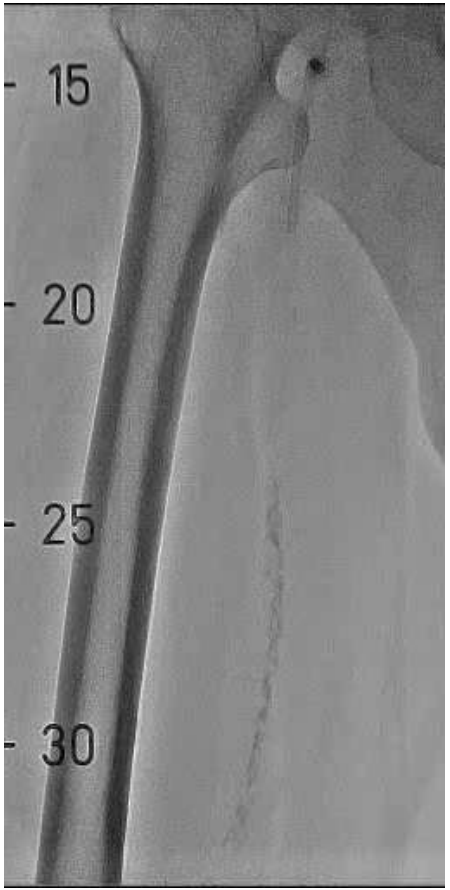
Complete SE 6 x 80 mm



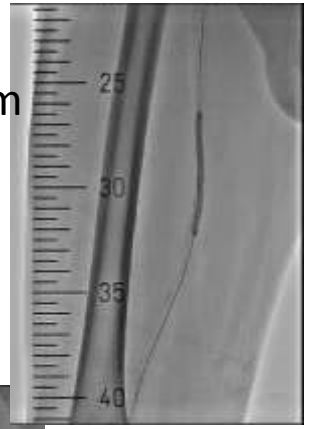
Postdilation with balloon 5 x 40 mm

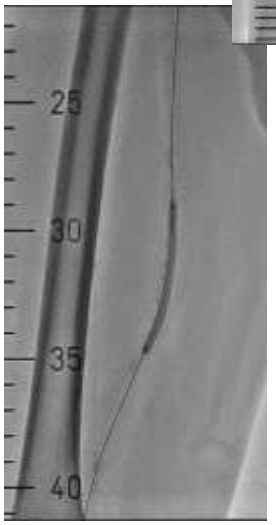


Rt. SFA



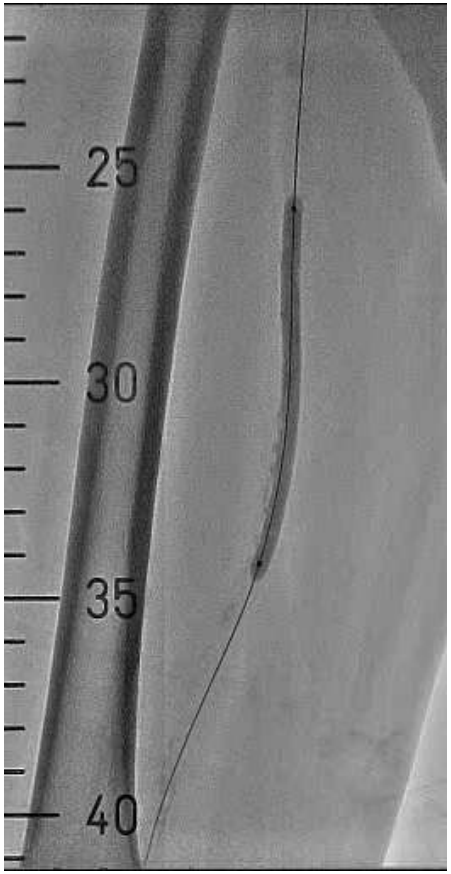
Predilation
with 5 x 80 mm
balloon

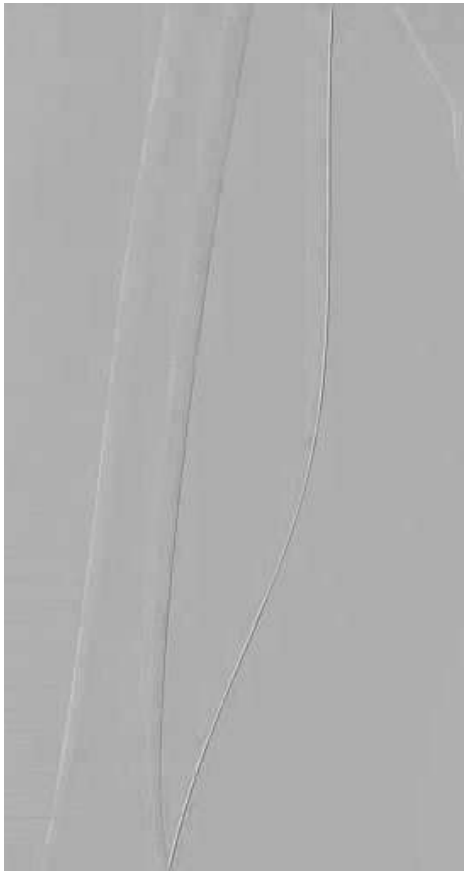




DEB

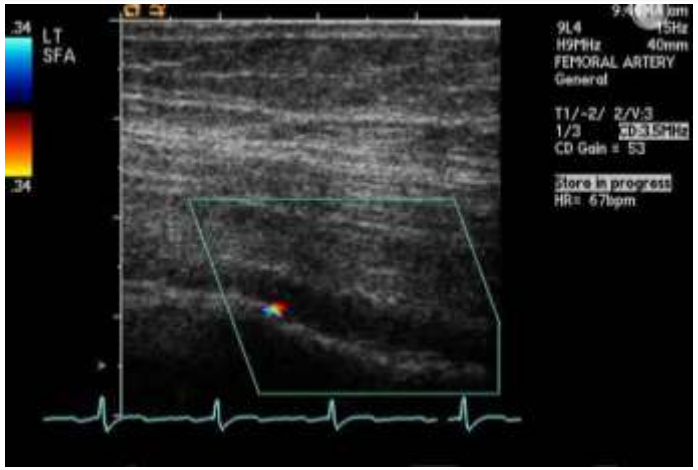
IN.PACT Admiral 6 x 120 mm

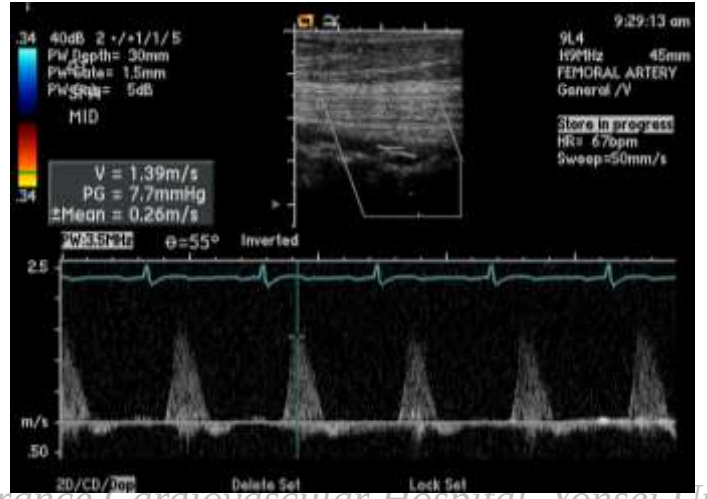


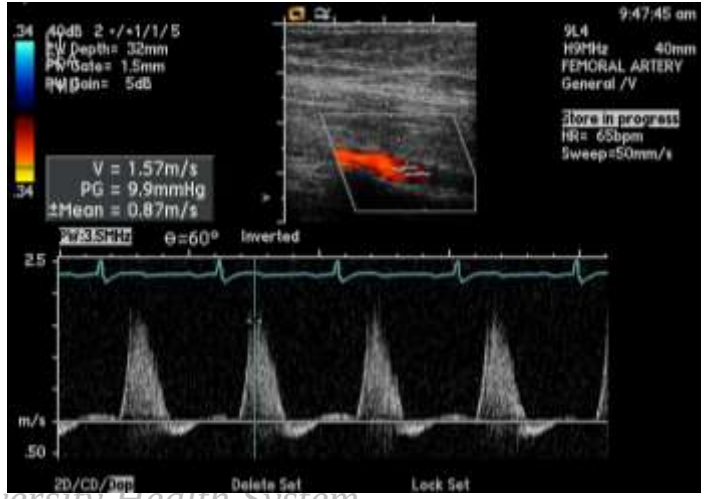


Duplex US Follow-up at 1 year

Right SFA



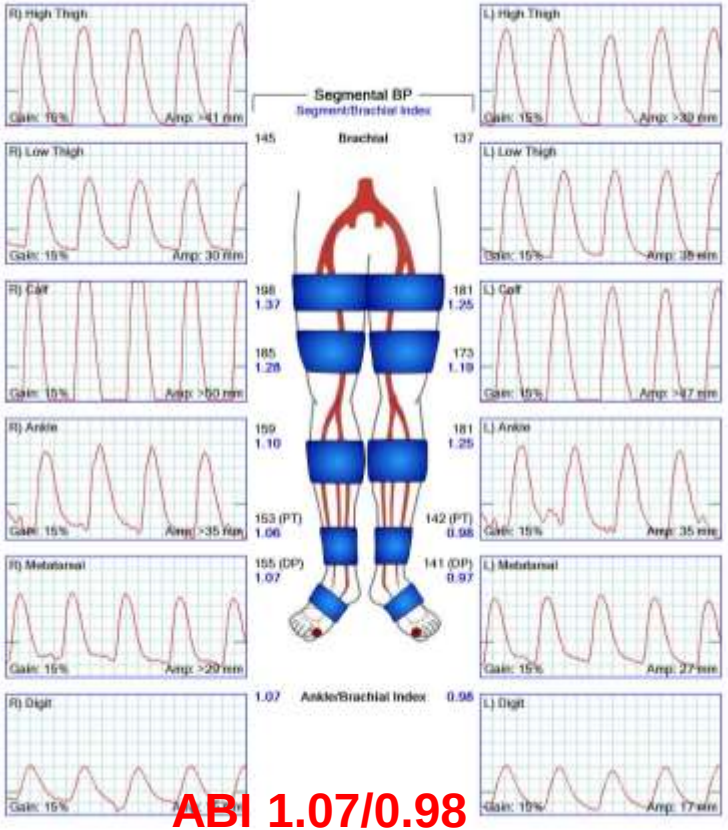




Left SFA

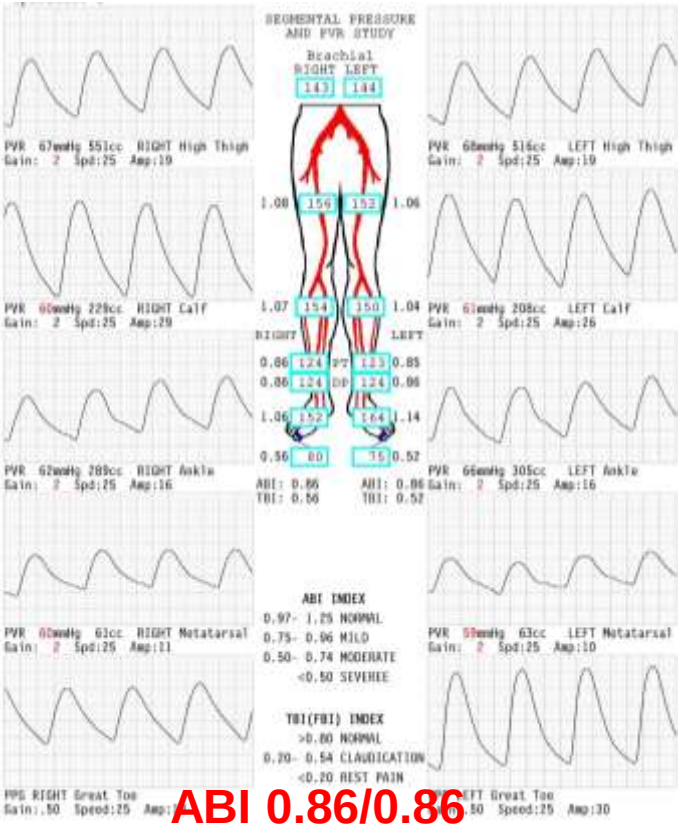
ABI Follow-up

At 1 year



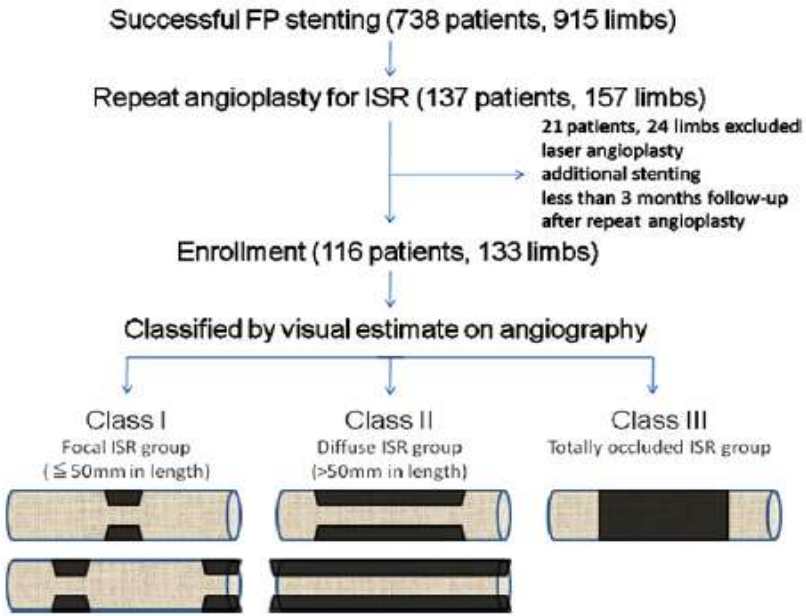
ABI 1.07/0.98

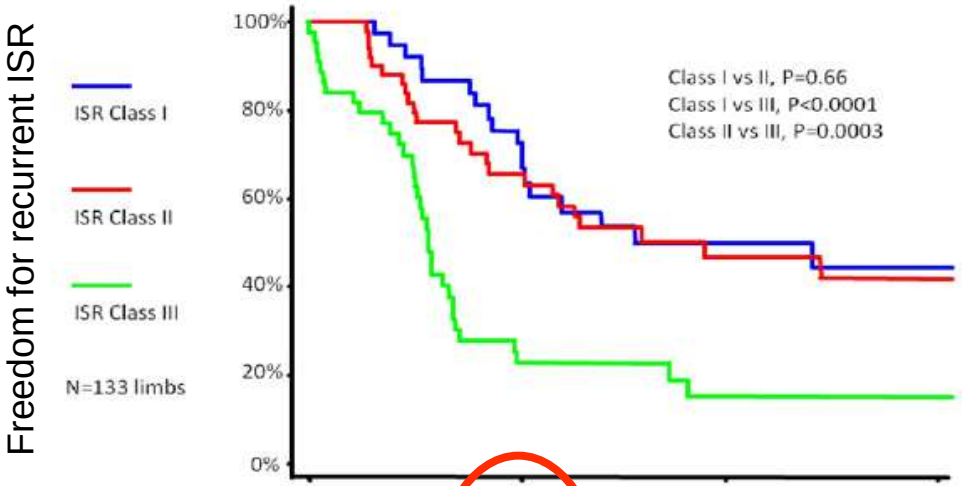
At 2 years



ABI 0.86/0.86

Balloon angioplasty for ISR





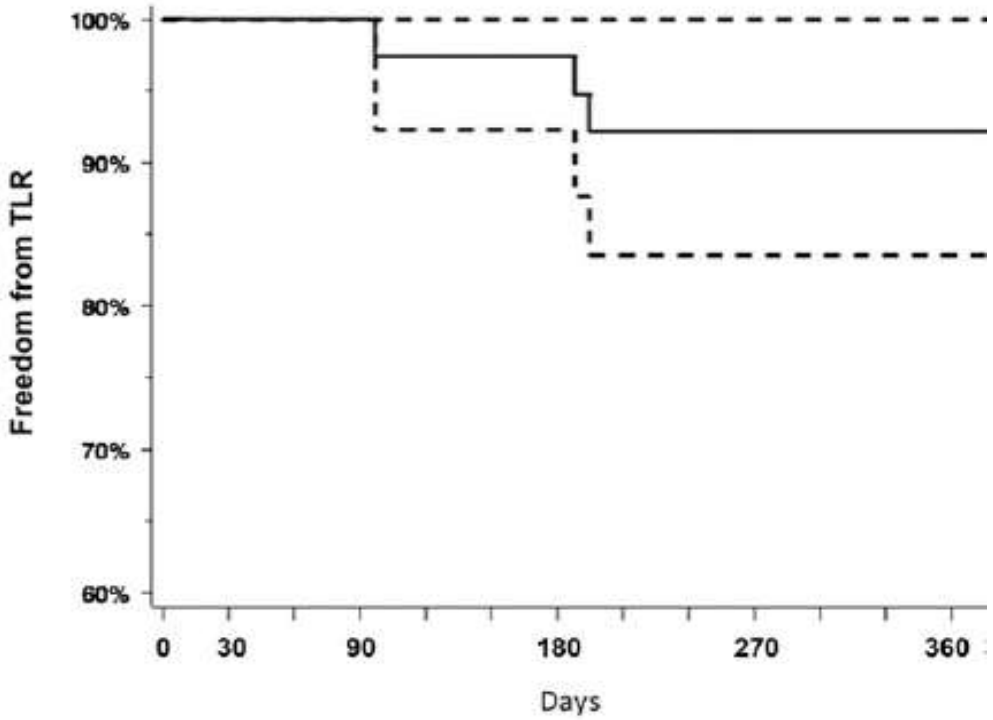
Follow-up interval (years)		0	1	2	3
Class I	at risk	39	25	11	5
	%	100	72.5	50.1	44.5
Class II	at risk	50	28	12	5
	%	100	65.6	46.7	42.0
Class III	at risk	44	9	4	2
	%	100	22.7	15.2	15.2

Tosaka et al, JACC 2012;59:16-23

DEB for ISR Lesions

- 39 patients
- SFA-ISR lesions
  - Type I: 31%
  - Type II: 49%
  - Type III: 21%
- Paclitaxel-eluting balloons (IN.PACT)
- 1 year patency: 92%

Freedom from TLR



Stabile et al, JACC 2012;60:1739-42

Severance DEB for ISR Data: Baseline characteristics

	Conventional therapy (n=56)	Drug eluting balloon (n=21)	P value
Age (years)	66.2 ± 10.6	65.5 ± 13.9	0.80
Sex (male, %)	42 (72.4)	20 (87)	0.16
DM (%)	28 (48.3)	10 (43.5)	0.7
HTN (%)	37 (63.8)	11 (47.8)	0.19
Smoking (%)	30 (51.7)	17 (73.9)	0.14
Dyslipidemia (%)	33 (56.9)	17 (73.9)	0.16
CKD (%)	15 (25.9)	7 (30.4)	0.68
Rutherford category	3.1 ± 1.3	2.6 ± 0.7	0.02
Pre ABI	0.43 ± 0.19	0.78 ± 0.19	<0.0001
Post ABI	0.63 ± 0.16	1.08 ± 0.25	<0.0001

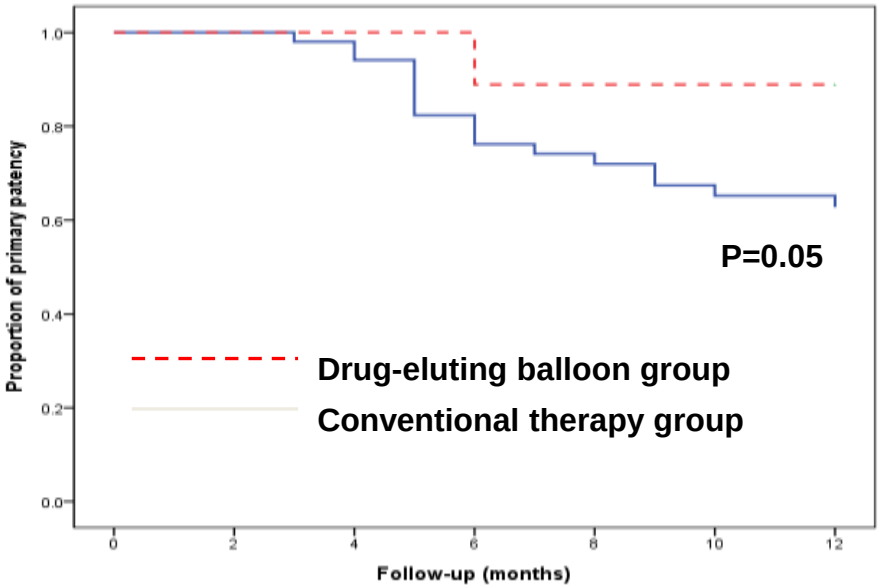
Procedural data

	Conventional therapy (n=56)	Drug-eluting balloon (n=21)	P value
ISR pattern (%)			0.07
Focal	3 (5.2)	5 (21.7)	
Diffuse	9 (15.5)	2 (8.7)	
Total	46 (79.3)	16 (69.6)	
BTK runoff vessel	2.09 ± 0.88	2.05 ± 0.89	0.84
Stent diameter (mm)	7.07 ± 0.75	7.1 ± 1.45	0.93
Stent length (mm)	87.8 ± 28.7	94.4 ± 32.6	0.39
Stent fracture (%)	4 (6.9)	2 (8.7)	0.78

Clinical outcomes

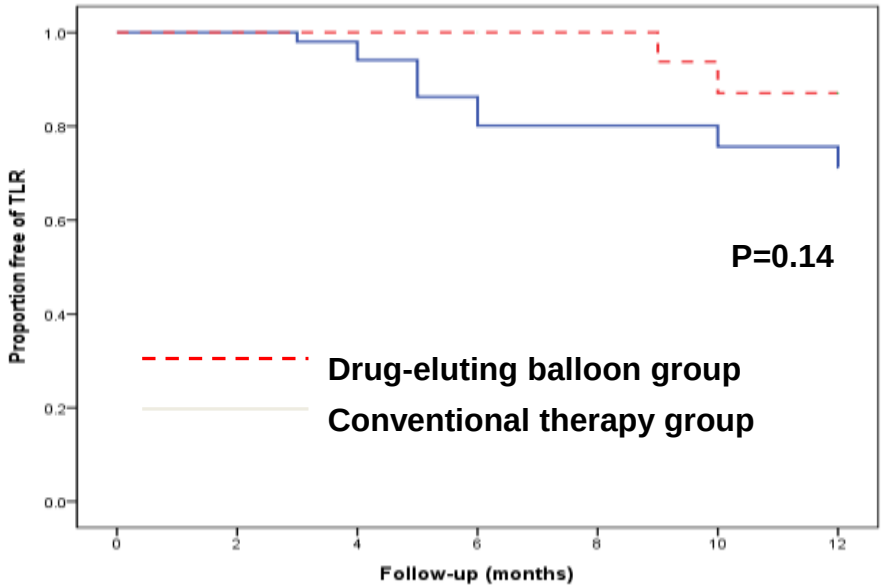
Primary patency

DEB vs. Conv Tx: 91.3% vs. 69%



Freedom from TLR

DEB vs. Conv Tx: 91.3% vs. 75.9%



Summary & Conclusions

- 1-year interim data suggest safe and effective use of IN.PACT Admiral in the treatment of de novo and ISR SFA diseases in the Asian population.
- Remarkably low CD-TLR (3.1%) was demonstrated in this patient subset with mean lesion length of 17.97 ±12.57cm.
- Low incidence of provisional stenting (5.3%) and low CD-TLR preserves future treatment options.
- Additional 12-month data from the Asian population from the full study cohort is awaited.

Thank you
for your attention!