Reflection on use of IN.PACT DCB in Chinese population — a single center perspective

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Disclosure

Speaker name:

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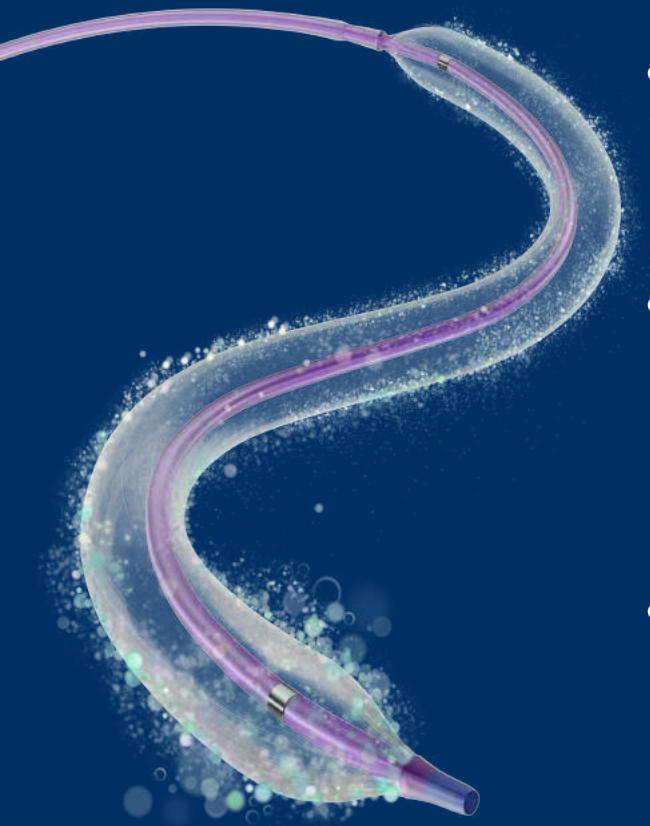
I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☒ I do not have any potential conflict of interest

Background



- Drug-coated balloons have shown improved patency results over PTA in randomized trials[1-7]
- IN.PACT™ Admiral™ DCB is the only DCB to show long term benefits through 4 years in the IN.PACT SFA trial and 2 years in the IN.PACT Global study[1-4, 8, 9]
- Performance of DCBs in several populations is still poorly understood

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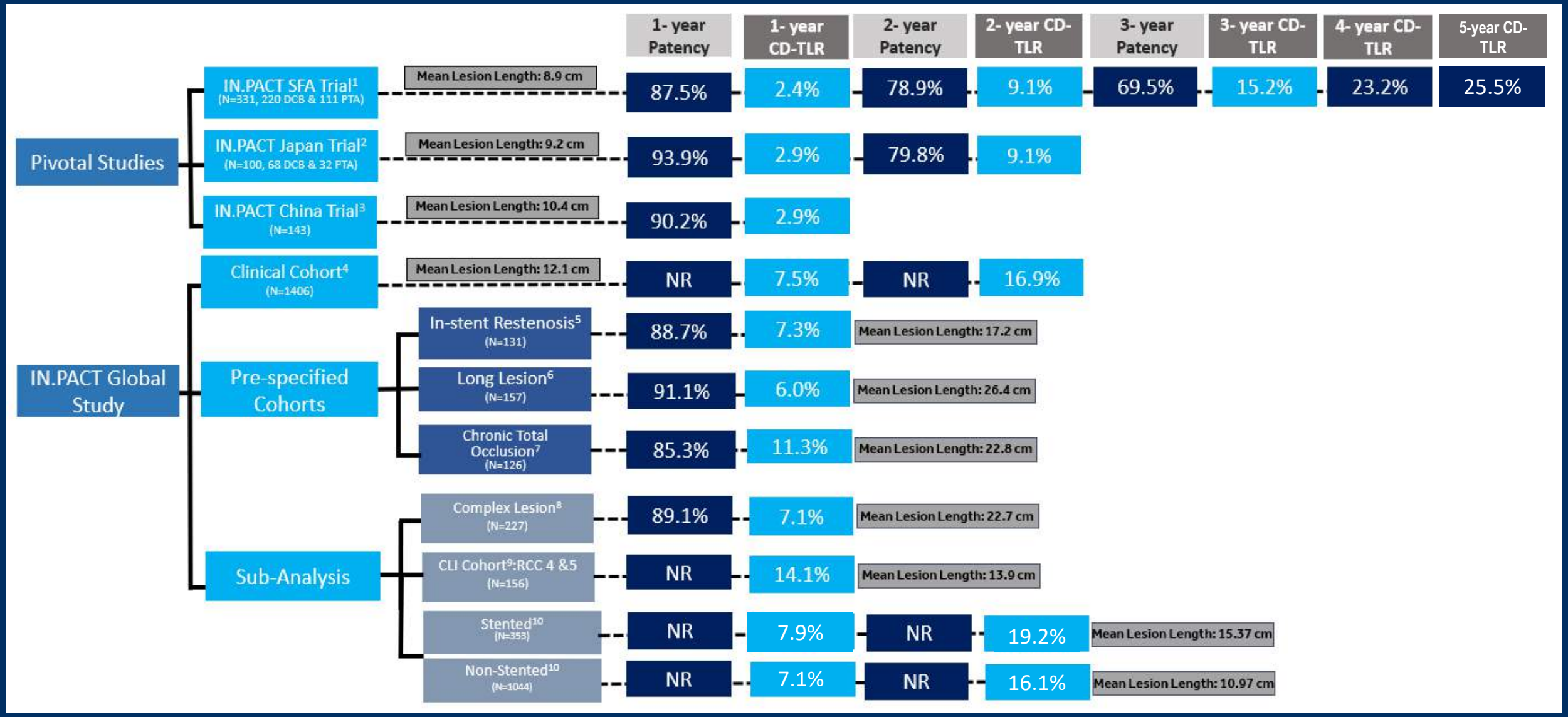
IN.PACT DCB Clinical Program



IN.PACT SFA China Study

- Prospective, multi-center (15 sites) single-arm study

Study Population

Chinese patients (n=**143**), with
de-novo and non stented restenotic lesions in
SFA/PPA, RCC 2-4

Treatment

IN.PACT Admiral DEB*

Follow-up	30 D	6 M	12 M
			
	± 7D	± 30D	± 30D

Rigor

Independent Core labs[1,2],Clinical events committee[3]

Primary Endpoints

Efficacy Endpoints:
Primary patency within **12 months** [4]

Safety Endpoint: 30-day safety composite[5]

Both endpoints were powered and compared to a Performance Goal Derived from the Literature!

1. VasCore DUS Core Laboratory, Boston, MA, US
2. Beth Israel Deaconess Medical Center, Boston, MA, US
3. Clinical Event Committee and Data Safety Monitoring provided by Syntactx, NY, US

• After completion of the clinical trial the study product name has been updated to IN.PACT Admiral Paclitaxel coated PTA balloon catheter which is also referred to as IN.PACT Admiral DCB. The generic name of the product used is Drug Coated Peripheral Balloon Dilating Catheter

4. Defined as freedom from clinically-driven TLR and freedom from restenosis as as determined by DUS and PSVR ≤ 2.4 within 12 months post-index procedure.
5. Defined as composite of freedom from device- and procedure-related mortality, freedom from major target limb amputation and freedom from clinically-driven TLR within 30 days post-index procedure.

IN.PACT SFA China Study

Select Baseline and Procedural Characteristics

Patient Characteristics	N=143 Subjects
Age, Y ± SD	66.8 ± 7.7
Male Gender (%)	74.8% (107/143)
Diabetes Mellitus (%)	46.2% (66/143)
Current Smoker (%)	36.4% (52/143)

Lesion Characteristics	N=143 Subjects N=143 Lesions
Lesion Type [1] De novo Restenotic (non-stented)	 99.3% (142/143) 0.7 % (1/143)
Lesion length (cm ± SD) [2]	10.40 ± 6.51
Total occlusions, % (n) [2]	52.4% (75/143)
Severe calcification, % (n) [2]	11.9% (17/143)

1. Site-reported
2. Normal-to-normal by Core Lab QVA evaluation

Procedural Characteristics		N=143 Subjects N=143 Lesions
Pre-Dilatation (%) [1]		100% (143/143)
Post-dilatation (%) [1]		14.0% (20/143)
Dissections (%)	0 A B-C D E-F	 18.9% (27/143) 0.0% (0/143) 55.3% (79/143) 25.9% (37/143) 0.0% (0/143)
Provisional Stenting (%) [1]		4.2% (6/143)
Device Success (%) [3]		97.6% (206/211)
Procedural Success (%) [4]		91.5% (130/142)
Clinical Success (%) [5]		89.4% (127/142)

3.Device success: Successful delivery, inflation, deflation and retrieval of the intact study balloon without burst < RBP
4.Procedural success: Residual stenosis ≤ 50% for non-stented subjects or ≤ 30% for stented subjects
5.Clinical success: Procedural success without procedural complications (death, major target limb amputation, thrombosis of target lesion or TVR) prior to discharge

IN.PACT SFA China Study

Primary Outcomes

	DEB	95%CI	Performance Goal	p-value
Primary Efficacy Primary Patency [1]	88.6% (109/123)	[81.6%, 93.6%]	50%	< 0.001

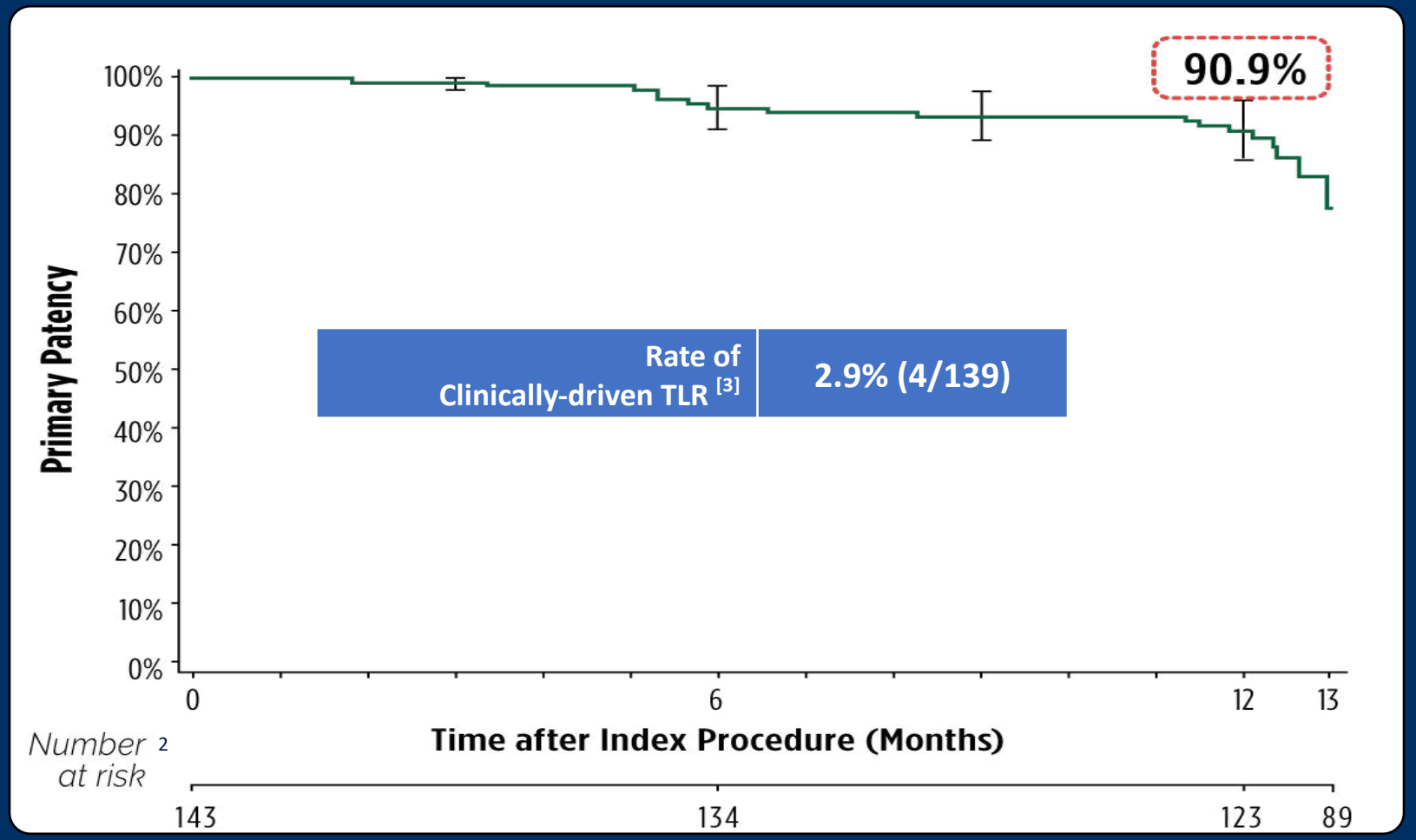
	DEB	95%CI	Performance Goal	p-value
Primary Safety Composite [2]	99.3% (141/142)	[96.1%, 100.0%]	88%	< 0.001

Primary endpoints met

1. 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 in ITT non-stented subjects.
2. Primary safety composite is defined as freedom from device- and/or procedure-related mortality, freedom from major target limb amputation and freedom from clinically-driven TLR within 30 days post-index procedure in ITT subjects.

IN.PACT SFA China Study

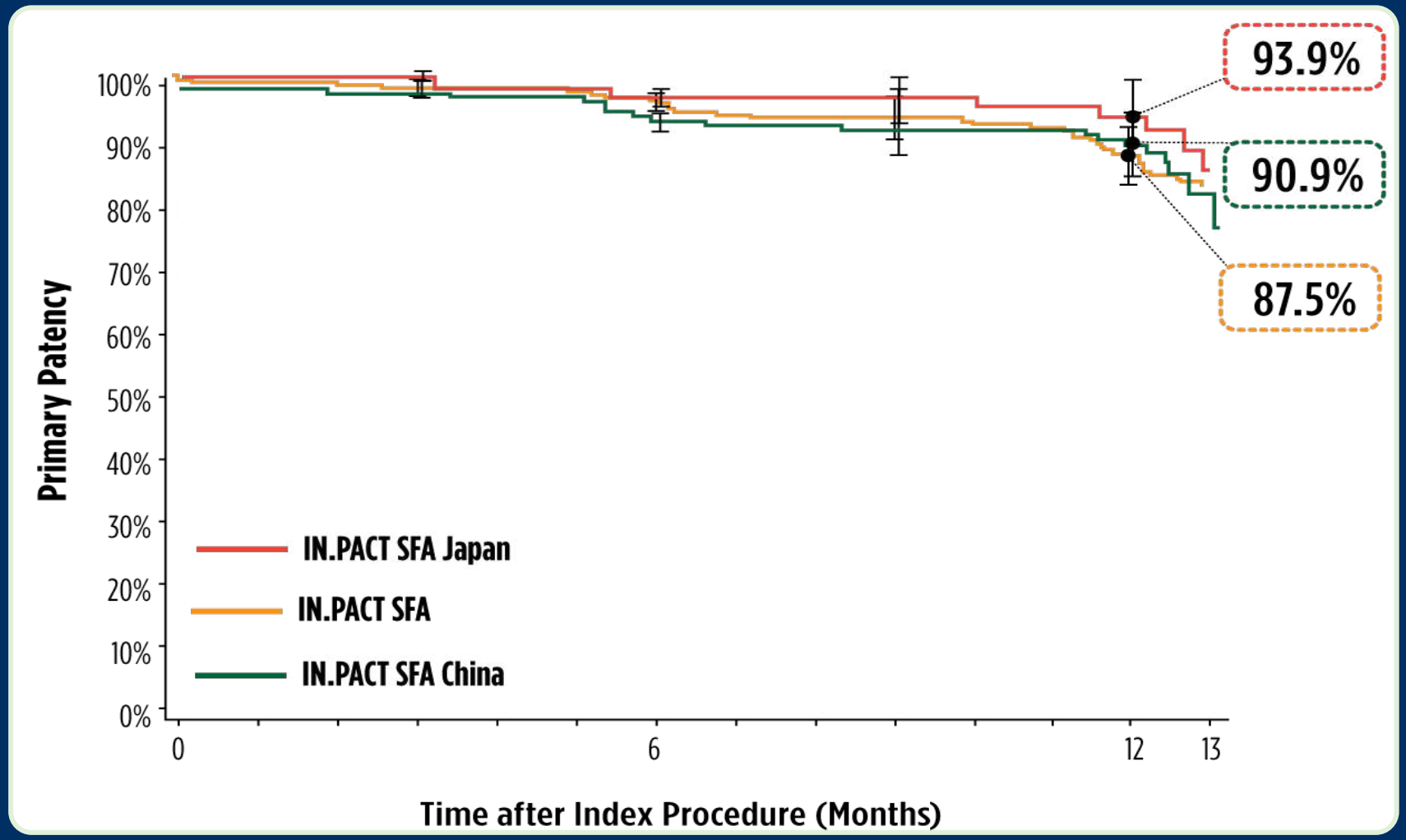
12-Month Primary Patency[1] (ITT)



1. Freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) and clinically-driven target lesion revascularization through 12 months (adjudicated by a Clinical Events Committee)
2. Number at risk represents the number of evaluable subjects at the beginning of the 30-day window prior to each follow-up interval
3. Clinically-driven TLR is defined as any re-intervention at the target lesion due to symptoms or drop of ABI/TBI of ≥20% or >0.15 when compared to post-procedure baseline ABI/TBI.

IN.PACT SFA China Study

Consistent Patency Results Across IN.PACT Studies



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2. Iida, O. IN.PACT Japan 12 Month Results. LINC 2017
3. Guo,. IN.PACT China 12 Month Results, J. Endo Therapies, June, 2019.

12-month Outcomes Across IN.PACT Trials

	IN.PACT SFA	IN.PACT	IN.PACT	IN.PACT
	China	Japan[4]	SFA[1]	Global[2]
	n=143	n=68	n=220	n=1406
Lesion Length (Mean ± SD, cm)	10.4 ± 6.5	9.2 ± 5.9	8.9 ±4.5	12.1 ± 9.5
Total Occlusion% （n）	52.4%（75/143）	13.2% (48/364)	25.8% (57/221)	35.5%（629/1773）
Calcification %（n）	66/143 (46.2)	62.6% (218/348)	59.3%（131/221）	68.7%（1217/1773）
Severe Calcification%（n）	11.9%（17/143）	8.0% (28/348)	8.1%（18/221）	10.2%（181/1771）
Provisional Stenting	4.20%	4.40%	7.30%	0.253
Primary Patency (KM @ 360 days)	90.90%	93.90%	87.50%	NA
CD-TLR	2.90%	2.90%	2.40%	7.50%
Any TLR	3.60%	2.90%	2.90%	7.80%
Mortality	2.90%	0.00%	1.90%	3.50%
Major Target Limb Amputation	0.00%	0.00%	0.00%	0.20%
Thrombosis	2.20%	0.00%	1.40%	2.90%

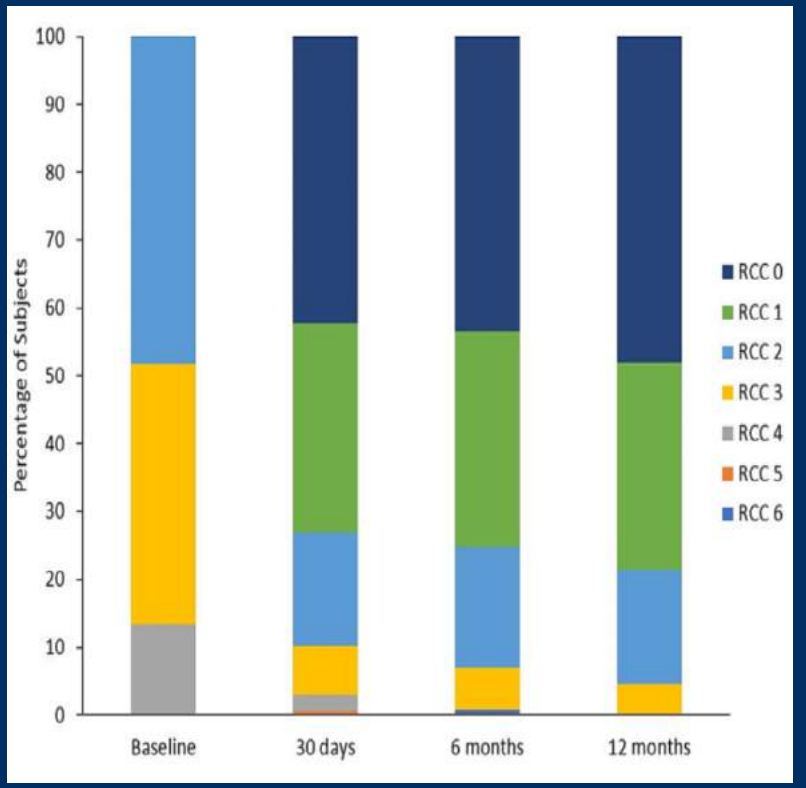
Long
ISR
Ca++
CTO

1. Tepe et al., Circulation 2015; Medtronic Data on File
2. Jaff, M. VIVA 2016.
3. Choi, D. LINC 2017.
4. Iida, O. LINC 2017.

IN.PACT SFA China Study

Functional Outcomes Through 12 Months

	Baseline	12 Months
Ankle-branchial index	0.64±0.22(139)	0.90±0.19(128)
6-minute walk test, m	275.6±104.7(137)	324.4±96.3(126)
Walking Impairment Questionnaire		
Walking impairment	44.1±20.2(141)	71.6±25.5(131)
Walking distance	46.9±29.9(120)	76.7±26.8(86)
Walking speed	37.8±23.2(120)	53.6±27.3(86)
Stair climbing	60.2±31.6(120)	75.4±28.8(86)
EQ-5D index	0.77±0.15(141)	0.86±0.14(131)
EQ-5D Visual Analogue Scale	74.1±13.7(141)	77.6±13.6(131)



Change in Rutherford category through 12 months
(p <0.001 between baseline and 12 months)

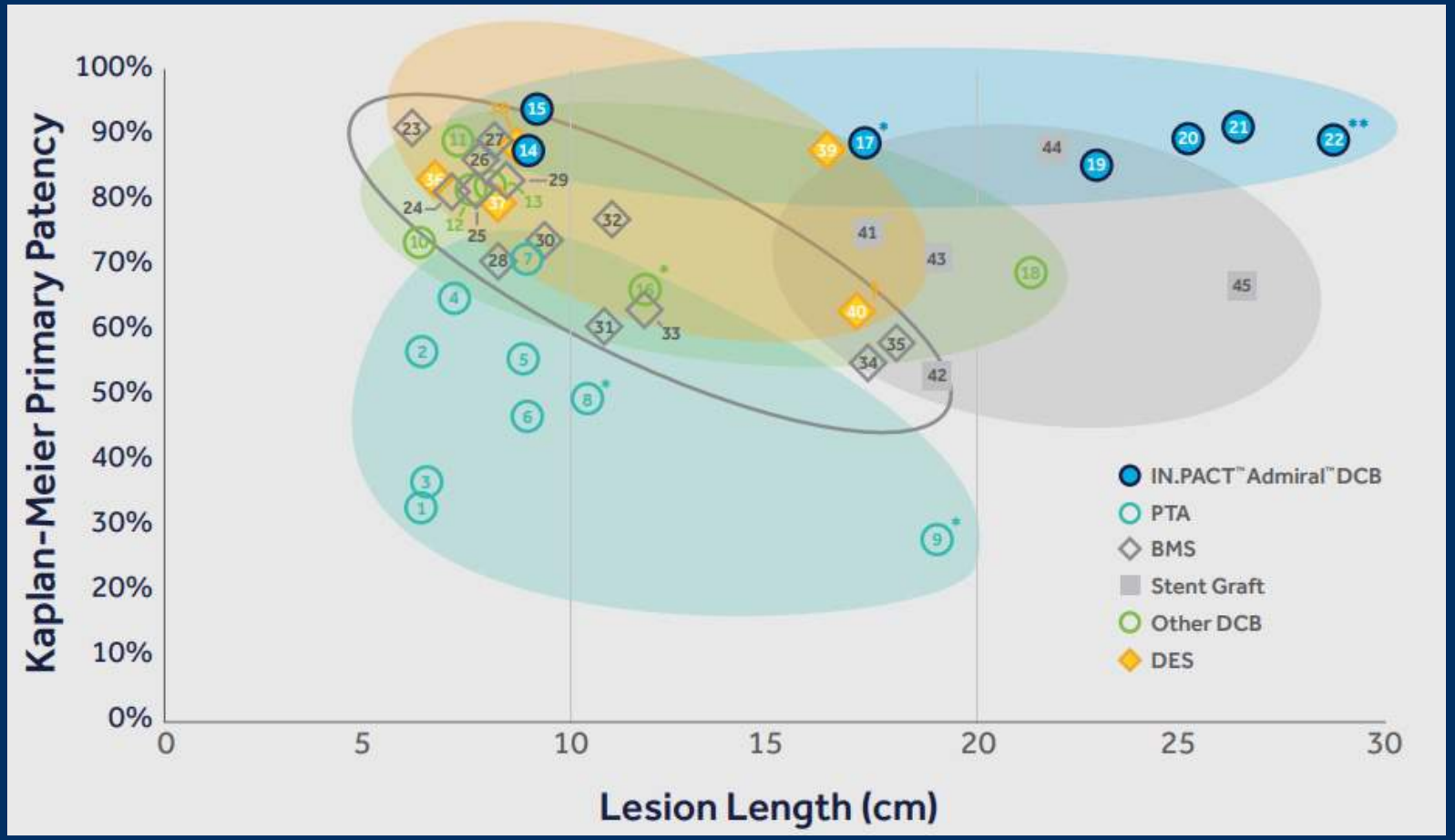
- At 12months, subjects showed improvement compared with baseline in all outcome metrics;
- Transition of all CLI subjects (RCC4) to the claudication categories at the 12-month point.

IN.PACT SFA China Study **Summary**

Results demonstrate remarkable performance of the IN.PACT™ Admiral™ DEB in a Chinese population at 12 months

- By Kaplan-Meier estimate, primary patency at 12 months was **90.9%**
- Results show a low CD-TLR rate of **2.9%** at 12 months
- Study met predefined safety and efficacy objectives
- These data are consistent with outcomes reported from other IN.PACT Trials, showing strong performance of IN.PACT™ Admiral™ DCB/DEB

Femoropopliteal Artery Disease Clinical Data Landscape

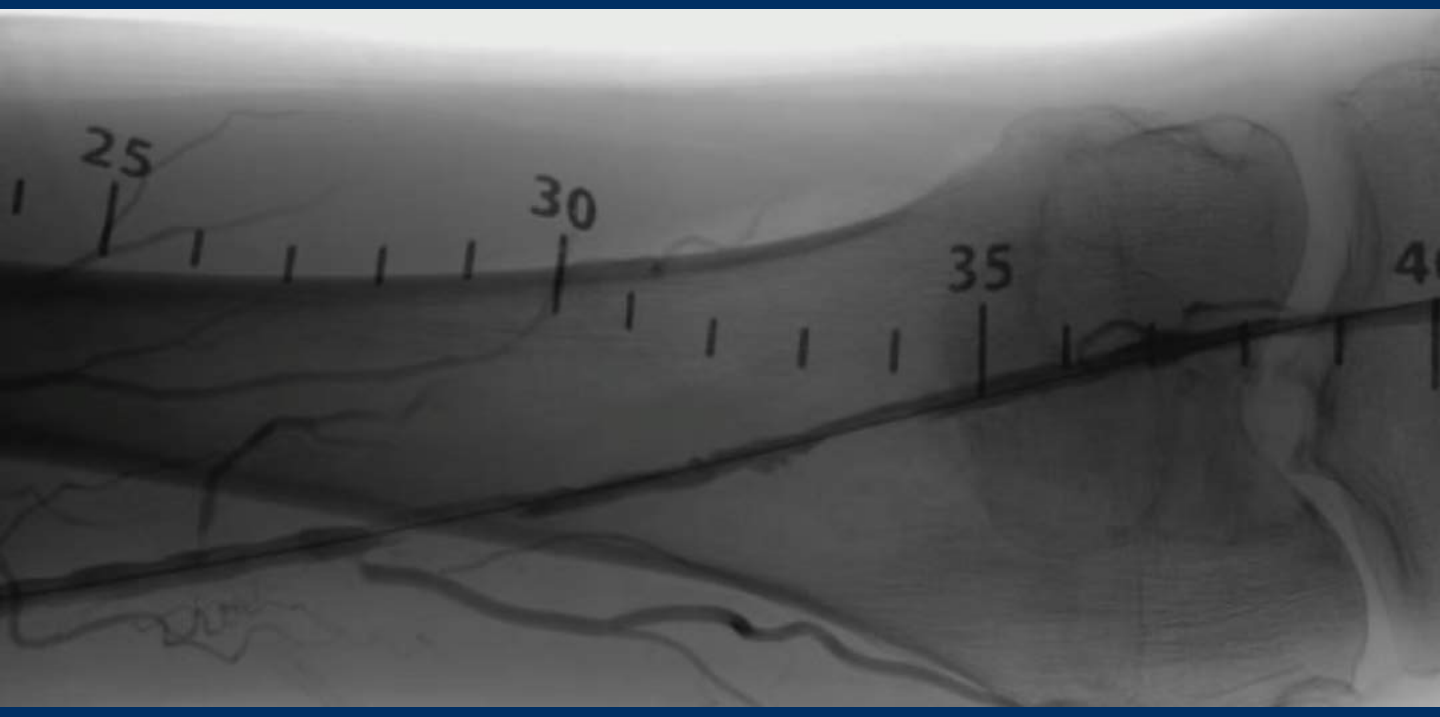


*ISR studies.

†Iida O, et al., report proportion-based patency of the ZEPHYR study.

**Subset analysis of previously reported data. IN.PACT Global Complex Lesion cohort consists of 227 subjects enrolled in the three IN.PACT Global pre-specified imaging cohorts (long lesion, chronic total occlusion, and in-stent restenosis) exhibiting lesion lengths > 18 cm.

[1] Phillips JA, Falls A, Kolluri R, et al. Full Drug-Eluting Stent Jacket: Two-Year Results of a Single-Center Experience With Zilver PTX Stenting for Long Lesions in the Femoropopliteal Arteries. J Endovasc Ther. June 2018;25(3):295-301.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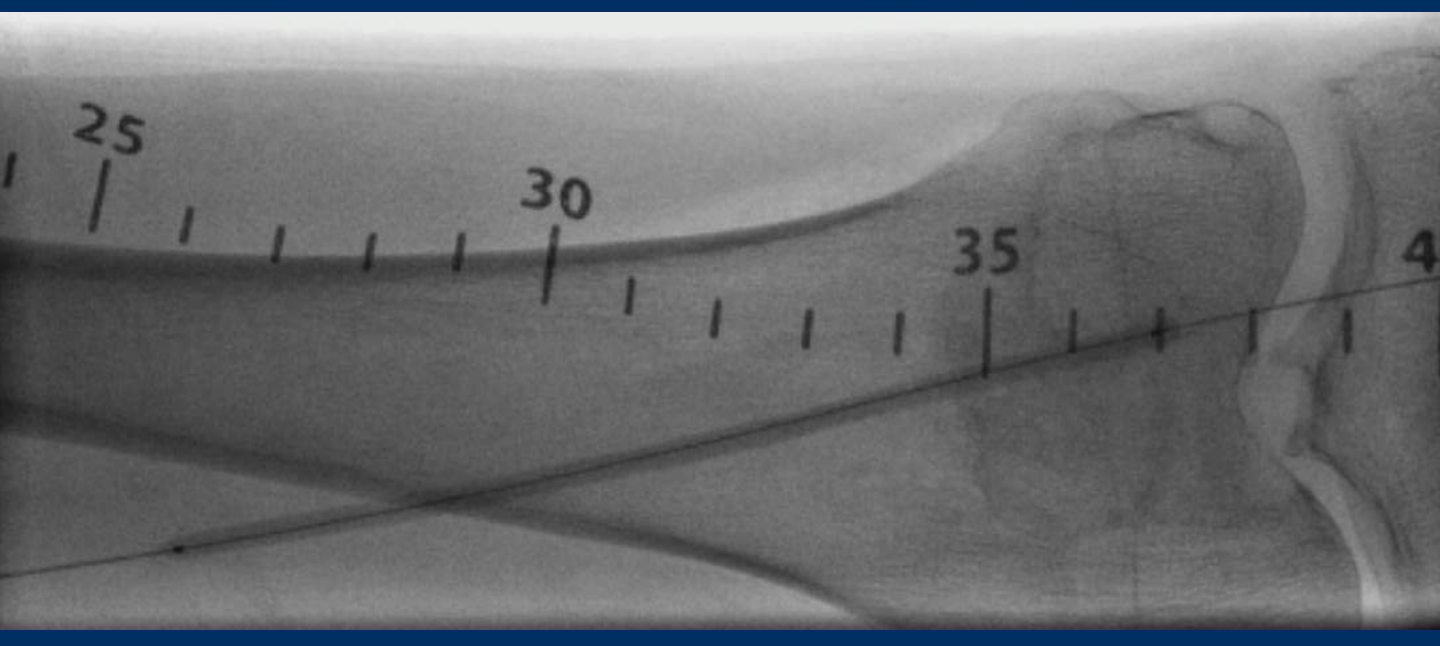
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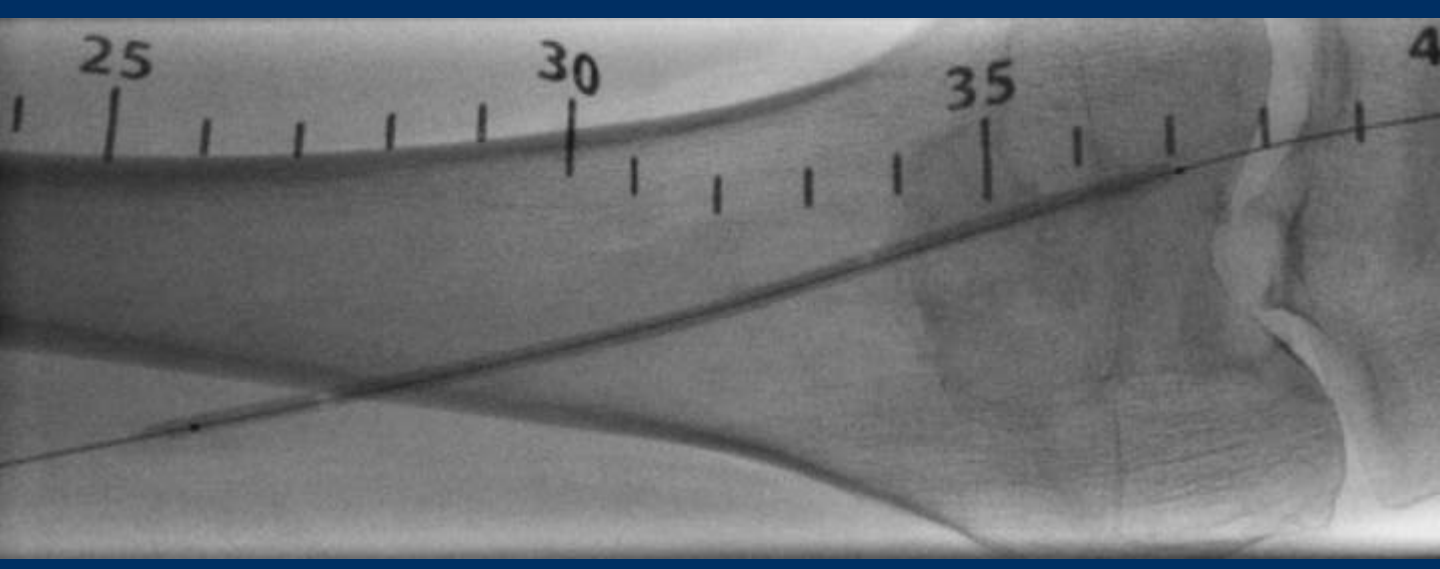
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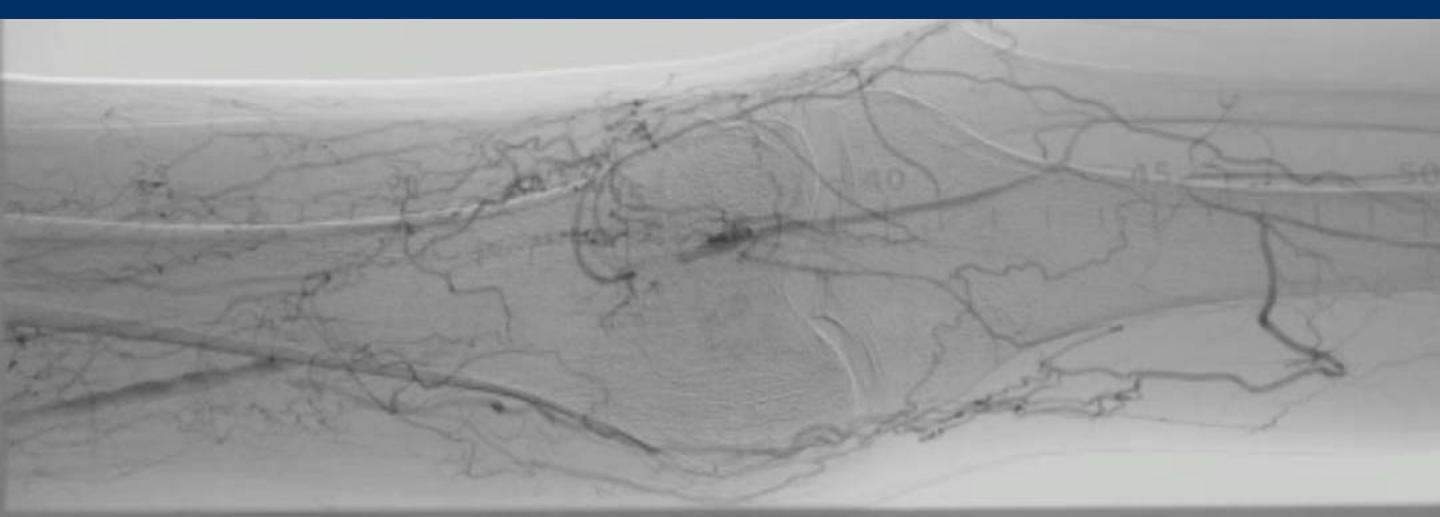

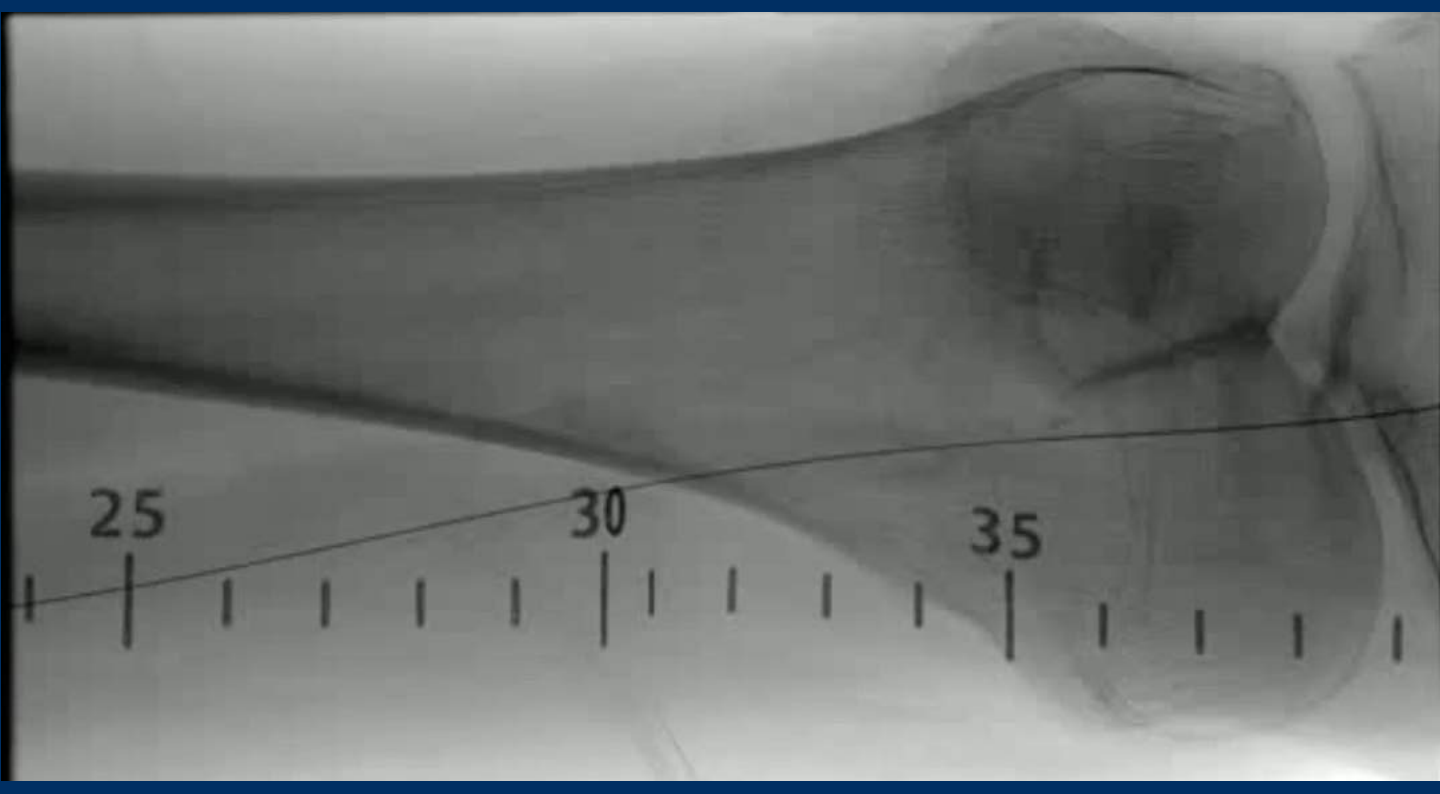
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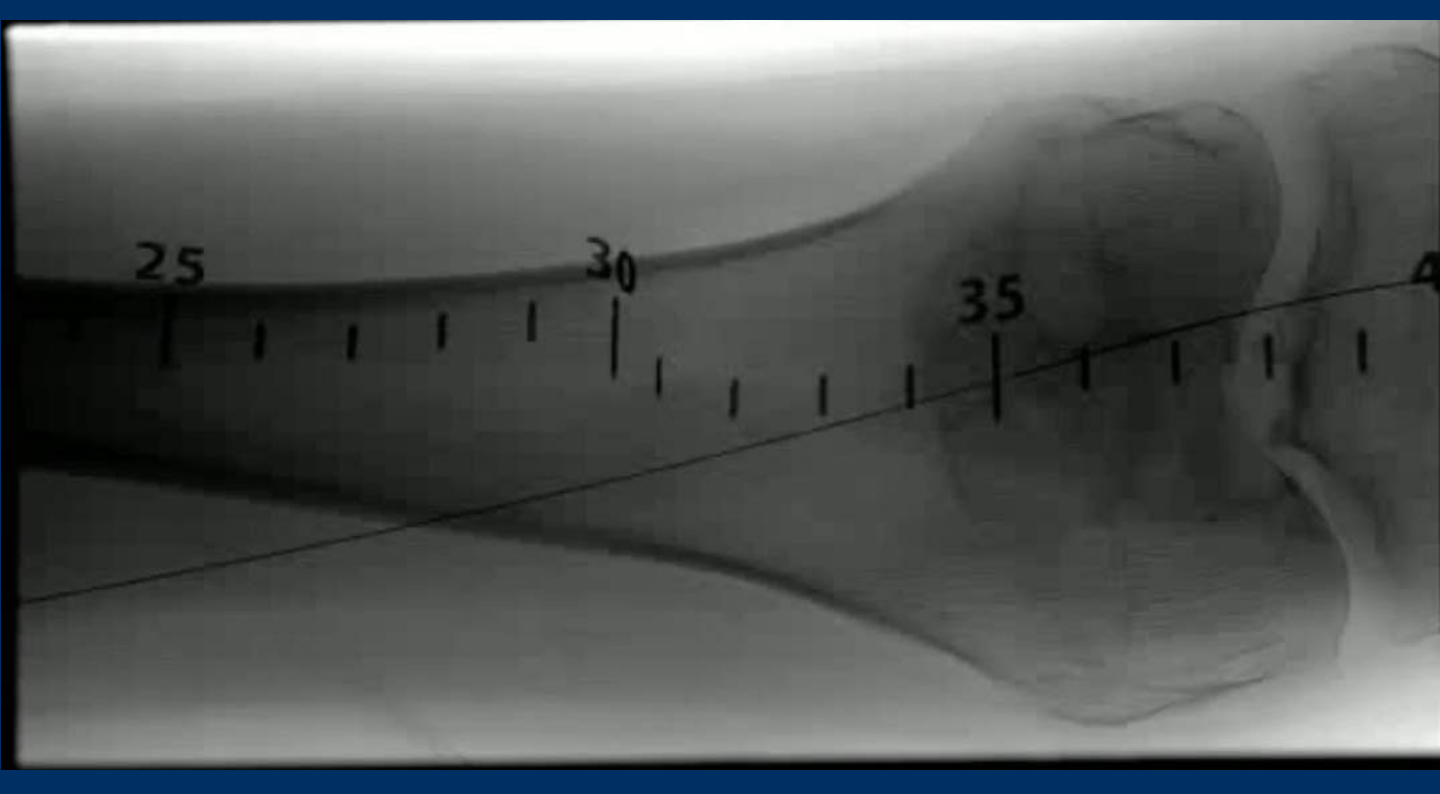
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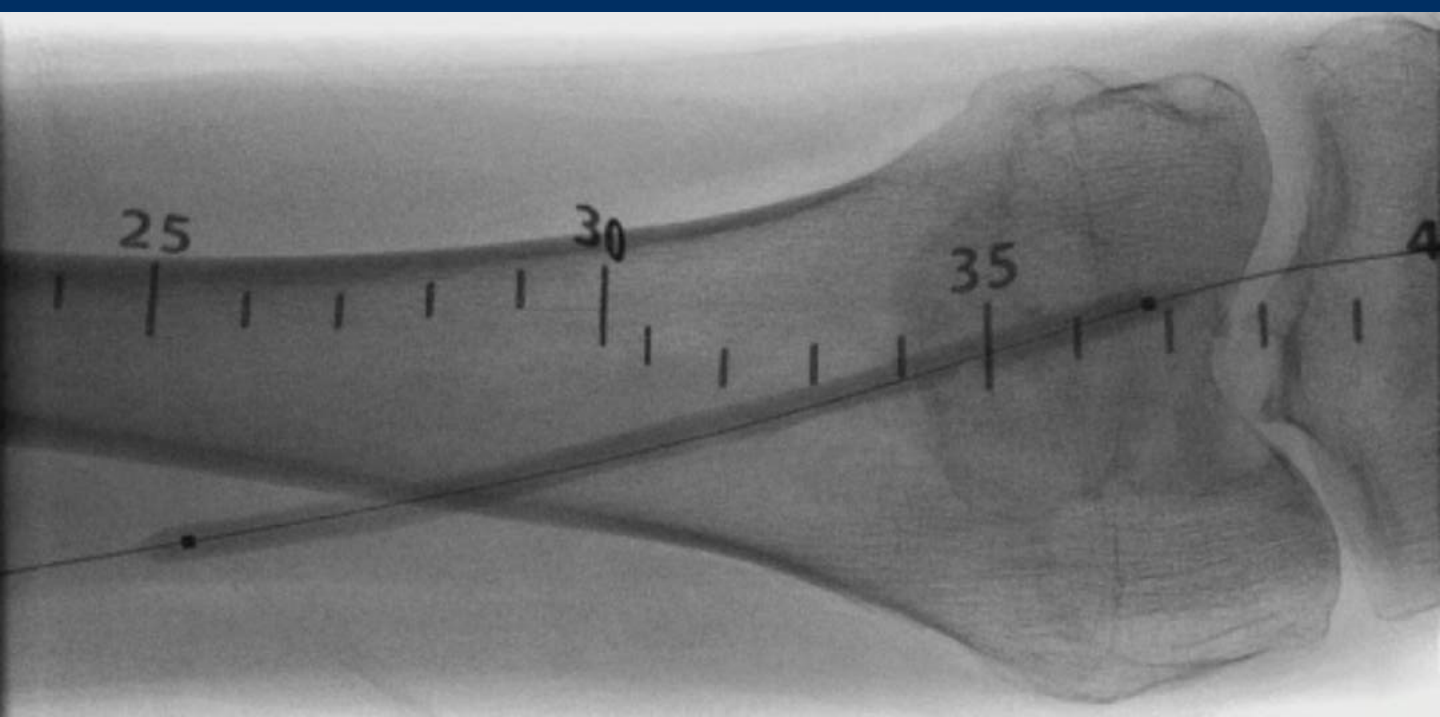
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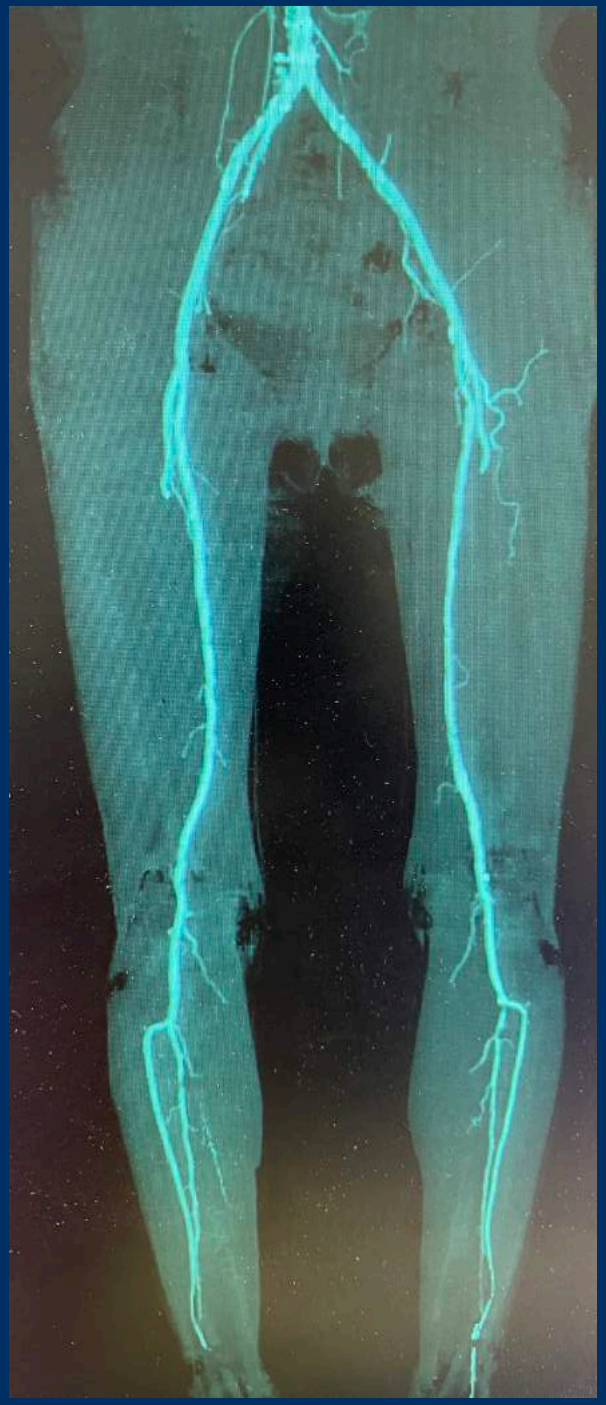
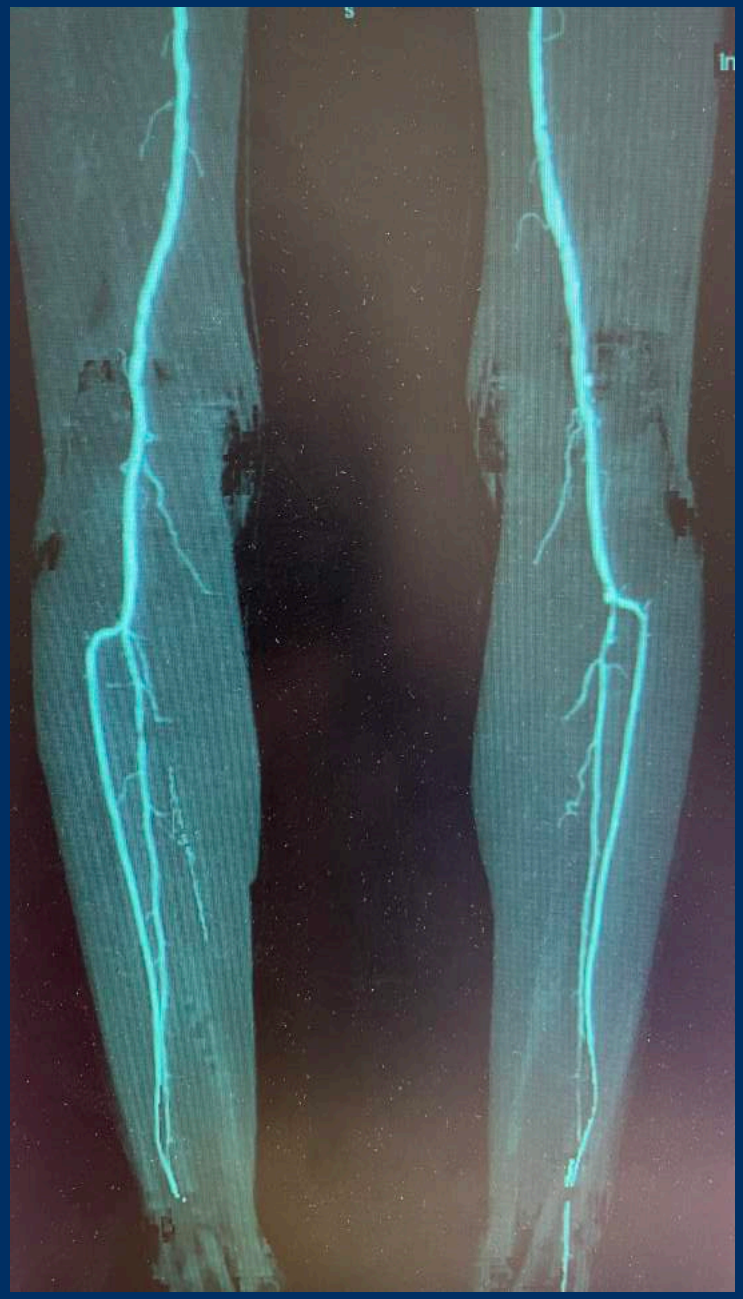
2-year
Follow-up





Thank you!