DAART for Femoro-popliteal Artery Atherosclerotic Disease

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DAART Clinical Trial
DEFINITIVE AR

	Randomized	
	DA + DCB	DCB Only
Mean ± SD (N), baseline	81.9±16.0% (48)	84.2±14.9% (54)
Mean ± SD (N), 1 y	33.6±17.7% (33)	36.4±17.6% (39)
Median (Q1, Q3), baseline	85.5 (70.5–97.5)	87.5 (77.0–100.0)
Median (Q1, Q3), 1 y	30.0 (25.0–36.0)	32.0 (23.0–47.0)
Primary patency via angiography	82.4% (28/34)	71.8% (28/39)
Primary patency* via ultrasound at 6 mo	95.0% (38/40)	88.9% (40/45)
Primary patency* via ultrasound at 1 y	84.6% (33/39)	81.3% (39/48)

*Primary patency is defined as PSVR ≤ 2.4 by Duplex ultrasound

Zeller T. et al. Twelve-Month Results of the DEFINITIVE AR Study Circ Cardiovasc Interv. 2017 Sep; 10(9): e004848.

DAART Clinical Trial

DEFINITIVE AR

Complication	DA + DCB	DCB Only	P Value*
Arterial perforation	4.2% (2/48)	0% (0/54)	0.22
Arteriovenous fistula	6.3% (3/48)	11.1% (6/54)	0.49
Dissection—grade C/D or greater	2.1% (1/48))	18.5% (10/54)	0.009
Distal embolism (clinically significant)	4.2% (2/48)	0% (0/54)	0.22
Distal embolism (not clinically significant)	2.1% (1/48))	0% (0/54)	0.47
Aneurysm	0% (0/48)	0% (0/54)	.
Pseudoaneurysm	6.3% (3/48)	0% (0/54)	0.10
Total*	22.9% (11/48) [12]	25.9% (14/54) [16]	0.82

*Percentage of patients (n/n patients affected) [total number of events].

Zeller T. et al. Twelve-Month Results of the DEFINITIVE AR Study Circ Cardiovasc Interv. 2017 Sep; 10(9): e004848.

DAART Clinical Study

Heavily Calcified Lesions – One Year Single Center Results

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
Major 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 1yr	27 (90%)
Secondary patency at 1 year	30 (100%)

Cioppa A. et al. Cardiovascular Revascularization Medicine 13 (2012) 219–223.

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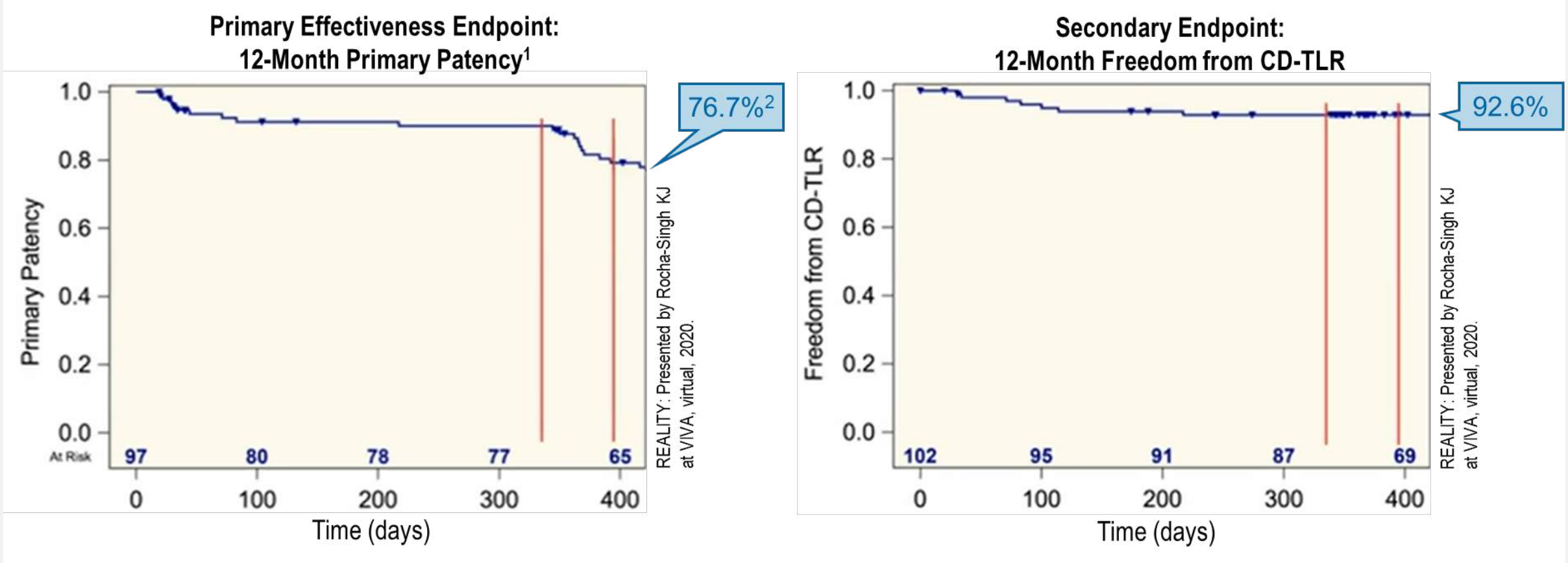
REALITY Study
Effectiveness Outcomes



1. Primary patency defined as freedom from restenosis (DUS peak systolic velocity ratio >2.4) and CD-TLR, defined as any reintervention to the target lesion due to a return of symptoms and/or ankle-brachial index (ABI) decrease of 20% or > 0.15 when compared with the post index procedure baseline ABI.
2. 12-month data include patients beyond the follow-up window. Red lines indicate the 12-month follow-up window.

Rocha-Singh KJ, et al. Catheter Cardiovasc Interv 2021 Jun 3. doi: 10.1002/ccd.29777.

DAART Study from China

Data from Beijing An Zhen Hospital

- 2016.12 - 2019.12, 139 ASO
- DAART：59, DCB alone:　　80
- There was no significant difference in PACSS classification between the two groups （P>0.05）
- There was no significant difference in general data, risk factors and target lesion length (P>0.05)

DAART Study from China

Data from Beijing An Zhen Hospital

	DAART (n=59)	DCB (n=80)	P value
Age (yrs)	69.84 ± 10.81	65.98 ± 9.23	0.383
Gender (M)	42 (71.2%)	61 (76.3%)	0.403
Lesion Length (mm)	135.6 ± 86.9	118.16 ± 72.7	0.183
Rutherford Classification			0.132
2	0 (0.0%)	0 (0.0%)	
3	22 (21.2%)	26 (32.5%)	
4	27 (57.4%)	42 (52.5%)	
5	8 (17.0%)	12 (15.0%)	
6	2 (4.3%)	0 (0.0%)	
PACSS Classification			0.118
1	0 (0.0%)	0 (0.0%)	
2	2 (3.4%)	8 (10.0%)	
3	47 (79.7%)	67 (83.6%)	
4	10 (16.9%)	5 (6.25%)	
Lesion type			0.317
Stenosis Lesion	13 (12.8%)	14 (17.5%)	
Occlusive Lesion	46 (87.2%)	66 (82.5%)	

DAART Study from China

Data from Beijing An Zhen Hospital

Perioperative Results

- Technique success rate: DAART: 98.3%, DCB:100% (P=0.24)
- ABI was significantly improved 7 days after operation (P=0.01), no significant difference between 2 groups (P=0.85)
- Rutherford classification was improved 7 days after operation (P=0.02) no significant difference between 2 groups (P=0.61)
- Bail-out stents: DAART group: 4 (6.8%) DCB group: 23 (28.8%), there was a significant difference between 2 groups (P=0.001)
- There was no significant difference in the incidence of complications

DAART Study from China

Data from Beijing An Zhen Hospital

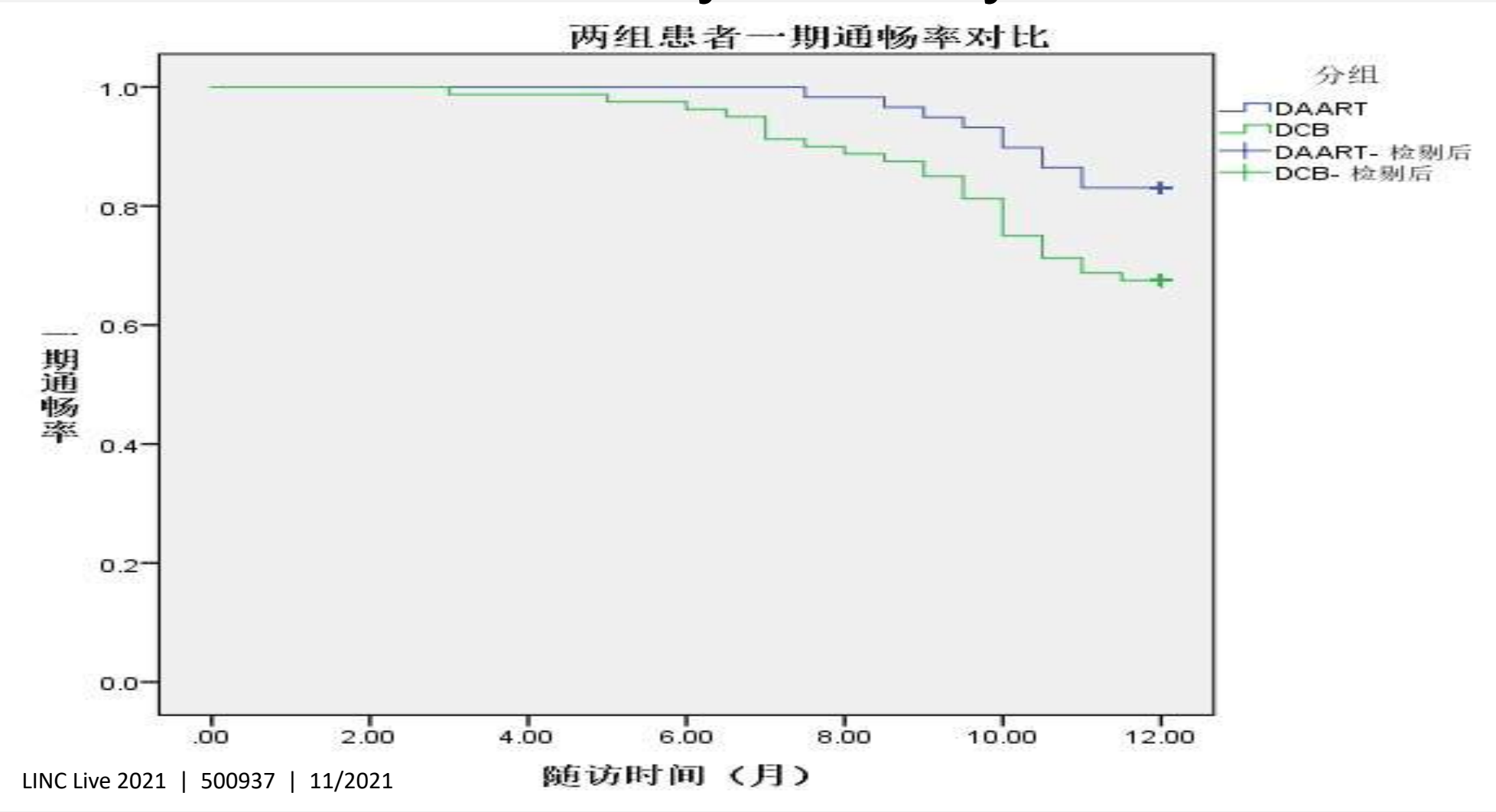
Follow-up

	DAART (n=59)	DCB (n=80)	P value
Primary Patency	2 (96.6%)	13 (83.8%)	0.303
6 months	49 (83.1%)	54 (67.5%)	0.032
12 months			
FF-TLR			
6 months	59 (100%)	78 (97.5%)	0.309
12 months	57 (96.6)	61 (76.3%)	0.001
Secondary Patency			
6 months	59 (100%)	79 (98.8%)	0.686
12 months	59 (100%)	78 (97.5%)	0.631

DAART Study from China

Data from Beijing An Zhen Hospital

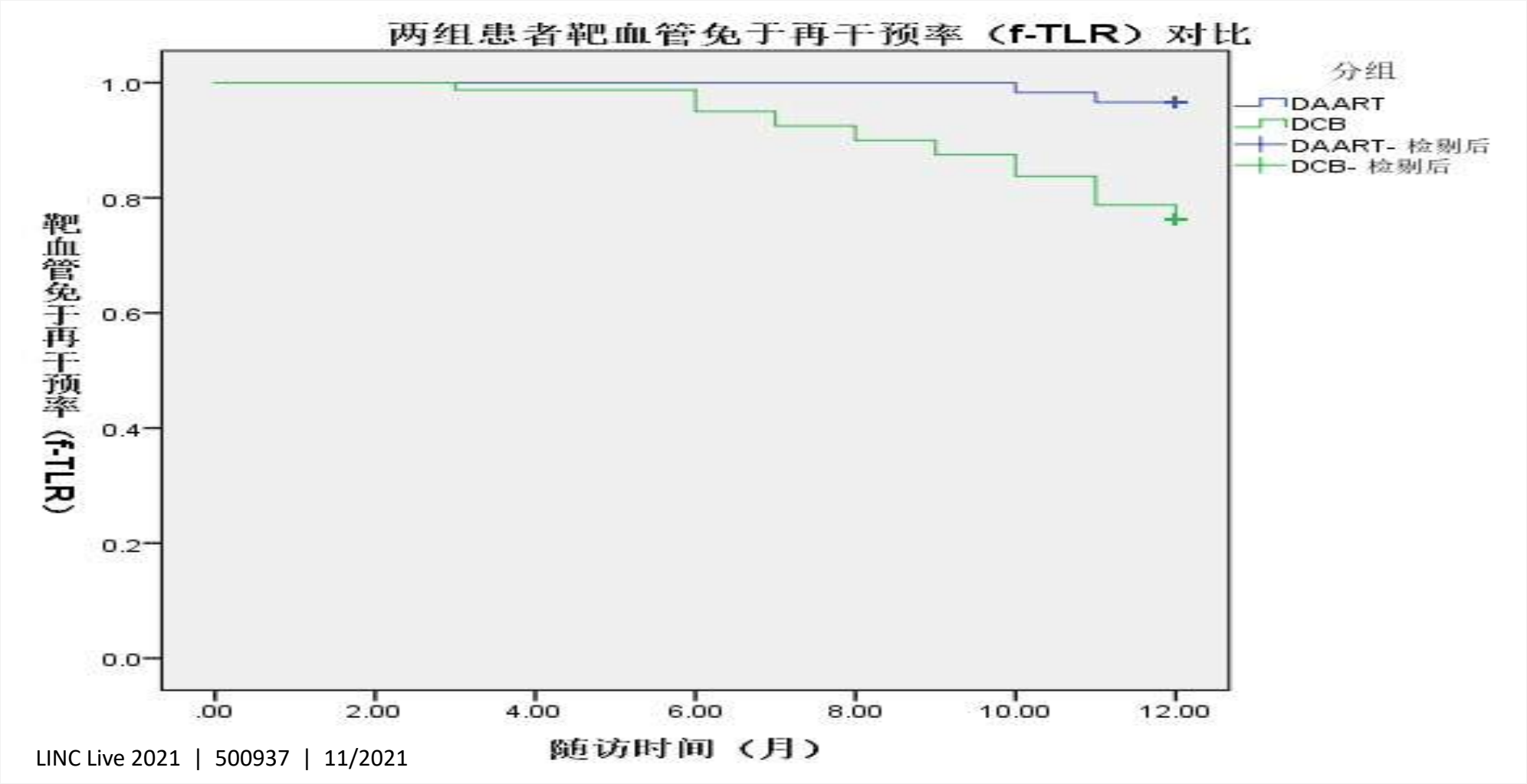
Primary Patency



DAART Study from China

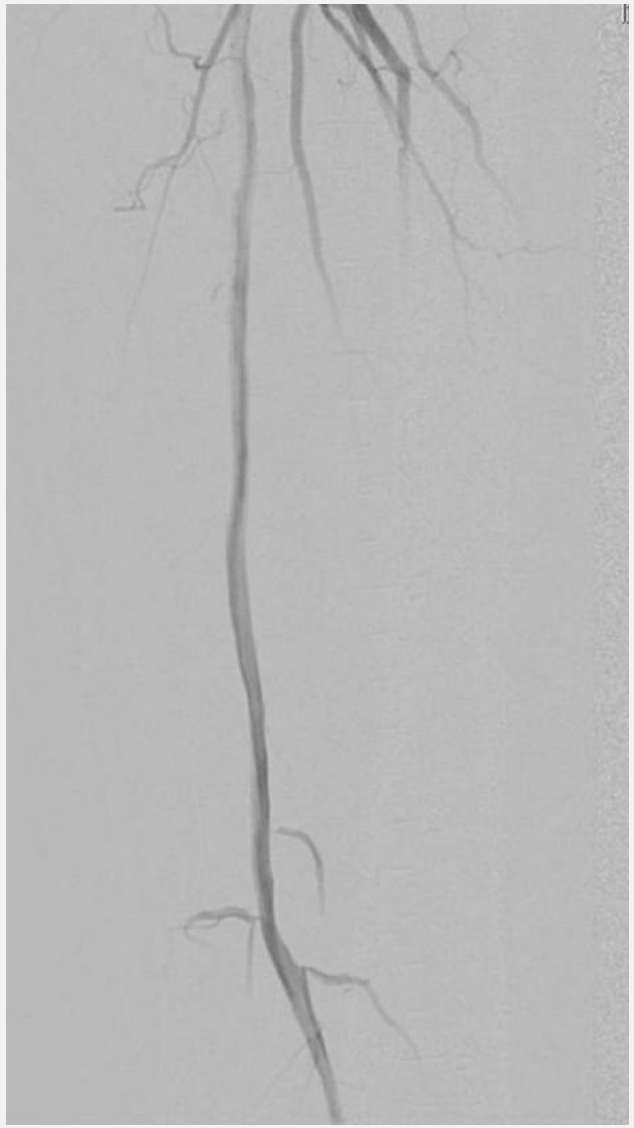
Data from Beijing An Zhen Hospital

Freedom From TLR



DAART for Femoro-popliteal Artery

Femoro-popliteal Artery Occluded Lesion



Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

DAART also suitable for Common Femoral Artery lesion

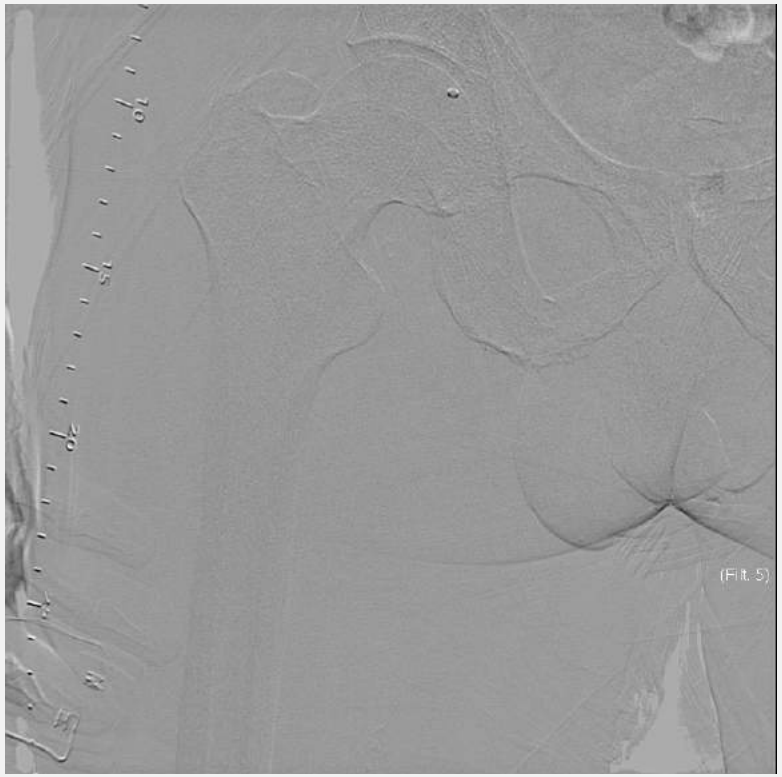
Common Femoral Artery Lesion

Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

Distal Embolism

Distal Embolism



SFA occluded lesion

Safari technique

TurboHawk atherectomy

Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

Distal Embolism

DCB dilation

Distal Embolism

Retreat distal embolic protection device

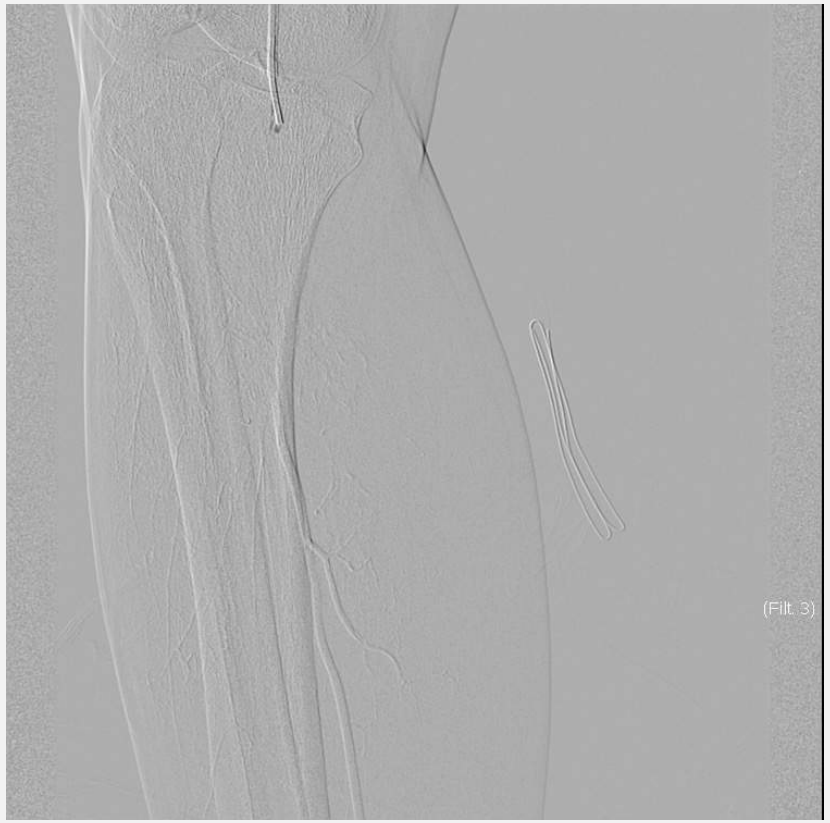
What happened?

Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

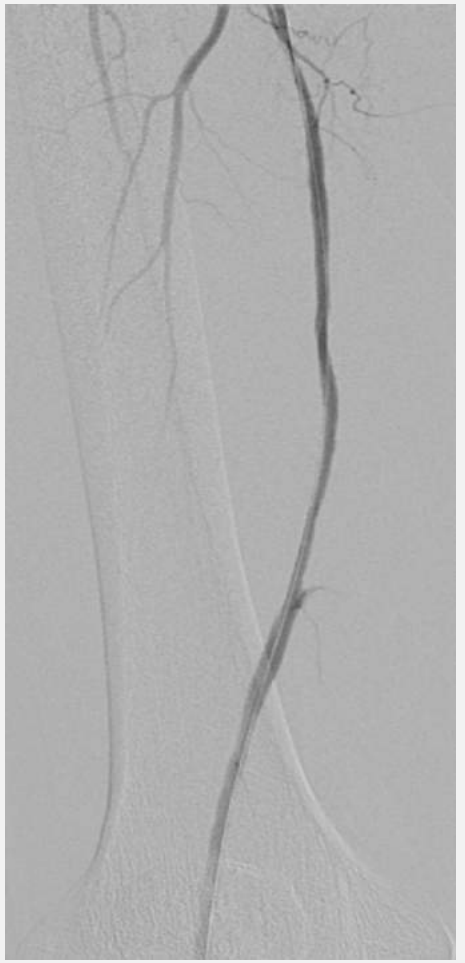
Distal Embolism

Distal Embolism



Popliteal artery embolism

8F guiding catheter suction



Final result

Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

Heavy Calcified Lesion

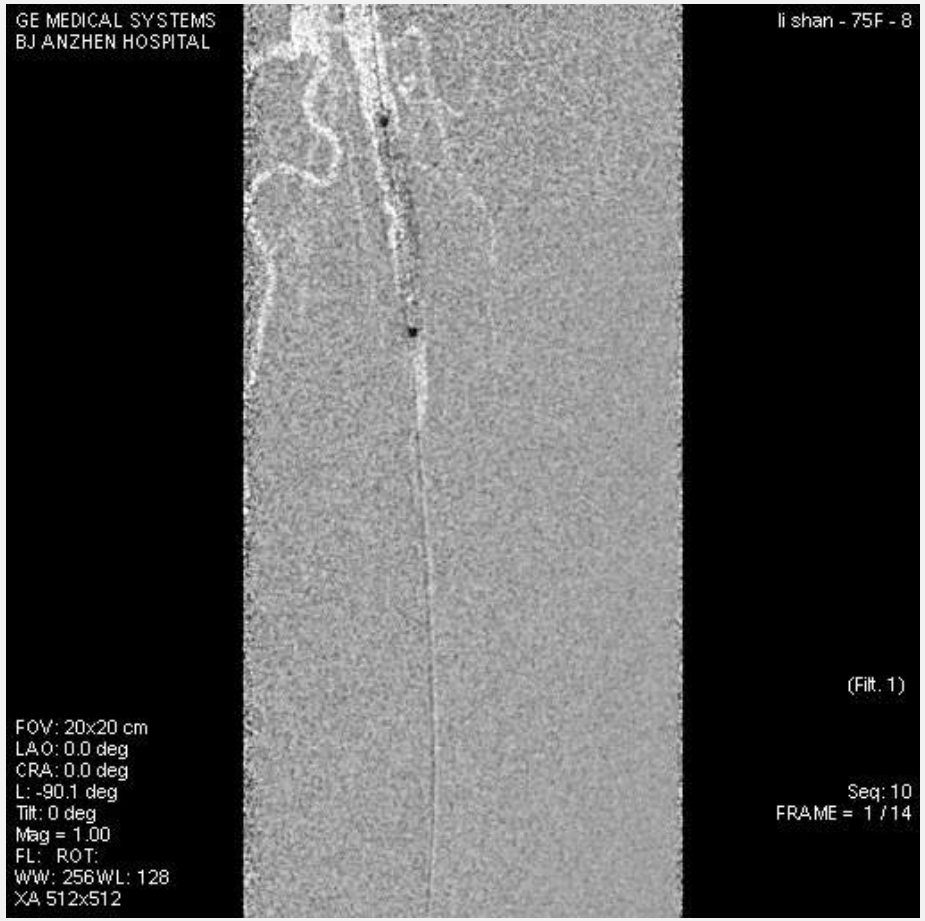
Heavy calcified lesion — vessel preparation is important

Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

Heavy Calcified Lesion

Heavy calcified lesion — vessel preparation is important



Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

Bail-out Stent

Bail-out stent

- Risk factors：
  - Heavy calcified lesion
  - Lesion with obvious elastic recoil
  - Long lesion
  - Subintimal angioplasty
  - Size of directional Atherectomy system is too small

DAART for Femoro-popliteal Artery

Bail-out Stent

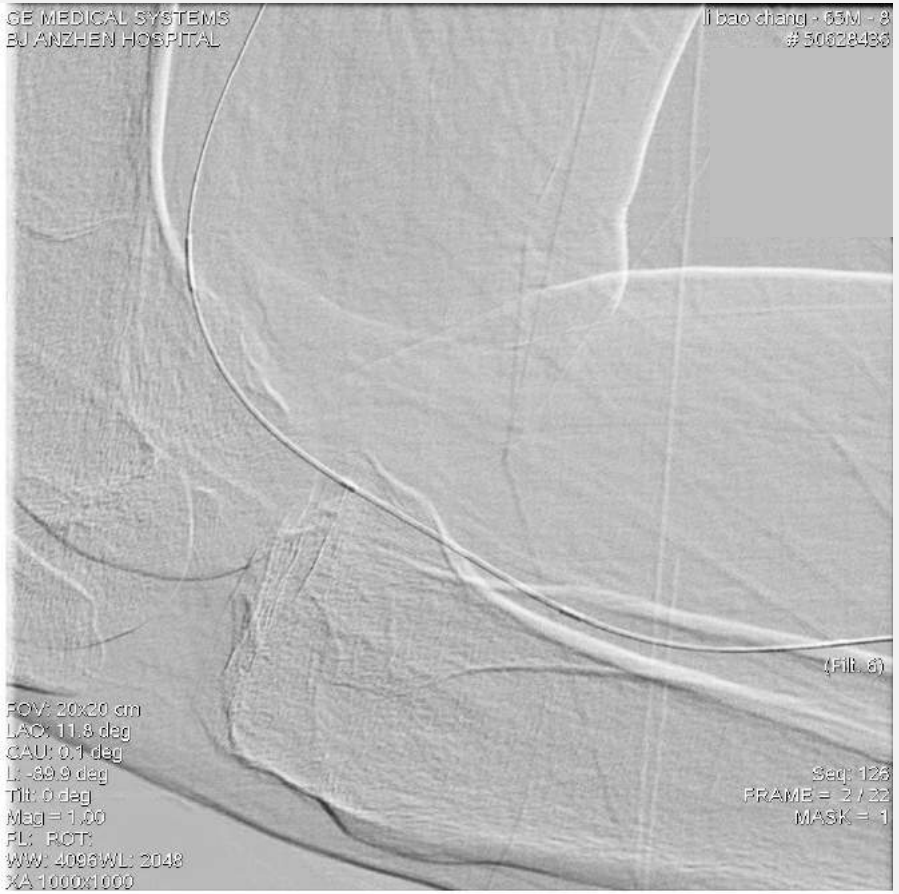
Bail-out stent

Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

Bail-out Stent

Bail-out stent—is not necessary in most patients, but cannot be entirely avoided



Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

Bail-out Stent

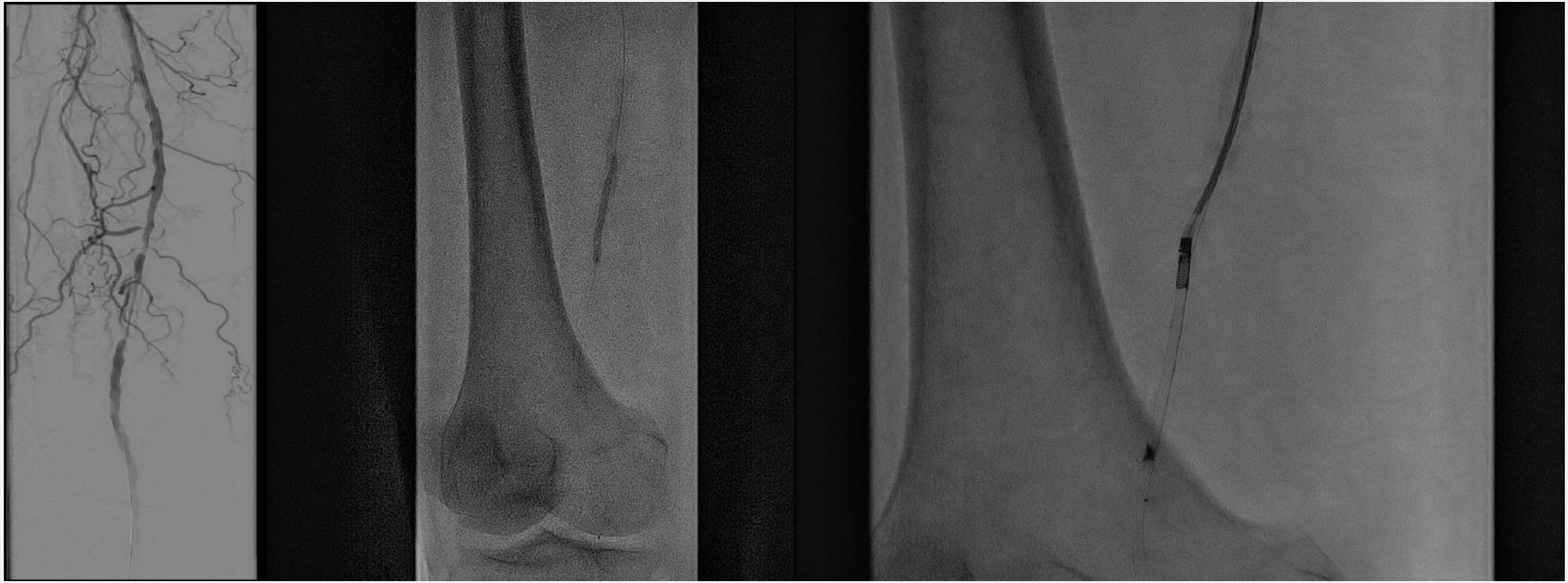
Bail-out stent—is not necessary in most patients, but cannot be entirely avoided

Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

Dissection

Some dissections can be treated with Directional Atherectomy



Images courtesy of Sheng Wang, MD

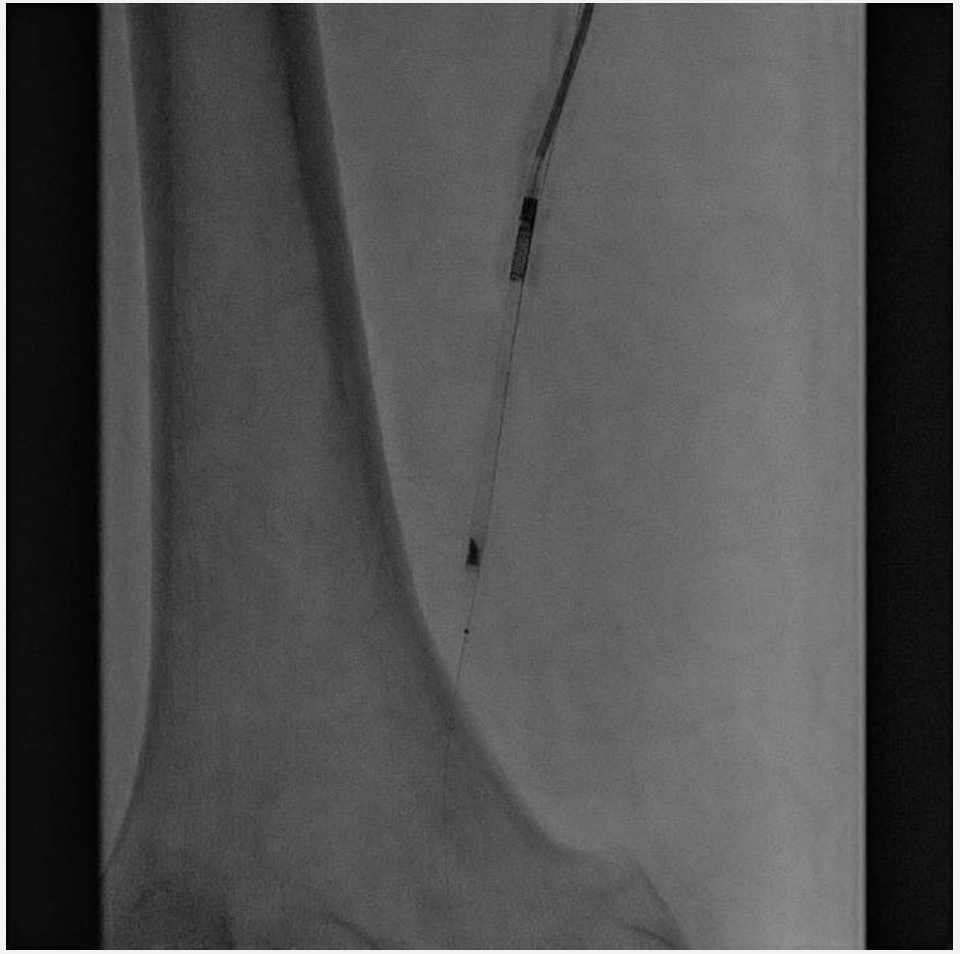
DAART for Femoro-popliteal Artery

Dissection

Some dissections can be treated with Directional Atherectomy

Remain stenosis and dissections after atherectomy

Put cutter to the direction of stenosis and dissections

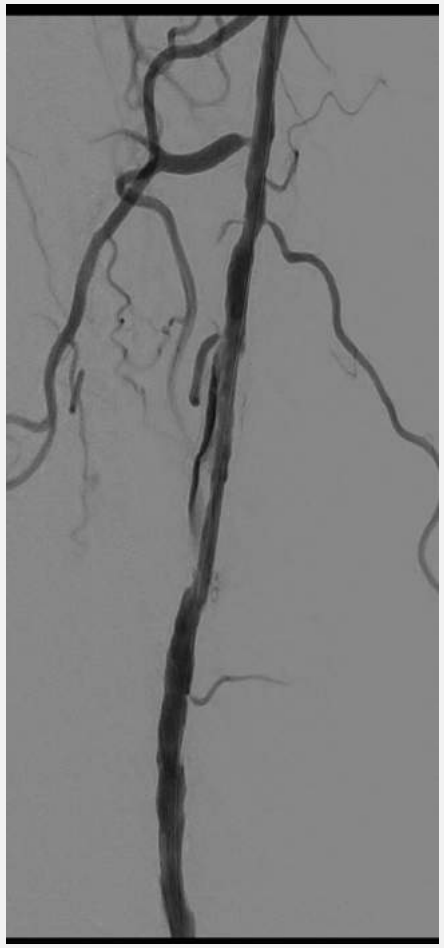


Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

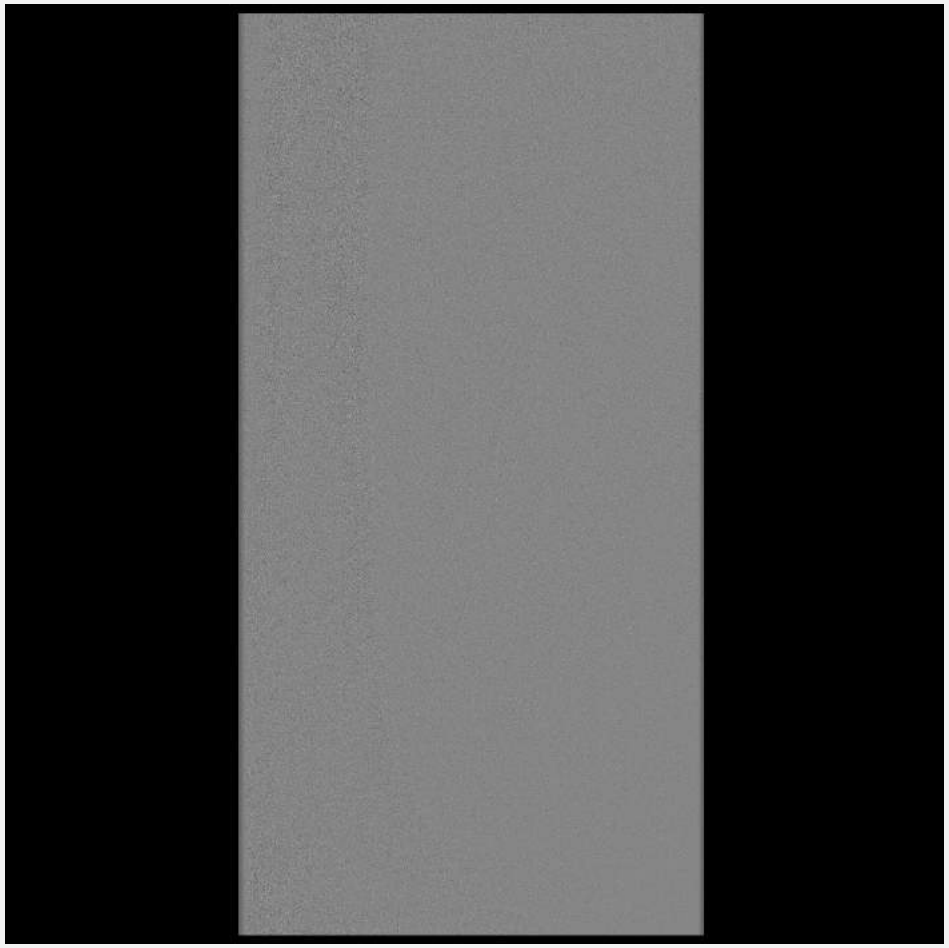
Dissection

Some dissections can be treated with Directional Atherectomy



Better, but dissection still existed

Orchid™* 5-150 DCB



No flow-limiting dissections, avoid stent implanting

Images courtesy of Sheng Wang, MD

DAART for Femoro-popliteal Artery

Summary

- DAART is safe and effective for Femoro-popliteal Artery Atherosclerotic Disease
  - Low bailout stent rate
  - Promising results of primary patency and freedom from TLR
  - Vessel preparation is important for heavy calcified lesion
  - Embolism can be avoided with distal embolic protection device, pay attention to the details
  - The long-term efficacy and safety of DAART has to be proved in more patients and longer follow-up time.

谢谢！

THANK YOU！