



Use of Rotarex[®]S and Drug Coated Balloons for ISR: Beijing experience

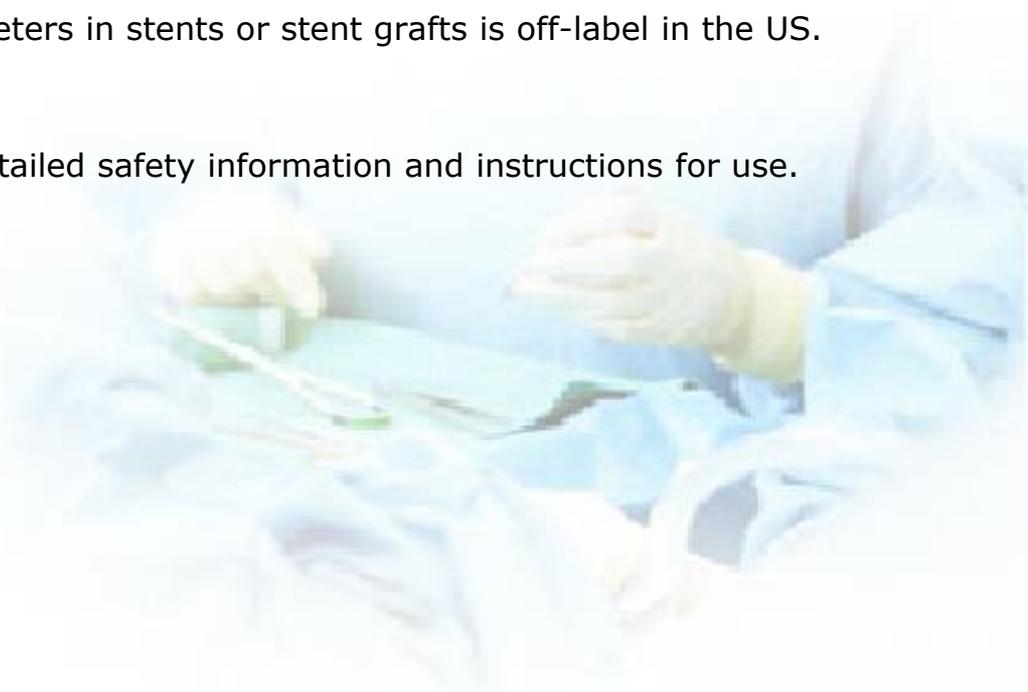
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Disclaimer

- This presentation is intended for an audience outside of the US where marketing authorization for the Rotarex™ Catheters has been granted (“OUS Countries”)
- In such OUS Countries, use of the Rotarex™ Catheters in stents or stent grafts is on-label, but is contraindicated if the guidewire has become threaded at any point in the wire mesh/construction of the stent or stent graft or the lining of the stent graft.
- Please note that the use of Rotarex™ Catheters in stents or stent grafts is off-label in the US.
- Please consult package inserts for more detailed safety information and instructions for use.



Femoral and popliteal artery disease

- Self-expanding bare-metal stent (BMS) has become one of the most common approaches for treating native femoropopliteal arterial disease
- However, the incidence rate of in-stent restenosis (ISR) ranges from 14% to 50% at 12-months



Katsanos K, Spiliopoulos S, Reppas L, et al. Debulking atherectomy in the peripheral arteries: is there a role and what is the evidence? *Cardiovasc Intervent Radiol* 2017;40:964-77.

Kim W, Choi D. Treatment of femoropopliteal artery in-stent restenosis. *Korean Circ J* 2018;48:191-7.

Laird JR, Katzen BT, Scheinert D, et al. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: twelve-month results from the RESILIENT randomized trial [J]. *Circ Cardiovasc Interv*, 2010, 3(3): 267-276.

Reasons for FP-ISR

- Smoking
- Diabetes
- Small vessel diameter
- Long and multi-segmental lesions
- Local inflammatory reaction of vascular wall caused by stent implantation

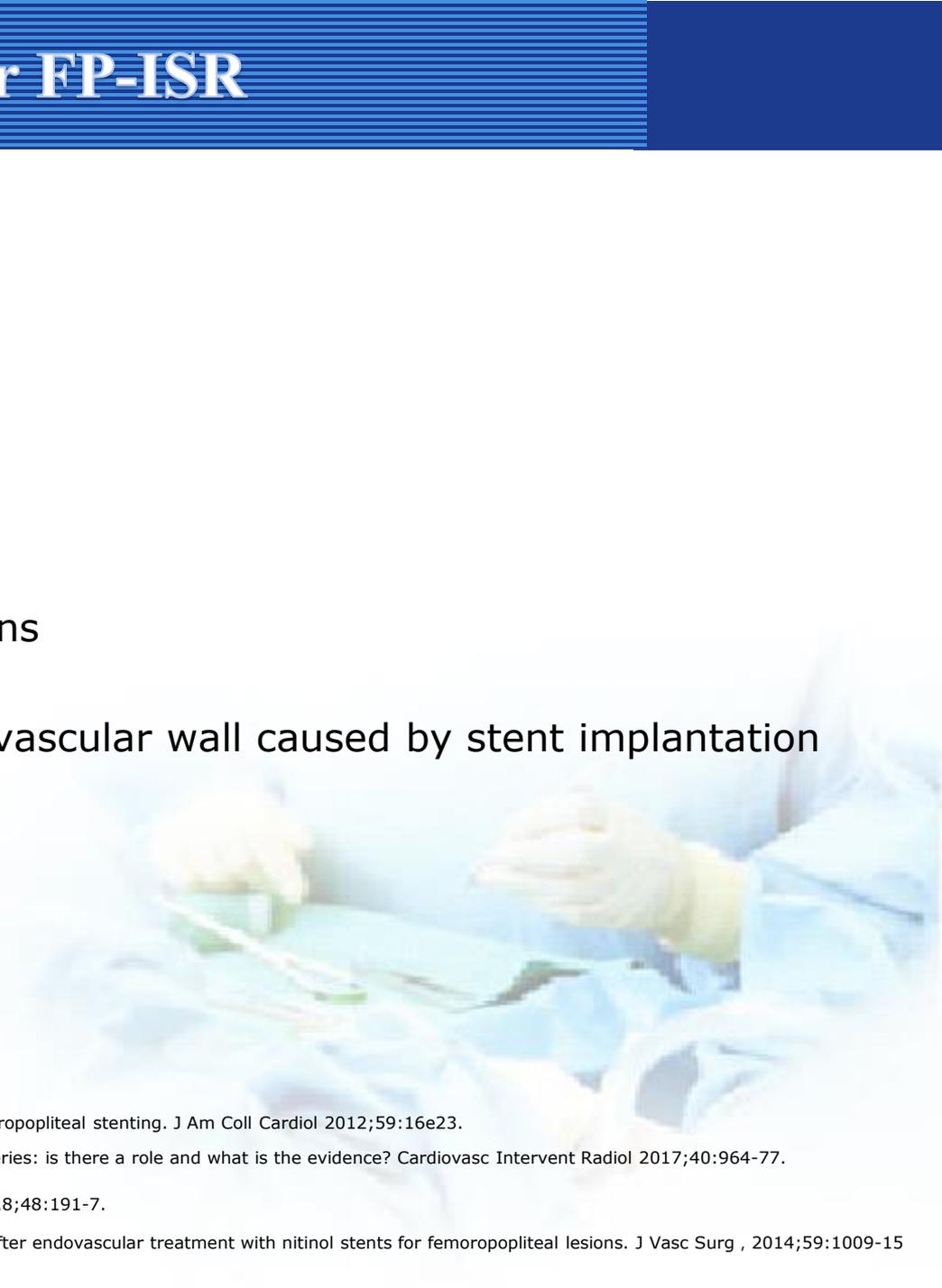
Femoropopliteal in-stent restenosis (FP-ISR)

Tosaka A, Soga Y, Iida O, et al. Classification and clinical impact of restenosis after femoropopliteal stenting. *J Am Coll Cardiol* 2012;59:16e23.

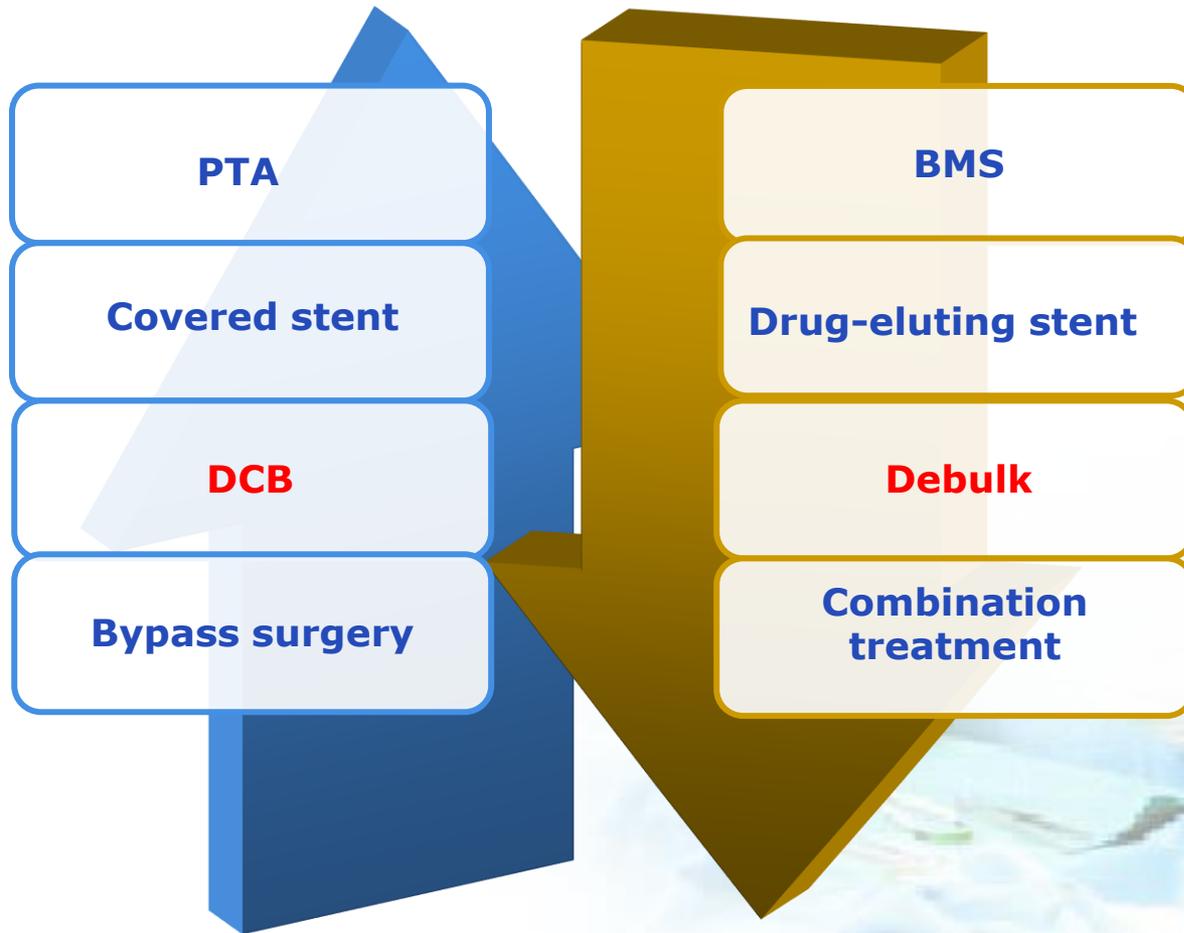
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Dohi T, Iida O, Soga Y, et al. Incidence, predictors, and prognosis of in-stent occlusion after endovascular treatment with nitinol stents for femoropopliteal lesions. *J Vasc Surg* , 2014;59:1009-15



Treatment of FP-ISR



DCB in treatment of FP-ISR

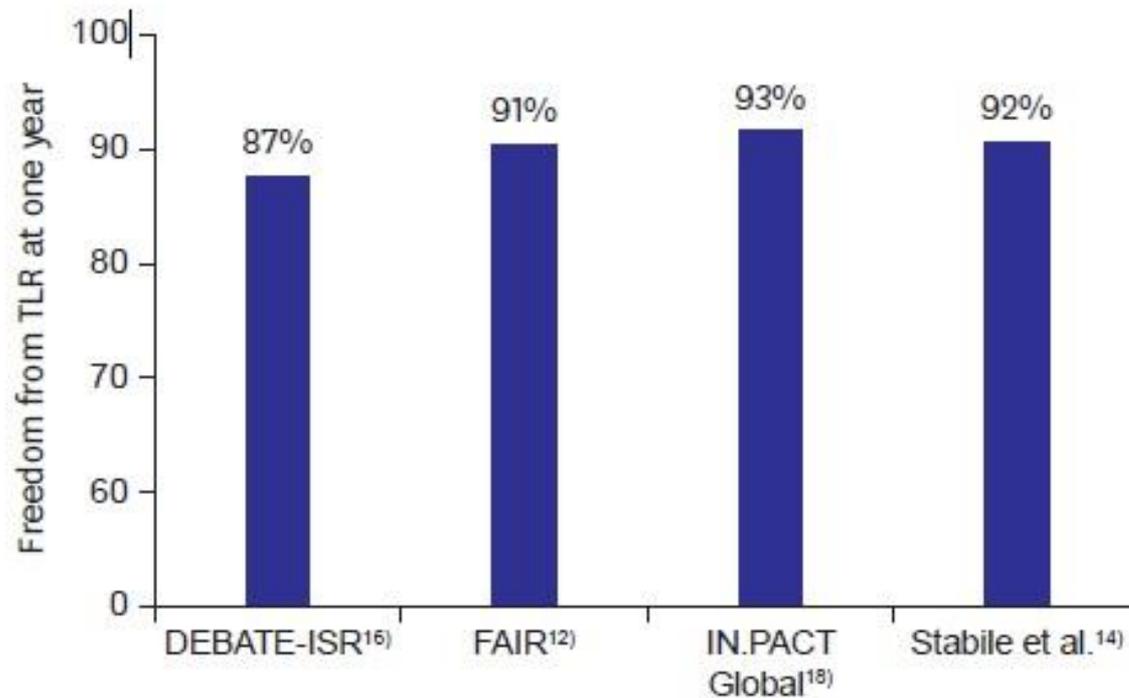
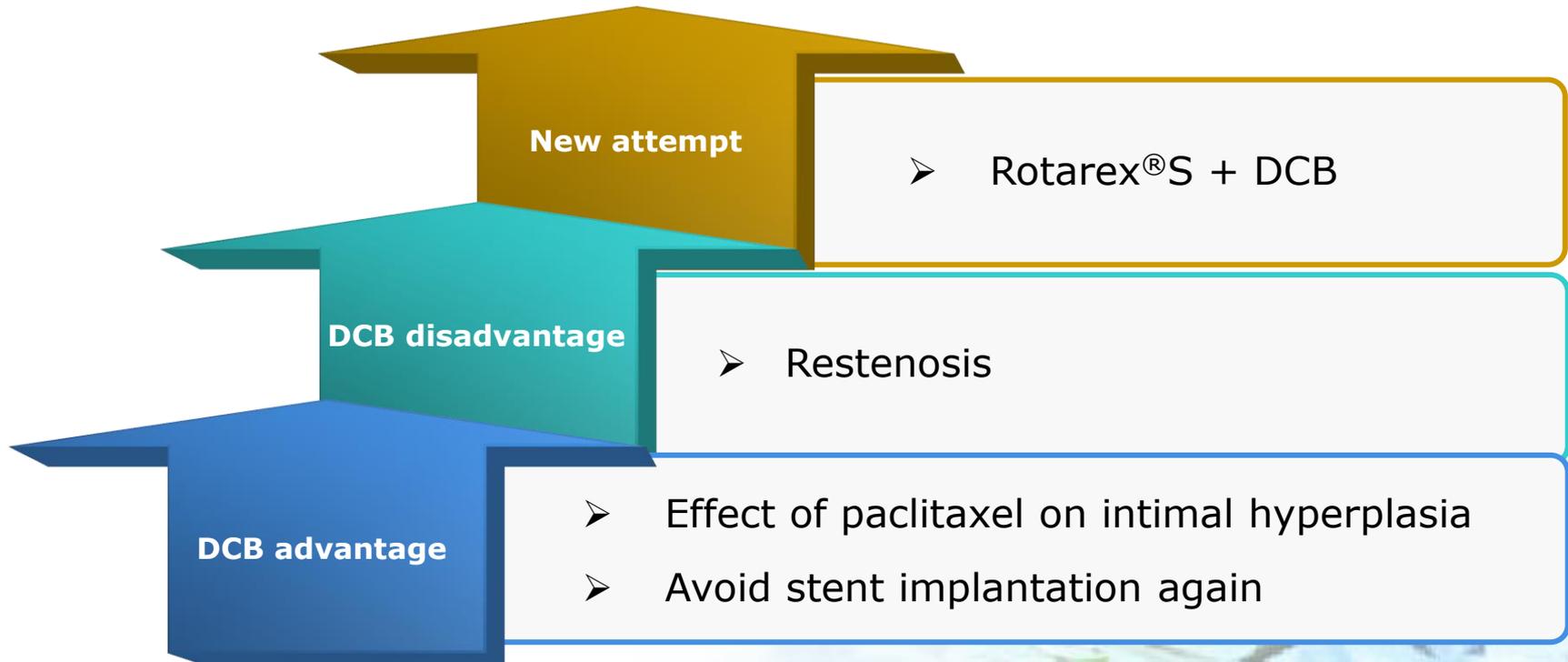


Figure 1. Freedom from TLR at one year in patients with FP artery-ISR.

DEBATE-ISR = Drug-Eluting Balloon in peripheral inTervention for In-Stent Restenosis; FAIR = Femoral Artery In-Stent Restenosis; FP = femoropopliteal; ISR = in stent restenosis; TLR = target lesion revascularization.

Rotarex[®]S + DCB in treatment of FP-ISR



Kim W, Choi D. Treatment of femoropopliteal artery in-stent restenosis. Korean Circ J 2018;48:191-7.

Katsanos K, Spiliopoulos S, Reppas L, et al. Debulking atherectomy in the peripheral arteries: is there a role and what is the evidence? Cardiovasc Intervent Radiol 2017;40:964-77.

- Male, 67y
- Stent implantation history for 2 years
- ABI 0.50



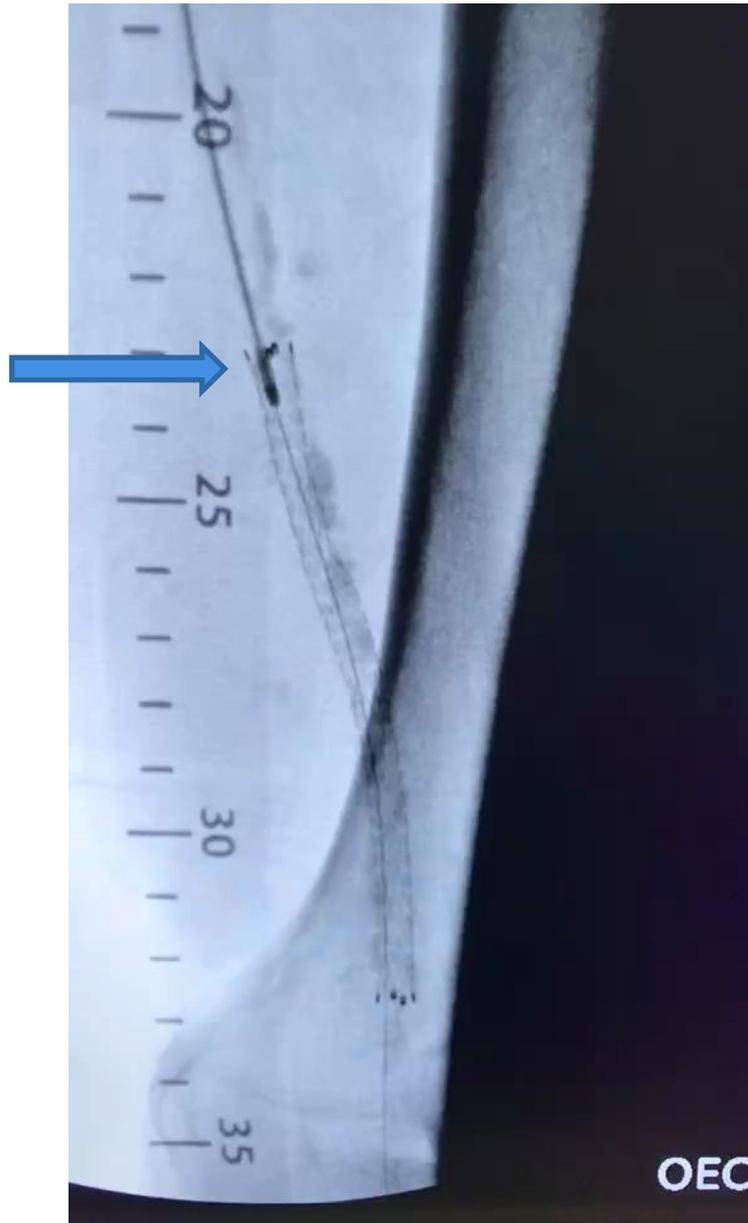
Angiography before treatment



6F Rotarex[®]S catheter



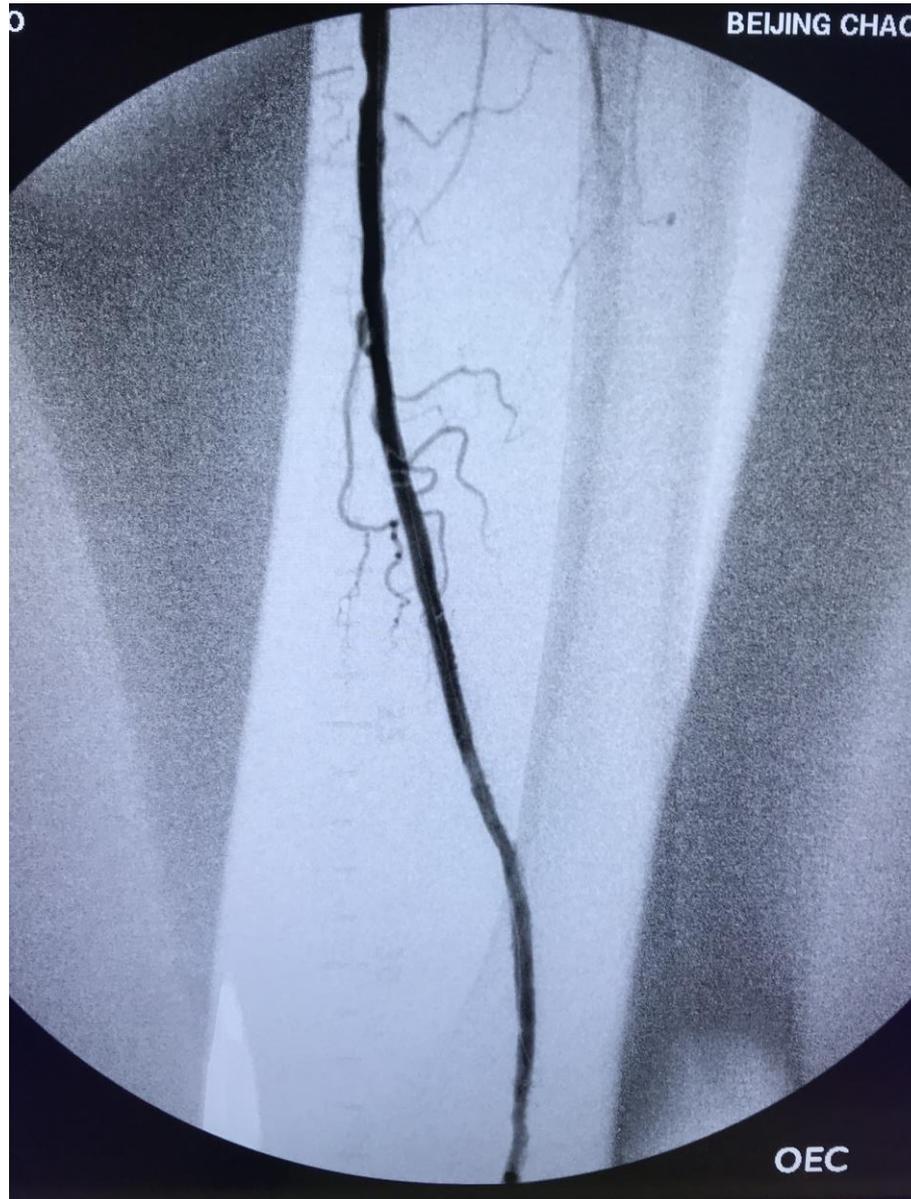
Rotarex[®]S debulking in action



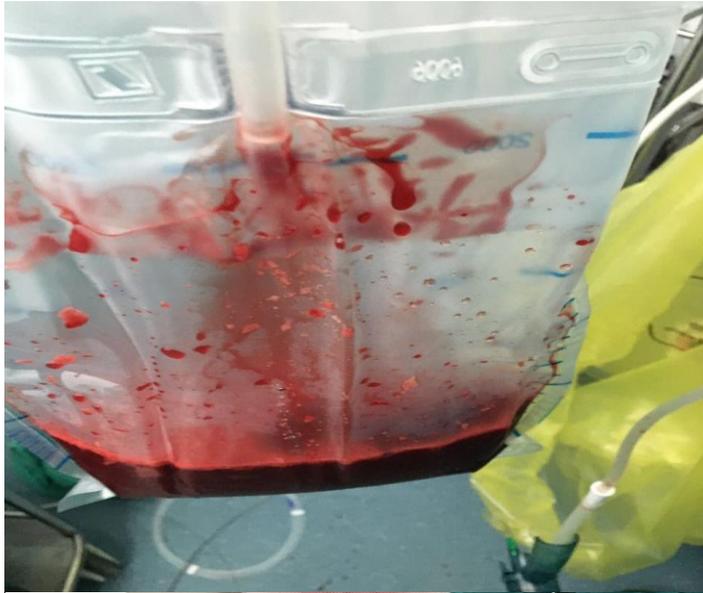
5*80 mm DCB



Angiography after DCB treatment



Aspirated material



Condition after treatment

- ABI 0.50 to **0.87**
- The patient was followed up for **3-years**. The blood circulation of lower limb was good without intermittent claudication



- Female, 75y
- Stent implantation history for 3-years
- ABI 0.48

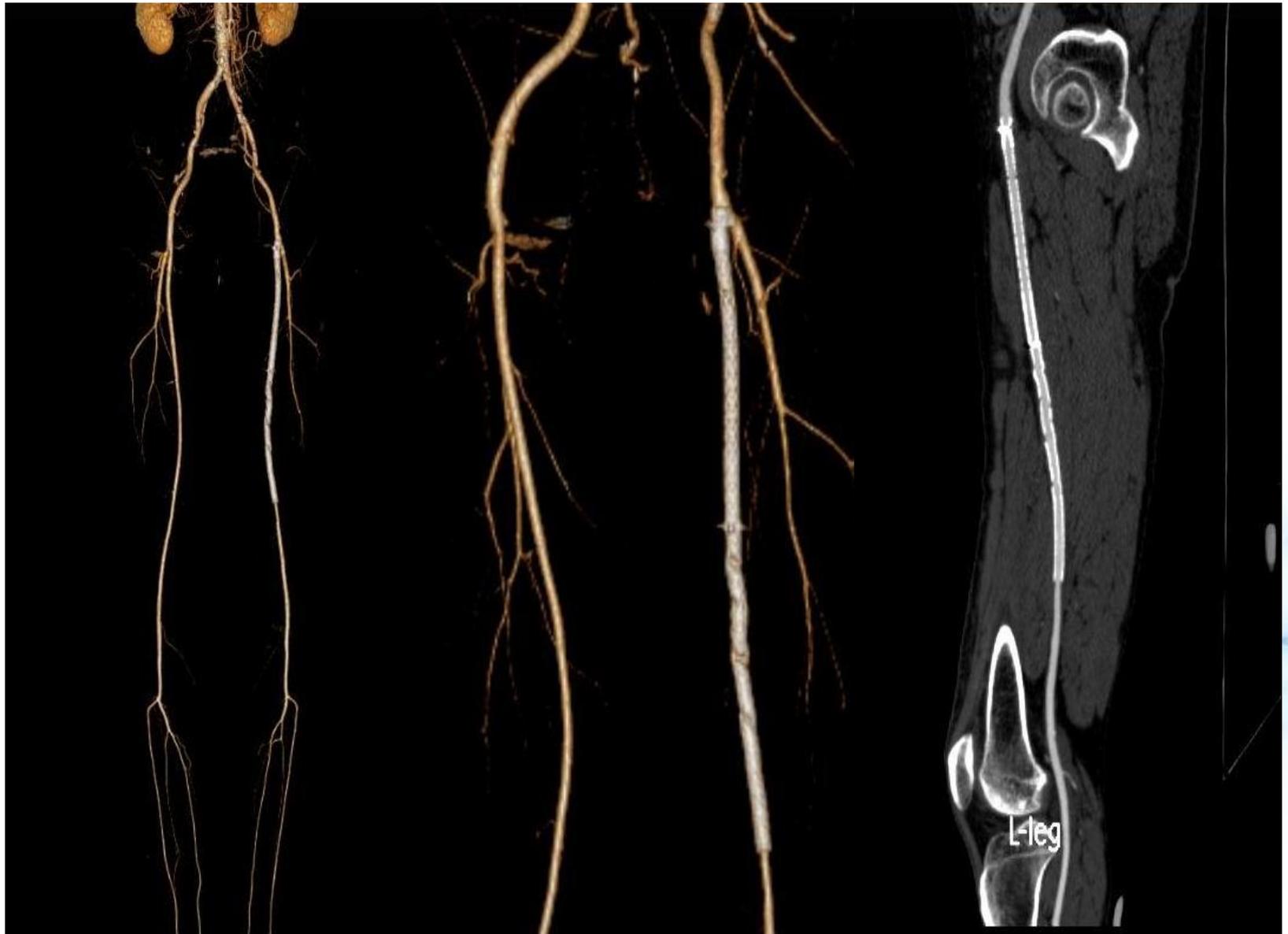


CTA before stent implantation (2013-09-22)

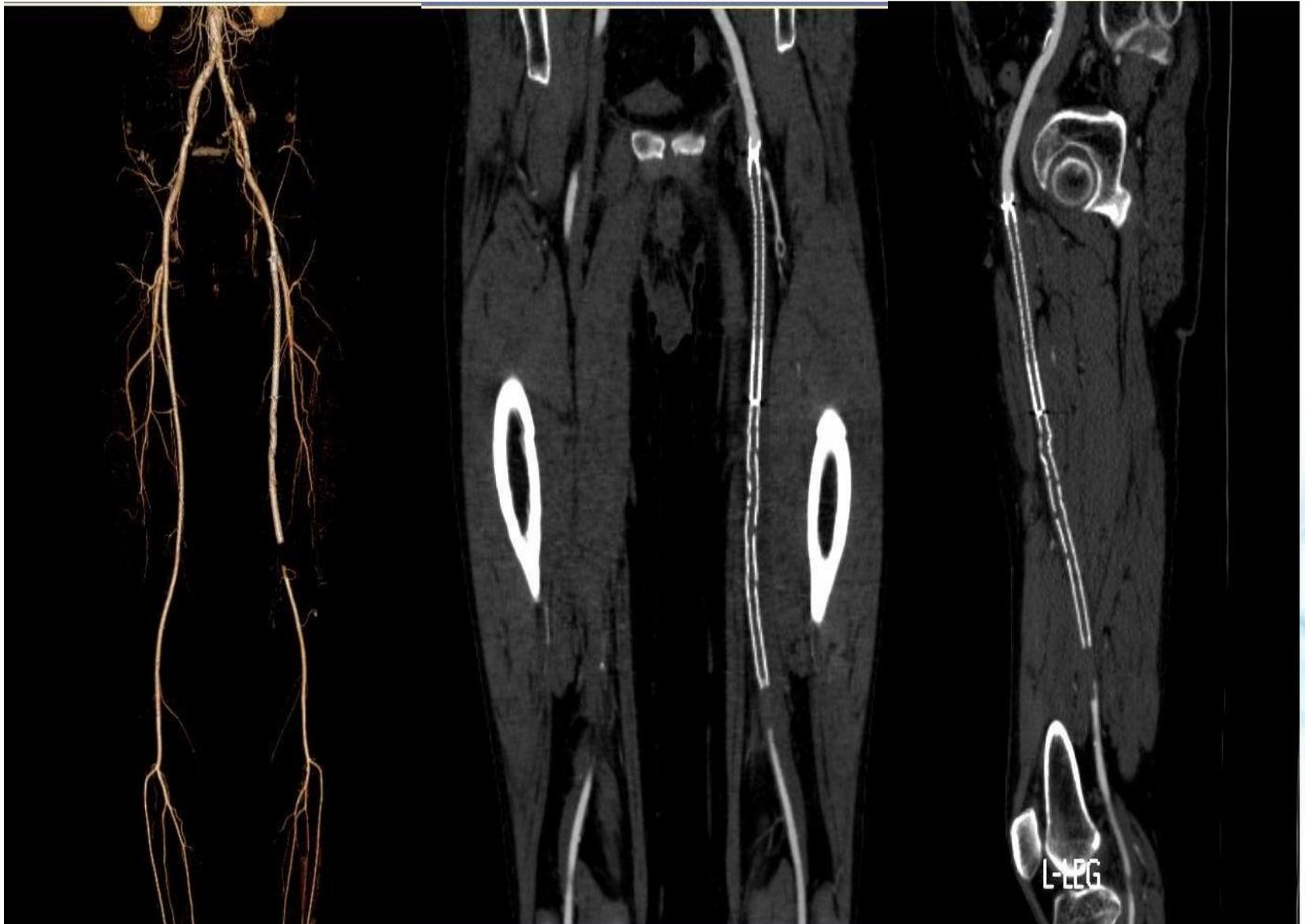


CTA after stent implantation (2015-11-04)

2-years
later



CTA before ISR treatment (2016-10-28)



Angiography before ISR treatment

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6F Rotarex[®]S catheter



Angiography after Rotarex[®]S debulking



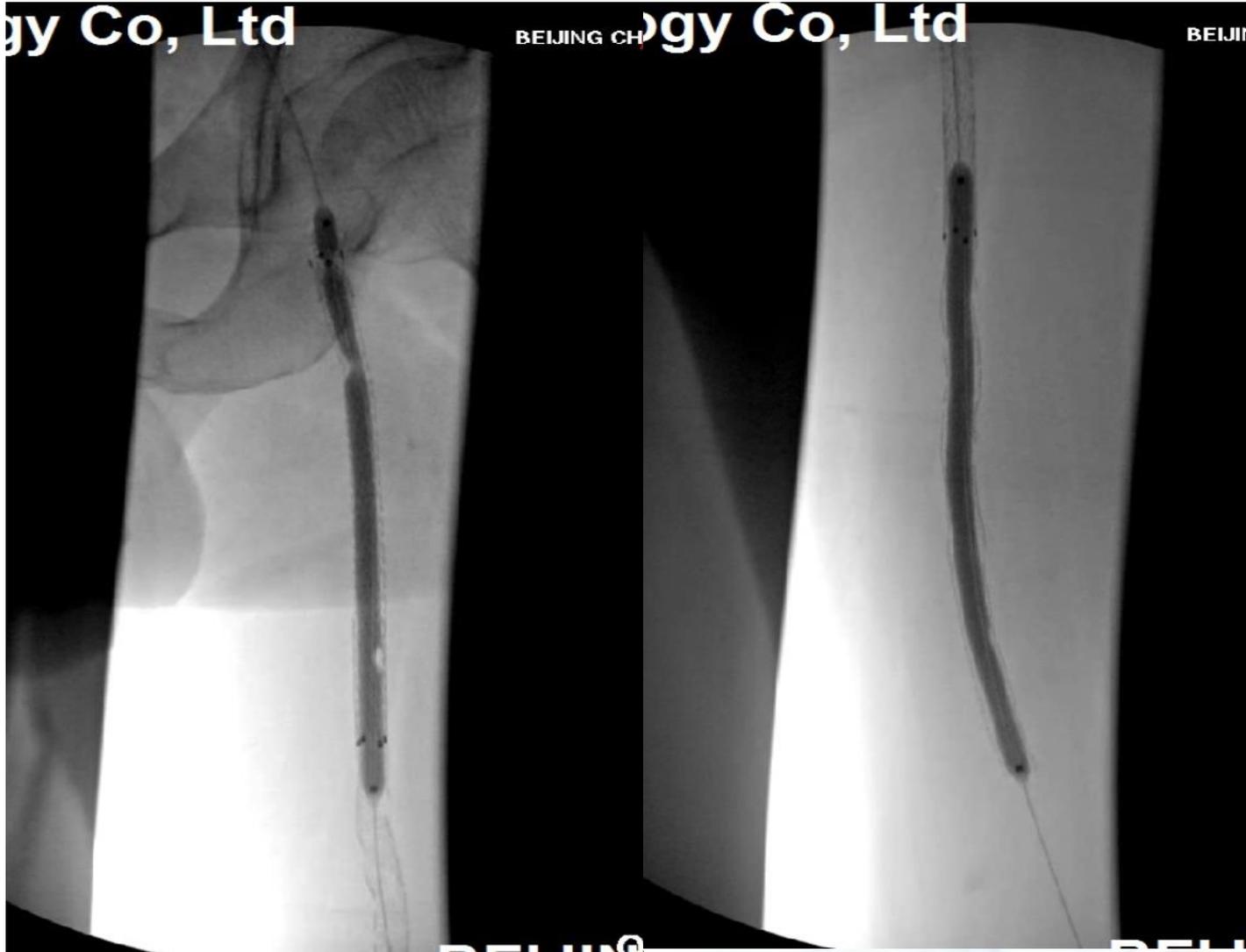
5*120 mm DCB

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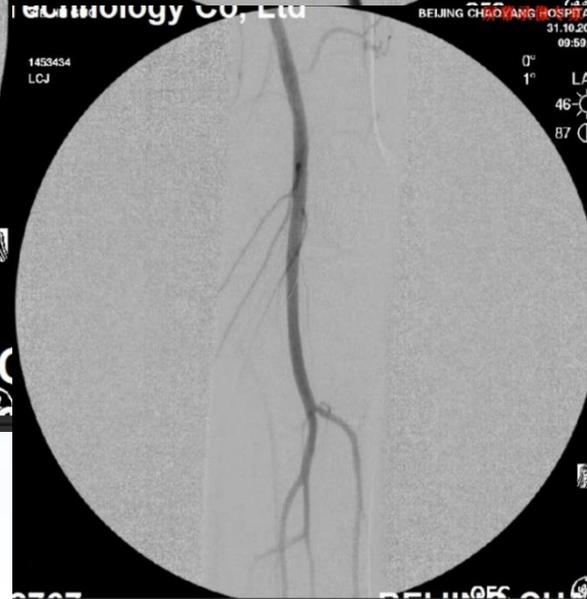
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Angiography after DCB treatment



Condition after treatment

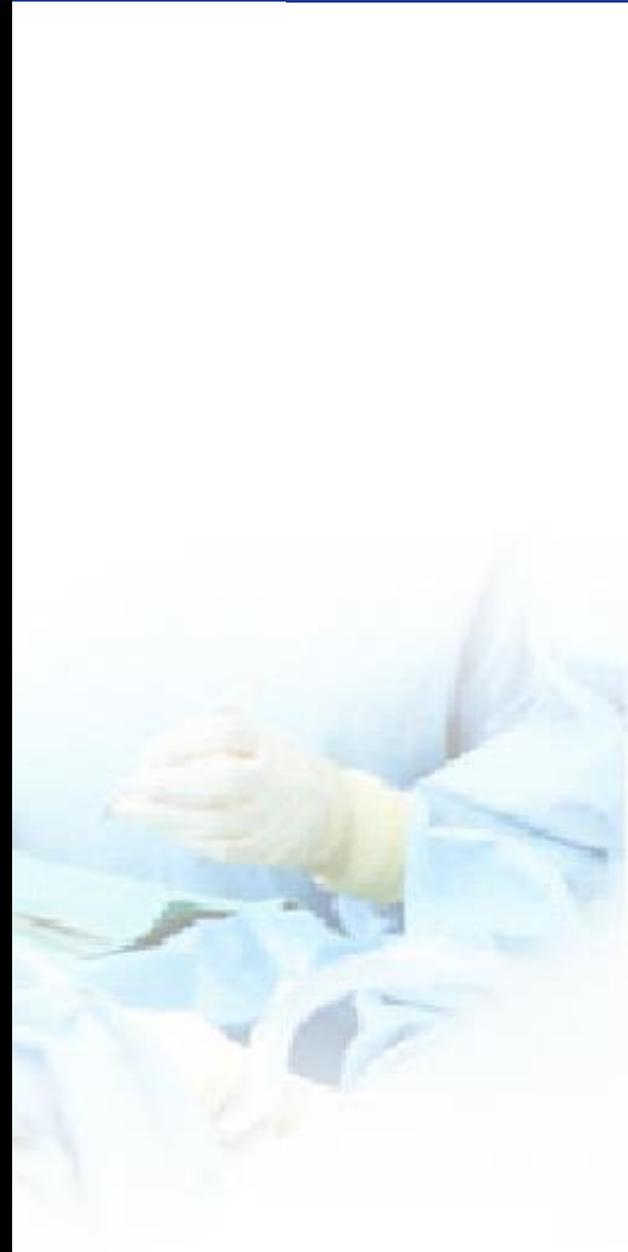
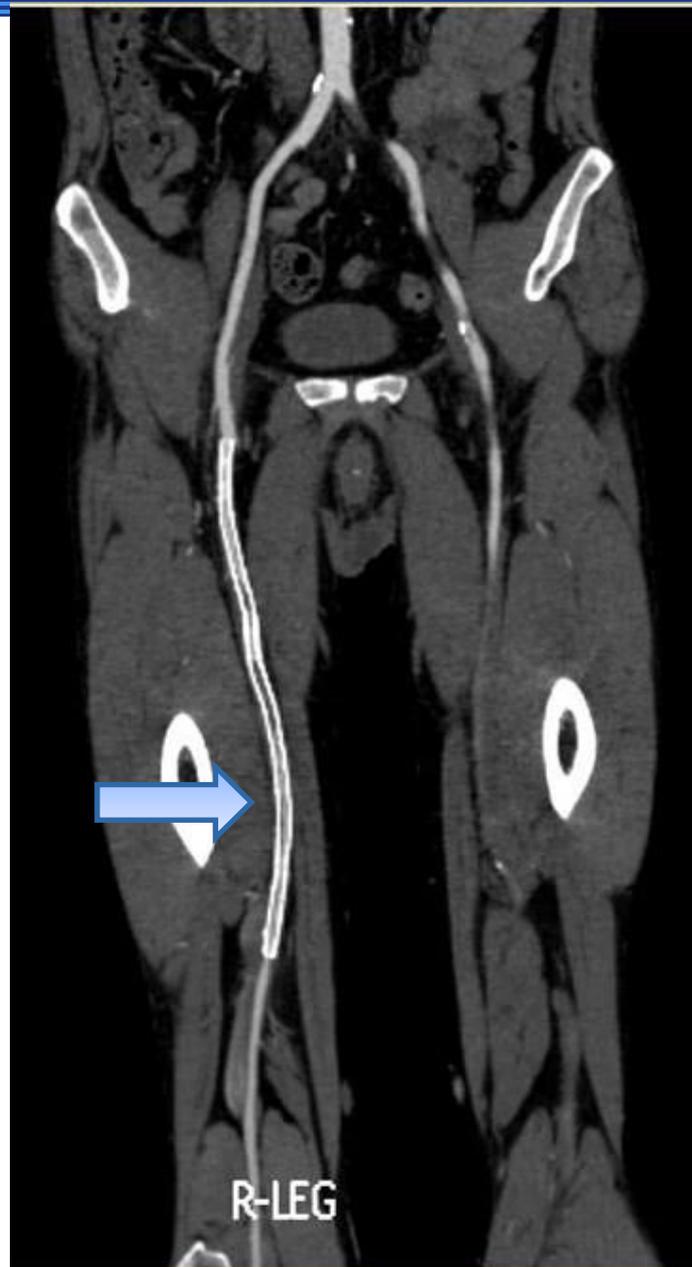
- ABI 0.48 to 0.92
- The patient was followed up for 3-years. The blood circulation of lower limb was good without intermittent claudication



- Male, 77y
- Stent implantation history for 3-years
- ABI 0.69



CTA before ISR treatment (2017-04-14)



Angiography before ISR treatment



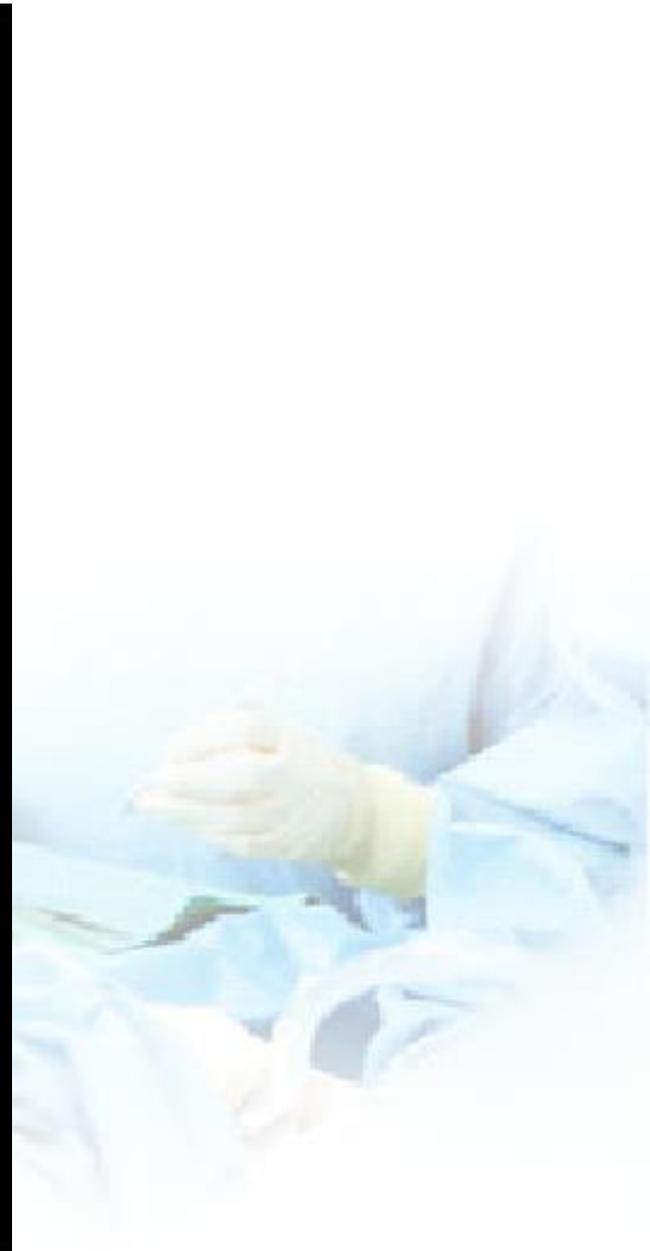
5*120 mm DCB after Rotarex[®]S debulking



Angiography after DCB treatment



CTA after ISR treatment (2017-05-19)



Condition after treatment

- ABI 0.69 to **0.96**
- The patient was followed up for **2-years**. The blood circulation of lower limb was good without intermittent claudication



Combination of Rotarex Thrombectomy and Drug-Coated Balloon for the Treatment of Femoropopliteal Artery In-Stent Restenosis

Chuan-jun Liao, Sheng-han Song, Tan Li, Yang Zhang, and Wang-de Zhang, Beijing, China

- Prospective registry
- 32 patients (June 2016 to July 2017)
- ISR treated with Rotarex[®]S and DCB
- Rutherford Class: 2-6
- Primary endpoint: Primary Patency
- Secondary endpoints: MALE, WIQ
 - An independent clinical events committee (CEC) adjudicated all major adverse events
 - Independent core laboratory analyzed all images, including those obtained by duplex ultrasonography and angiography

Baseline factors

Patient Demographics	
Age (years \pm SD)	69.8 \pm 11.0
Gender (m)	62.5 %
Hyperlipidemia	62.5 %
Diabetes mellitus	50.0 %
Current smoker	34.4 %
Mean ABI	0.45 \pm 0.14
CLI	81.3 %
WIQ score	30.45 \pm 21.14
Tosaka classification*	I 9.4 %
	II 34.4 %
	III 56.2 %

Lesion Characteristics	
Mean lesion length	12.3 \pm 9.0
Occlusions	100 %
Isolated popliteal artery	12.9 %



*Tosaka A, Soga Y, Iida O, et al. Classification and clinical impact of restenosis after femoropopliteal stenting. J Am Coll Cardiol 2012;59:16e23.

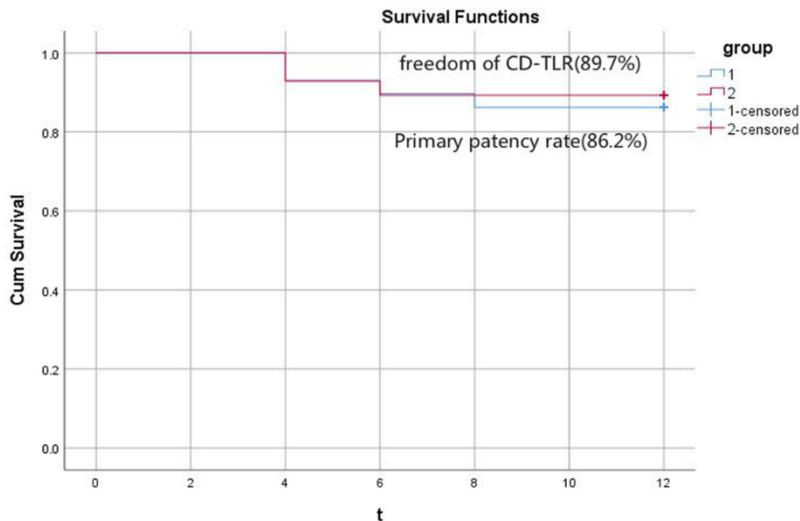
Efficacy rates

Immediate Results	
Technical success	100 %
Procedure success	100 %
Adjunctive lysis (ISR)	0 %

12-month Efficacy Rates	
Primary Patency (KM)	86.2 %
Freedom from cd-TLR	89.7 %
Mean ABI	0.45 ± 0.14
WIQ score	52.68 ± 29.75

$p < 0.05$

$p < 0.05$



12-month Efficacy Rates by Tosaka Class	
Primary Patency	I & II 84.6 %
	III 87.5 %
Freedom from cd-TLR	I & II 92.3 %
	III 87.5 %

$p < 0.05$

$p < 0.05$

Technical success was defined as the successful delivery and deployment of the Rotarex[®]S catheter and DCBs at the target lesion with attainment of <30% residual stenosis.

Procedural success was defined as the technical success without the occurrence of any in-hospital major adverse cardiac and cerebrovascular events.

Safety rates

1-month Safety Rates	
Distal embolisation*	6.3 %**
Procedure-related complications	0 %
Dissection	3.1 %
Perforation	0 %
Device-related Death	0 %
Procedure-related Death	0 %

12-month Safety Rates	
Major Amputation	0 %

*Distal protection devices used in 56.2%
**2 patients, resolved with PTA or thrombolysis



Discussion points

- FP-ISR is still a common and difficult problem
- A number of endovascular treatment methods are available for treating FP-ISR, Nevertheless, the optimal treatment method for FP-ISR remains controversial
- Paclitaxel has proven to inhibit neointimal growth and thus reduce restenosis
- Directional atherectomy is considered a minimally invasive treatment that removes atheromatous plaques, and restores blood flow in the native FP artery
- However, the theoretical advantage of minimizing invasiveness to the vessel wall has not been achieved as clinical benefits in the treatment of FP-ISR

Concluding statements

- In our experience, patients treated with the combining approach obtained significantly higher patency rates at 12-months
- This is particularly important considering that the ISR lesion length was 12.3 ± 9.0 cm, and 56.2% patients were of Tosaka class III
- The data suggest that combination of Rotarex[®]S thrombectomy and DCB for treatment of FP-ISR is safe and effective with satisfactory primary patency rate and freedom from CD-TLR at 12-month follow-up

A pair of glasses with a thin frame and a pen are resting on a blue surface. The glasses are positioned in the lower-left quadrant, and the pen is partially visible below them. The background is a solid, vibrant blue with a subtle gradient and soft shadows.

Thank You !