

Treating all Morphologies with Directional Atherectomy

Yaoguo Yang, Zhong Chen

Beijing Anzhen Hospital, Capital Medical University,
Beijing, China



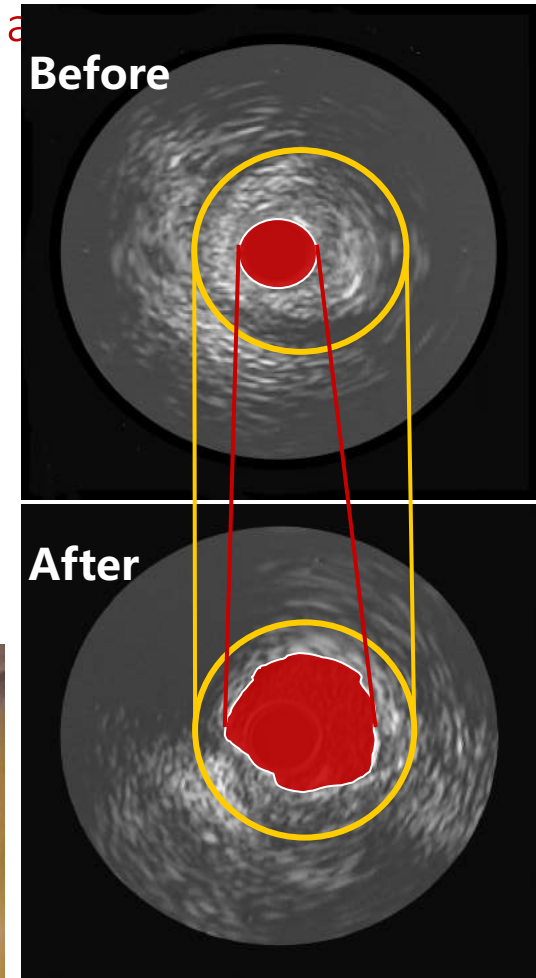
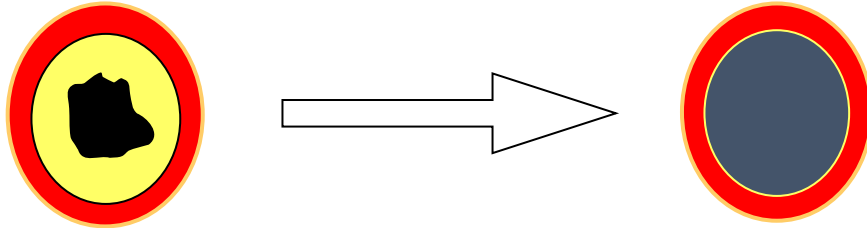
BEIJING ANZHEN HOSPITAL
CAPITAL MEDICAL UNIVERSITY

Directional Artherectomy

Remove plaques permanently by mechanical excision. Restore the autologous vascular lumen.

Remove plaques permanently

- Balloon dilation is unessential– Avoid barotrauma and elastic retraction of blood vessels
- Reduce stent placement
- Restore the autologous vascular lumen



Direct atherectomy is suitable for a variety of sites and plaques





American
Heart
Association®



AMERICAN
COLLEGE of
CARDIOLOGY

Guidelines have recommended atherectomy devices for the treatment of lower limb artery disease since 2005. But the recommendations regarding stent implantation for femoral, popliteal, and tibial artery disease have not been updated.

Class IIa

Stents (and other adjunctive techniques such as lasers, cutting balloons, atherectomy devices, and thermal devices) can be useful in the femoral, popliteal, and tibial arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis greater than 50%, or flow-limiting dissection). *(Level of Evidence: C)*

1. Hirsch AT, et al. *Circulation*. 2006 Mar 21;113(11):e463-654 .
2. *Circulation*. 2011 Nov 1;124(18):2020-45.
3. Anderson JL, et al. *Circulation*. 2013 Apr 2;127(13):1425-43.

DEFINITIVE clinical trials have demonstrated the clinical safety of Turbohawk.

DEFINITIVE RESULTS

Leave only the facts behind



Lower Extremity Revascularization Using Directional Atherectomy

12-Month Pro

James F. McKinsey, MD
Lawrence A. Garcia, MD

ABSTRACT

OBJECTIVES: The safety and effectiveness of SilverHawk™ and TurboHawk™ for the treatment of lower extremity arterial disease in patients with limb ischemia.

BACKGROUND: The safety and durability of DA and differences in outcomes.

METHODS: DEFINITIVE™ LE study centers with an initial cohort of 800 patients and a second cohort of 598 patients. The hypothesis evaluated and angiographic core.

RESULTS: A total of 1398 patients (69.9%) were treated with SilverHawk™ (70.0%) or TurboHawk™ (80.6%)

Clinical Investigation

A Comparison of Clinical Outcomes for Diabetic and Nondiabetic Patients Following Directional Atherectomy in the DEFINITIVE LE Claudicant Cohort

Lawrence A. Garcia, MD¹, Michael R. Jaff, DO², Krishna J. Rocha-Singh, MD³, Thomas Zeller, MD¹, Christopher Bosarge, MD², Suraj Kamat, MD², and James F. McKinsey, MD¹

Abstract

Purpose: To report a subset analysis that evaluated the hypothesis that directional atherectomy for peripheral artery disease in diabetic claudicants has noninferior primary patency at 12 months compared with nondiabetic claudicants. **Methods:** DEFINITIVE LE, a US/European multicenter study, assessed the effectiveness of directional atherectomy using SilverHawk™/TurboHawk™ systems for treatment of peripheral artery disease in the superficial femoral, popliteal, and infrapopliteal arteries. Of the 800 patients enrolled in the study, only the 598 claudicant patients (mean age 69.3±10.4 years; 336 men) who were classified at baseline as Rutherford category 1-3 were eligible for this analysis. Of these, 46.8% (280/598) had diabetes. Follow-up to 12 months included duplex ultrasound examination, functional assessments, and adverse event evaluations. Independent angiographic and duplex ultrasound core laboratories assessed primary patency and secondary endpoints; a clinical events committee adjudicated adverse events. **Results:** Although diabetics had significantly more baseline comorbidities, 12-month primary patency (77.0%) was no different than for nondiabetics (77.9%; superiority p=0.98; noninferiority p<0.001) across all anatomic territories treated. Freedom from clinically driven target lesion revascularization was no different between diabetics (83.8%) and nondiabetics (87.5%) overall (p=0.19) or by lesion



Journal of Endovascular Therapy
2015, Vol. 22(5) 701-711
© The Author(s) 2015
Reprints and permissions:
sagepub.com/journalsPermissions.nav
DOI: 10.1177/15267566152344058
www.jet.org
SAGE

Original Studies

Effective Endovascular Treatment of Calcified Femoropopliteal Disease With Directional Atherectomy and Distal Embolic Protection: Final Results of the DEFINITIVE Ca⁺⁺ Trial

David Roberts,^{1*} MD, Khusrow Niazi,² MD, William Miller,³ MD, Prakash Krishnan,⁴ MD, Roger Gammon,⁵ MD, Theodore Schreiber,⁶ MD, Nicolas W. Shammas,⁷ MD, MS, and Daniel Clair,⁸ MD on behalf of the DEFINITIVE Ca⁺⁺ Investigators

Objectives: The purpose of the DEFINITIVE Ca⁺⁺ study was to evaluate the safety and effectiveness of directional atherectomy and distal embolic protection, used together to treat moderate to severely calcified femoropopliteal lesions. **Background:** Despite advances in endovascular treatment modalities, treatment of calcified lesions remains a challenge. **Methods:** A total of 133 subjects with 188 moderate to severely calcified lesions were enrolled. Lesions were treated with directional atherectomy devices, coupled with distal embolic protection. **Results:** The 30-day freedom from MAE rate was 93.1%. Per angiographic core laboratory assessment, the primary effectiveness endpoint (≥50% residual diameter stenosis) was achieved in 80.0% (lower confidence bound of 67.6%) of lesions. By core lab analysis, these results did not achieve the success criteria (80%) for the primary effectiveness objective. Per site assessment, the objective was met with the endpoint being achieved in 97.0% (lower confidence bound 93.8%). A mean residual diameter stenosis of 33.3% was achieved with the directional atherectomy device. This was further decreased to 24.1% with the use of adjunctive therapy. The proportion of asymptomatic subjects [Rutherford Clinical Category (RCC) = 0] increased from 0% at baseline to 52.3% at the 30-day follow-up visit. In total, 88.5% of subjects experienced an improvement of one or more Rutherford categories. **Conclusions:** The results of the DEFINITIVE Ca⁺⁺ study demonstrate that the SilverHawk™ and TurboHawk™ atherectomy devices are safe and effective in the endovascular treatment of moderate to severely calcified lesions in the superficial femo-

Contents lists available at ScienceDirect
Cardiovascular Revascularization Medicine

Combined treatment of heavy calcified femoro-popliteal lesions using directional atherectomy and a paclitaxel coated balloon: One-year single centre clinical results[†]

Angelo Cioppa^a, Eugenio Stabile, Grigore Popusoi, Luigi Salemmè, Linda Cota, Armando Puccarelli, Vittorio Ambrosini, Giovanni Sorropago, Tullio Tesoro, Alessia Agresta, Giancarlo Blamini, Paolo Rubino

Division of Invasive Cardiology, "Materaugusta" CHU, 80137 Montegiughe (Avellino), Italy

ARTICLE INFO

Article history:
Received 15 March 2012
revised 16 April 2012
accepted 26 April 2012
Available online xxxx

Keywords:
Peripheral intervention
Directional atherectomy
Atherectomy
Drug coated balloon

ABSTRACT

Background: The use of Directional Atherectomy (DA) for the treatment of calcified femoro-popliteal lesions remains to improve the acute procedural success, however without reducing the long-term outcomes rate. Drug coated balloons (DCB) reduced restenosis rate in non heavy calcified lesions. Aim of this study was to demonstrate safety and efficacy of a combined endovascular approach using DA and DCB for the treatment of heavy calcified lesions of the femoro-popliteal tract.

Methods: From January 2010 to November 2010, 240 patients underwent PTA of the femoro-popliteal tract in our institute. Within the cohort a total of 50 patients had all Lesion Characteristics (LC) 1 (r=1-10 and L1 a Critical limb ischemia (CLI) with baseline Rutherford class 4-2, 1-2) underwent PTA of heavy calcified lesions with intracatheter ultrasound guided DA and DCB. All procedures have been performed using a distal protection device. Stent implantation was allowed only in case of flow limiting dissections or suboptimal result (residual stenosis >50%) by visual estimation. After the intervention a primary care was followed up to 12 months. Lesions free residual and clinical success were achieved in all cases. Post-occlusion restenosis was necessary in only four (5.5%). At two-month follow up residual Rutherford class was 2.2 ± 1.2, ABI was 0.8 ± 0.1 and limb salvage rate was 100%. Two minor foot finger or toe/heel amputations, were performed to reach complete wound healing and/or prevent debridement. Degree control was performed in all the cases (n=20). In these cases degree score showed a significant lower lesion restenosis requiring a reintervention (10 = 10), leading a total one-year secondary patency rate of 100%. All the three reintervened patients were insulin dependent diabetics and none of them were treated during the procedure.

Conclusions: The data suggest that combined use of DA and DCB may represent a potential alternative strategy for the treatment of femoro-popliteal heavily calcified lesions. These very promising data need the confirmation hypothesis have to be confirmed in a multicenter randomized trial.

© 2012 Elsevier Inc. All rights reserved.

DEFINITIVE LE trial : Primary patency for 12 months in directional atherectomy of SFA, POA and Infrapopliteal artery reached >75%



Primary patency for 12 months

75%

SFA

77%

POA

90%

Infrapopliteal artery

Primary patency in DM/non-DM group

77%

DM

78%

Non-DM

DEFINITIVE Ca++ trial : Turbohawk和Spider FX联合使用可有效治疗严重钙化病变



• **133 cases**

• **17 clinical centers**

A blue rectangular box containing a grid of 133 small human icons arranged in 4 rows (34 in the first three rows, 25 in the fourth). To the right of the icons, there are two bullet points in yellow text: '• 133 cases' and '• 17 clinical centers'.

0.8% Incidence of flow-limiting dissection

2.3% Incidence of perforation

2.3% Incidence of distal embolism

A blue rectangular box with three rows of text. Each row features a large yellow percentage followed by a white text description of an adverse event: '0.8% Incidence of flow-limiting dissection', '2.3% Incidence of perforation', and '2.3% Incidence of distal embolism'.

DEFINITIVE CA++ 12 months trial

- Evaluating safety and efficacy of directional atherectomy combined with embolic protection system for the treatment of moderately and severely calcified femoral popliteal artery lesions

A grey rectangular box with a blue header and a white body. The header reads 'DEFINITIVE CA++ 12 months trial' in blue. Below it is a single bullet point in black text: '• Evaluating safety and efficacy of directional atherectomy combined with embolic protection system for the treatment of moderately and severely calcified femoral popliteal artery lesions'.

Roberts D, et al Catheter Cardiovasc Interv 2014;84:236-44

CASE 1

- Male , early 60s
- Medical history : Intermittent claudication of both lower limbs for 10 years, **left side** is more severe. Maximal walking distance is about **200m**, no resting pain
- Risk factors : Hypertension,DM,CAD.

Smoke history, 20 cigarettes*30 years , quit for 5 years



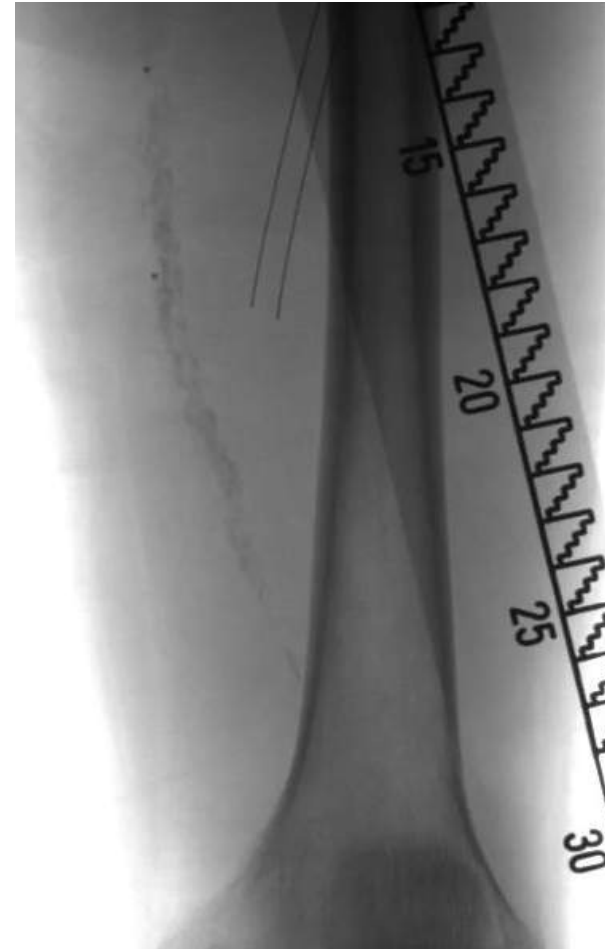
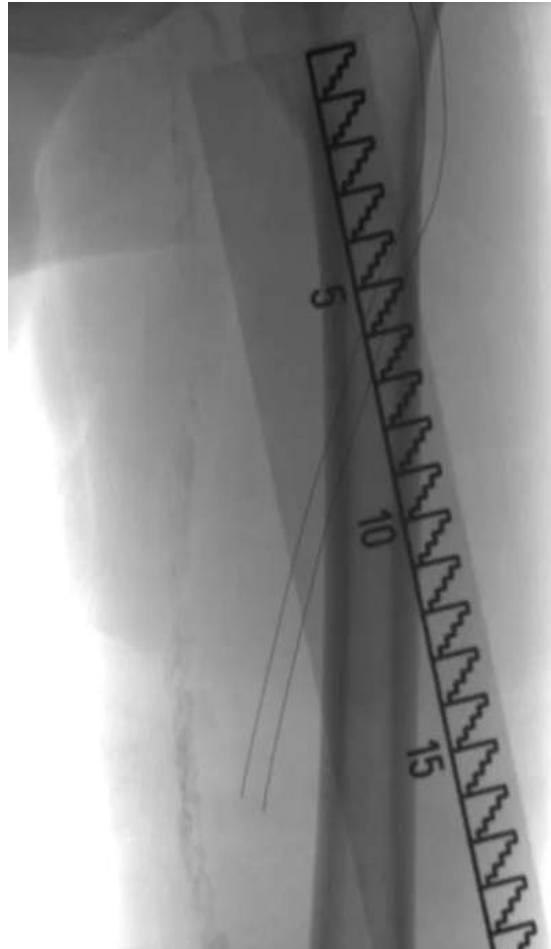
- **Ultrasound :**

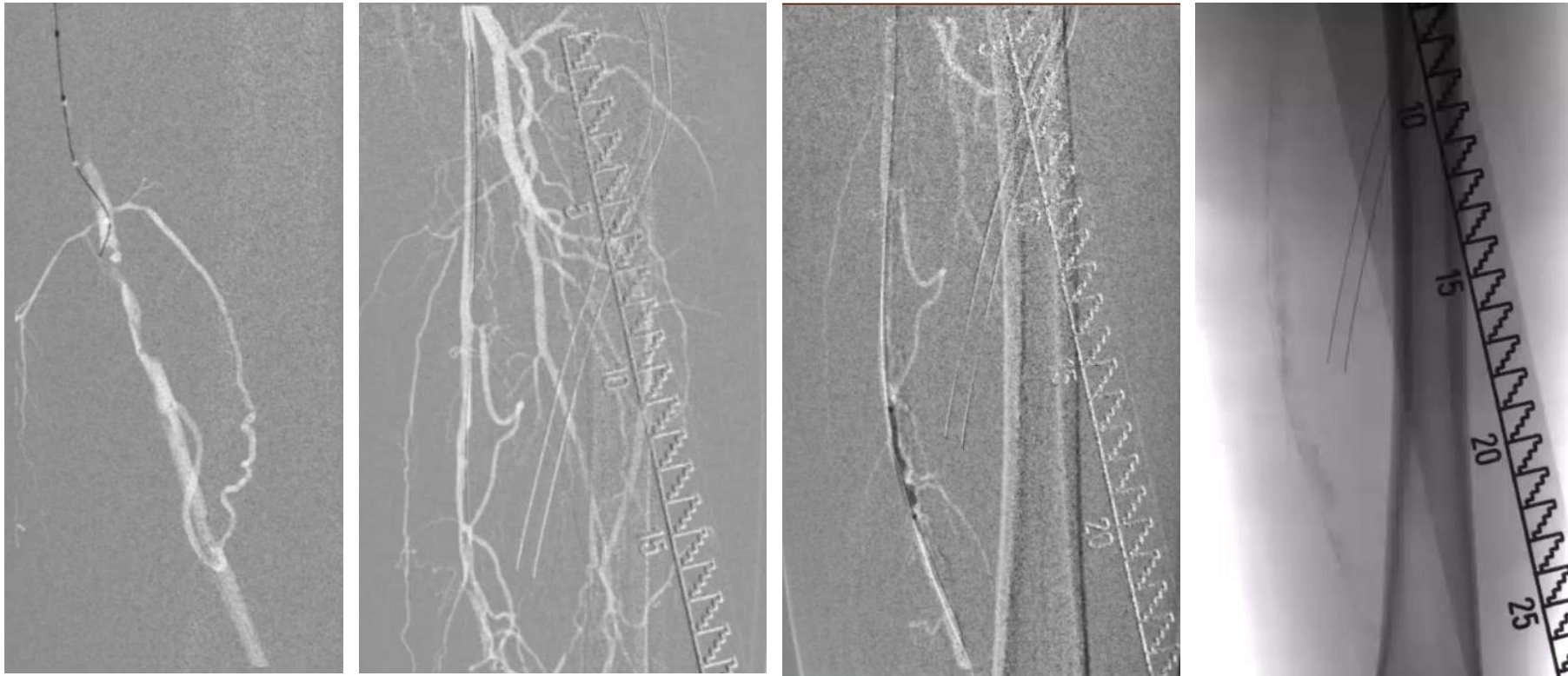
- multiple **strong echo plaques** in the left superficial femoral artery
- **occlusion in the middle segment**
- multiple stenosis in the proximal and distal segments

	Internal Diameter (cm)	PSV (cm/s)
LCFA	0.65	—
LSFA	0.21/0.45	0/52.3

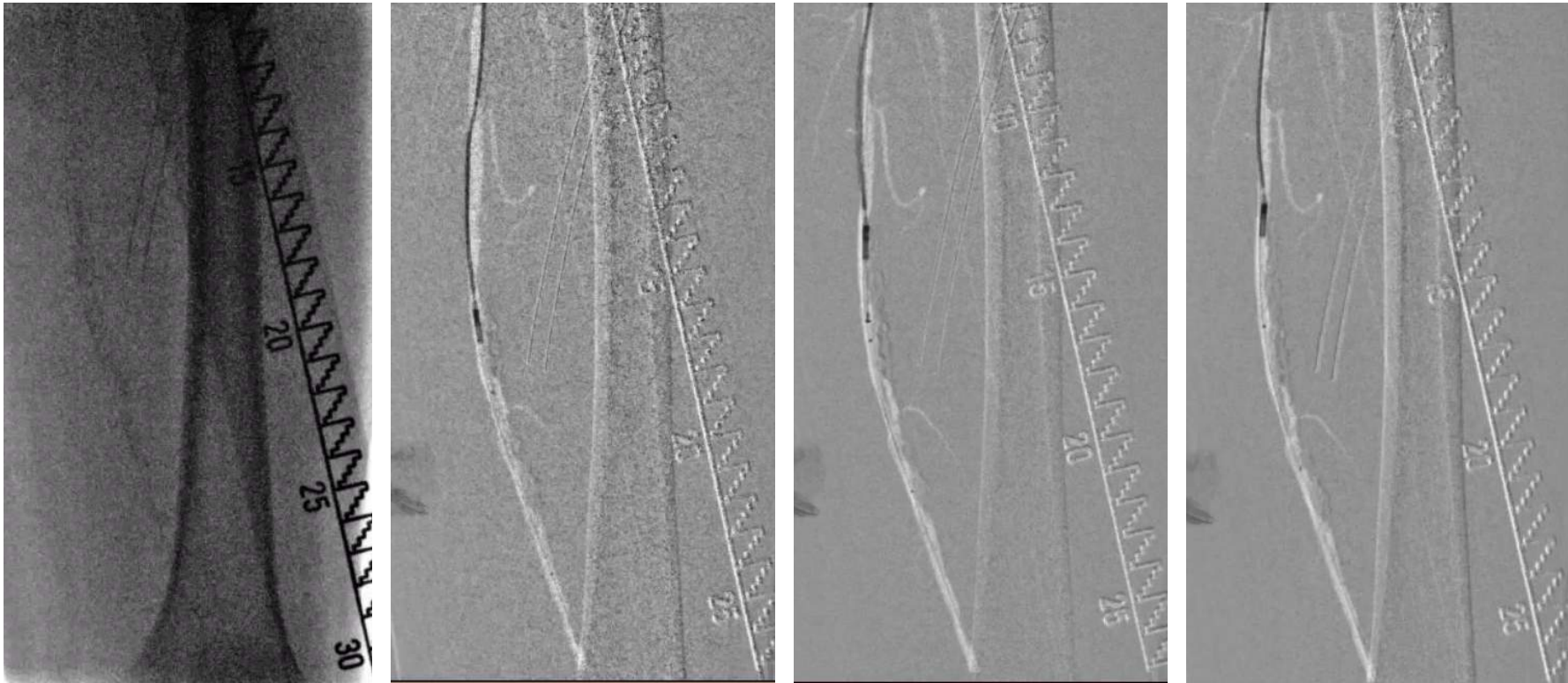


DSA before surgery

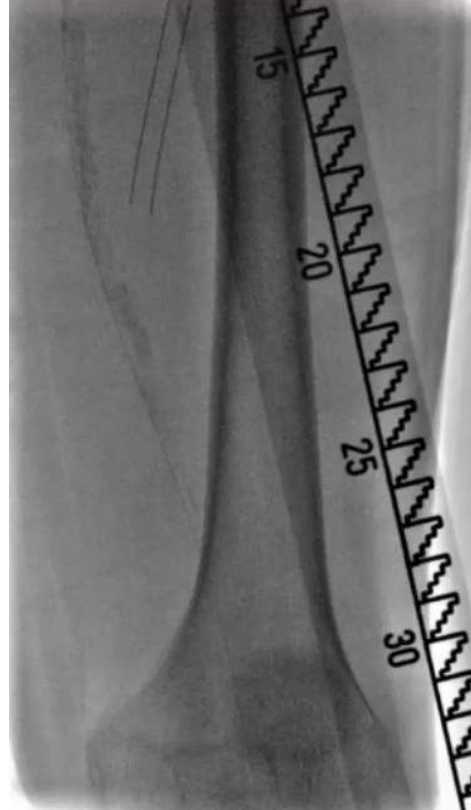
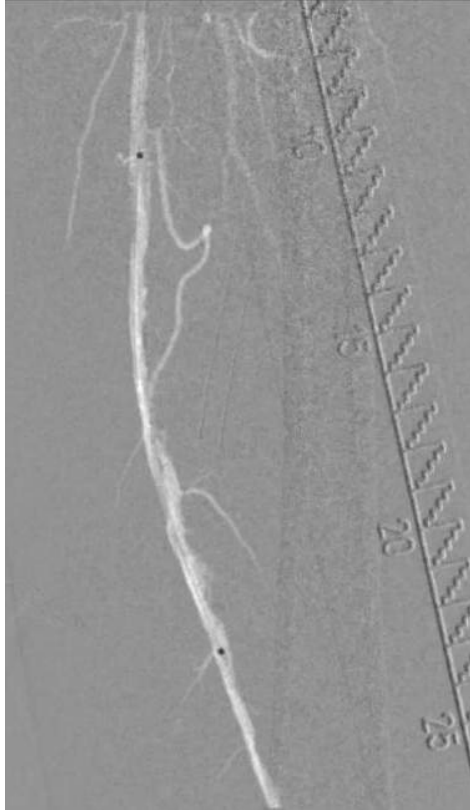




The guide wire coordinated with trailblazer support catheter reopened the occlusion, pre dilated the lesion.



- Filter was placed **distal popliteal artery** with the tip of the head reached the tibiofibular trunk.
- Directional atherectomy using Turbohawk in SFA.



- Angiography showed that blood flow was patent, 5*120mm balloon was used to dilate the lesion. Then **5*150mm DCB** was applied to dilate the lesion, the dilation time was 3min.
- The filter was retrieved, angiography showed SFA patency.

CASE 2

- Male , early 60s
- Medical history : Intermittent claudication of both lower limbs for 2 years, **right side** is more severe. Maximal walking distance is about **50m**, no resting pain.
- Risk factors : Hypertension.

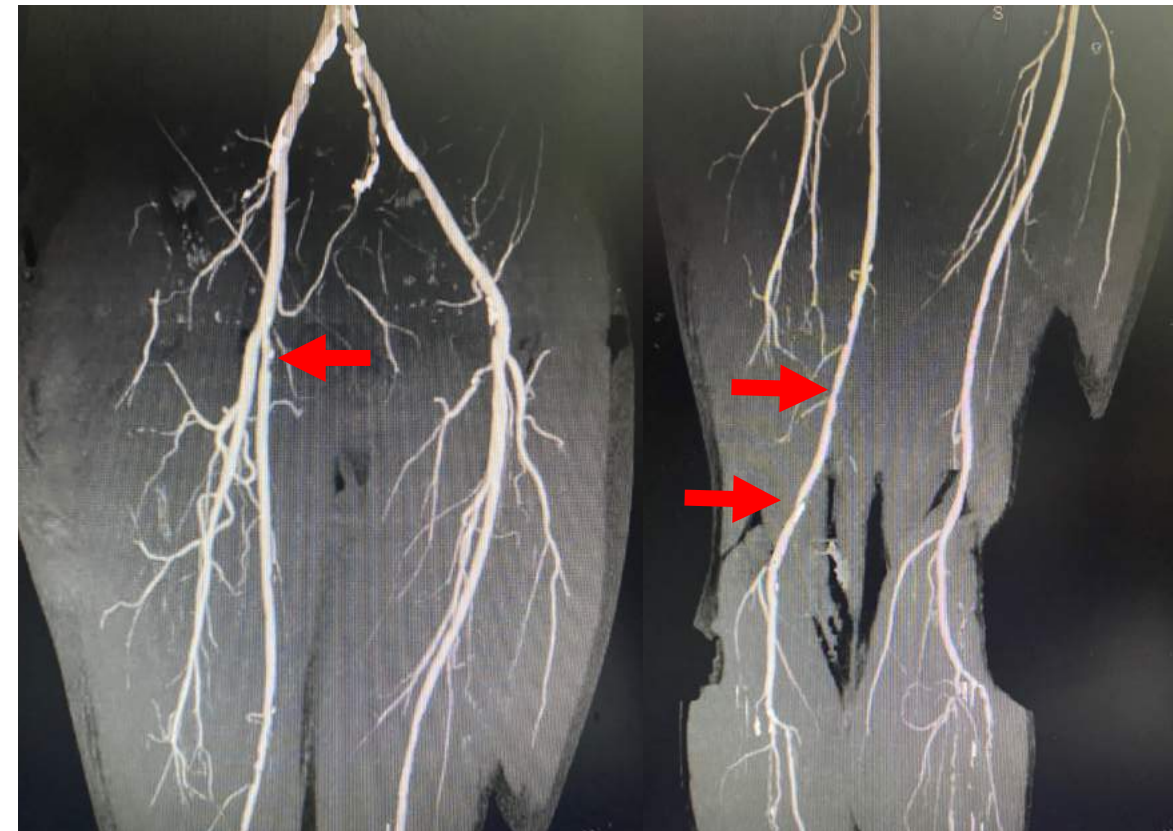
Smoke history, 20 cigarettes*40 years



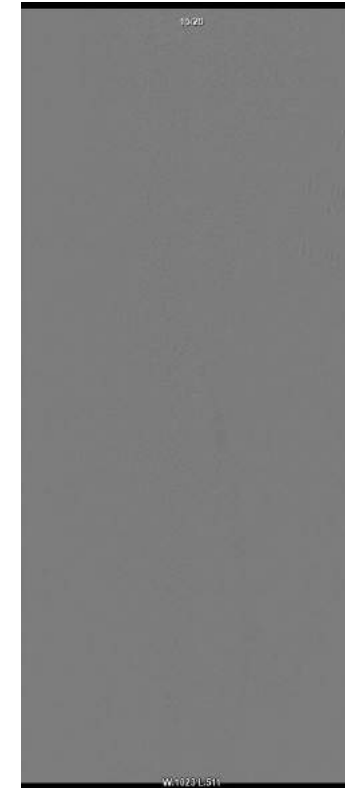
- **Ultrasound :**

- **Stenosis in RCFA (50%).**
- **Stenosis in the middle and distal segment of RSFA (70%), strong echo plaques.**
- **Anterior tibial artery and the peroneal artery was occluded.**
- **Stenosis in LSFA (40%).**

	Internal Diameter (cm)	PSV (cm/s)
LSFA	0.33/0.49	87.5
RCFA	0.37/0.67	50.6
RSFA	0.12/0.48	221.0



DSA before surgery

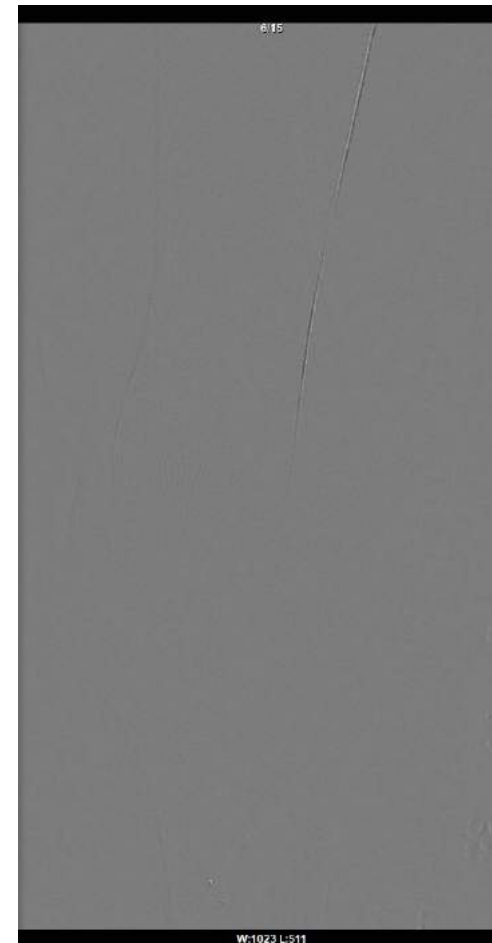


Severe stenosis in the proximal and distal segment of RSFA, Anterior tibial artery and the peroneal artery was occluded.

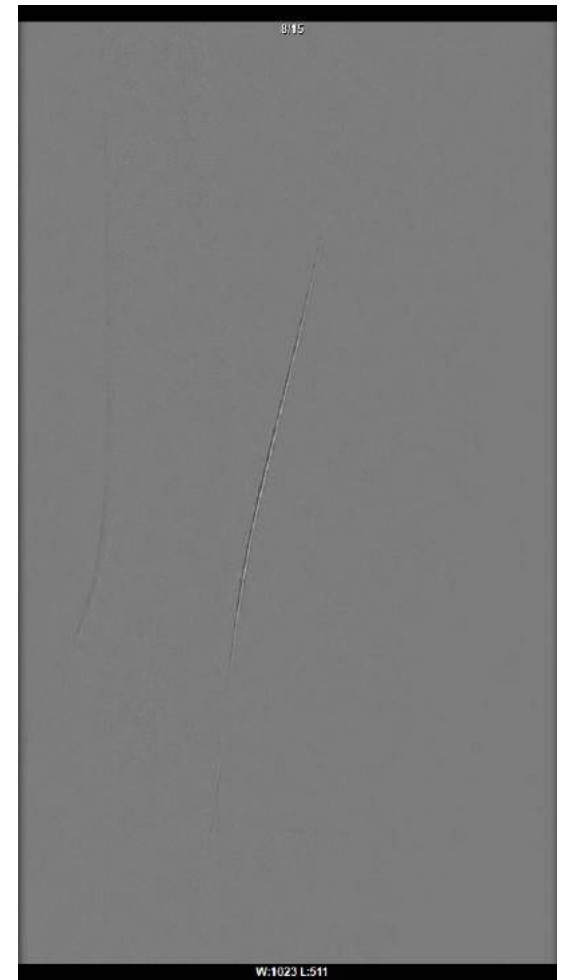
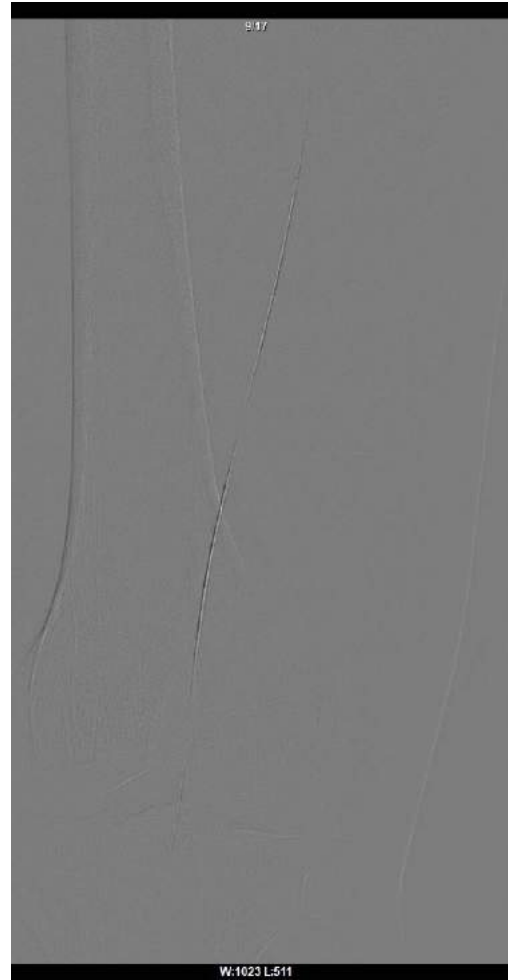
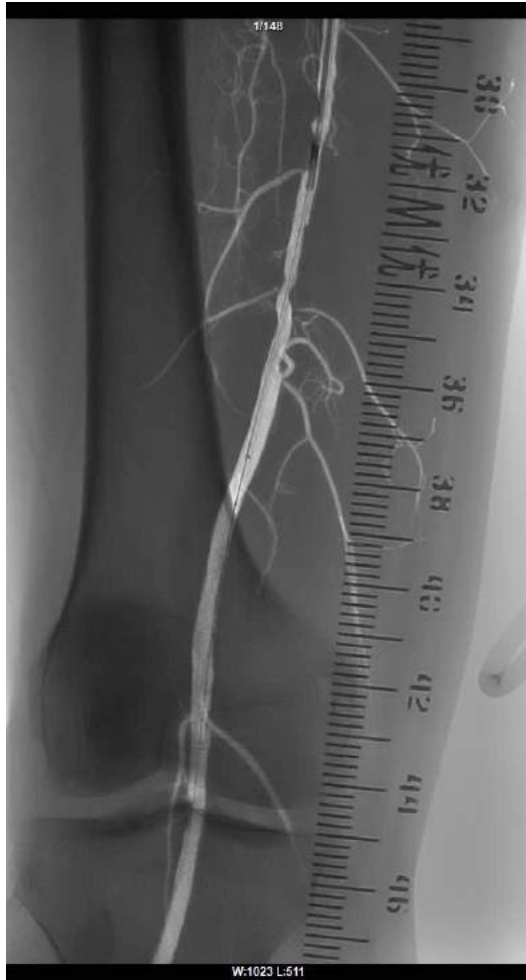


Guide wire passed lesion, Filter was placed in **Tibiofibular trunk**.

Directional atherectomy using Turbohawk in **POA**.

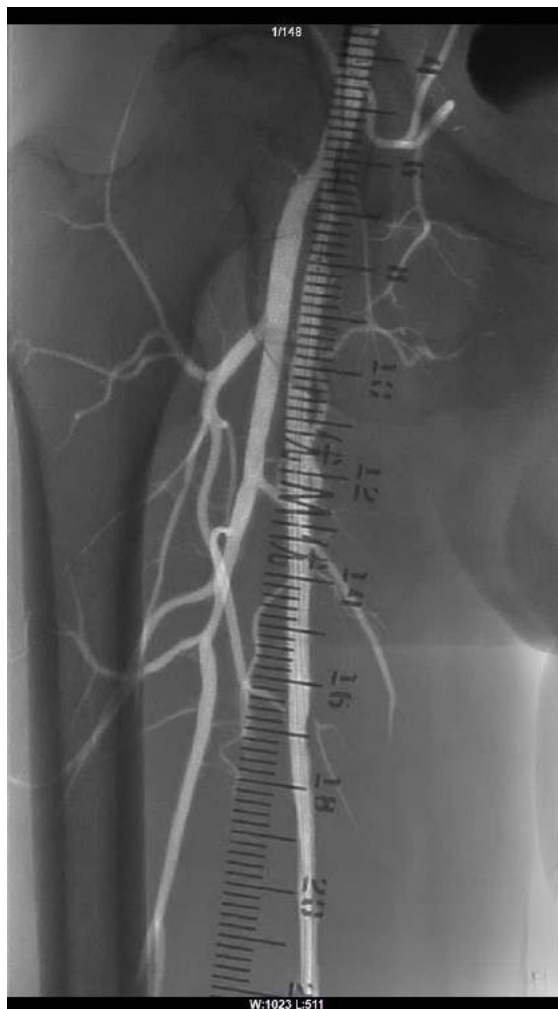


After directional atherectomy, angiography showed that blood flow was patent.

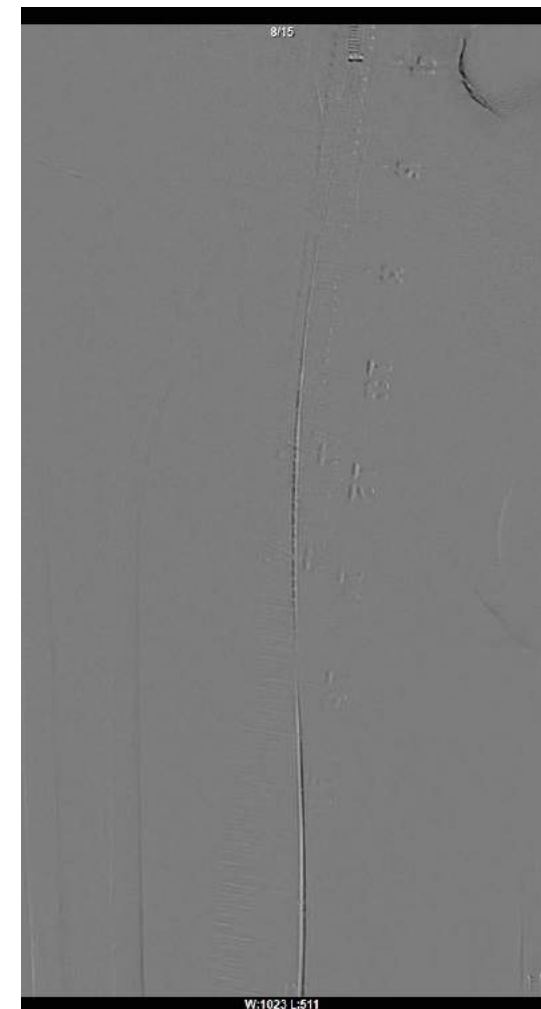
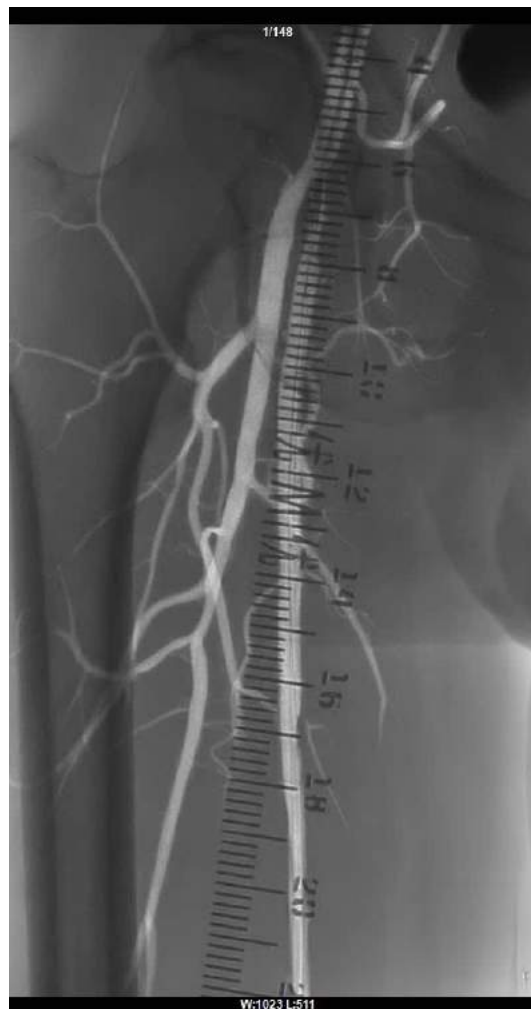


Directional atherectomy using Turbohawk in **distal SFA**.

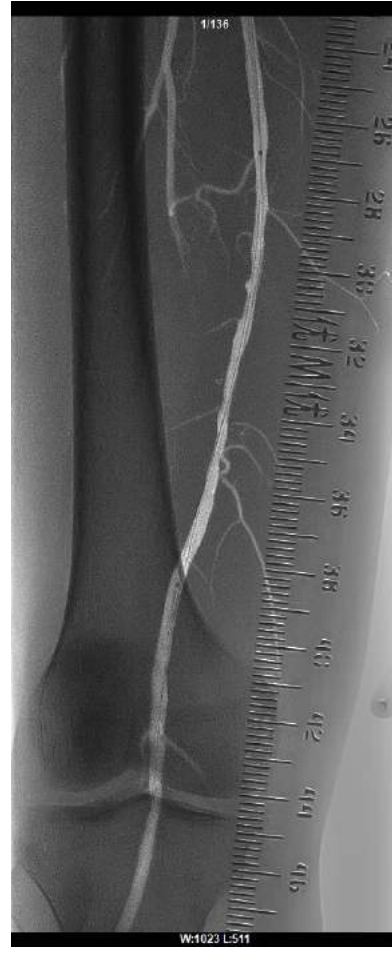
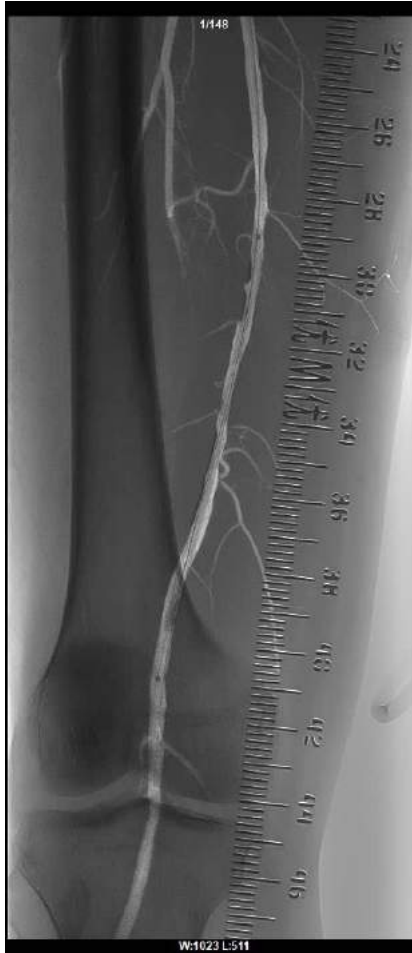
Angiography showed that blood flow was patent.



Directional atherectomy using Turbohawk in proximal SFA.

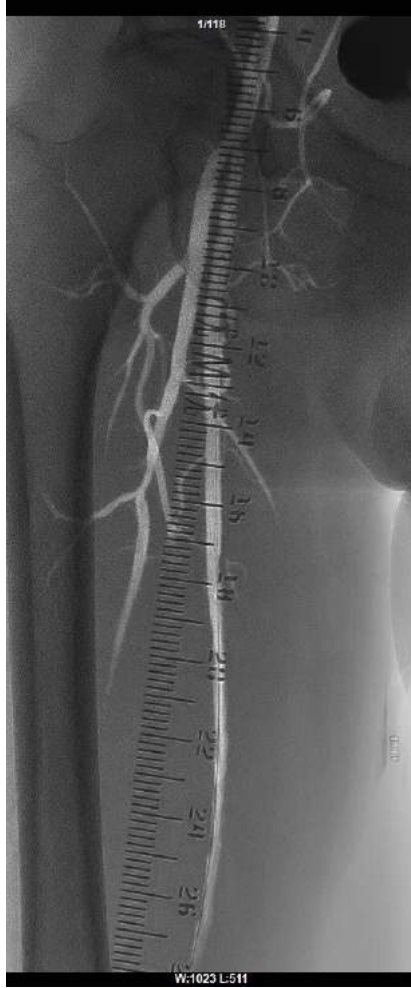


Angiography showed that blood flow was patent.

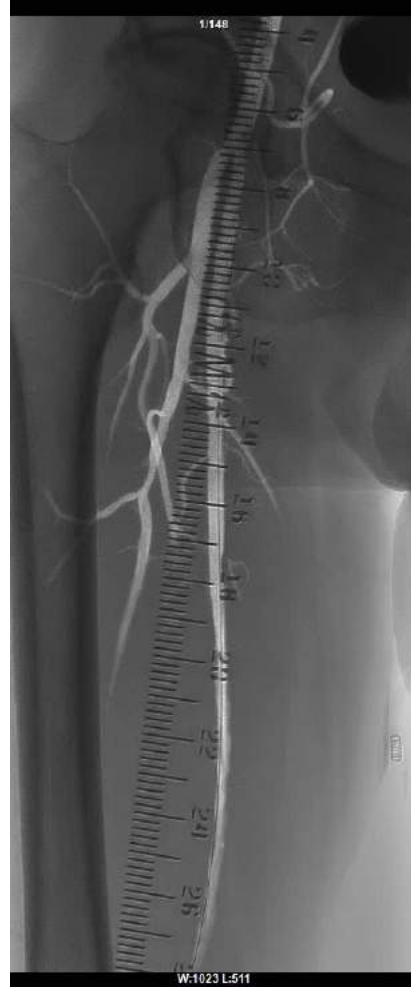


**Pre dilate distal SFA and POA
with 4*150mm balloon.**

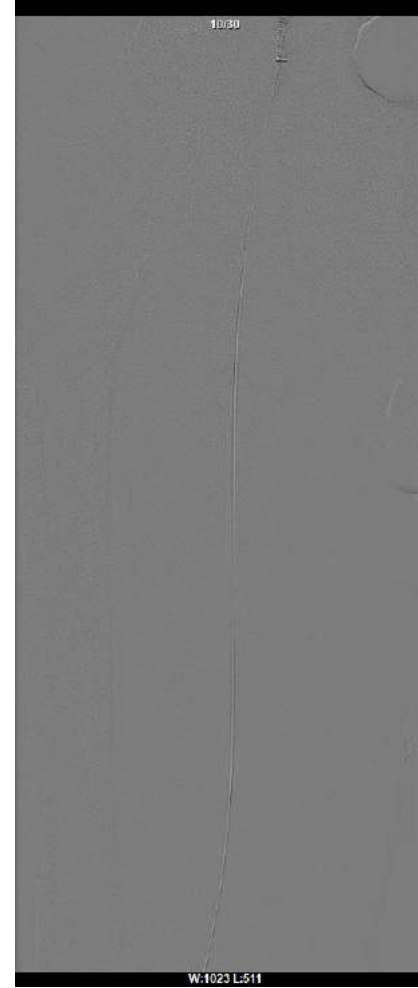
**5*200mm DCB was applied,
the dilation time was 3min.**

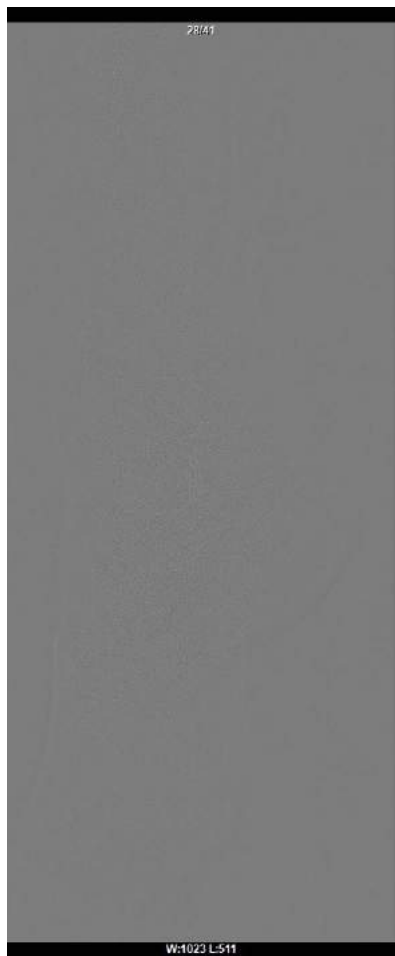
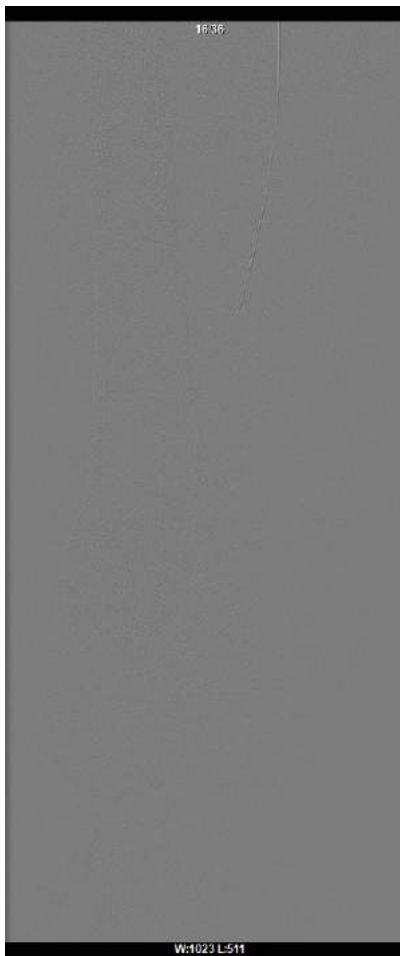


**Pre dilate proximal SFA
with 5*40mm balloon.**



**5*40mm DCB was applied,
the dilation time was 3min.**





- DSA after surgery
- Retrieve filter.



- Some of the plaques

CASE 3

- Female , early 80s
- Medical history : Intermittent claudication of **left** lower limb for 1 year. Treated by directional atherectomy and DCB for occlusion of POA 1 year ago, maximal walking distance improved from 20m to **300m**, no resting pain.
- Risk factors : Hypertension, DM.

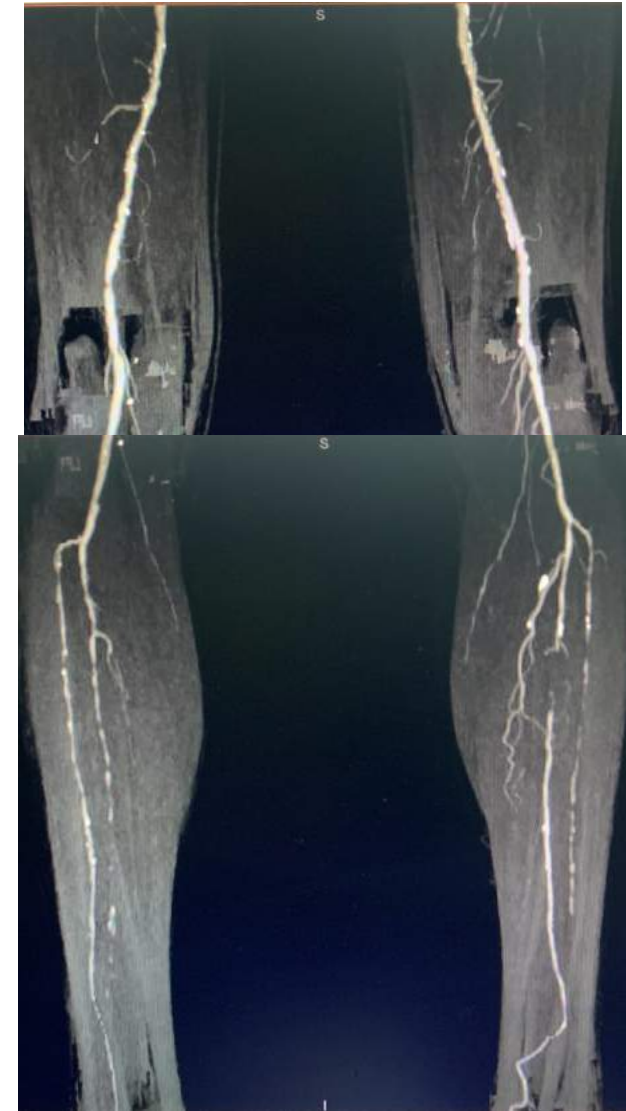
Smoke history, 20 cigarettes*50 years, quit for 1 year.



- **Ultrasound :**

- **Severe stenosis in LPEA, occlusion in the middle segment of LPEA.**
- **Occlusion in LATA, LPTA.**
- **Strong echo plaques.**

	Internal Diameter (cm)
LATA	0.08/0.24
LPTA	0.10/0.22
LPEA	0.10/0.25





DSA before surgery.



**Reopened PEA
successfully.**



**Pre dilate with 2*120mm balloon,
filter was placed in **distal PEA.****



**Directional
atherectomy using
Turbohawk in PEA**

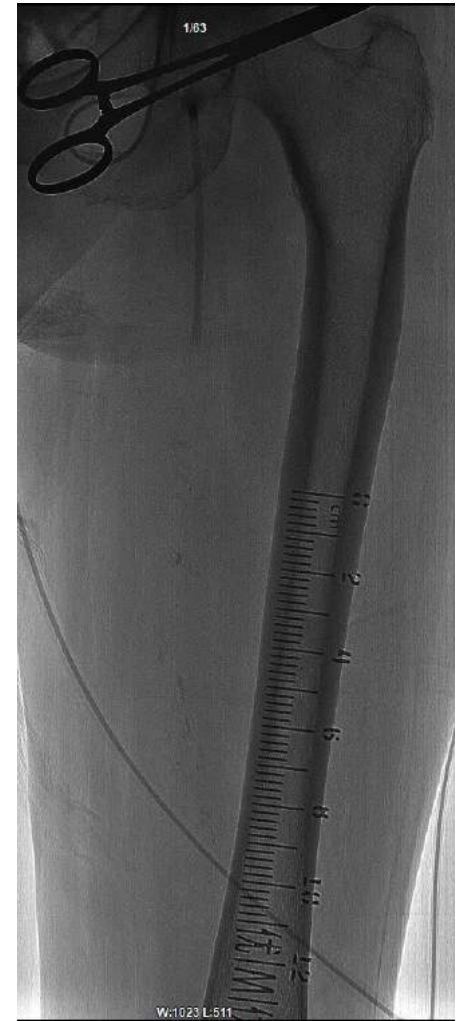
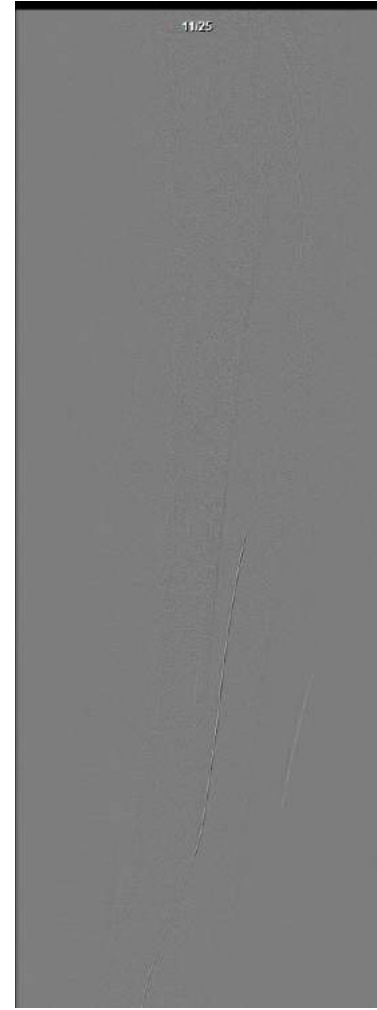
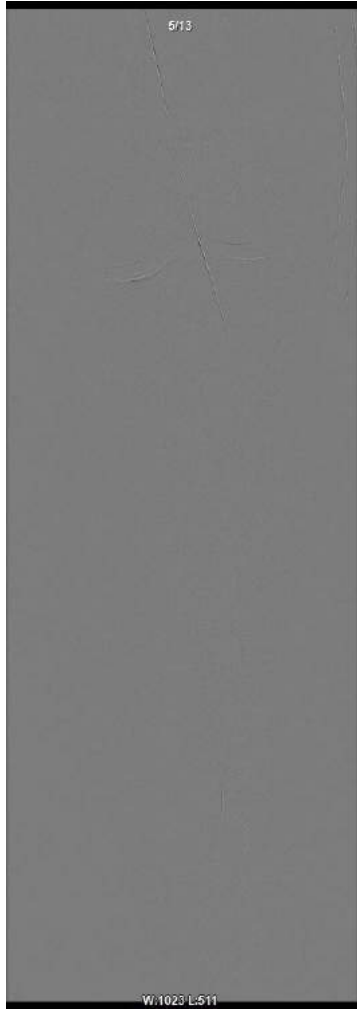


**Directional atherectomy
using Turbohawk in
distal POA**





3*200mm DCB
3min.



Retrieve filter.

CASE 4

- **Male , late 60s**
- **Medical history : Intermittent claudication of right lower limb for 1 year, maximal walking distance is about **100m**, no resting pain.**
- **Risk factors : DM, CAD.**

Smoke history, 10 cigarettes*40 years.



- **Ultrasound :**

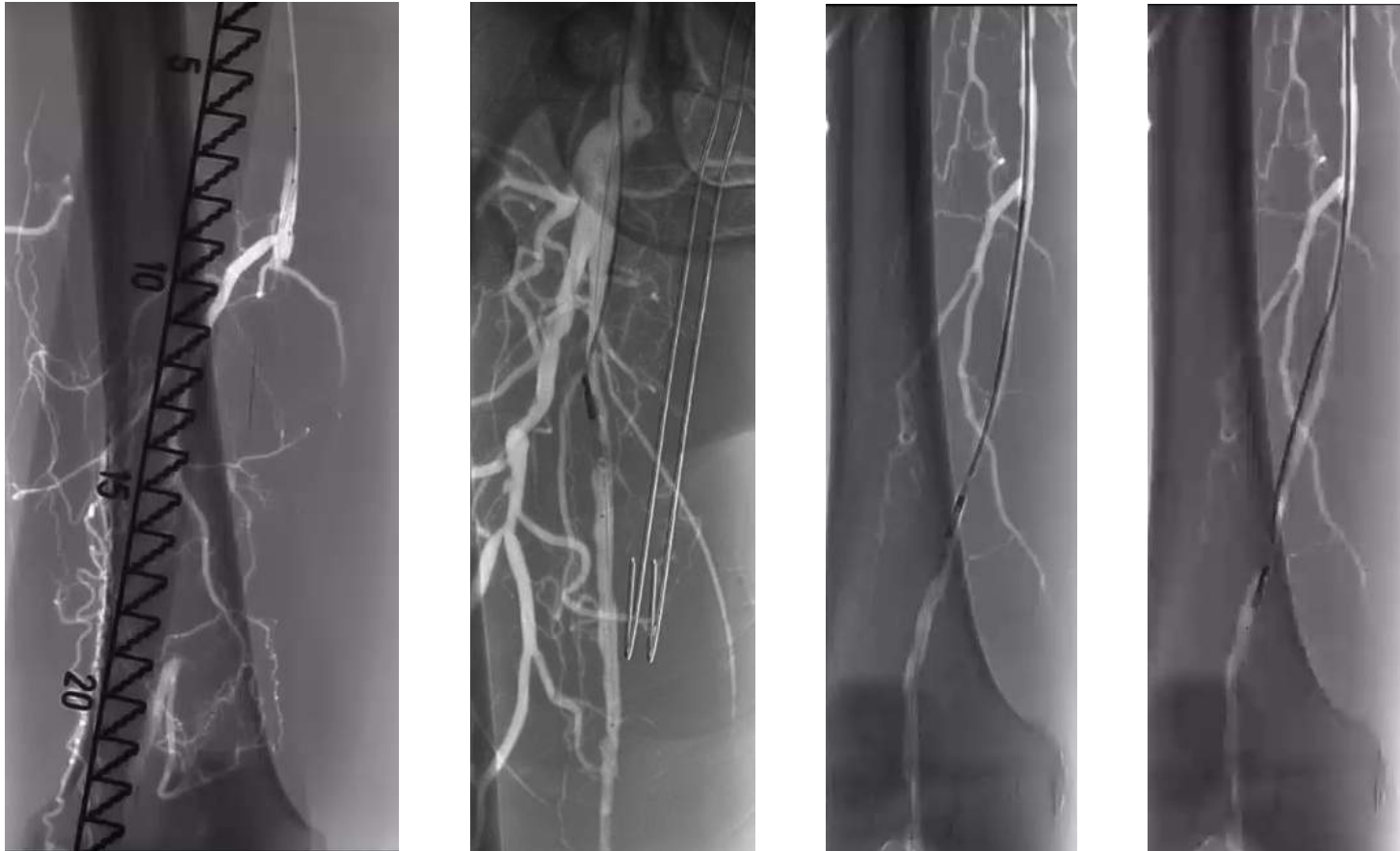
- **Severe stenosis in LSFA, occlusion in the middle segment. Multiple strong echo plaques.**
- **Occlusion in LATA, LPTA.**

	Internal Diameter (cm)	PSV (cm/s)
RCFA	0.47/0.98	151
RSFA	0.15/0.56	0/41.5
RPOA	0.28/0.51	74.6

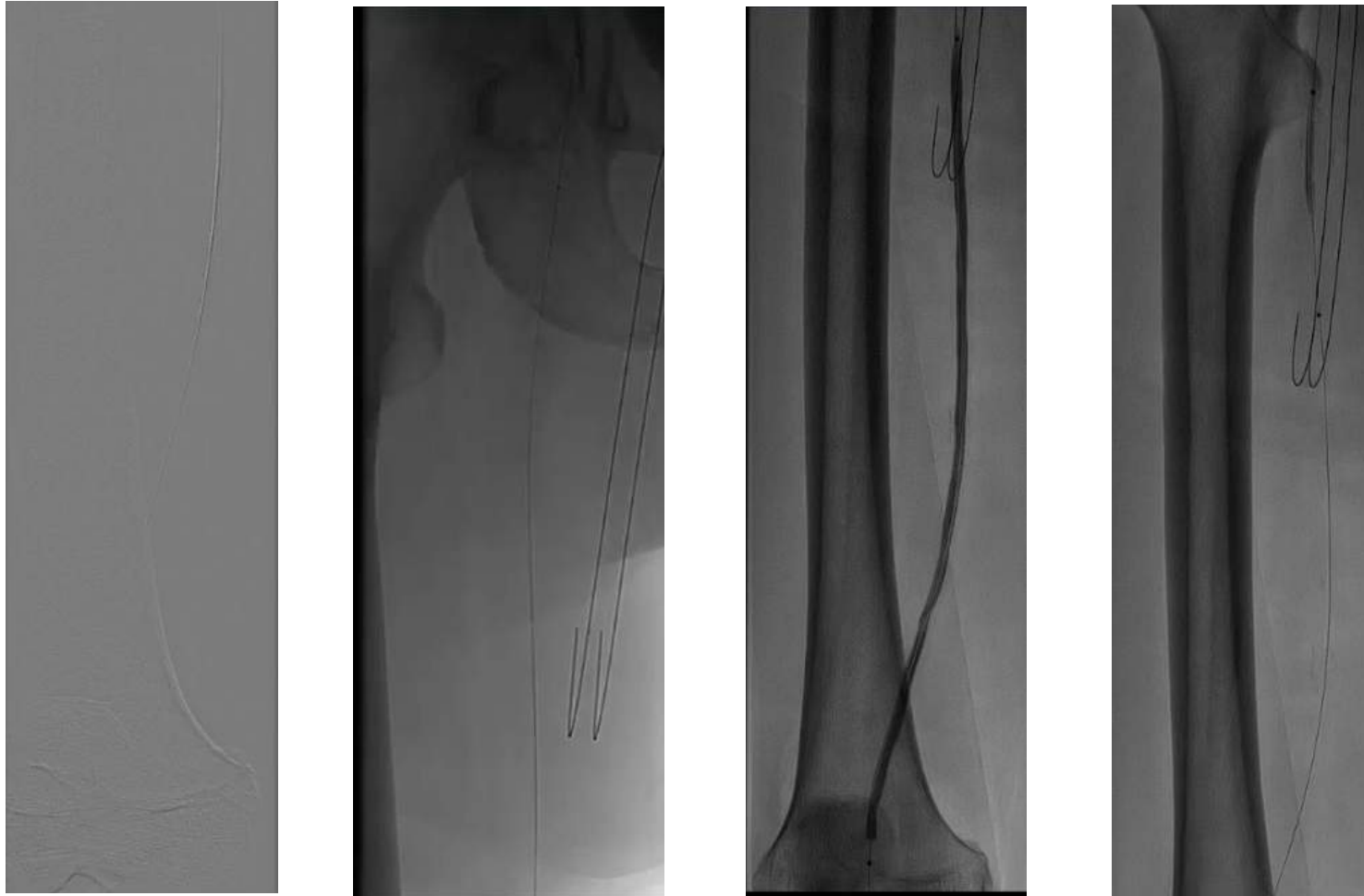


DSA before surgery



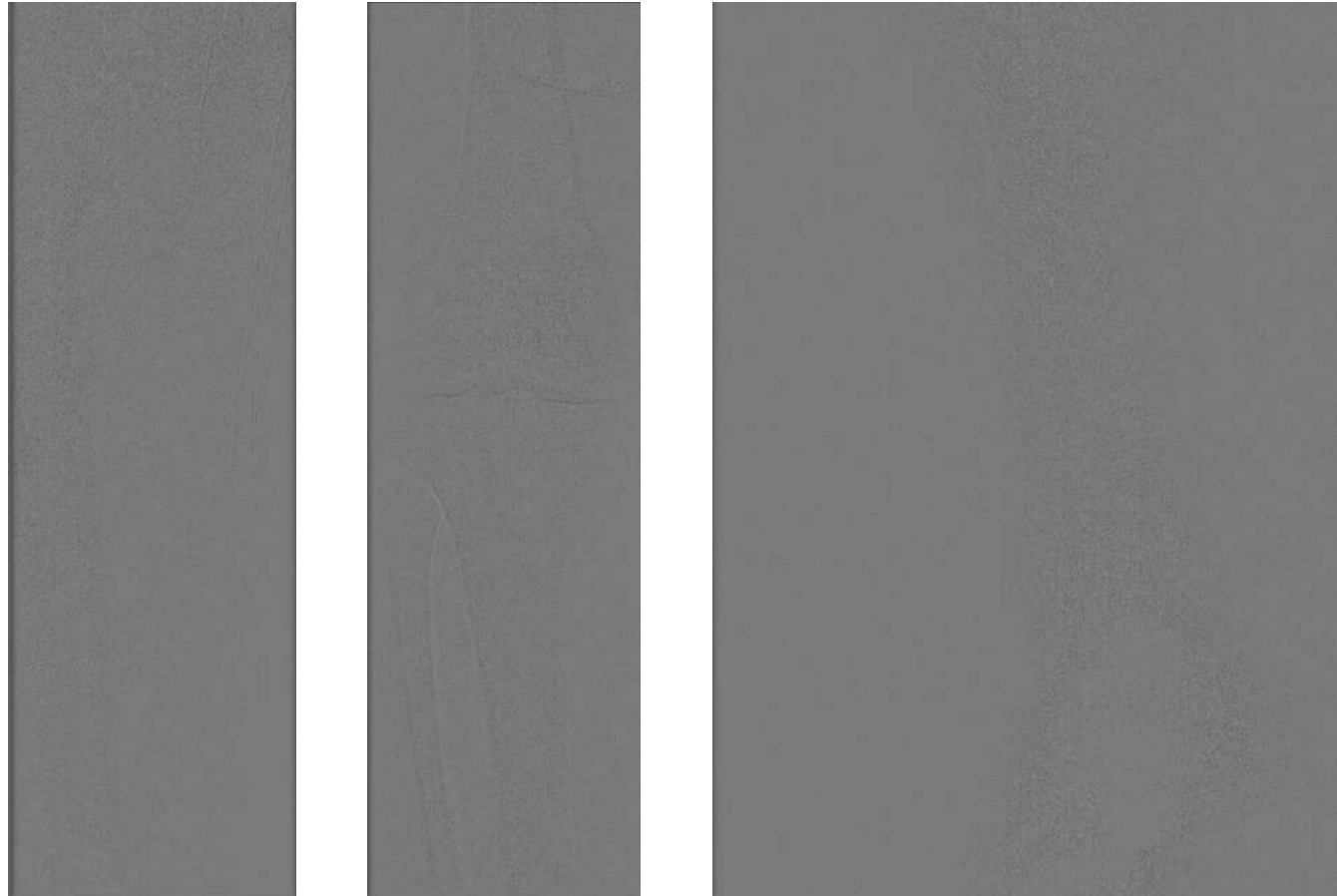


- **Guide wire passed lesion, Filter was placed in distal POA.**
- **Directional atherectomy using Turbohawk in proximal and distal segments of SFA.**



- Angiography showed that blood flow was patent.
- **5.5*300mm DCB** was applied in middle and distal segment, **5.5*80mm DCB** was applied in proximal segment of SFA , the dilation time was 3min.

DSA after surgery



Conclusions

- **Directional atherectomy is safe and effective**
- **Directional atherectomy can be widely used in:**
 - **Atherosclerotic plaque or calcified plaque**
 - **CFA or SFA or POA or infrapopliteal artery**
 - **Eccentric or circumferential or subintimal recanalization**
- **Selection of appropriate surgical indication is the crucial factor**
 - **Not applicable to carotid artery, renal artery, iliac artery**
 - **Not applicable to thrombosis**



Thank you!

Treating all Morphologies with Directional Atherectomy

Yaoguo Yang, Zhong Chen

Beijing Anzhen Hospital, Capital Medical University,
Beijing, China



BEIJING ANZHEN HOSPITAL
CAPITAL MEDICAL UNIVERSITY