Treating all Morphologies with Directional Atherectomy

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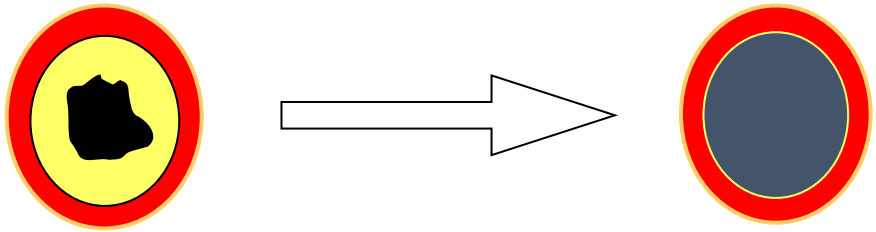
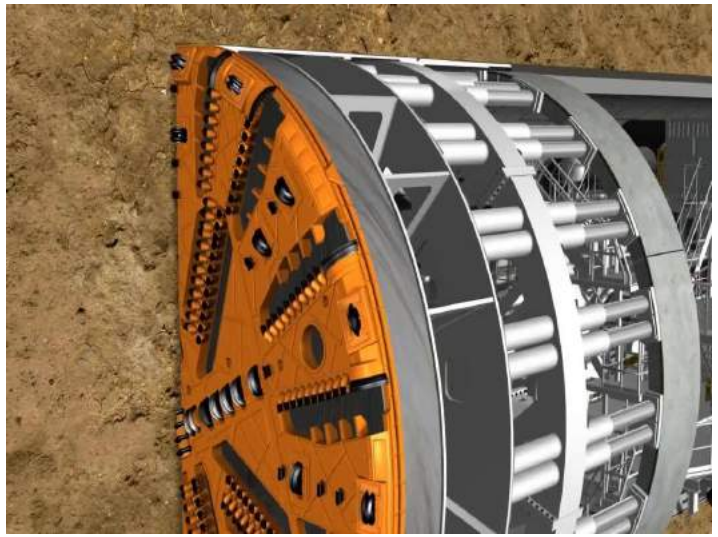
Directional Artherectomy

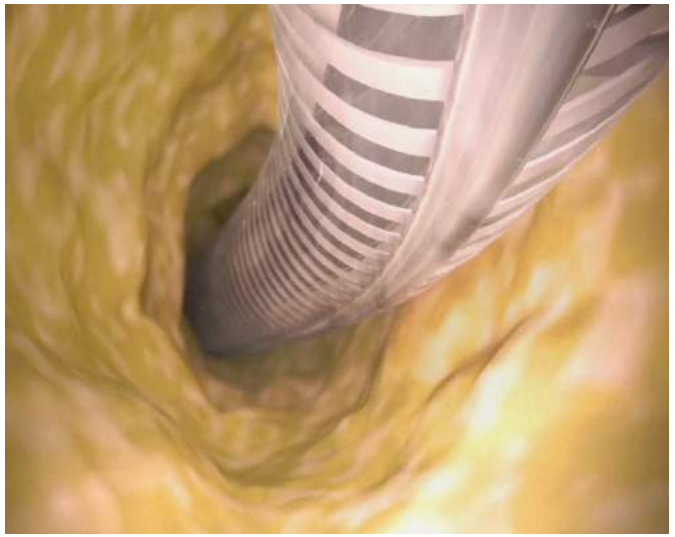
Remove plaques permanently by mechanical excision. Restore the a…en.

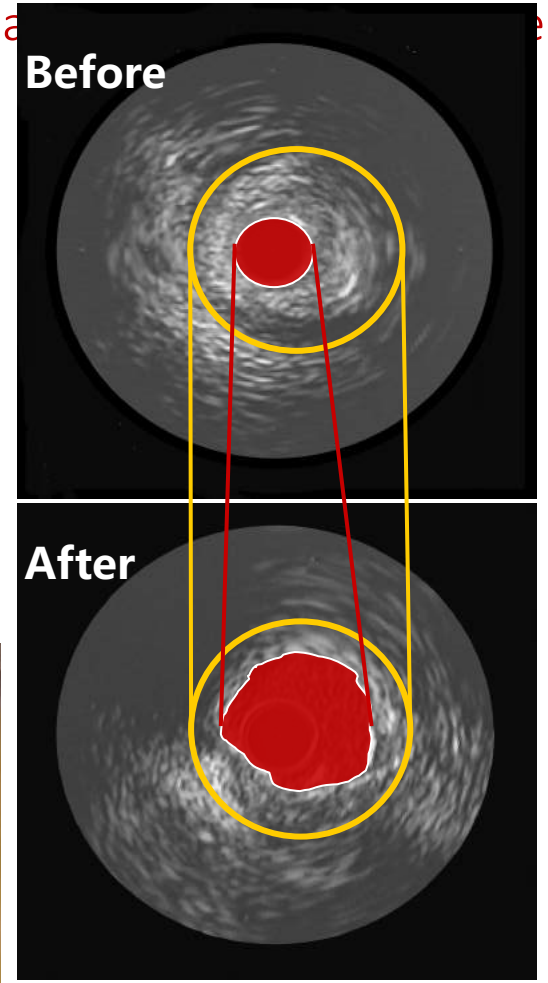
Remove plaques permanently

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

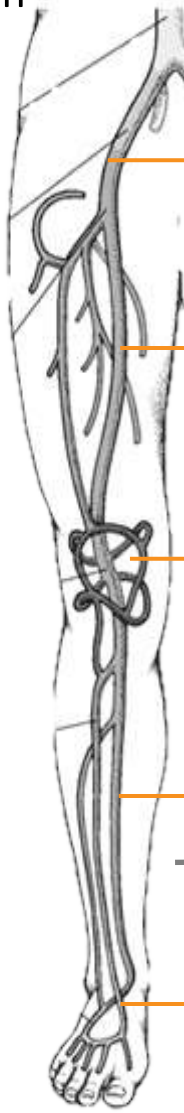








Directinal atherectomy is suitable for a variety of sites and plaques



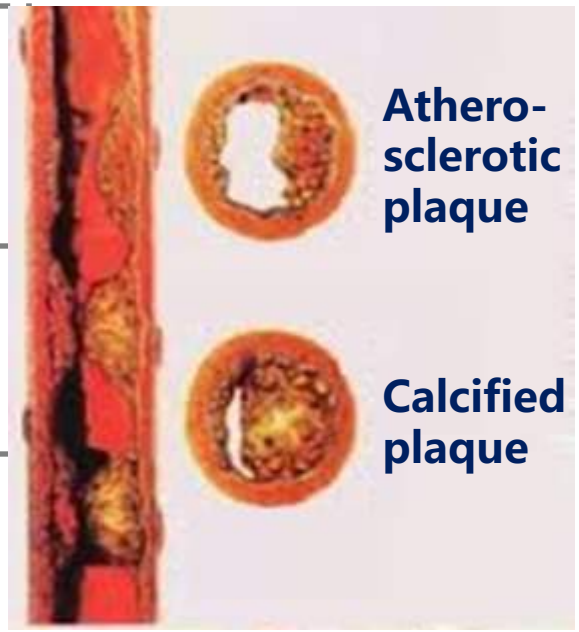
SFA ✓

Multiple segments of SFA ✓

POA ✓

Long or bifurcation lesions of infrapopliteal artery ✓

arteria dorsalis pedis ✓



Athero-sclerotic plaque ✓

Calcified plaque ✓

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)*

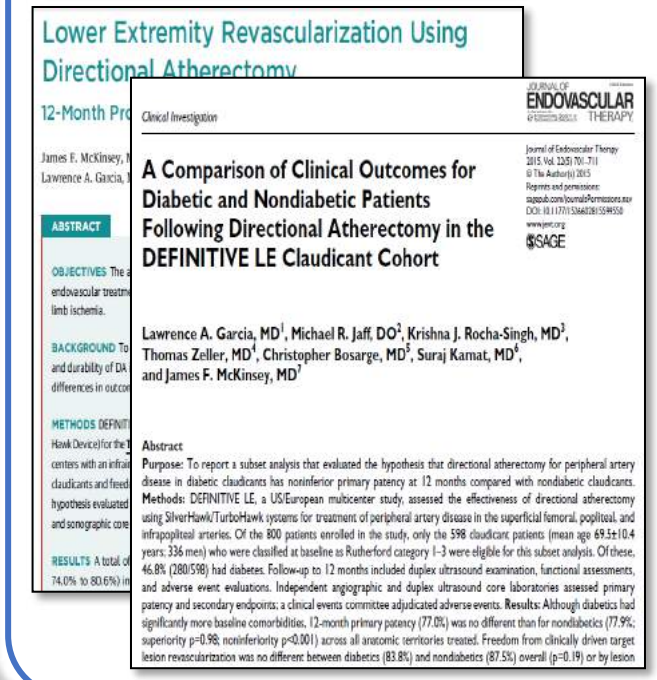
1. Hirsch AT, et al. Circulation. 2006 Mar 21;113(11):e463-654 .
2. Circulation. 2011 Nov 1;124(18):2020-45.
3. Anderson JL, et al. Circulation. 2013 Apr 2;127(13):1425-43.

DEFINITIVE clinical trials have demonstrated the clinical safety of Turbohawk.

DEFINITIVE RESULTS

Leave only the facts behind

DEFINITIVE™ LE



Lower Extremity Revascularization Using Directional Atherectomy

12-Month Pr

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

ABSTRACT

OBJECTIVES The a
endovascular treatme
limb ischemia.

BACKGROUND To
and durability of DA
differences in outcom

METHODS DEFINIT
Hawk Device) for the T
centers with an infrai
claudicants and freed
hypothesis evaluated
and sonographic core

RESULTS A total of
74.0% to 80.6%) in

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

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

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DOI: 10.1177/1526602815594550
www.jevt.org

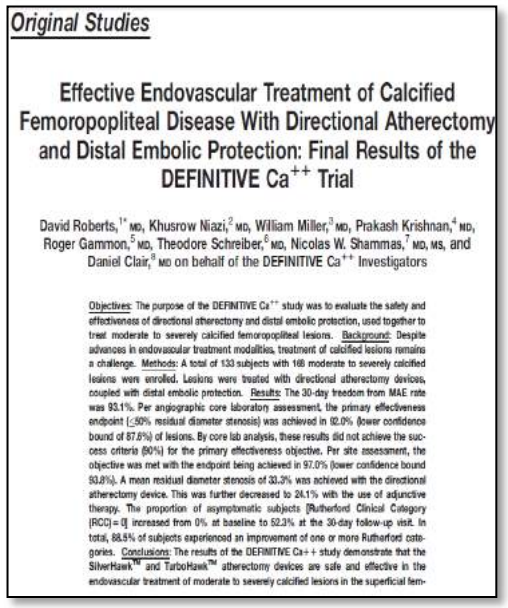
SAGE

Lawrence A. Garcia, MD[1], Michael R. Jaff, DO[2], Krishna J. Rocha-Singh, MD[3], Thomas Zeller, MD[4], Christopher Bosarge, MD[5], Suraj Kamat, MD[6], and James F. McKinsey, MD[7]

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 69.5±10.4 years; 336 men) who were classified at baseline as Rutherford category 1–3 were eligible for this subset 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

DEFINITIVE™ Ca++



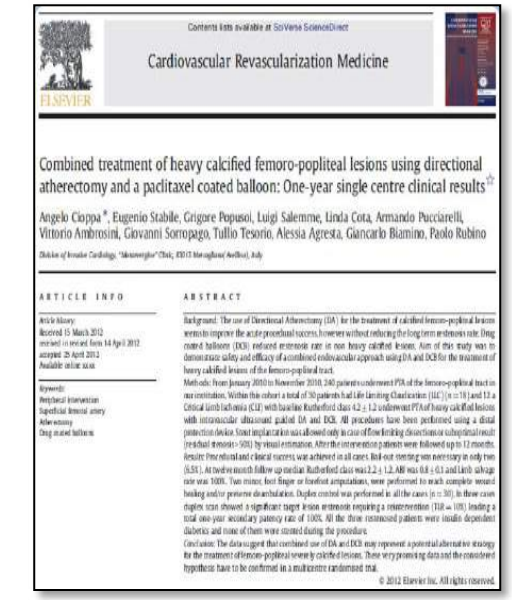
Original Studies

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 168 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 92.0% (lower confidence bound of 87.6%) of lesions. By core lab analysis, these results did not achieve the success criteria (90%) 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 fem-

DEFINITIVE™ AR



Contents lists available at SciVerse ScienceDirect

Cardiovascular Revascularization Medicine

ELSEVIER

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

Angelo Cioppa *, Eugenio Stabile, Grigore Popusoi, Luigi Salemme, Linda Cota, Armando Pucciarelli, Vittorio Ambrosini, Giovanni Sorropago, Tullio Tesorio, Alessia Agresta, Giancarlo Biamino, Paolo Rubino

ARTICLE INFO

ABSTRACT

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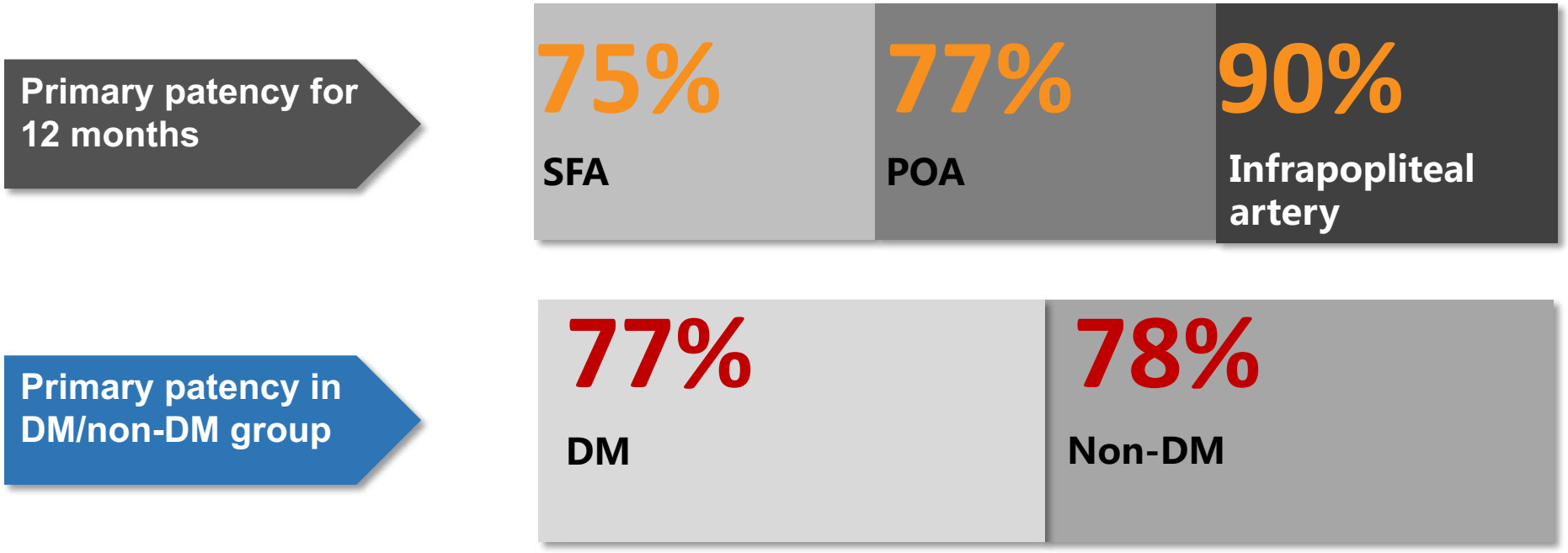
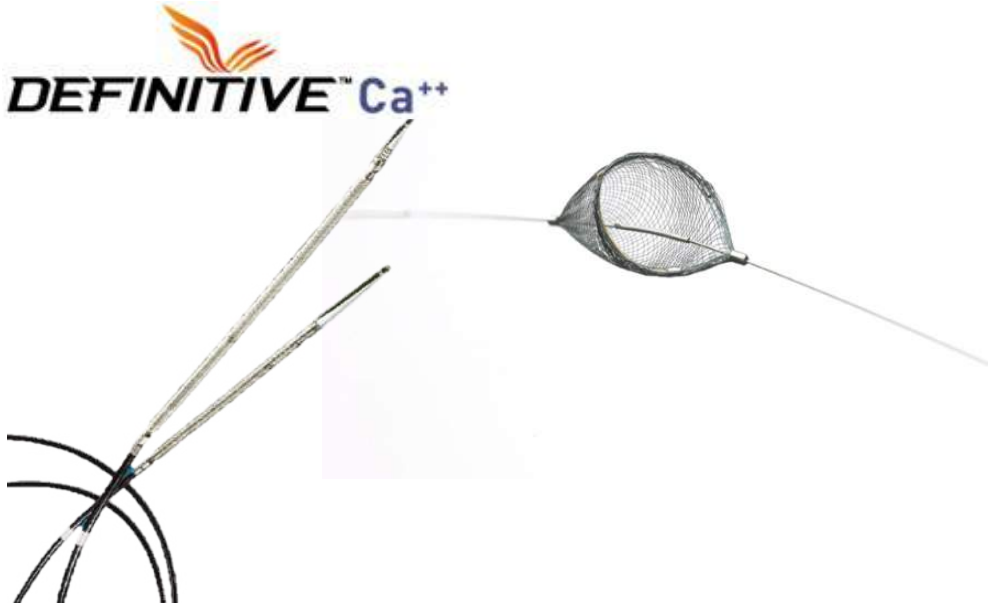
DEFINITIVE LE trial：Primary patency for 12 months in directional atherectomy of SFA, POA and Infrapopliteal artery reached >75%

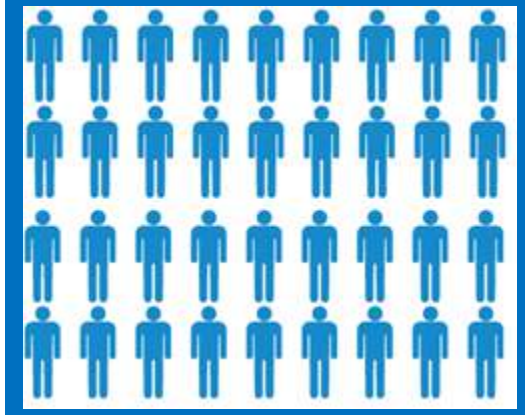
DEFINITIVE™ LE



1. McKinsey J, et al. JACC Cardiovasc Interv 2014; 7(8):923-33

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

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

0.8% Incidence of flow -limiting dissection

2.3% Incidence of perforation

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

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

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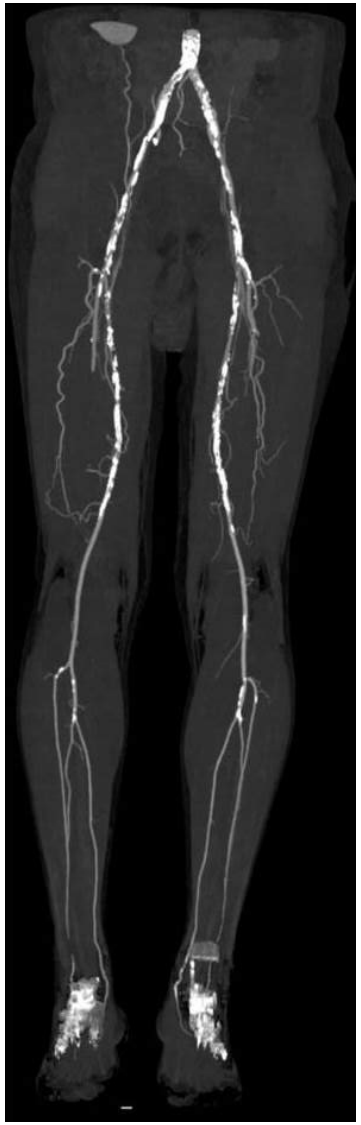
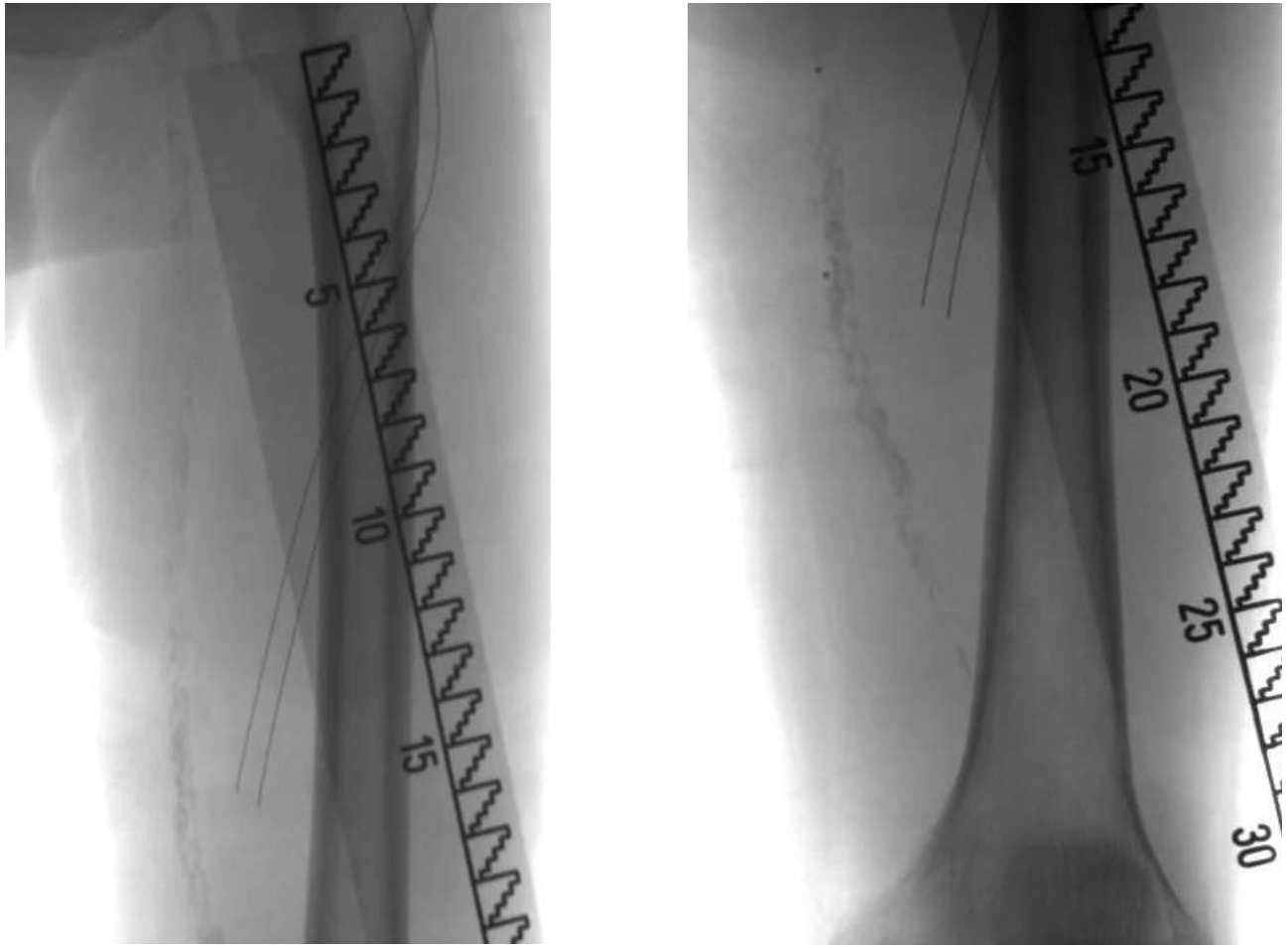
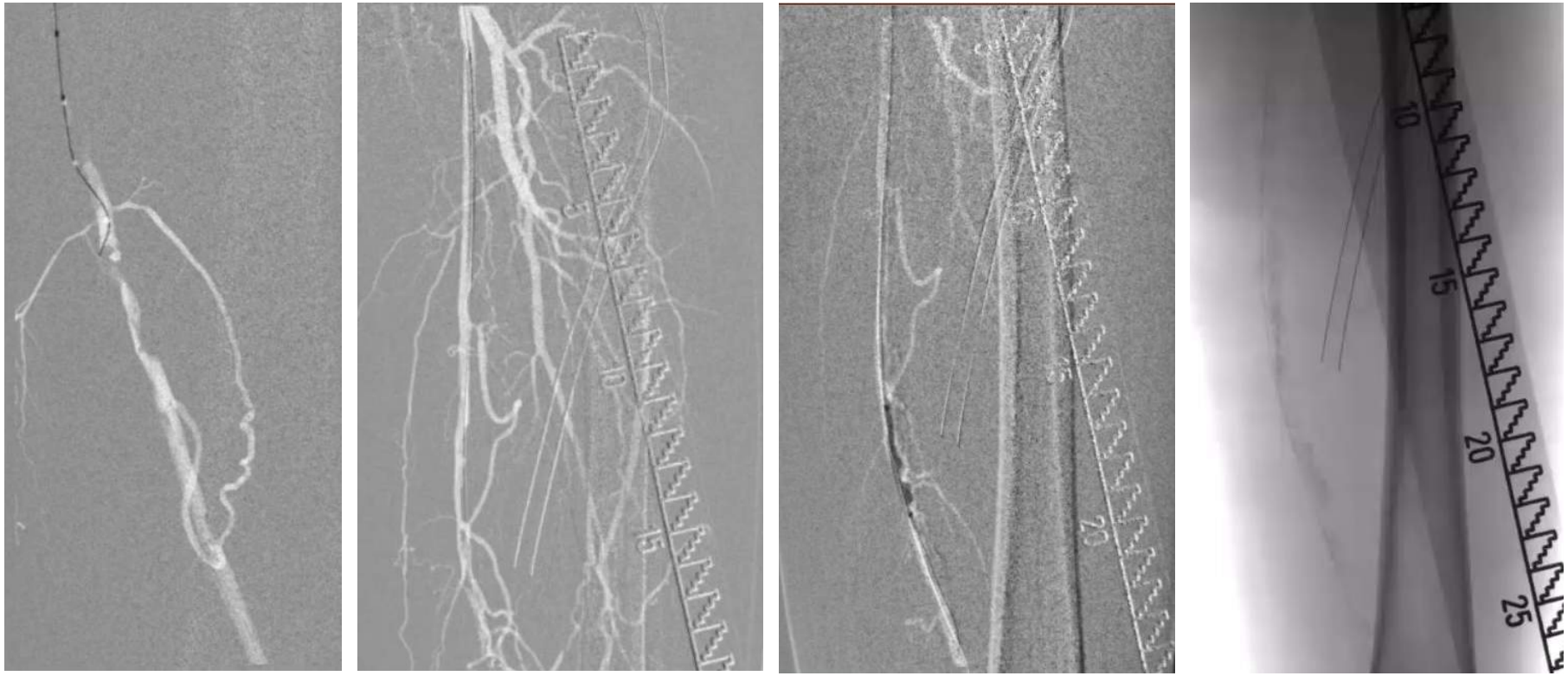
- **Ultrasound :**
  - **multiple strong echo plaques in the left superficial femoral artery**
  - **occlusion in the middle segment**
  - **multiple stenosis in the proximal and distal segments**

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

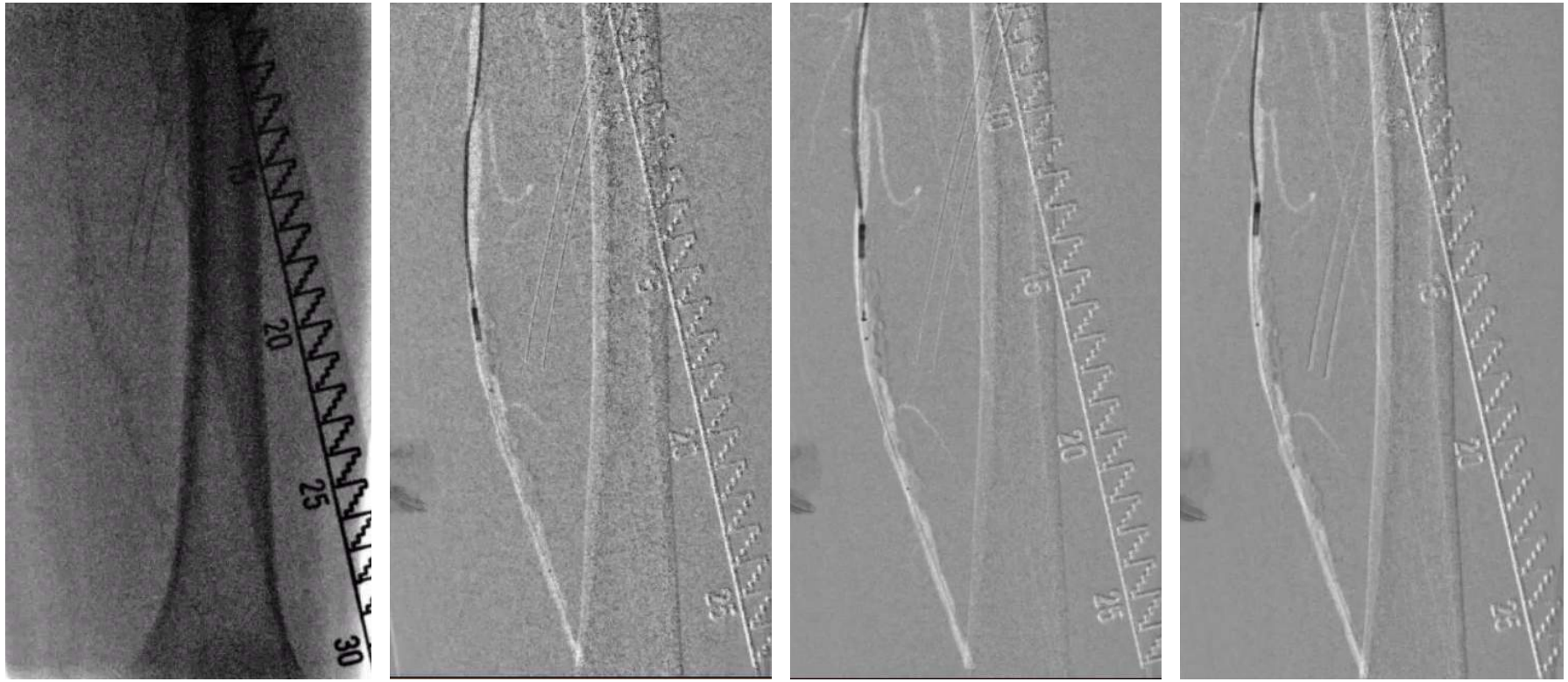


DSA before surgery

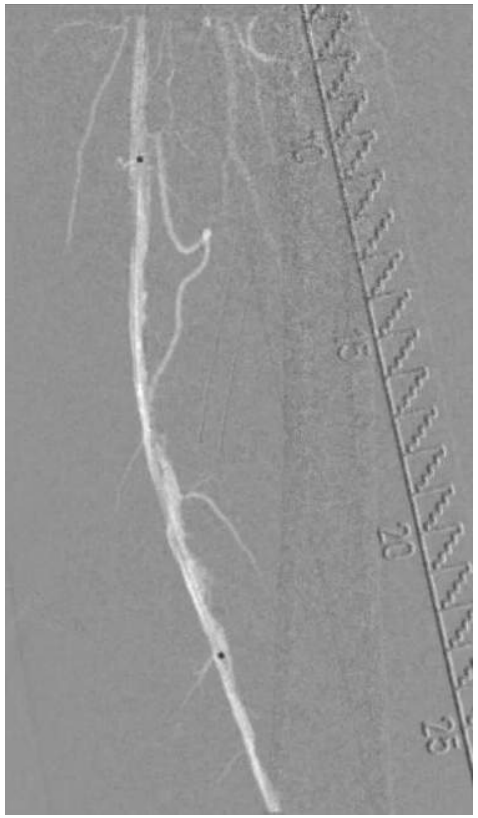


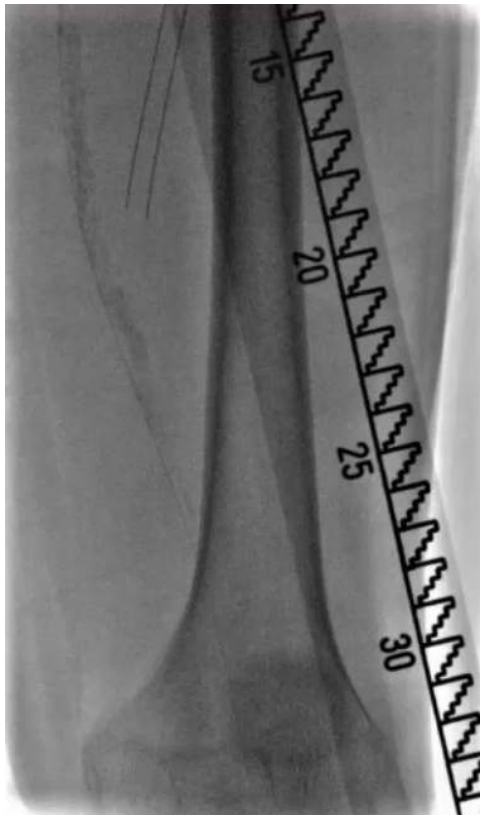


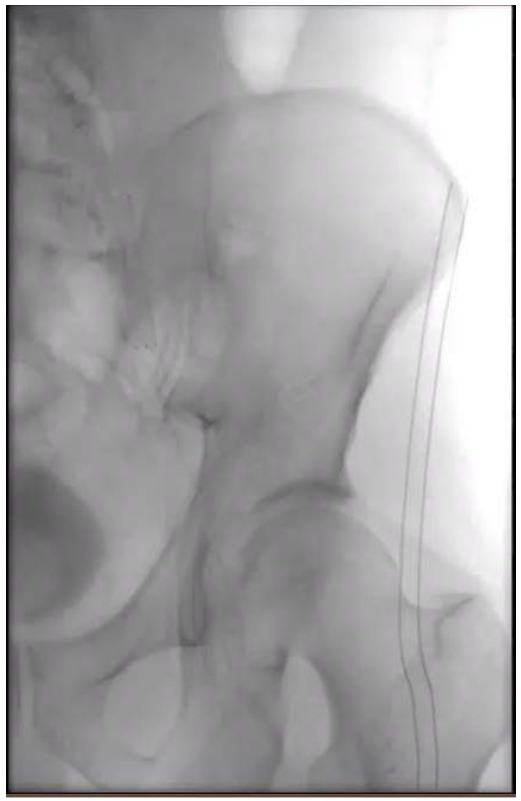
The guide wire coordinated with trailblazer support catheter reopened the occlusion, pre dilated the leision.



- **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 leision. Then 5*150mm DCB was applied to dilate the lesion, the dilation time was 3min.**
- **The filter was retrieved, angiography showed SFA patency.**

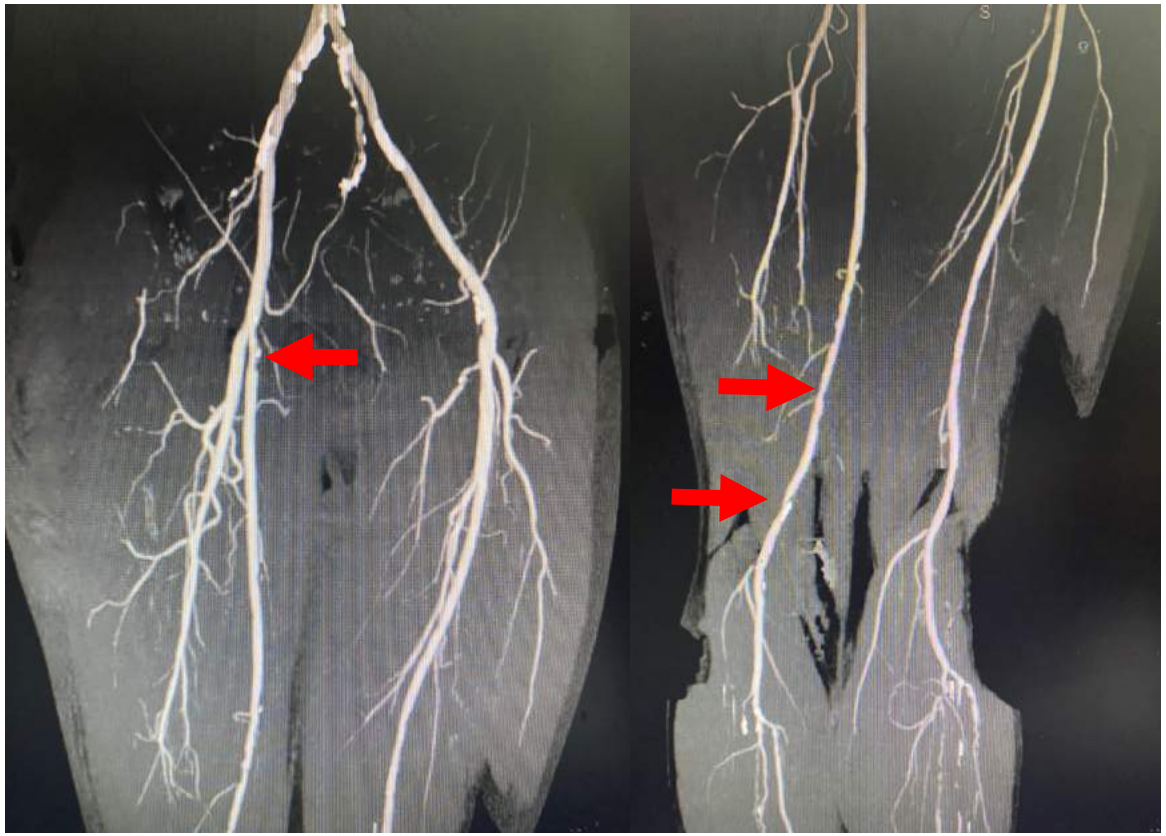
CASE 2

- 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.

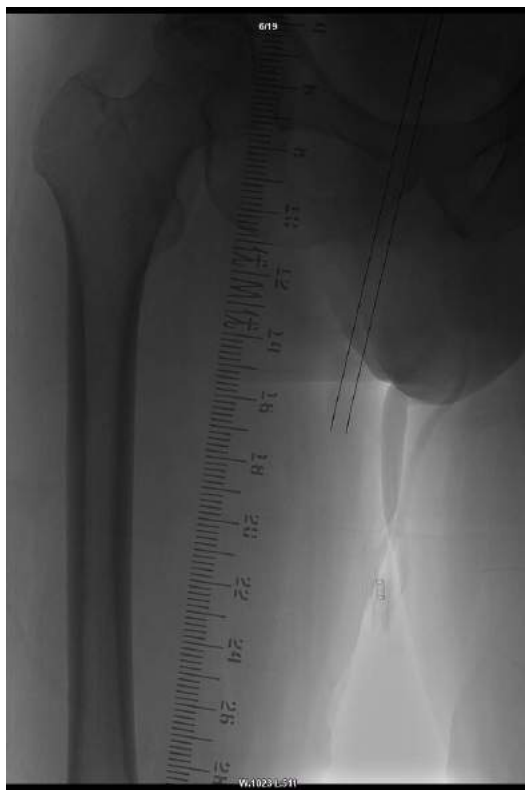
  Smoke history, 20 cigarettes*40 years

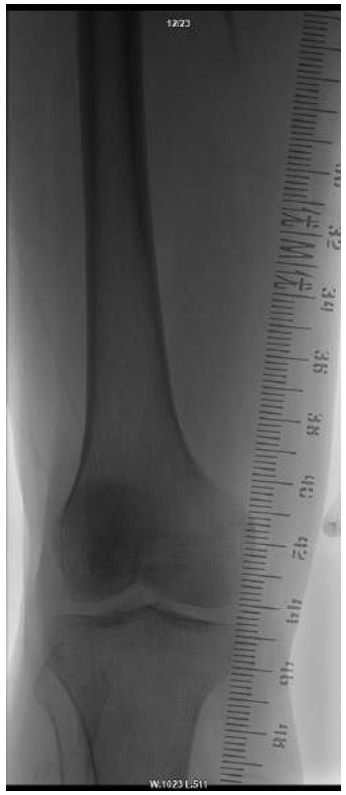
- **Ultrasound :**
  - **Stenosis in RCFA (50%).**
  - **Stenosis in the middle and distal segment of RSFA (70%), strong echo plaques.**
  - **Anterior tibial artery and the peroneal artery was occluded.**
  - **Stenosis in LSFA (40%).**

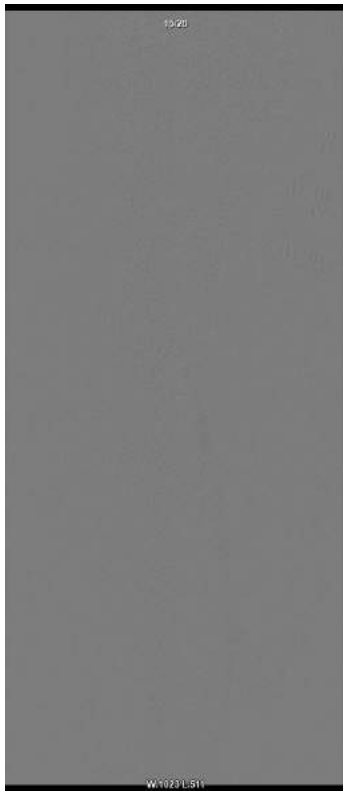
	Internal Diameter (cm)	PSV (cm/s)
LSFA	0.33/0.49	87.5
RCFA	0.37/0.67	50.6
RSFA	0.12/0.48	221.0



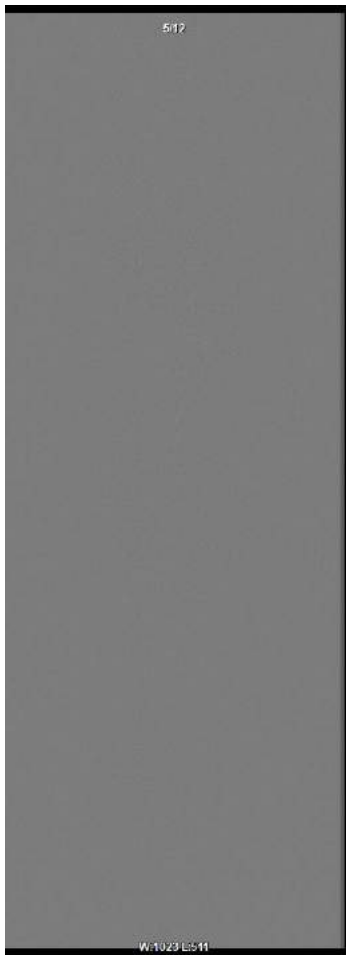
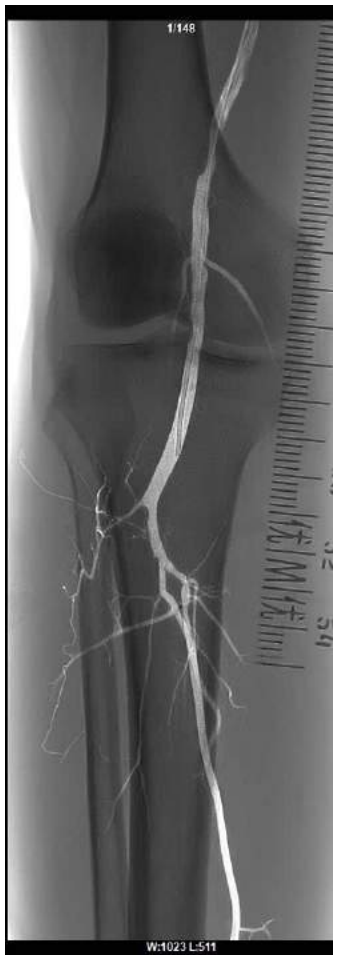
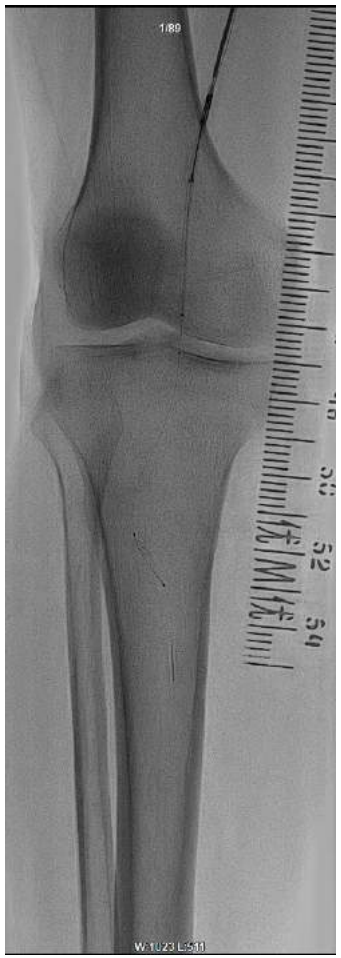
DSA before surgery



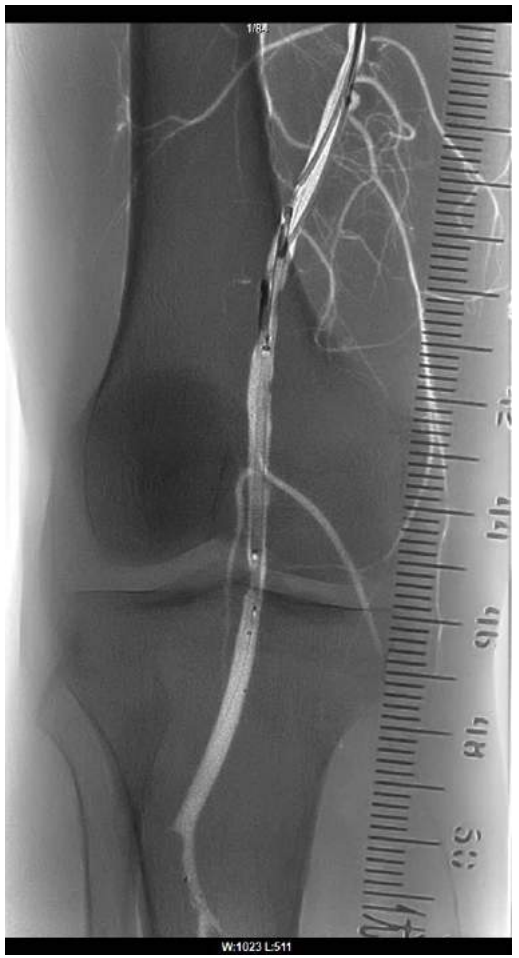
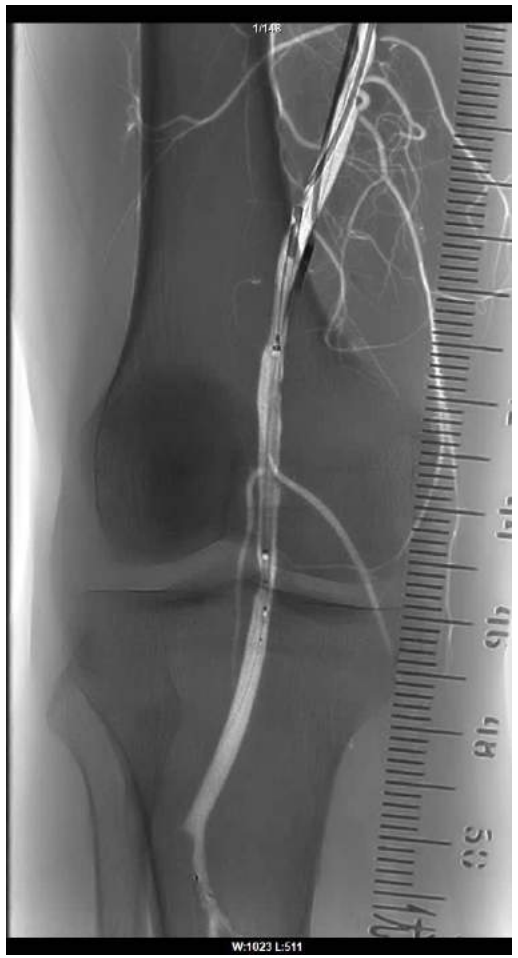




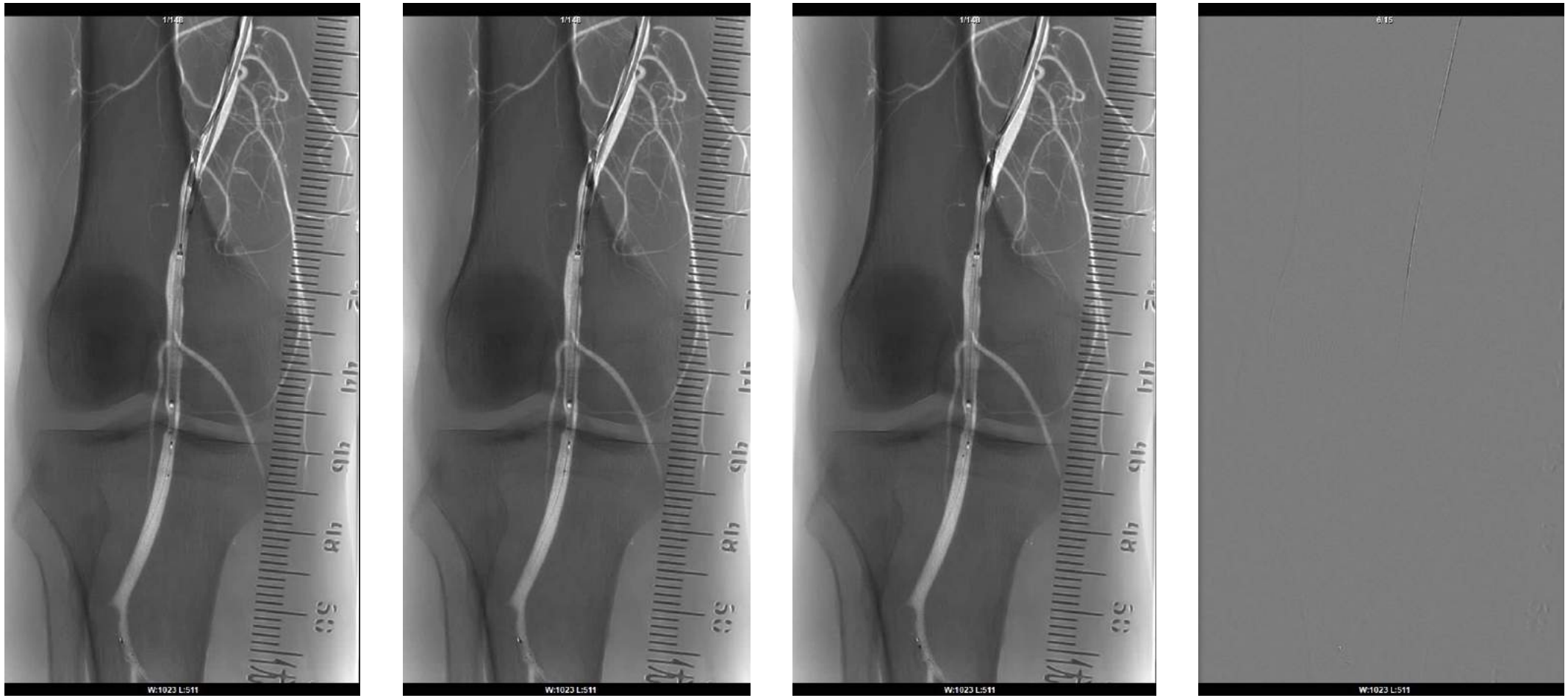
Severe stenosis in the proximal and distal segment of RSFA, Anterior tibial artery and the peroneal artery was occluded.

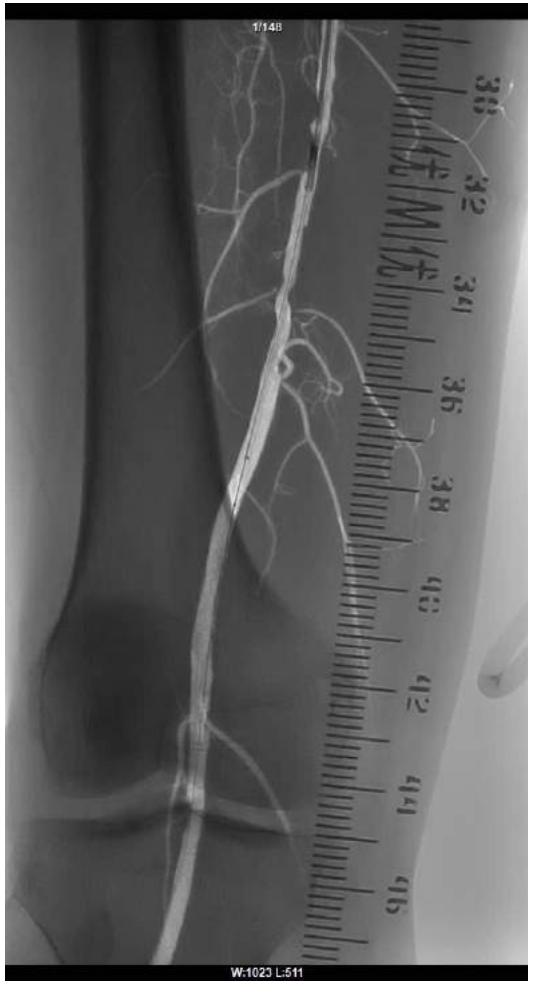
Guide wire passed leision, Filter was placed in Tibiofibular trunk.

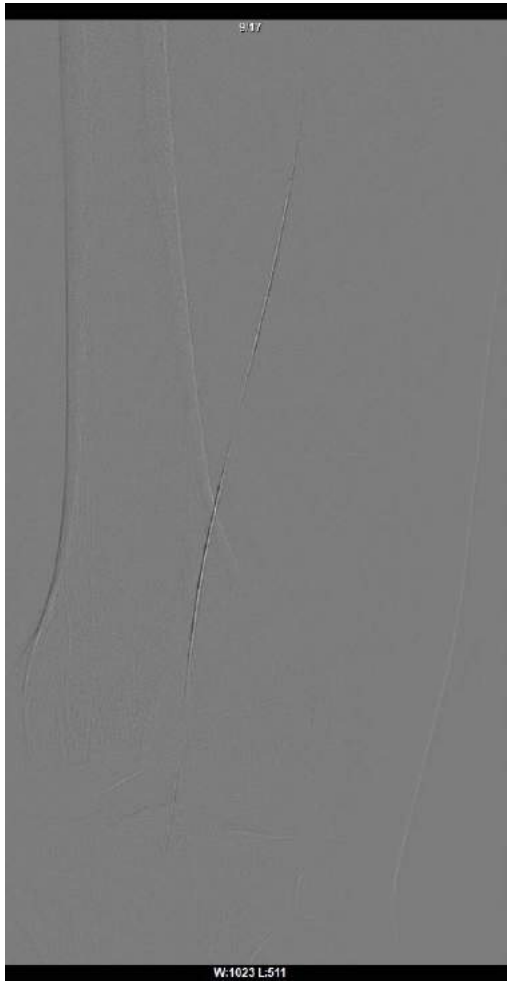



Directional atherectomy using Turbohawk in POA.

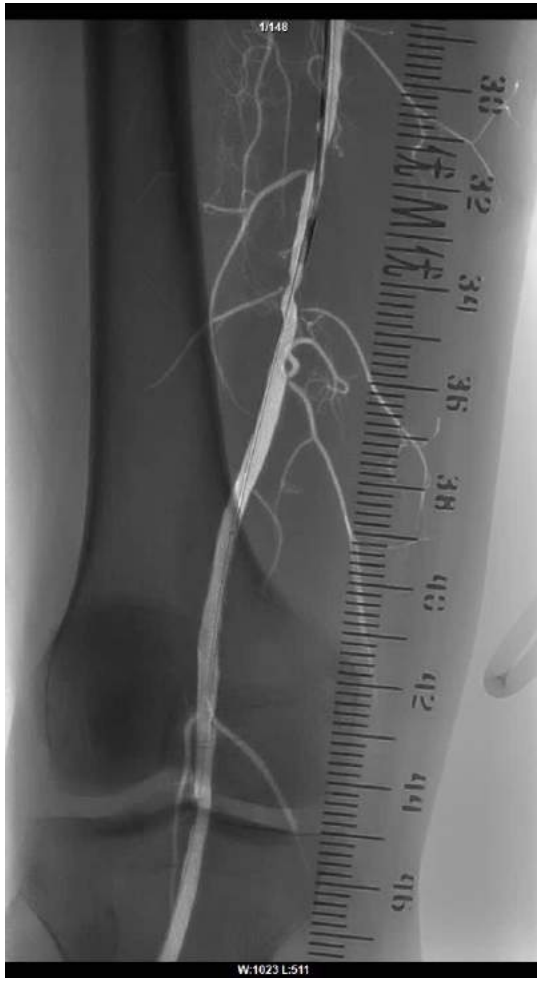


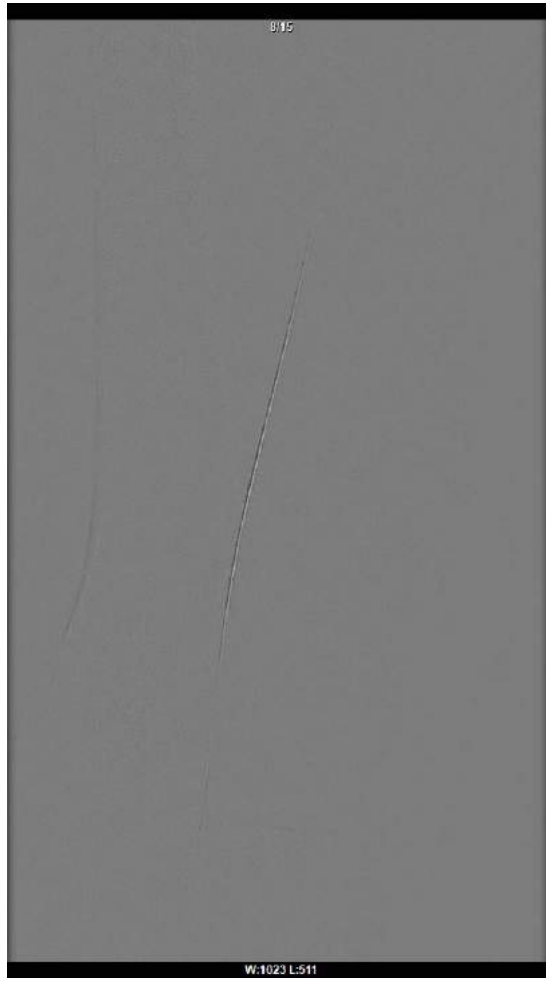
After directional atherectomy, angiography showed that blood flow was patent.



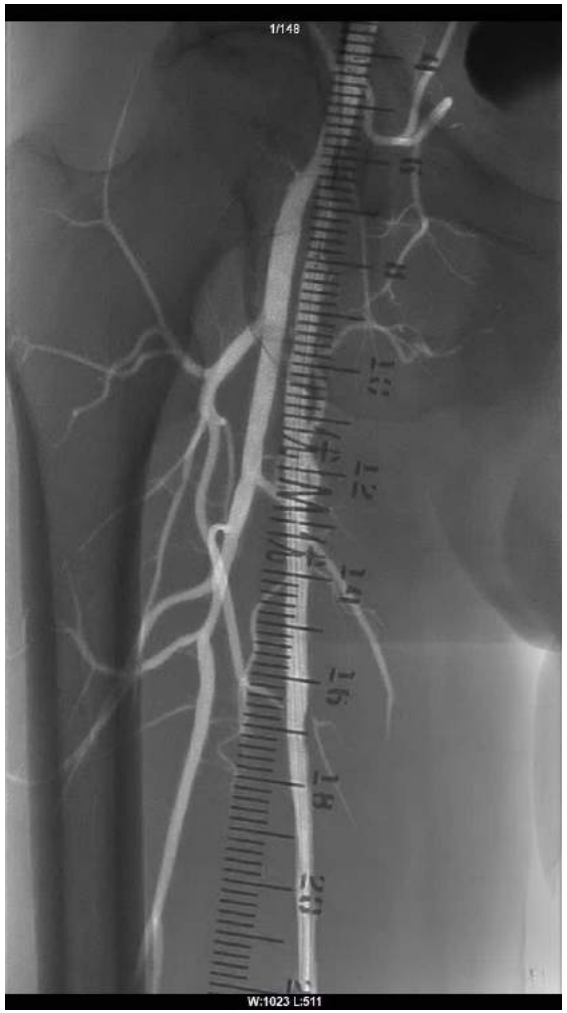


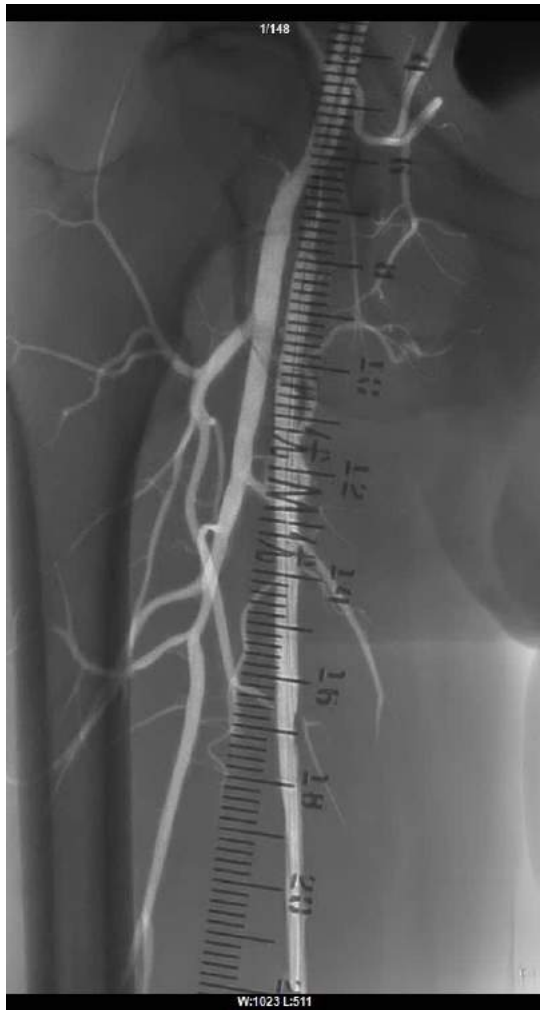
Directional atherectomy using Turbohawk in distal SFA.





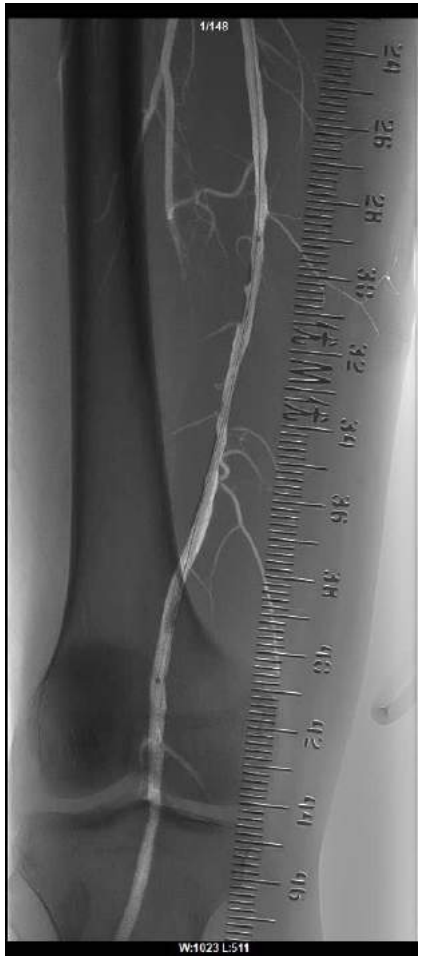
Angiography showed that blood flow was patent.

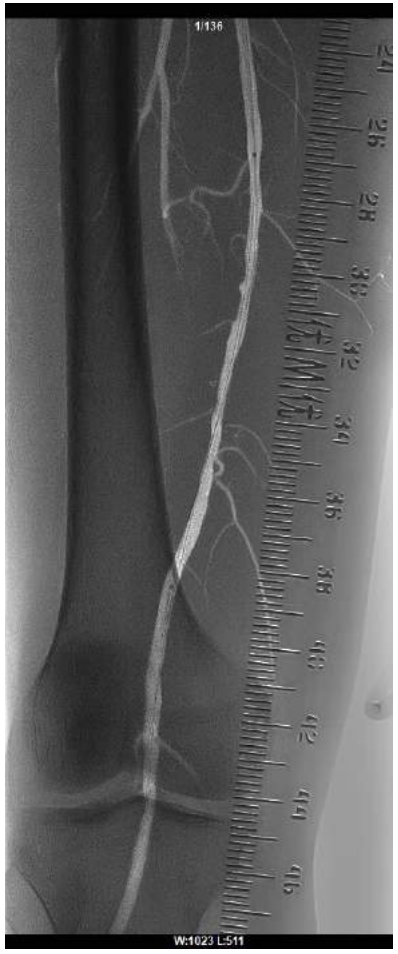




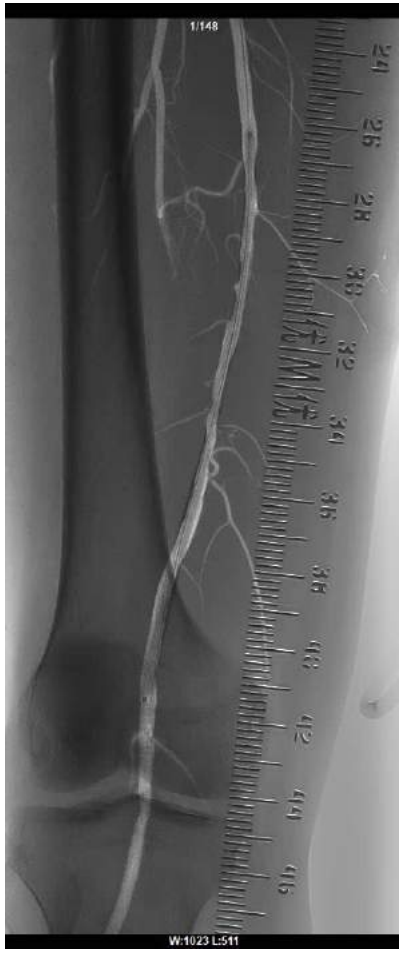
Directional atherectomy using Turbohawk in proximal SFA.

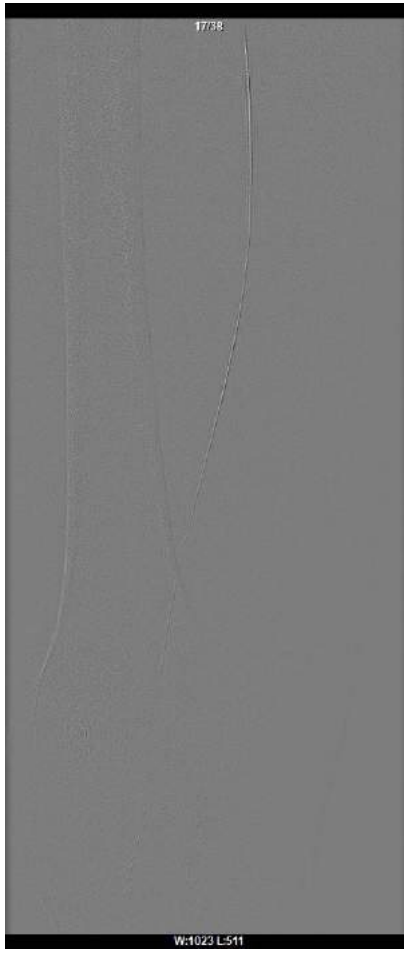
Angiography showed that blood flow was patent.



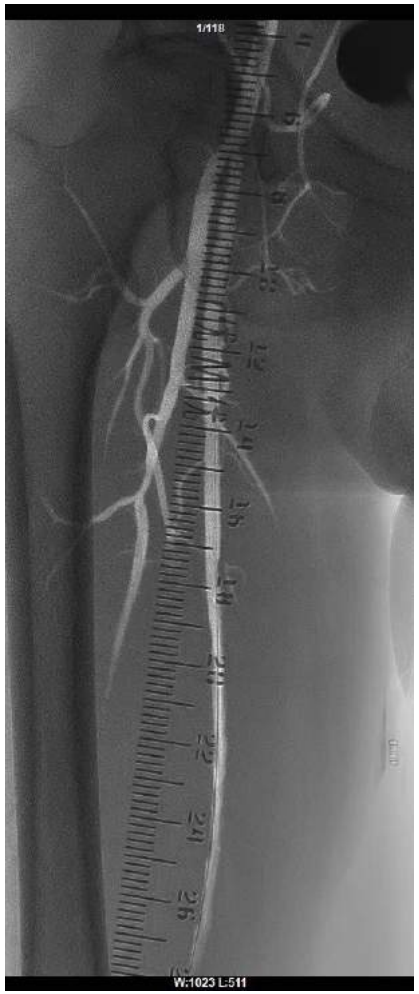


Pre dilate diatal SFA and POA with 4*150mm balloon.

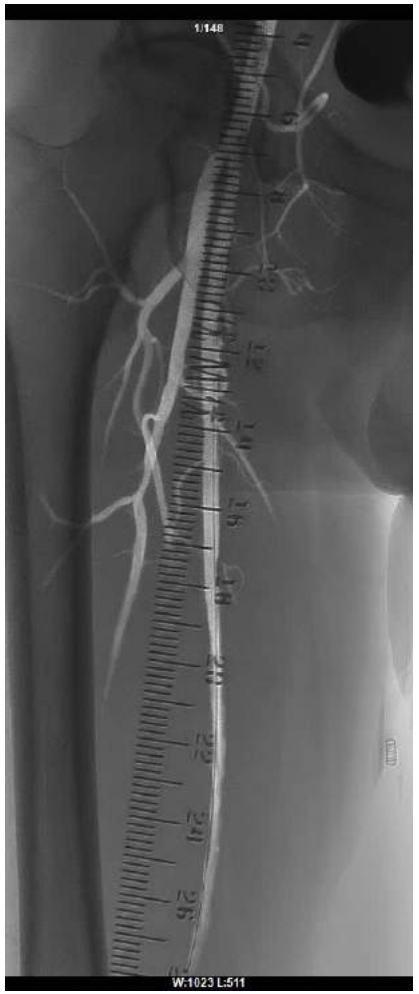




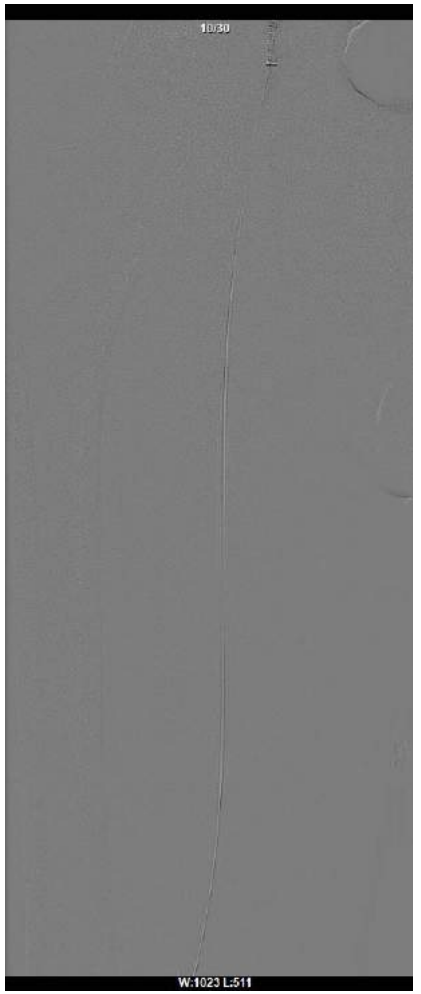
5*200mm DCB was applied, the dilation time was 3min.

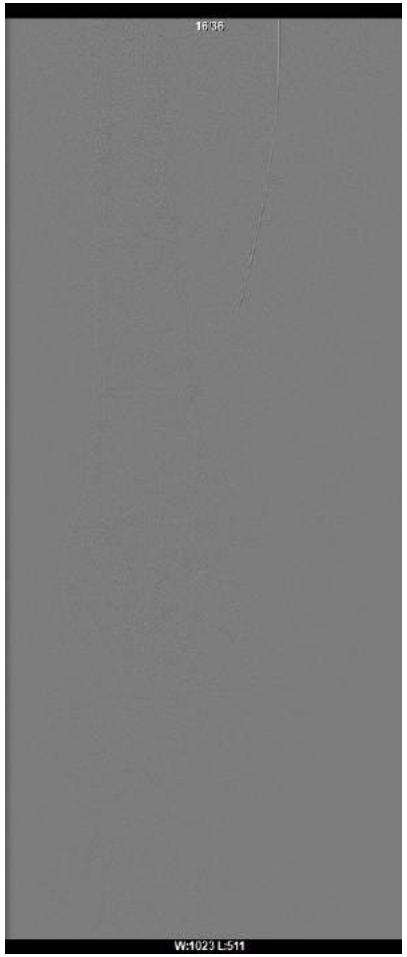


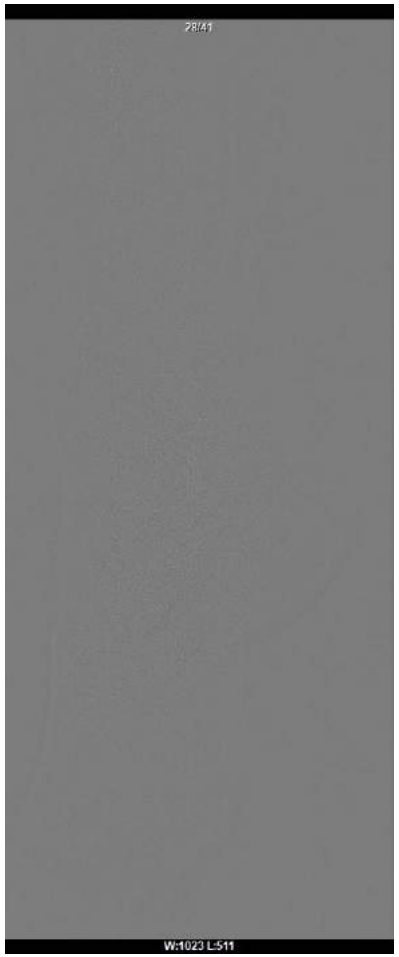
Pre dilate proximal SFA with 5*40mm balloon.

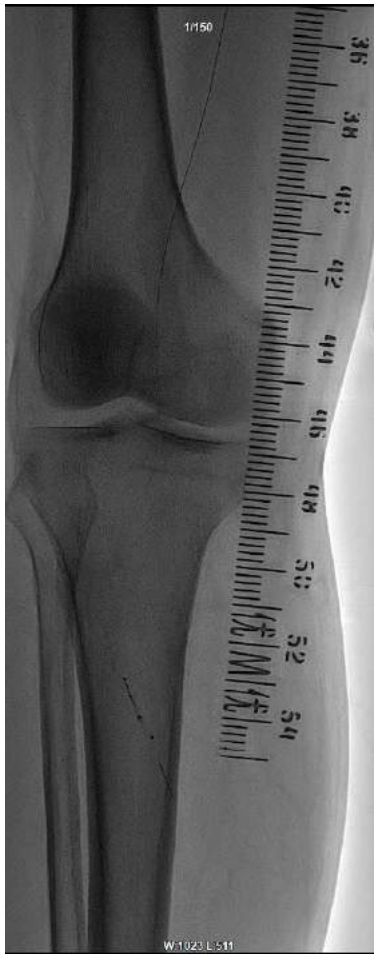


5*40mm DCB was applied, the dilation time was 3min.









- **DSA after surgery**
- **Retrieve filter.**

- **Some of the plaques**

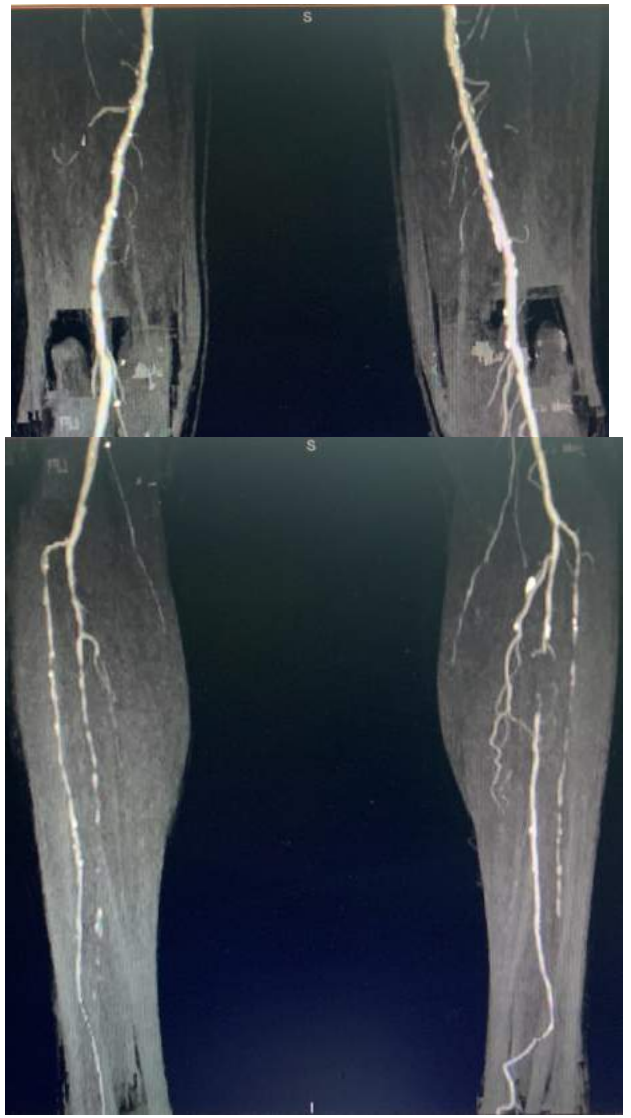
CASE 3

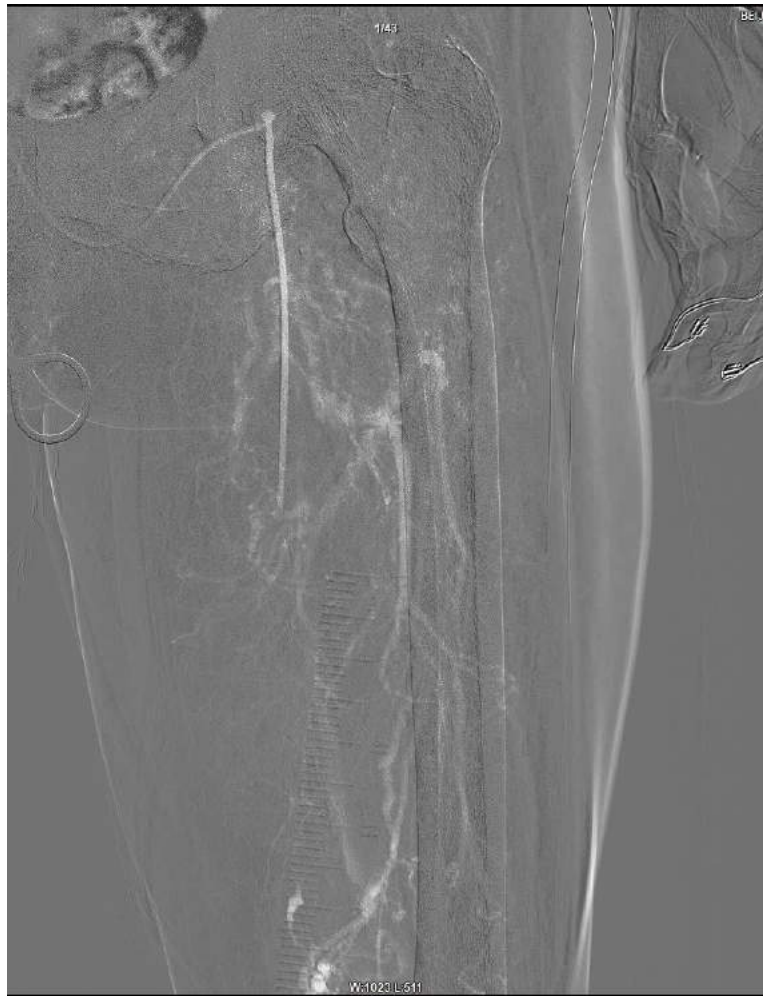
- Female，early 80s
- Medical history：Intermittent claudication of left lower limb for 1 year. Treated by directional atherectomy and DCB for occlusion of POA 1 year ago, maximal walking distance improved from 20m to 300m, no resting pain.
- Risk factors：Hypertension, DM.

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

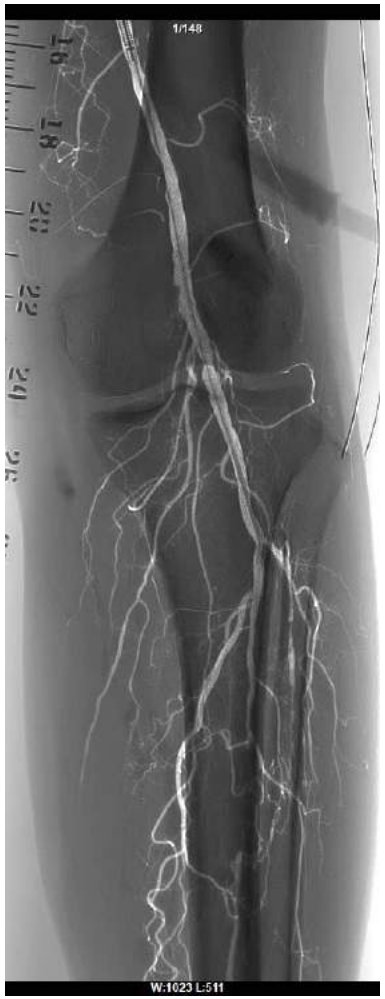
- **Ultrasound :**
  - **Severe stenosis in LPEA, occlusion in the middle segment of LPEA.**
  - **Occlusion in LATA, LPTA.**
  - **Strong echo plaques.**

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

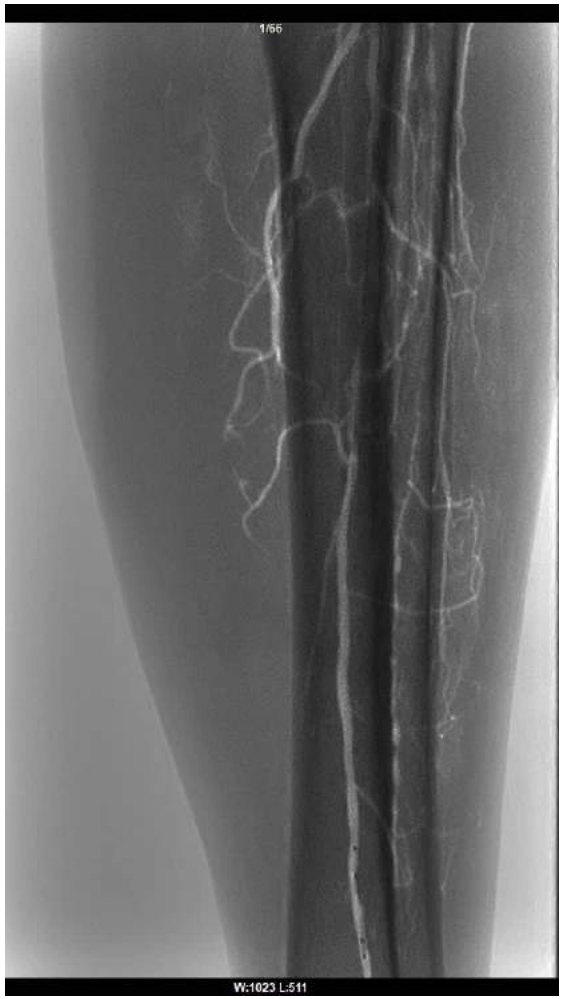




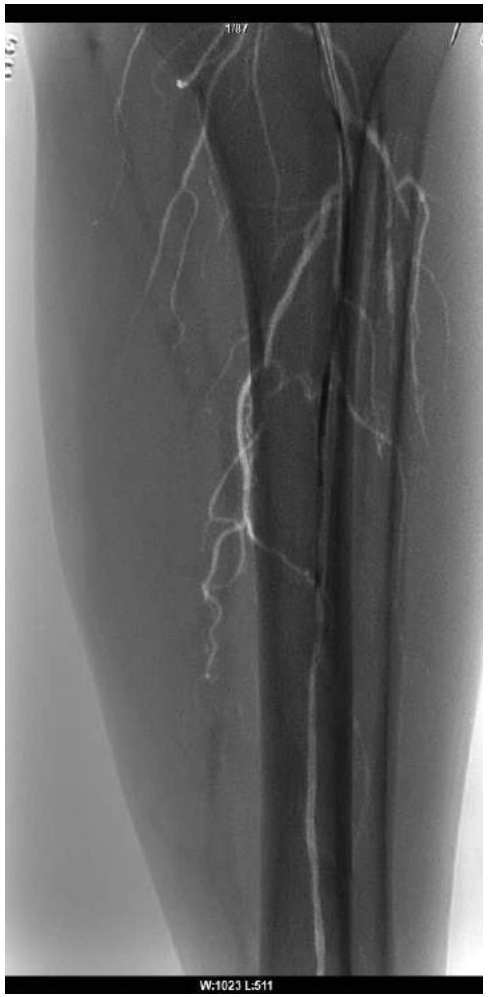
DSA before surgery.



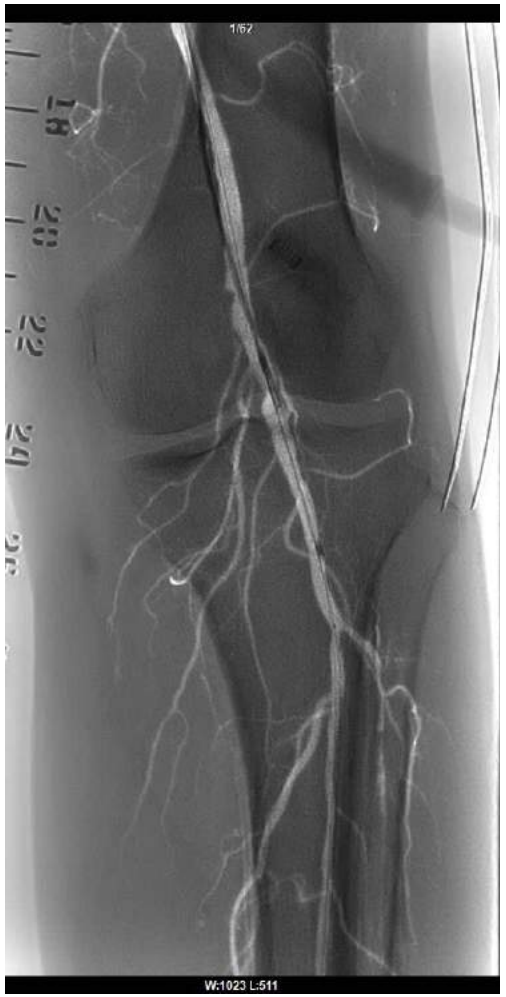
Reopened PEA successfully.



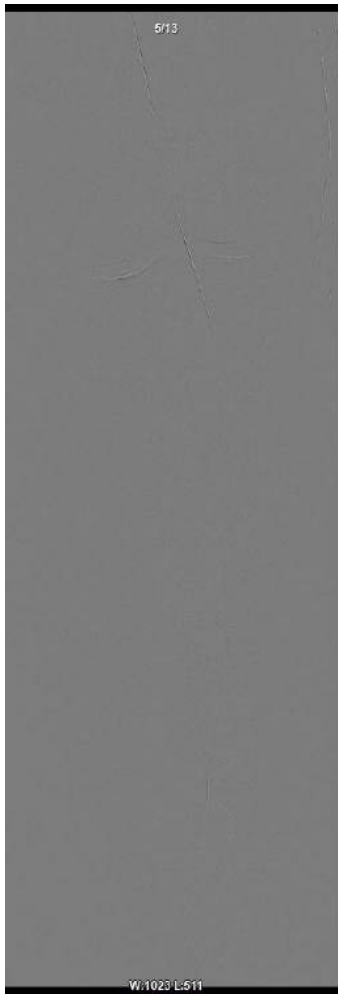
Pre dilate with 2*120mm balloon, filter was placed in distal PEA.

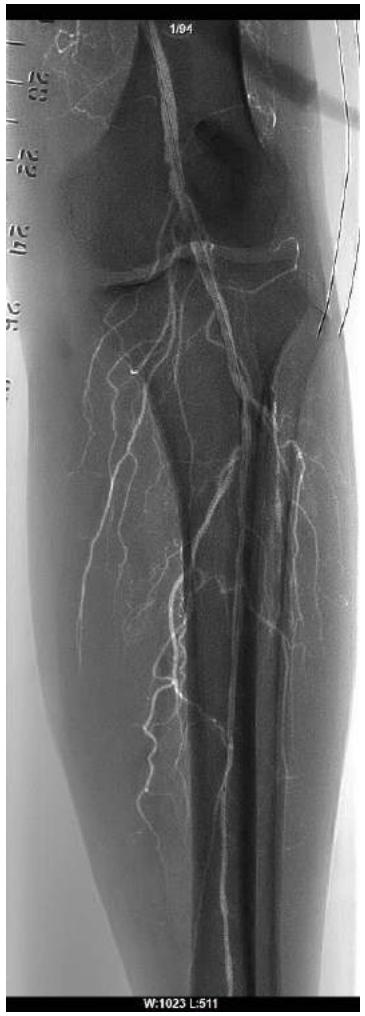


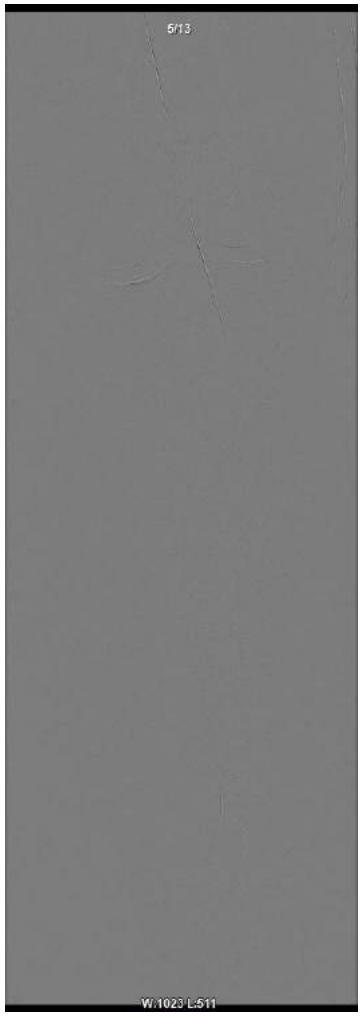
Directional atherectomy using Turbohawk in **PEA**



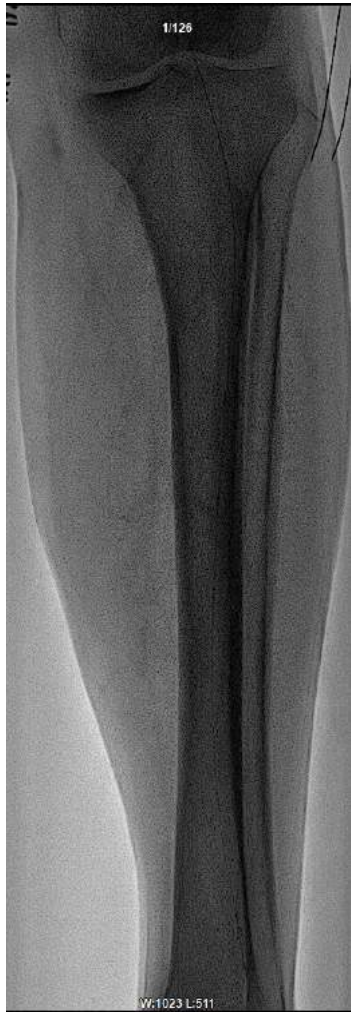
Directional atherectomy using Turbohawk in **distal POA**

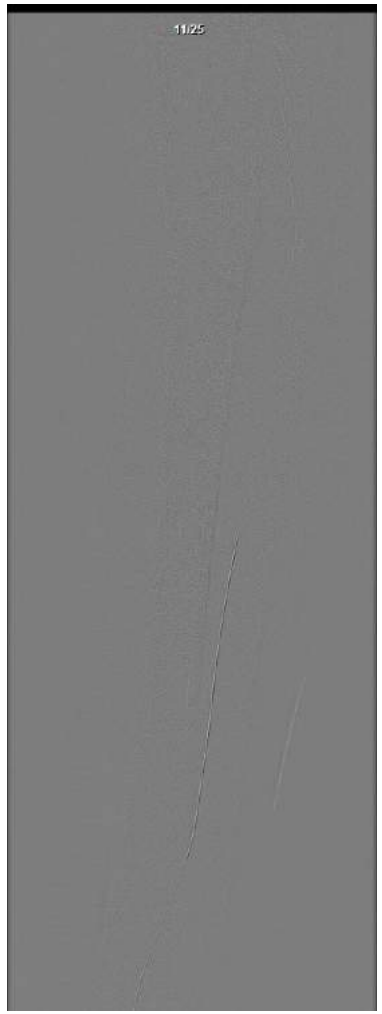




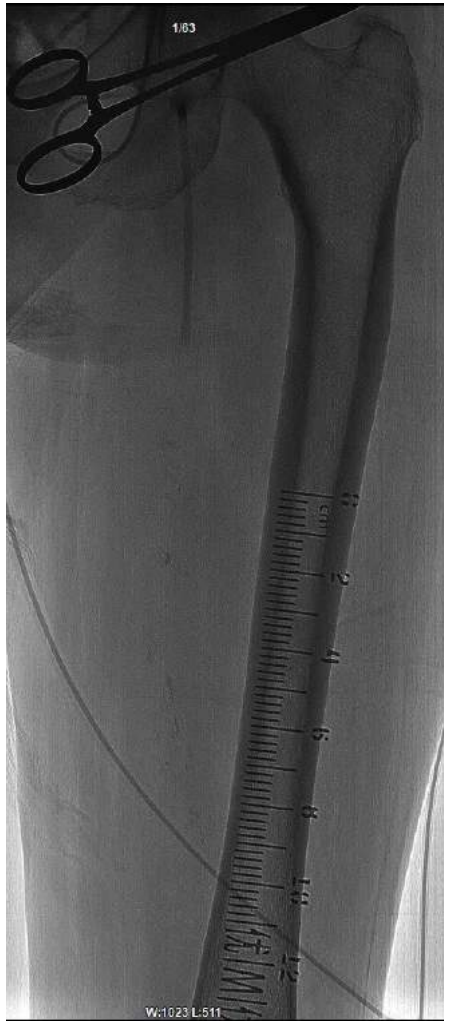


3*200mm DCB
3min.





Retrieve filter.



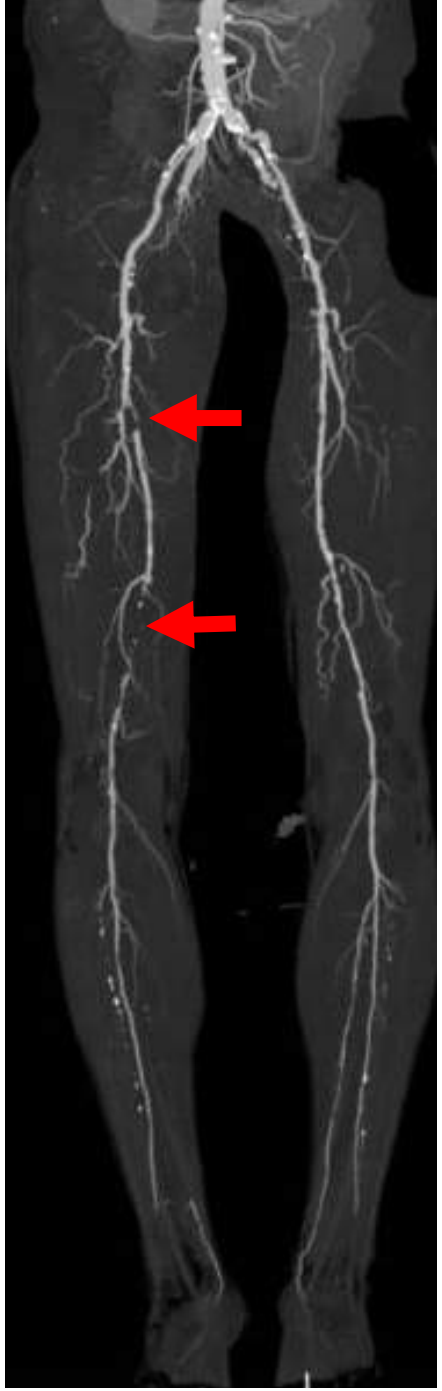
CASE 4

- 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.

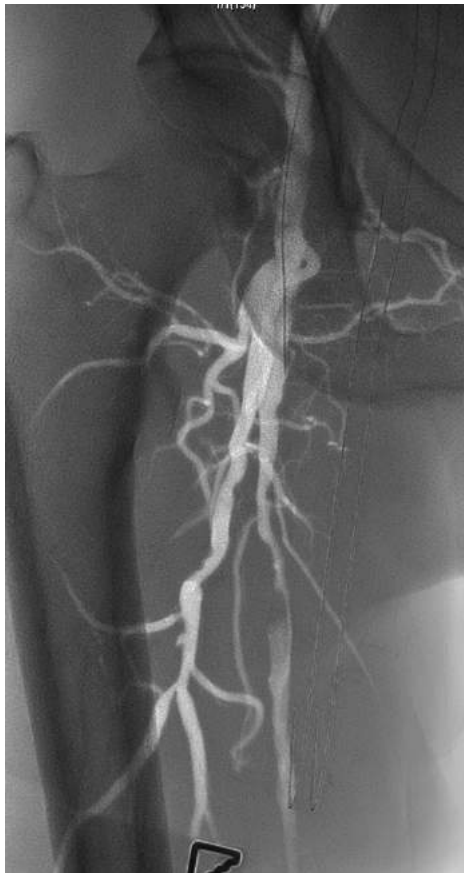
  Smoke history, 10 cigarettes*40 years.

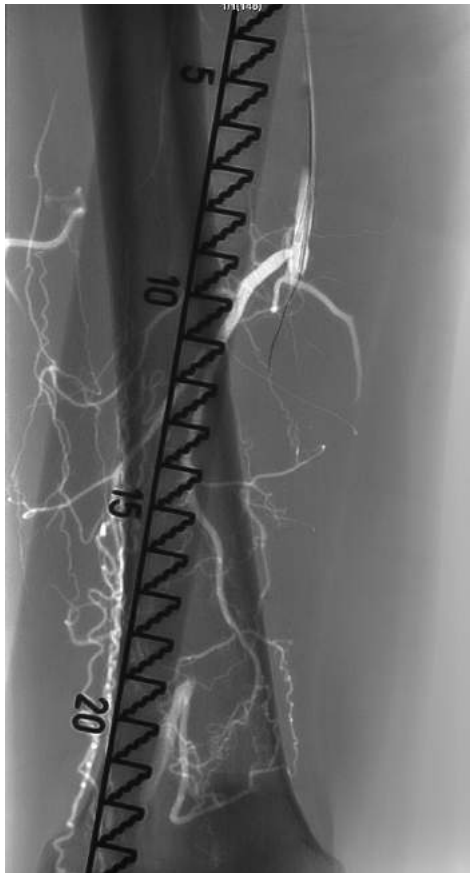
- **Ultrasound :**
  - **Severe stenosis in LSFA, occlusion in the middle segment. Multiple strong echo plaques.**
  - **Occlusion in LATA, LPTA.**

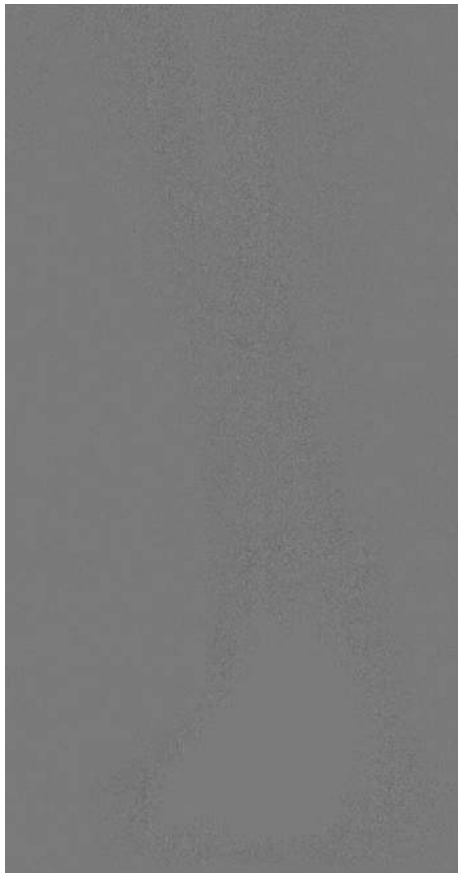
	Internal Diameter (cm)	PSV (cm/s)
RCFA	0.47/0.98	151
RSFA	0.15/0.56	0/41.5
RPOA	0.28/0.51	74.6

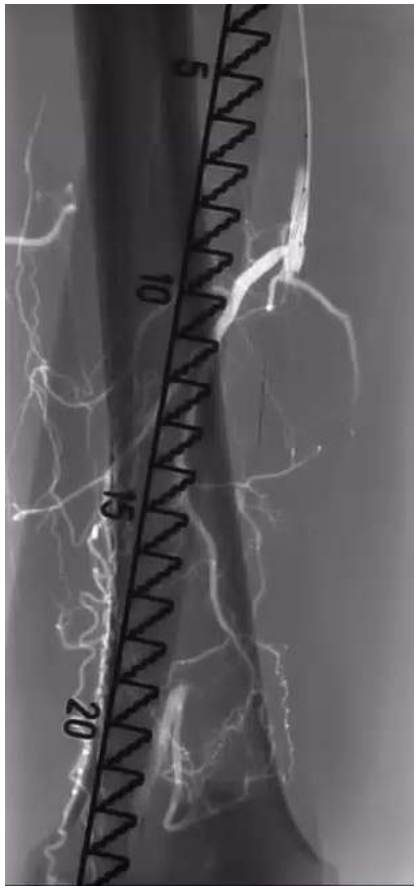


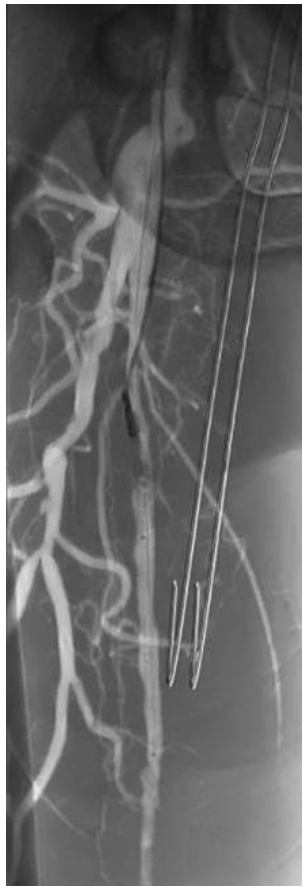
DSA before surgery



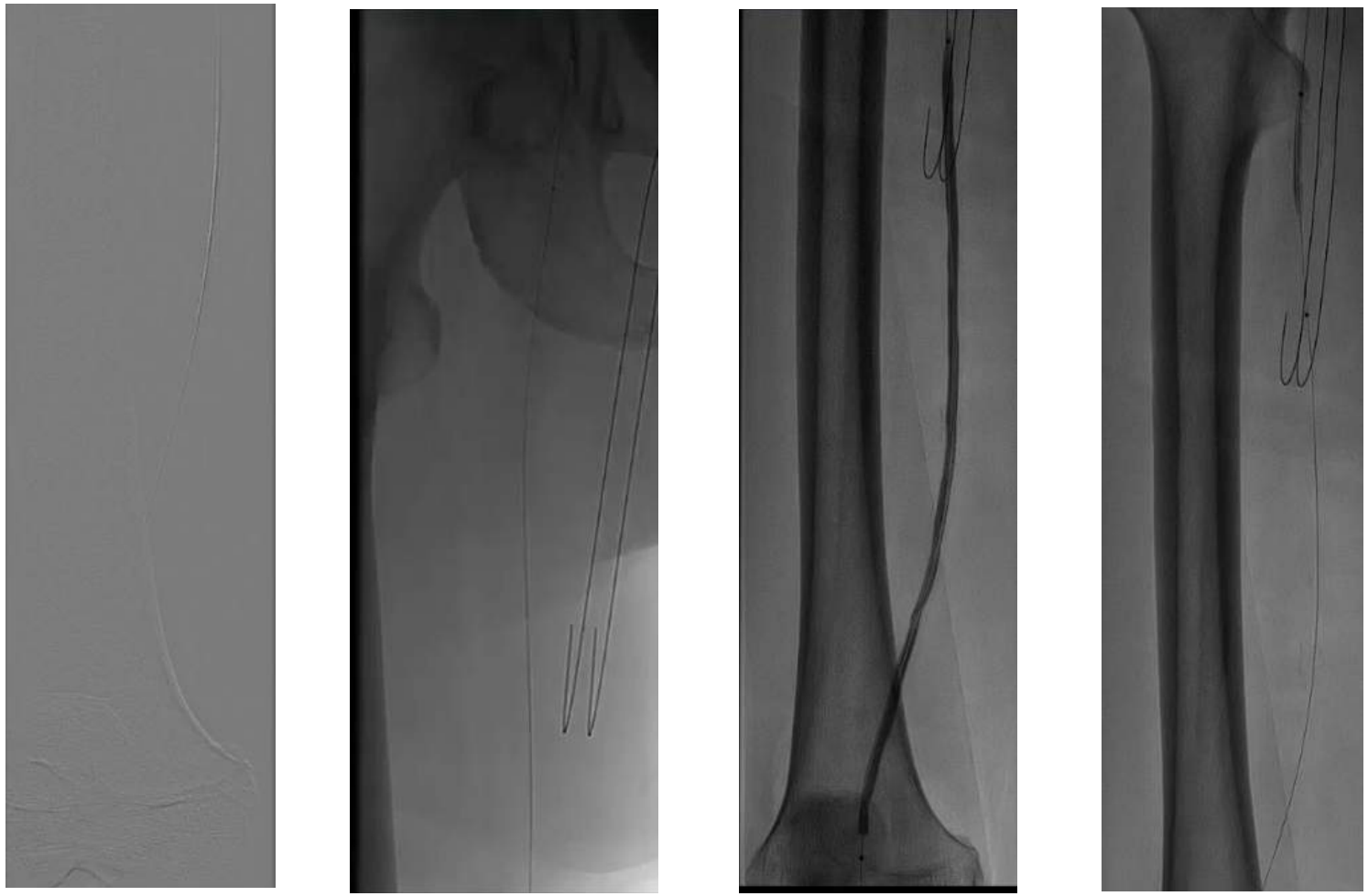






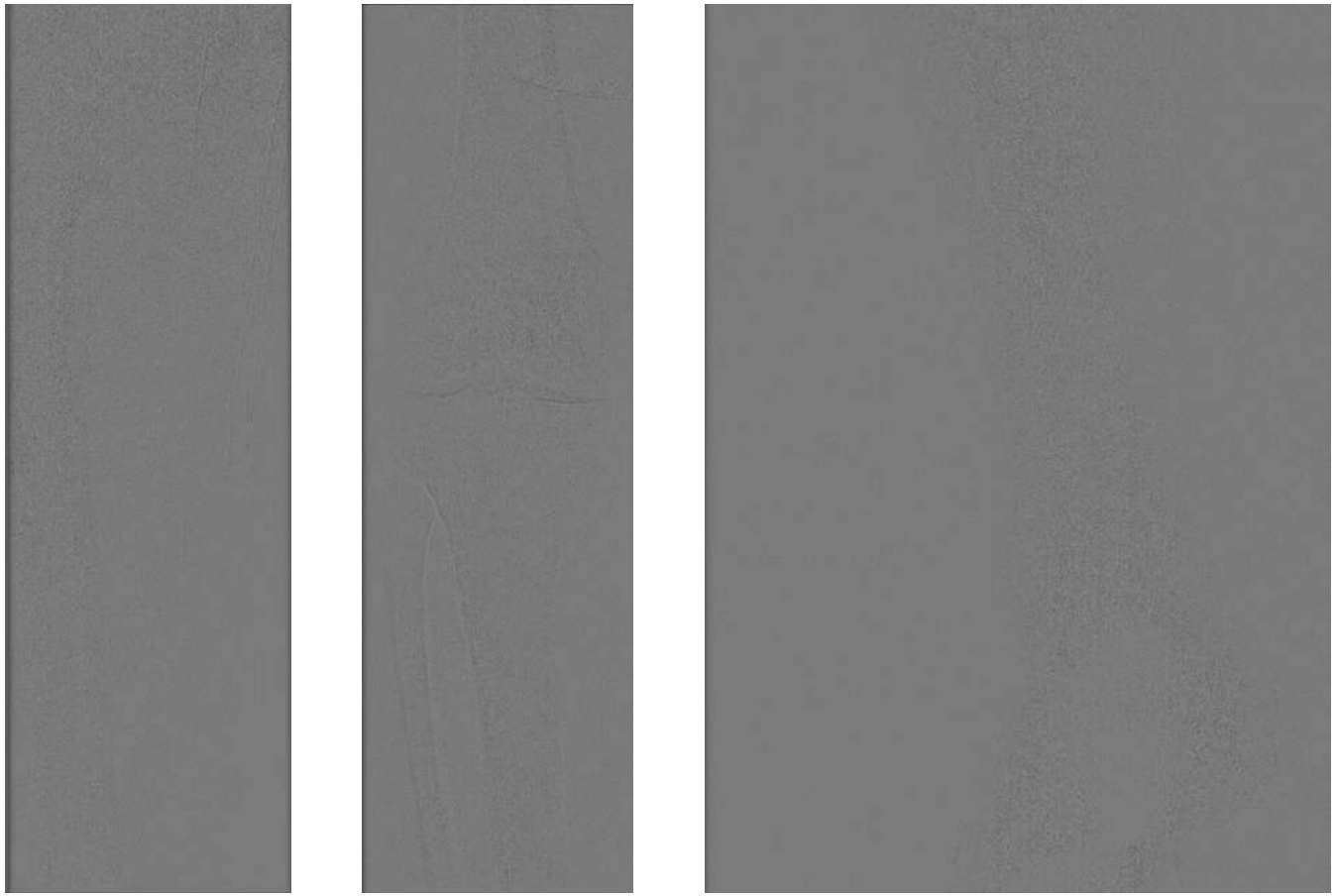


- **Guide wire passed leision, Filter was placed in distal POA.**
- **Directional atherectomy using Turbohawk in proximal and distal segments of SFA.**



- **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 infrapopiliteal 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

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