

Scoring Balloon for vessel preparation



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Disclosure of Interest

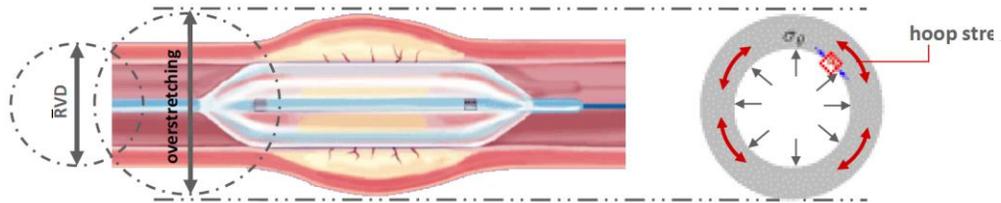
Disclosure

Speaker name:

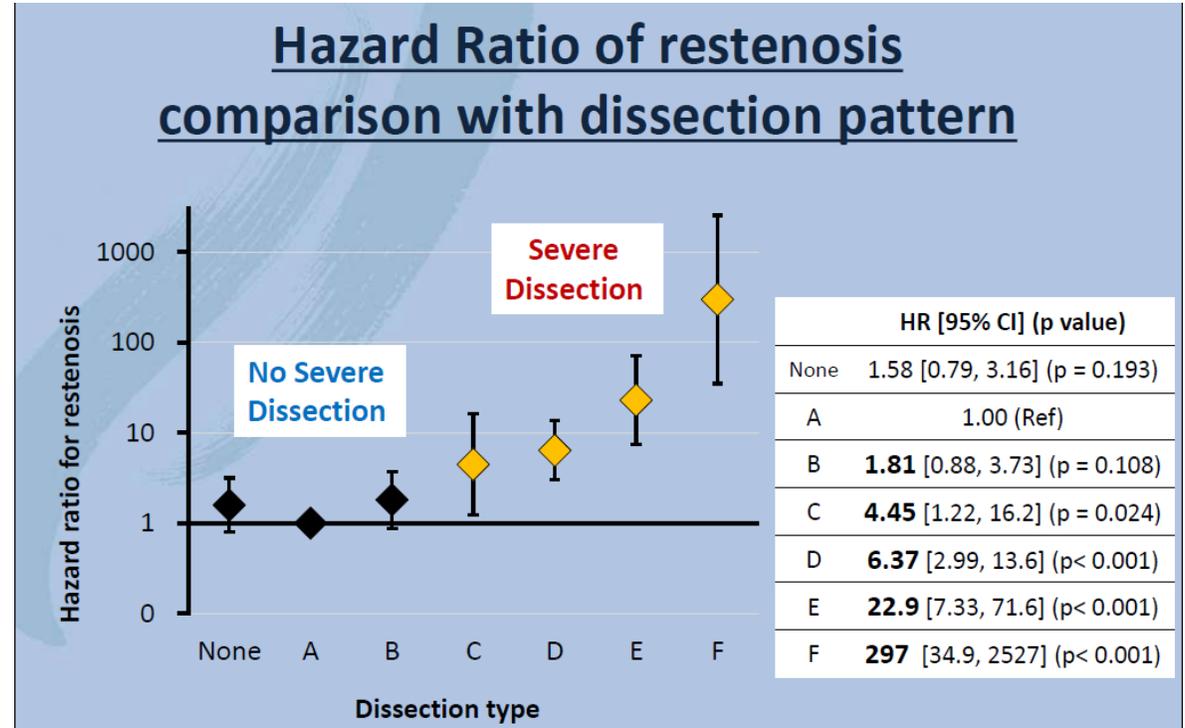
Raphael Coscas

- I have the following potential conflicts of interest to report:
- Consulting: Medtronic, Bard, Boston, Spectranetics, Terumo
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

Angioplasty creates uncontrolled dissections that are associated with restenosis

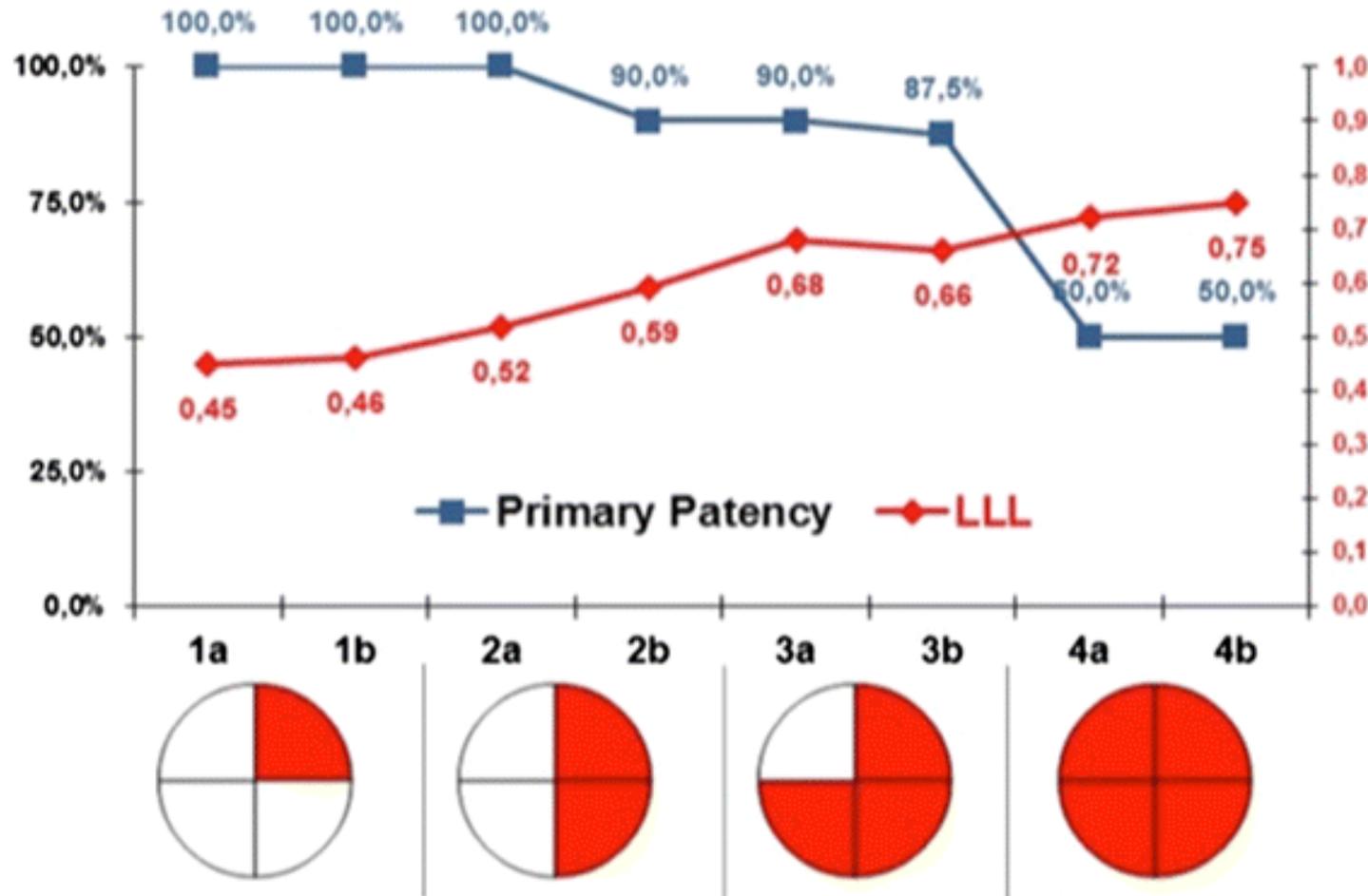


Study	Dissection Rate
PACIFIER ²	47.4% POBA 73.5% DCB
THUNDER ³	56%
LEVANT 2 ⁴	72.3% POBA 63.7% DCB
Fujihara ¹	84% POBA



Fujihara et al, J Endovasc Ther 2017
Werk et al, Circ Cardiovasc Interv 2012
Tepe et al, N Engl J Med 2008
Rosenfield et al, N Engl J Med Supp 2015

Calcium is a key cause of dissection and alters DCB results



- Severe Ca^{++} is a barrier to optimal drug uptake
- Circumferential Ca^{++} is worse than longitudinal

Scoring balloons in the SFA

- Why ?

To address limitations of conventional angioplasty balloons

- How ?

By concentrating the dilating force along the scoring element

- More predictable luminal expansion

- Break calcium

- Lower rate of uncontrolled dissections

- Less barotrauma



Main scoring balloons

	Angiosculpt Philips	Vascutrak/Ultrascore Bard	Chocolate balloon Medtronic	Cutting balloon Boston Scientific
Picture				

No oversizing

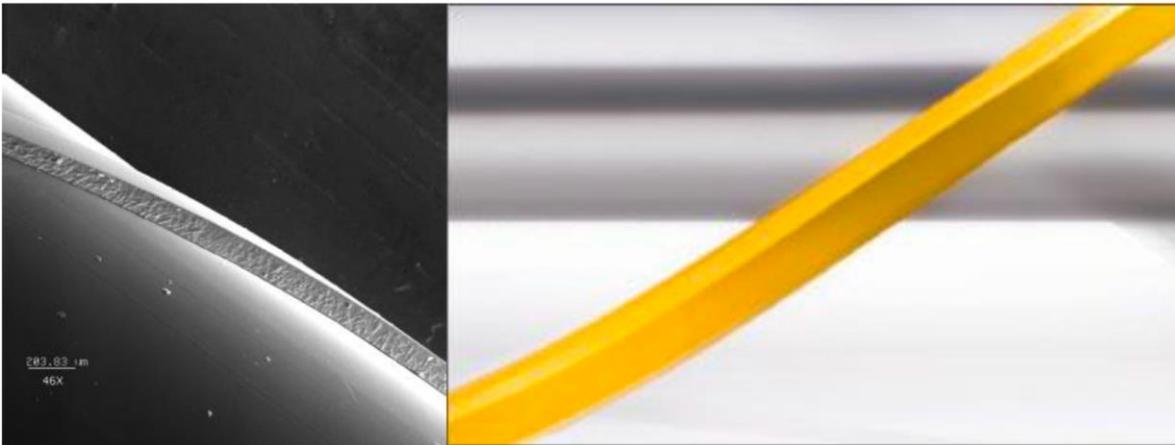
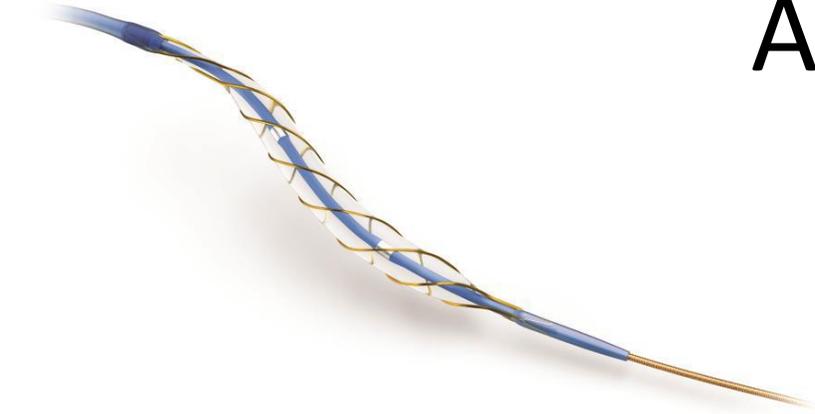
Slow inflation

Long inflation time

Repeat inflations

Slow deflation

Angiosculpt Balloon



Element strut height .005" or .007"
 Rectangular laser-cut nitinol electropolished
 Helical configuration

For 2.0-3.5 mm diameter balloons
 → Angiosculpt ≤ 1.0 Ref vessel diameter

For 4.0-8.0 mm diameter balloons
 → Angiosculpt 0.5 mm less than Ref vessel diameter

Study	Studied devices	Studied lesions	Conclusion
PANTHER Trial	Angiosculpt stand-alone/ + stent/ + DCB	Fem-pop	After lesion preparation with AngioSculpt, calcium was no predictor for loss of patency at 12 months In complex lesions, vessel preparation for DCBs is important to potentially enhance drug uptake and ensure durable results
MASCOT trial	Angiosculpt stand-alone	Fem-pop	ASC is safe with a low rate of complications Favorable 1-year Primary Patency for ASC stand-alone in SFA lesions
FIH European Registry	Angiosculpt stand-alone	Infra-pop	ASC highly effective in a broad range of complex lesion morphologies, with a low complication rate and no device slippage during deployment
International Registry	Angiosculpt stand-alone	Infra-pop	
Belgian Registry	Angiosculpt stand-alone	Infra-pop	High limb salvage rate and low dissection rate with ASC in infra-popliteal lesions

Treatment of femoropopliteal lesions with the AngioSculpt scoring balloon – results from the Heidelberg PANTHER registry

Real World, prospective, single-center, non randomized
101 patients, 124 femoro-popliteal lesions

- AngioSculpt alone (n=46)
- AngioSculpt + DCB (n=38)
- AngioSculpt + stent (n=40)

AngioSculpt in fem-pop stenotic disease

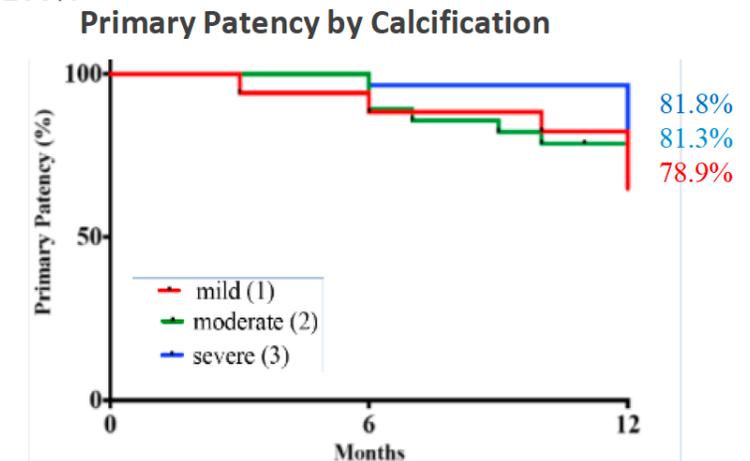
Key Patient Characteristics	
Age (years)	70
Gender (m) (%)	78
Rutherford 2 (%)	12
Rutherford 3 (%)	64
Rutherford 4 (%)	12
Rutherford 5 (%)	12
Diabetes (%)	34
Hypertension (%)	62
Previous vasc history (%)	64

Key Lesion Characteristics	
Lesion length (mm)	19.1
RVD (mm)	5.3
DS (%)	87.9
Calcification (%)	68
Lesion Location (n):	
Prox SFA	8
Mid SFA	22
Distal SFA	16
Pop P1	2
Pop P2	2

12-Month Results:

	Total	AS alone	AS + Stent	AS + DCB
Lesion Length (cm)	7.4	6.1	10.1	5.9
Occlusions	16.1%	2.2%	31.6%	17.5%
12 m prim patency	81.2%	81.5 %	77.8 %	83.9%

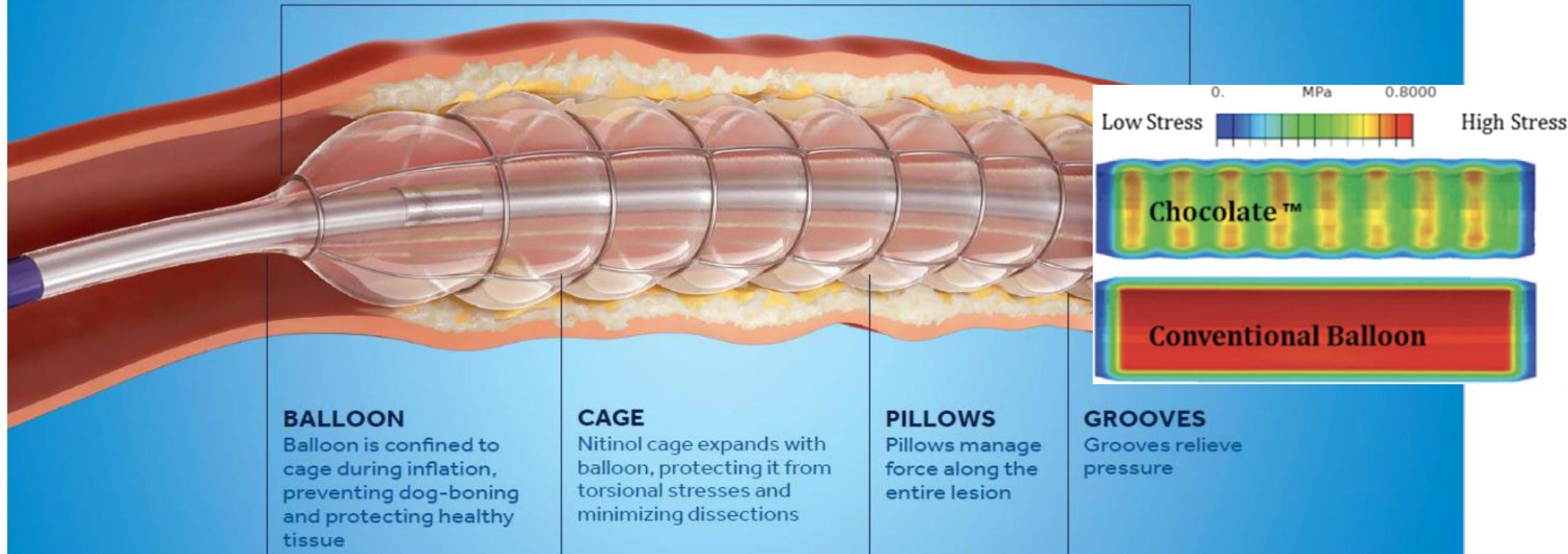
Technical Success: 100%



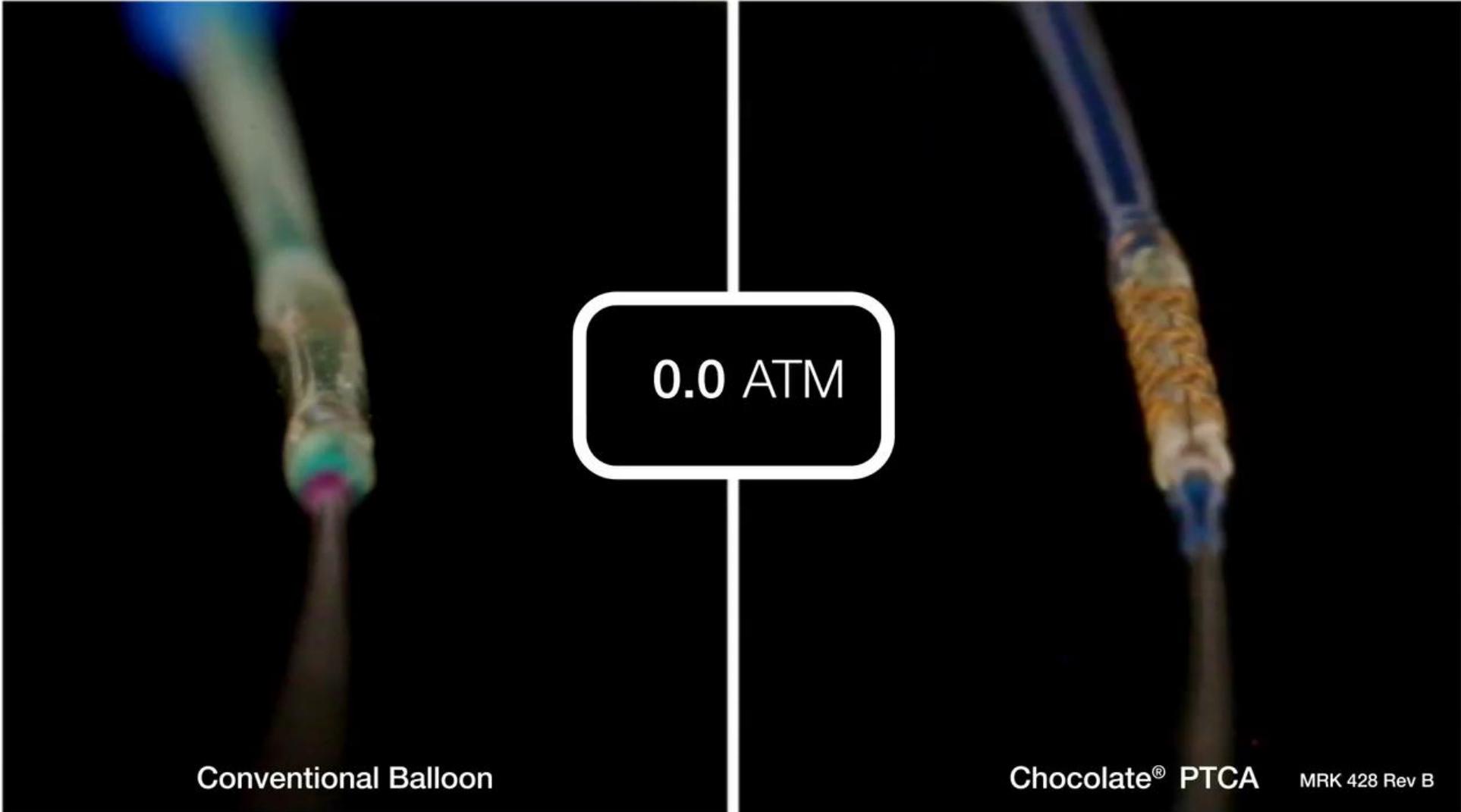
Key result
No influence of Calcifications on Primary patency

Chocolate Balloon

Pillows and grooves formed by cage minimize pressure differentials that can cause dissections

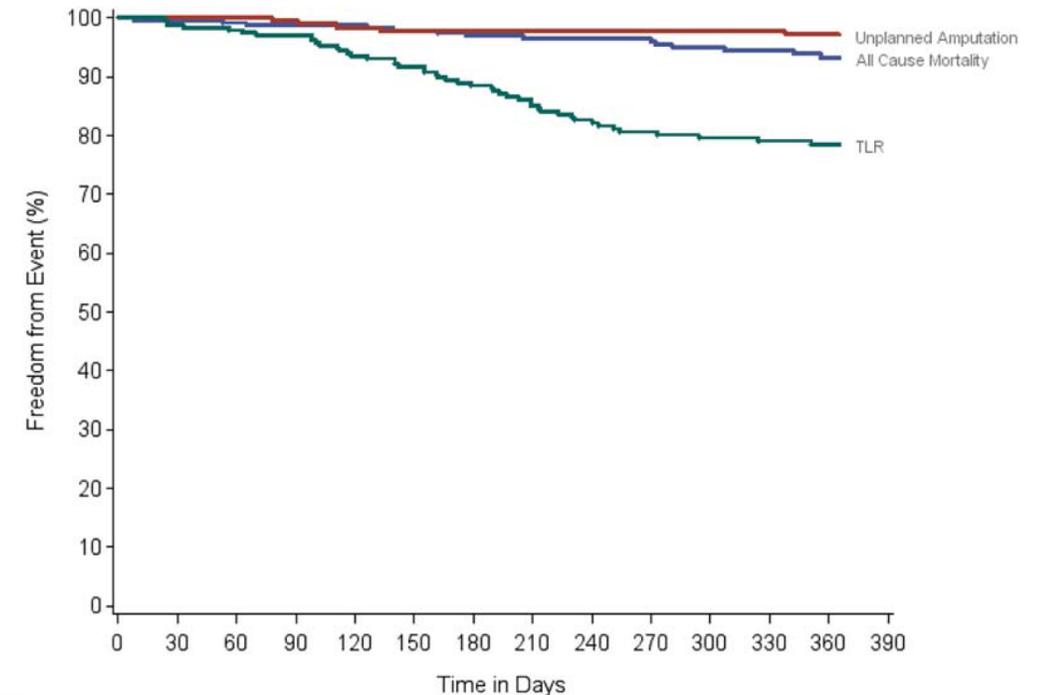


Conventional PTA vs Chocolate



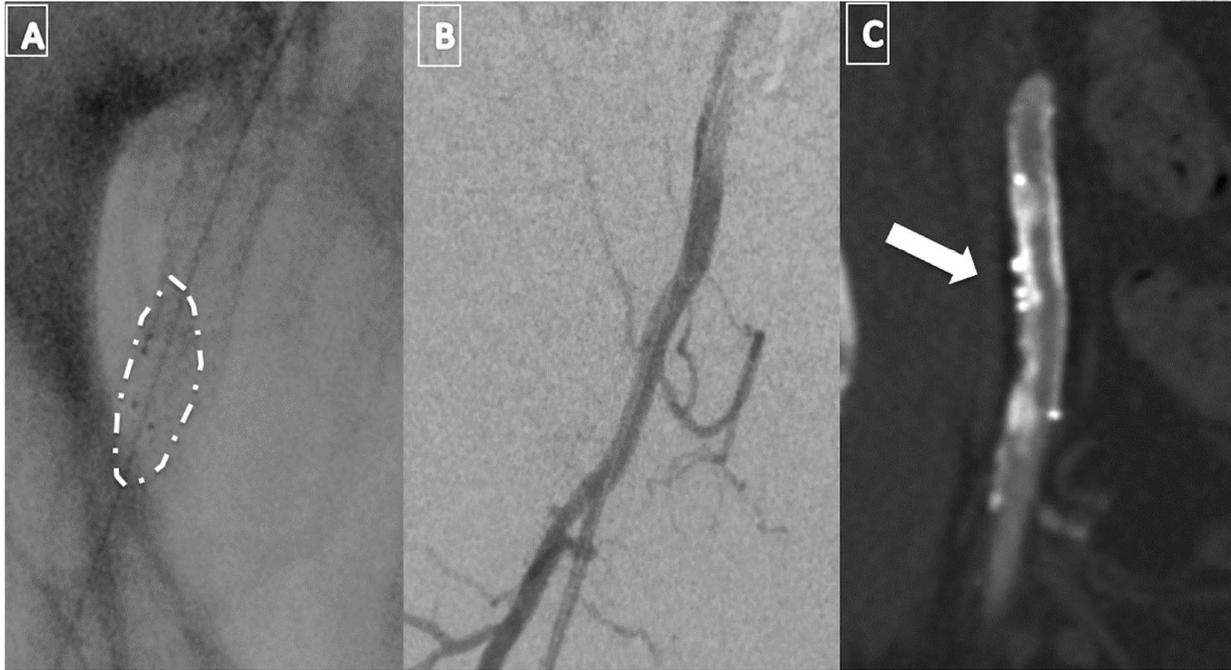
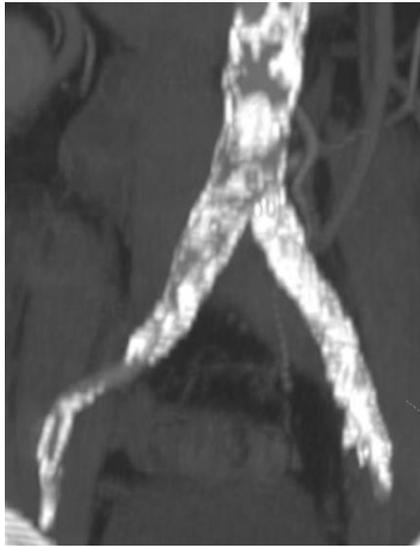
A prospective, multi-center study of the chocolate balloon in femoropopliteal peripheral artery disease: The Chocolate BAR registry

Lesion characteristics	N = 263
Lesion length (mm)	83.5 ± 59.9 (n = 250)
Total occlusions	60/260 (23.1%)
Lesion calcification	
None/Mild	93/254 (36.6%)
Moderate	110/254 (43.3%)
Severe	51/254 (20.1%)
% diameter stenosis, pre-treatment (mean ± SD)	73.5 ± 17.3
% diameter stenosis, post-treatment (mean ± SD)	22.0 ± 8.4
Minimal lumen diameter (mm), pre-treatment (mean ± SD)	1.3 ± 0.9
Minimal lumen diameter (mm), post-treatment (mean ± SD)	4.1 ± 0.7
Acute luminal gain (mm) (mean ± SD)	2.8 ± 0.7
Achieved ≤30% DS without flow-limiting dissection	85.1%



0 % Flow-limiting dissection
1.6 % bail out stenting

Mustapha et al. Catheter Cardiovasc Interv 2018

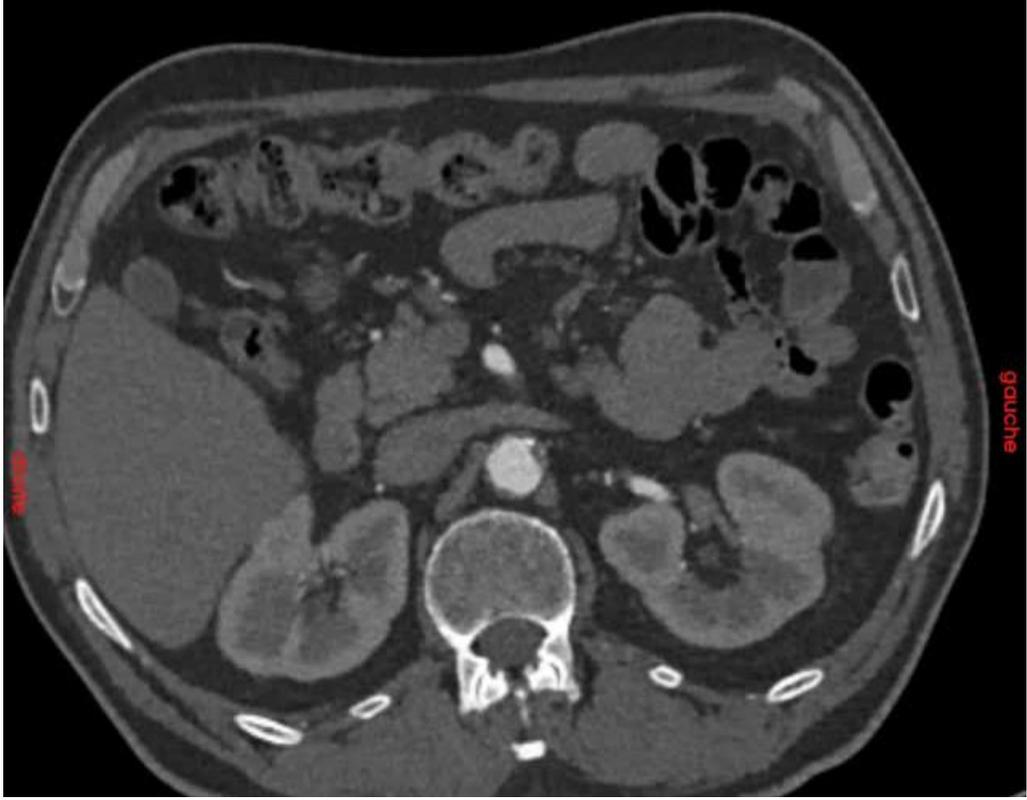


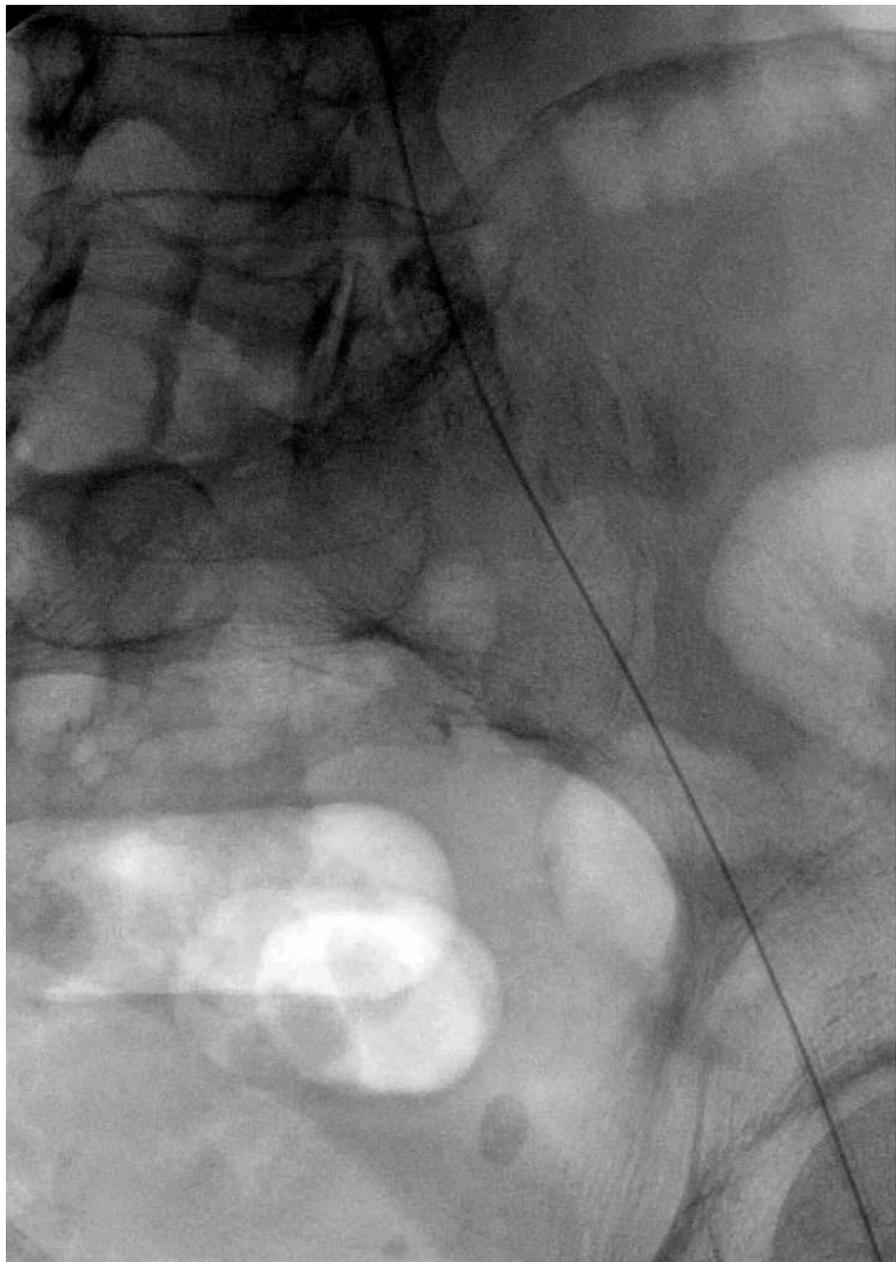
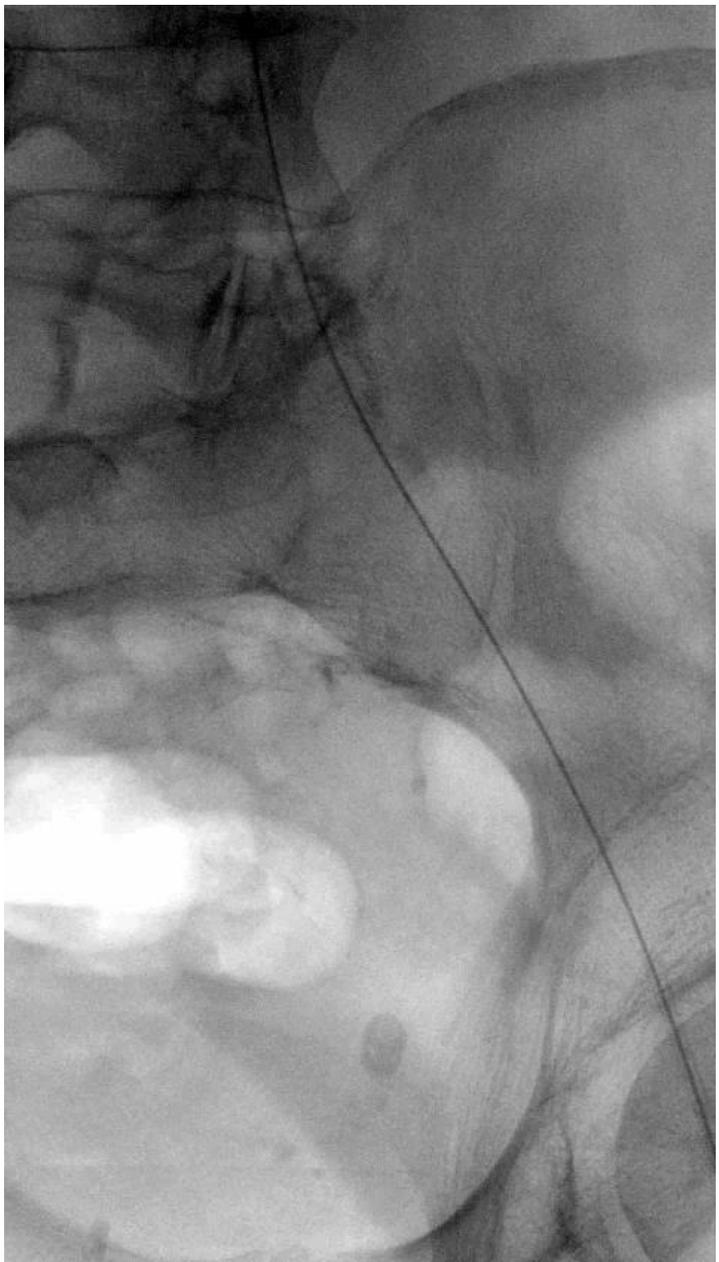
A rare case of loss of the nitinol cage in a previous iliac stent

Case 1

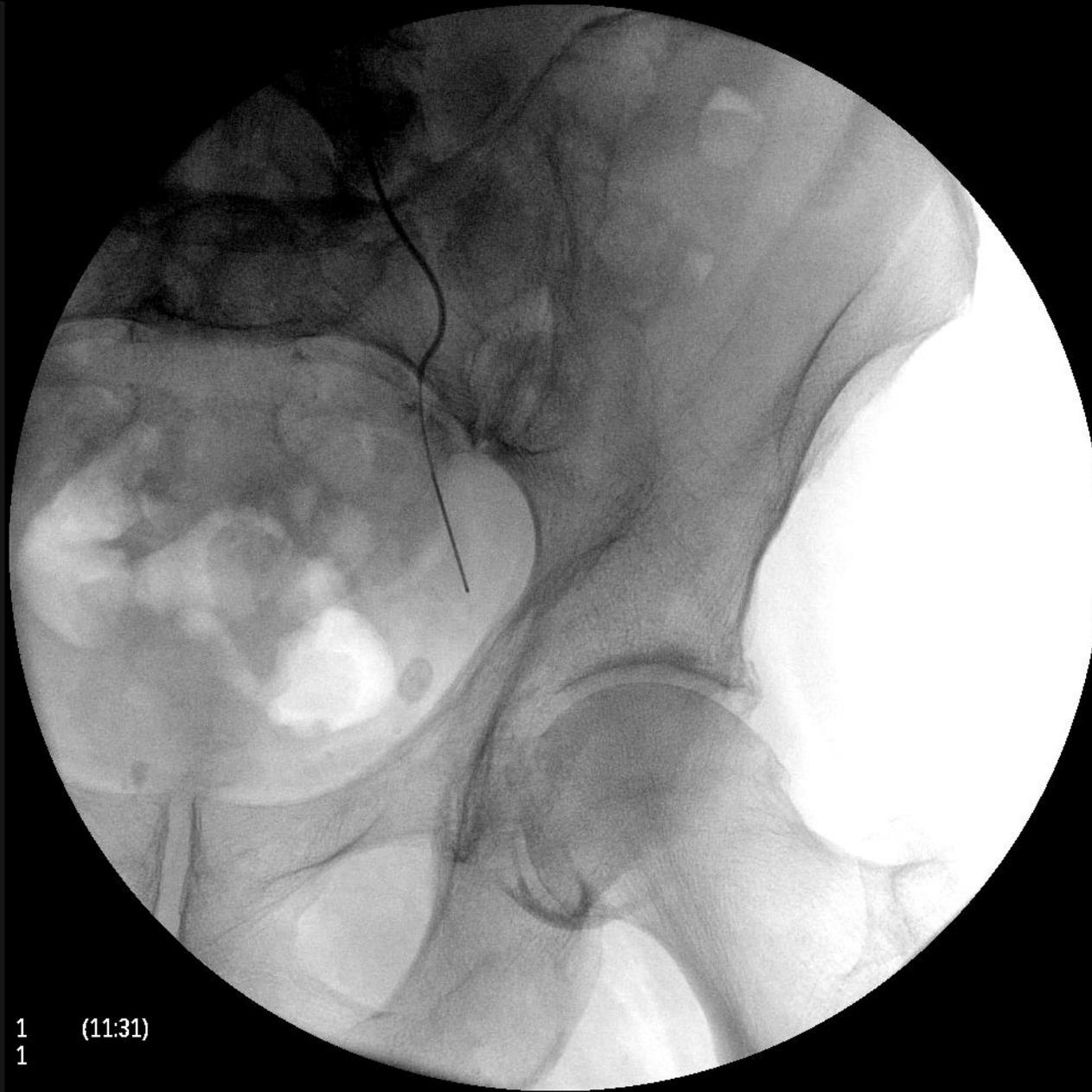
- Age: 66 yo
- Sex: Male
- **Medical history:**
 - Left lower limb claudication 300 m
- Co-morbidities:
 - Diabetes Mellitus (type 2)
 - Hypertension
 - Hyperlipidemia
 - Coronary angioplasty 2016 and 2018 (negative stress test)
 - Bladder cancer 2010
- ABI : 0.75
- **Ultrasound : Moderate left common iliac stenosis + long SFA occlusion with significant flow decrease**
- CTA is shown



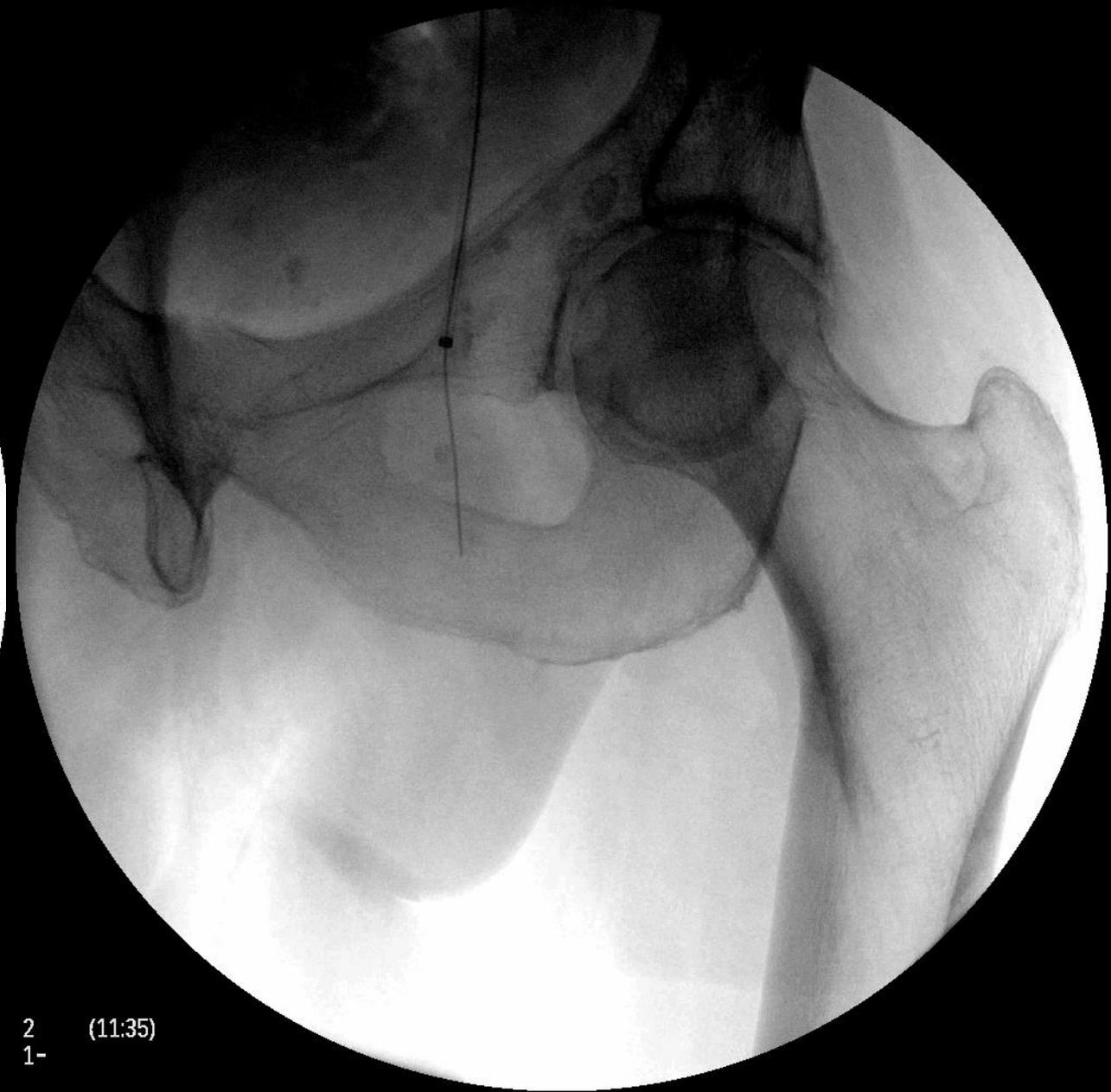




Six months later,
the pain is still here...
And the same !



1 (11:31)
1



2 (11:35)
1-

Dec 2018 : Angiography through contralateral approach



5 (11:37)
1-



3 (11:36)
1-

Dec 2018 : Angiography



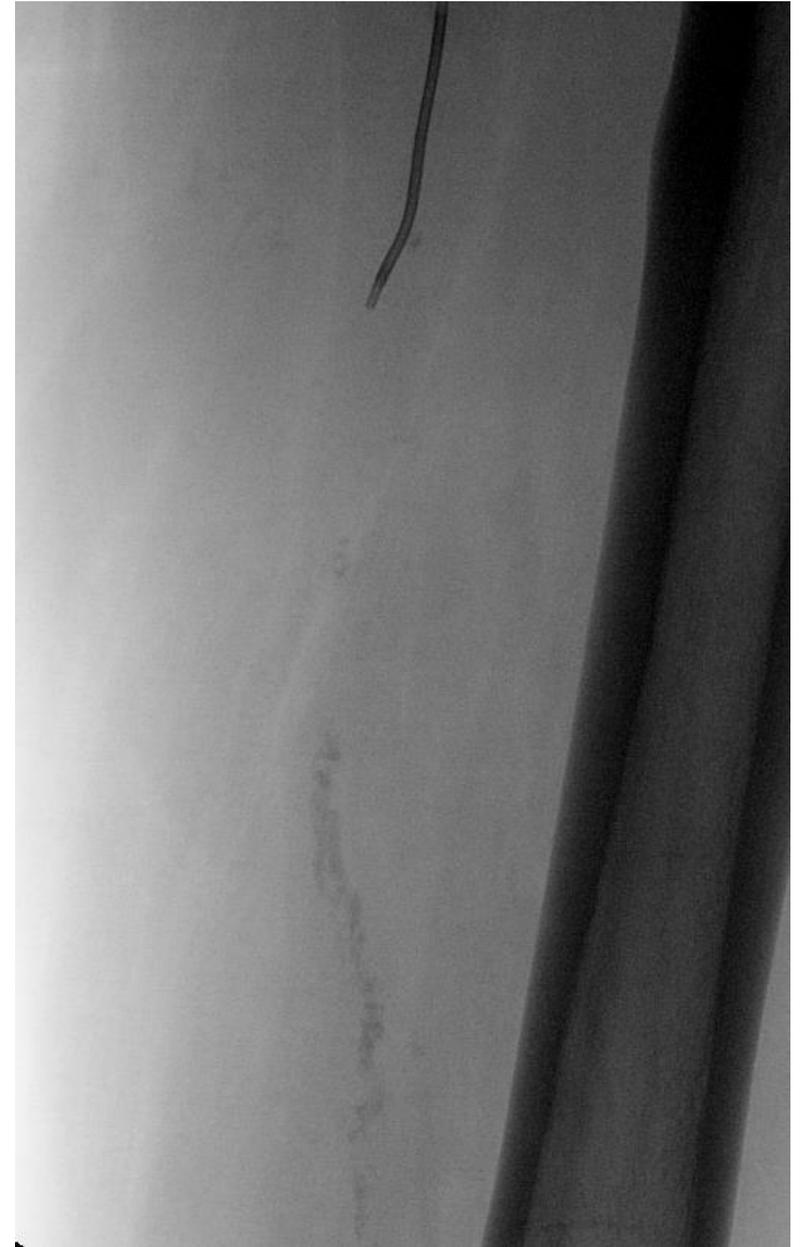
6 (11:37)
1-

What would you do ?

1. Stop the procedure because the risk to compromise collaterals is high – discuss a femoro-popliteal bypass (acceptable saphenous vein)
2. Stop the procedure because the risk to compromise collaterals is high – reinforced medical therapy
3. Retrograde access first to stay in the true lumen
4. Anterograde endoluminal recanalisation + Preparation + DCB + Provisional stenting
5. Anterograde endoluminal recanalisation + Total stenting “Full metal jacket”
6. Subintimal recanalisation

Material

- Contralateral femoral access + 6F 45cm sheath
- Angiography catheter (Merit)
- Recanalisation catheter (Rubicon or Trailblazer)
- 0.035' Terumo straight and 0.018' V18 wires
- Retrograde access planned "in case of"
- Re-entry device planned "in case of" (Outback)
- 4 and 5 mm standard PTA balloons
- 5 mm x 120 mm Chocolate balloon
- Several 5 mm x 150 mm and 5 mm x 120 mm DCBs to avoid geographic miss
- Provisional self expandable stenting 6 mm



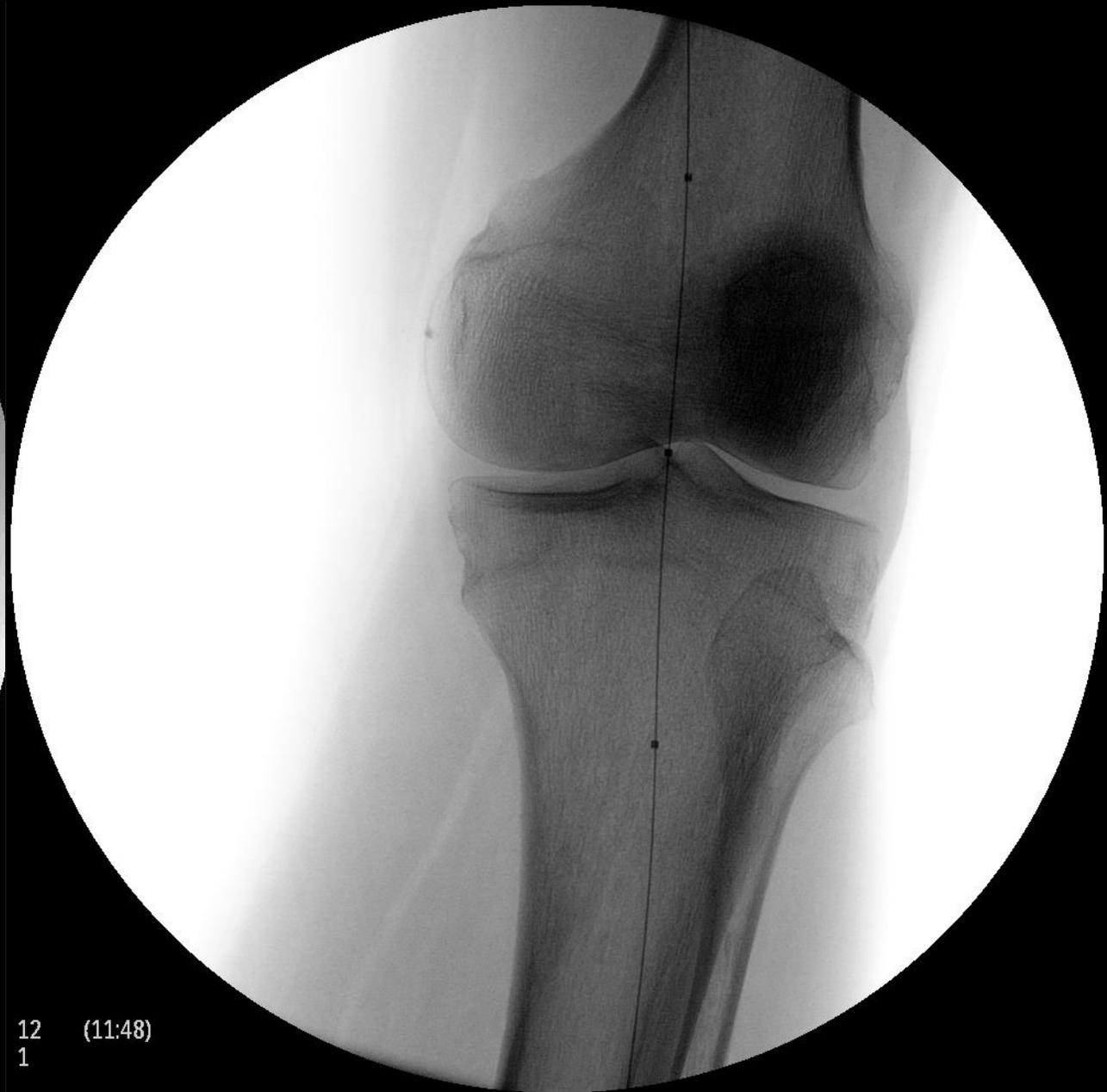
Procedure



Stay in the true lumen as much as possible



11 (11:46)
1-

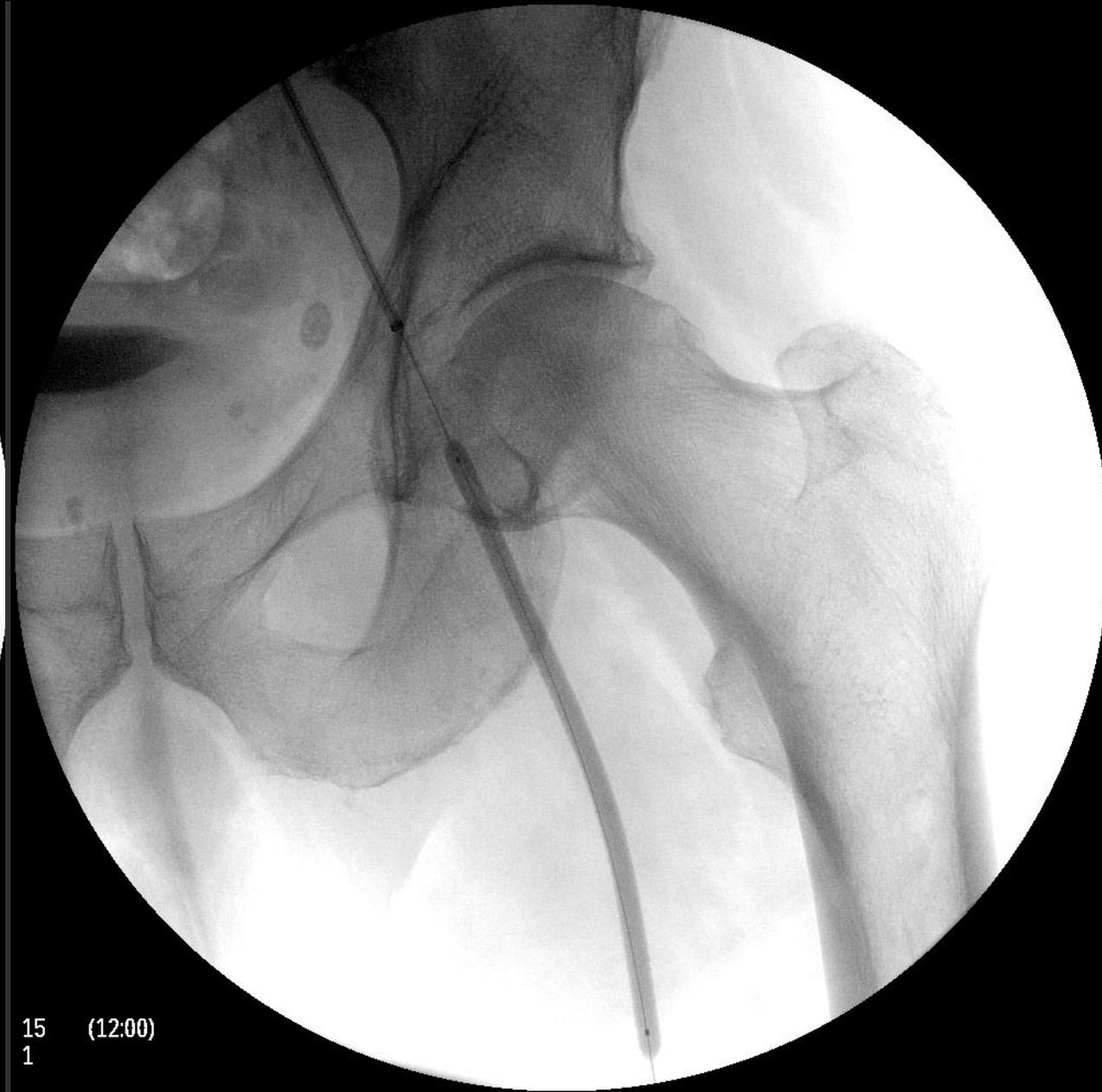


12 (11:48)
1

Recanalisation catheter due to heavily calcified lesions

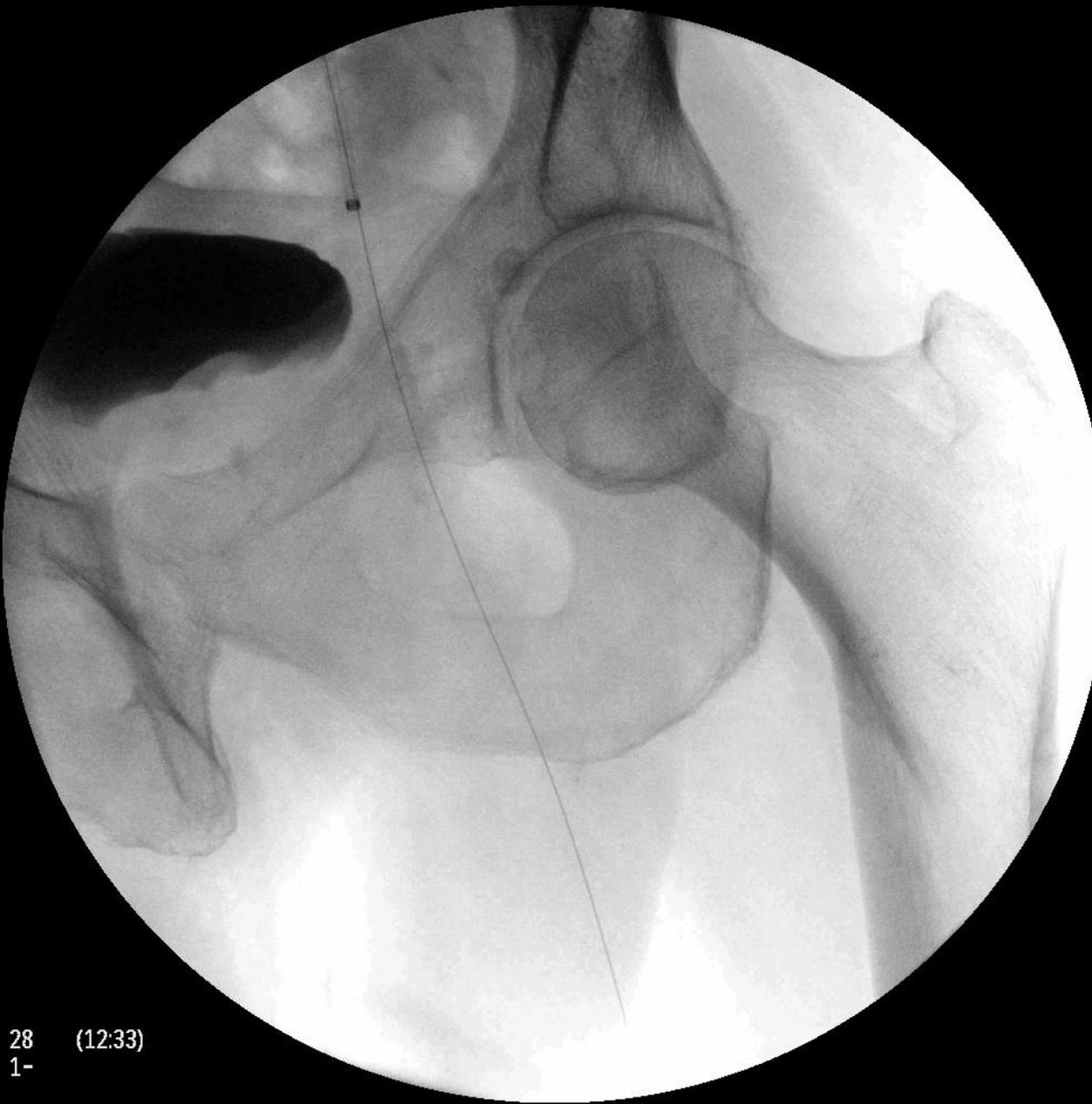


13 (11:52)
1



15 (12:00)
1

Vessel preparation with the CHOCOLATE balloon (5x120mm) – 0.018' wire



28 (12:33)
1-



29 (12:33)
1-

Nice vessel prep but dissection at the distal SFA – to stent or not ?

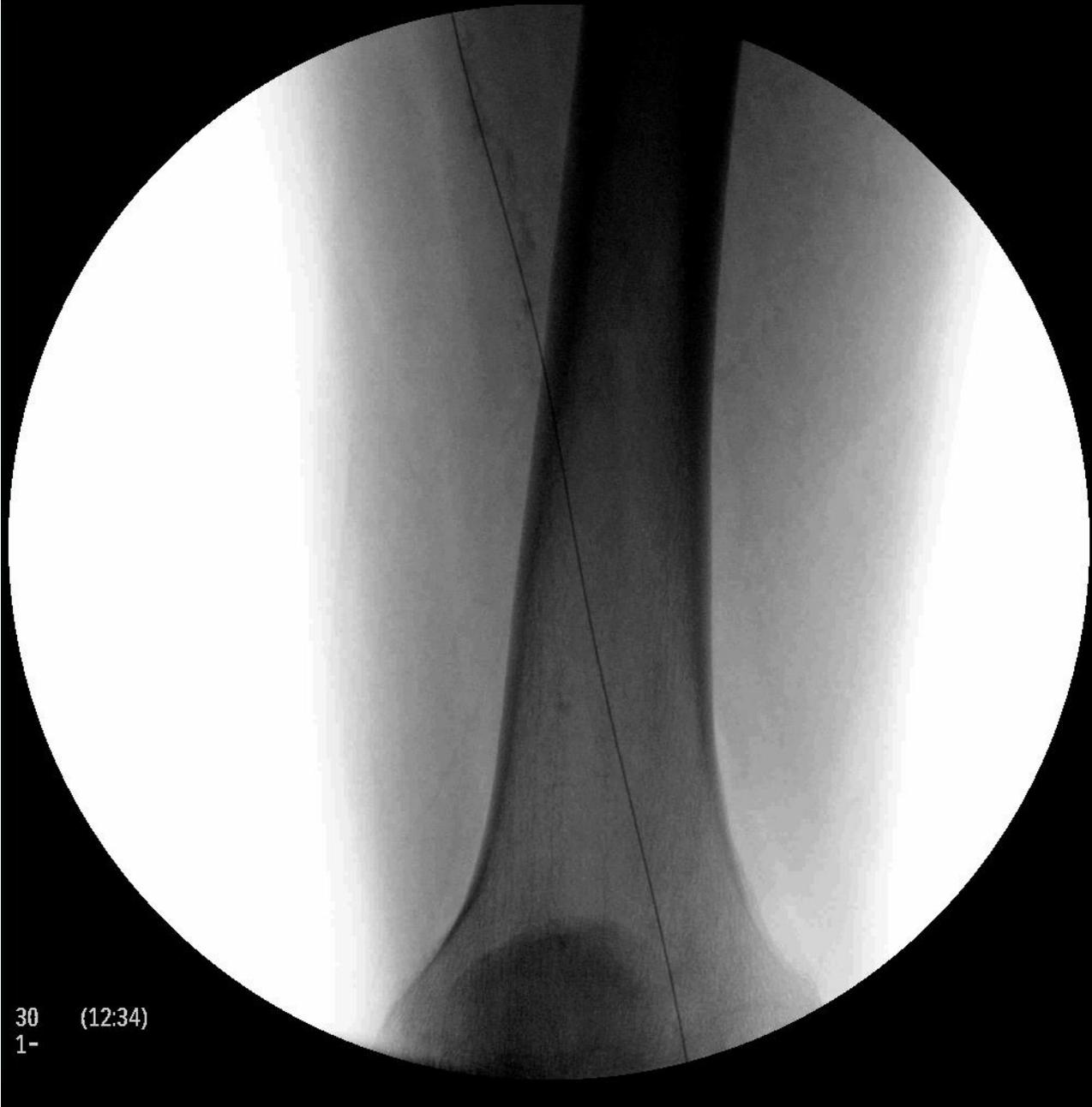


26 (12:27)
1



27 (12:31)
1

**3 more minutes of vessel preparation with 5 mm x 120 mm Chocolate balloon
+ 3 minutes 5 x 150 mm DCB inflations (2 balloons)**



30 (12:34)
1-



31 (12:37)
1-



32 (12:37)
1-

Angiography without the wire after 1 minute

Patient Follow Up

- Postop:
 - 1 night in hospital
 - DAPT
 - Distal pulses
- 1 month visit:
 - No claudication
 - Distal pulses
 - ABI 0.96
 - Duplex: « history of SFA angioplasty ?? »
- 6 months:
 - Result is maintained

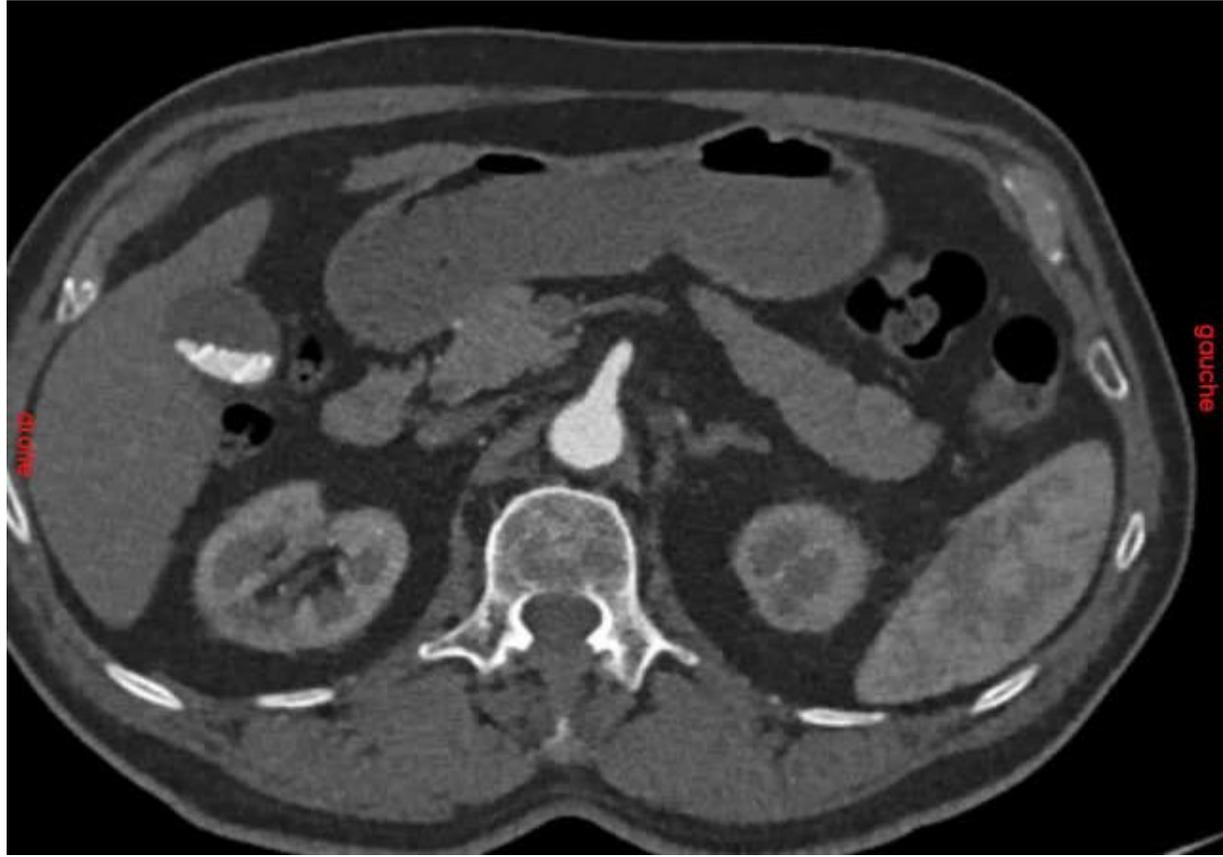
Conclusions

- Scoring balloons intend to reduce severe and/or flow limiting dissections after angioplasty
 - Less bail-out stenting
 - Increase DCB and DES efficiency
- Specific but simple technical aspects should be respected
- The global level of evidence remains weak

Case 2

- Age: 83 yo
- Sex: Male
- **Medical history:**
 - Rest pain
- **Co-morbidities:**
 - Diabetes Mellitus (type 2)
 - Prostate cancer
 - Left common iliac angioplasty 14 months before





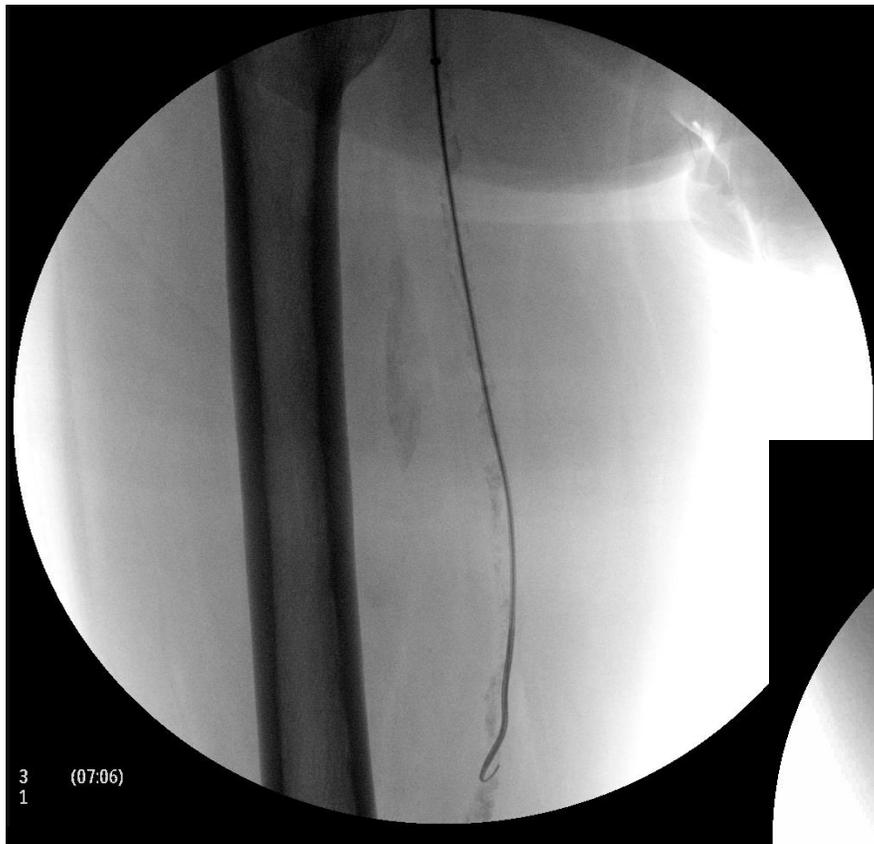


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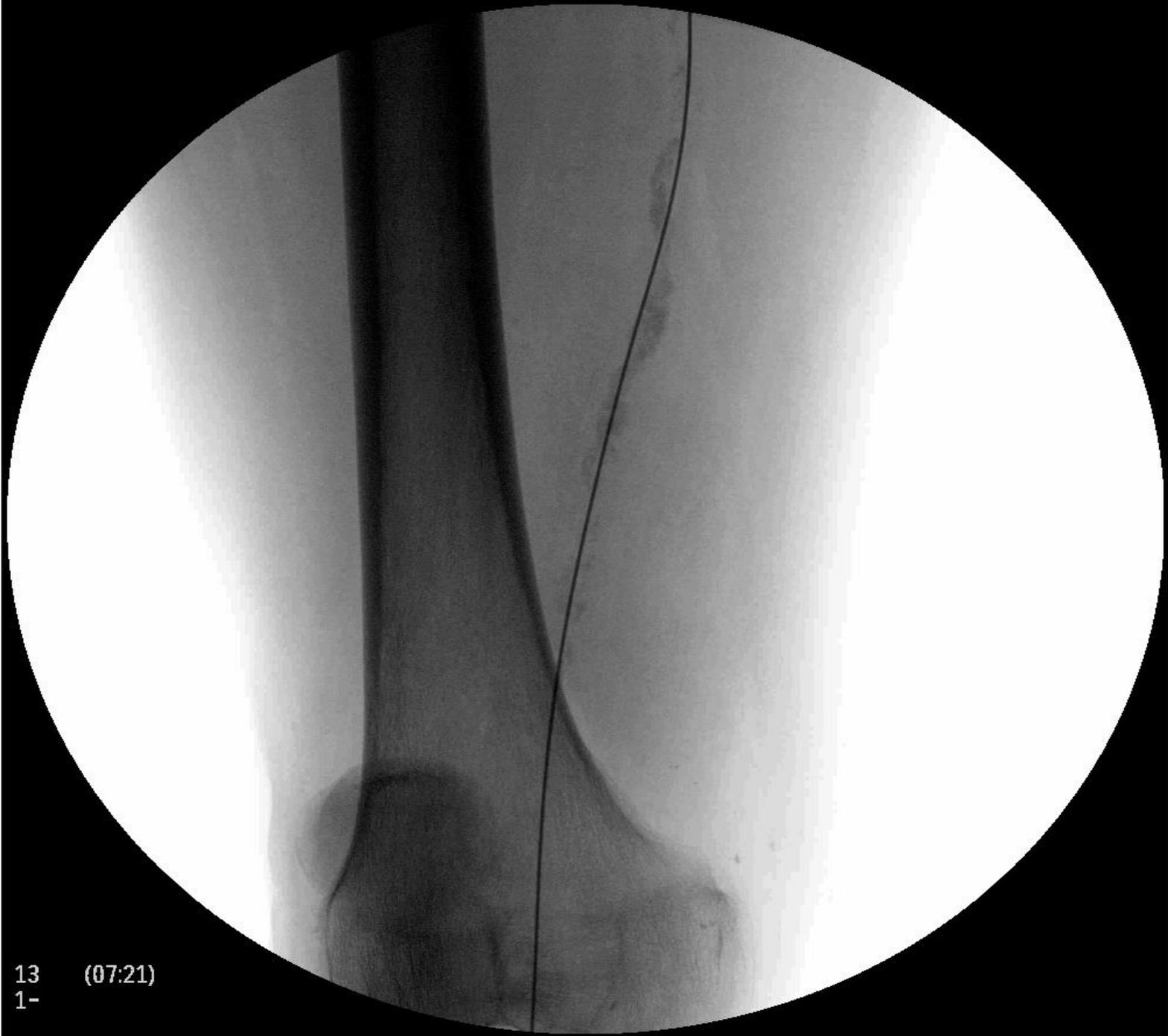
(07:03)



2 (07:03)
1-



Lesion crossing in challenging – mandating progressive balloon/wire inflation/advance



13 (07:21)
1-



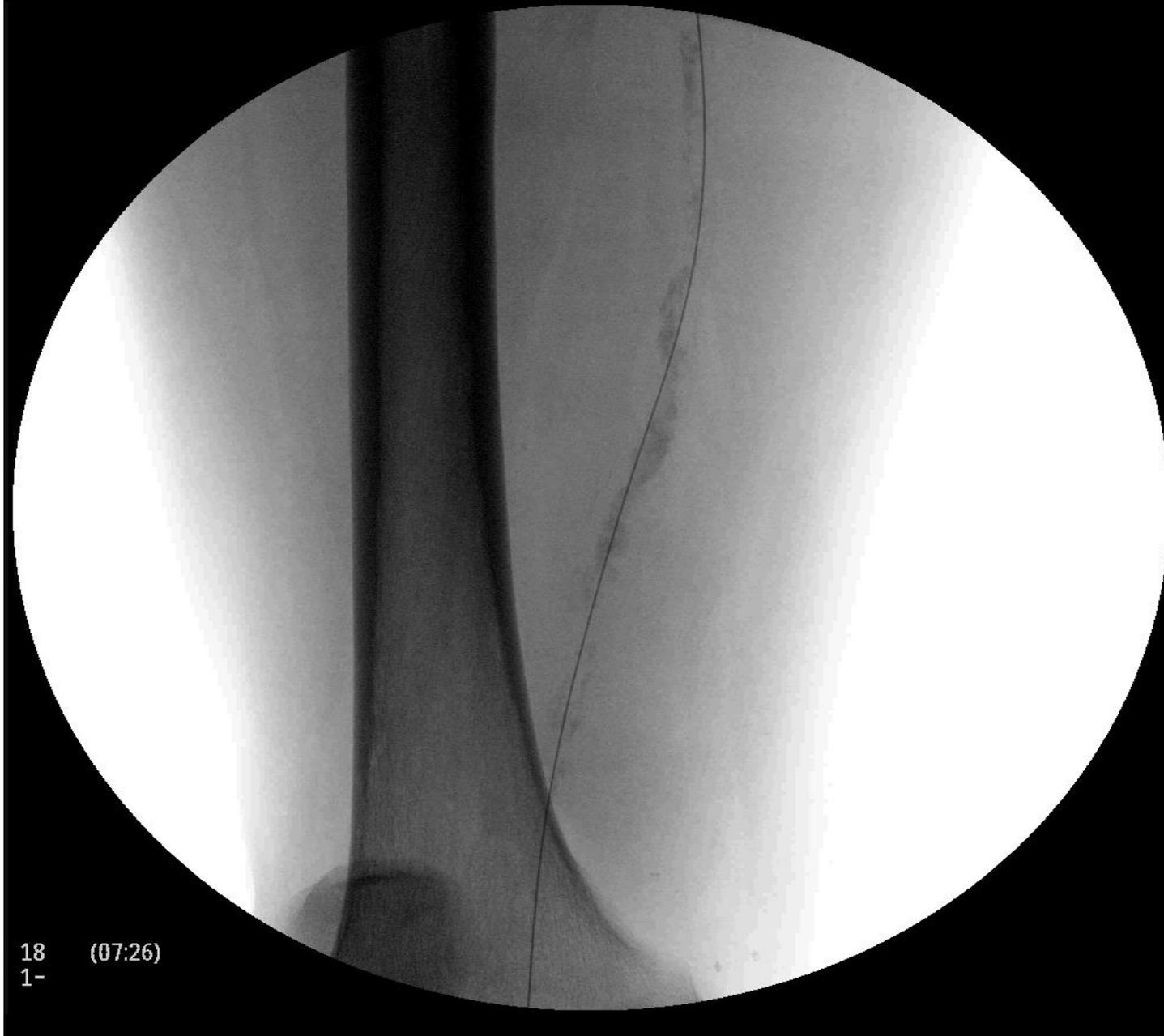
14 (07:23)
1

Lesion at high risk for angioplasty and risk of stent compression in case of stenting

Predilatation
with semi-compliant 3 x 20 mm
Armada 035 balloon



16 (07:24)
1



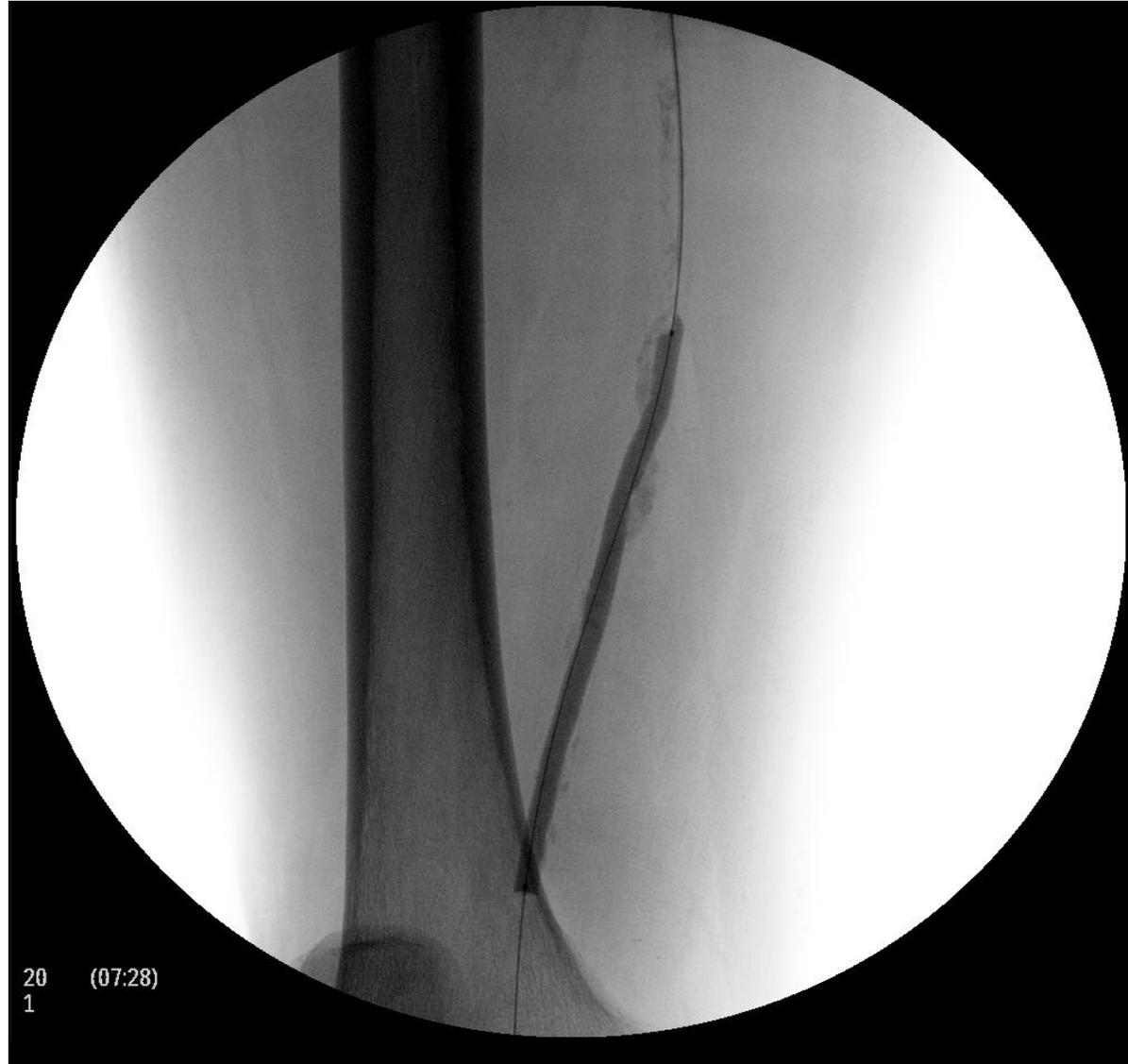
18 (07:26)
1-

Lesion crossing in challenging – mandating progressive balloon/wire inflation/advance

Vessel preparation
Chocolate balloon
5 x 120 mm



22
1 (07:31)



20
1 (07:28)



49 (08:03)
1-



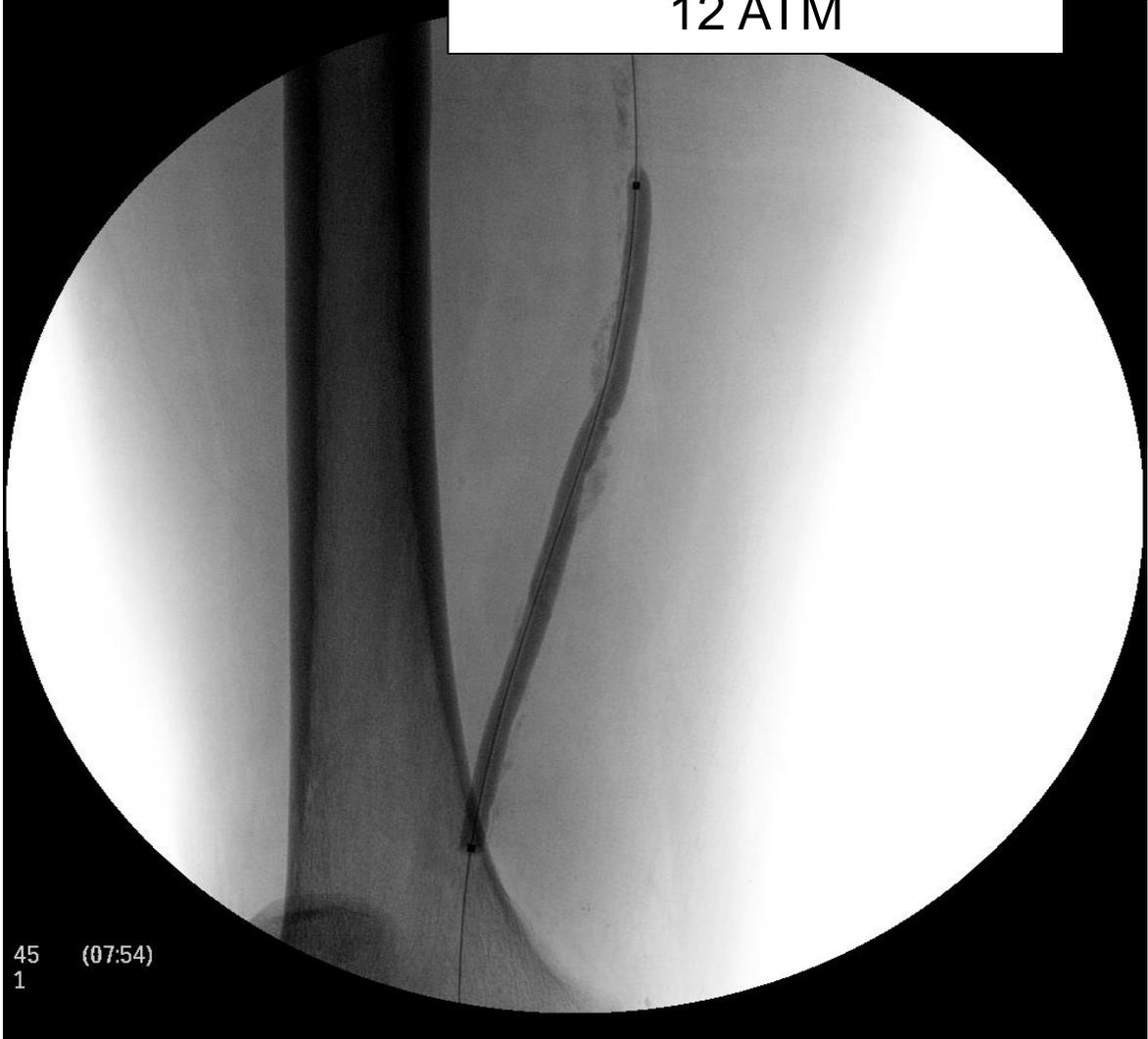
52 (08:06)
1-



48 (08:03)
1-



2 DCBs
5 x 150
5 x 150
3 minutes
12 ATM

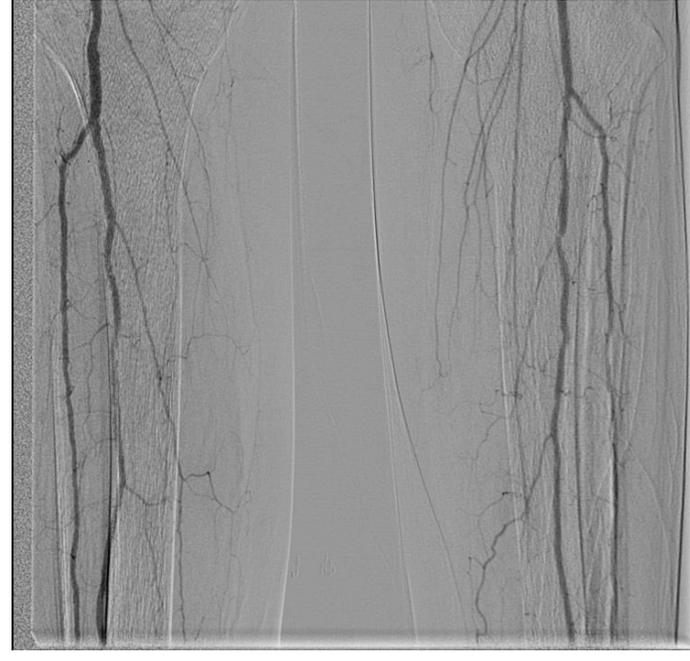


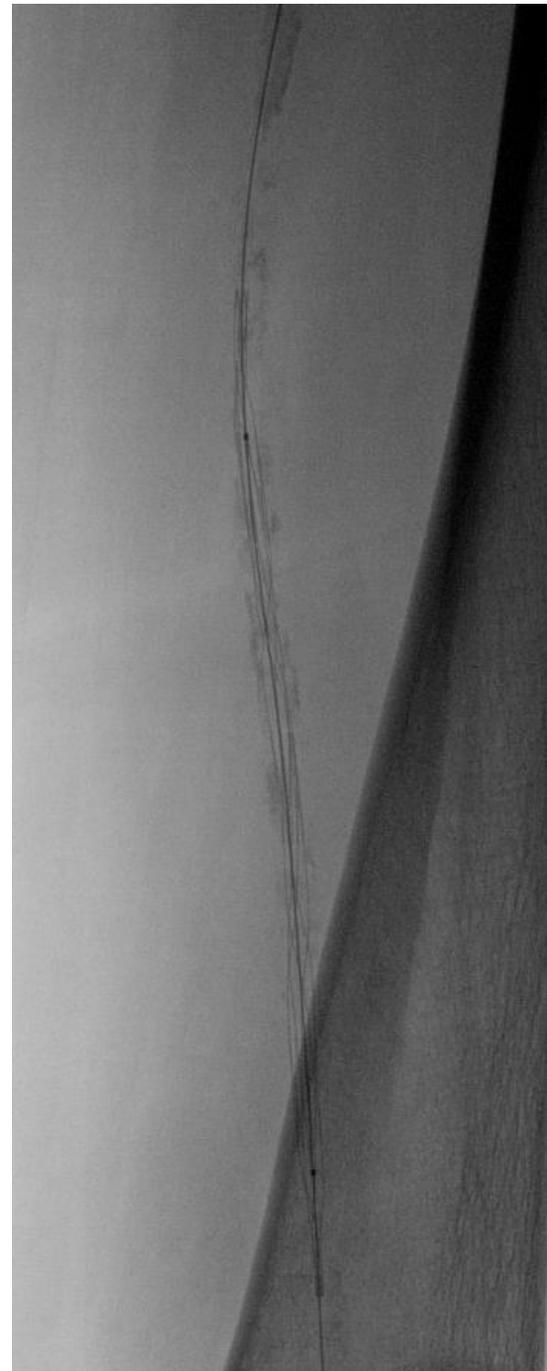
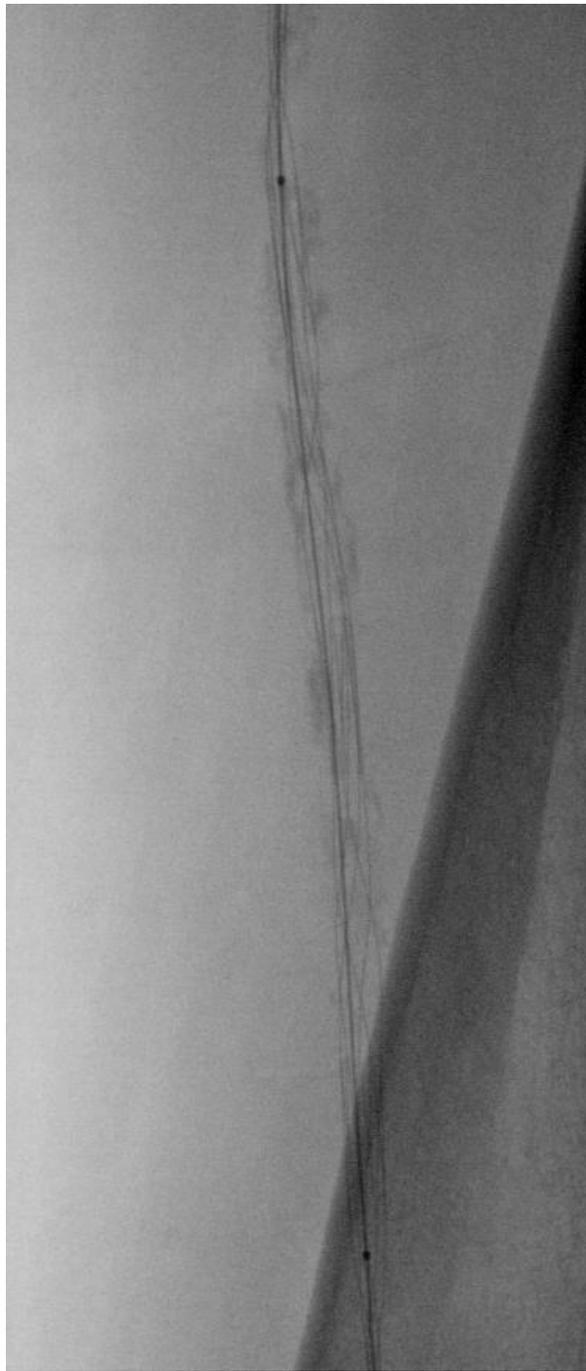
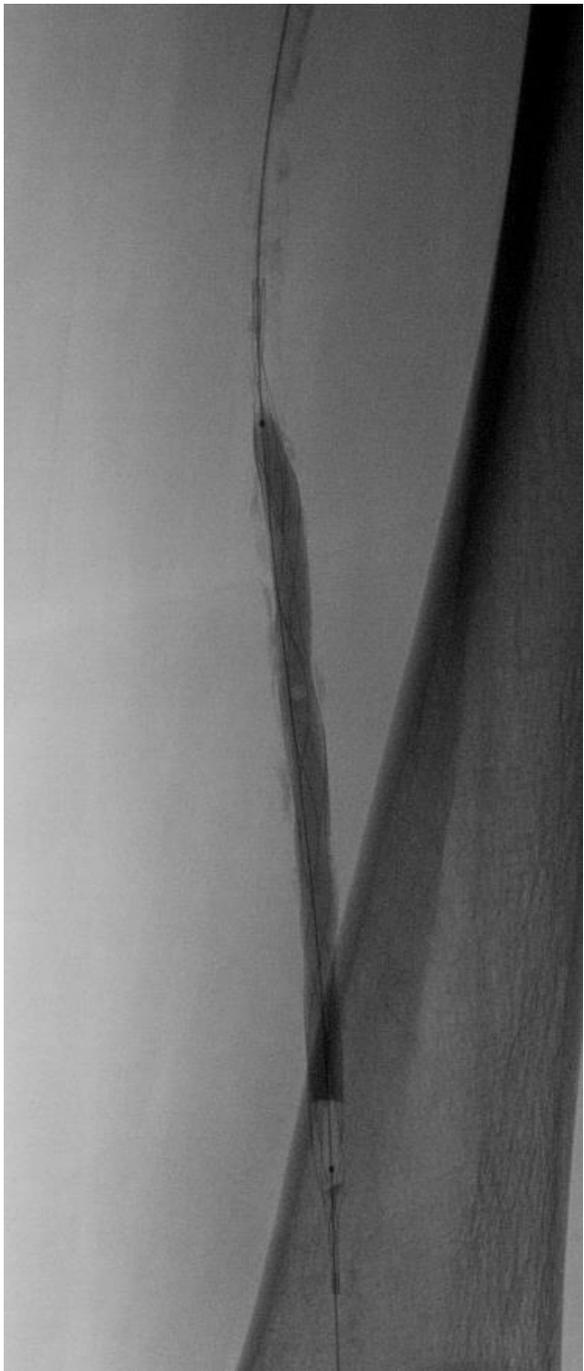
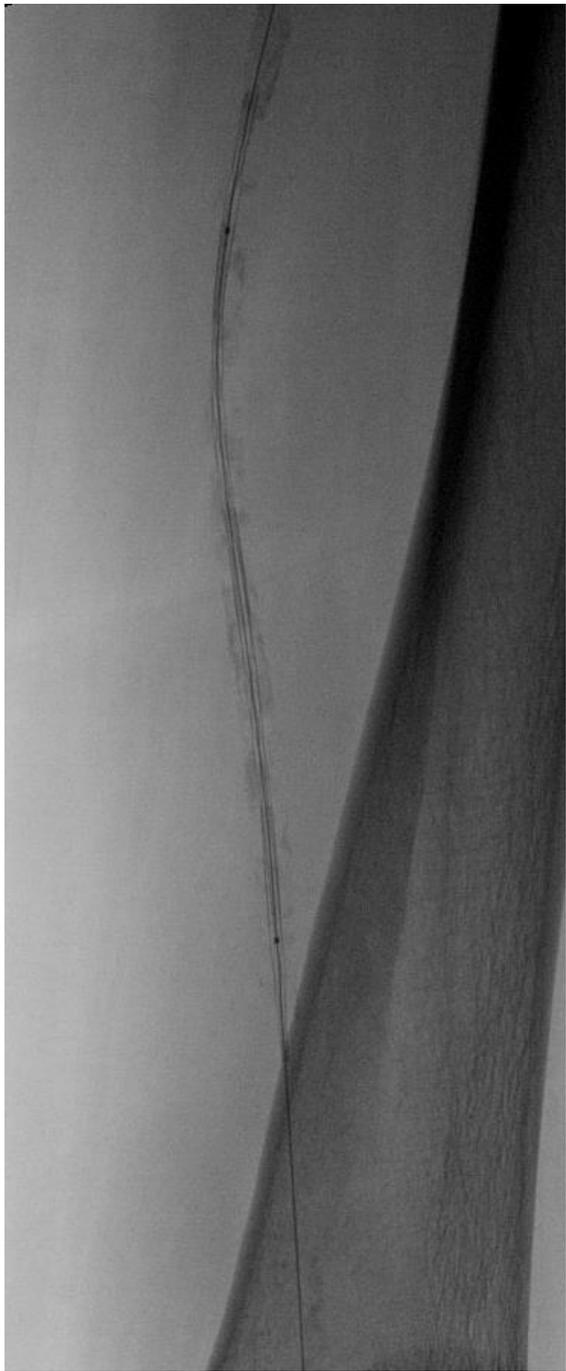


Case 3

- Age: 63 yo
- Sex: Female
- **Medical history:**
 - Left 5th Toe necrosis
- **Co-morbidities:**
 - Diabetes Mellitus (type 2)
 - Tobacco use
 - Severe COPD
- **Duplex:**
 - Left SFA thrombosis









35 (15:30)
1-



40 (15:39)
1-

Conclusions

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 - Less bail-out stenting
 - Increase DCB and DES efficiency
- Specific but simple technical aspects should be respected
- The global level of evidence remains weak

