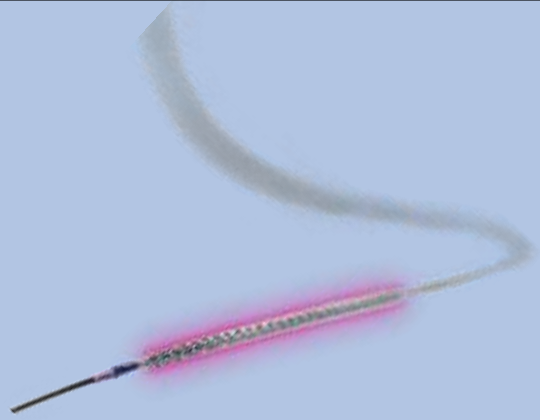

Is there still any space left for DES in the BTK area ??? (Angiolite BTK trial, 6 month Data)

(Angiolite BTK DES, IVascular)

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Disclosure

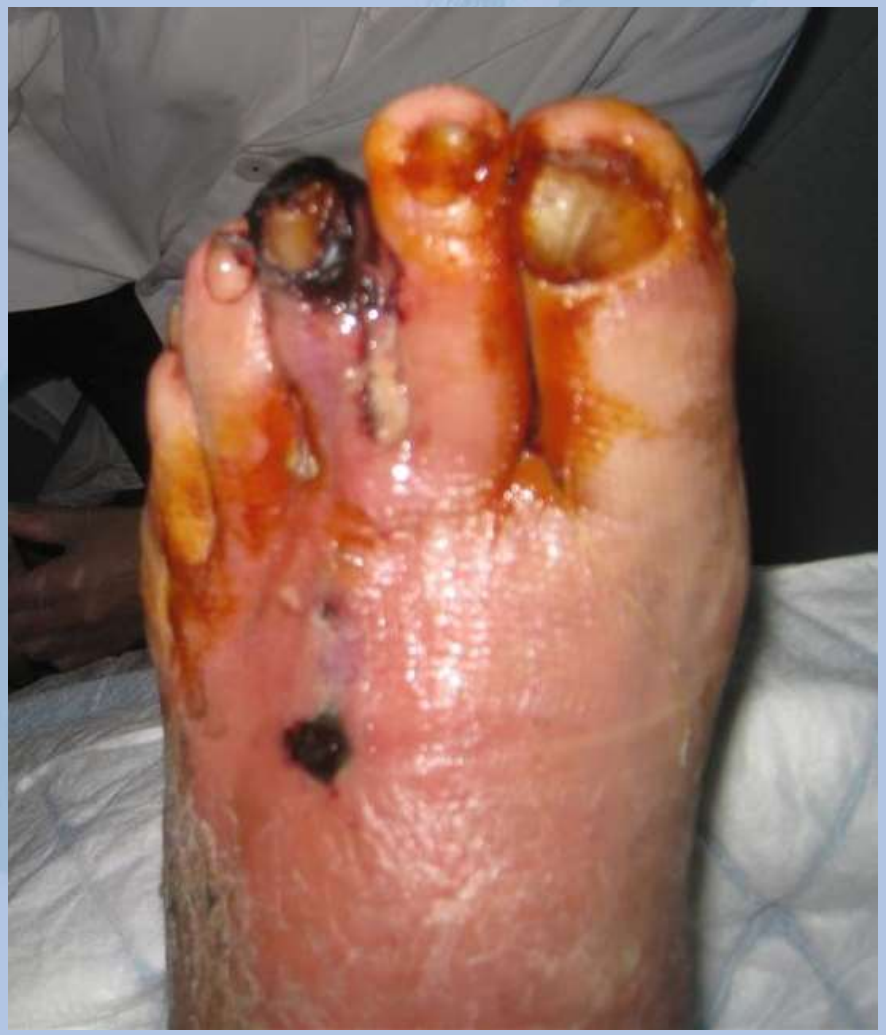
Speaker's name: Peter Goverde

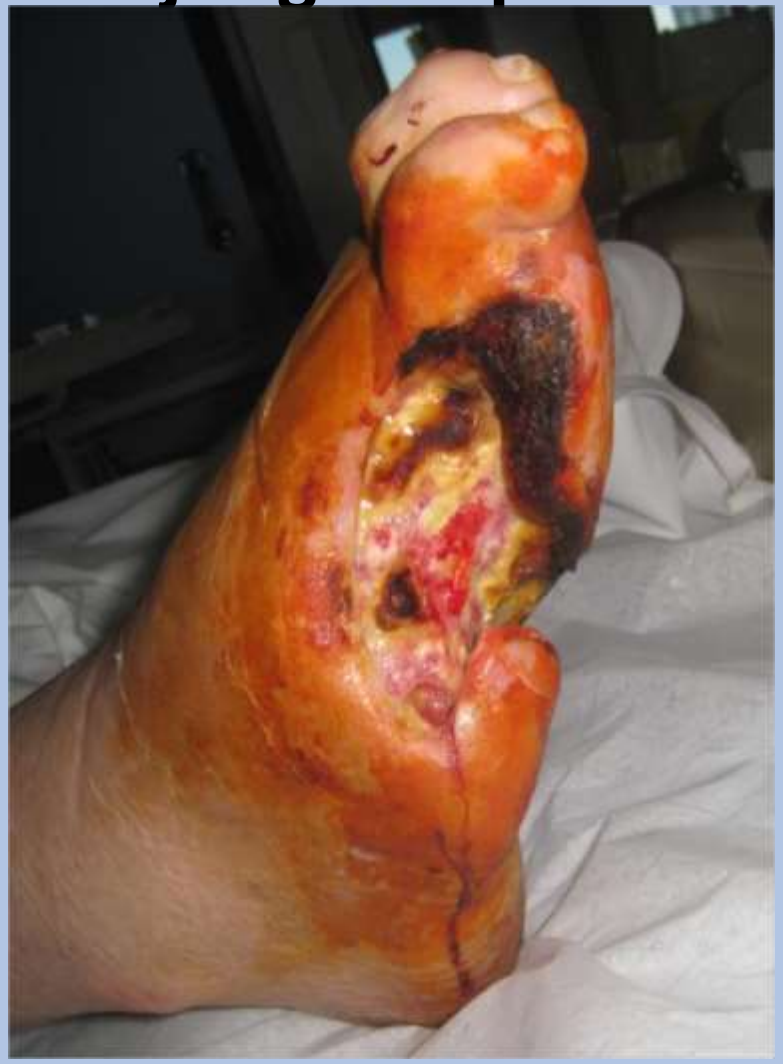
- **I have the following** potential conflicts of interest to report:

Grant/Research Support/Consulting Fees/Honoraria:

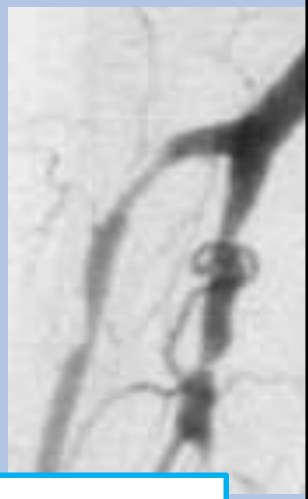
Abbott Vascular; Angioslide; Bard Peripheral Vascular; Bentley; B Braun endovascular; Cardionovum; Cordis Cardinal Health; CTI; IMDS; Ivascular; Getinge group; Stille; Ziehm Imaging

Major goal : prevention





Endo treatment strategy BTK



Successful recanalization

long diffuse

short focal / Medium

POBA

DCB ?

DES

Recoil/dissection/
intraluminal cacification

Mission accomplished

Re-POBA

Recoil/dissection

Bail out stenting BTK SX stent
+ prior DCB ?

Angiolite BTK safety and feasibility study

- Safety & feasibility study with IVascular Angiolite BTK BX DES as bail out in BTK procedures
- Start Aug 2016
- Single center, physician initiated, prospective, real-life nonRCT
- N= 50 patients
- Rutherford-Becker : 4-5-6

Angiolite BTK safety and feasibility study

A. Primary Endpoint

1. **Safety & feasibility using IVascular Angiolite BTK BX DES in BTK bail out procedures**
2. **Absence of clinically driven target lesion revascularization @ 12 months.**

B. Secondary Endpoints (1/2)

1.Technical success defined as a successful access and deployment of the device and determined by less than 30 % residual stenosis by angiography at the baseline procedure.

2. Clinical success defined as technical success without the occurrence of serious adverse events during procedure

Angiolite BTK safety and feasibility study

B. Secondary Endpoints (2/2)

3. Primary and secondary patency rate (if duplex ultrasound available) defined as < 50 % diameter reduction and peak systolic velocity < 2.4 at 12 months

4. Ankle-Brachial Index improvement of ≥ 0.1 (ABI before procedure compared with ABI at 1,6,9 & 12 months).

5. Clinically driven Target Vessel Revascularization at 6, 9 and 12 months.

6. Major complications at 6,9 and 12 months, including amputation of a part of the foot, the leg below and above the knee.

7. The Rutherford-Becker classification of chronic limb ischemia at 1, 6, 9 and 12 months post procedure.

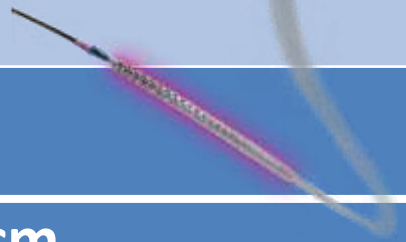
angiolite

Sirolimus eluting stent

Exclusive stent design for DES

TransferWise

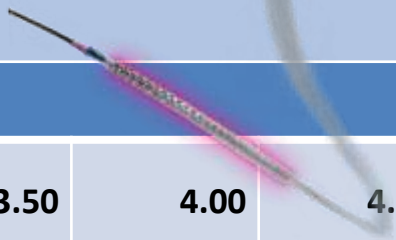
STENT CHARACTERISTICS	
STENT MATERIAL	CoCr L605
WALL THICKNESS	75 microns for stent 2 to 2.5mm 80 microns for stent 2.75 to 3.5mm 85 microns for stent 4 to 4.5mm
% RECOIL	< 5%
% FORESHORTENING	< 3%
% SURFACE IN CONTACT WITH ARTERY	10-20%
VESSEL CONFORMABILITY	High
DRUG COATING FEATURES	
DRUG	Sirolimus
DRUG DOSE	1,4 µg/mm²
POLYMER	Biostable



SYSTEM DIMENSIONS	
Working length of the catheter	142 cm
Catheter shaft (diameter)	2F Proximal 2.6F Middle 2.2F Distal
Distance guidewire entry to tip	25 cm
Entry profile	0.016 inch
Recommended guidewire	0.014 inch

CHARACTERISTICS OF THE STENT PRE-MOUNTED ON BALLOON	
MATERIAL	Nylon and Pebax. Final product without latex components
BALLOON	Semi-compliant
NOMINAL PRESSURE	9 - 12 atm
RATED BURST PRESSURE (RBP)	16 atm
AVERAGE BURST PRESSURE (ABP)	22 atm
STENT CROSSING PROFILE (at max. length of the stent)	
Diameter (mm)	INCHES –mm-FRENCH
2.00	0.043 – 1.10 – 3.30
2.25	0.043 – 1.10 – 3.30
2.50	0.043 – 1.10– 3.30
2.75	0.046 – 1.18– 3.54
3.00	0.046 – 1.18– 3.54
3.50	0.047 – 1.20– 3.60
4.00	0.049 – 1.25– 3.75
4.50	0.051 – 1.30– 3.90
RADIOPAQUE MARKERS	2 metallic markers on the catheter delimiting the stent
GUIDING CATHETER COMPATIBILITY	5F

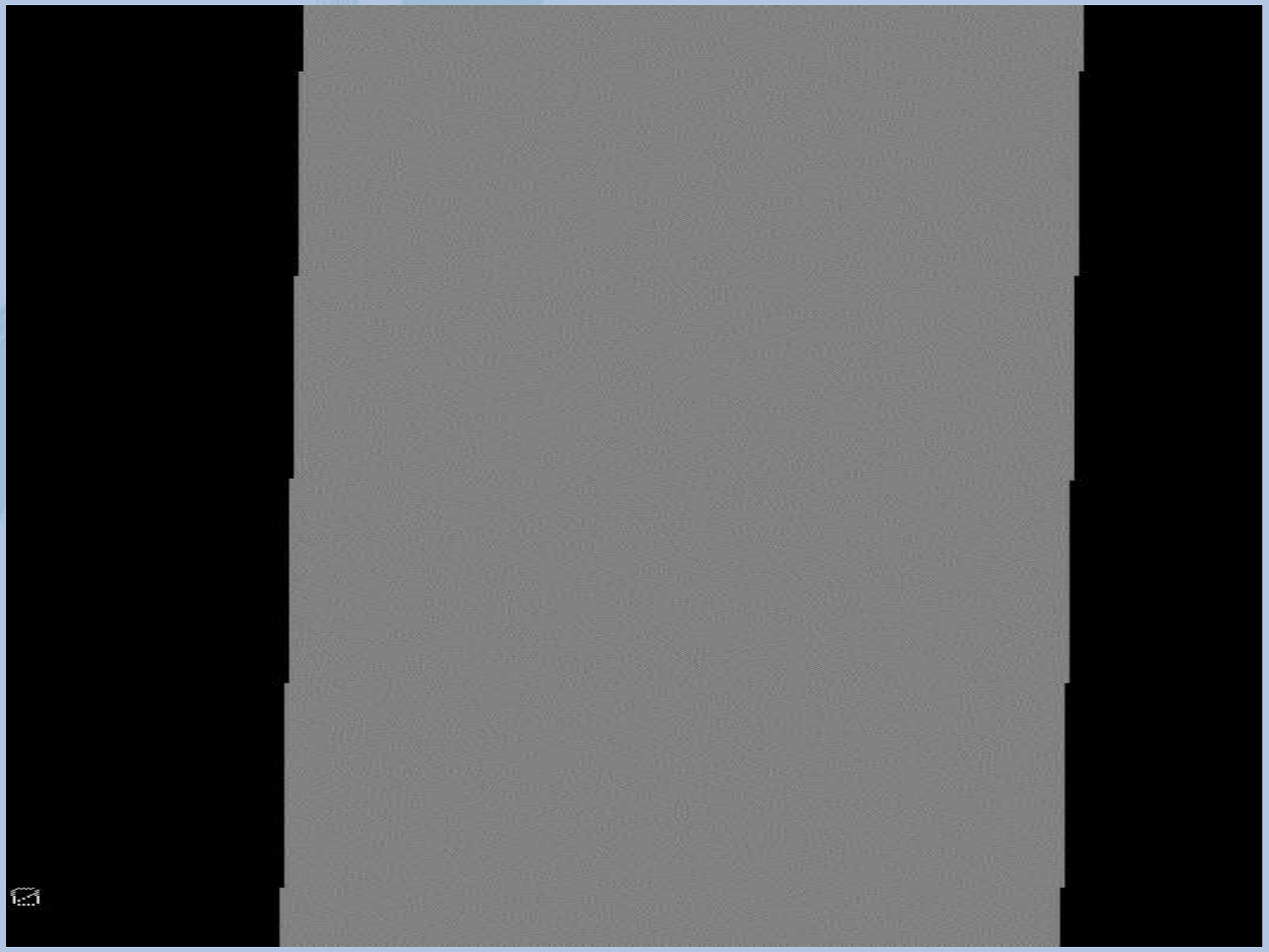
Angiolite BTK : Portfolio of 63 different stents

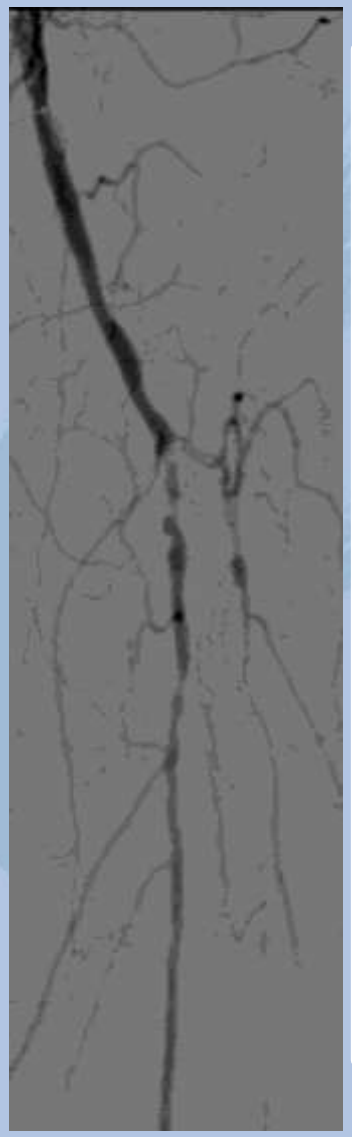
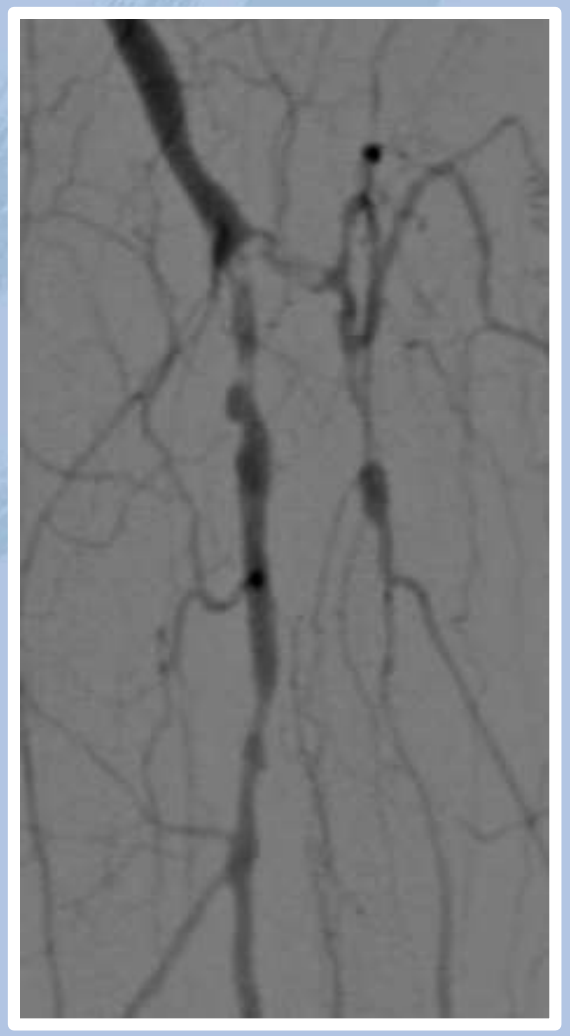
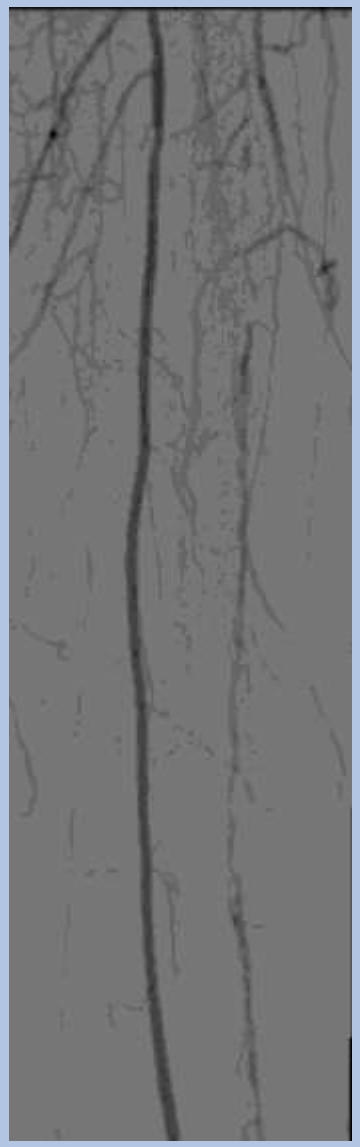
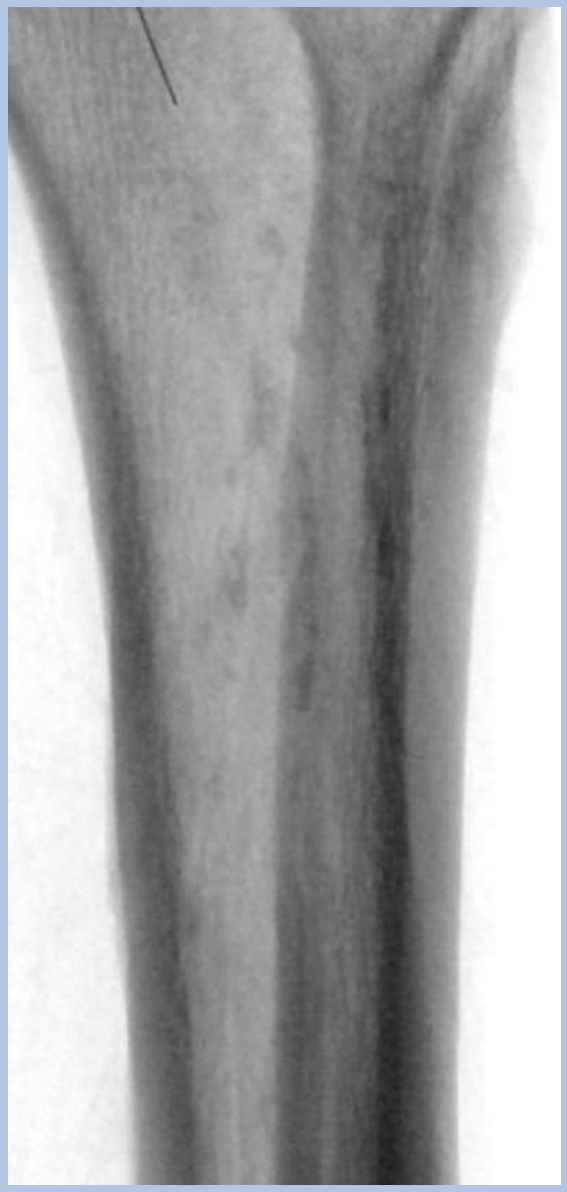


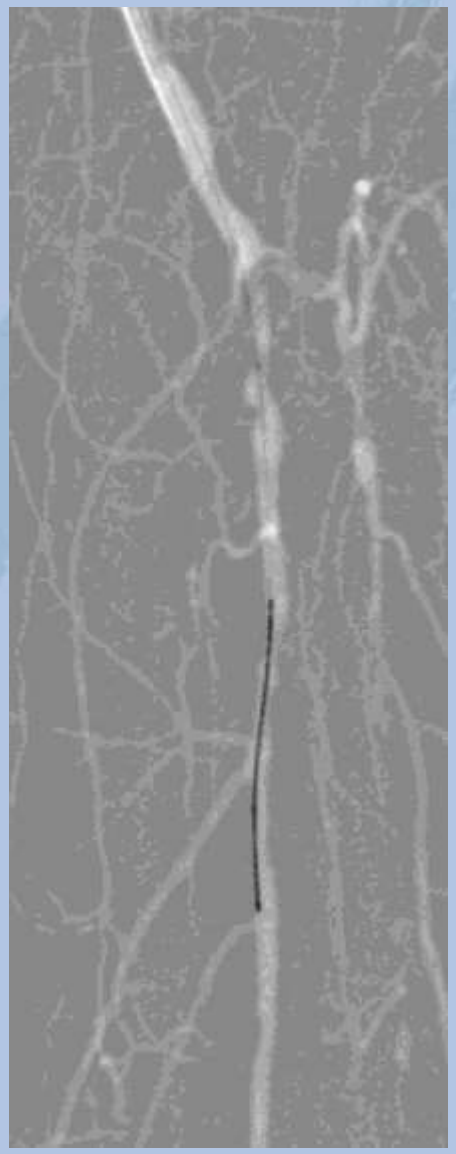
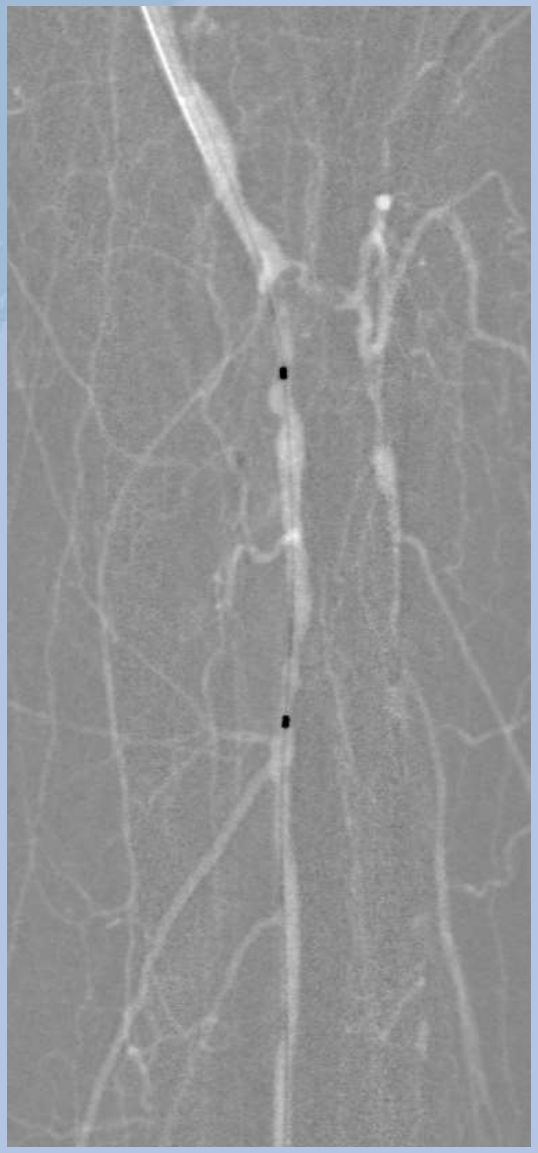
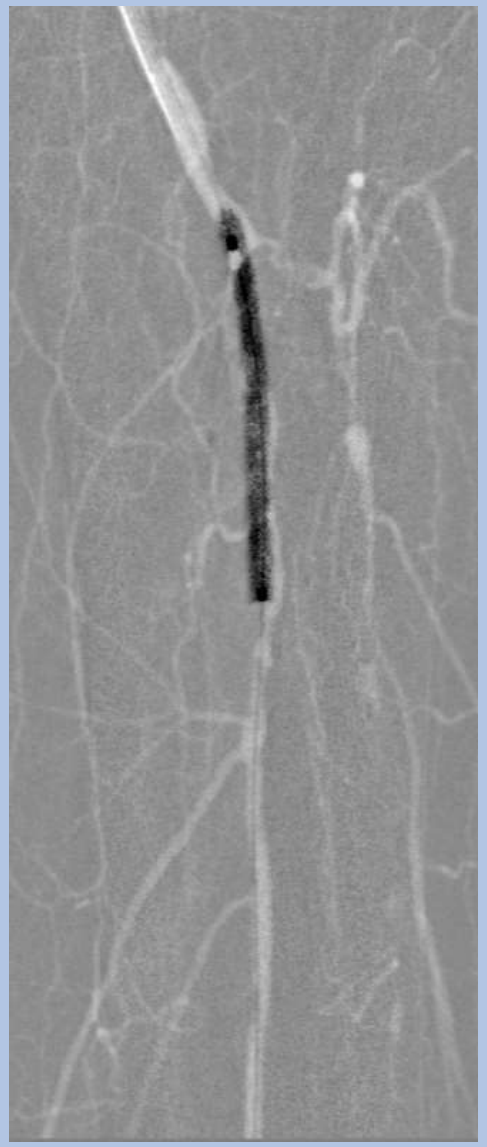
		STENT DIAMETERS (mm)							
		2.00	2.25	2.50	2.75	3.00	3.50	4.00	4.50
STENT LENGTHS (mm)	9	X	X	X	X	X	X	X	
	14	X	X	X	X	X	X	X	X
	16	X	X	X	X	X	X	X	X
	19	X	X	X	X	X	X	X	X
	24	X	X	X	X	X	X	X	X
	29	X	X	X	X	X	X	X	X
	34	X	X	X	X	X	X	X	X
	39	X	X	X	X	X	X	X	X

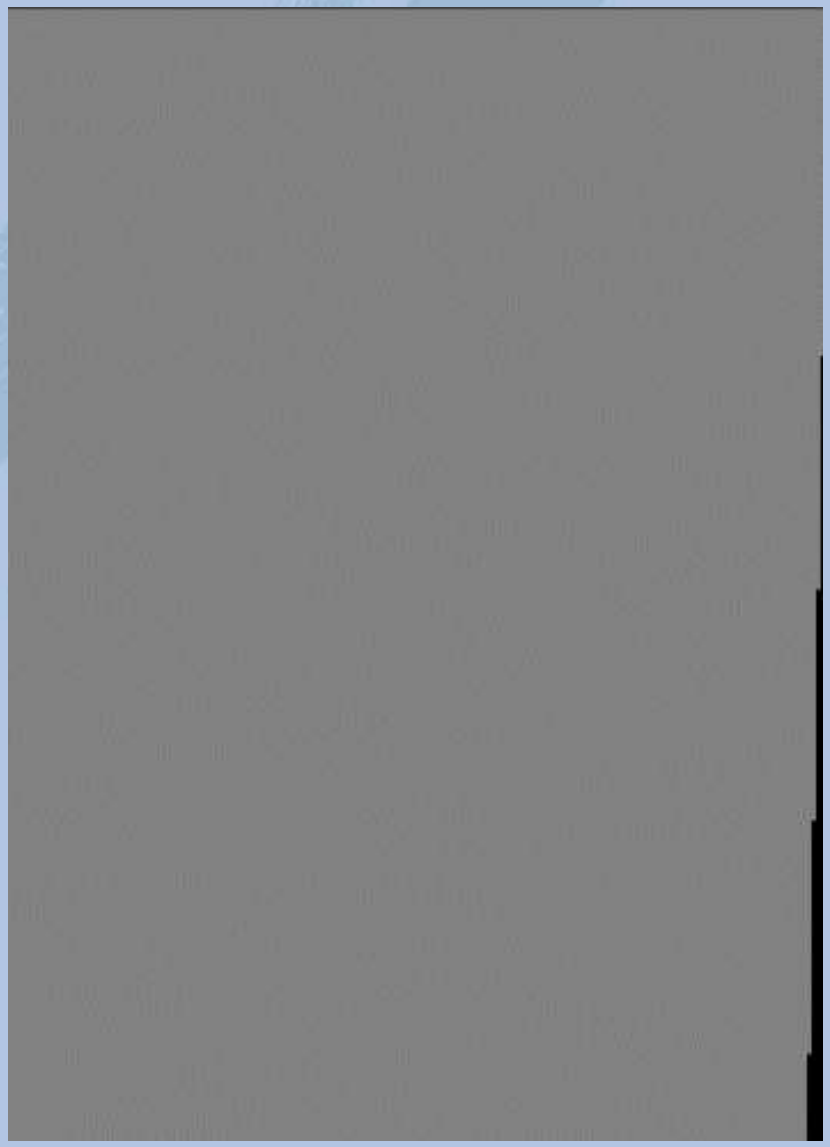
case

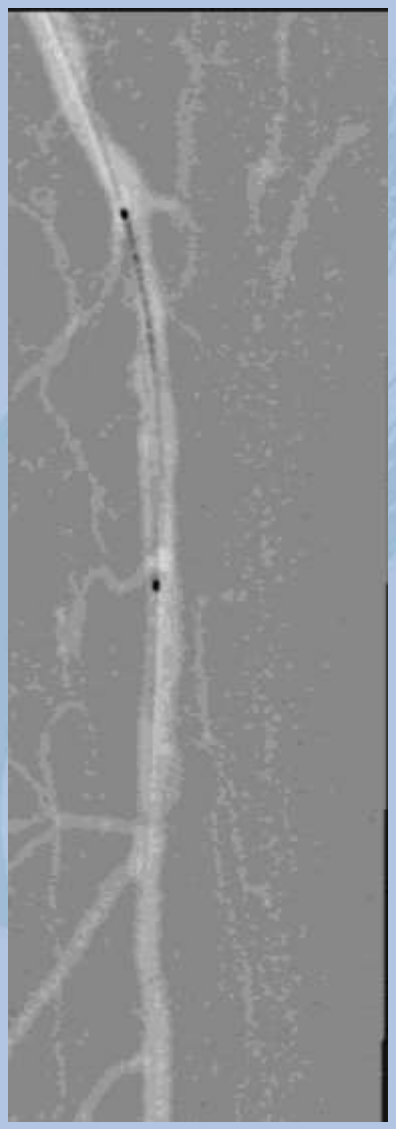
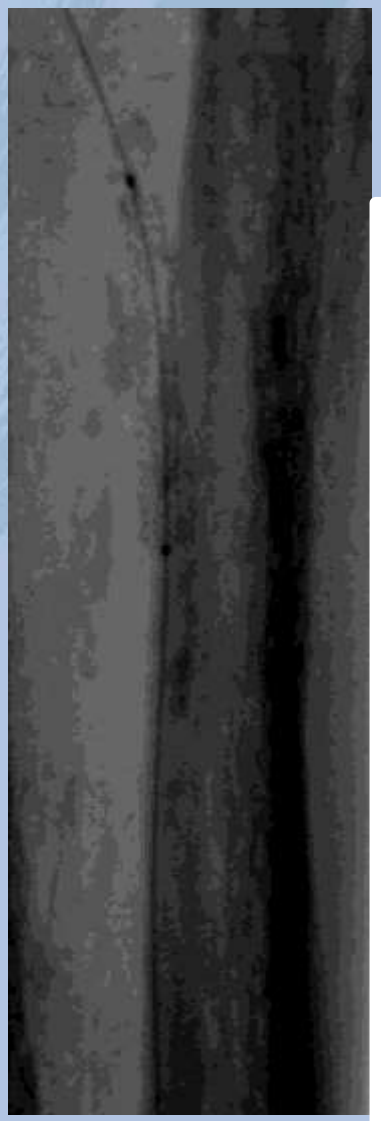
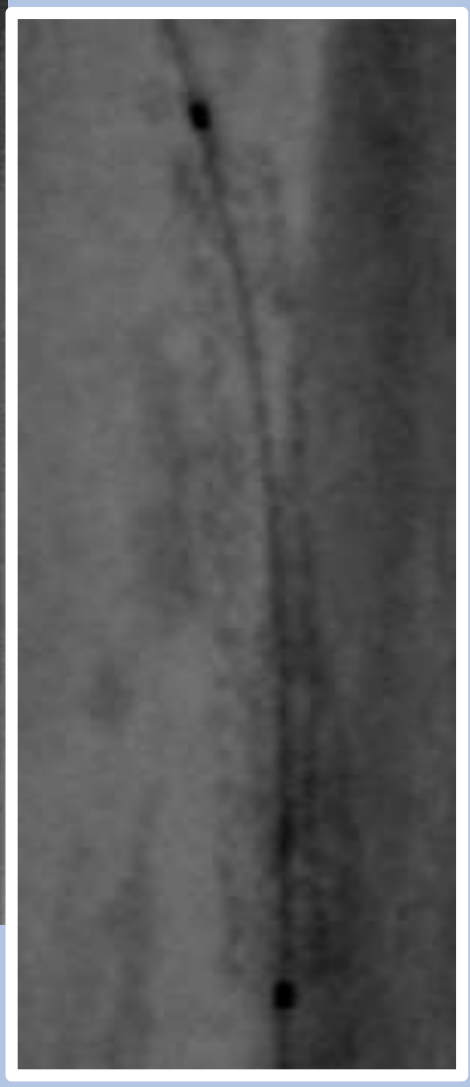
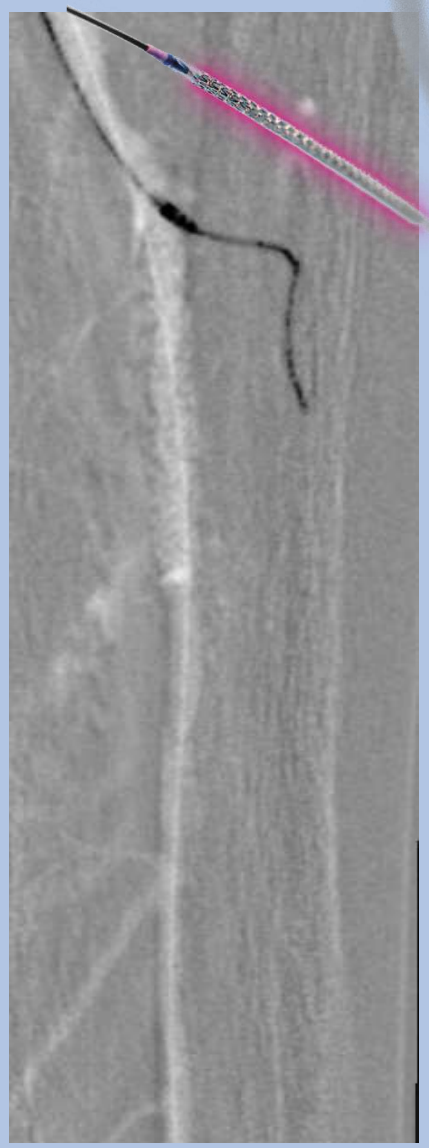
- 77 y man
- Diabetes type1
- AHT
- AMI/PTCA/CABG
- Hypercholesterolemia
- 5 PTAs fempop region
- Rutherford Becker 5
- Ulcers D1/D3/D5

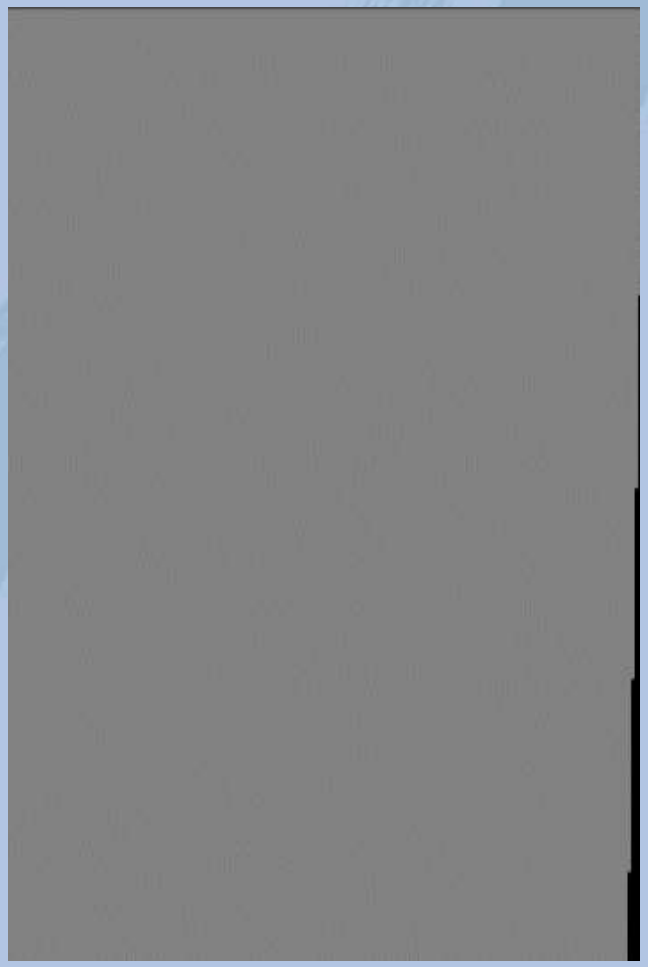


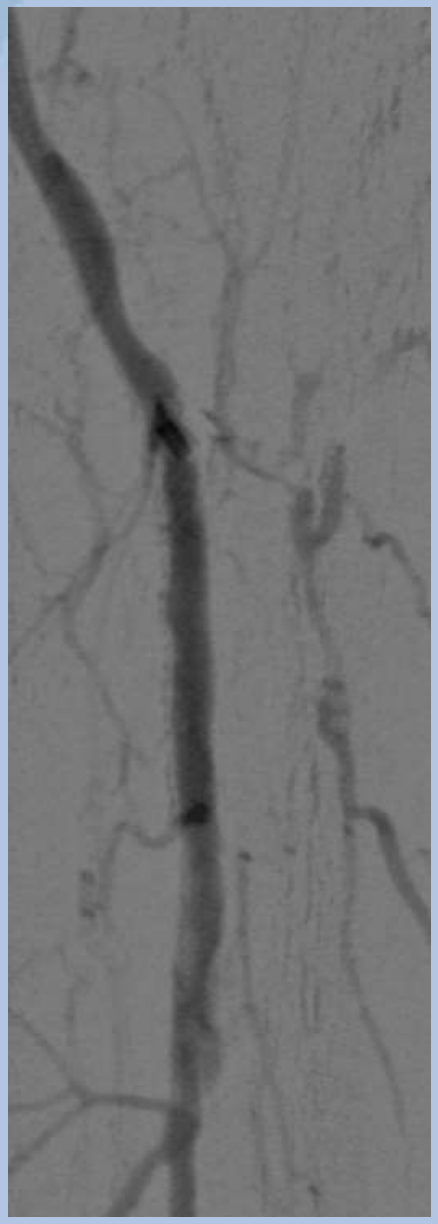





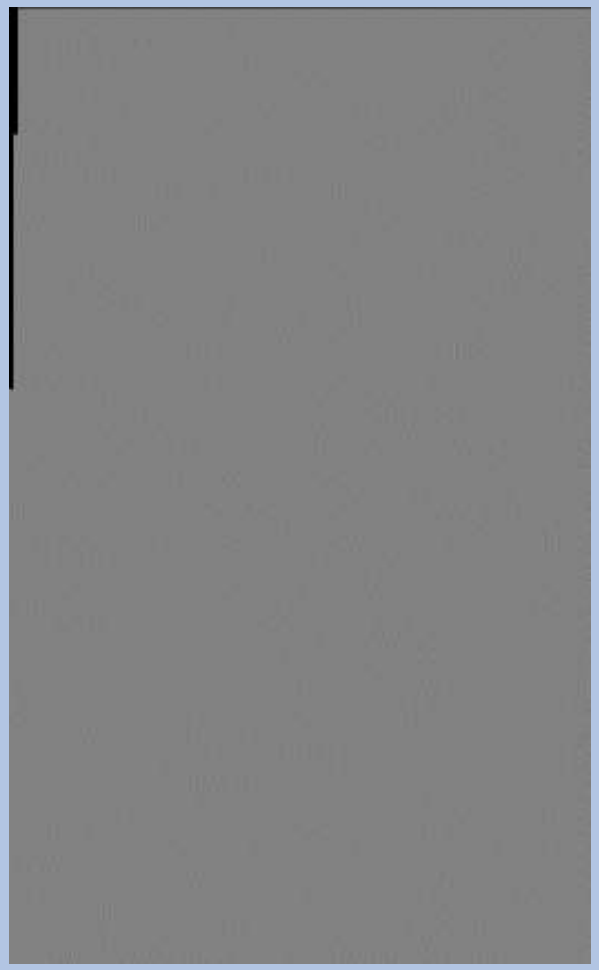




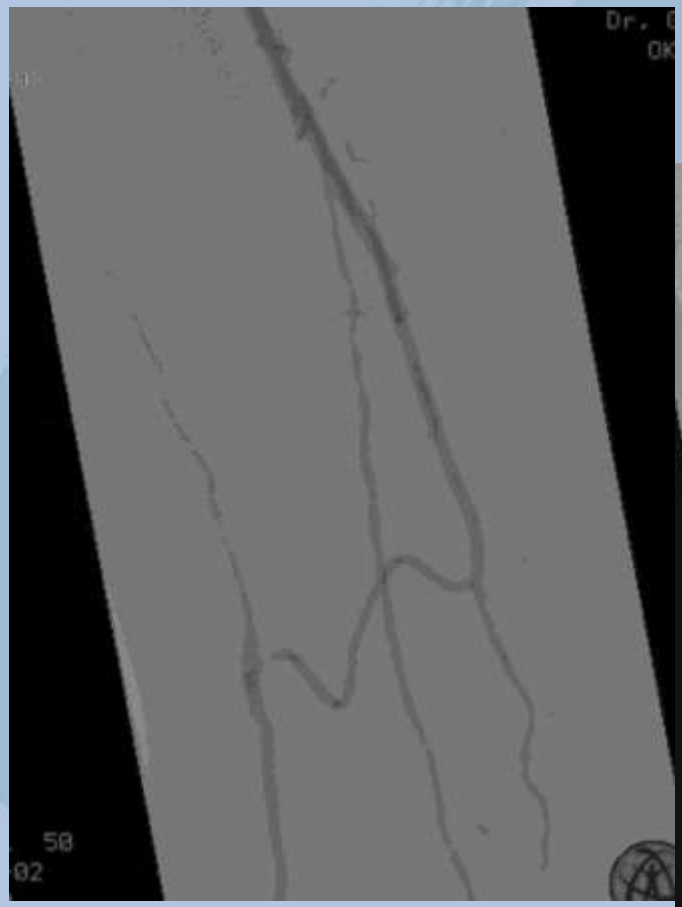


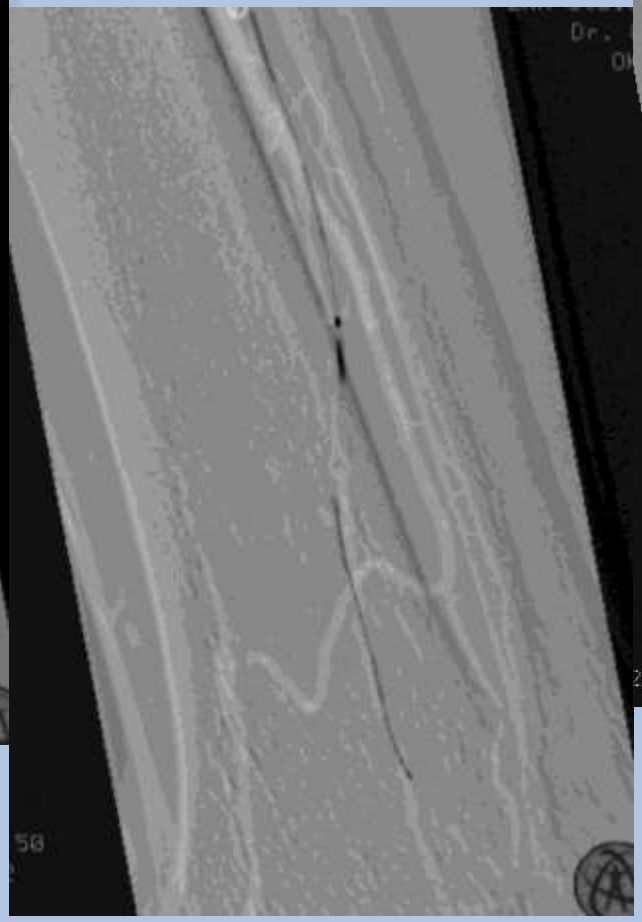





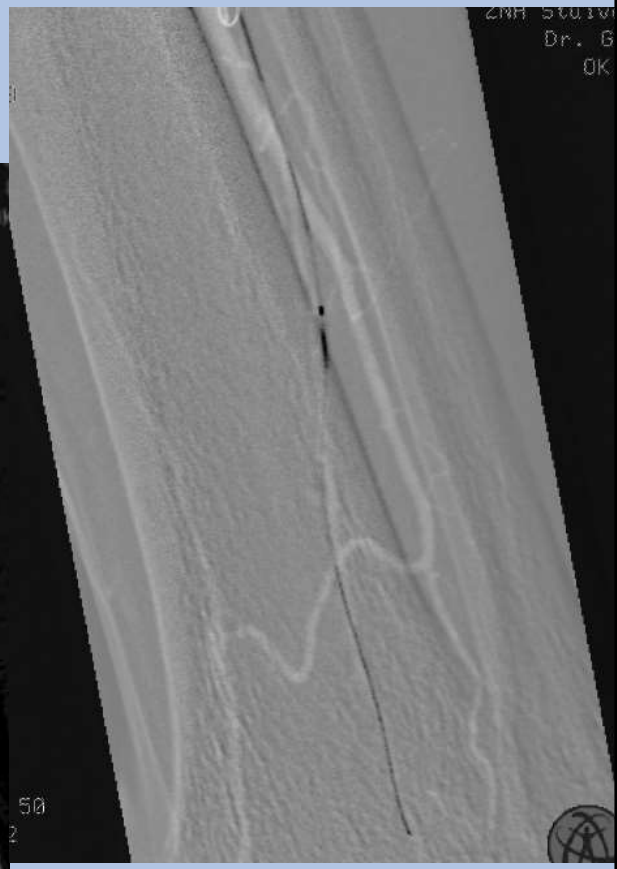


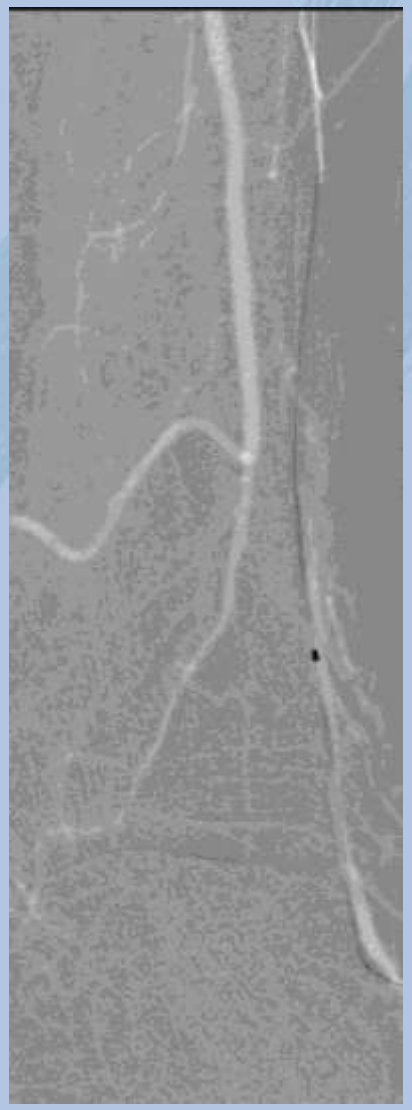
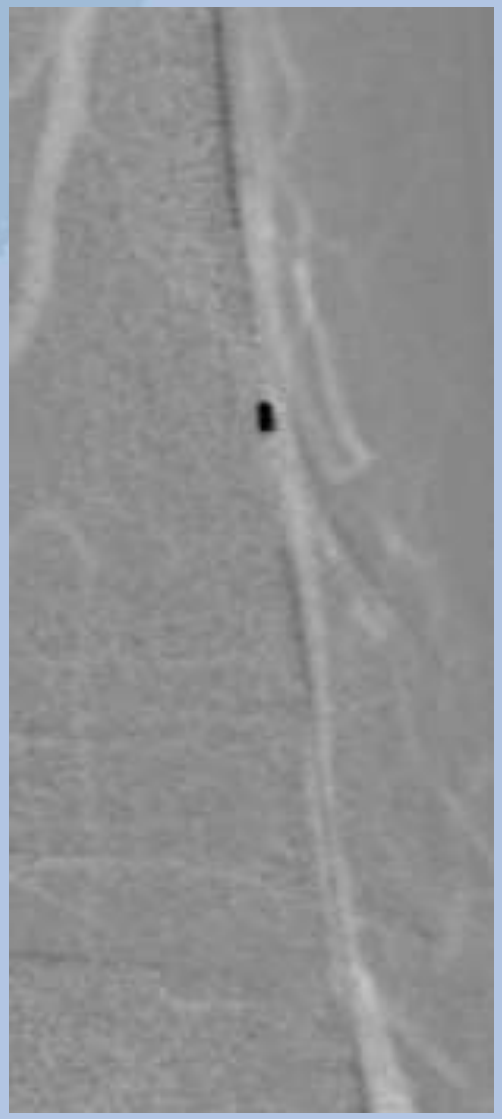
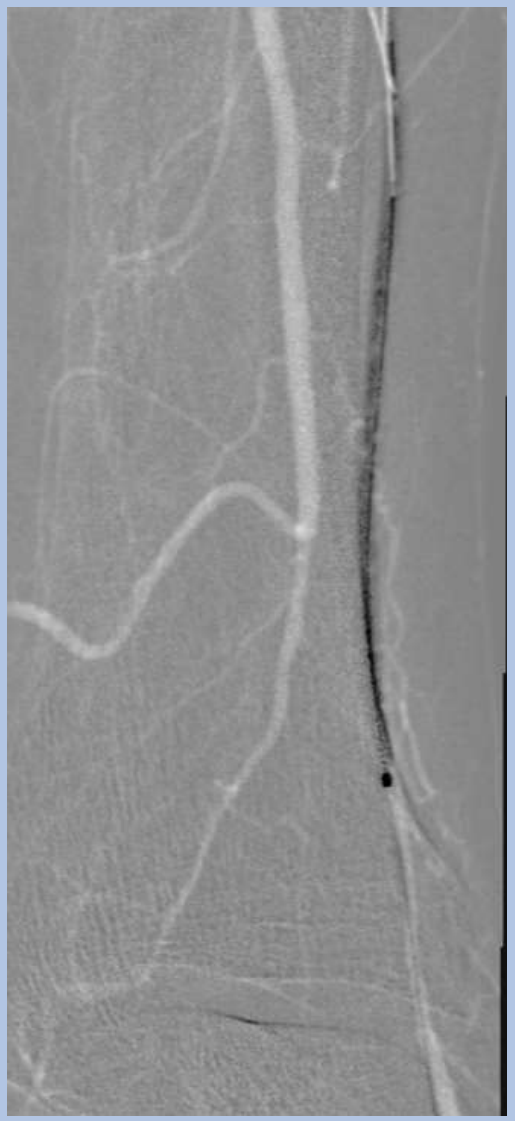


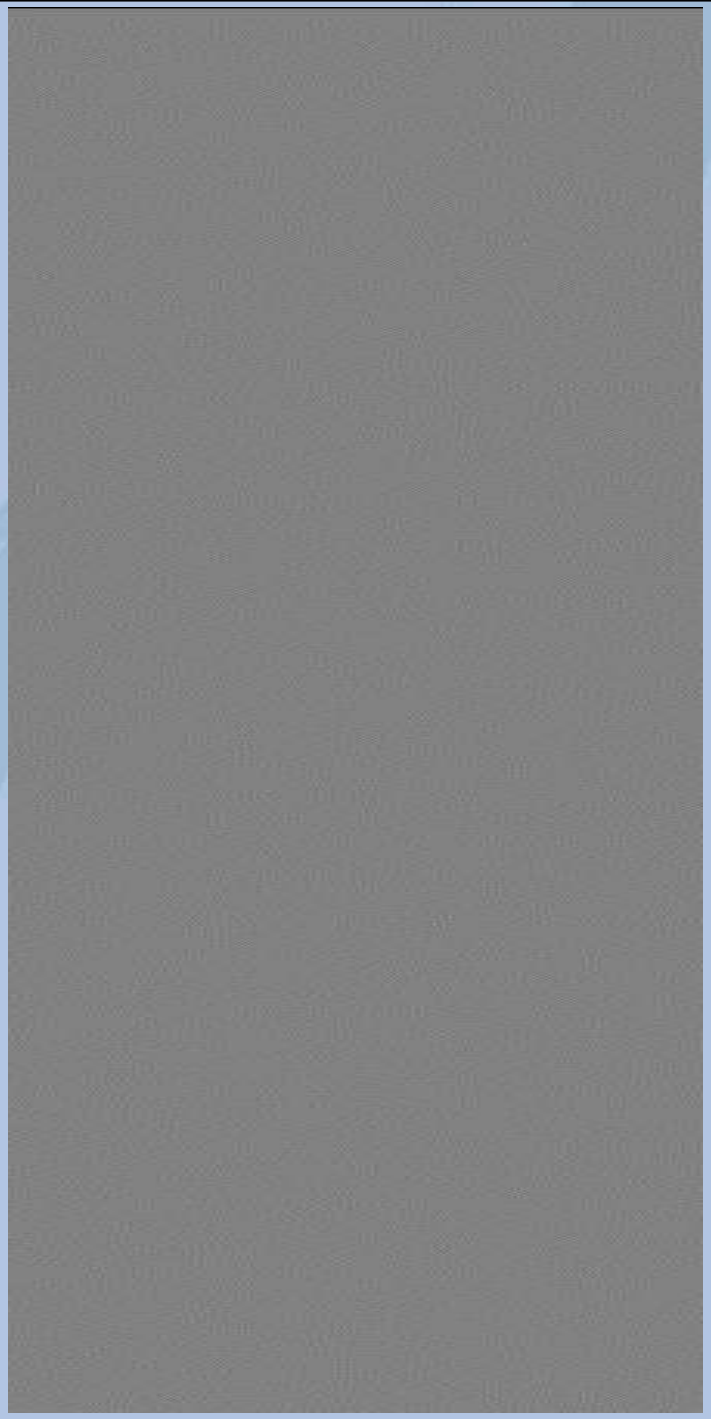


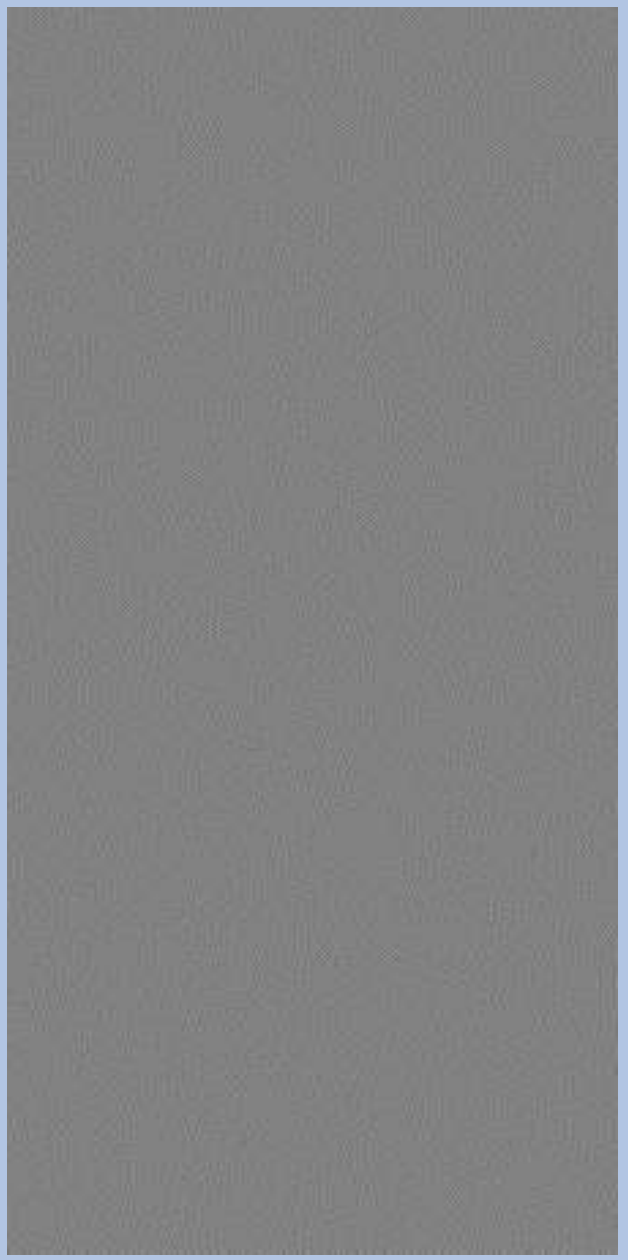


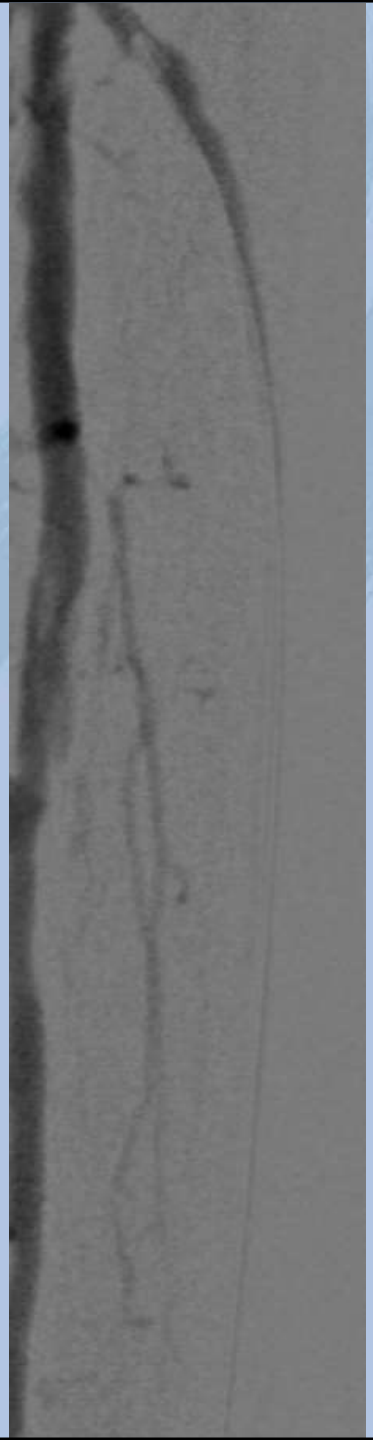
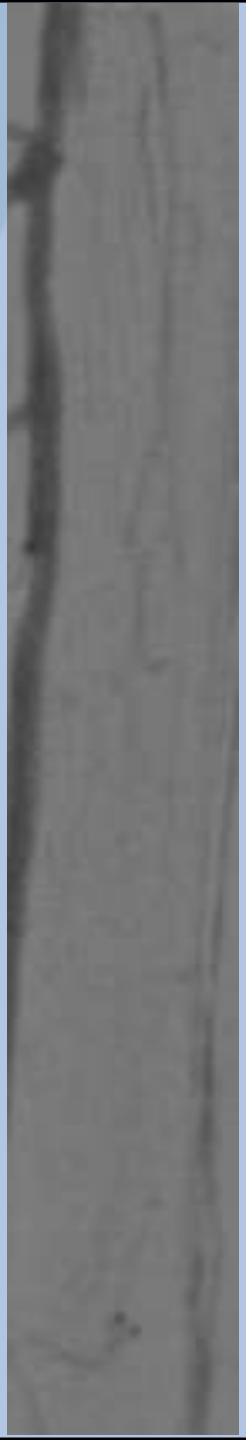
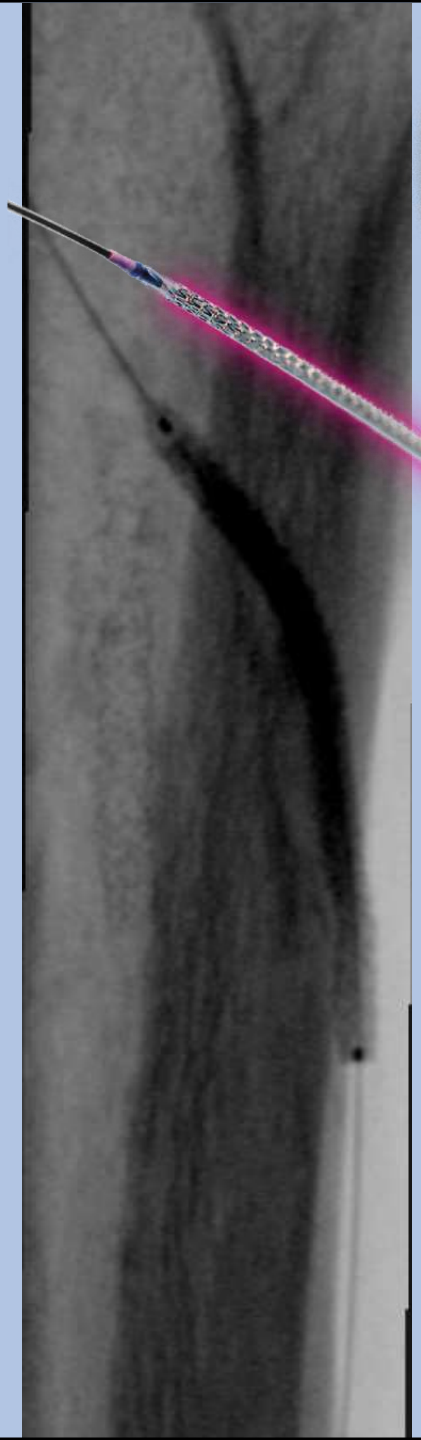


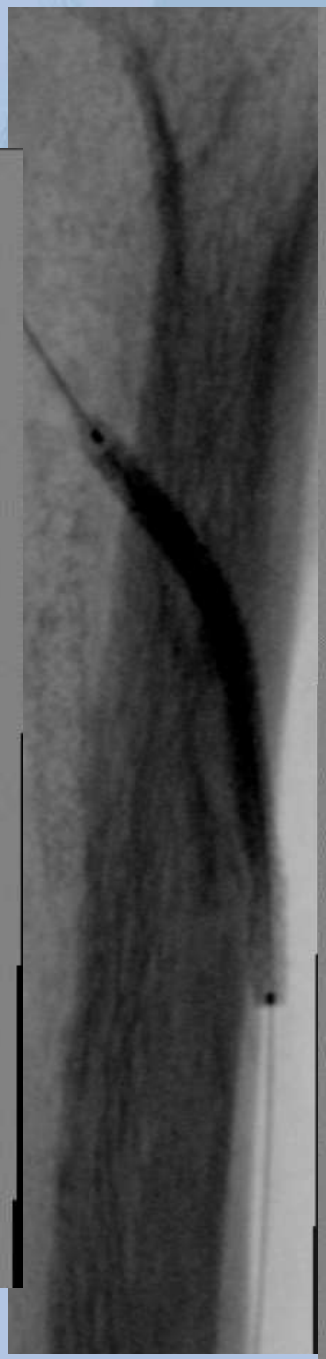
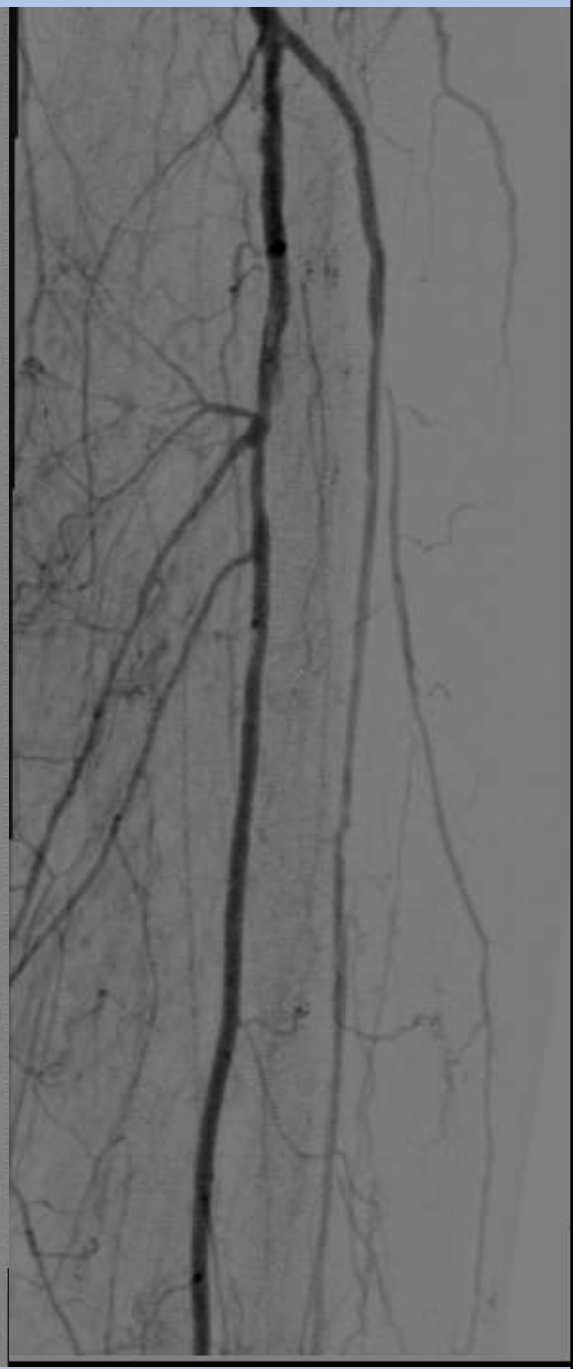






Angiolite BTK safety and feasibility study

Baseline Patient Demographics : n = 50

Male Gender	35
Mean Age	71.1
Mean BMI	31.7
Nicotine abuse (present&past) (%)	88
Hypertension (%)	84
Hypercholesterolemia (%)	56
Diabetes (type 1=2) (%)	72
Vascular History (%)	48
Recurrent disease (%)	34
Coronary History (%)	58
Cerebrovascular History (%)	22
Renal insufficiency (%)	58

Angiolite BTK safety and feasibility study

Rutherford Beccker	
4	18
5	23
6	9
LESION LOCATION	**N = 64**
Tibioperoneal Trunc	24
Anterior Tibial Artery	16
Peroneal Artery	15
Posterior Tibial Artery	9

Angiolite BTK safety and feasibility study : ABI

Grade	ABI	Ankle systolic pressure	N
0	>0.80	>100 mm Hg	0
1	0.6-0.79	70-100 mm Hg	6
2	0.4-0.59	50-70 mm Hg	11
3	<0.39	<50 mm Hg	33

(WIfI) (J Vasc Surg 2014;59:220-34.)

Angiolite BTK safety and feasibility study

Procedure (1/3)	
Vessel preparation	
Predilatation/balloonangioplasty	49
Primary stenting	15
Mean lesion length	51.45 mm
Reference vessel diameter	3.43 mm
Mean stenosis before treatment	93.43 %
Number of occlusions	52%
Presence Moderate to heavy calcifications	78%
Use of Drug Coated Balloon (mainly for distal vessel treatment)	34%

Angiolite BTK safety and feasibility study

Procedure (2/3)	
Stents used	68
Tibioperoneal trunc	24
Anterior Tibial artery	18
Peroneal Artery Posterior Tibial Artery	15 11
Mean stent diameter	3.32 mm
Mean stent length	32.1 mm
Number stents / patient	1,36
1	34
2	14
3	2

Angiolite BTK safety and feasibility study

Procedure (3/3)	N
Access site	
ipsilateral	43
cross-over	7
Mean residual stenosis at end of procedure (%)	18.5%
Mean Heparine (IU)	6250IU
Mean contrast	94.5 ml
Patients + CO^2 angio	26
Access hemostasis closure device	47/50
Technical success (<30% diameter residual Stenosis)	100

Angiolite BTK safety and feasibility study

- **Post procedure** :
  - aspirin (for life) + clopidogrel (min 6 mo)
  - Anticoagulation or NOAC + clopidogrel (6 mo)
- Follow-up :
  - 1,3,6,9,12 (18,24, 36) months ultrasound
  - 2-14months
- Death : 3
  - D41 : AMI
  - D87 : sepsis/MOF
  - D135 : cardiovascular
-

Angiolite BTK safety and feasibility study: wound follow-up

1)PEDIS Classification

Definition

The **PEDIS classification** is a faceted classification that provides a taxonomy for classifying lesions in patients with diabetic foot syndrome.

Every lesion is described according to the following scheme:

- **Perfusion**
  - Grade 1: no symptoms/signs of PAD
  - Grade 2: symptoms or signs of PAD, but not CLI
  - Grade 3: CLI
- **Extent/size (cm^2)**
- **Depth/tissue loss**
  - Grade 1: Superficial full-thickness ulcer
  - Grade 2: Ulcer penetrating below dermis to skin structures
  - Grade 3: All subsequent layers of foot, including bone/joint

Angiolite BTK safety and feasibility study: wound follow-up

PEDIS Classification

- **Infection**
  - **Grade 1: no symptoms/signs**
  - **Grade 2: Inflammation of skin/sc only**
  - **Grade 3: Extensive erythema deeper than skin/sc**
  - **Grade 4: Systemic inflammatory response syndrome (SIRS)**
- **Sensation**
  - **Grade 1: No loss of protective sensation**
  - **Grade 2: Loss of protective sensation**

Example: P2E1D2I1S2.

Angiolite BTK safety and feasibility study: wound follow-up : 30 days

PEDIS Classification

- **PEDIS Pre-intervention :**
  - **P: 3 E: 5.2 D: 2.41 I: 2.63 S: 1.73**
- **PEDIS 30 days :**
  - **P: 1.37 E: 2.13 D: 1.32 I: 0.83 S: 0.49**

Angiolite BTK safety and feasibility study: wound follow-up

The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIfI) (J Vasc Surg 2014;59:220-34.)

	Grade	Pre-intervention	30 days
Wound	0-1-2-3	1.2	0.66
Ischemia	0-1-2-3	2.54	1.12
Foot Infection	0-1-2-3	1.22	0.23

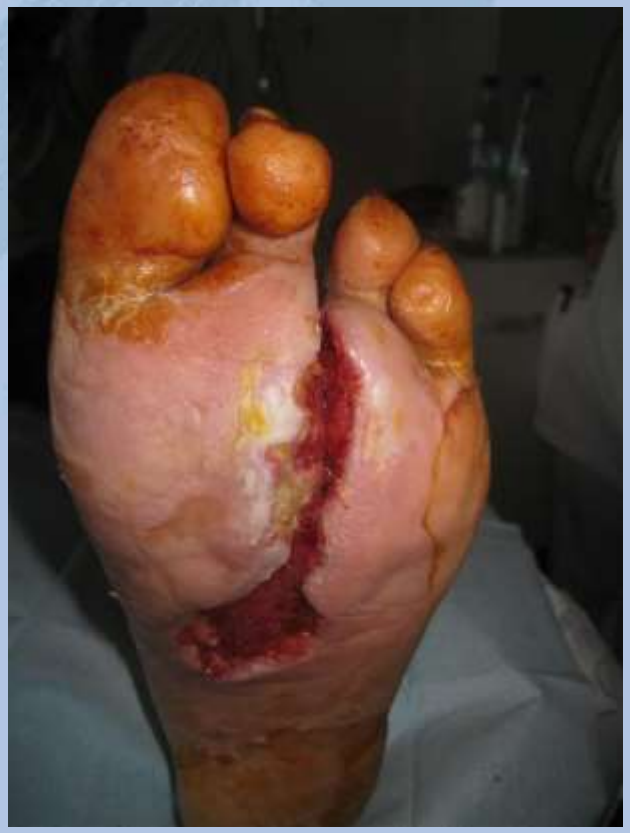
Angiolite BTK safety and feasibility study

(preliminary %)

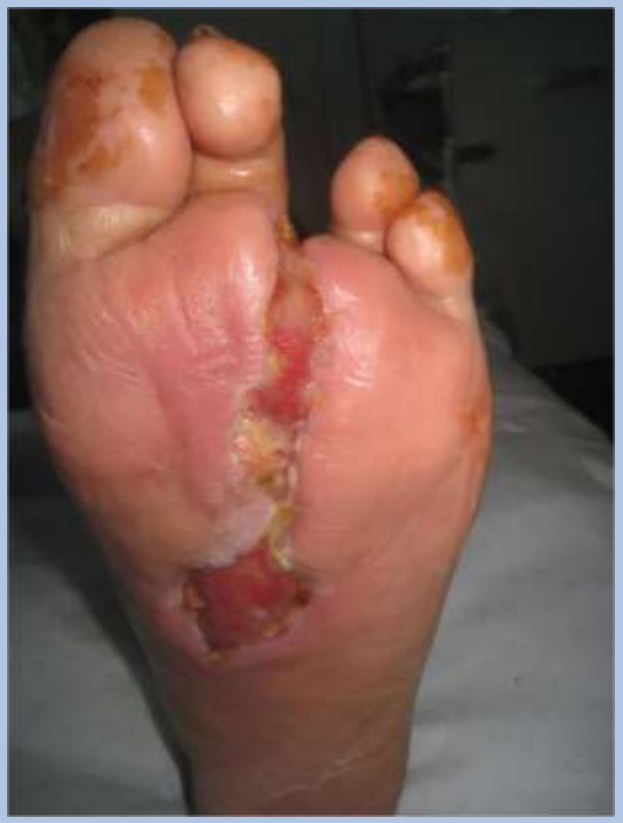
	30 days	6 Mo	9 Mo	12 Mo	18 Mo
Primary Patency	100 %	88%			
Secunadary Patency	100 %	96%			
Freedom TLR	100 %	94%			
Freedom of major amputation	98 %	94%			
Freedom Minor amputation	77.6%	72 %			

Vacuum therapy

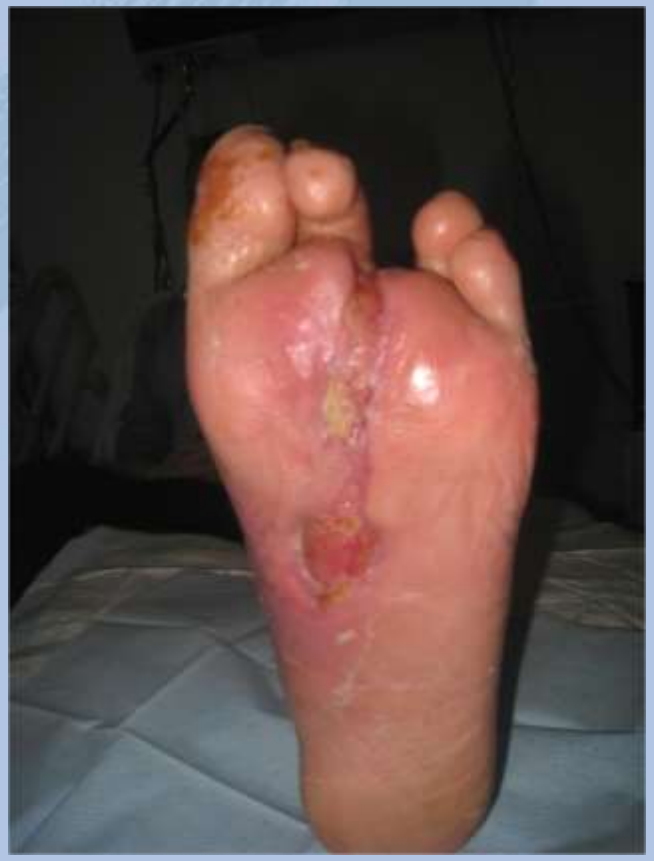
- After 2 weeks

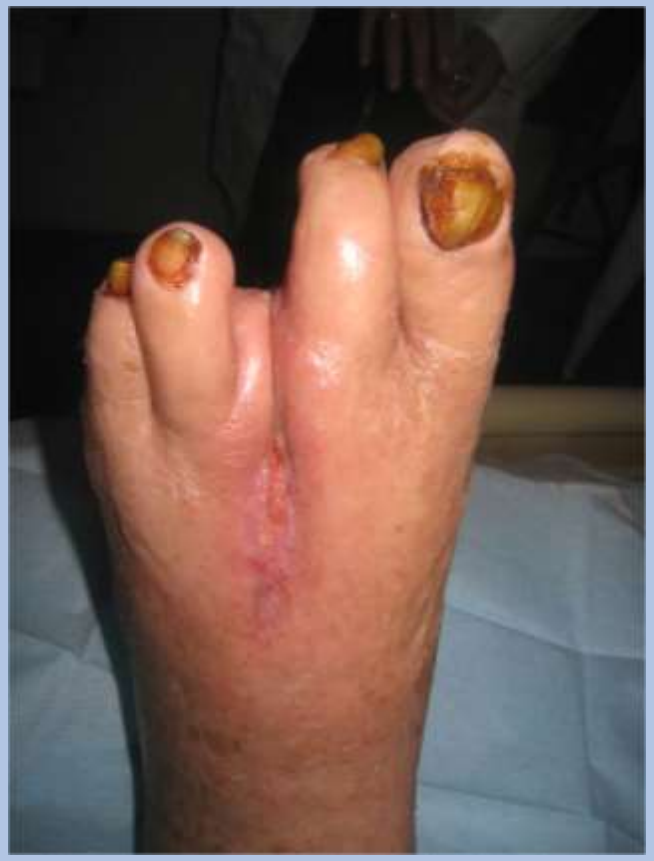


- After 5 weeks



- **After 7 weeks**

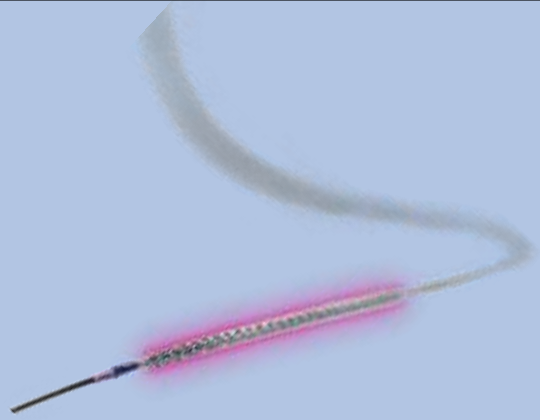




Conclusions

- Use of Angiolite BTK is safe and feasible
- Follow-up needs to confirm advantages
- Positive effect on revascularization/wound healing
- Further follow-up is needed


Thank You for your attention



Is there still any space left for DES in the BTK area ??? (Angiolite BTK trial, 6 month Data)

(Angiolite BTK DES, IVascular)

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