



Below-the-knee dedicated sirolimus eluting stent : 6 months results

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Disclosure

Speaker name: PETER GOVERDE

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- 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

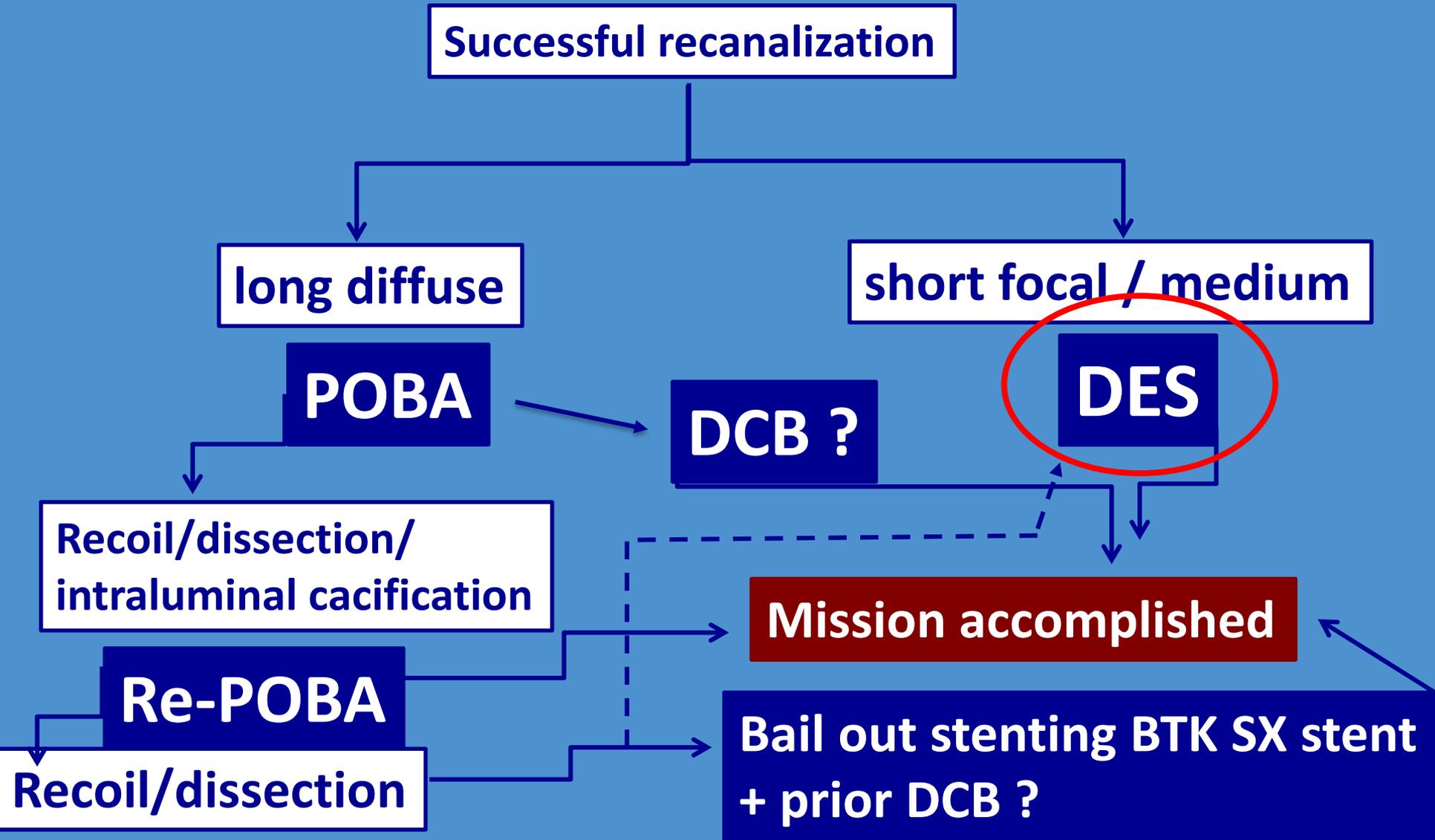


Treatment of BTK lesions





Endo treatment strategy BTK





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 , non randomized trial**
- **N= 50 patients**
- **Rutherford-Becker : 4-5-6**



Angiolite BTK safety and feasibility study

Primary Endpoints

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

Secondary Endpoints

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



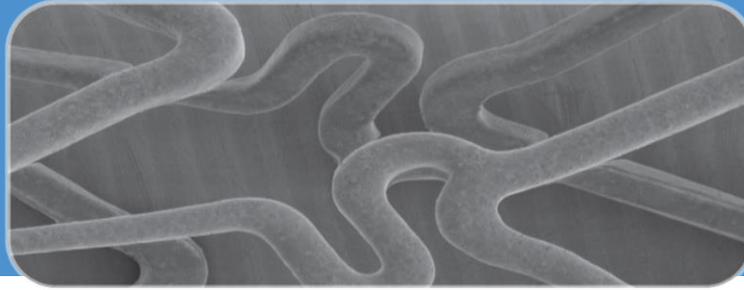
Angiolite BTK safety and feasibility study

Secondary Endpoints

- **Primary and secondary patency rate (duplex ultrasound) defined as $< 50\%$ diameter reduction and peak systolic velocity < 2.4 at 12 months**
- **Ankle-Brachial Index improvement of ≥ 0.1 (ABI before procedure compared with ABI at 1,6,9 & 12 months)**
- **Clinically driven Target Vessel Revascularization at 6, 9 and 12 months**
- **Major complications at 6,9 and 12 months, including amputation of a part of the foot, the leg below and above the knee**
- **The Rutherford-Becker classification of chronic limb ischemia at 1, 6, 9 and 12 months post procedure**



Open cell design



angiolute BTK



New peripheral drug-eluting stent system

Vascular

STENT MATERIAL

CoCr L605

DRUG

Sirolimus

DRUG DOSE

1,4 µg/mm²

FLUOROPOLYMER

Biostable

RECOMMENDED GUIDEWIRE

0.014 inch

RX catheter

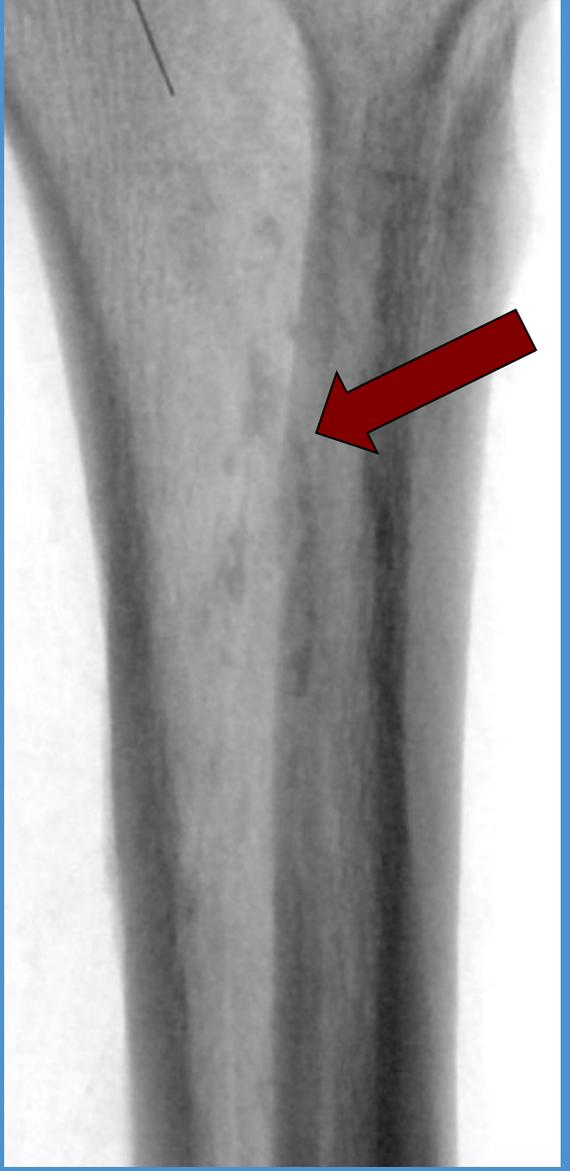
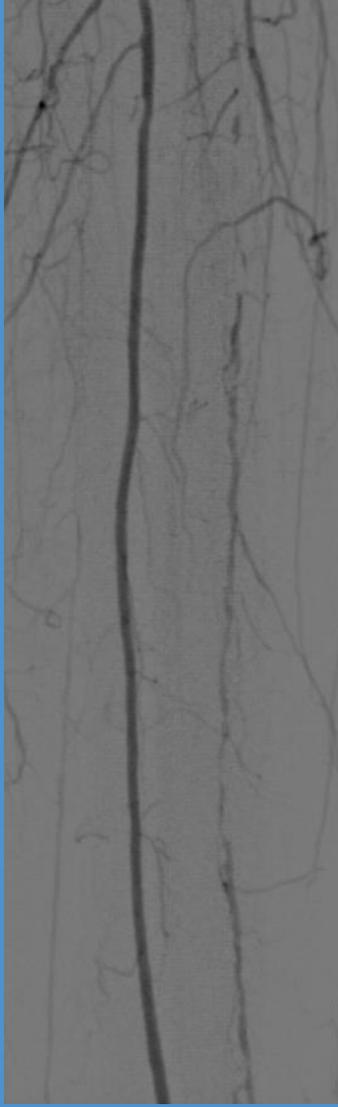
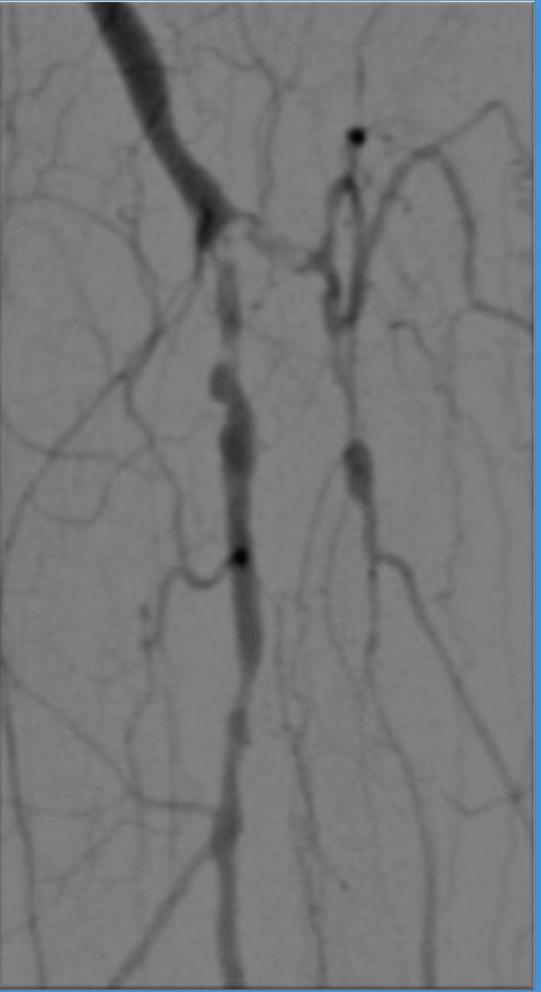
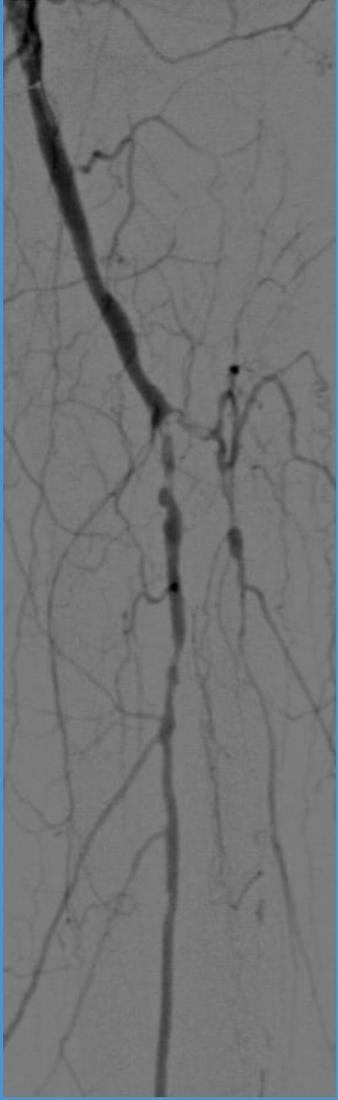
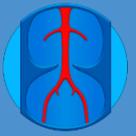
Working catheter length: 142 cm

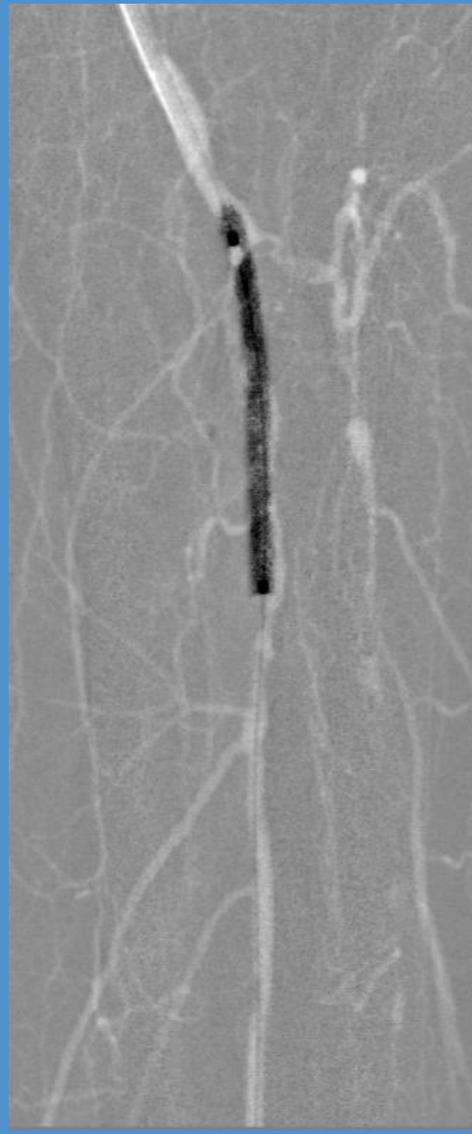
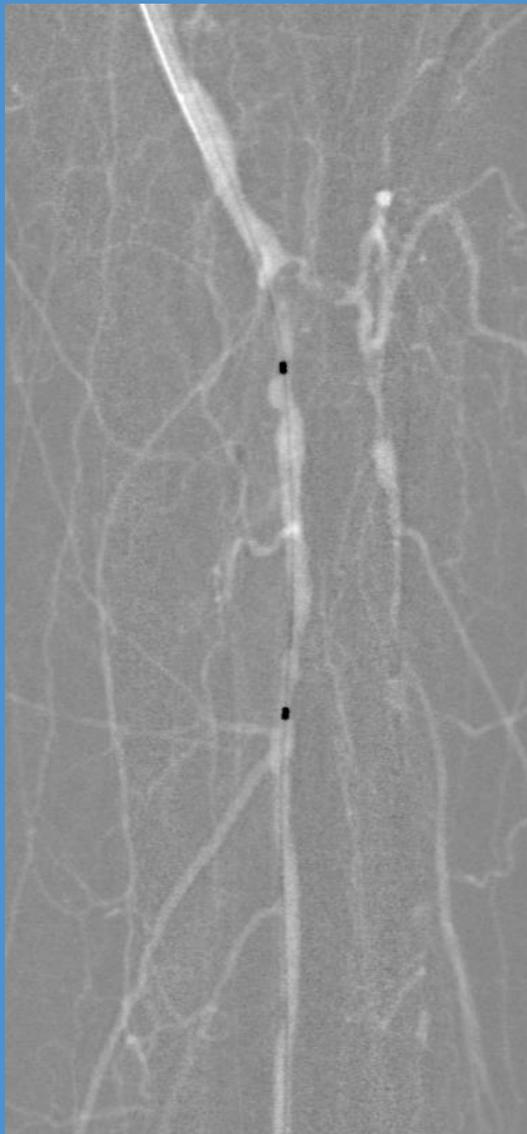
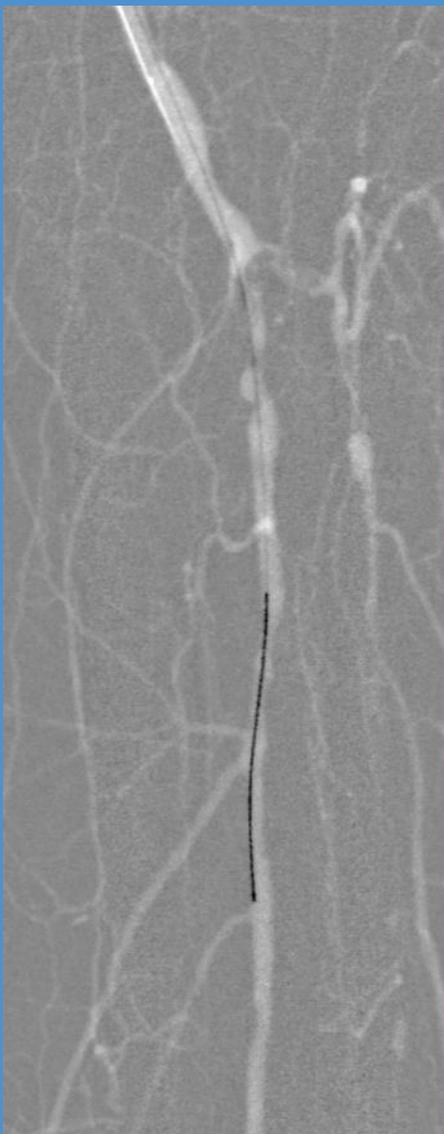
Stent diameter (mm)	Stent length (mm)							
	9	14	16	19	24	29	34	39
	2.00	SCC DSR14 150 200 009	SCC DSR14 150 200 014	SCC DSR14 150 200 016	SCC DSR14 150 200 019	SCC DSR14 150 200 024	SCC DSR14 150 200 029	SCC DSR14 150 200 034
2.25	SCC DSR14 150 225 009	SCC DSR14 150 225 014	SCC DSR14 150 225 016	SCC DSR14 150 225 019	SCC DSR14 150 225 024	SCC DSR14 150 225 029	SCC DSR14 150 225 034	SCC DSR14 150 225 039
2.50	SCC DSR14 150 250 009	SCC DSR14 150 250 014	SCC DSR14 150 250 016	SCC DSR14 150 250 019	SCC DSR14 150 250 024	SCC DSR14 150 250 029	SCC DSR14 150 250 034	SCC DSR14 150 250 039
2.75	SCC DSR14 150 275 009	SCC DSR14 150 275 014	SCC DSR14 150 275 016	SCC DSR14 150 275 019	SCC DSR14 150 275 024	SCC DSR14 150 275 029	SCC DSR14 150 275 034	SCC DSR14 150 275 039
3.00	SCC DSR14 150 300 009	SCC DSR14 150 300 014	SCC DSR14 150 300 016	SCC DSR14 150 300 019	SCC DSR14 150 300 024	SCC DSR14 150 300 029	SCC DSR14 150 300 034	SCC DSR14 150 300 039
3.50	SCC DSR14 150 350 009	SCC DSR14 150 350 014	SCC DSR14 150 350 016	SCC DSR14 150 350 019	SCC DSR14 150 350 024	SCC DSR14 150 350 029	SCC DSR14 150 350 034	SCC DSR14 150 350 039
4.00	SCC DSR14 150 400 009	SCC DSR14 150 400 014	SCC DSR14 150 400 016	SCC DSR14 150 400 019	SCC DSR14 150 400 024	SCC DSR14 150 400 029	SCC DSR14 150 400 034	SCC DSR14 150 400 039
4.50	-	SCC DSR14 150 450 014	SCC DSR14 150 450 016	SCC DSR14 150 450 019	SCC DSR14 150 450 024	SCC DSR14 150 450 029	SCC DSR14 150 450 034	SCC DSR14 150 450 039

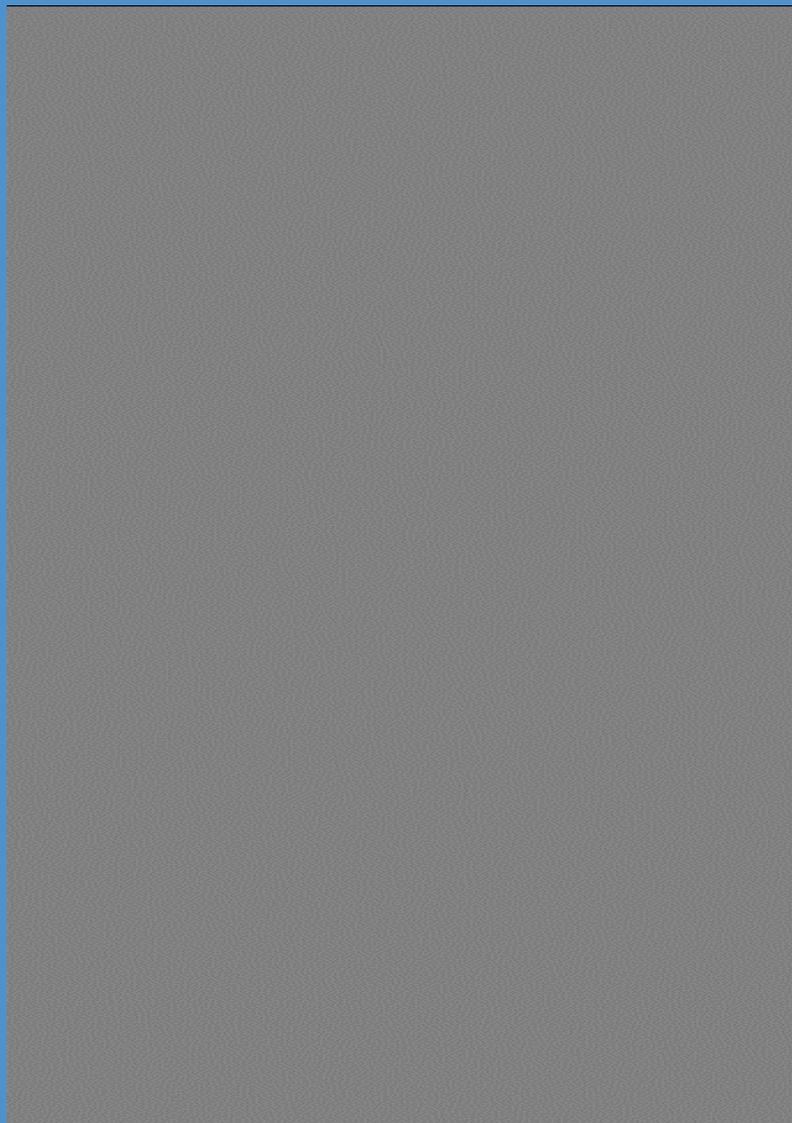


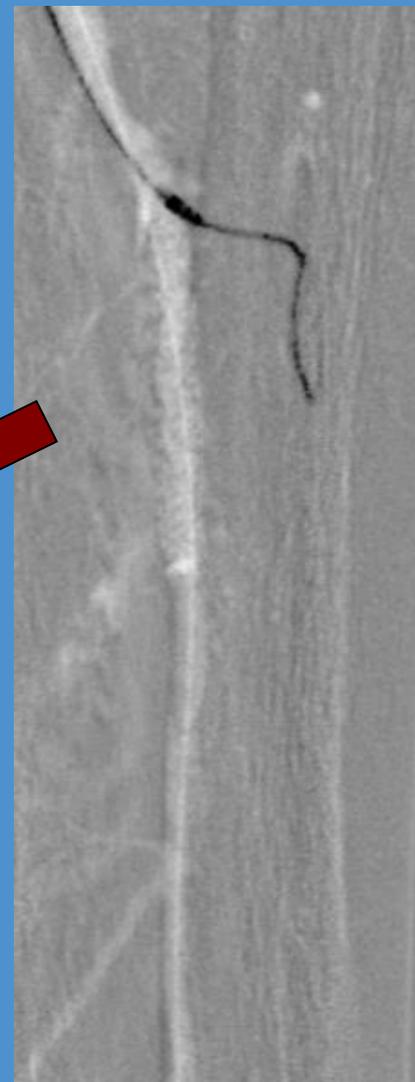
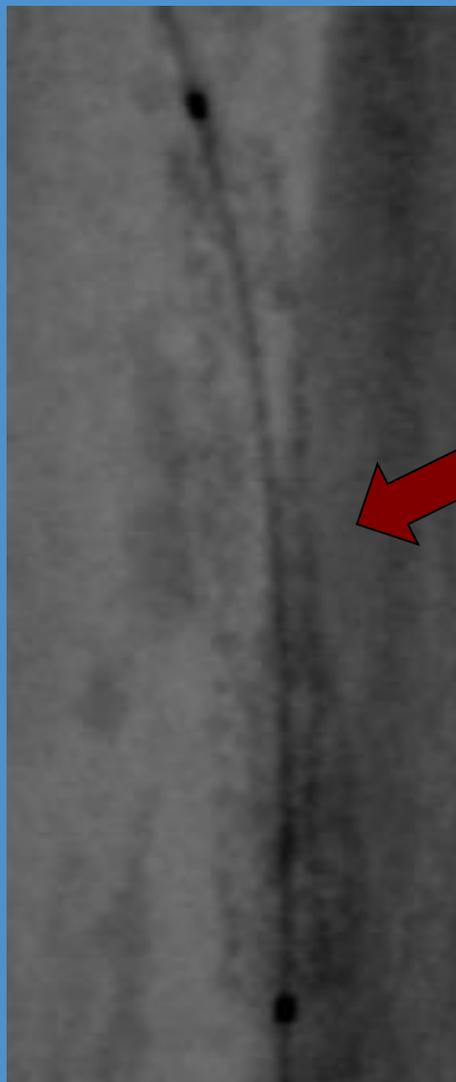
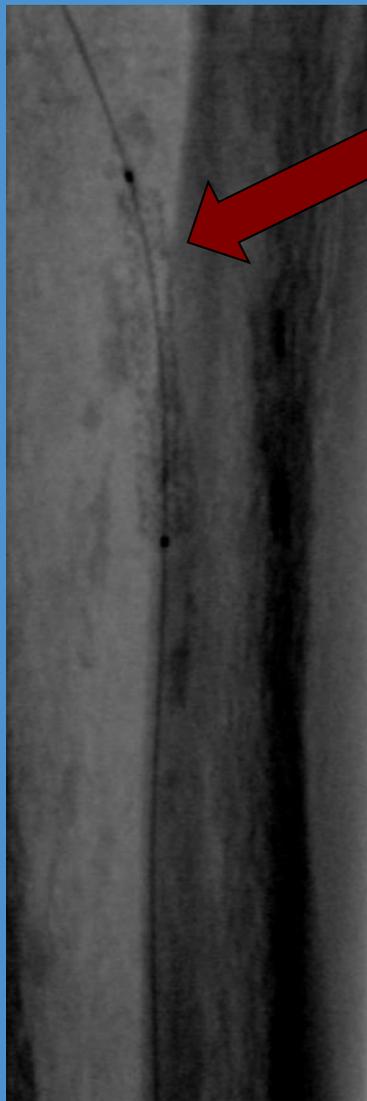
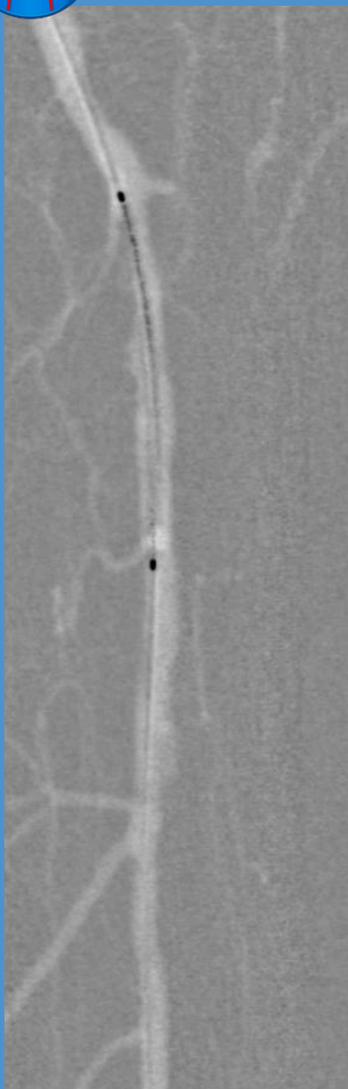
Case

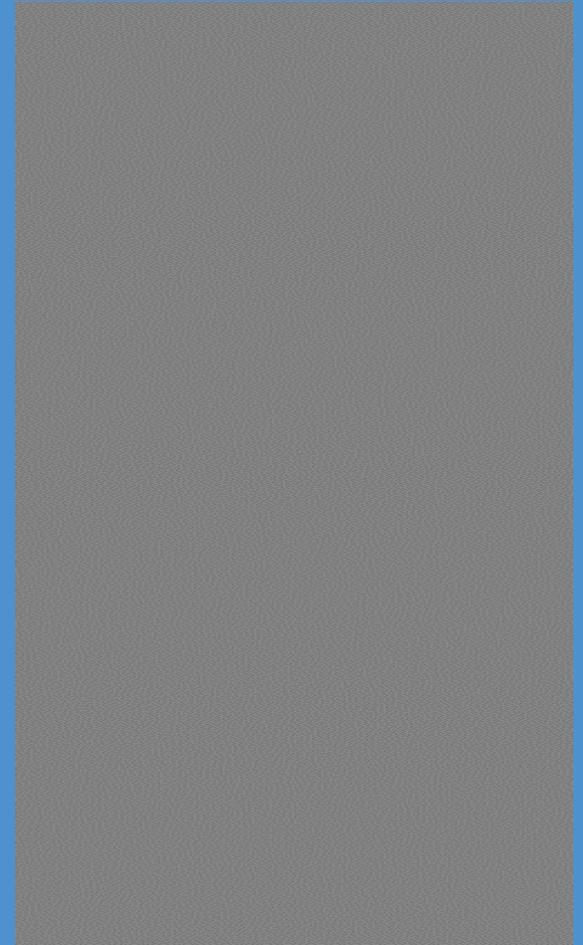
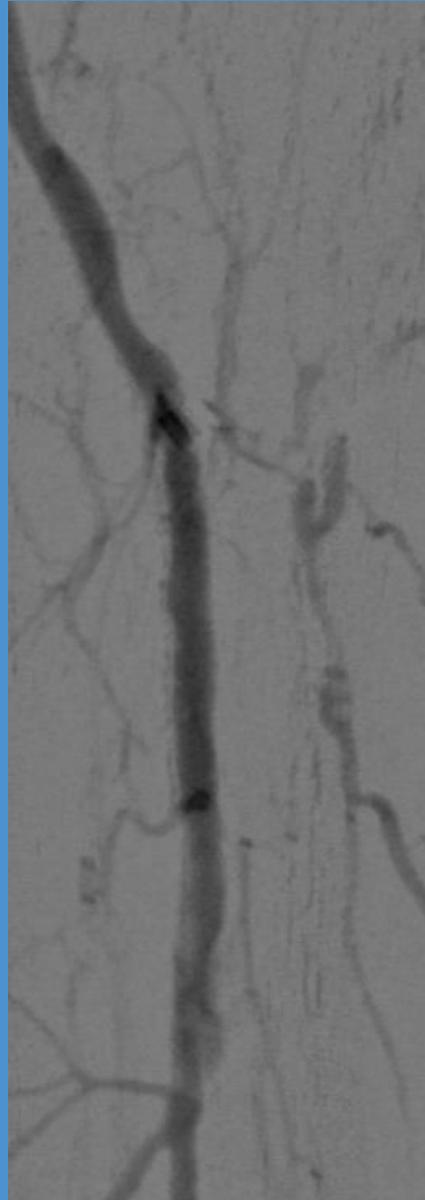
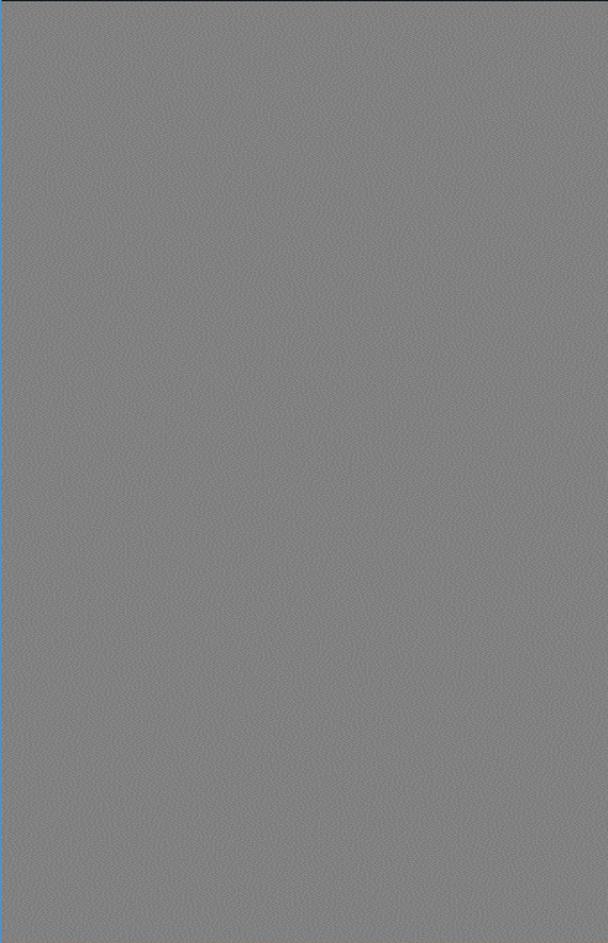
- **77 y male**
- **Diabetes type1**
- **AHT**
- **AMI/PTCA/CABG**
- **Hypercholesterolemia**
- **5x PTA fempop region**
- **Rutherford Becker 5**
- **Ulcers D1/D3/D5**

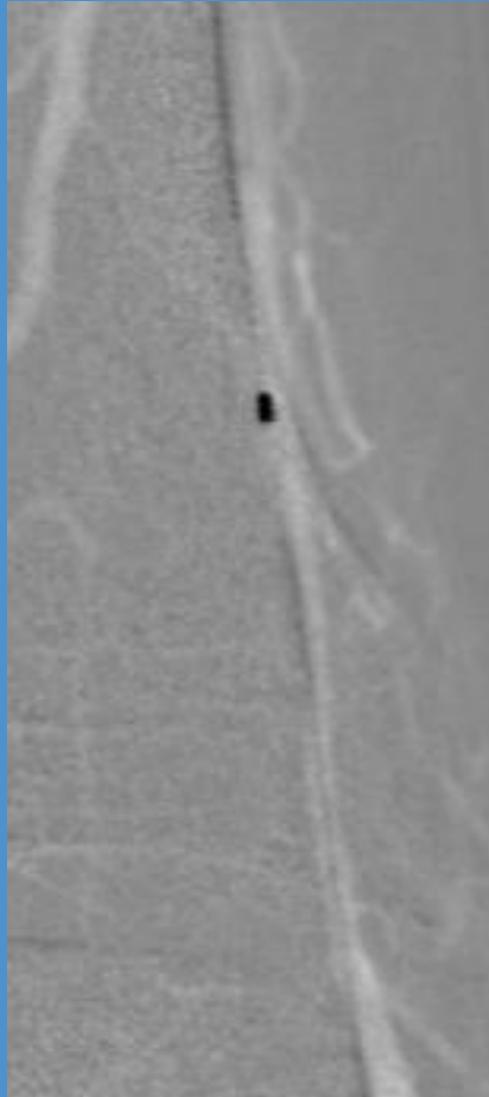
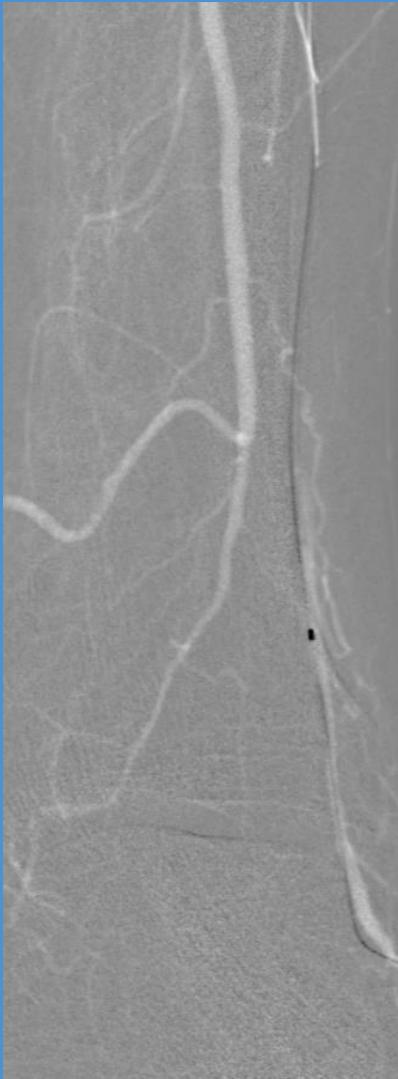


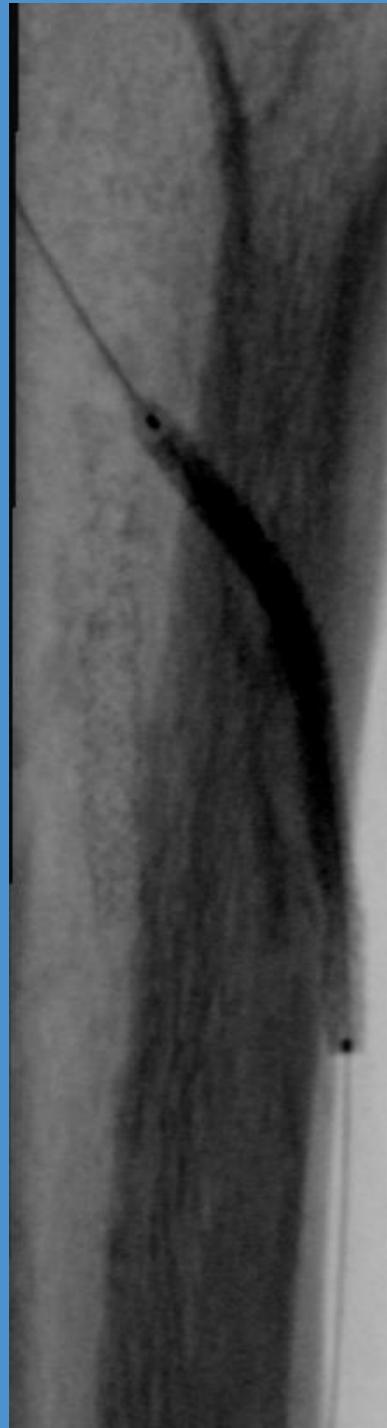
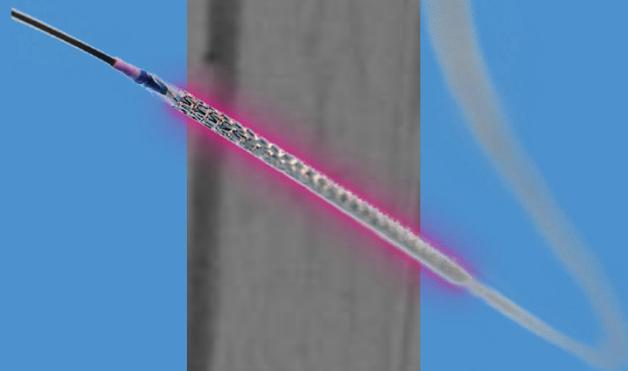
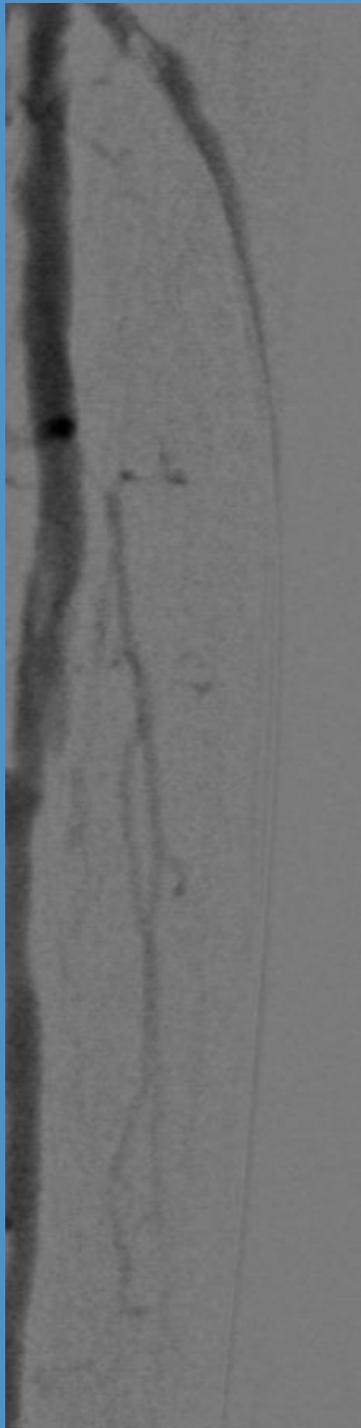


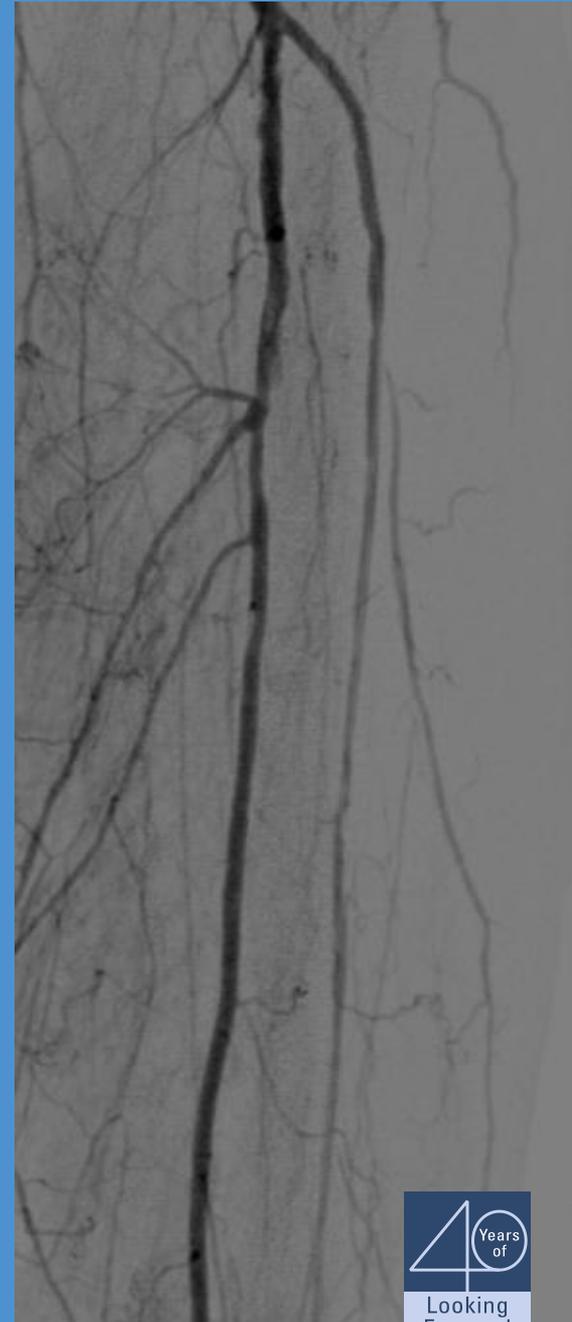
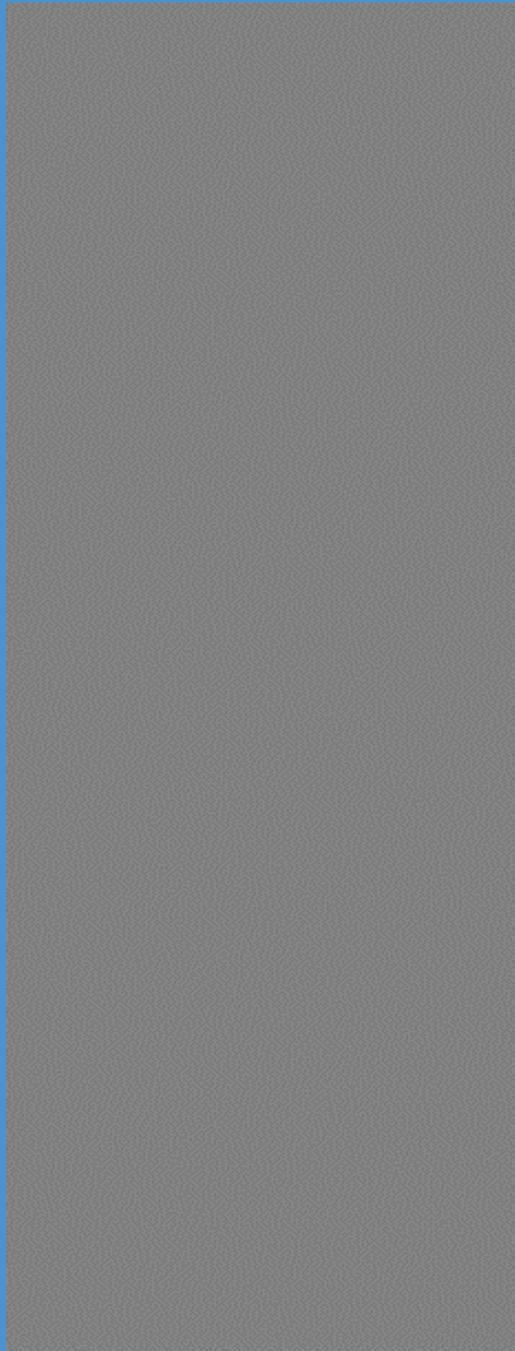
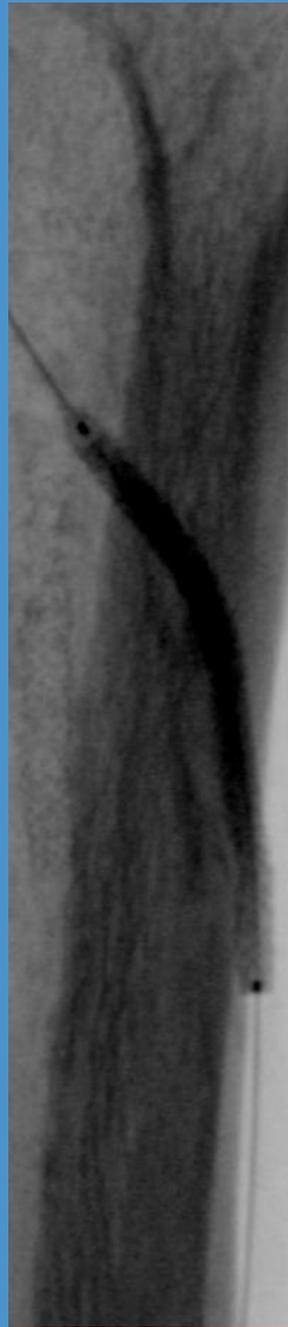














Angiolite BTK safety and feasibility study

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 CATEGORY

N = 50

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

Procedure		
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 DCB (mainly for distal vessel treatment)		34%



Angiolite BTK safety and feasibility study

Procedure	
Stents used	68
Tibioperoneal Trunc	24
Anterior Tibial artery	18
Peroneal Artery	15
Posterior Tibial Artery	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	
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 + CO² 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

(preliminary %)

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



Angiolite BTK safety and feasibility study

RUTHERFORD CATEGORY	6 Mo N= 44	9 Mo	12 Mo	18 Mo
1	3			
2	14			
3	12			
4	9			
5	6			
6	0			

(N = 44= 50 – 3 amp – 3 +)



Clinical outcome

After 2 weeks



After 5 weeks





Clinical outcome

After 7 weeks





Conclusions

- **Use of Angiolite BTK is safe and feasible**
- **Positive effect on revascularization/wound healing**
- **Longer term follow-up is needed to confirm the advantages of the use of the Angiolite BTK BX DES**

**Thank you for your
attention**



Vascular Clinic ZNA