A Multi-center study on Safety and Efficacy of BTK Everolimus-Eluting Stent from Taiwan

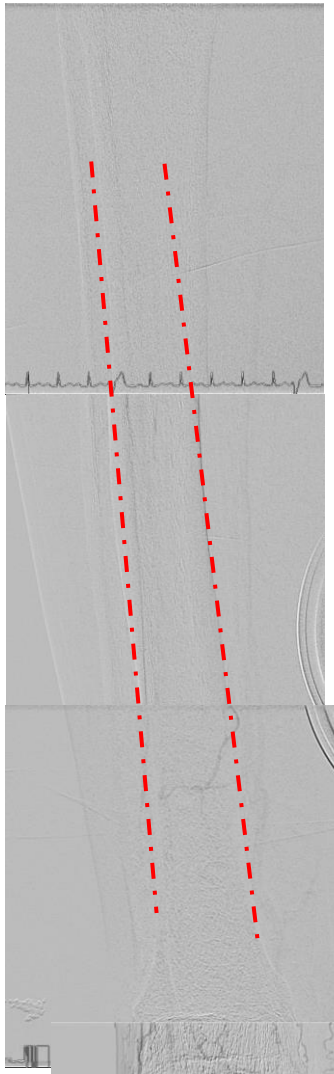
Jen-Kuang Lee (李任光), M.D., Ph.D.

Clinical Assistant Professor

Division of Cardiology, Department of Internal Medicine/ Laboratory Medicine

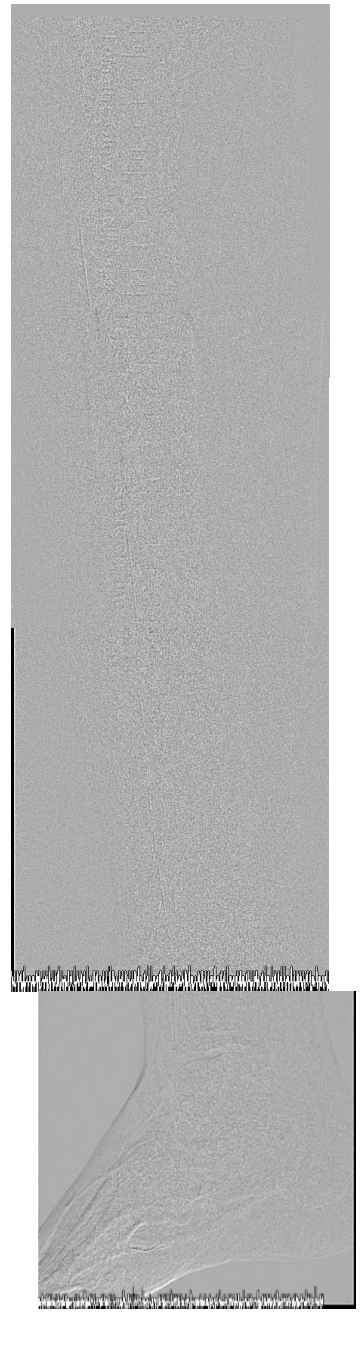
Cardiovascular Center/ Telehealth Center

National Taiwan University College of Medicine & Hospital



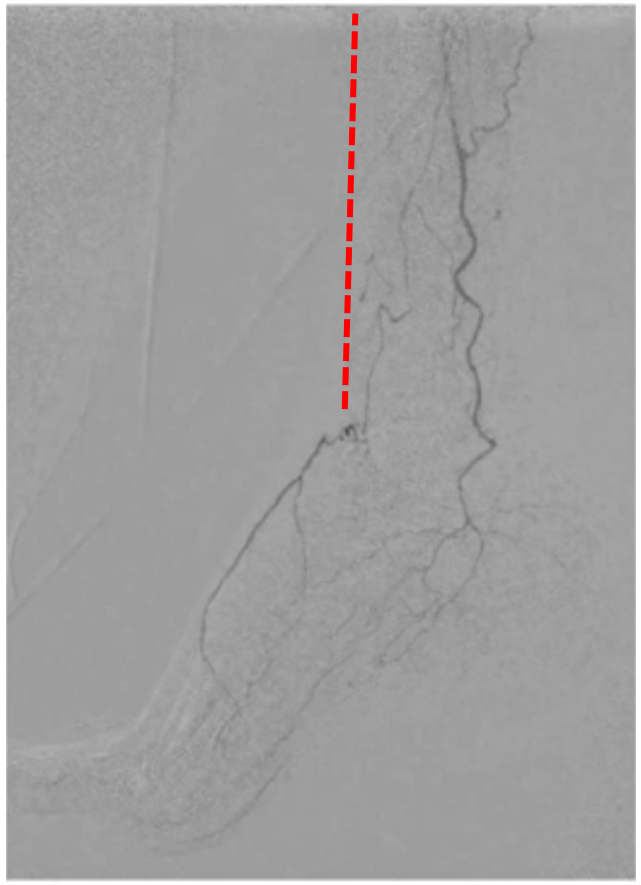
Daily routine for BTK intervention

Long vessel, long lesion, long procedure time

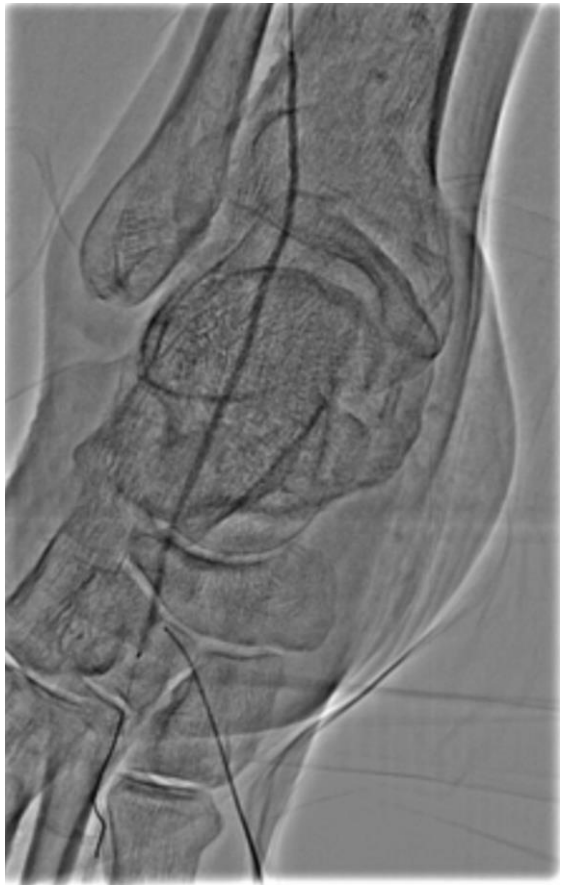


The outcome of BTK is frustrated

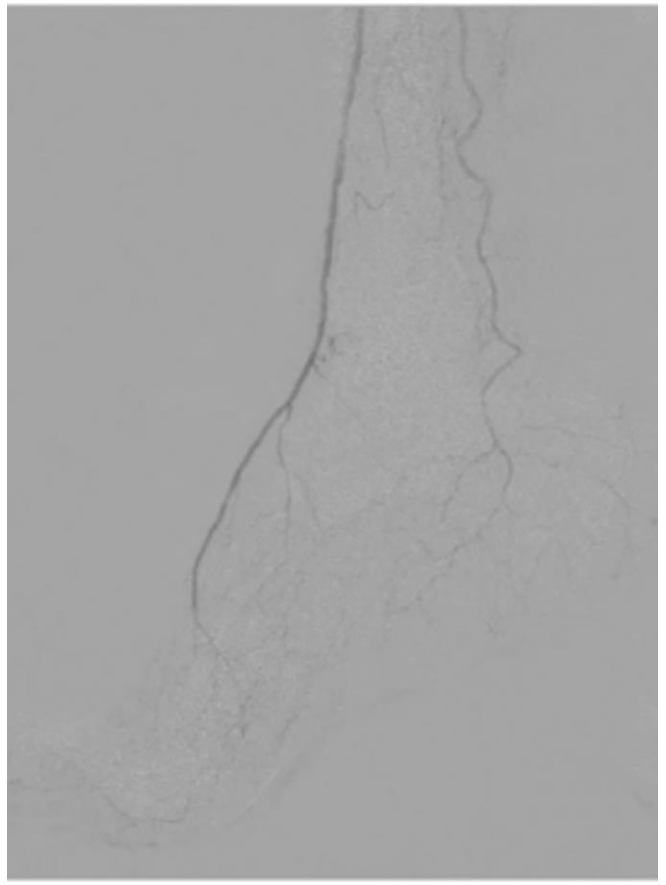
Pre EVT



Angioplasty



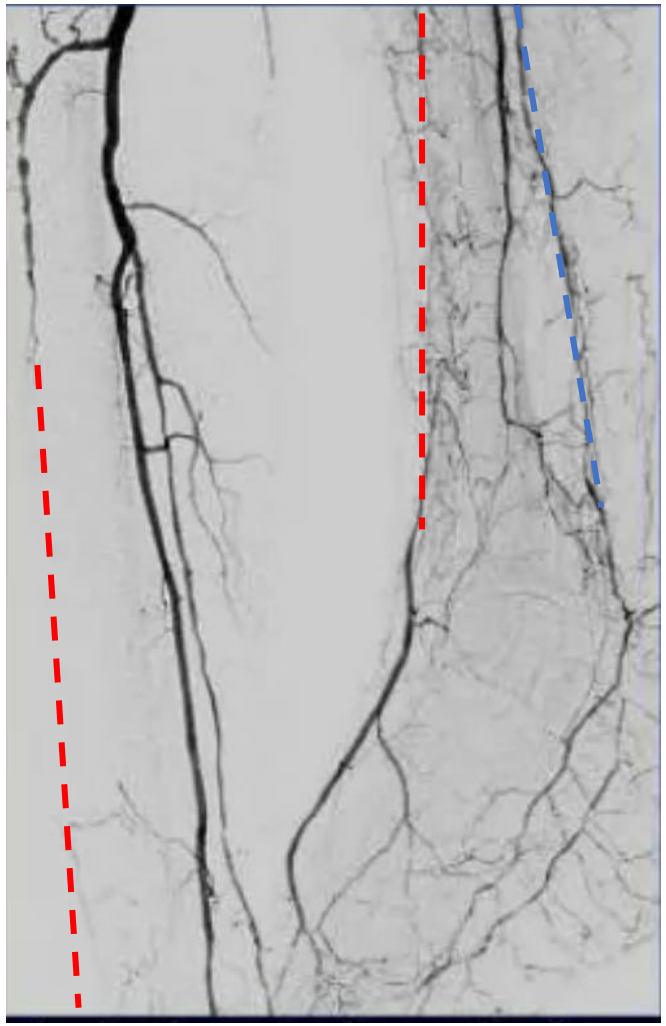
Post EVT



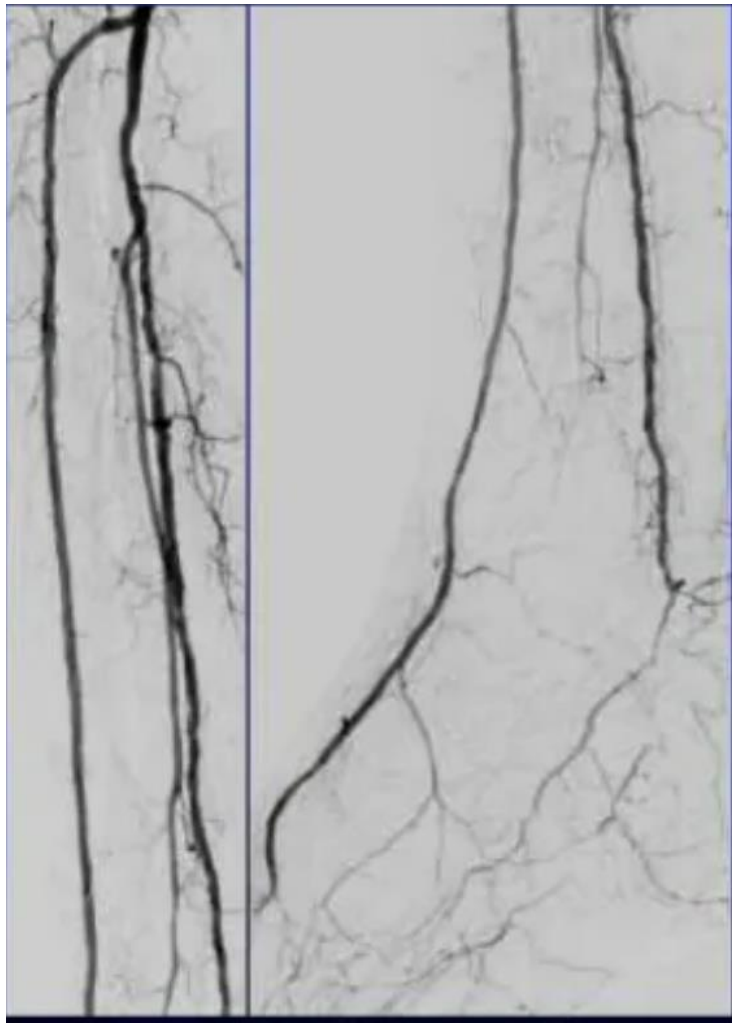
1 month later

The outcome of BTK is frustrated

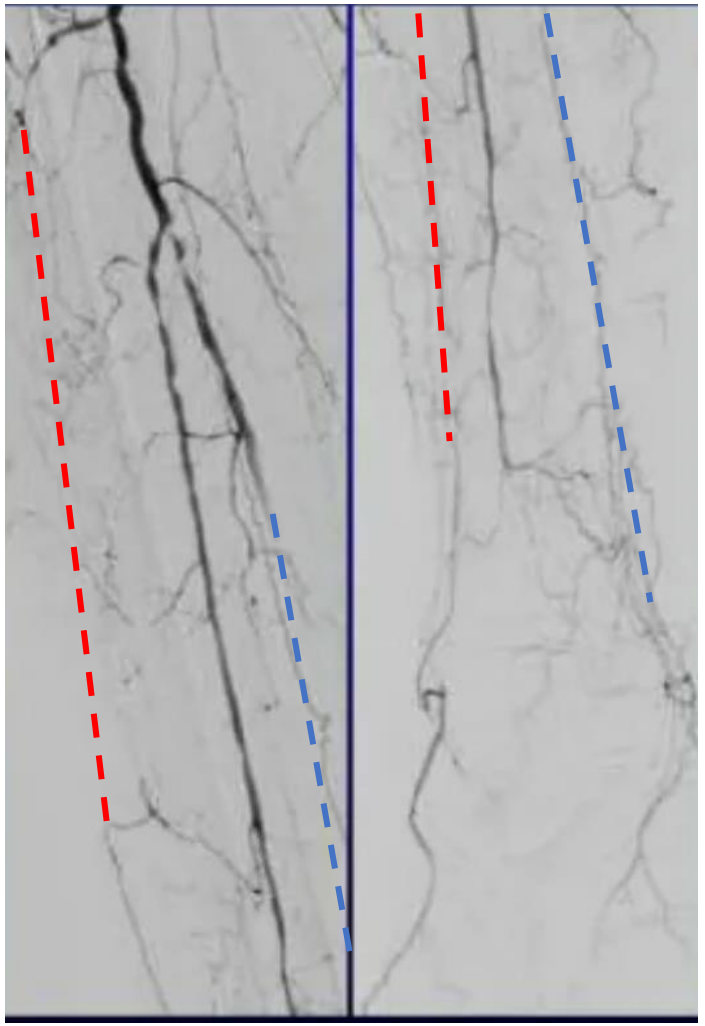
Pre EVT



Post EVT



2 month later

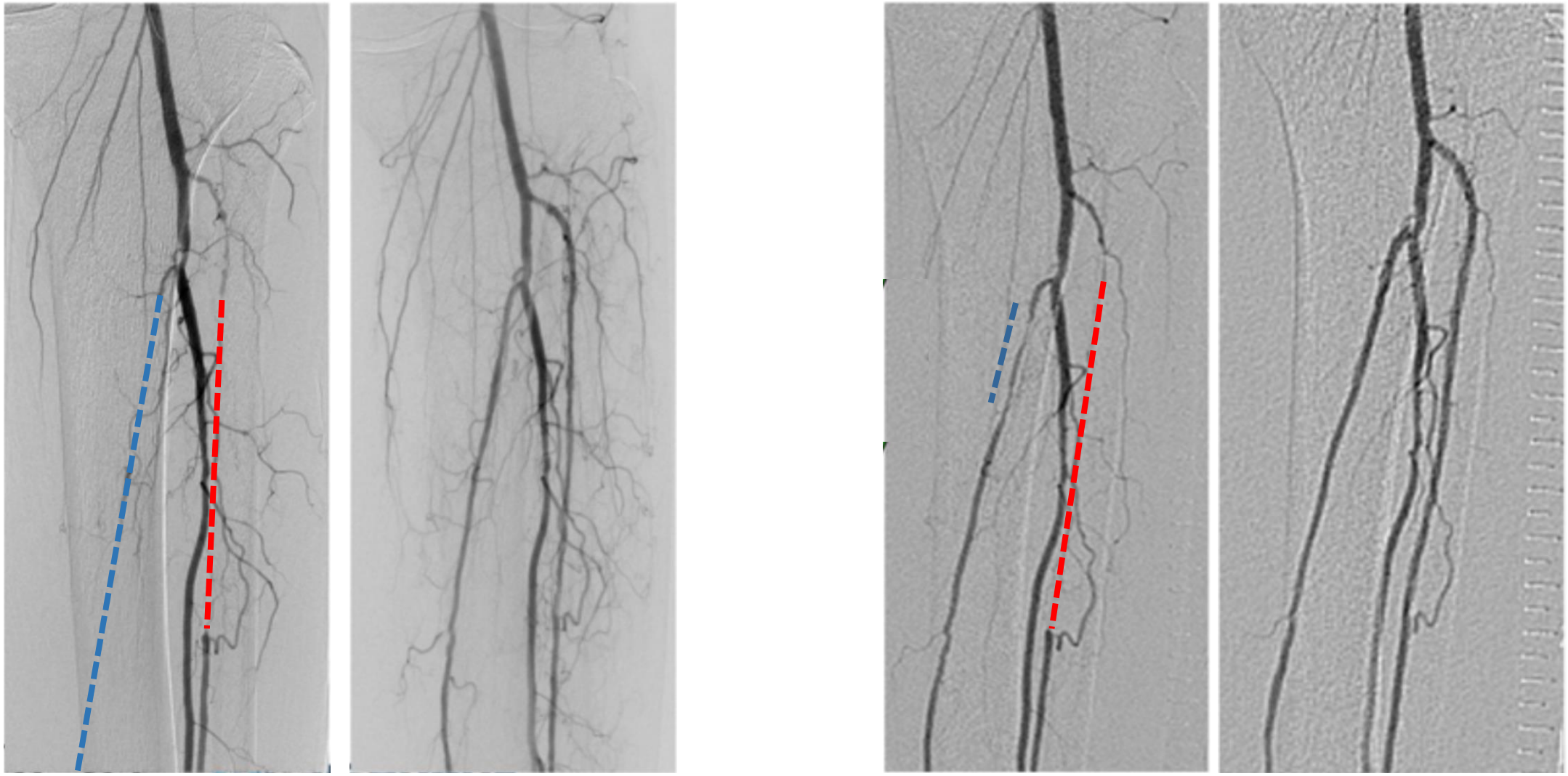


The outcome of BTK is frustrated

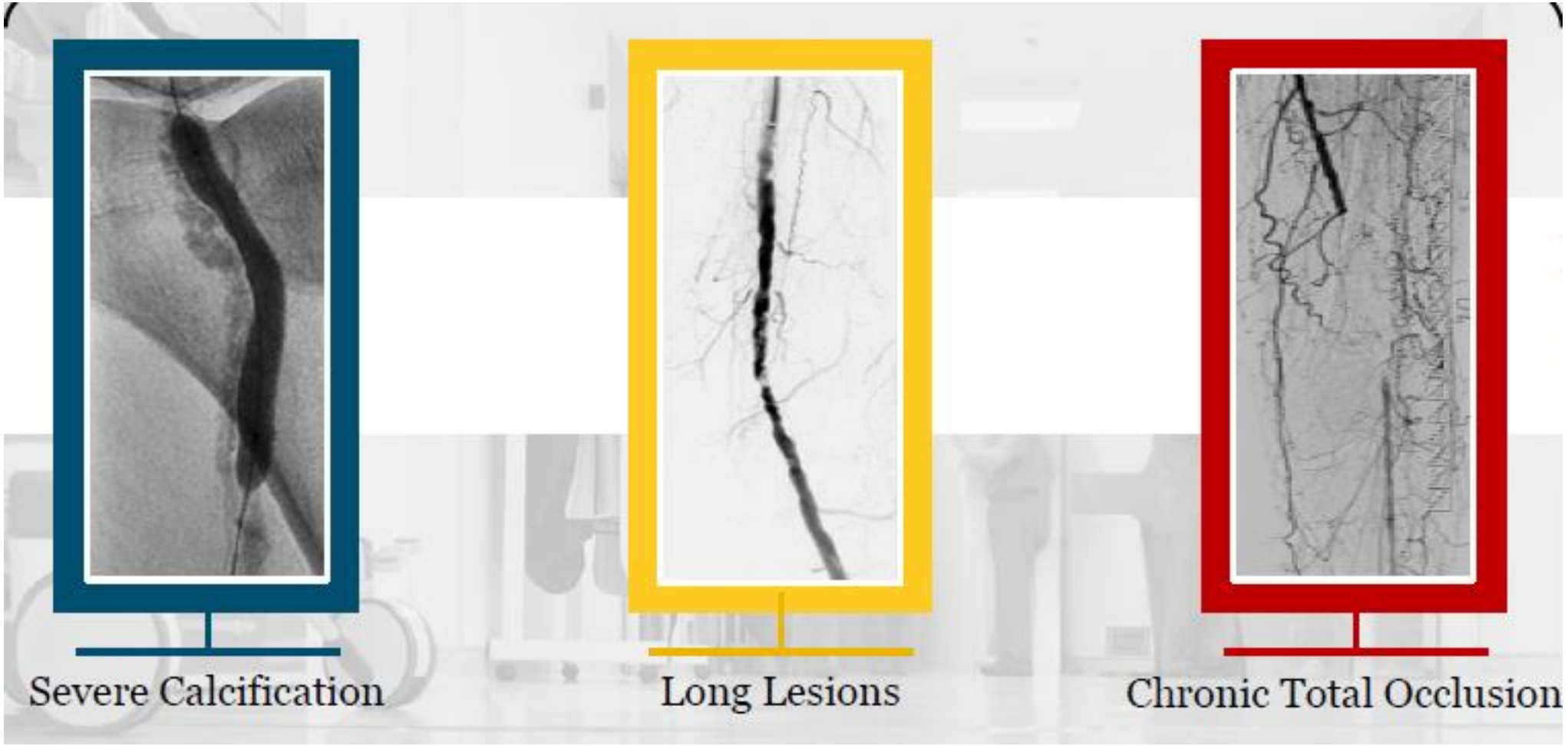
Pre EVT

Post EVT

3 month later



BTK = Calcified, Long, CTO



Limitation of infrapopliteal angioplasty

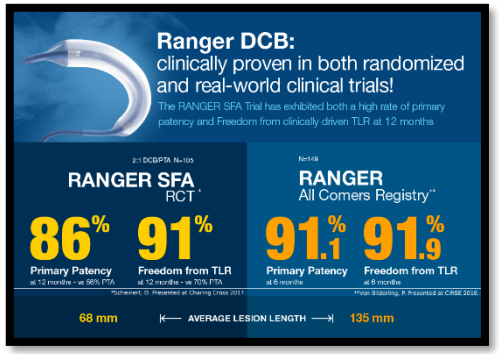
Repeat EVT
@ 1 year
40%

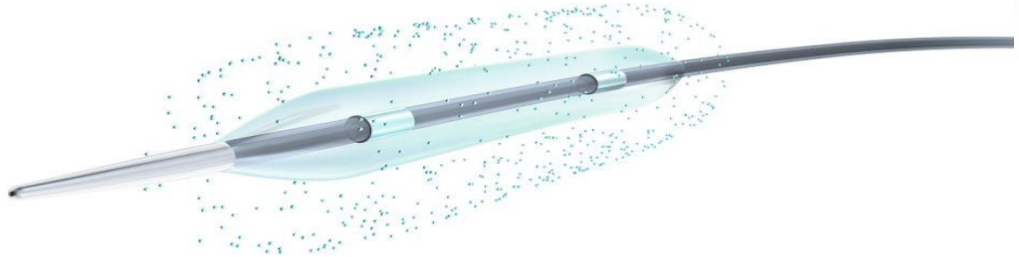
Restenosis
@ 3 months
70%

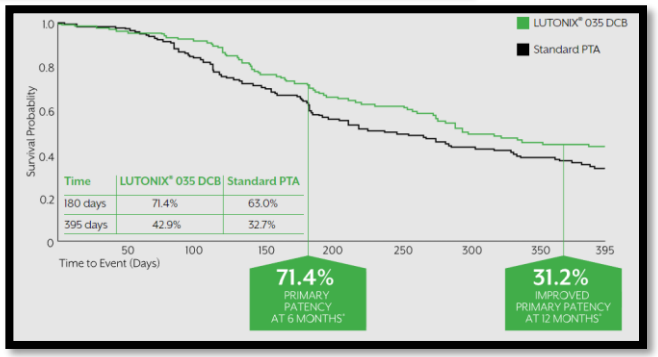
Early Recoil
@ 15 minutes
97%

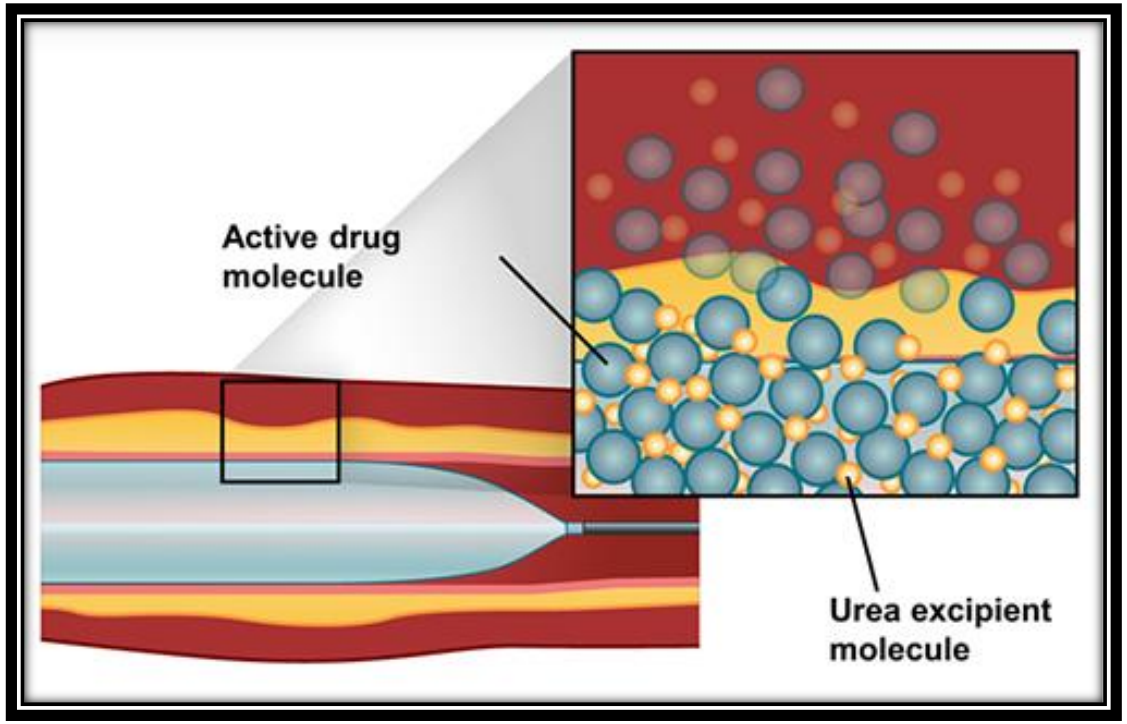
Iida et al.

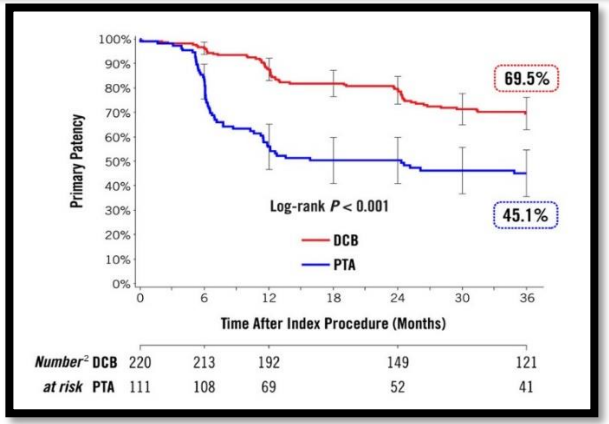
Drug-Coated Balloon







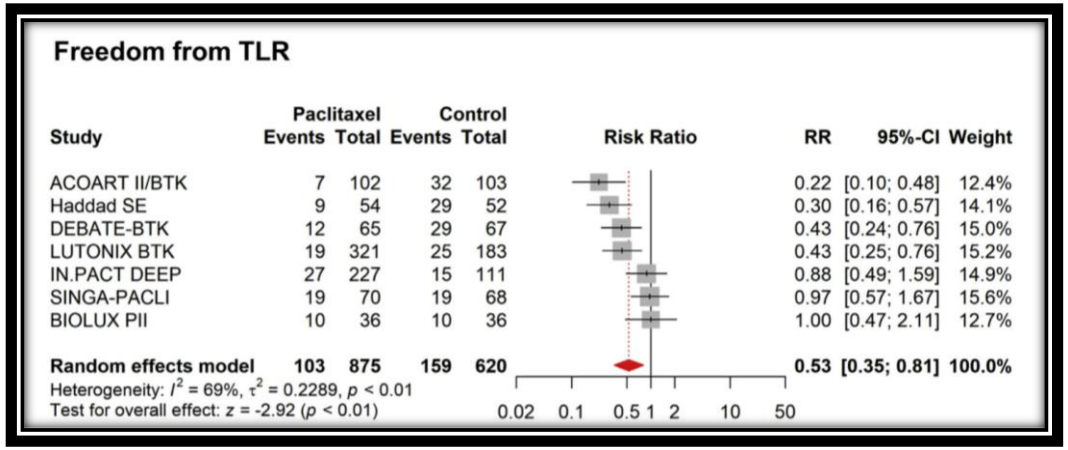


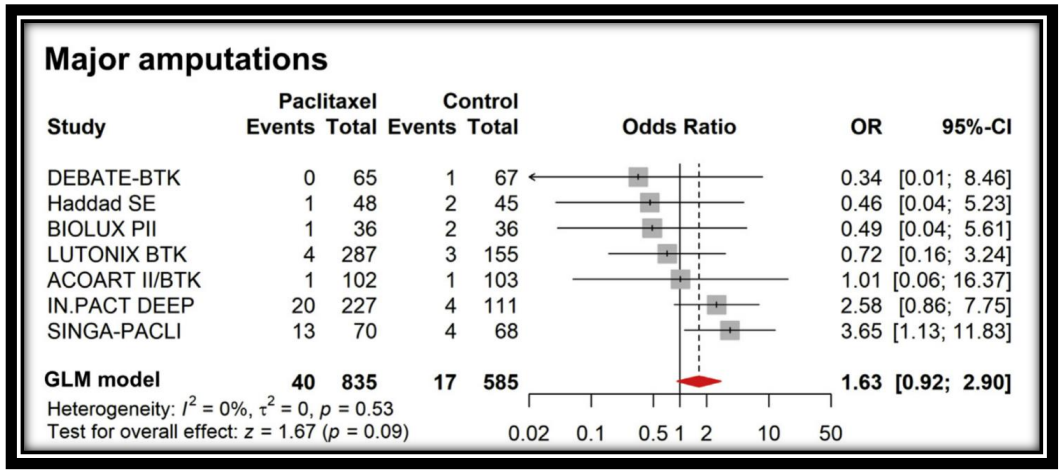


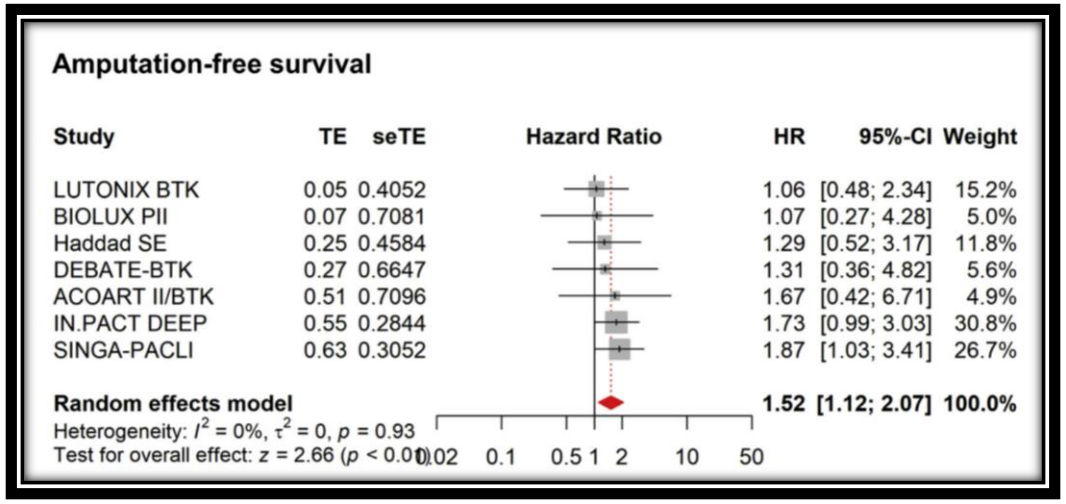
EVIDENCE-BASED REVIEW

Risk of Death and Amputation with Use of Paclitaxel-Coated Balloons in the Infrapopliteal Arteries for Treatment of Critical Limb Ischemia: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

J Vasc Interv Radiol 2020; 31:202–212

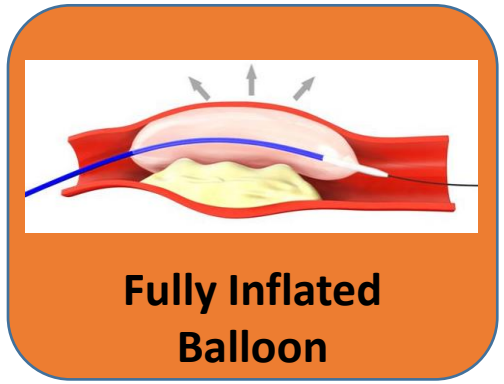




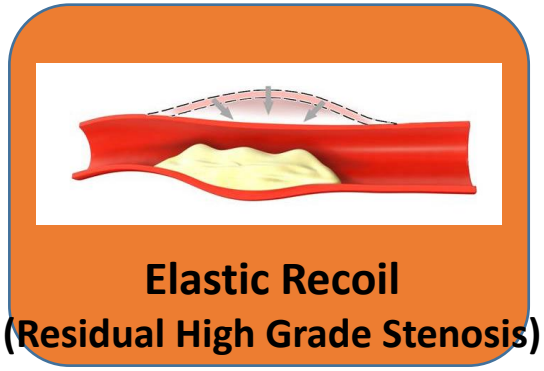


Calcium Limits DCB efficacy

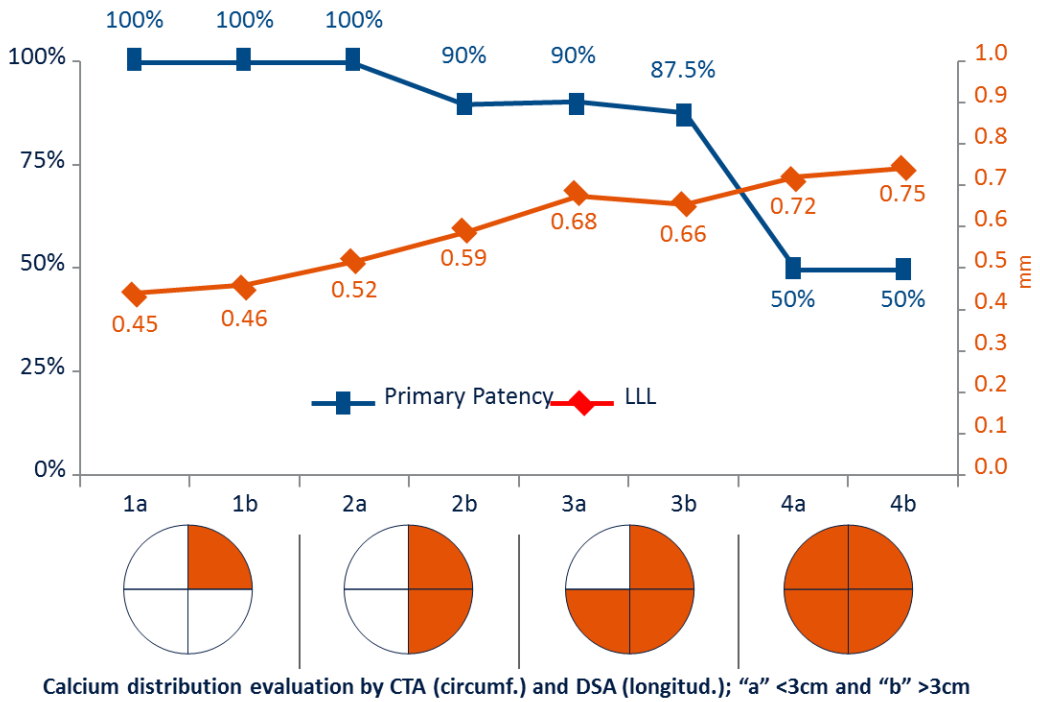
- Calcium distribution and severity may affect late lumen loss (LLL) and primary patency
- Calcium may represent a barrier to optimal drug absorption



Fully Inflated Balloon



Elastic Recoil (Residual High Grade Stenosis)



Calcium distribution evaluation by CTA (circumf.) and DSA (longitud.); "a" <3cm and "b" >3cm

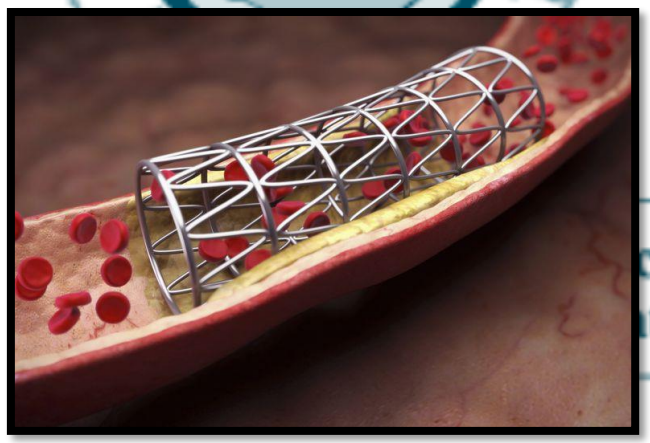
Minimal Calcification — High Calcification

Restenosis: Causes & Solution

Causes

Recoil & Negative Remodeling (70%)

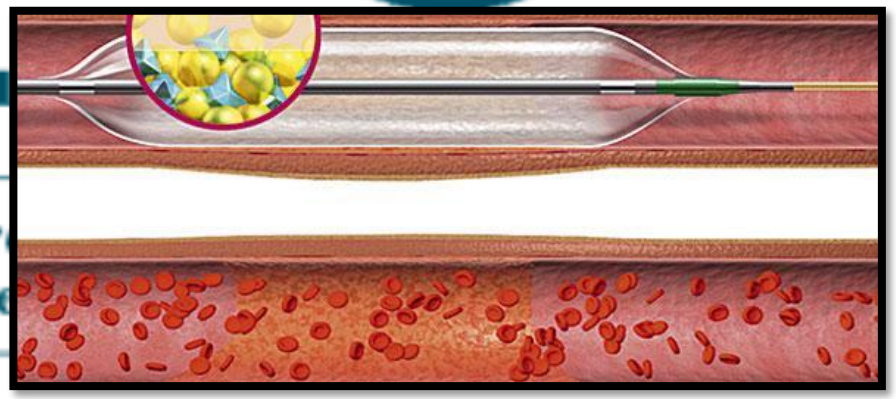
Neointimal Hyperplasia (30%)



Solu

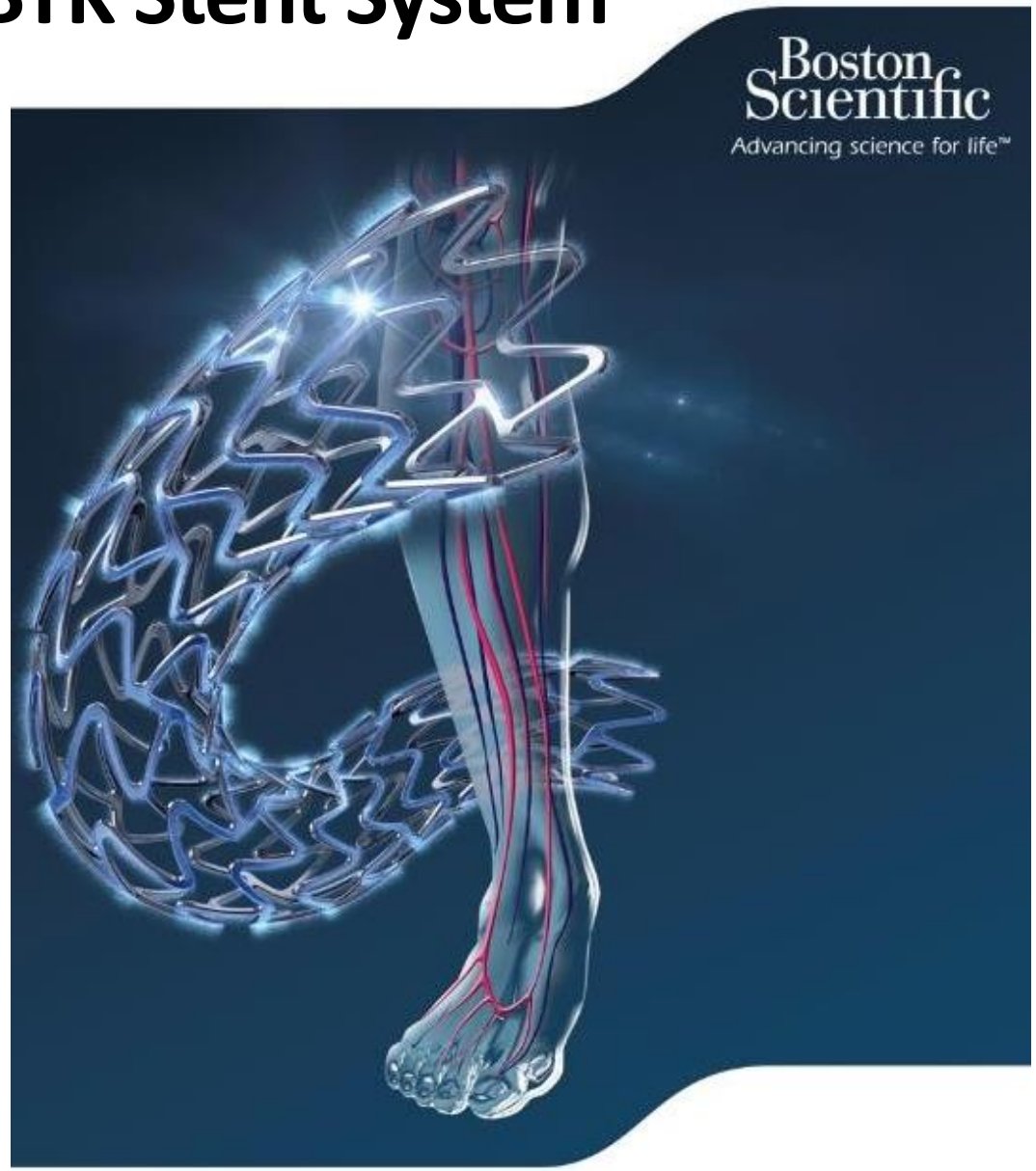
coil and r

t to preve



PromusPREMIER™ BTK Stent System

Key Components	Advantages
Customized PtCr Stent Architecture	• Balance of Strength and Flexibility
Proven Everolimus & PVDF-HFP Copolymer Combination	• Outstanding Safety and Efficacy[1]
Enhanced Delivery System	• Improved Deliverability[2]



Multi-center PromusPREMIER™ BTK registry

Jen-Kuang Lee

Dien-Yu Wu

Chiun-Chi Chen

Pin-Hsu Wu

Shu-Kai Hsueh
Wen-Jung Chung

Chung-Ho Hsu

Po-Chao Hsu

Multi-center PromusPREMIER™ BTK registry

- The **efficacy** and **safety** of DES(Boston Promus®) in CLTI patients with BTK lesion

Inclusion

- **CLTI patients** with Rutherford IV and V
- **Three** stents most in each BTK vessel

Outcome (180 days)

- ABI, wound recovery time, amputation, primary patency, all-cause mortality

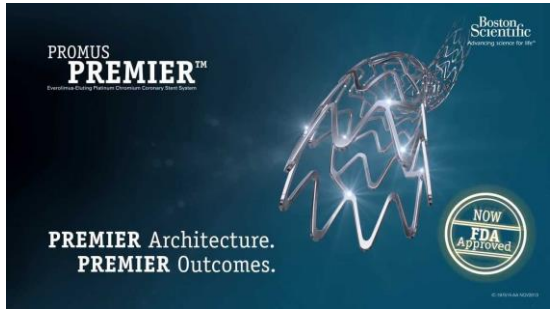
	N=84
Age	72.9 ± 12.5
Sex	44
DM	60
HTN	56
Dyslipidemia	62
CKD	64
ESRD	41
CAD	63
MI	25
Stroke	12
Rutherford IV	32
ABI	0.35 ± 0.21

Intervention BTK	
ATA	64
Peroneal	45
PTA	55
De novo	72
CTO	61
Calcium	
Severe	57
Intravascular image	
IVUS	10
OCT	28
BTK portion	
Proximal	57
Mid	38
Distal	3
PP stent	
Size (mm)	3.17
Length (mm)	73.4
Concomitant lesion	
SFA	43
iliac	12
BTA	32

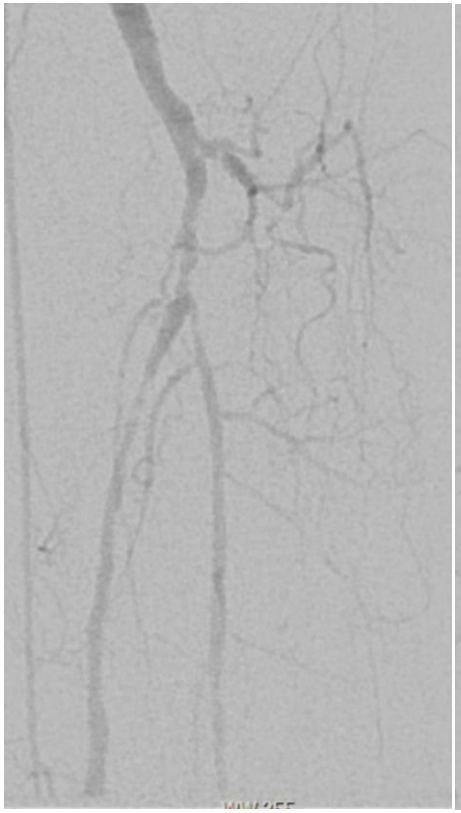
Result

- ABI: **0.87 ± 0.23**
- Amputation: **0**
- All-cause mortality: **0**

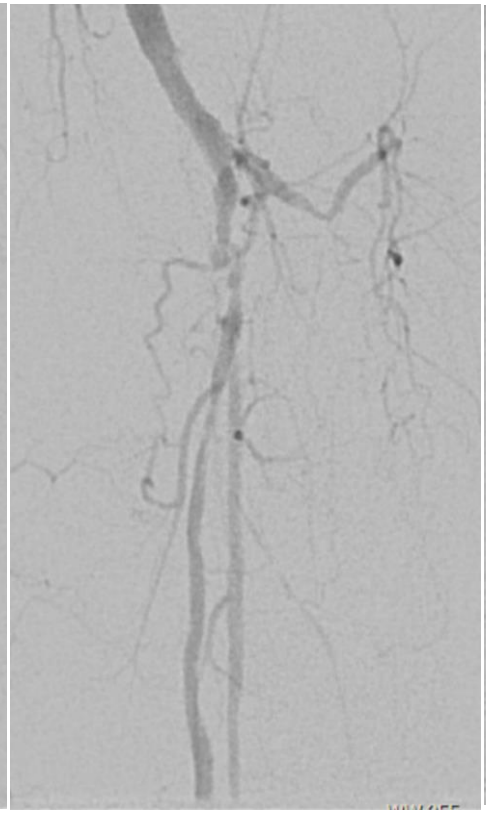
78 y/o man, H/D, RC V



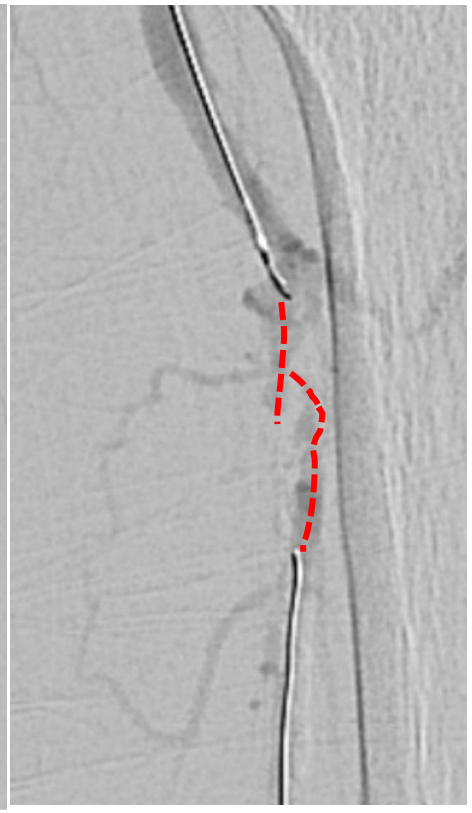
Pre EVT-AP



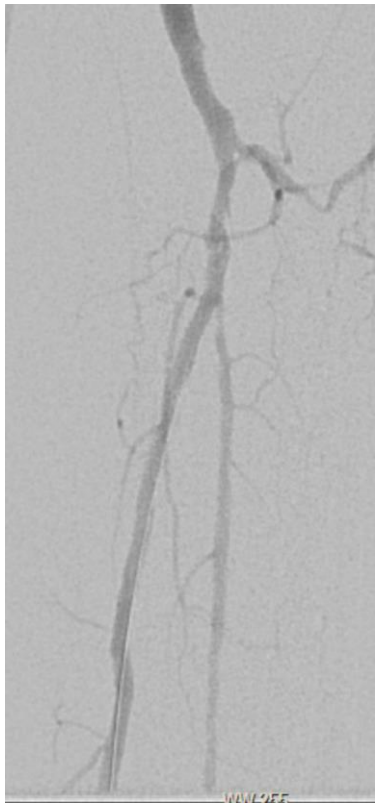
Pre EVT-RAO



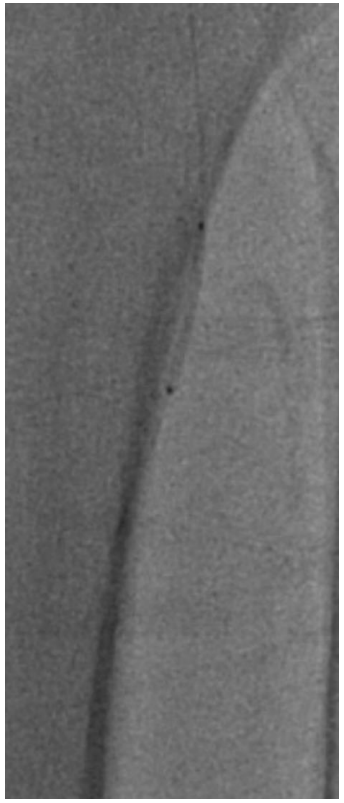
Wiring



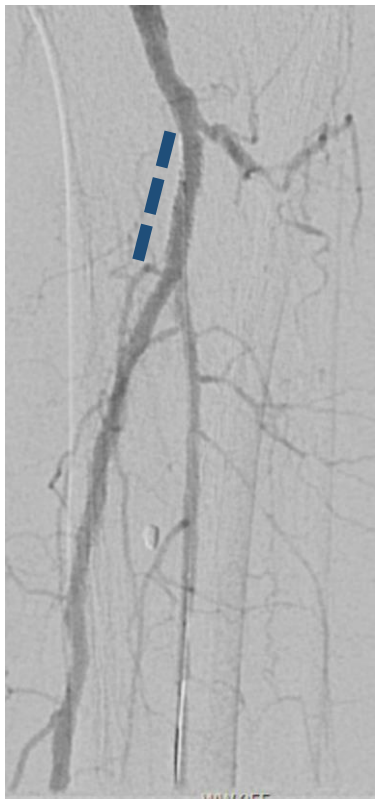
Angioplasty



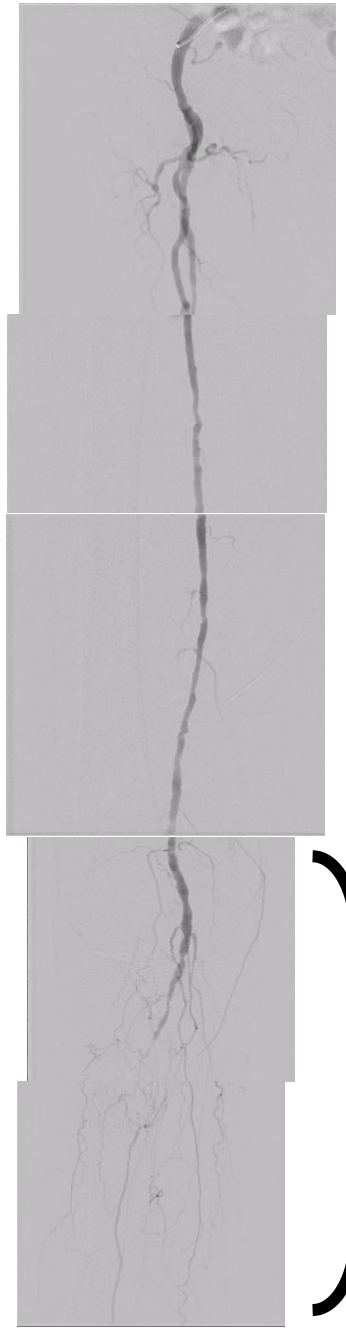
Stenting

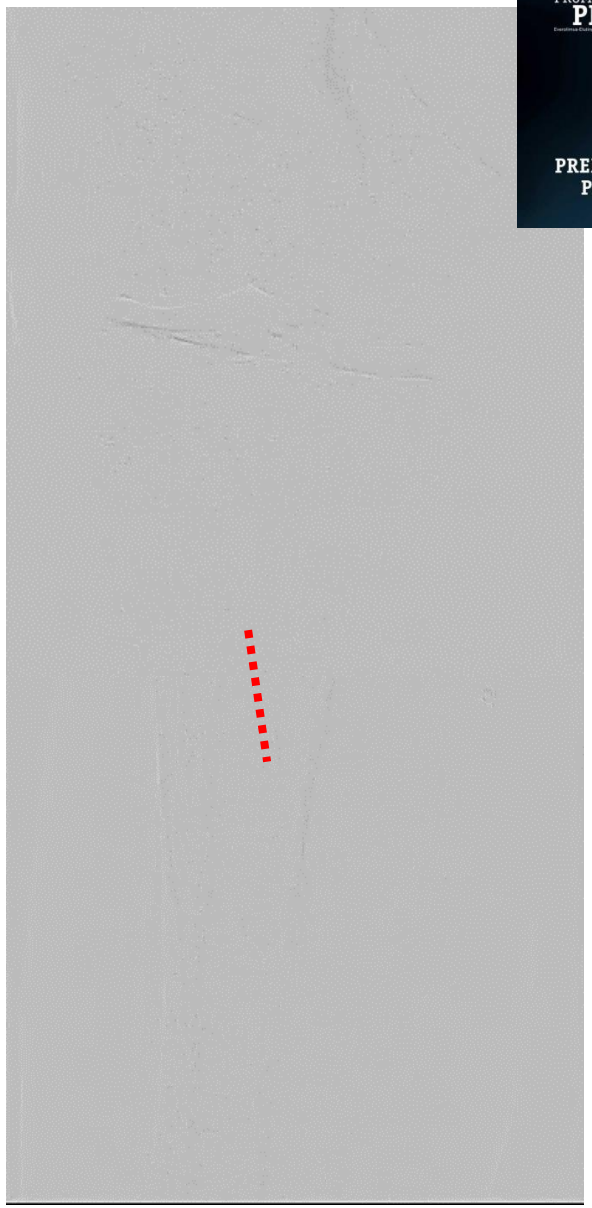


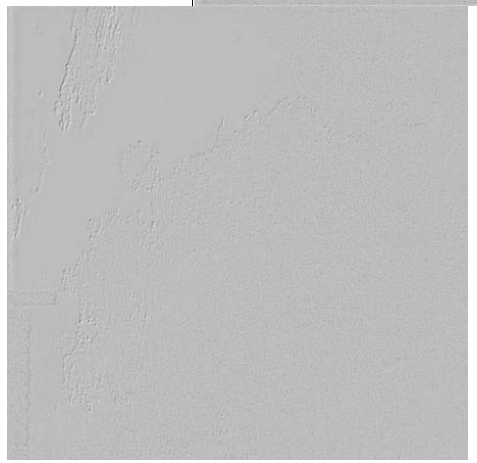
Post EVT

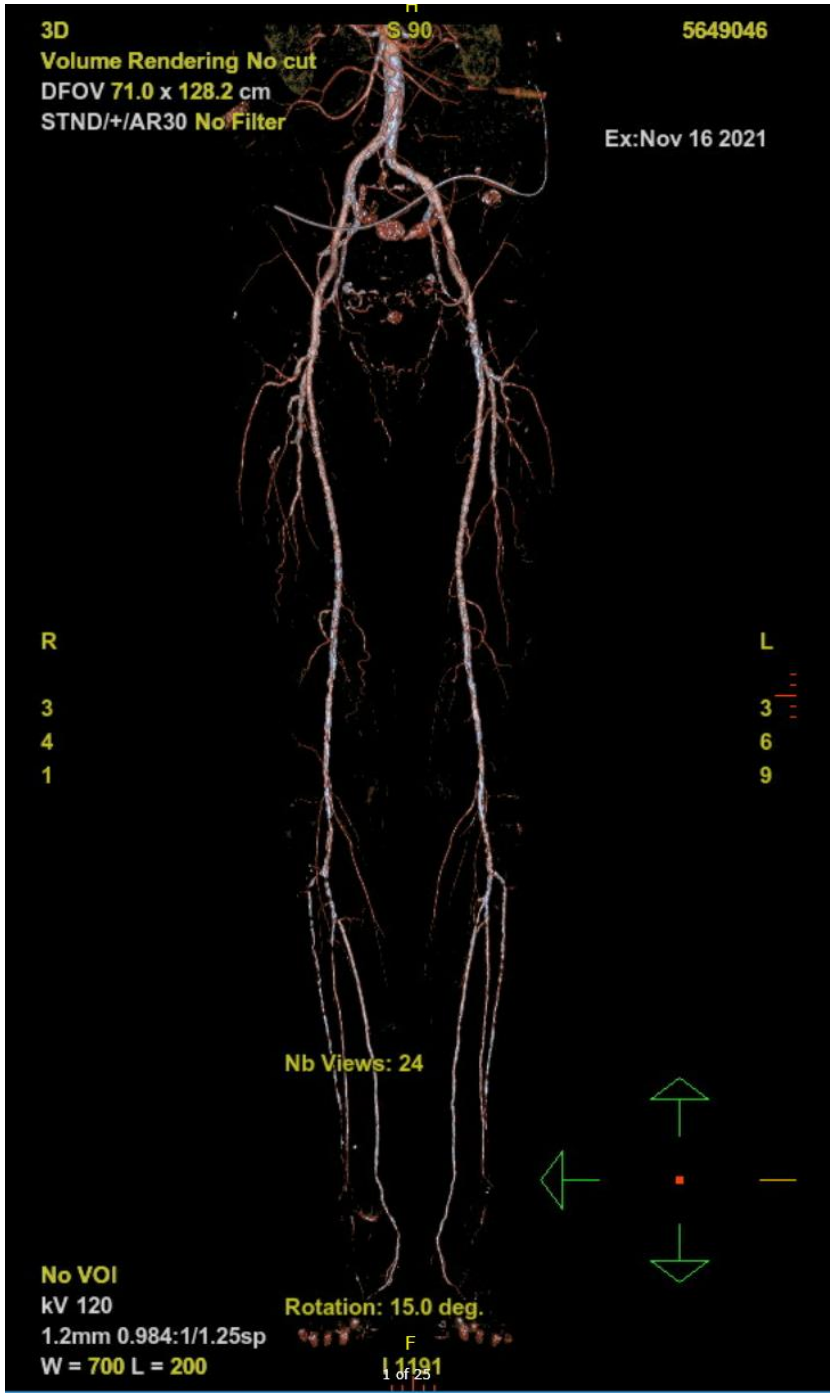


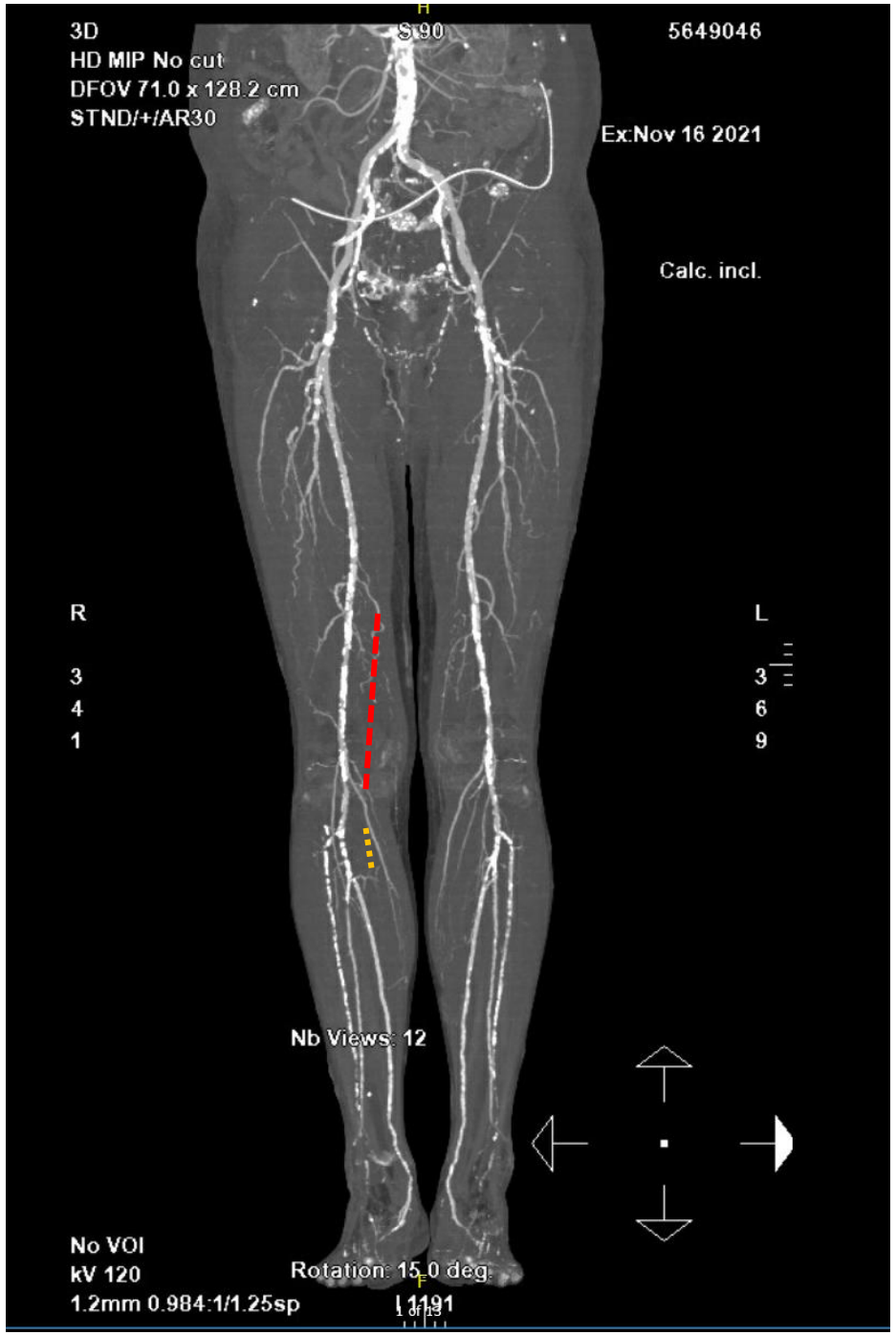
86 y/o woman, H/D, RC V

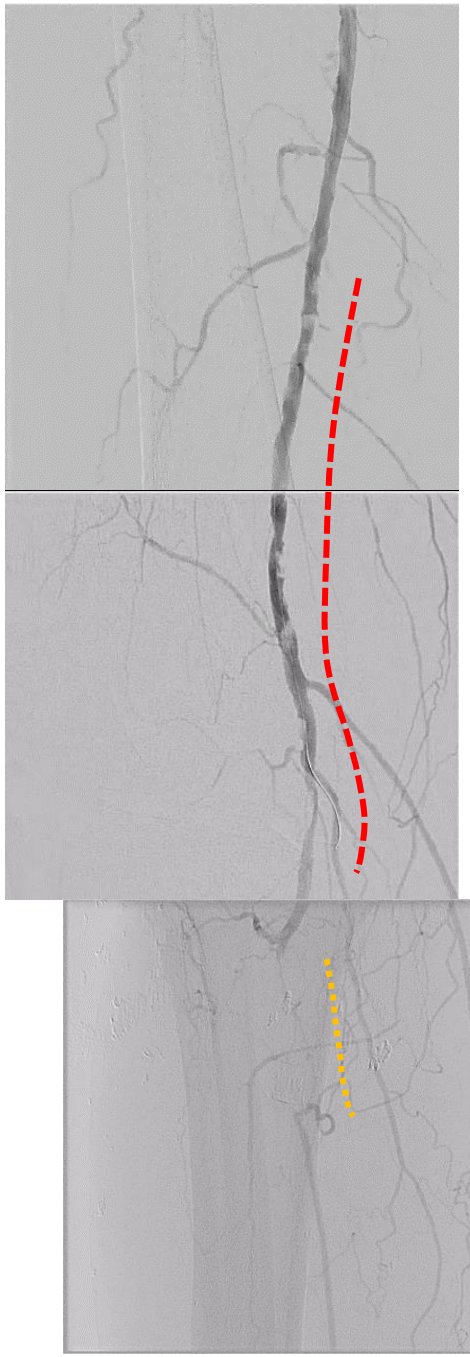


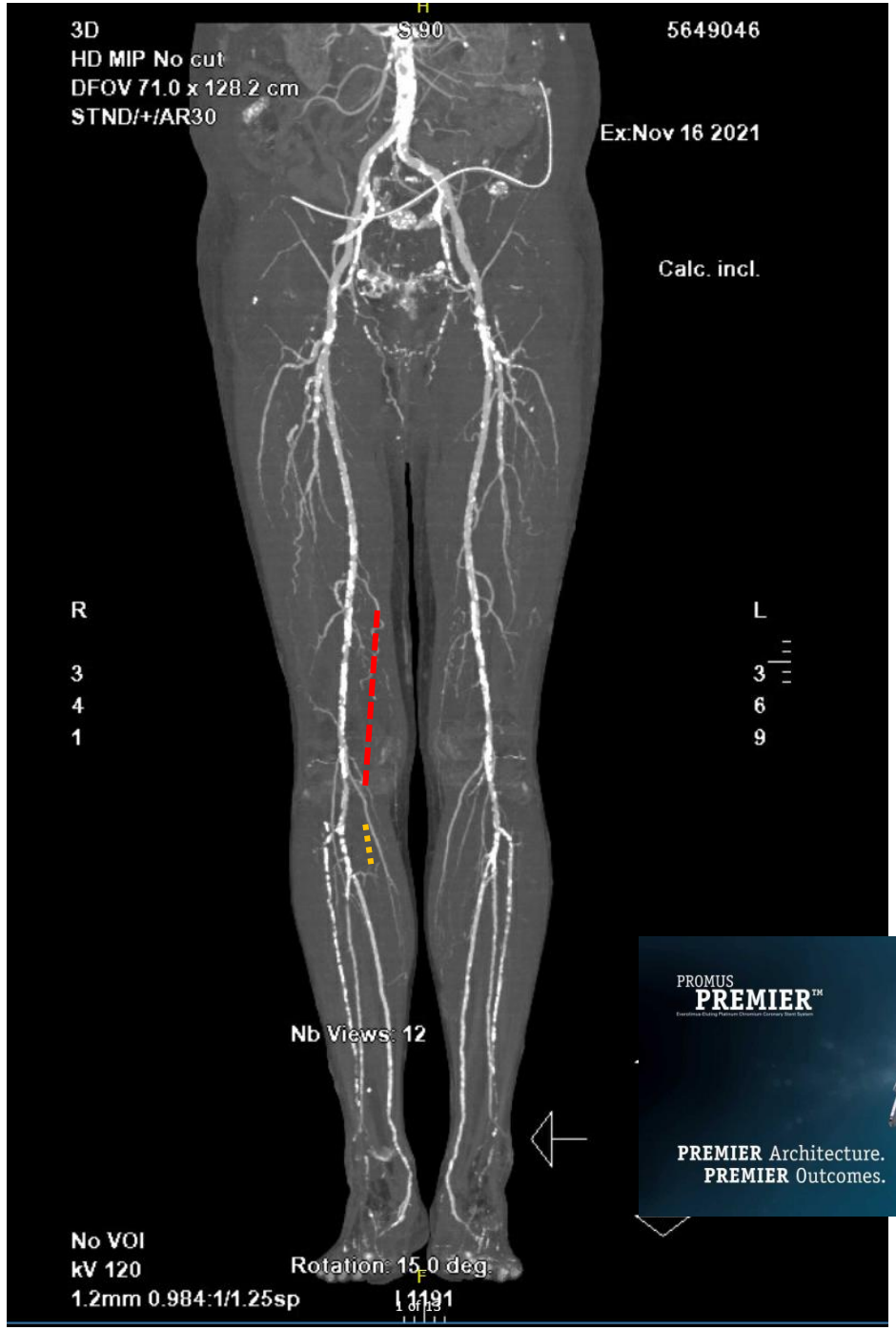




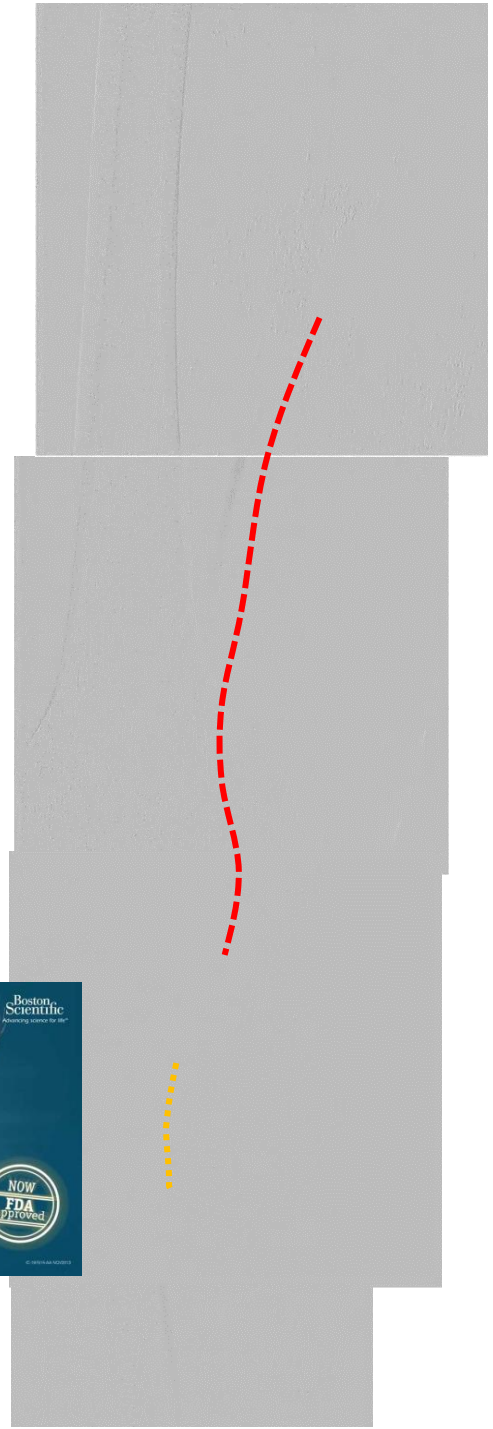

3D
Volume Rendering No cut
DFOV 71.0 x 128.2 cm
STND/+/AR30 No Filter
S 90
5649046
Ex:Nov 16 2021
R
L
3
4
1
3
6
9
Nb Views: 24
No VOI
kV 120
1.2mm 0.984:1/1.25sp
W = 700 L = 200
Rotation: 15.0 deg.
I 1191
1 of 25


3D
HD MIP No cut
DFOV 71.0 x 128.2 cm
STND/+/AR30
S 90
5649046
Ex:Nov 16 2021
Calc. incl.
R
L
3
4
1
3
6
9
Nb Views: 12
No VOI
kV 120
1.2mm 0.984:1/1.25sp
Rotation: 15.0 deg.
I 1191
1 of 13

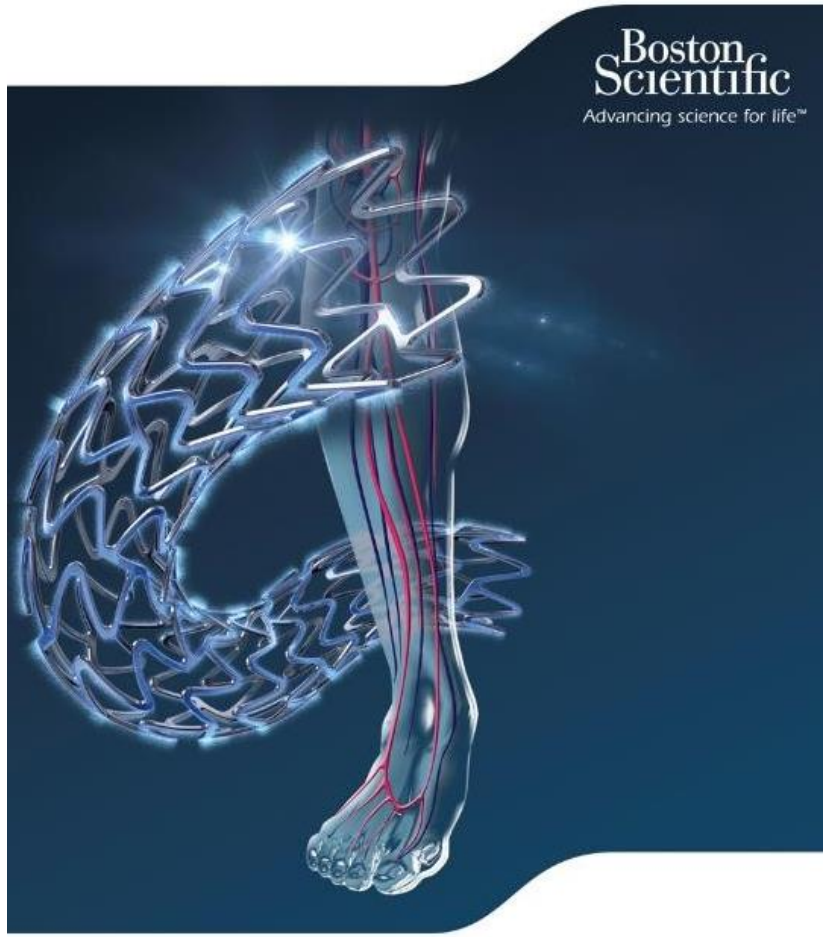



3D
HD MIP No cut
DFOV 71.0 x 128.2 cm
STND/+/AR30
S 90
5649046
Ex:Nov 16 2021
Calc. incl.
R
3
4
1
L
3
6
9
Nb Views: 12
No VOI
kV 120
1.2mm 0.984:1/1.25sp
Rotation: 15.0 deg
I 1191

PROMUS
PREMIER™
Boston Scientific
PREMIER Architecture.
PREMIER Outcomes.
NOW
FDA Approved



Chronic limb-threatening ischemia (CLTI) @6 months



Take home message

- **BTK lesion** is **difficult** to maintain even **short-term** patency
  - **Calcification, long lesion, CTO**
- **DCB** is **NOT** the **"Savior"** in **BTK lesion**
  - **RCT, meta-analysis, RWD, personal experience**
- **DES (PromusPREMIER™)** may be the **"Game Changer"**
  - **Location, length, radial force, long-term result**