MEET 2015 – Nice

FMRP
Flanders Medical Research Program

A.Z. Sint-Blasius, Dendermonde
Marc Bosiers
Koen Deloose
Joren Callaert

Imelda Hospital, Bonheiden
Patrick Peeters
Jürgen Verbist
W Van Den Eynde

OLV Hospital, Aalst
Lieven Maene
Roel Beelen

R.Z. Heilig Hart, Tienen
Koen Keirse
Bart Joos

OffRoad Re-entry Catheter System for Subintimal Recanalization of Chronic Total Occlusions in Femoropopliteal Arteries

Primary Safety and Efficacy Results of the Re-ROUTE Trial

Koen Keirse, Regional Hospital Heilig Hart Tienen, Tienen, Belgium
Andrej Schmidt, Park-Hospital Leipzig,, Leipzig, Germany
Erwin Blessing, University of Heidelberg, Heidelberg, Germany
Ralf Langhoff, Ev. Krankenhaus Königin Elisabeth, Berlin, Germany
Thomas Zeller, Herzzentrum Bad Krozingen, Bad Krozingen, Germany
Juan Diaz-Cartelle, Boston Scientific, Natick, MA, USA

Disclosure slide

Speaker name: Koen Keirse, MD

☐ I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☑ I do not have any potential conflict of interest

Subintimal Approach to Chronic Total Occlusions

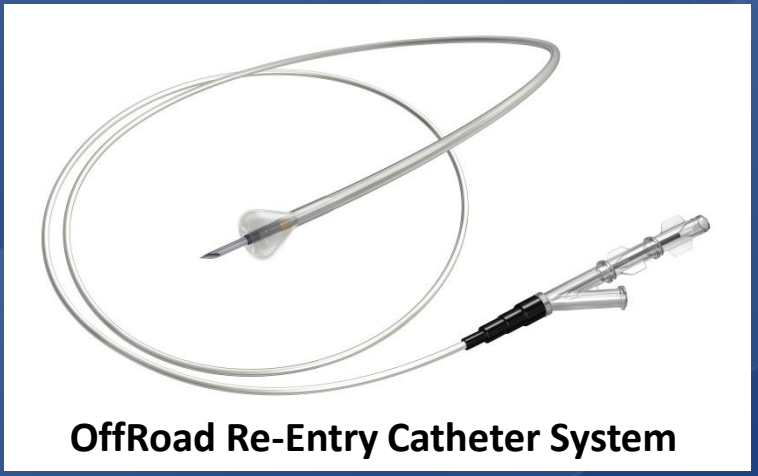
- Chronic total occlusions (CTOs) are common in peripheral vascular disease
- Subintimal angioplasty is an option for CTOs that cannot be crossed with conventional intraluminal approaches
- Failure to advance a guidewire into the true lumen is the main cause of subintimal procedure failure[1-3]
- Re-entry devices are intended to access the true lumen and contribute to procedure technical success

1. Müller-Hülsbeck S. CardioVascular and Interventional Radiology. 2009;32:236-237.
2. Husmann M, Federer J, Keo HH, et al. J Endovasc Ther. 2009;16:206-212.
3. Scott EC, Biuckians A, Light RE, et al. J Vasc Surg. 2008;48:878-884.

OffRoad Re-Entry Catheter System

- Positioning Balloon Catheter
  - Over-the-wire
  - Tipless shape and flexible neck for natural movement into the true lumen
- Microcatheter Lancet
  - Single-lumen hypotube catheter with a lancet tip
  - Advanced coaxially in the inner lumen of the Positioning Balloon Catheter

OffRoad System Components	
Nominal balloon diameter	5.4 mm
Nominal inflation pressure	2 atm
Radiopaque marker	Within balloon body
Guide sheath diameter	6F
Recommended guidewire	≤0.035 in (balloon) ≤0.014 in (lancet)



OffRoad Re-Entry Catheter System

- Intended to facilitate the placement and positioning of guidewires within the peripheral vasculature
- Available for commercial use in Europe and Canada

The Re-ROUTE Trial

- Prospective, single-arm, non-randomized, multicenter (Europe and Canada), post-market study
- Assess safety rates and device technical success of the OffRoad Re-entry Catheter System for subintimal recanalization of *de novo* or re-occluded CTOs in native femoropopliteal arteries

Re-ROUTE Trial

Eligibility Screening

- Claudication or critical limb ischemia (Rutherford Category 2-5)
- Age ≥18 years
- Informed consent

Index Procedure

Clinically successful treatment of non-target lesion, if applicable

Target Vessel Angiogram

Angiographic inclusion criteria:

- *De novo* or re-occluded CTO in native femoropopliteal artery
- Occlusion length 1-30 cm
- Vessel diameter ≥4 mm
- Distal vessel visualization
- (collateral supply)

Angiographic exclusion criteria:

- Thrombus or intraluminal filling defects
- Occlusion in a stent
- Target lesion within/near an aneurysm
- Perforated vessel
- Heavily calcified lesion

OffRoad introduced to treat the target lesion (enrollment)

30-Day Follow-up

- Rutherford Category assessment
- Duplex ultrasound, if applicable

Re-ROUTE Trial Endpoints

Primary Safety

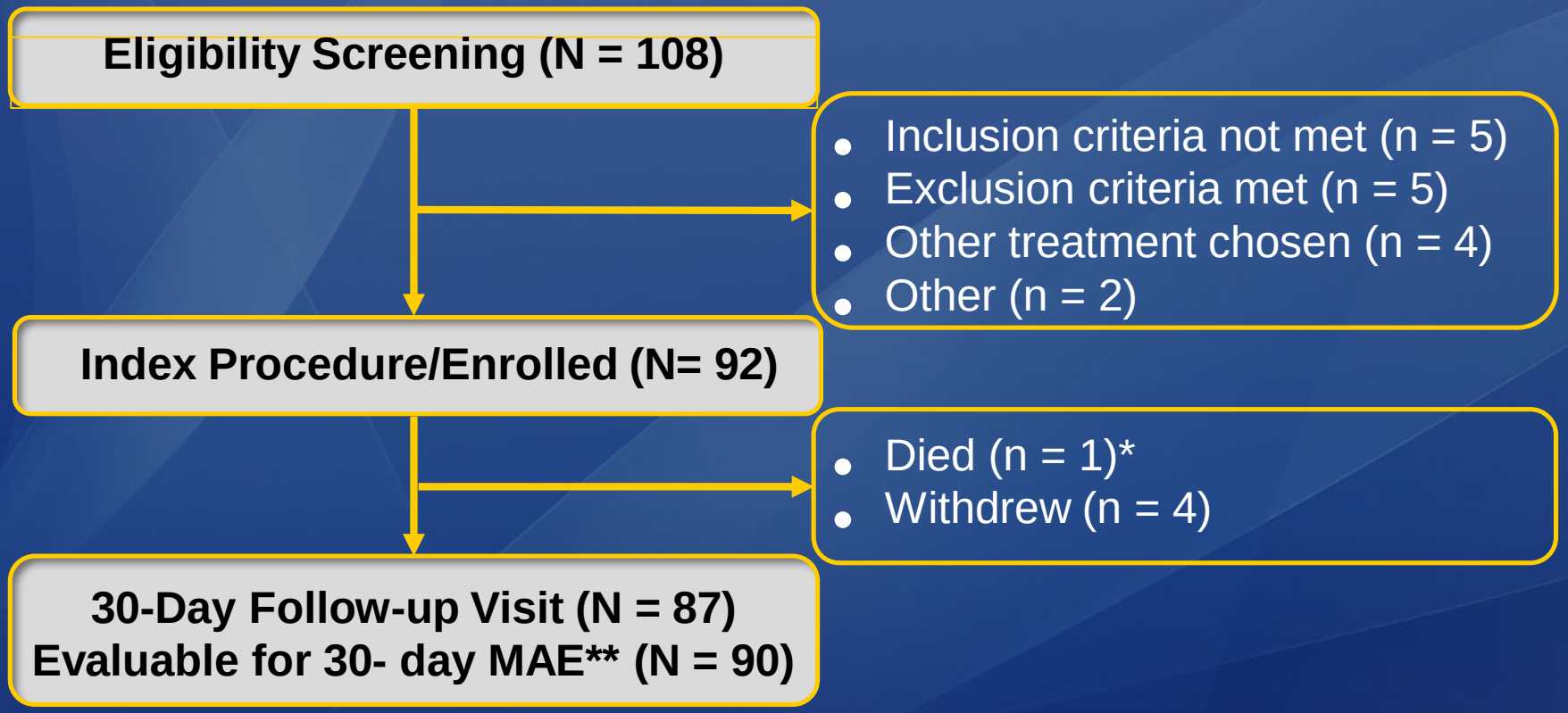
- Device-related MAEs through 30 days following the index procedure
  - Death
  - Perforation requiring intervention
  - Clinically significant peripheral embolism
  - Major amputation
- Adjudicated by clinical events committee
- Performance goal of 15% MAE rate

Primary Effectiveness

- Device technical success
  - Placement of a guidewire in the true lumen distal to the CTO
- Performance goal of 76% technical success rate

MAE = major adverse event

Re-ROUTE Subject Disposition



** Subject died 15 days after the procedure due to cholecystitis. The Clinical Events Committee determined that this death was not related to the study device.*

*** Follow-up ≥23 days or had an event within 30 days.*

MAE = major adverse event

Baseline Patient Characteristics

Demographic Characteristics (N = 92)	
Age, mean ± SD	70.29 ± 10.56
Male gender	69.6%
Caucasian race	98.9%

General Medical History (N = 92)	
History of smoking	77.2%
Current diabetes mellitus	51.1%
History of hyperlipidemia requiring medication	66.3%
History of hypertension requiring medication	81.5%
History of chronic obstructive pulmonary disease (COPD)	9.8%
History of renal insufficiency	19.6%

Cardiovascular History

Cardiovascular History (N = 92)	
History of coronary artery disease (CAD)	32.6%
History of myocardial infarction	17.4%
History of chronic heart failure (CHF)	6.5%
History of percutaneous coronary intervention (PCI)	17.4%
History of coronary artery bypass graft (CABG)	5.4%
History of cerebrovascular accident	12.0%
History of other peripheral interventions	43.5%
History of claudication	89.1%

Lesion Characteristics

Baseline Lesion Characteristics (N = 92)	
Reference vessel diameter (mm)	5.18 ± 0.62
% Occluded	100.00 ± 0.00
Lesion length (mm)	175.12 ± 85.42
Calcification	
None/mild	46.7%
Moderate	47.8%
Severe	5.4%
Primary diagnosis	
Claudication	84.8%
Critical limb ischemia	15.2%

Case 2046-07 presentation

- 71 year-old female
- Vascular risk factor
  - nicotine abuse
- Current status:

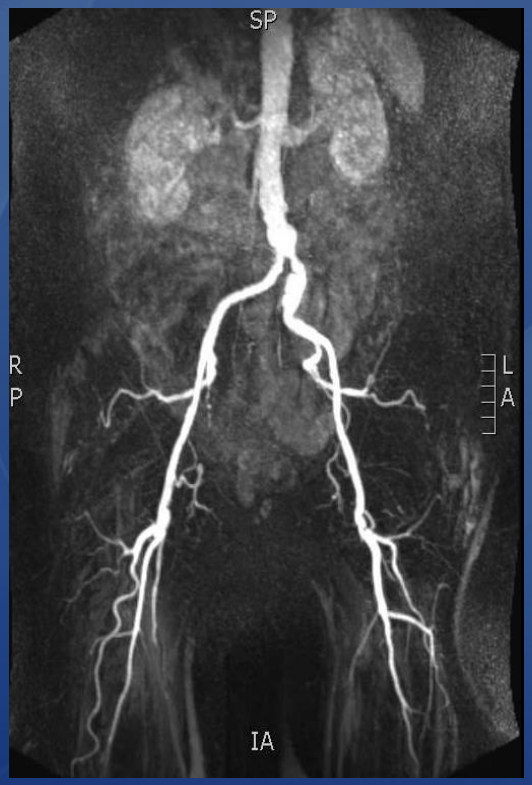
  R2 bilateral

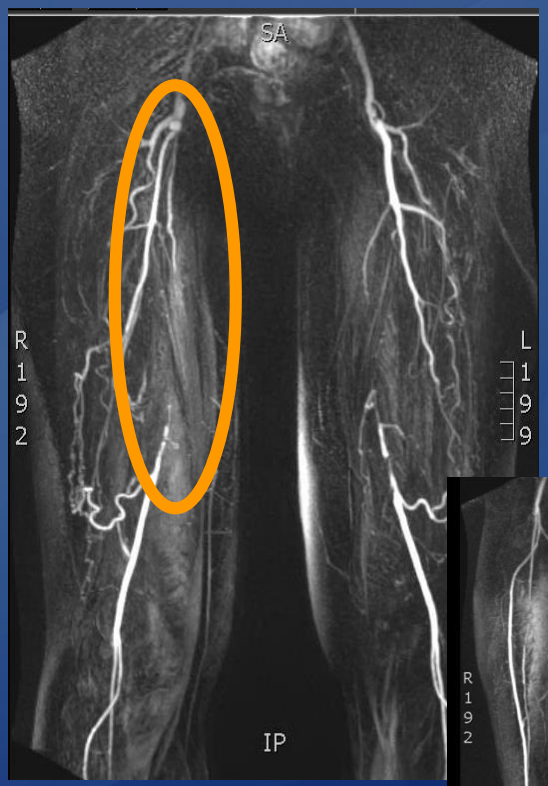
  Pulsations only femoral, no distal

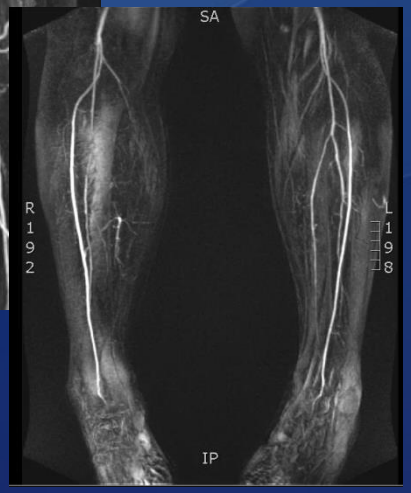
  ABI 0.7

  CFDU: ostial-SFA occlusion

  MRI





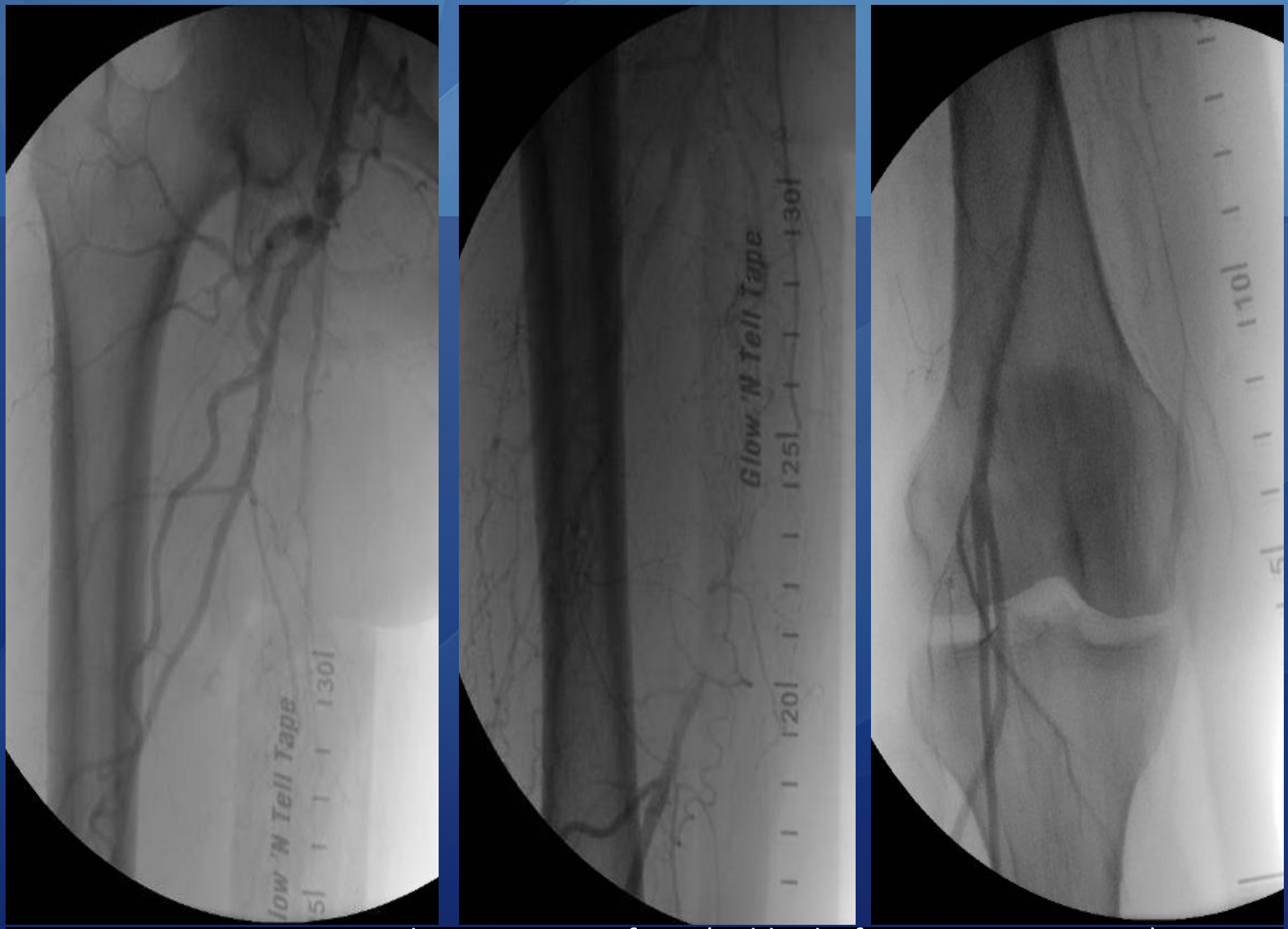


10/2012

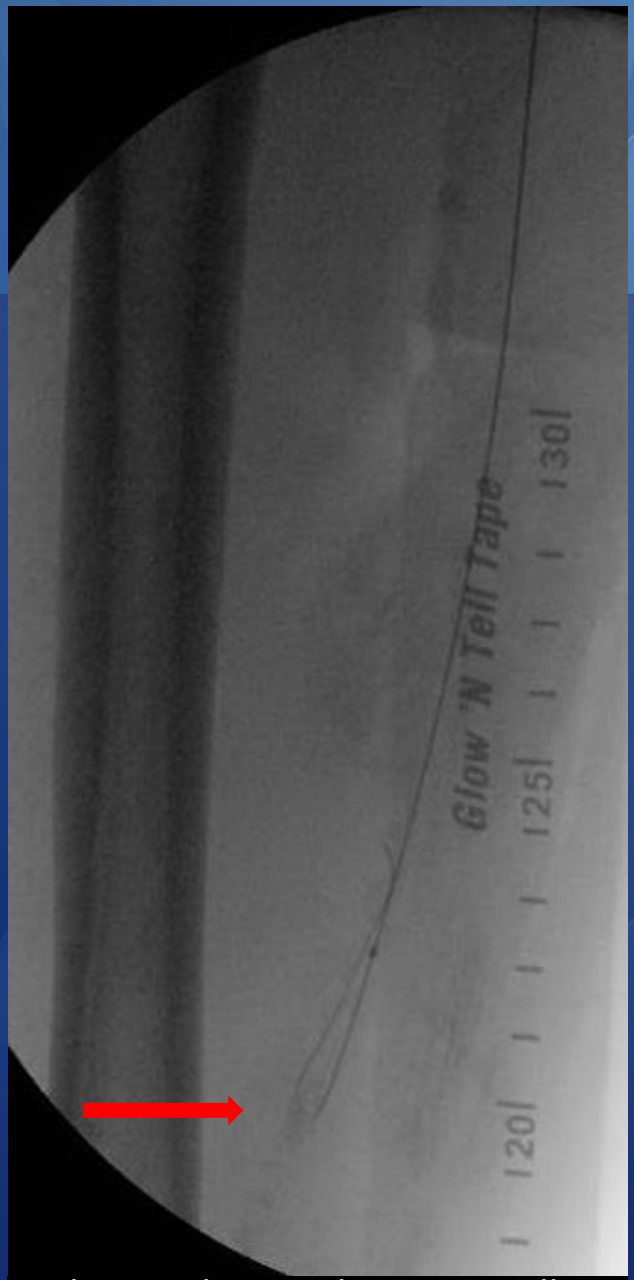
Normal inflow

Ostial 180mm occlusion right SFA

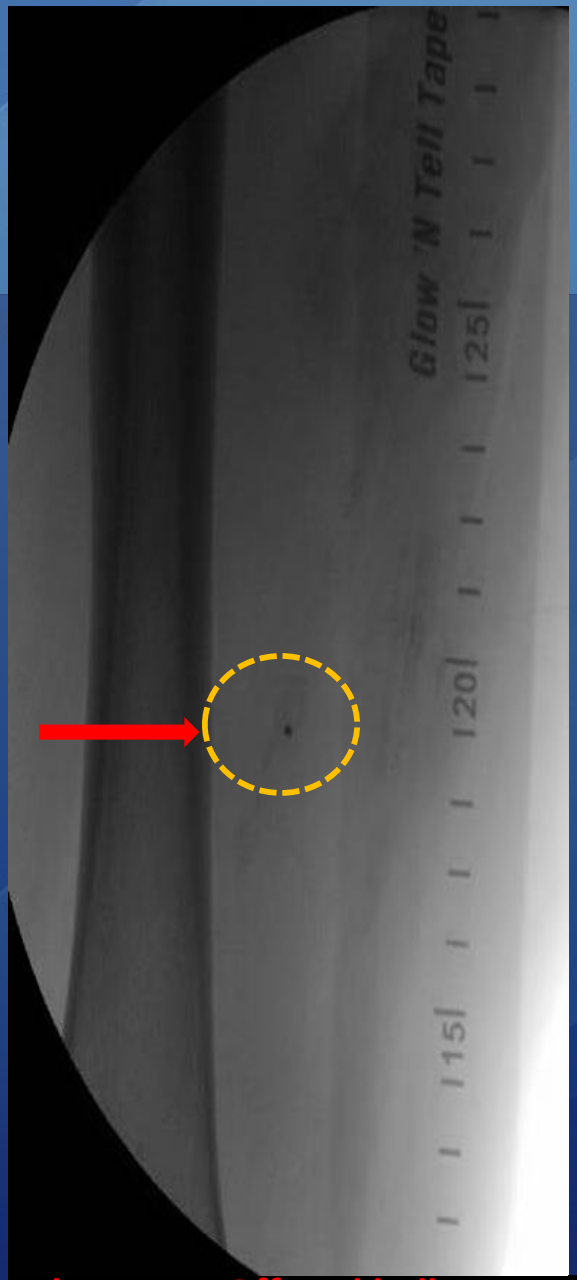
Abnormal origin ant. tibial artery)



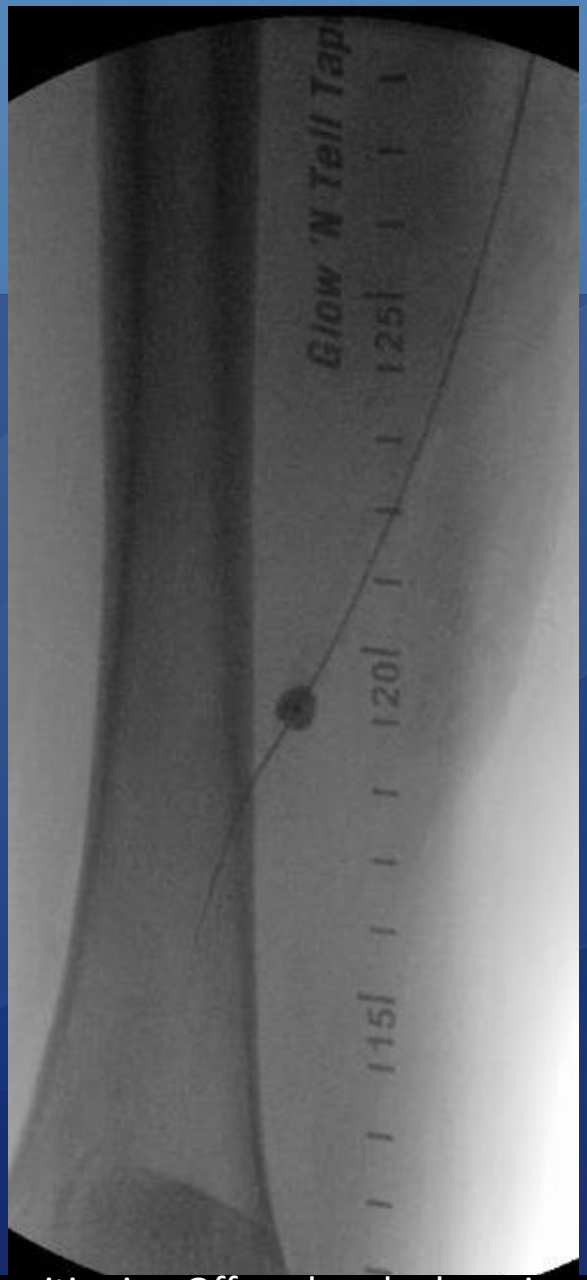
Case 2046-07: Ostial 180mm CTO of SFA (mild calicification, RVD 4.5 mm)



Subintimal recanalization untill intented re-entry

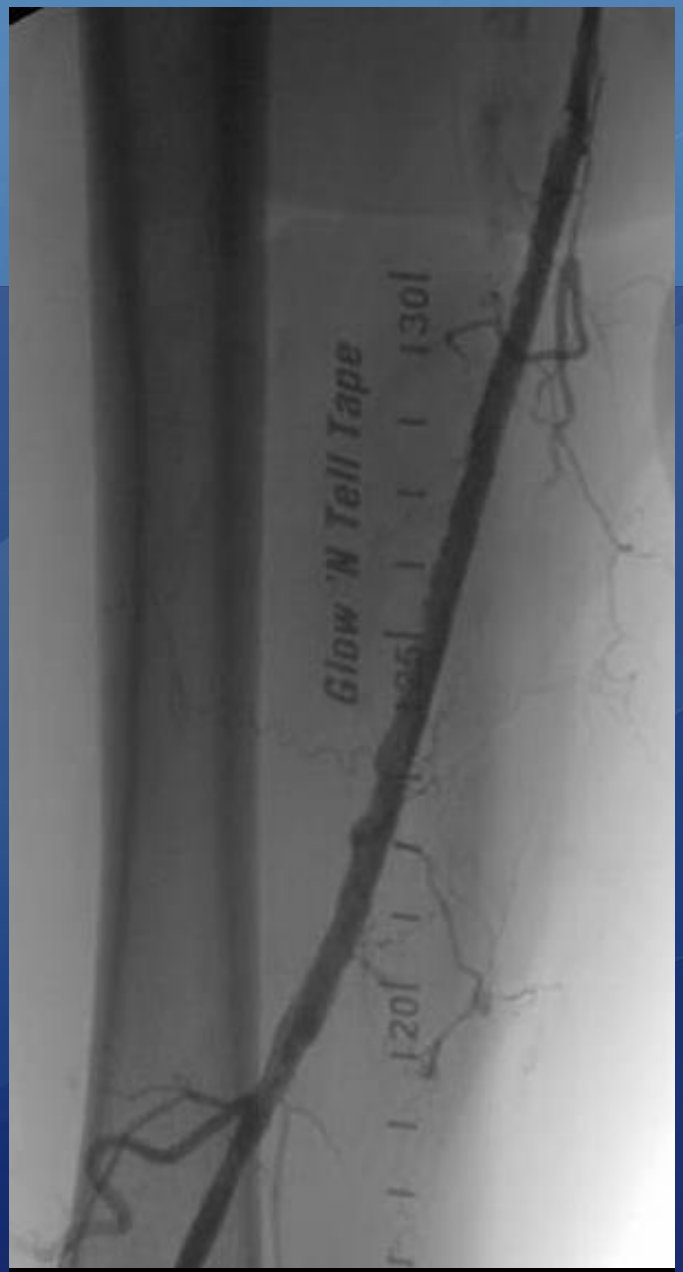


Placement Offroad balloon catheter



Positioning Offroad and advancing microcatheter lancet and GW

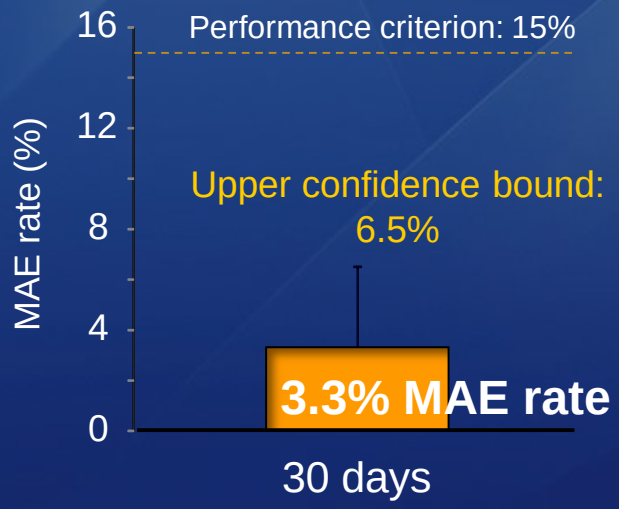
PTA 4 x 60



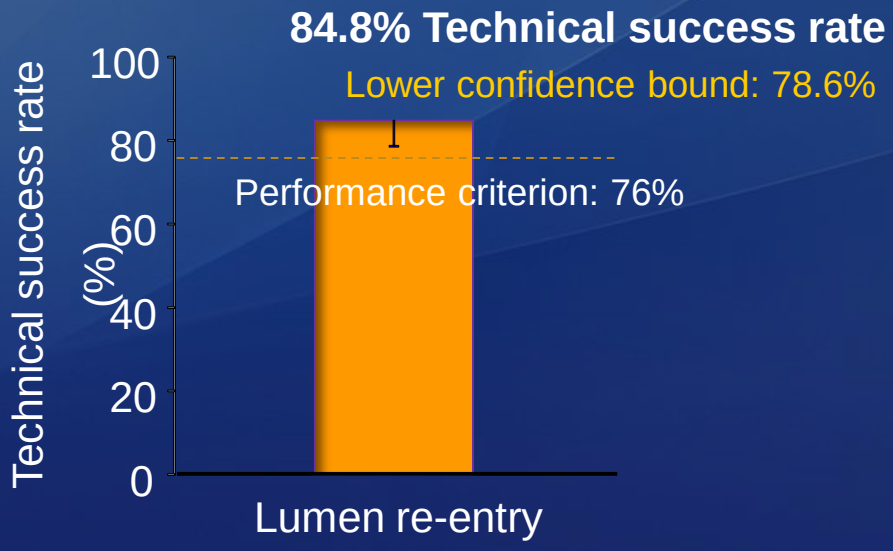
Final angiogram after PTA

Re-ROUTE Primary Endpoint Results

- Primary Safety Endpoint Met
  - 3.3% composite rate of device-related MAEs at 30 days
  - The 3 events were clinically significant peripheral emboli
  - Upper confidence bound MAE rate (6.5%) less than the performance goal of 15%

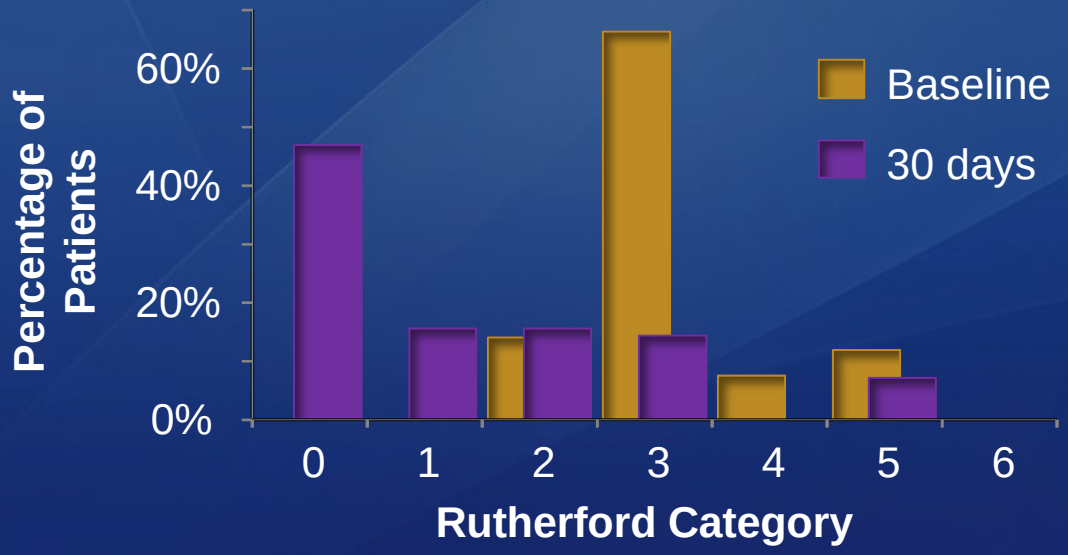


- Primary Effectiveness Endpoint Met
  - Site-reported technical success (lumen re-entry) 84.8% (78/92)
  - Lower confidence bound for site-reported technical success (78.6%) exceeded the performance goal of 76%



Re-ROUTE Symptom Outcomes

- Rutherford Assessments
  - 75% of subjects decreased ≥1 category at 30 days post-procedure
  - Range shifted from categories 2-5 at baseline to 0-5 at 30 days



CONCLUSION

The Re-ROUTE results demonstrate that the OffRoad System is a safe and effective treatment option for recanalization of femoropopliteal CTOs