

# Endovascular Revascularization of Long Femoropopliteal Occlusions Using the Outback Re-Entry Catheter

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**13th Annual MIT Interventional Radiology  
and Endovascular Therapy Seminar**

**Faculty Disclosure  
Mark W. Mewissen M.D.**

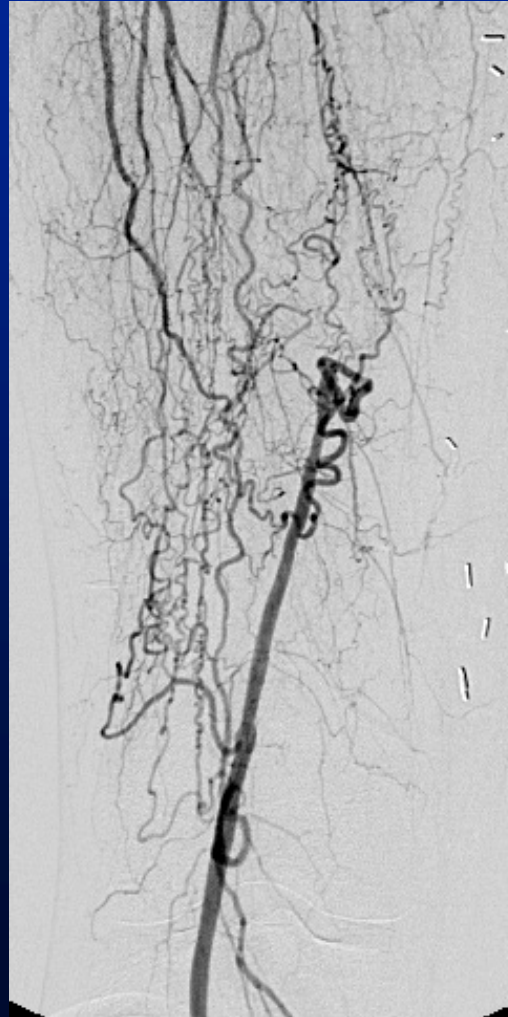
**I hereby disclose that I:**

**Am a consultant for Abbott, Cordis Endovascular, Medtronic,  
Bayer and Lumend**

**Am a shareholder of Fox-Hollow**

# BACKGROUND

## TOTAL SFA OCCLUSIONS



## Endovascular

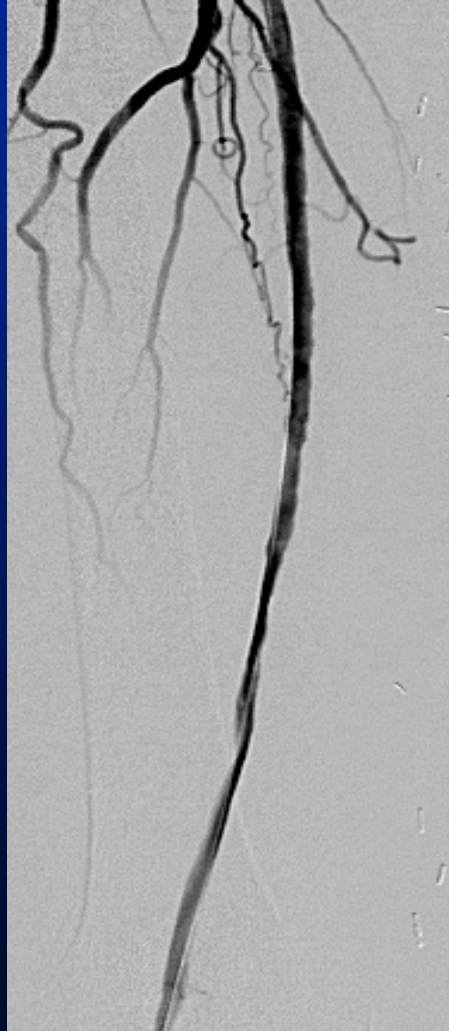
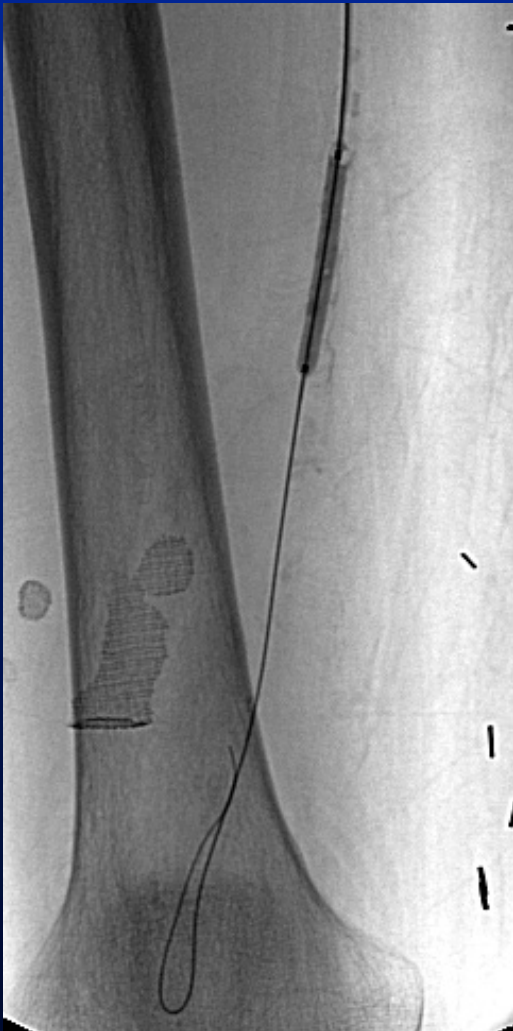
?

- **Technique**
- **Technical success**
- **Patency**

## BACKGROUND

Total SFA Occlusion: Bolia Technique: **PIER**

Bolia et al. PTA of occlusions of the femoral and popliteal arteries by subintimal dissections.  
CVIR 1990; 13: 357-363



**P**ercutaneous

**I**ntentional

**E**xtraluminal

**R**ecanalization

## BACKGROUND

Shaw et al: The Results of Subintimal Angioplasty in a District General Hospital. Eur J Vasc Endovasc Surg 2002; 24: 524-527

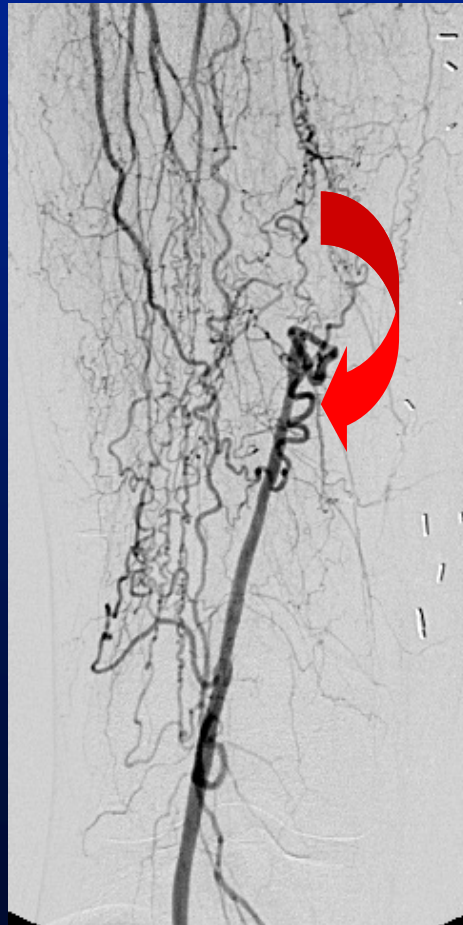
- N=50
- Lesion Length: 15 cm Median
- Primary Technical Success: N=39 (78%)
  - Vessel recanalization with antegrade flow
- 6 months Patency by Duplex
  - Intention to treat: 57%
  - Technical success only: 64%

# BACKGROUND

## PIER

- Relatively low technical success: 64-84%
  - Lumen reentry
- Low complication rate
- PIER Patency << Surgical Bypass
- Limb salvage > Hemodynamic patency
- Overall limited role
  - Critical ischemia
  - Severe comorbid risks
  - No suitable conduit

# TOTAL SFA OCCLUSIONS



## Endovascular

Must Re-enter True Lumen  
Irrespective of Device to be used

*PTA*

*Bare Stent*

*Covered Stent*

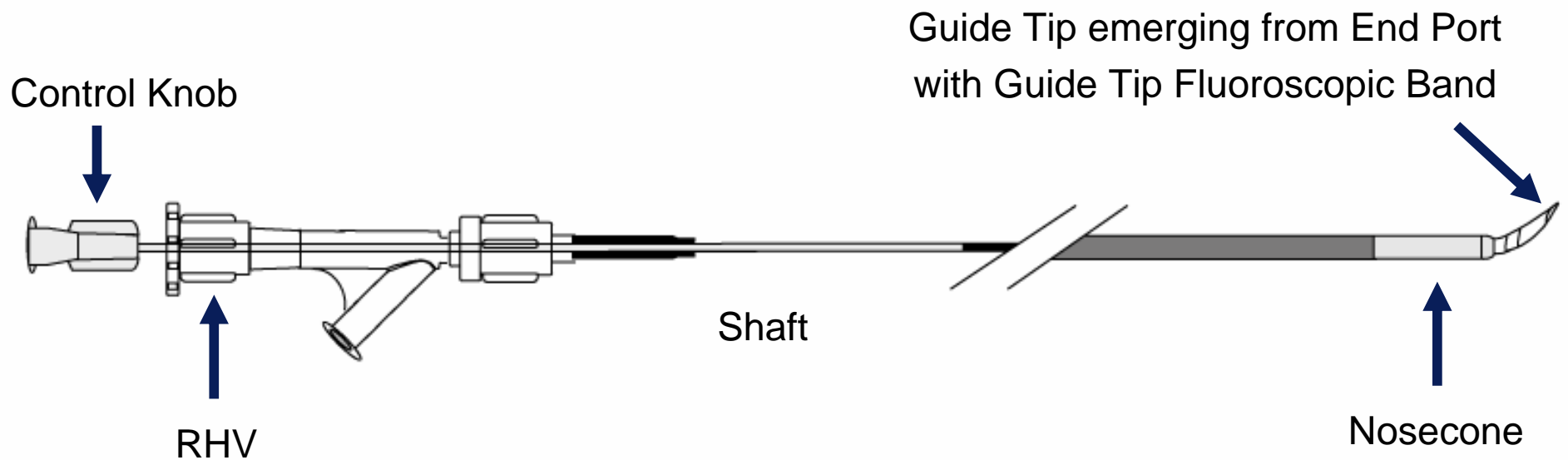
*Coated Stent*

*Any Future Device*

# Purpose

Evaluate the feasibility of using the Outback Re-Entry Catheter

- PIER
- Device re-entry



# Outback Re-Entry Catheter Technique

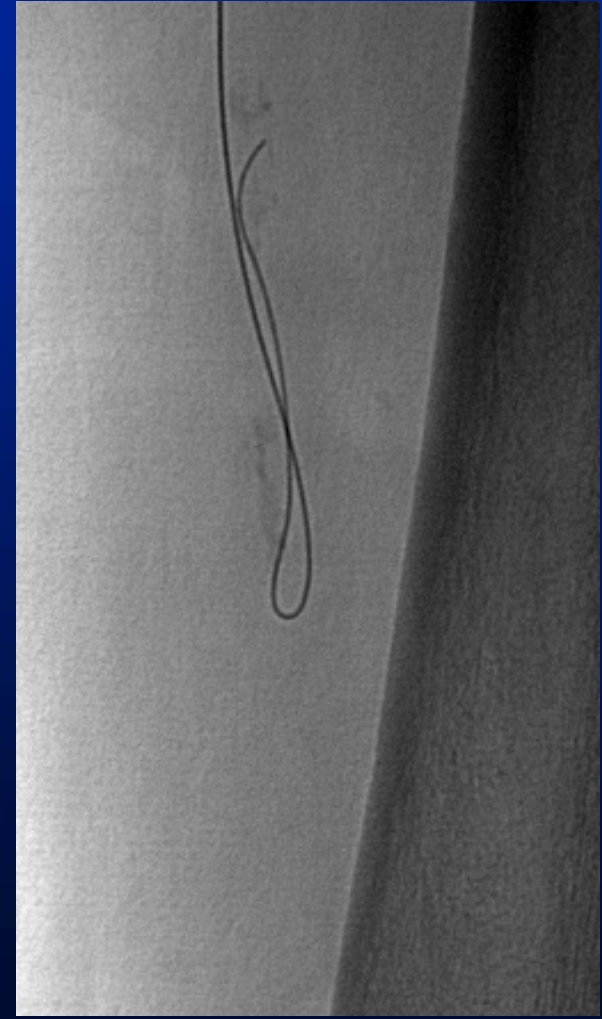
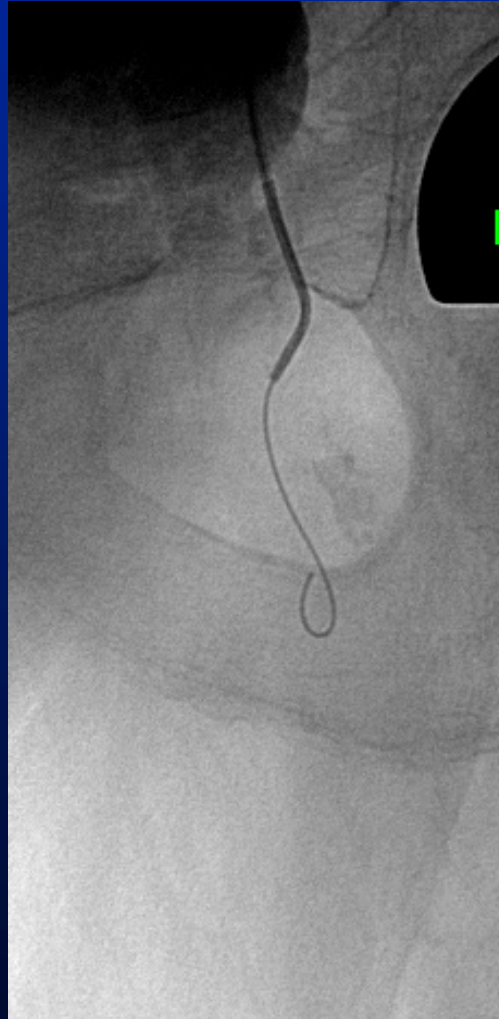


- 6F. Sheath over bifurcation
- 0.035 Rosen wire
- Angiographic localization of proximal SFA occlusion
- Proximal subintimal entry
- Create controlled subintimal dissection to level of true lumen reconstitution
- True lumen access
- Balloon Angioplasty/stent recanalization

# Outback Re-Entry Catheter Technique

## Proximal subintimal entry

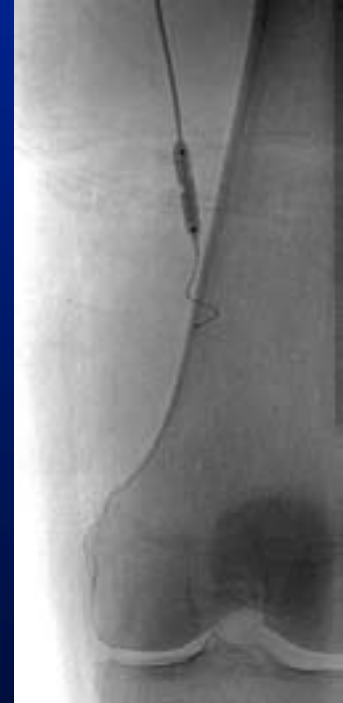
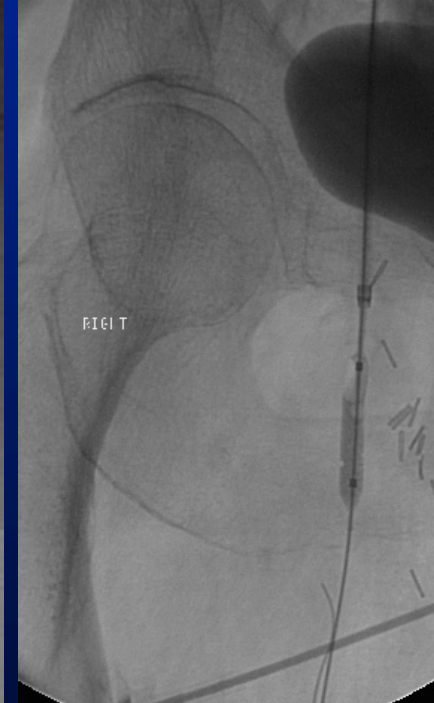
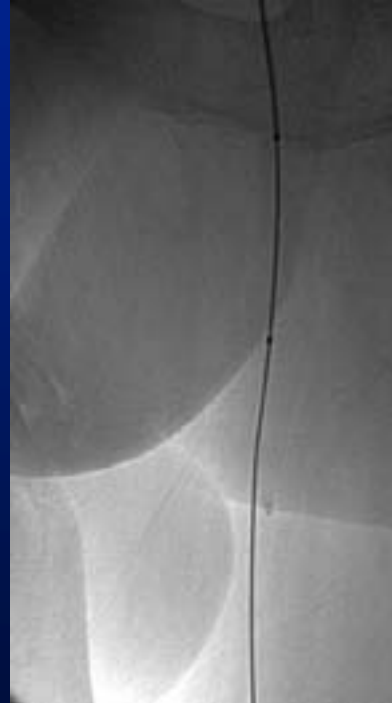
- Engage “nipple” with 5 F. curved catheter
- Probe with 0.035 curved-tip *exchange* glide wire
- Wire loop will form



# Outback Re-Entry Catheter Technique

Create controlled subintimal dissection to level of true lumen reconstitution

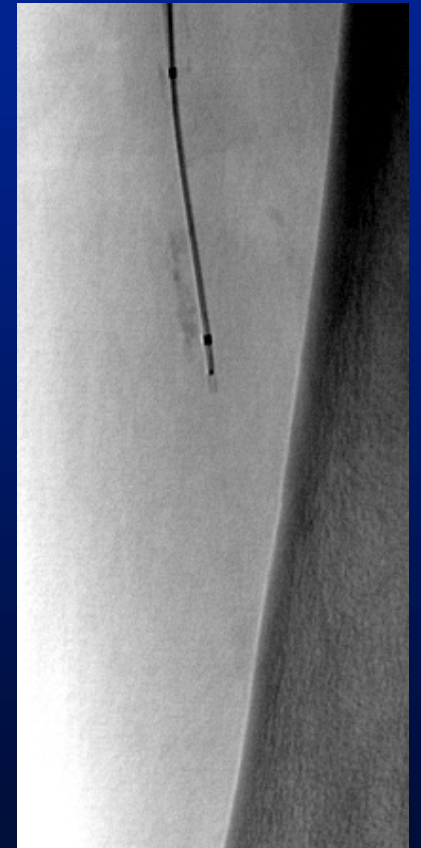
- Exchange for 5mm x 2cm PTA balloon
- Gently dilate at points of resistance in the subintimal space, if necessary (Calcium)



# Outback Re-Entry Catheter Technique

Create controlled subintimal dissection to level of true lumen reconstitution

- Advance looped wire PROXIMAL to reconstituted distal true lumen
- DO NOT PASS LOOPED WIRE DISTAL TO TRUE LUMEN RECONSTITUTION
- Advance PTA balloon to same level



# Outback Re-Entry Catheter Technique

## True lumen access

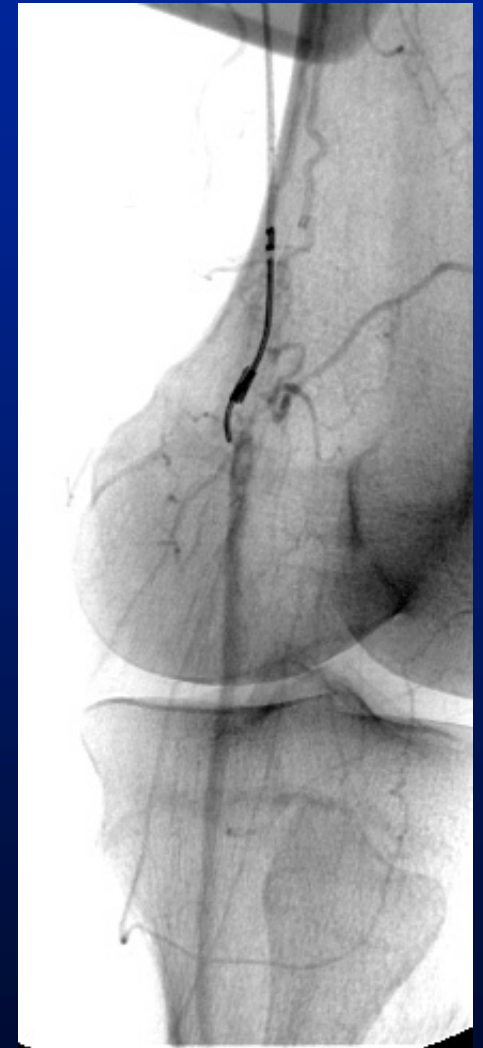
- Remove Glide wire
- Exchange for 0.014 or 0.018 wire
- Advance Outback device over wire to the level of true lumen



# Outback Re-Entry Catheter Technique

## True lumen access

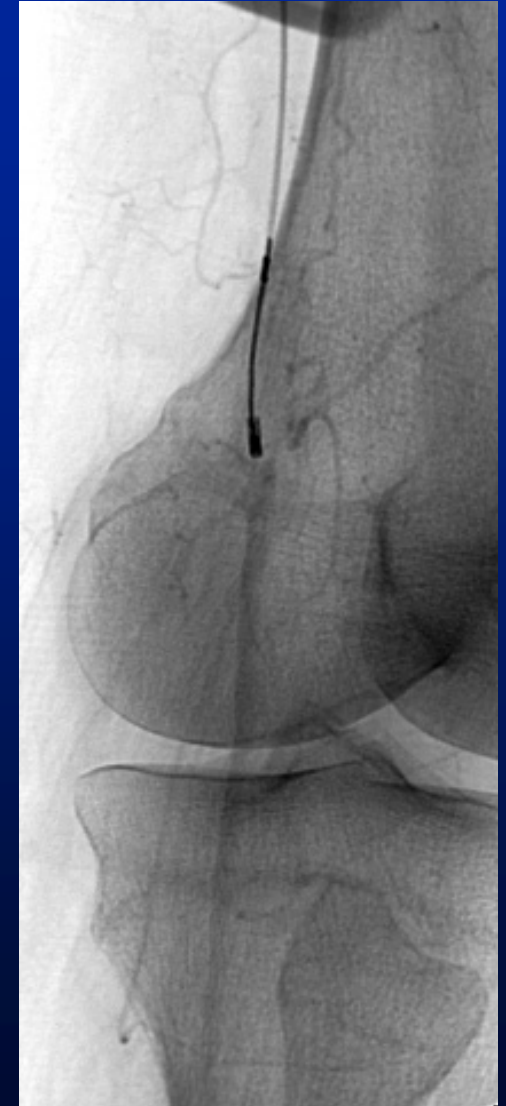
- Gently advance outback device as a unit until resistance is met
- Check position with respect to true lumen in 2 views
- Readjust position with gentle torque



# Outback Re-Entry Catheter Technique

## True lumen access

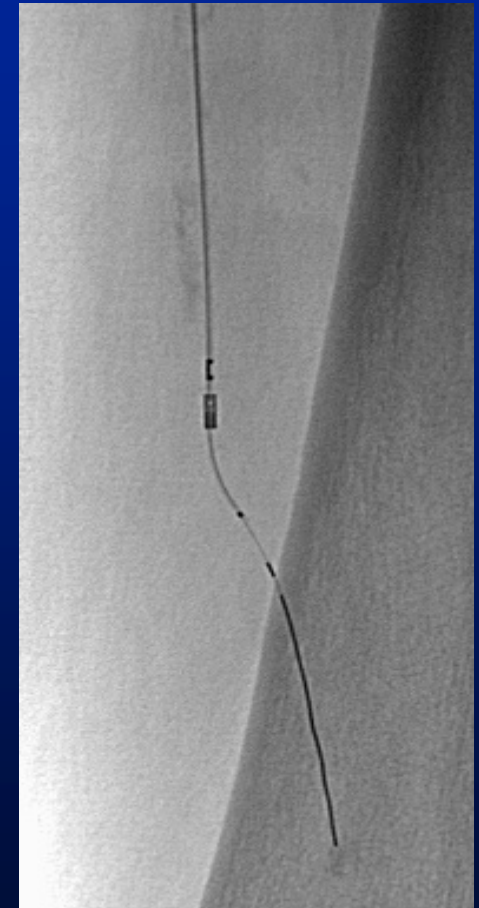
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# Outback Re-Entry Catheter Technique

## True lumen access

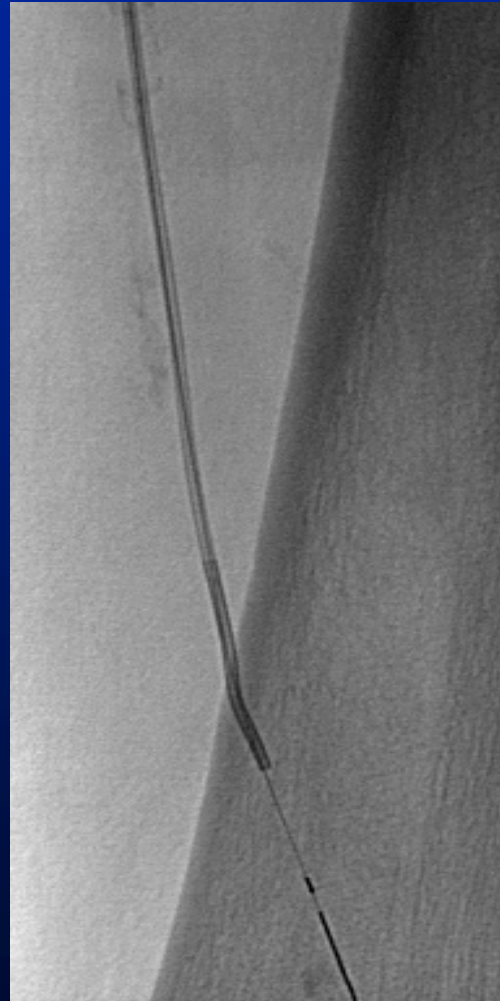
- Advance needle while keeping gentle forward force on unit
- Gently advance wire
- Wire should flow freely



# Outback Re-Entry Catheter Technique

## True lumen access

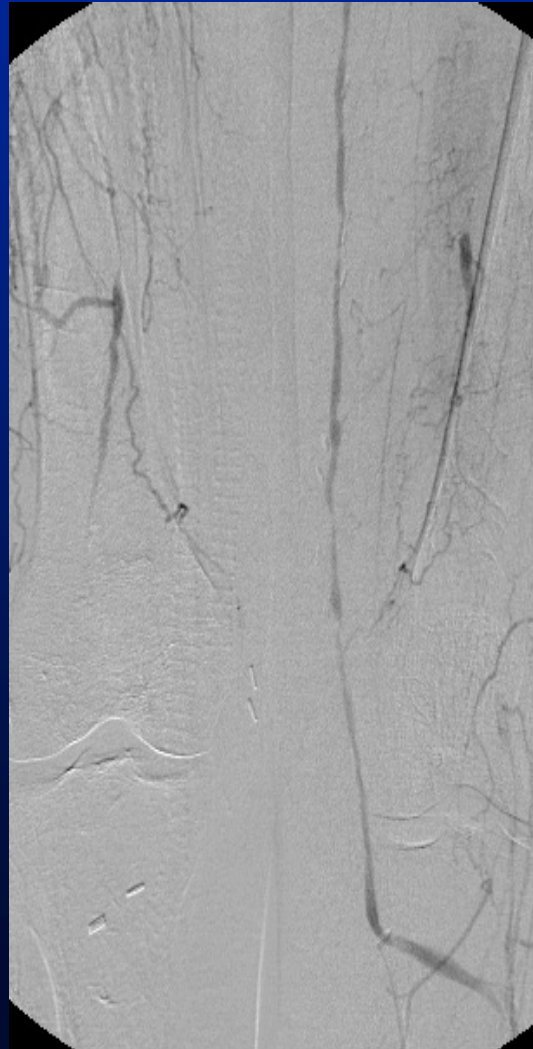
- Retract needle
- Remove outback device, leaving wire in true lumen
- Confirm location with 5 F. catheter



# Outback Re-Entry Catheter Patients

- From 12/17/03 to 10/10/04
- Patients: N=7
  - Male: N=4; Female: N=3
  - Critical ischemia and non-healing ischemic wounds: N=5
  - Life style limiting claudication: N=2
- SFA occlusion with AK Popliteal reconstitution in all
  - Mean occlusion length: 25.3 cm
  - Right: N=2; Left: N=5
  - Retrograde: N=6; Antegrade: N=1

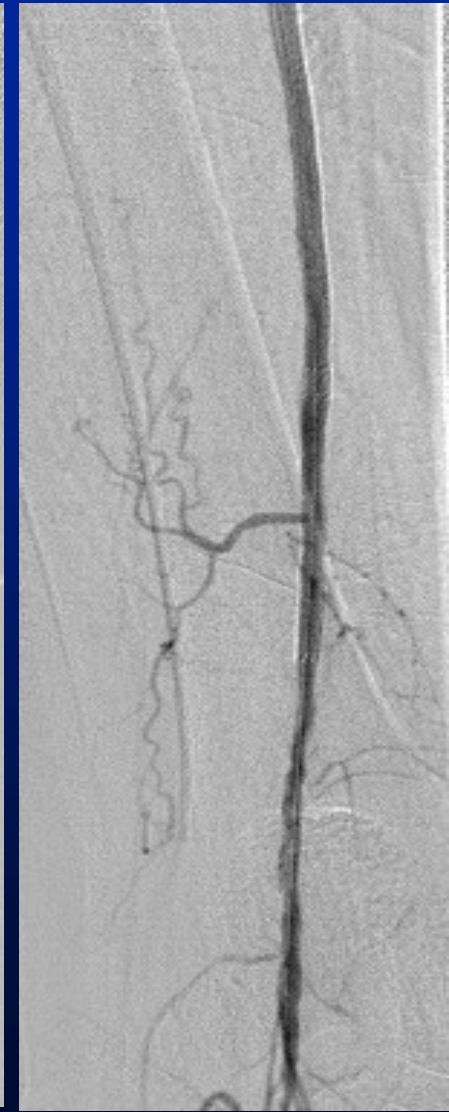
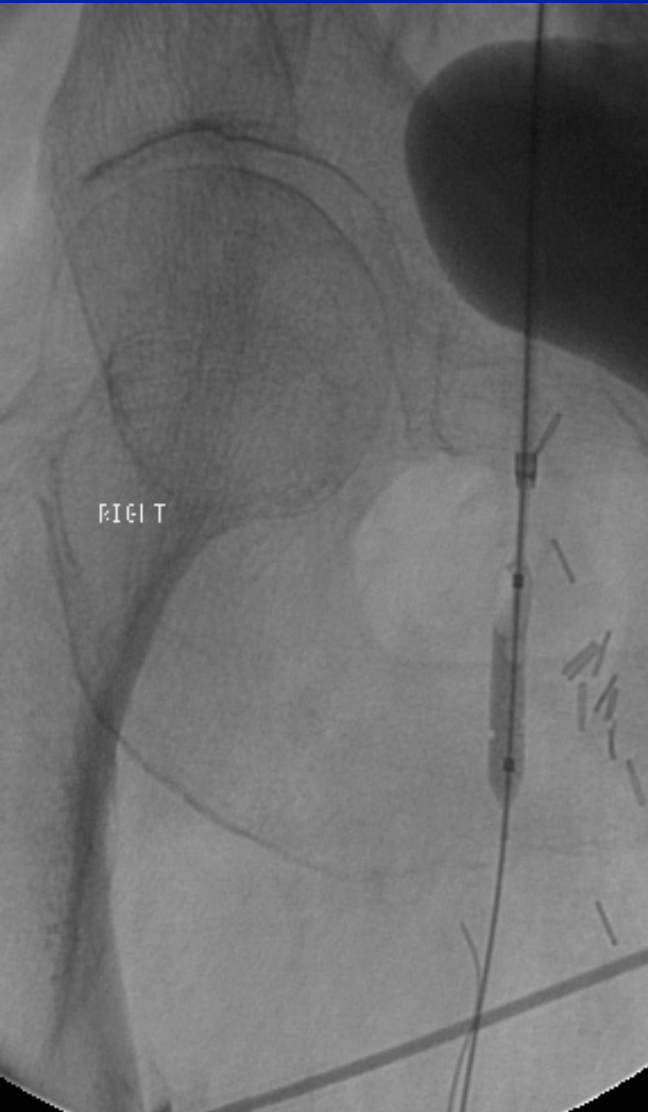
# Outback Re-Entry Catheter Case Presentation (TH)



**76 YO IDDM**

- **Non-healing Rt foot ulcer**
- **S/P Rt Infra-inguinal Bypass x 2**
- **CABG X 2**

# Outback Re-Entry Catheter Case Presentation

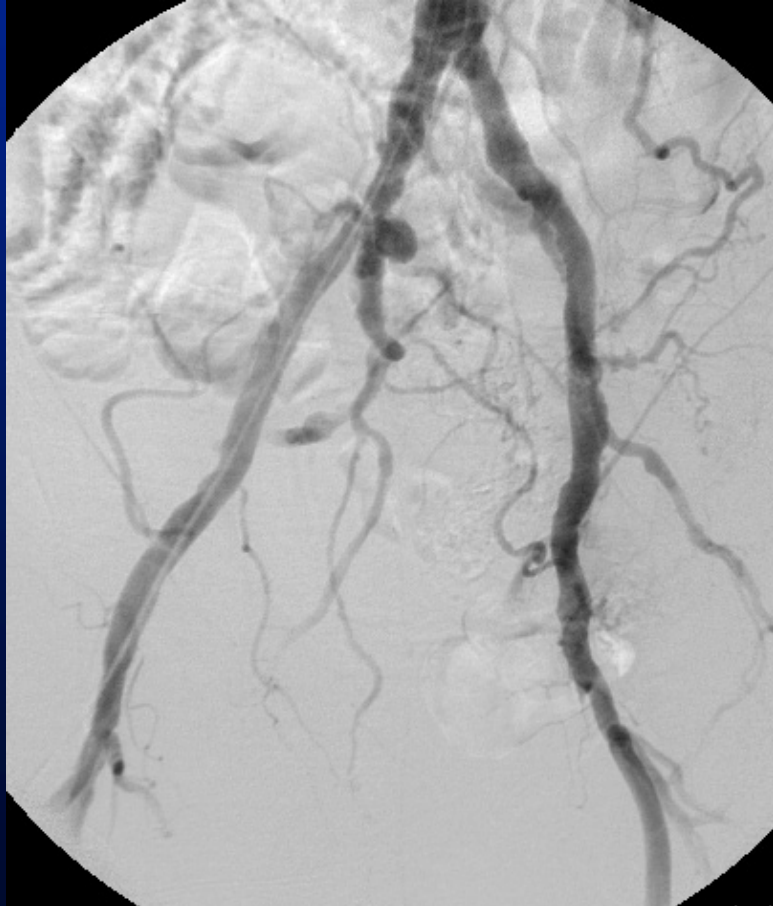


# Outback Re-Entry Catheter Case Presentation

- Duplex at 6 months show patent stents
- Right foot ulcer is healed

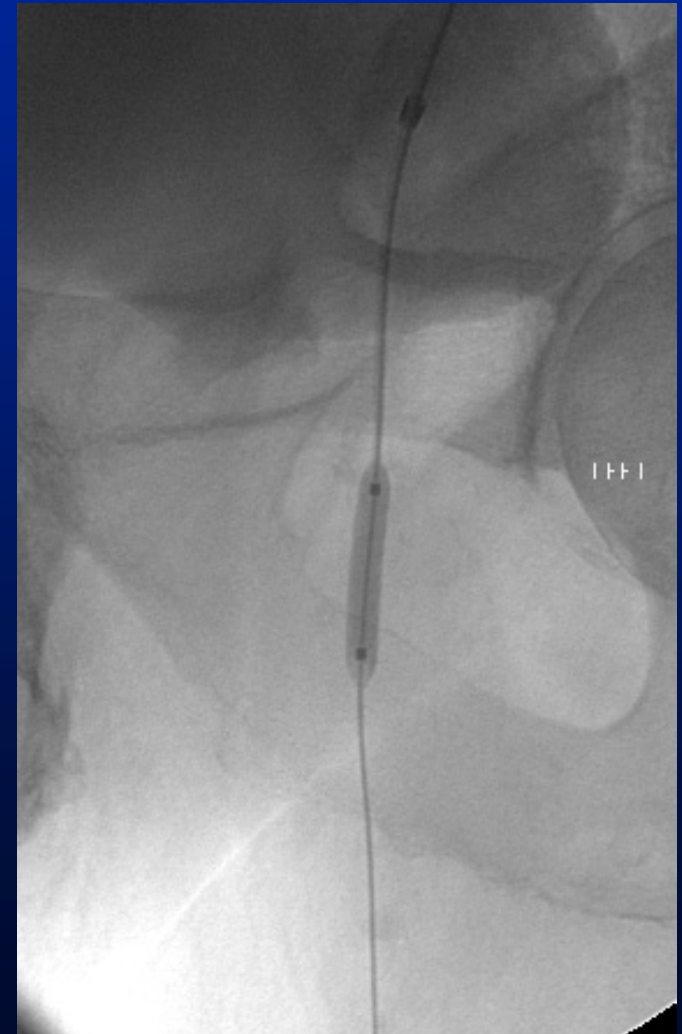
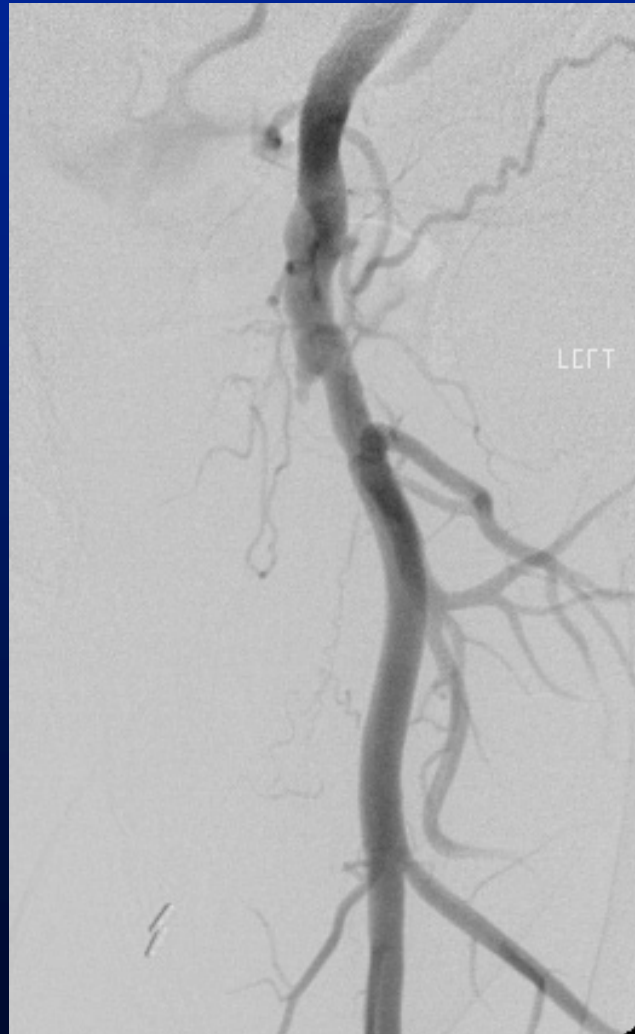
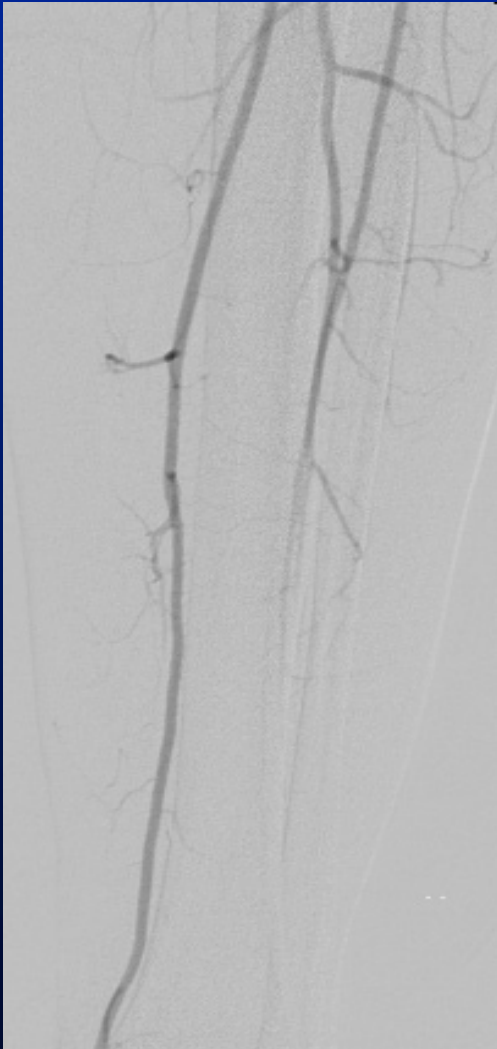
# •Outback Re-Entry Catheter Case Presentation (LJ)

Left Lower Extremity Claudication  
ABI: 0.5 at rest; 0.2 post Ex.



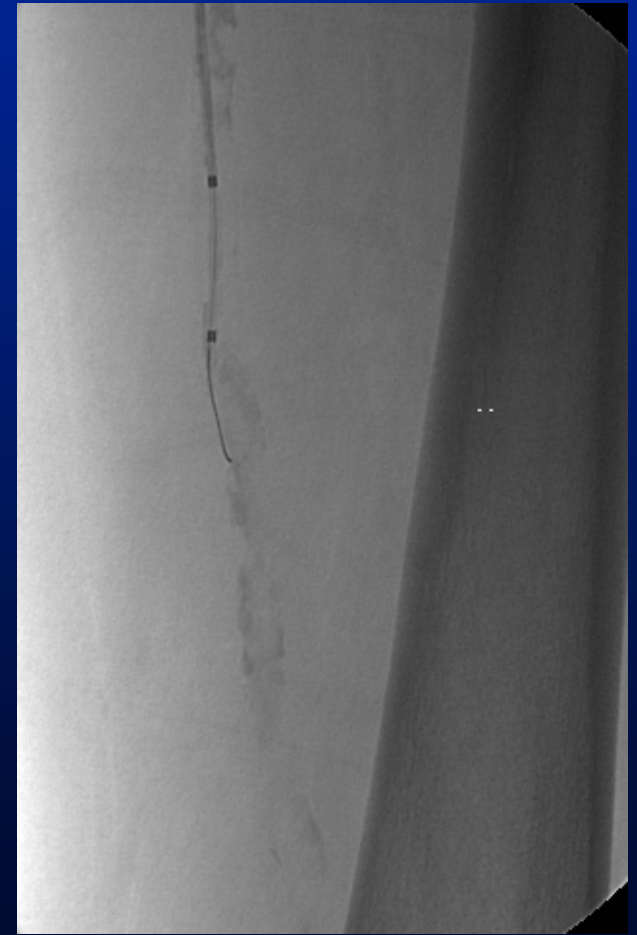
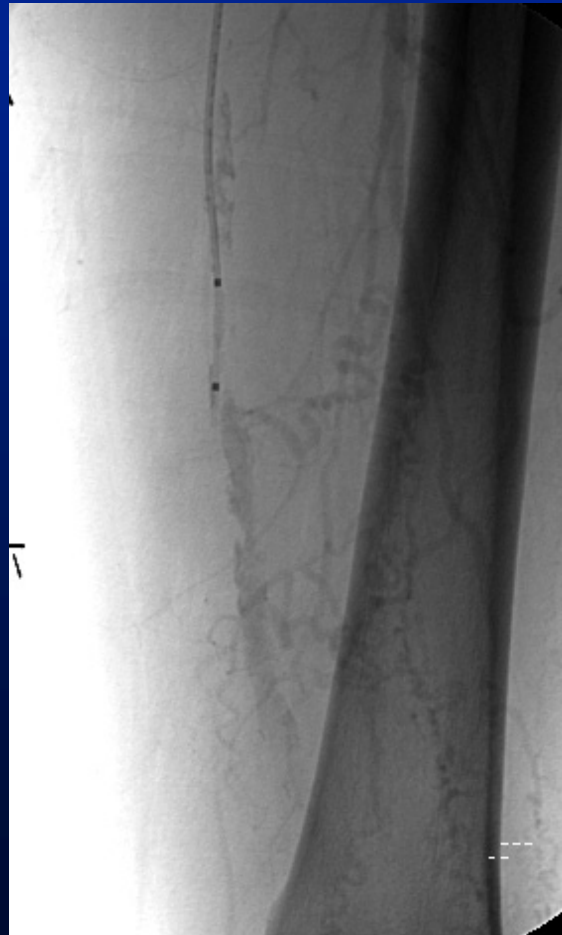
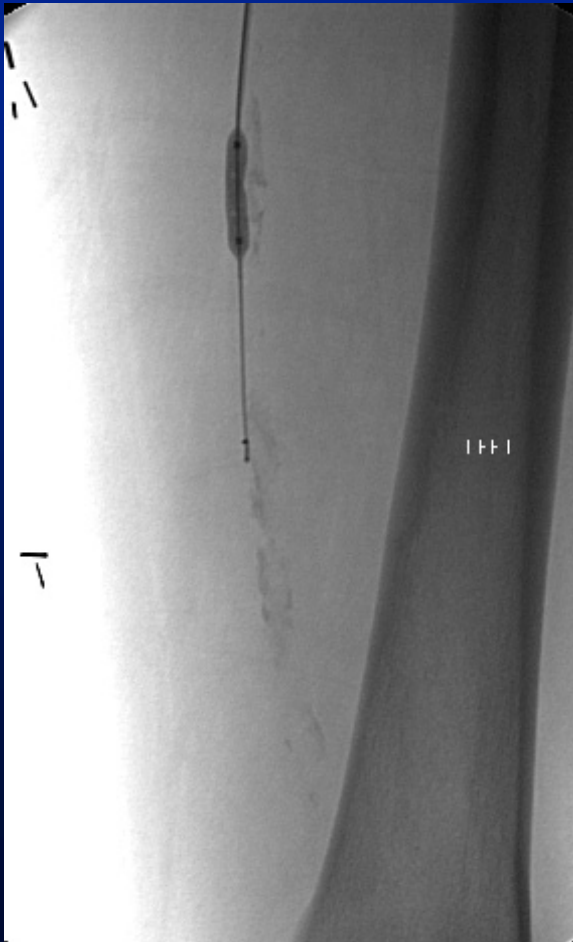
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Left Lower Extremity Claudication



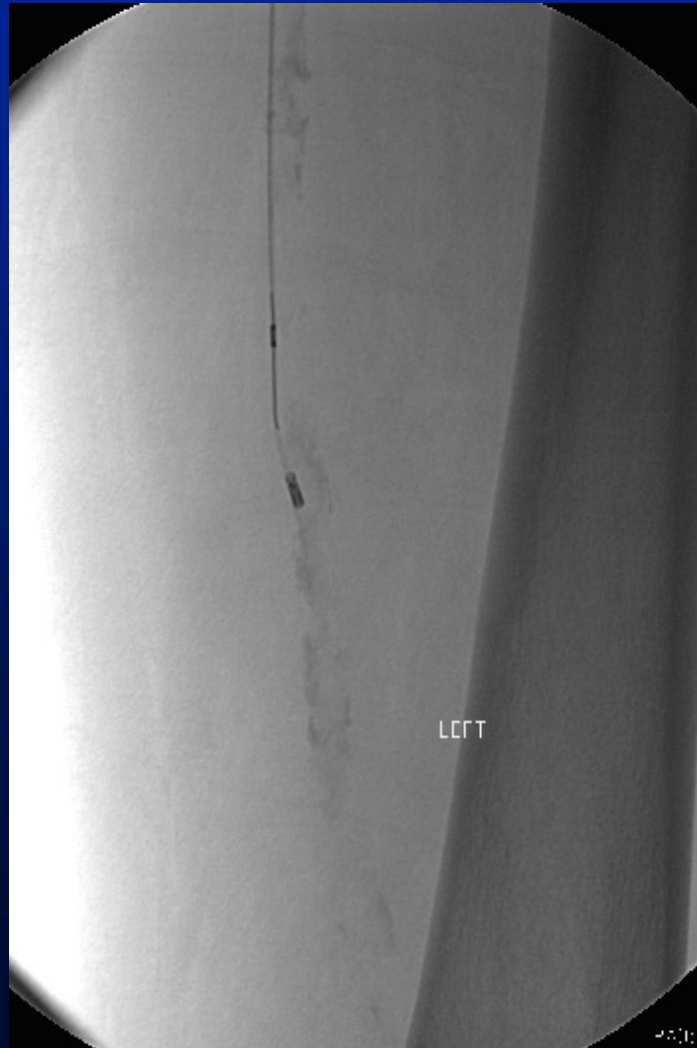
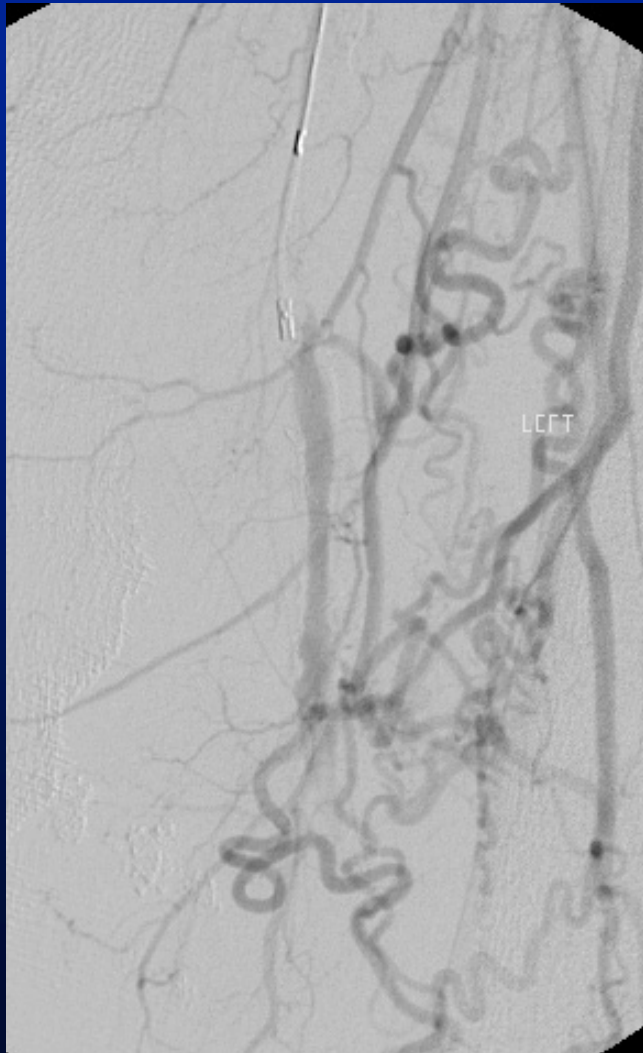
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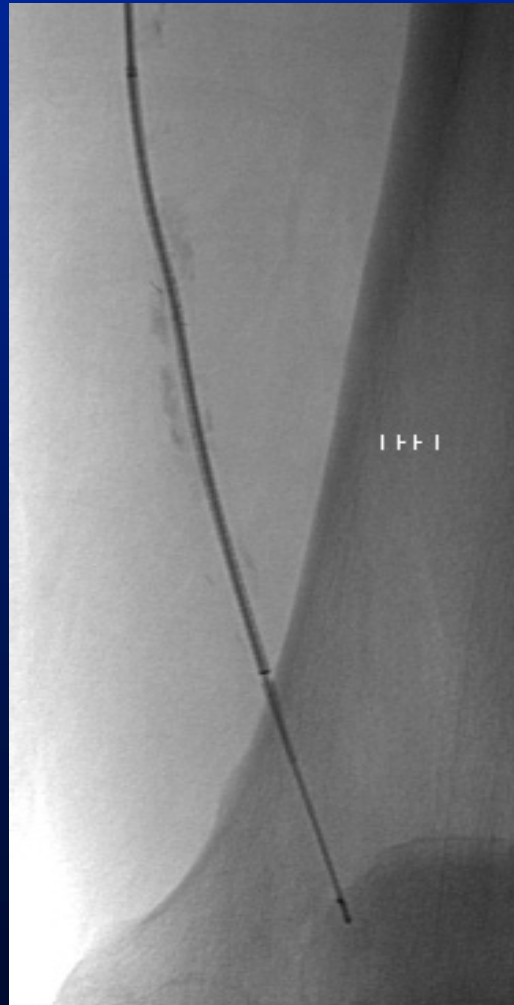
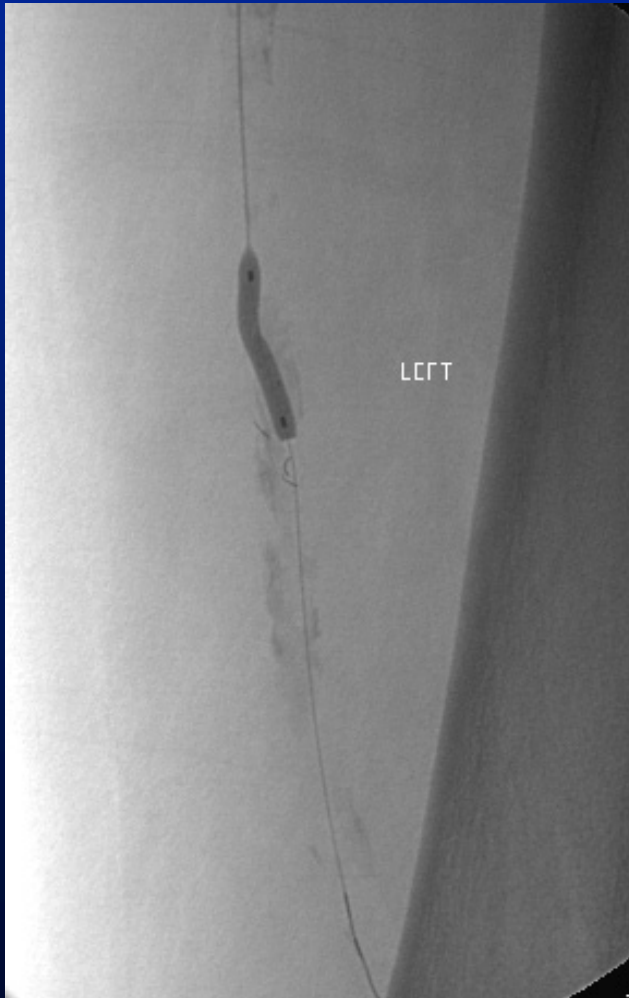
# •Outback Re-Entry Catheter Case Presentation (LJ)

Left Lower Extremity Claudication



# •Outback Re-Entry Catheter Case Presentation (LJ)

Left Lower Extremity Claudication



# •Outback Re-Entry Catheter Case Presentation (LJ)

Left Lower Extremity Claudication



# •Outback Re-Entry Catheter

## Case Presentation (LJ)

Left Lower Extremity Claudication

- Duplex at 6 months show patent stents
- ABI at 6 months: 0.95
- Asymptomatic

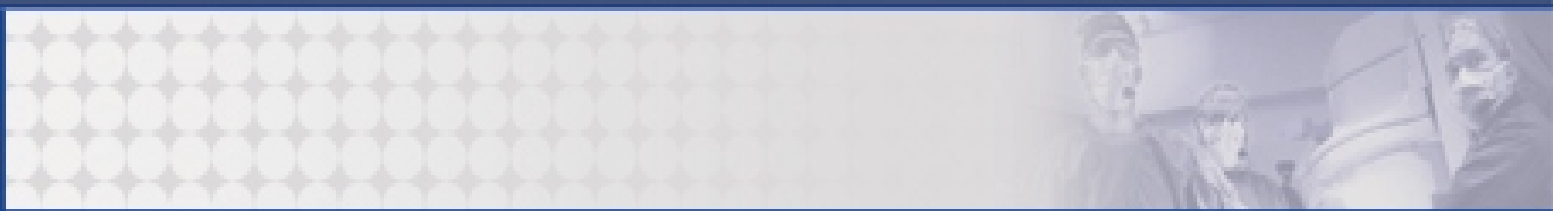
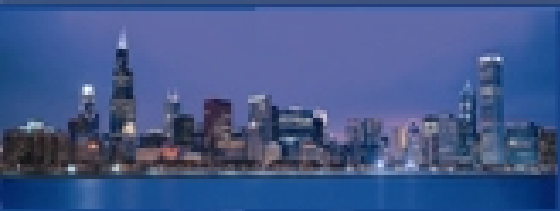
## Outback Re-Entry Catheter Results

- PIER successful with Outback Catheter in all patients
- PIER Stent Recanalization with Smart Stents
- No complication
- Duplex Follow-up:
  - 10 months cumulative Patency Rate=100%

# Outback Re-Entry Catheter

## Conclusion

- The use of the Outback Re-entry catheter to access the distal reconstituted true lumen of a superficial femoral arterial occlusion appears safe and effective
- As the profile and durability of endovascular revascularization devices become more refined, the endovascular treatment strategies for long SFA occlusions will become better defined
- The Outback Re-Entry Catheter plays an important role in the techniques of endovascular recanalization of long arterial occlusions



**Welcome to the**

**13<sup>th</sup> Annual MIT Interventional Radiology  
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**October 28-30, 2004**

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