



# Atherectomy is Still Live and Effective

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Professor of Medicine

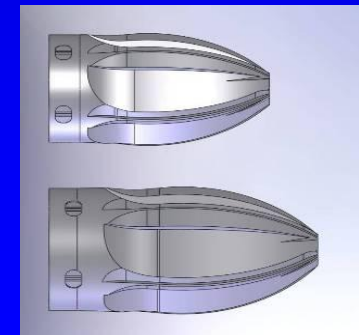
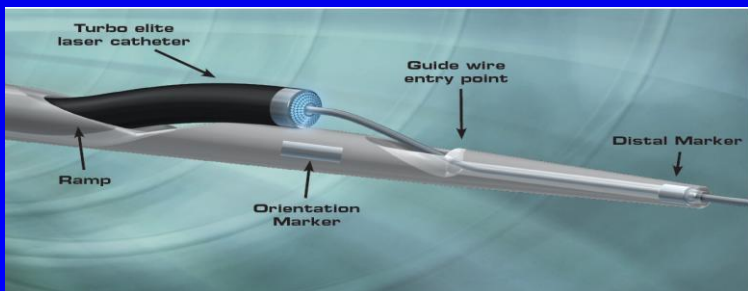
Medical Director of the Vascular Center

UC Davis Health System

# Why is Atherectomy Still Alive?

- Improved devices
- Better data (Definitive LE)
- Excellent reimbursement in US (outpatient labs)
- Niche applications (Calcium, ISR, non-stent zones)
- Possibility of Atherectomy plus DCB

# Device Evolution



# Case History

- 54 year old male
- Long standing diabetes mellitus
- ESRD on hemodialysis
- Low level claudication and ischemic rest pain (Rutherford 4)
- Referred for angiography and possible intervention



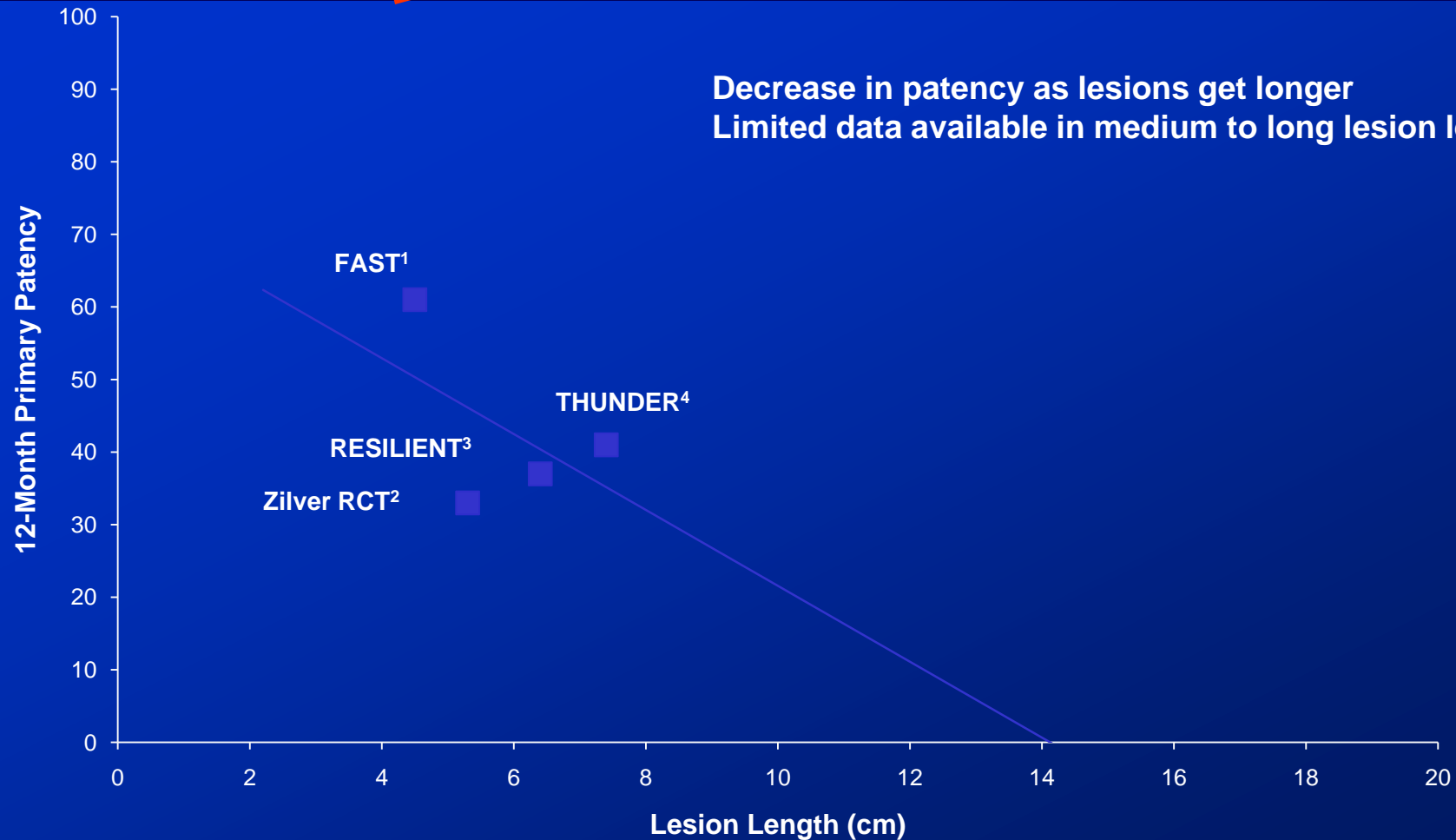
# Diffuse SFA Disease

What's the best treatment strategy?



# ~~PTA in SFA~~

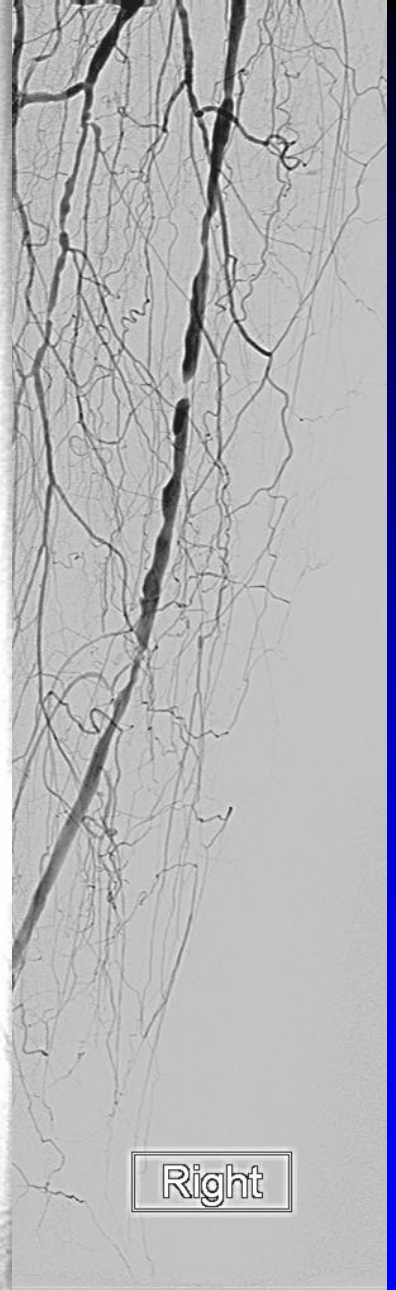
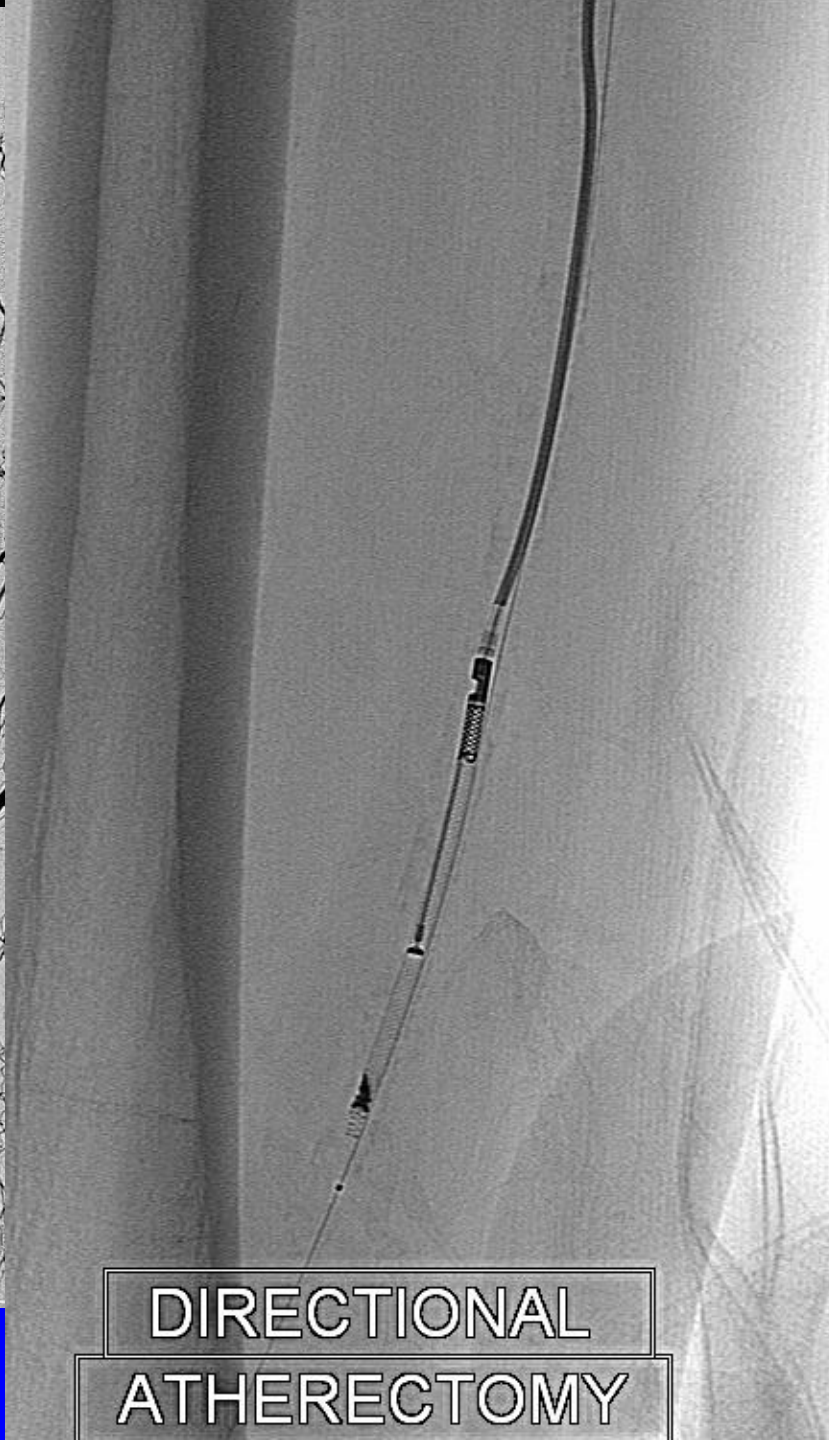
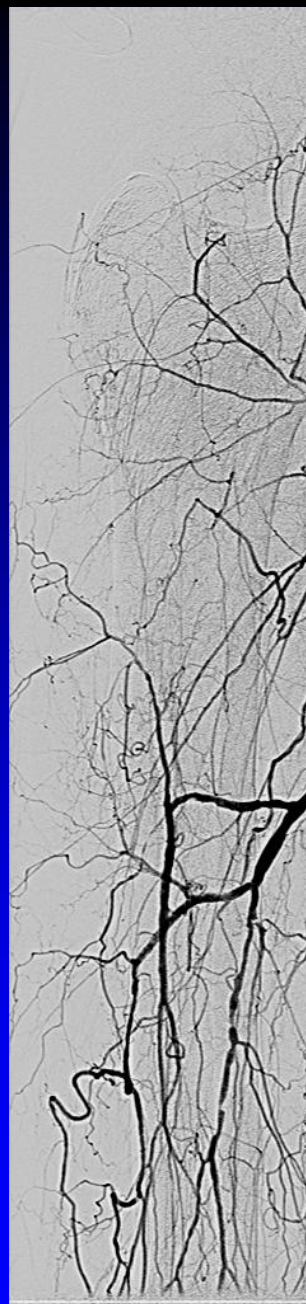
## ~~12-Month Primary Patency~~



1. Krankenberg et al. Circulation. 2007; 116(3): 285-92
2. Dake et al. Circ Cardiovasc Interv. 2011;4:495-504
3. Laird et al. Circ Cardiovasc Interv. 2010; 3: 267-276
4. Tepe et al. NEJM 2008;358:689-99

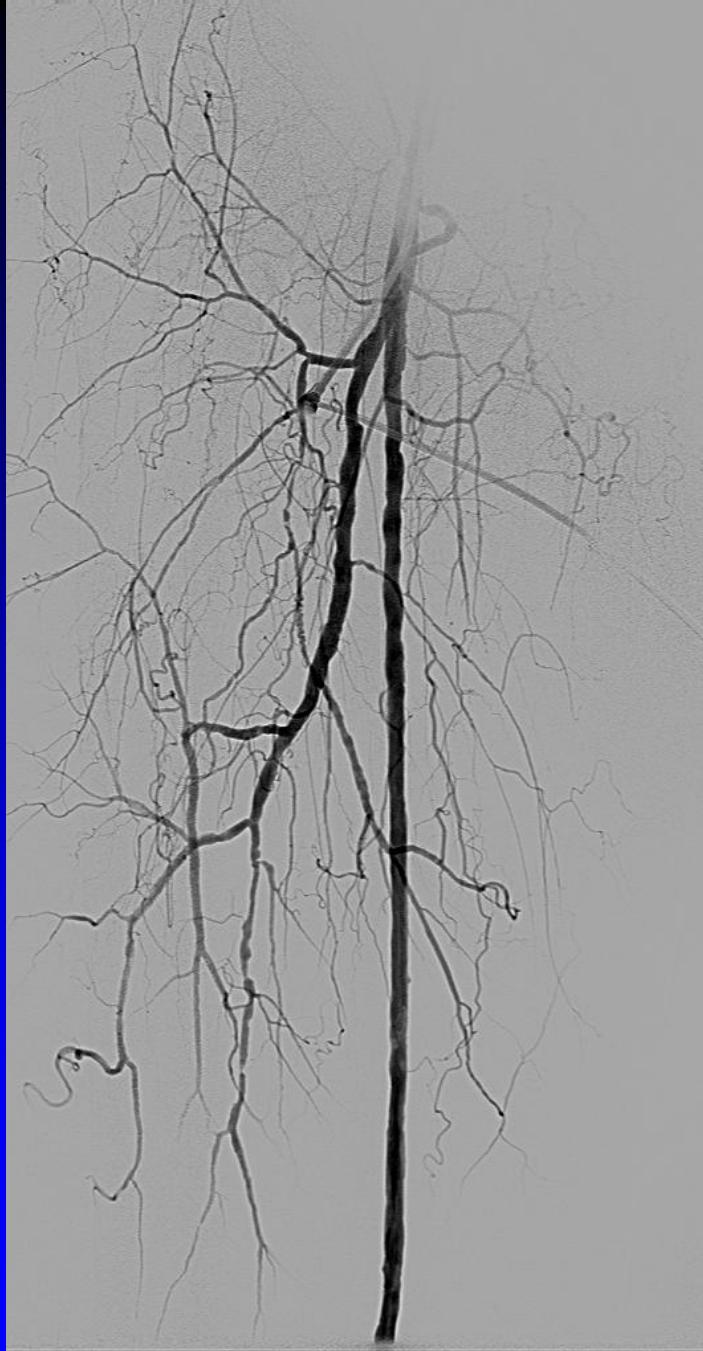


# Diffuse SFA Disease



Right

DIRECTIONAL  
ATHERECTOMY



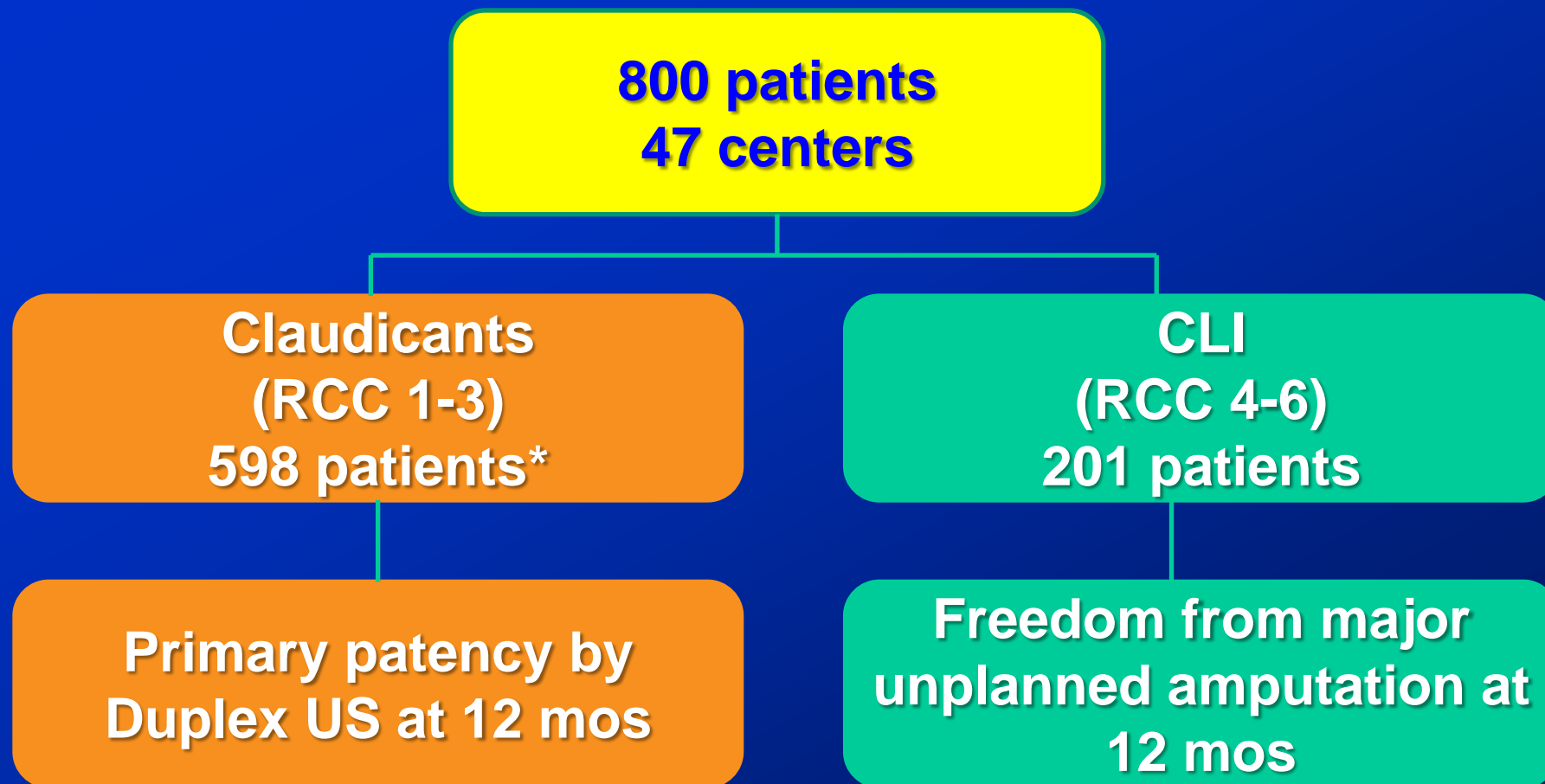
AFTER ATHERECTOMY



# Definitive LE - Study Design

- **Primary Objective:**
- To evaluate the intermediate and long-term effectiveness of stand-alone SilverHawk™ /TurboHawk™ Peripheral Plaque Excision Systems for endovascular treatment of peripheral arterial disease in the femoro-popliteal and tibial-peroneal arteries.
- **Details & Oversight:**
  - Pre-specified diabetic vs. non-diabetic patency analysis
  - Prospective, non-randomized, global study
  - 800 subjects enrolled at 47 centers
  - CEC and Steering Committee oversight
  - Angiographic and Duplex core laboratory analyses

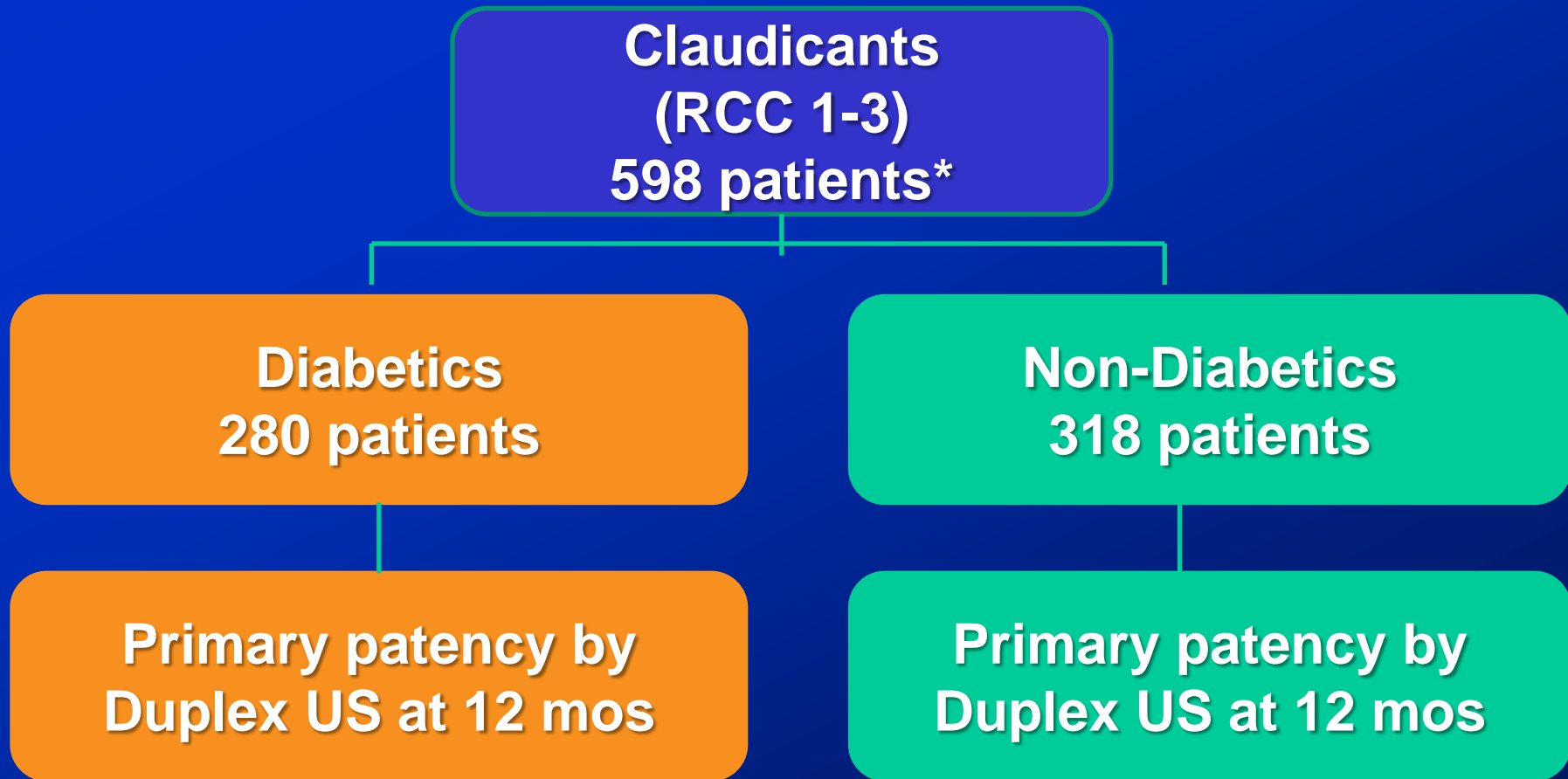
# Study Design and Primary Endpoints



\*1 censored due to informed consent violation

# Pre-Specified, Non-Inferiority Analysis

## Diabetic vs. Non-Diabetic Claudicants



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# Baseline Lesion Characteristics

## Core Lab Reported

Characteristic	Claudication (RCC 1-3)	CLI (RCC 4-6)	All Subjects (RCC 1-6)
Number of Patients	598	201	799
Number of Lesions	743	279	1022
Mean Length (cm)	7.5	7.2	7.4
Baseline Stenosis (%)	73	76	74
Occlusions (%)	17	30	21
<b>Anatomic location based on proximal edge of lesion treatment, % (n)</b>			
SFA	72% (536)	48% (135)	66% (671)
Popliteal	15% (114)	17% (48)	16% (162)
Infrapopliteal	13% (93)	34% (96)	18% (189)

# Periprocedural Outcomes

Outcome	Claudication (RCC 1-3)	CLI (RCC 4-6)	All Subjects (RCC 1-6)
<b>Device Success (<math>\leq 30\%</math> stenosis after directional atherectomy)</b>			
Investigator-Reported	87%	87%	87%
Core Lab	76%	72%	75%
<b>Procedure Success (<math>\leq 30\%</math> stenosis at end of procedure)</b>			
Investigator-Reported	99%	98%	99%
Core Lab	91%	83%	89%

# Pre-Dilation and Adjunctive Therapy

## Analysis by Lesion

Therapy	
Pre-Directional Atherectomy PTA	9%
Post-Directional Atherectomy PTA (no stent)	33%
Mean pressure	6.6 atm
Bail-Out Stent	3%



# 12-Month Primary Patency

## Claudicant Cohort

743

Lesions

7.5 cm

Mean lesion length

72.7%

Mean baseline stenosis

PSVR  $\leq$  3.5



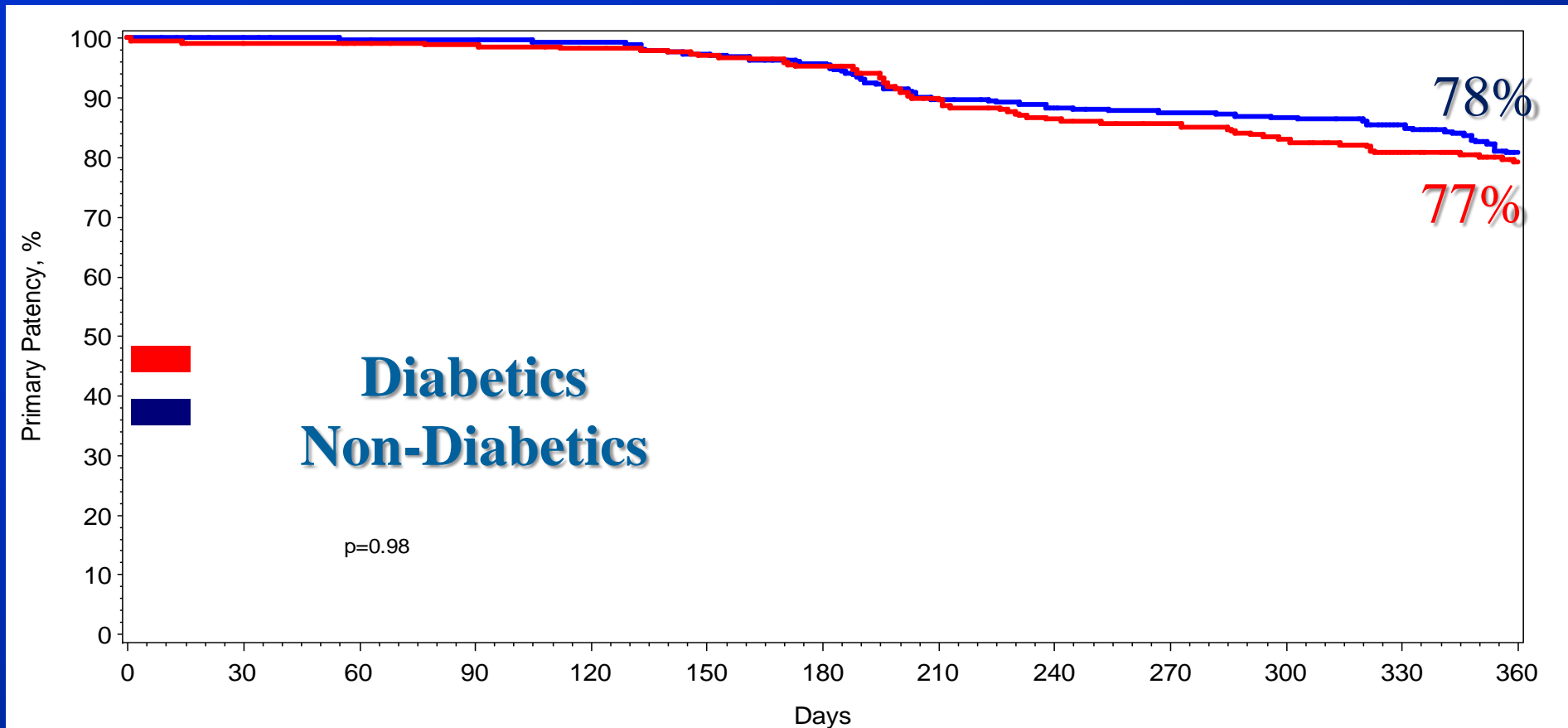
82%

PSVR  $\leq$  2.4



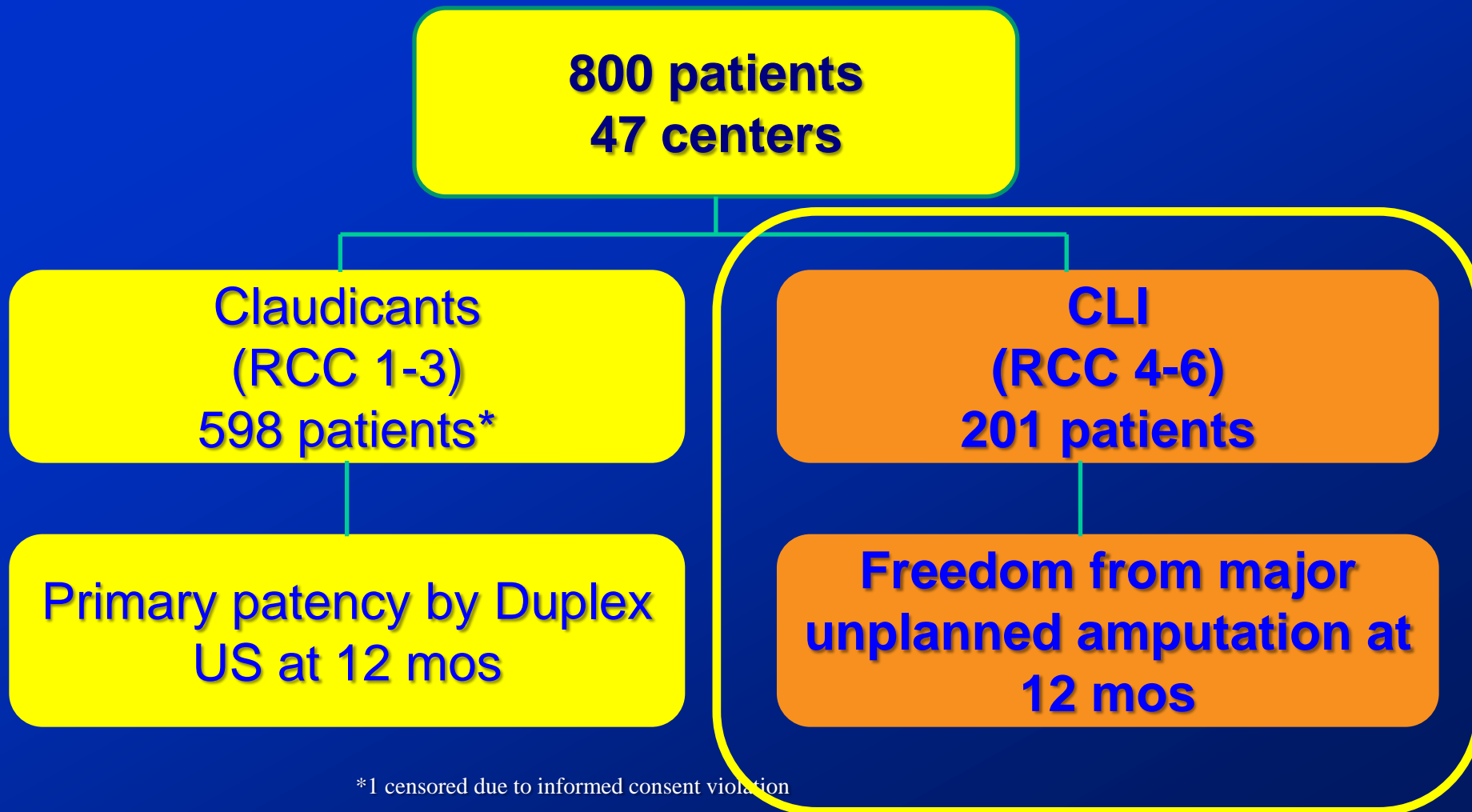
78%

# Primary Patency Rates are Equivalent Between Diabetic and Non-Diabetic Claudicants



\*PSVR  $\leq$  2.4

# Study Design and Primary Endpoints



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**DEF LE CLI Cohort Primary Endpoint:  
Freedom from Major Amputation at  
12 Months**

**95%**

# Primary Patency

## CLI Cohort

279

Lesions

7.2 cm

Mean lesion length

76%

Mean baseline stenosis

PSVR  $\leq$  2.4



71%

# Potential Niche Applications for Atherectomy

## Challenging Lesion Subsets

- Instant Restenosis
- Severe calcification
- Thrombus
- Long occlusion
- Ostial/eccentric

## Challenging Anatomy -Non-Stent Zones

- Common femoral artery/Profunda femorus
- Popliteal Artery

Prior to DCB

# Combination Therapies: *Best of Both Worlds?*

- Greater acute lumen gain of atherectomy without recoil/dissection of PTA
- DCB allows improved patency rates after atherectomy
- Reduced need for stents- less fractures, ISR, don't burn bridges



# Challenges for DCB

- Calcium – dissection, inability to achieve optimal drug uptake
- Thrombus containing lesions – distal embolization, inability to achieve optimal drug uptake
- Instant restenosis – tissue extrusion, recoil
- Long occlusion –restenosis rate still may be unacceptably high

# Directional Atherectomy & DCB

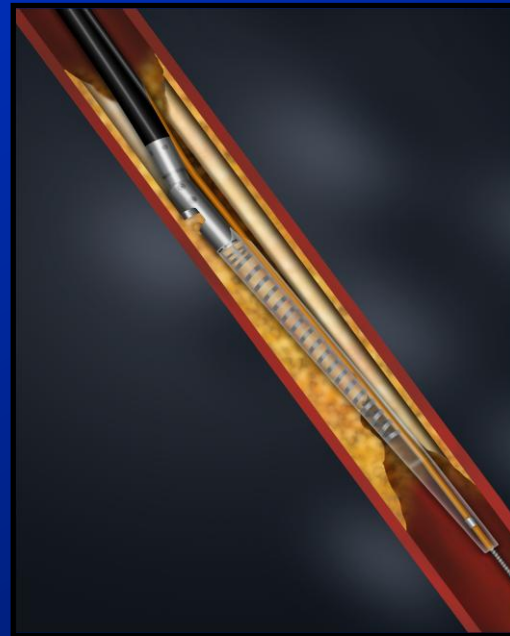
- N=30, RC 3-6 with heavily calcified SFA, length 5-15 cm
- IVUS pre and post DA and DCB
- Spider EPD
- Balloon 1:1, 180 sec
- Stents allowed only as bailout
- F/U at 1,3,6,12 months with DUS





# Directional Atherectomy & DCB

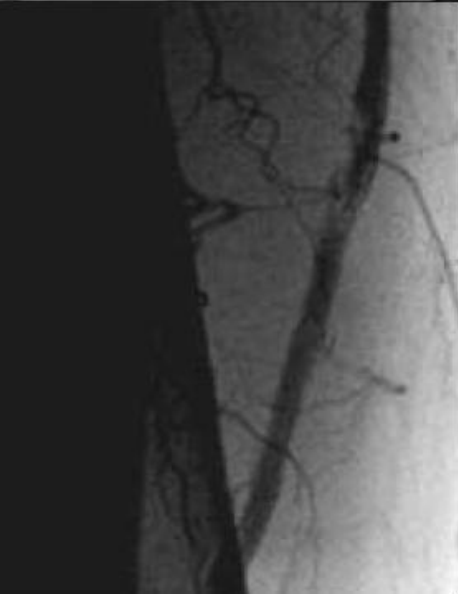
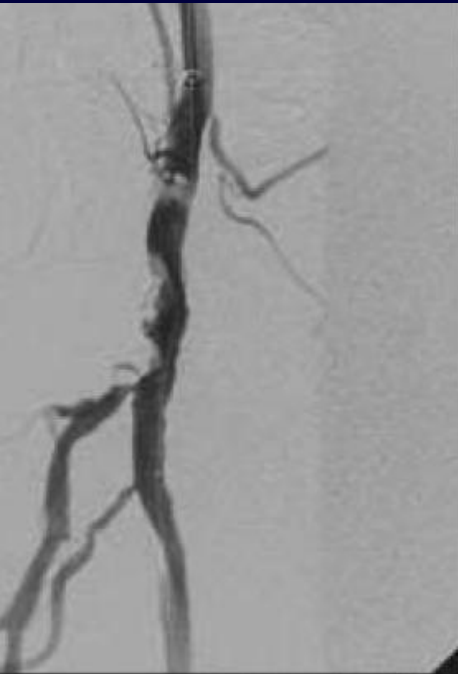
- 100% procedural success
- 7% bailout stenting
- 0% distal embolization
- IVUS MLD
  - $1.2 \pm 0.9$ mm pre DA
  - $4.2 \pm 0.5$ mm after DA
  - $5.1 \pm 0.8$ mm after DCB



+



# TurboHawk Calcium Cutter



# Directional Atherectomy & DCB: 12 Month Follow-Up

Baseline RC	4.7 ± 1.2
12 Month RC	2.2 ± 1.0
Baseline ABI	0.4 ± 0.2
12 Month ABI	0.8 ± 0.1
DUS Restenosis, PSVR > 2.5	<b>90% 1-Yr Primary Patency</b>
Major amputation	0
Minor amputations	10%
Limb salvage rate	100%
TLR	<b>10%</b>

# Atherectomy & DCB (Zeller)

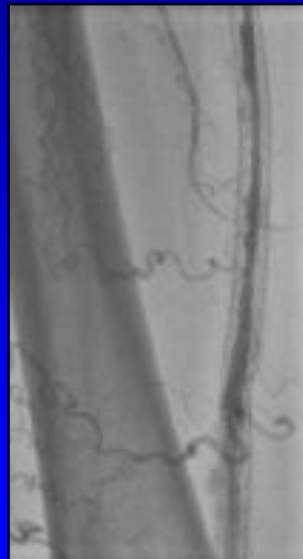
- Prospective, single center registry
- Rutherford class 2-5
- Native fem-pop disease (31%); ISR (69%)
- DA and DCB: 29 patients
- DA and uncoated balloon (PTA): 66 patients

# Atherectomy & DEB (Zeller): 1-Year Outcomes

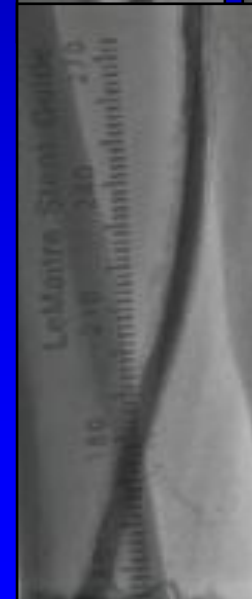
	DA/DCB	DA/PTA	P
Primary patency (%)	88%	43%	<0.001
TLR (%)	8%	47%	0.001
Restenosis (%)	13%	58%	<0.001
Secondary patency (%)	92%	63%	0.015

# Atherectomy & DCB: Case Example

*after DA*



*after DCB*



Courtesy of T Zeller



# DEFINITIVE AR

- Prospective, MC, EU RCT
- Assess Efficacy of plaque excision atherectomy and Medrad PTX DCB vs. DCB alone in Fem-pop disease
- N=100 patients; DUS at 1,6,12M; 1-yr. f/u angio
- Additional 25 patients with severe calcification will be enrolled in a non-randomized arm (atherectomy & DCB)
- Enrollment completed 12/2012
- PIs: G. Tepe/ T. Zeller

# Atherectomy in the DCB Era

- Better atherectomy devices available
- Device specific advantages for certain lesion subsets
- More options for heavily calcified lesions
- Helps overcome some of the limitations of DEB
  - Dissection/sub-optimal PTA result
  - Calcification
  - Thrombus
  - Long occlusion