

# Expanding Catheter Therapeutics; Ilio-Femoral Artery Disease

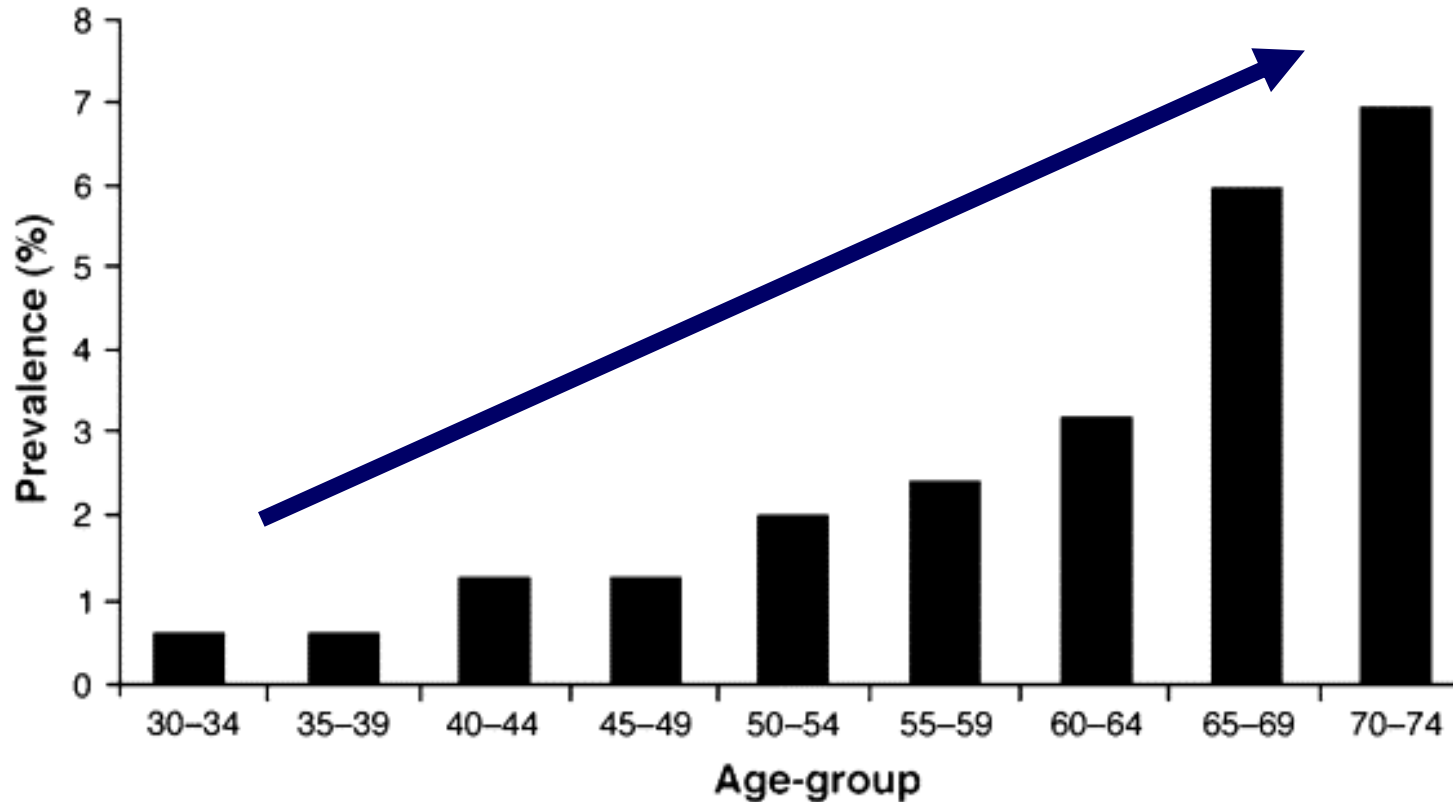
김 원

경희 의대 순환기내과

# 우리는 왜 Peripheral disease에 관심을 가지는가?

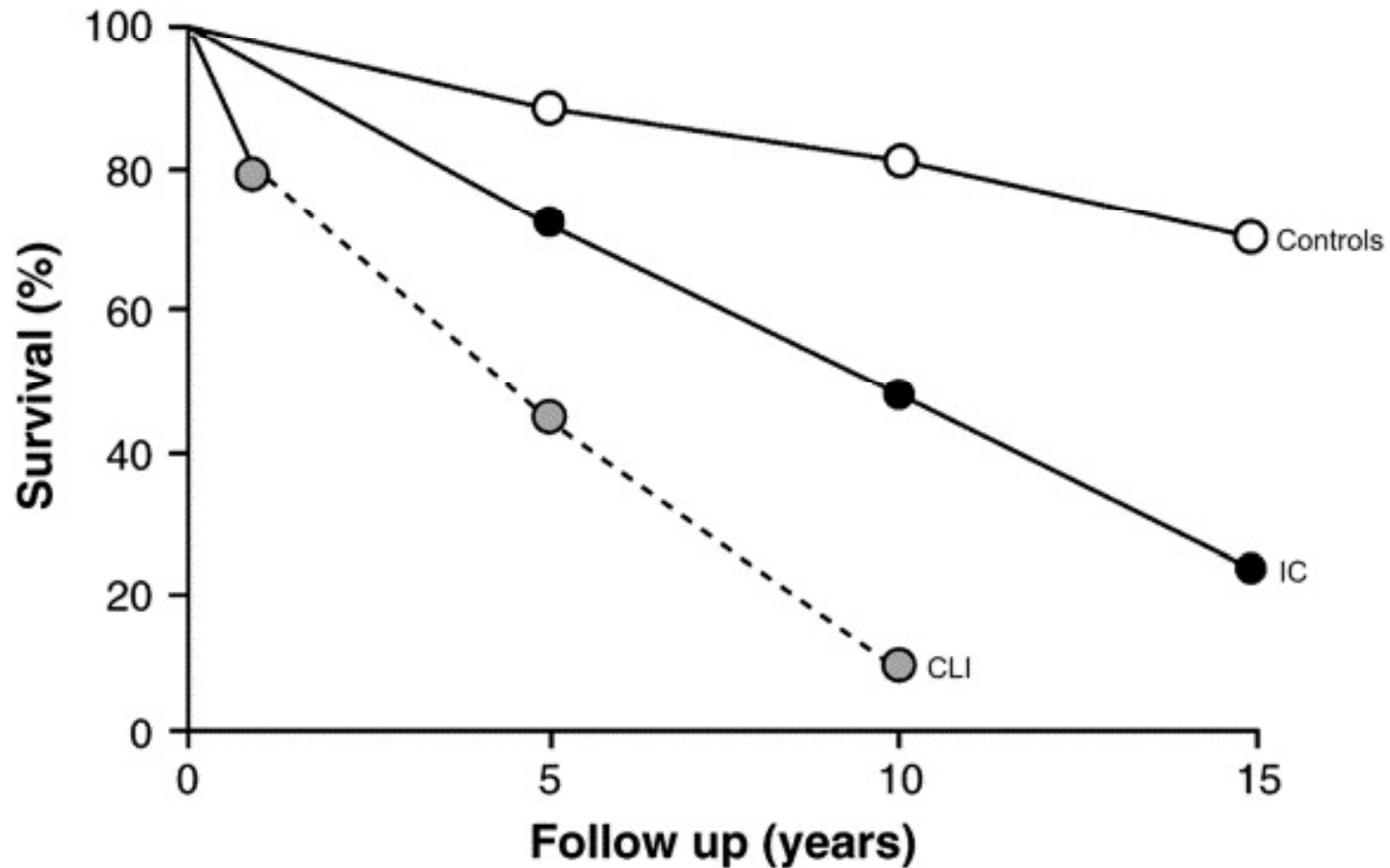


# Prevalence Increases with Age

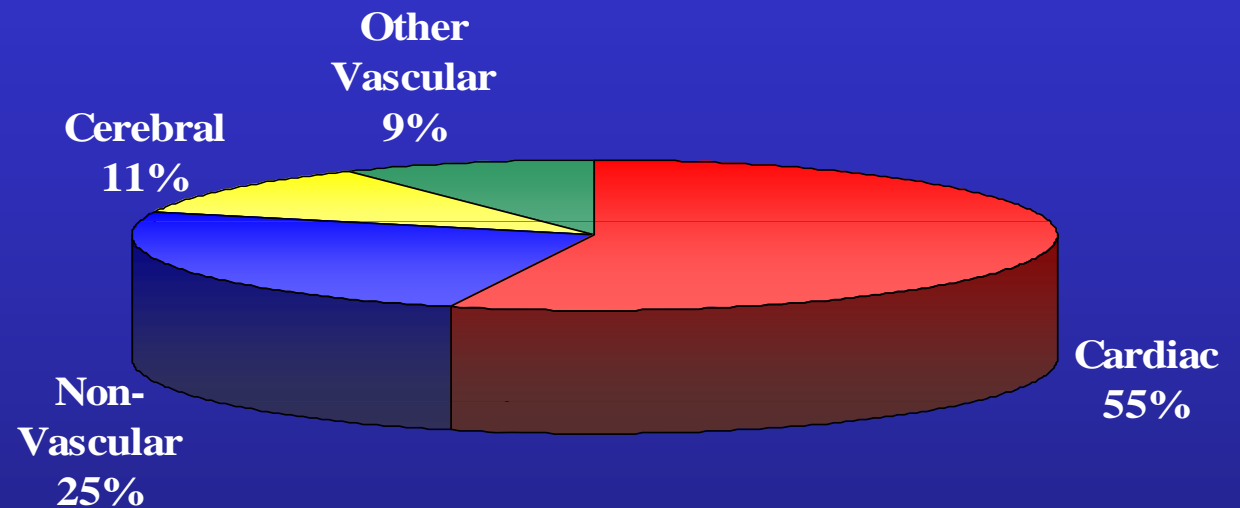
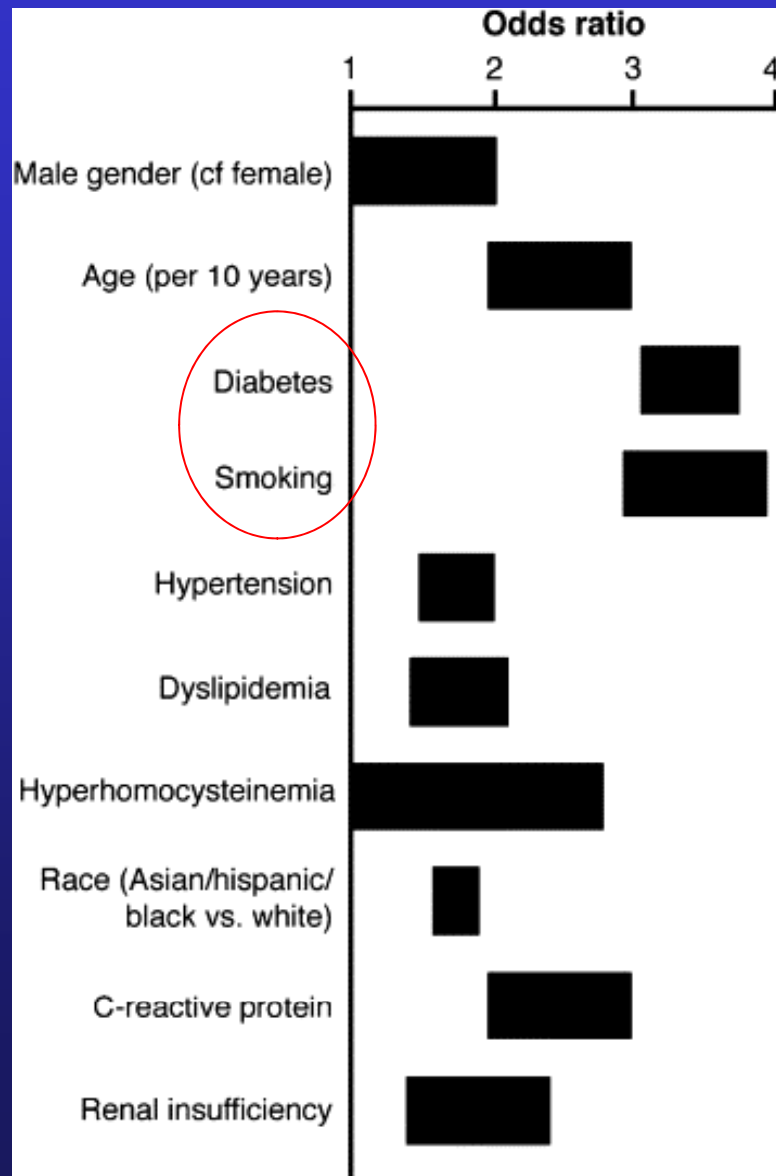


prevalence of intermittent claudication (symptomatic PAD) in large population-based studies.

# Patients Survival in PAD by Cardiovascular Survey



# PAD and Coronary Disease



**Causes of Death in Patients with Intermittent Claudication**

Approximate range of odds ratios for risk factors for symptomatic PAD

Norgren L, et al. TASCII, J Vasc Surg.2007

# Medical Tx of PVD

## Peripheral Arterial Disease

### Risk factor modification:

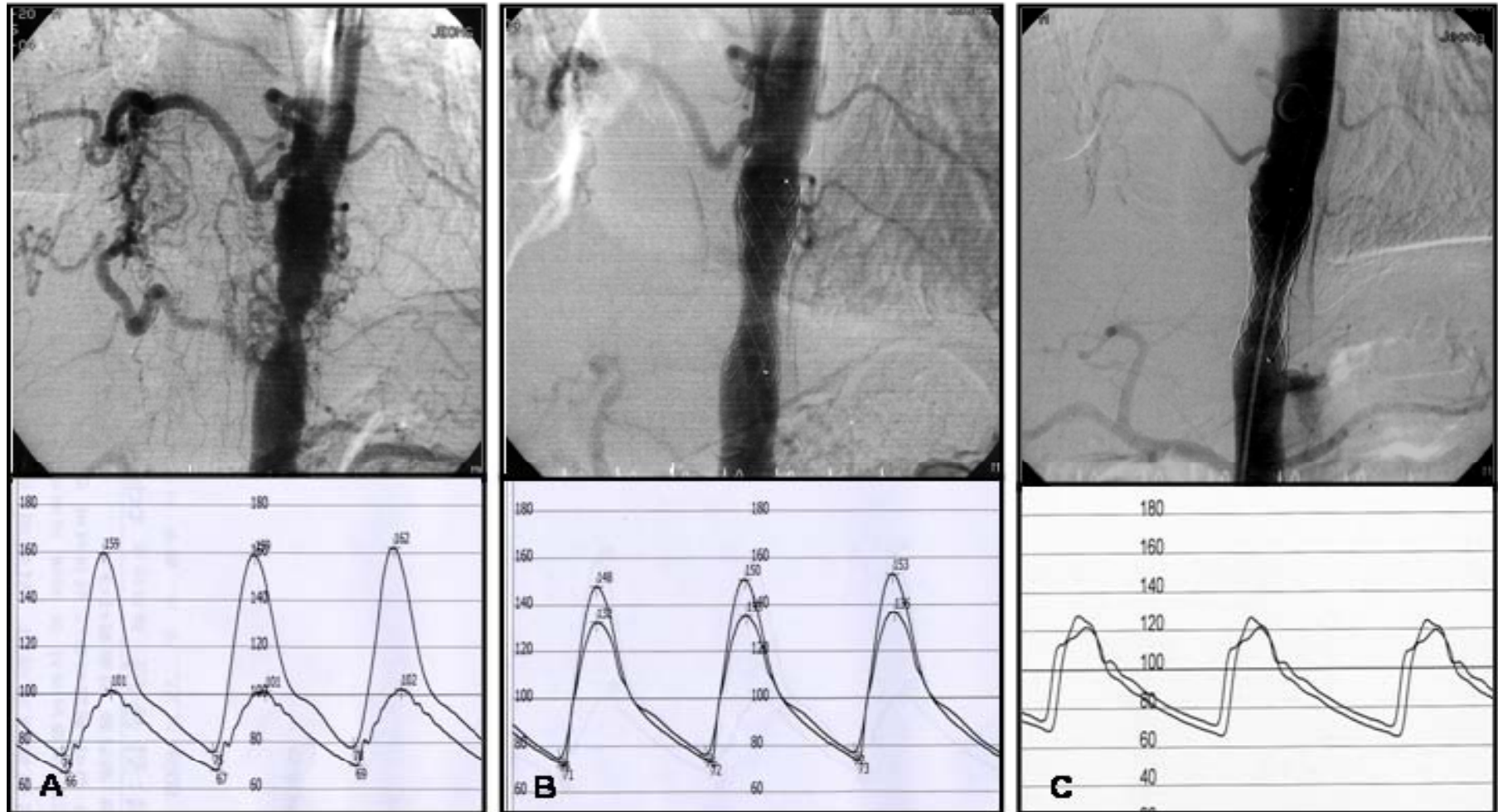
- Smoking cessation
- LDL cholesterol < 100 mg/dL
- LDL < 70mg/dL if high risk
- HbA1c < 7.0%
- BP < 140/90 mmHg
- BP < 130/80 mmHg if diabetic or renal disease
- Antiplatelet therapy

## Rx 3. Control of hypertension in PAD patients

- Beta-adrenergic-blocking drugs are not contraindicated in PAD [A]

# Coarctation of Aorta

## Both claudication: 45/M



- 김 원 교수님, 안녕하십니까?
- -----
- 지난 25년간 “다리 때문에 ” 저의 뇌리에는 근심, 걱정, 고민의 3단어가 항상 따라 다녔 습니다. “내 다리가 왜 이럴까 ” 근심, 걱정, 고민하면서 원인 찾기와 치료를 위해 병원, 의원, 한의원, 한약방, 약국, 지압, 민간요법, 운동 등 다양한 방법으로 검사와 치료를 병 행하면서도 치료를 못하고 헤메고 다녔지요.
- -----
- 그 동안 “다리 때문에 ” 하고 싶은 일도 못하였고, 친구, 가족, 직장에서 등산 가자고 하 면 빠져 나갈 궁리부터 하였으며, 논산훈련소에서 구보나 행군시 뒤로 쳐지면 궤병 부린 다고 얻어 터지고 하였던 괴롭고 아픈 기억들이 저의 뇌리를 스쳐 시술을 마치고 혈관찰 영실을 나온 순간 눈물이 하염없이 흘러 내렸습니다.
- -----
- 2003. 6. 9



# 우리는 왜 Peripheral disease에 관심을 가지는가?

- *"...claudication never killed anyone..."*  
-- 죽고 사는 문제이다.
- *"...you're not bad enough to operate yet..."*  
--- 많은 기술적 진보로 할일이 많다.
- *"...you've got more important problems first..."*  
--- 자체가 내과 질환이다.

# **Endovascular Therapy of PAD**

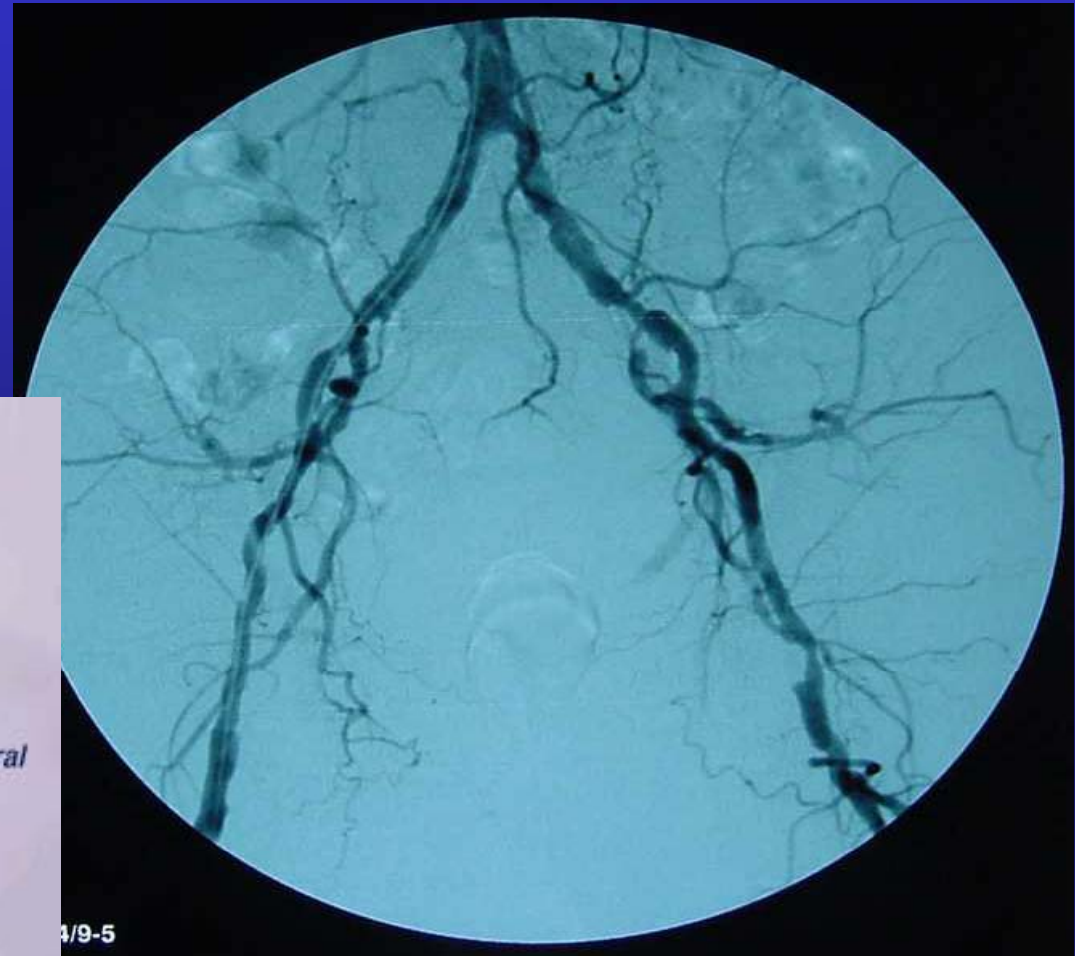
## **- Goal of Treatment -**

- **Avoid amputation**
- **Improves ;**
  - functional status**
  - Symptoms**
  - Quality of life**
- **Decreased need for repeat revascularization**

**Maintenance of Patency**

# Iliac arteries and Anatomy

- Common, External and internal.
- Iliac diameters: 6-12 mm



# Iliac Intervention for stenosis

	Patients	Technique	Follow-up	Primary Patency	Secondary Patency
Tegtmeyer 1991	200 (68% IC)	PTA	5yrs	85%	92%
Vorwerk 1996	109	SE stent	4 yrs	82%	91
Palmaz 1992	486	BE stent	2 yrs	84%	
Strecker 1993	114	SE stent	3 yrs	95%	
Henry 1998	184	BE stent	4 yrs	86%	94%
Murphy 1995	83	BE stent	4 yrs	86%	
Martin 1995	140	SE stent	2 yrs	71%	86%

# Iliac Intervention for Occlusion

	Patients	Technique	Follow-up	Primary Patency	Secondary Patency
Vorwerk 1995	103	stents	4 yrs	78%	88%
Henry 2000	155	stents	8 yrs	73%	86%
Mouanoutoua 2003	50	stents	2 yrs	93%	86%
Scheinert 2001	212	BE/SE/ covered	4 yrs	76%	85%

Table F3. Estimated success rate of iliac artery angioplasty from weighted averages (range) from reports of 2222 limbs

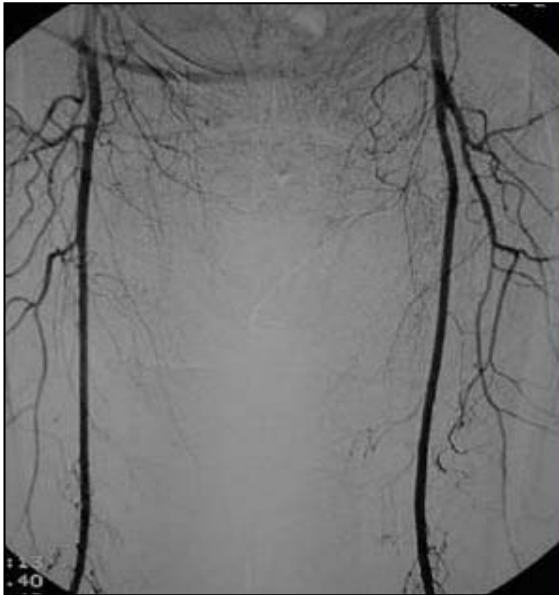
% Claudication	Technical success	Primary patency		
		1 yr	3 yr	5 yr
76% (81-94)	96% (90-99)	86% (81-94)	82% (72-90)	71% (64-75)

# Conclusions of Iliac Interventions



# Femoral arteries and anatomy

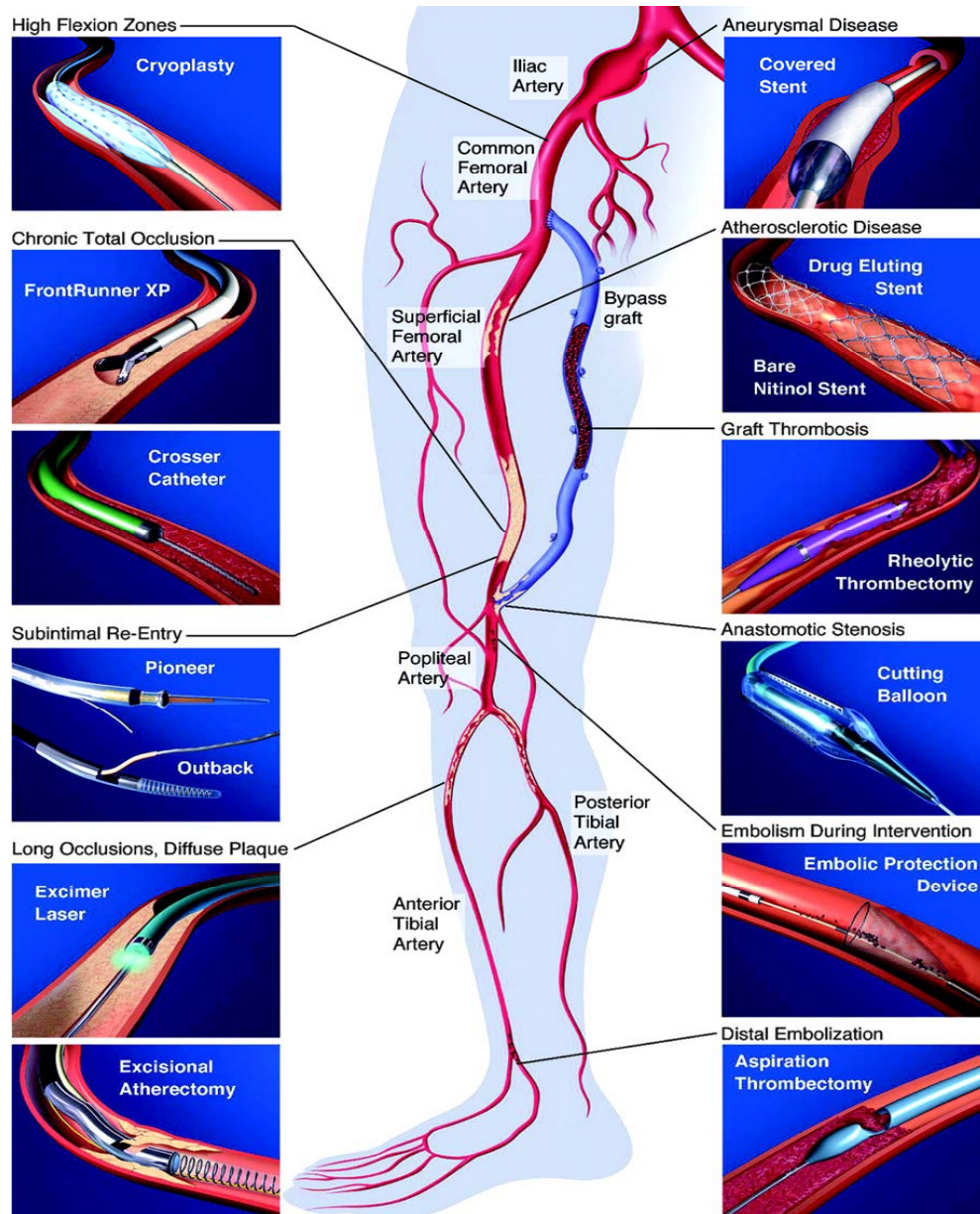
- Common, Superficial and Deep femorals.
- Femoral diameters: 5-8 mm



- **Unfavorable Anatomy**
  - Slow flow and dynamics
  - Two bifurcations
  - **Unique Vessel Forces:**  
Flexion, compression, torsion, pistoning
- **Diffuse Disease**
  - High incidence of CTO ds
  - Complex lesion morphologies (ostial lesions/ $\text{Ca}^{++}$ )
  - Competitive flow via PFA
  - About 30cm long

**Relatively poor endovascular results :  
Bypass surgery is the Gold standard ?**

# New technologies for lower extremity revascularization



- Drugs
- **Subintimal Angioplasty**
- **Bare Stents**
- Covered stents
- Drug eluting Stents
- Drug eluting balloon
- Bioabsorbable Stents
- Brachytherapy
- **Cryoplasty**
- **Cutting balloon**
- **Photodynamic therapy**
- **Debulking -arterectomy**

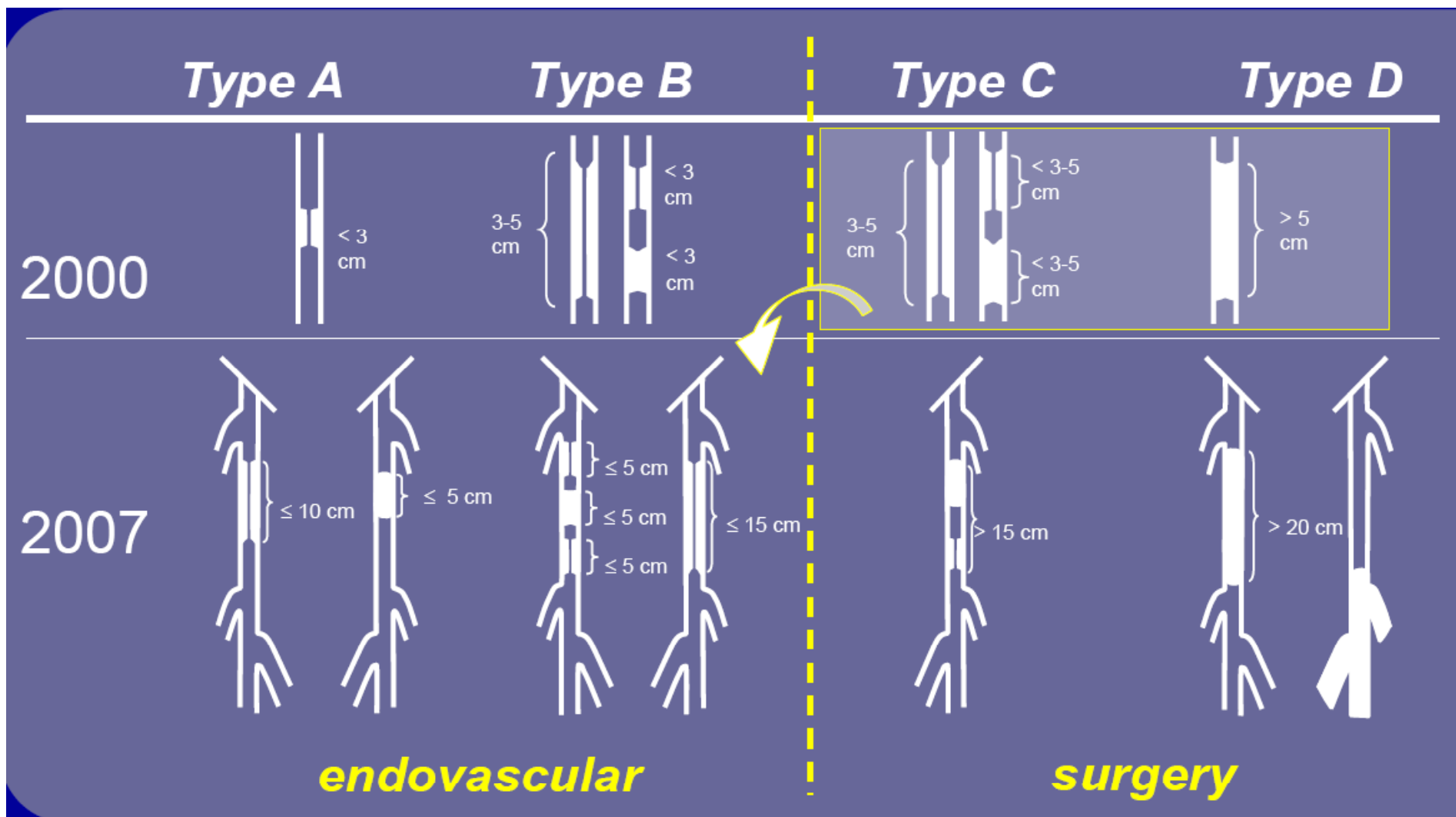


# Limitation : comparison difficult

- Lack of rigorous comparative studies
- Use of heterogenous outcome measure
- Outcome impacted by too many variables
- No good historical datas



# TASC II 2007 vs TASC 2000



# Results of Endovascular and Surgery Femoropopliteal

	<i>Acute</i>	<i>Late (1-3 yr)</i>
<b>Aorto-iliac</b>	<b>95-97%</b>	<b>85-93%</b>
<b>SFA/popliteal</b>	<b>72-95%</b>	<b>47-60%</b> <b>JVS 2000</b>

	<i>1-year % patency (range)</i>	<i>3-year % patency (range)</i>	<i>5-year % patency (range)</i>
PTA: stenosis	77 (78-80)	61 (55-68)	55 (52-62)
PTA: occlusion	65 (55-71)	48 (40-55)	42 (33-51)
PTA+stent: stenosis	75 (73-79)	66 (64-70)	
PTA+stent: occlusion	73 (69-75)	64 (59-67)	

Norgren L, et al. TASCII, J Vasc Surg.2007

**Above-knee femoral popliteal bypass**

**5-year Patency**

**Vein**

**74-76%**

**PTFE**

**39-52%**

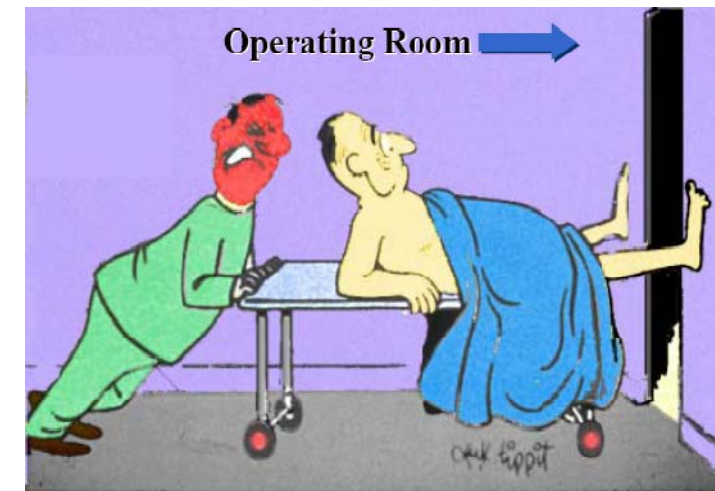
Norgren L, et al. TASCII, J Vasc Surg.2007

# TASC C&D !!

## Bypass or Intervention???

# Femoropopliteal venous bypass = GOLDEN STANDARD ??

- Individualized Tx account the risk and benefits of all available options.
- “Because I can” is harmful  
; “We are not Technician but Artist”
- Improved the technique and device – not enough



# Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised trial

severe limb ischaemia due to infra-inguinal disease and who are suitable for surgery and angioplasty

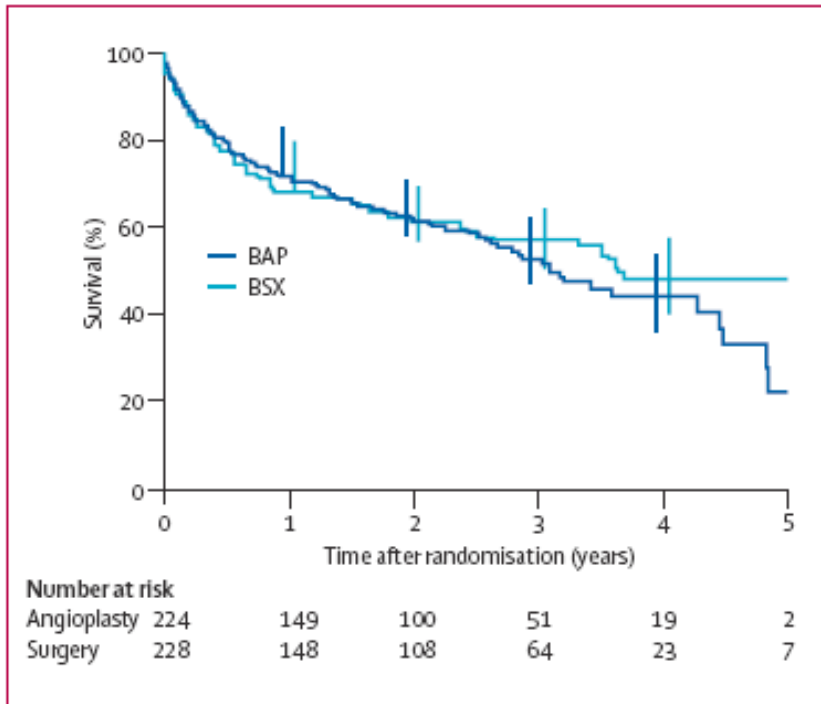


Figure 2: Amputation-free survival after bypass surgery and balloon angioplasty

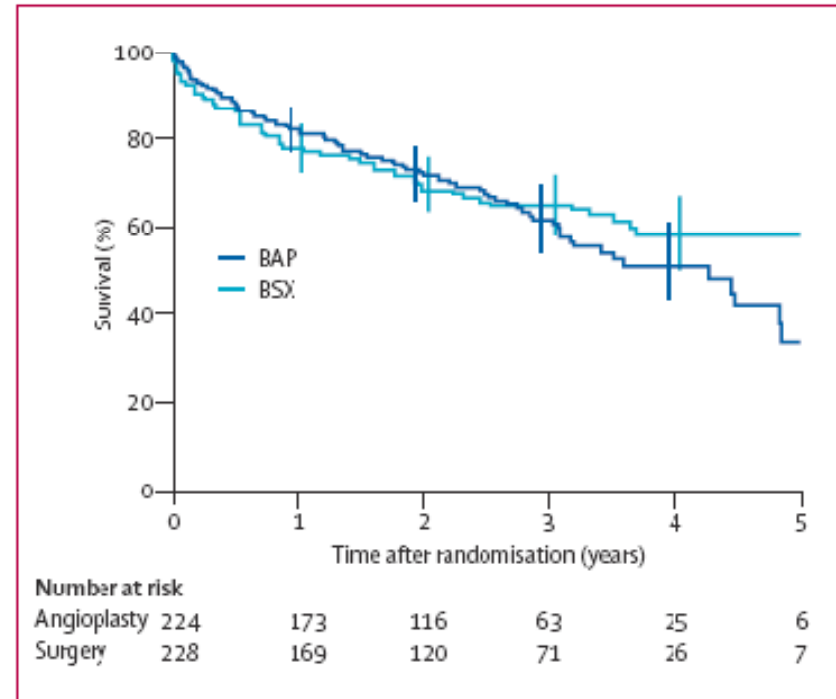


Figure 3: All-cause mortality after bypass surgery and balloon angioplasty

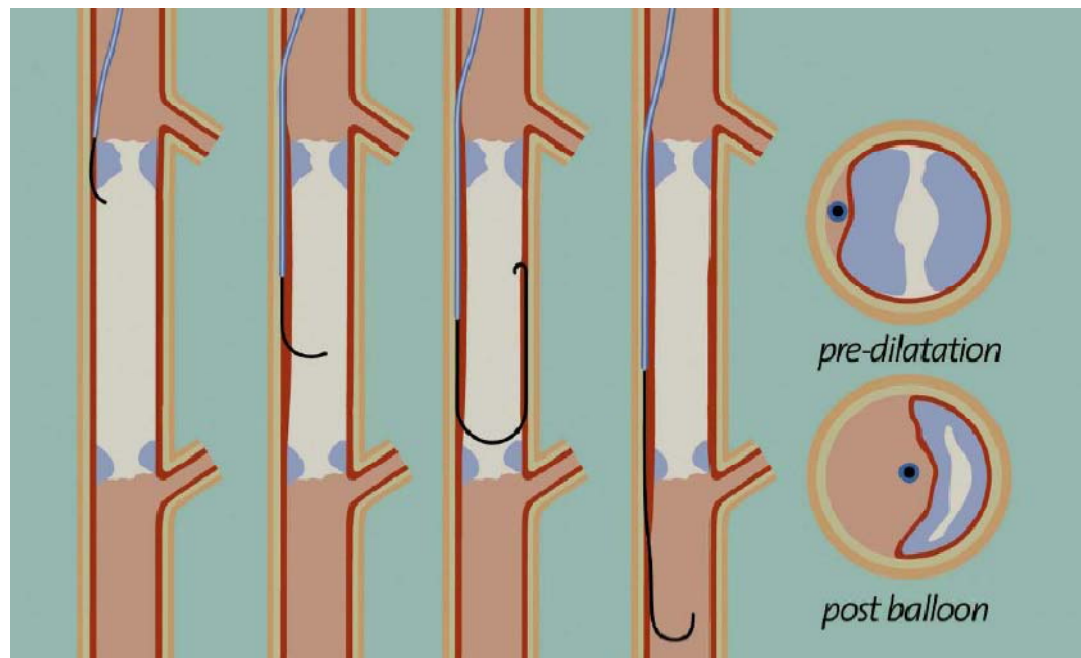
**Bypass-surgery-first and a balloon-angioplasty-first strategy  
are associated with similar outcomes in amputation-free  
survival**

**BASIL : 43/216 ( 20%) attempted angioplasties:  
immediate failures**

**42%: Lesion crossed subintimally and  
could not be re-entered**

**23%: Lumen could not be crossed with guide-wire**

# Useful intervention Tools: Subintimal Angioplasty



## Indications

- long occlusions , hard/long standing disease
- occlusions in diffuse disease, in a moderately calcified Vs
- previously failed intraluminal approach

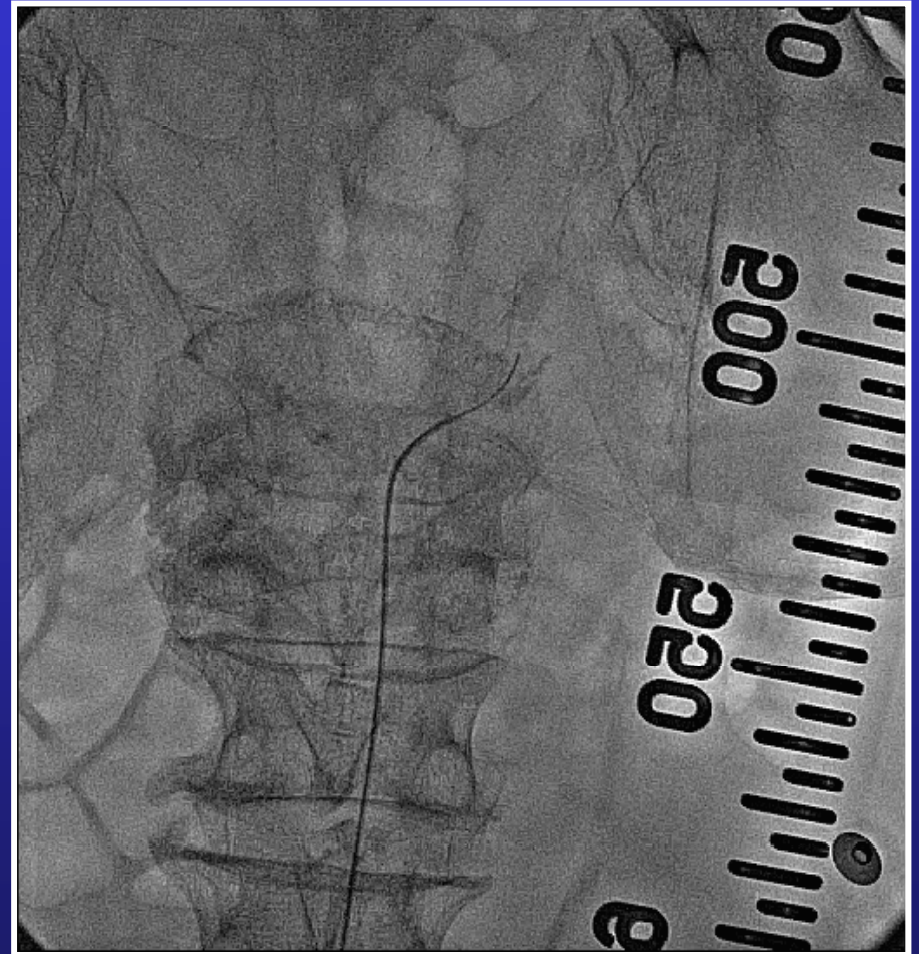
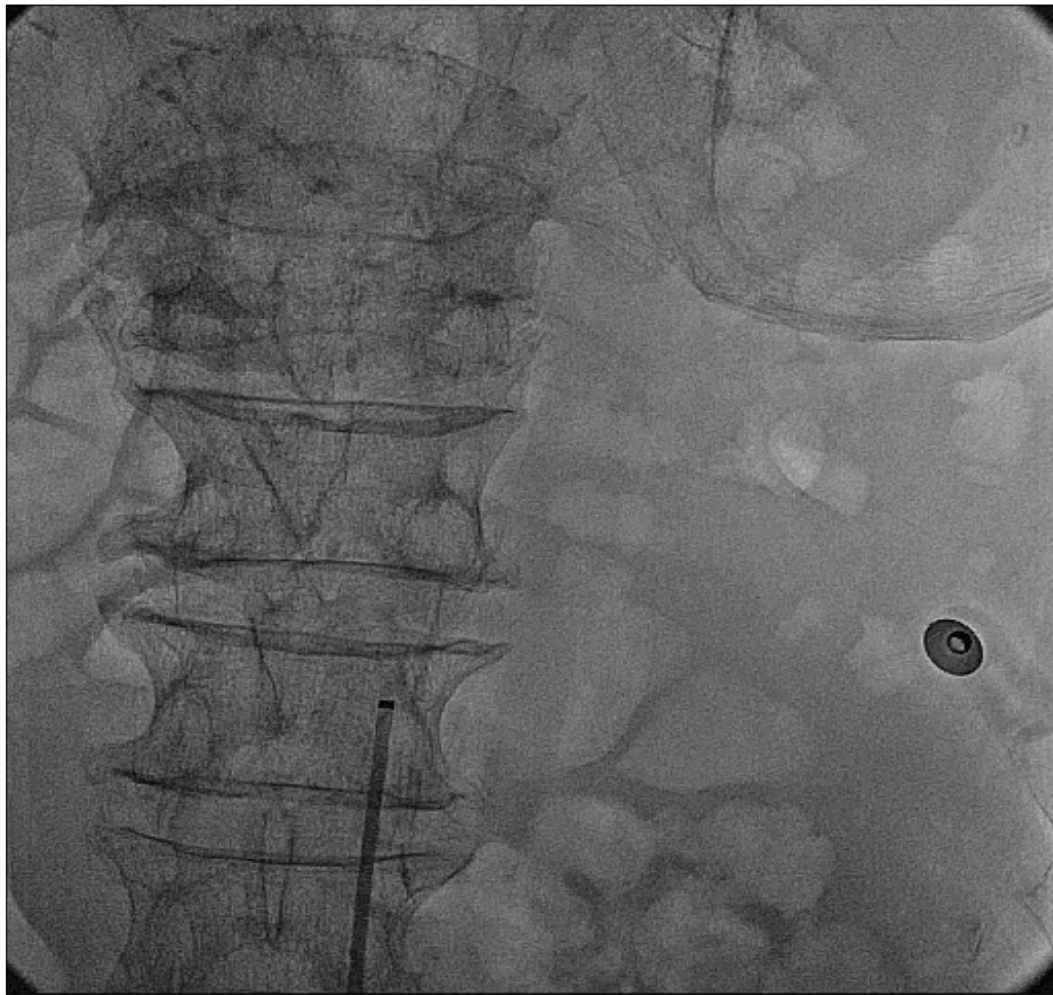
78/M Ulcer with necrosis at Lt. 3<sup>rd</sup> toe, tibial

ABI 0.9 / 0



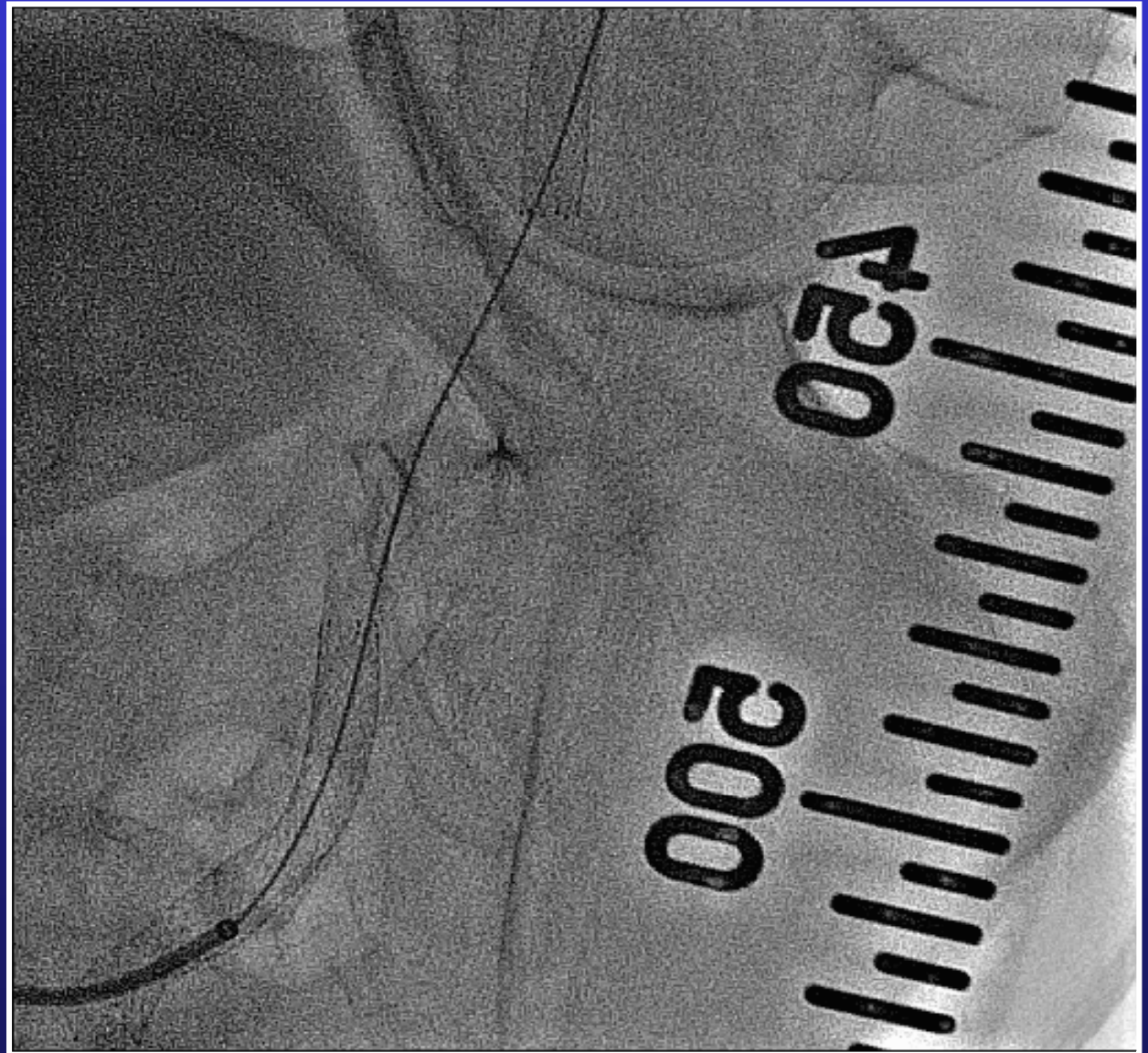
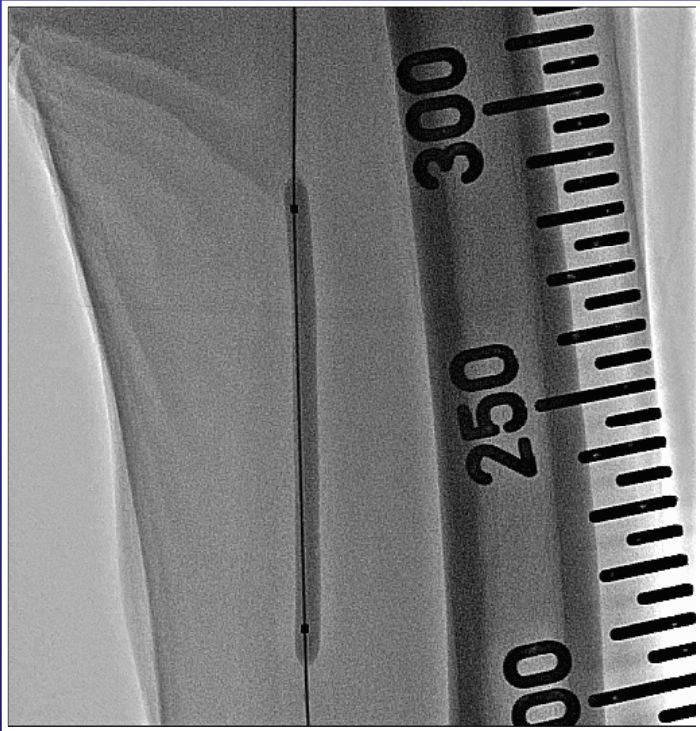


## Lower Ext angiogram

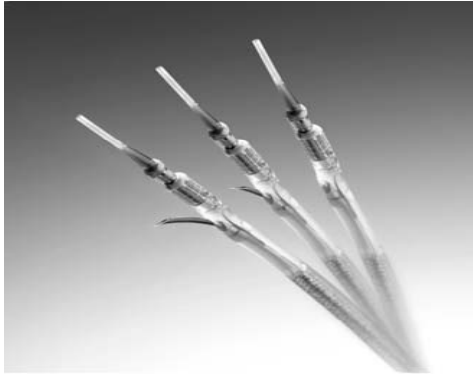


Total occlusion of Lt. CIA, m- SFA

# Final Angiogram



# The Outback Re-entry Catheter

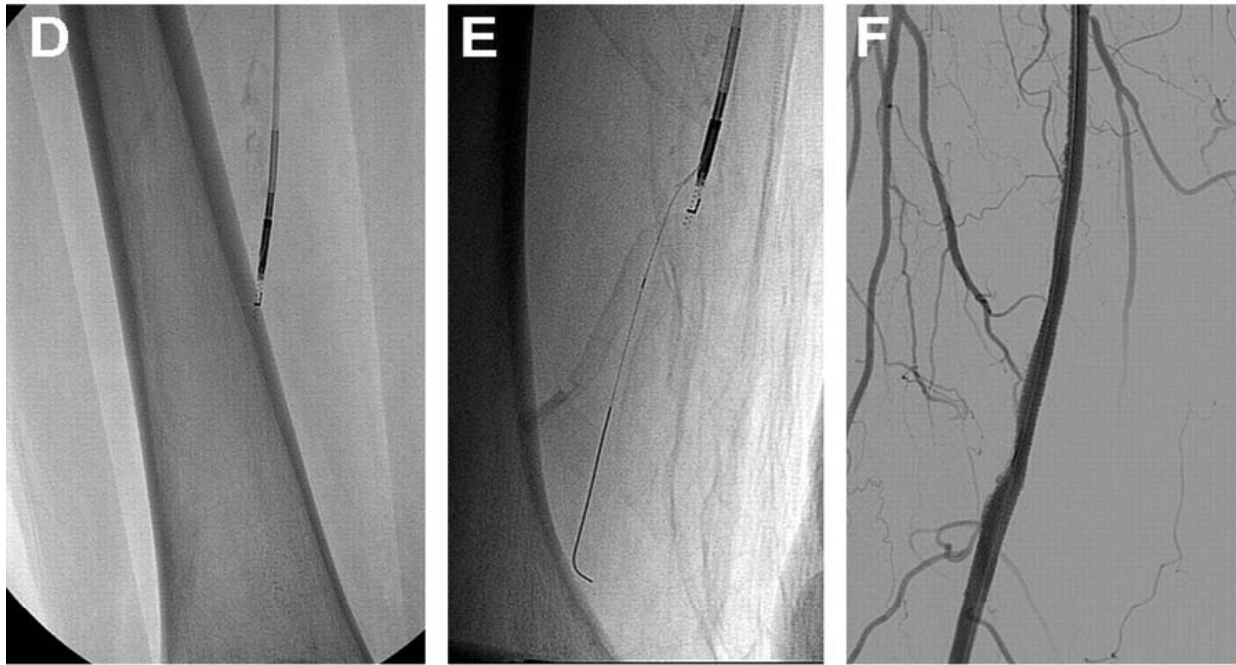


- 6F. Sheath over bifurcation
- 0.035 Terumo wire
- proximal SFA/Iliac occlusion
- Proximal subintimal entry
- Create controlled subintimal dissection to level of true lumen reconstitution
- True lumen access
- Balloon Angioplasty/stent recanalization

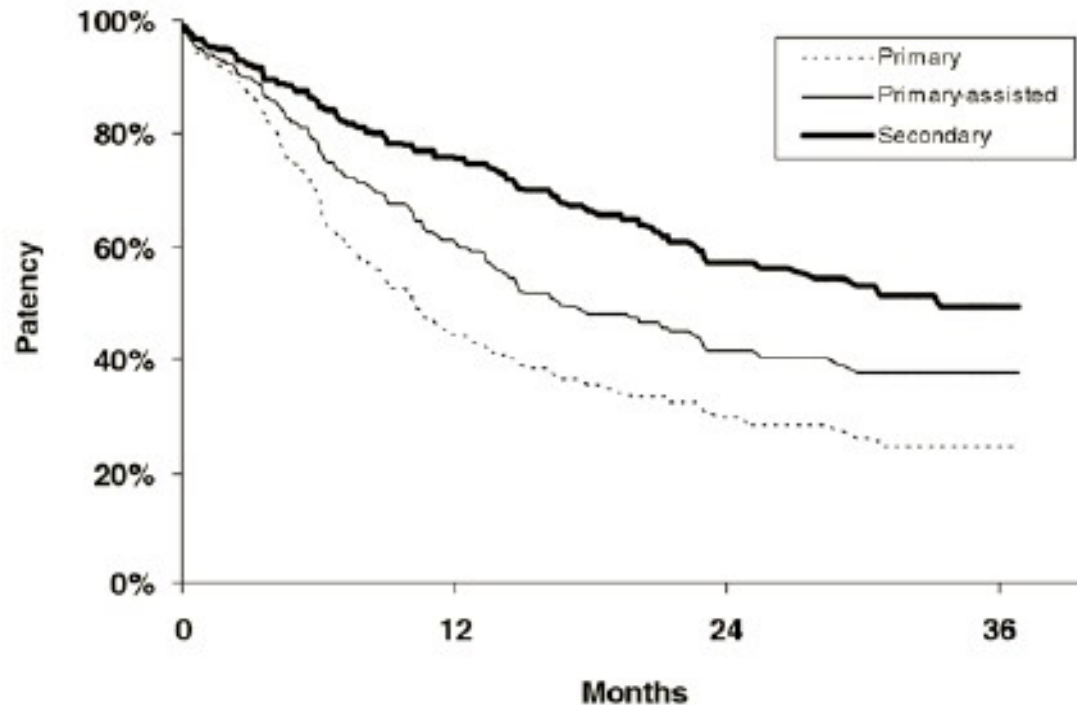


# Bailout Revascularization of Chronic SFA Occlusions With the New Outback Catheter Following Failed Conventional Endovascular Intervention

Revascularization was achieved in 95% of the cases

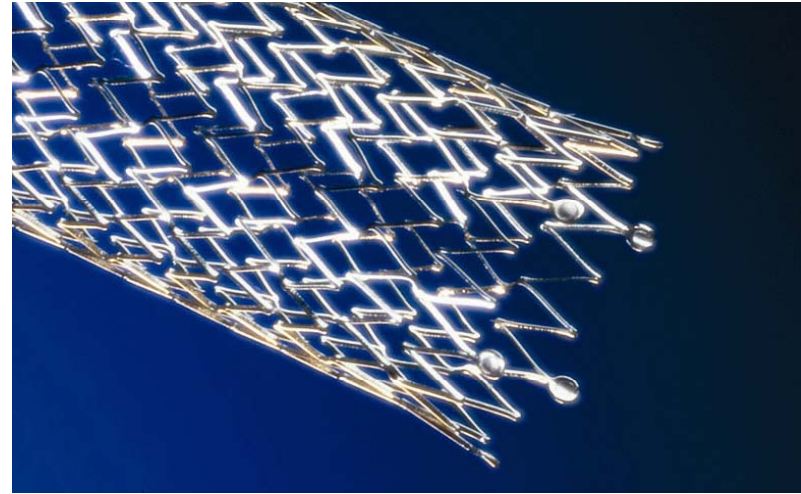
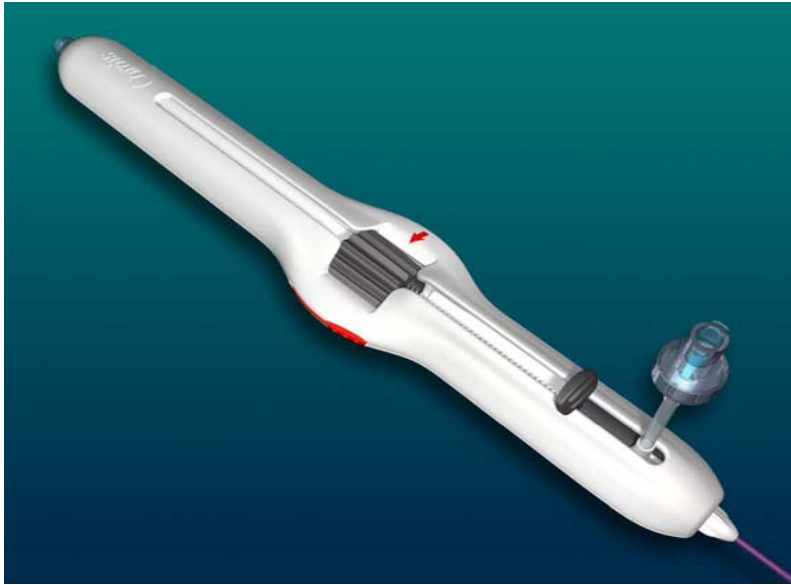


# Subintimal angioplasty: experience in the treatment of 506 infrainguinal arterial occlusions



**Primary patency at 12 and 36 months was 45% and 25%**

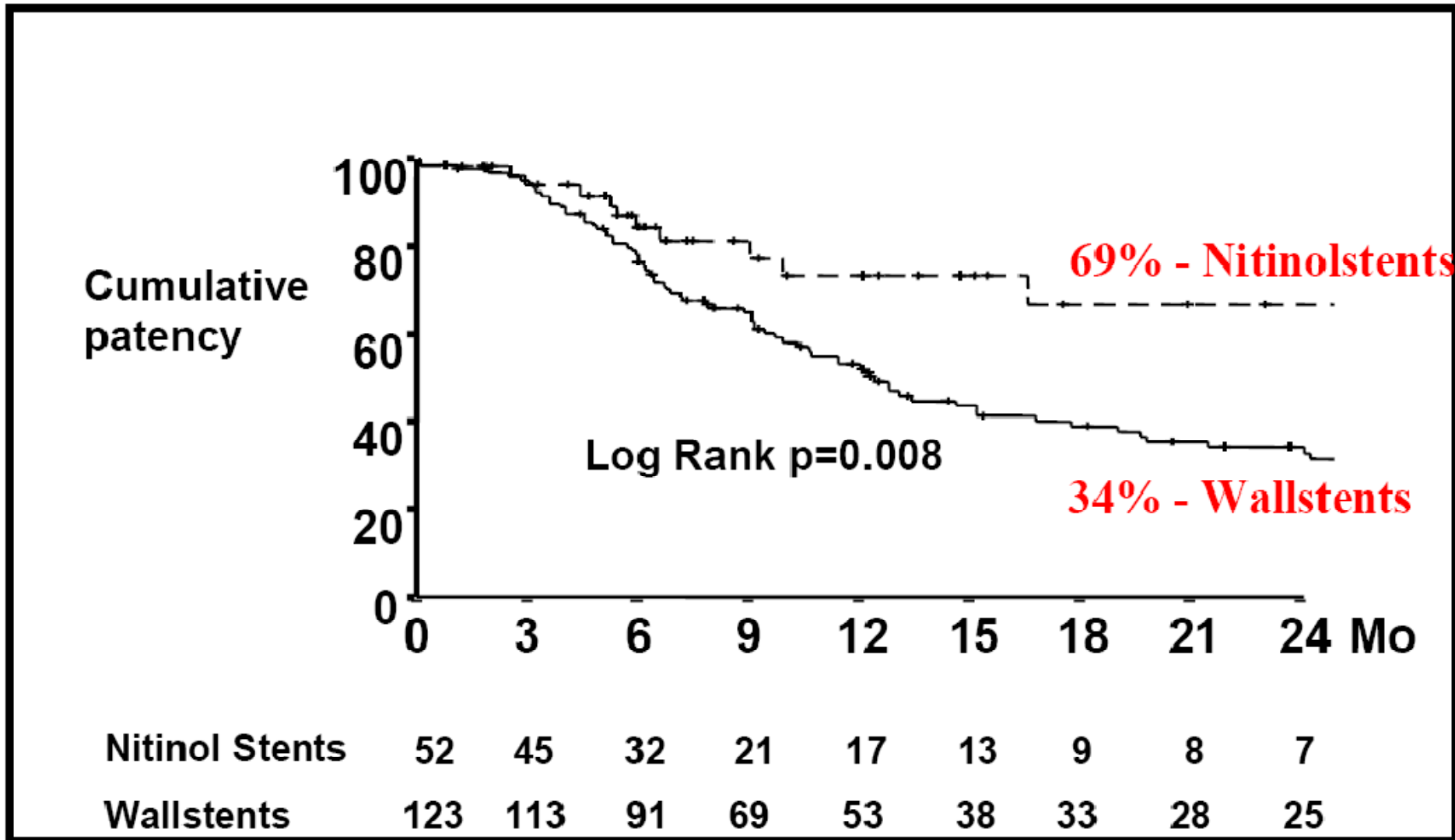
# Nitinol stent = nickel and titanium



Nitinol has 2 unique characteristics:

- superelasticity (ie, it returns to its original shape when an external force is removed)
- thermal shape memory (it returns to a preformed shape on warming, allowing self-expansion).

# Nitinol vs. Wall stents



# ***Absolute Vienna trial***

Prospective, randomized, controlled

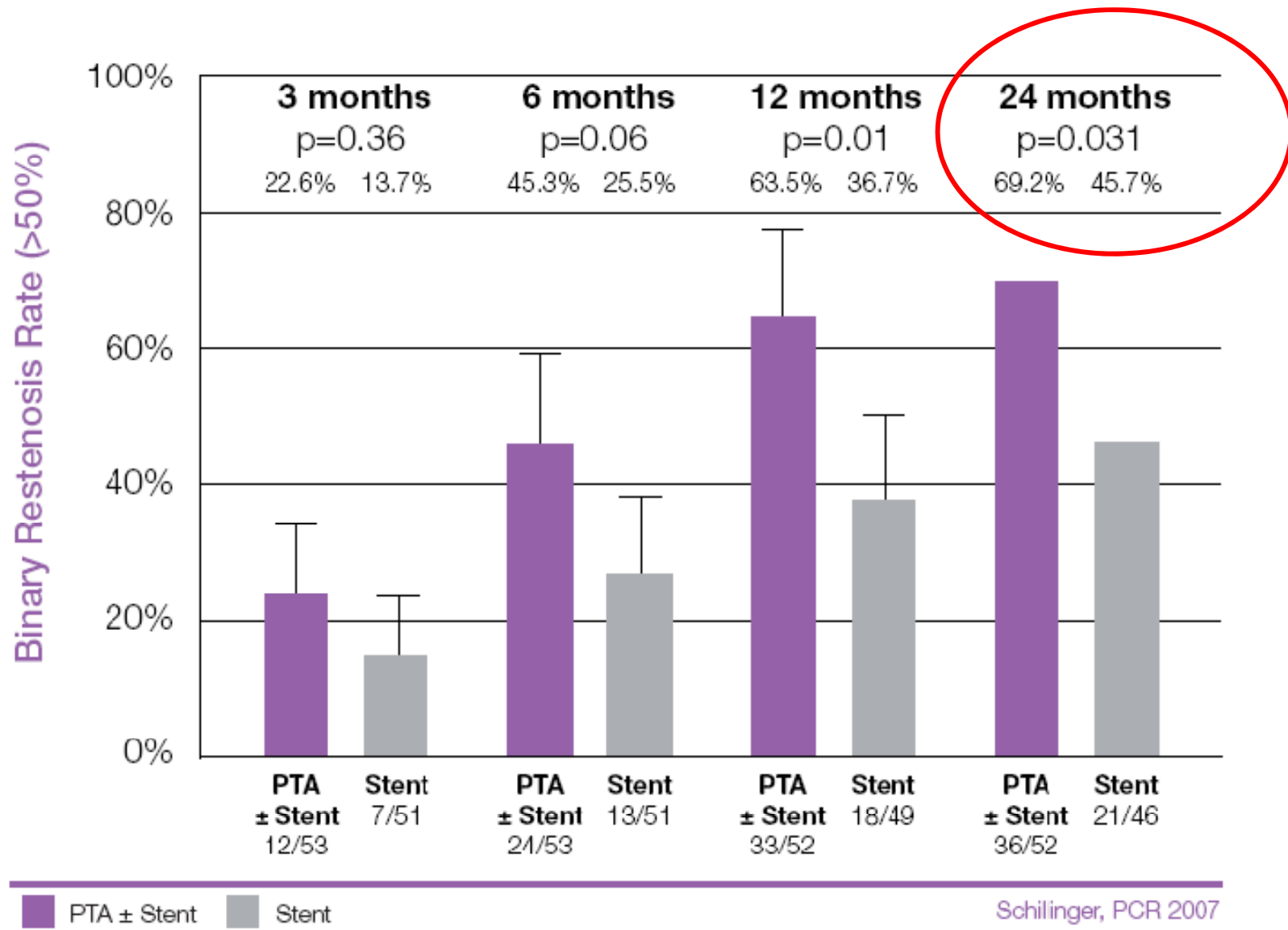
- ***PTA vs. Absolute nitinol stent (Abbott Vascular)***
- *Endpoints = Duplex based patency + Stent fractures*

	<b>PTA ± stent</b>	<b>Stent</b>	
Intention to treat	53	51	
On treatment	52	46	
<b>Lesion length</b>	<b>12.7cm</b>	<b>13.2cm</b>	
1Y patency	37%	63%	
<b>2Y patency (duplex)</b>	<b>31%</b>	<b>54%</b>	<i>p &lt; .05</i>
<b>2Y fracture rate</b>	-	<b>2%</b>	

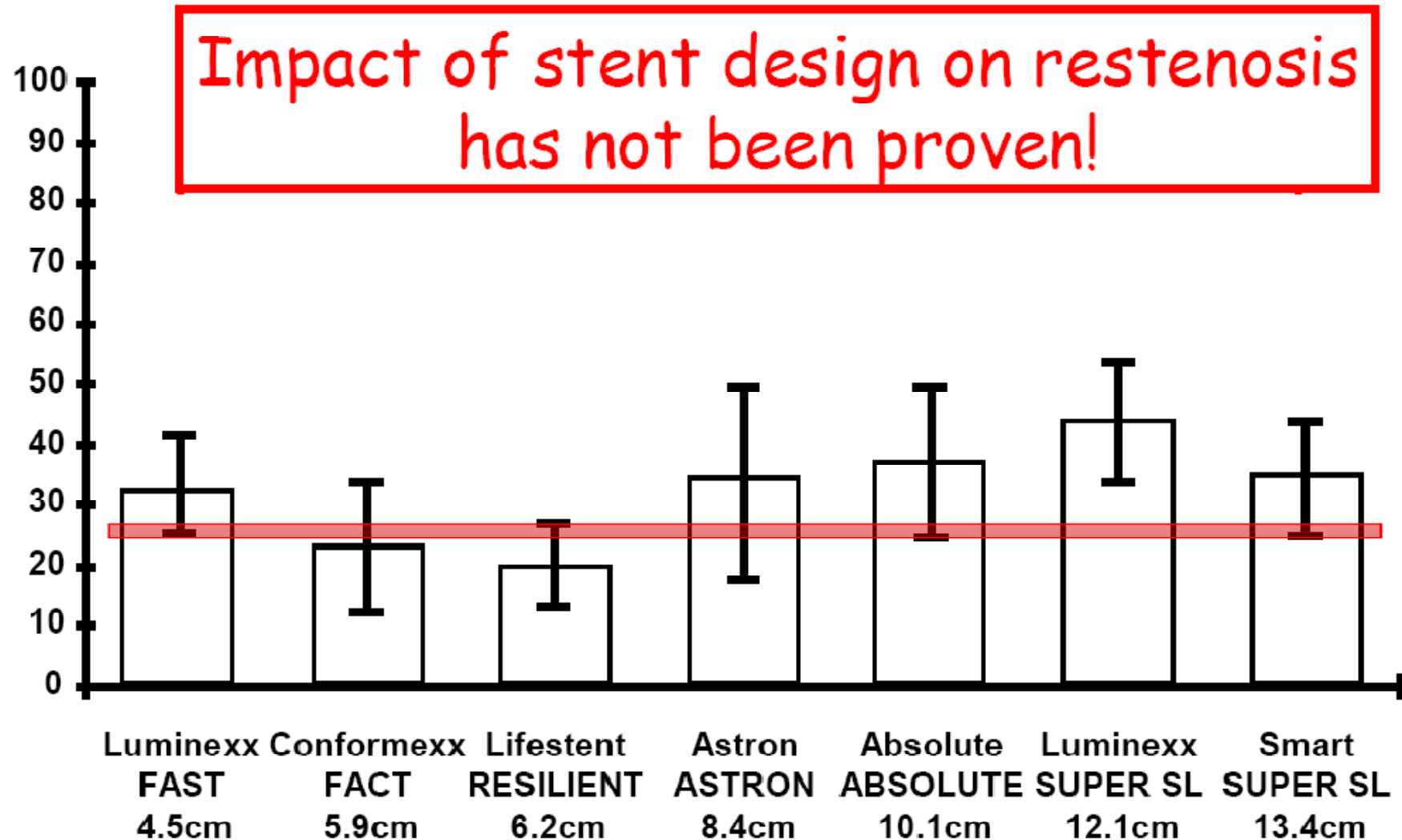
•Schillinger et al, N Engl J Med 2006;354:1879-88, Circulation 2007.



# Restenosis by Duplex Ultrasound

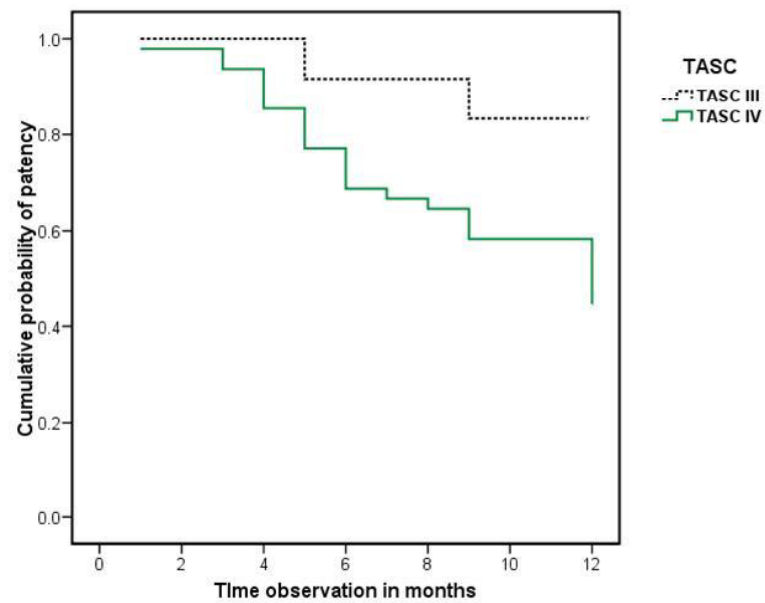
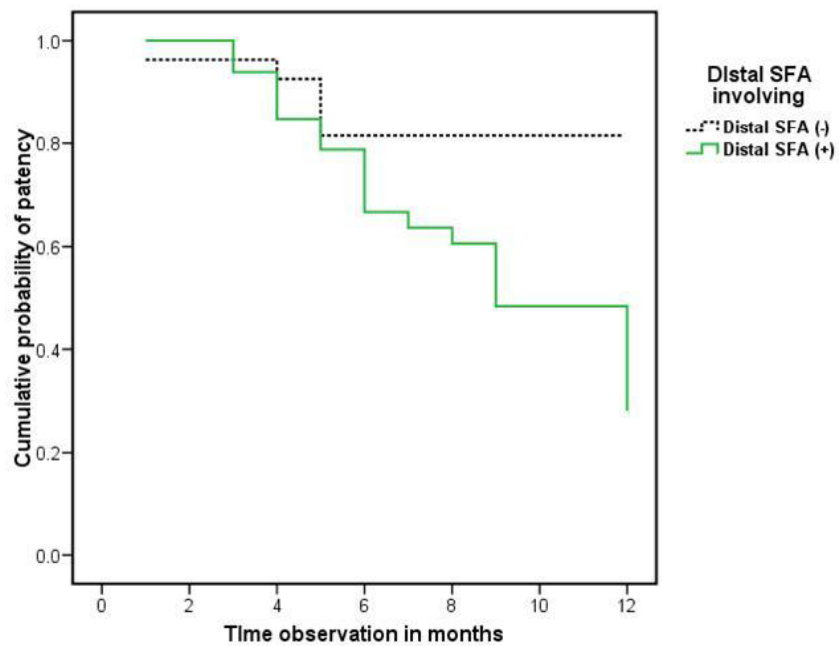
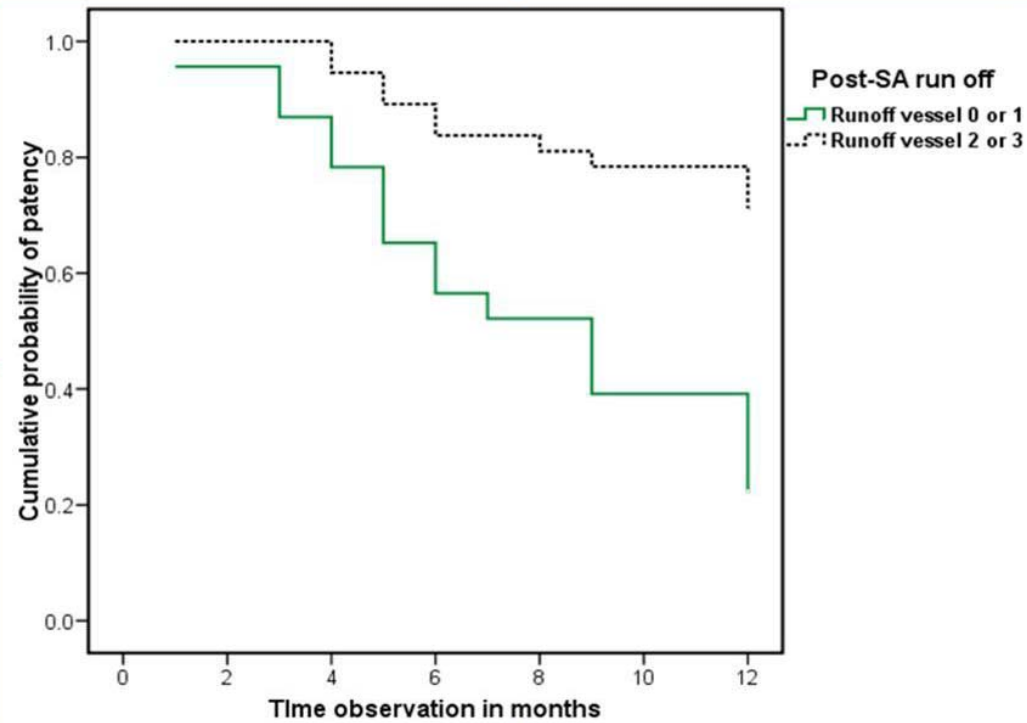
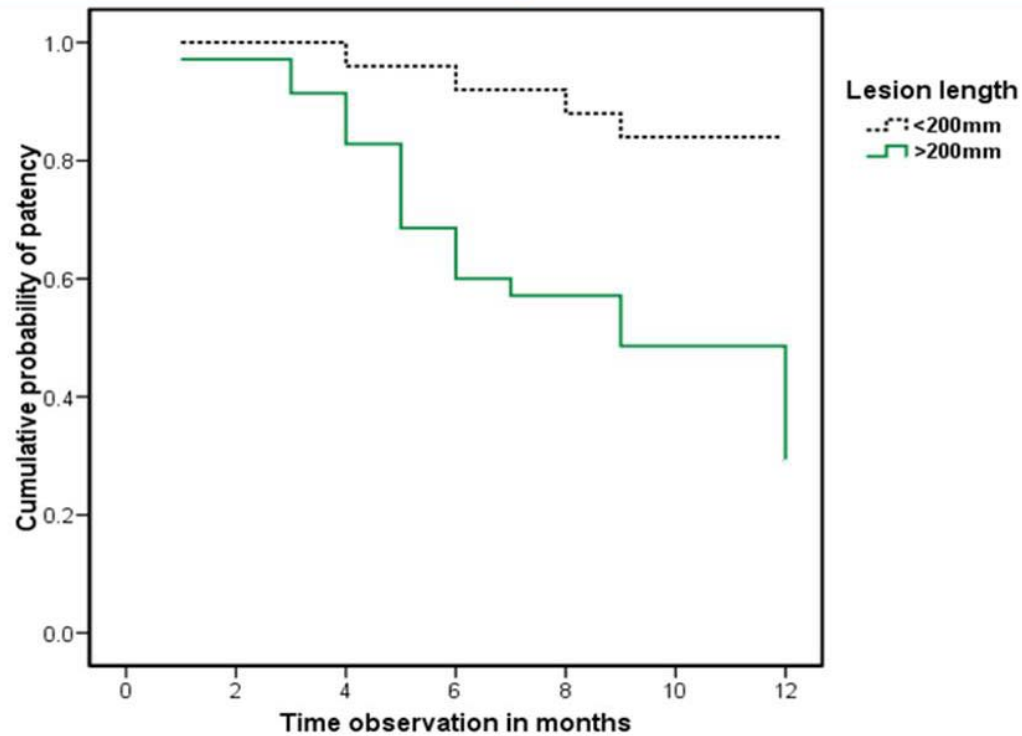


# 12 Months Restenosis Rates of different Stents

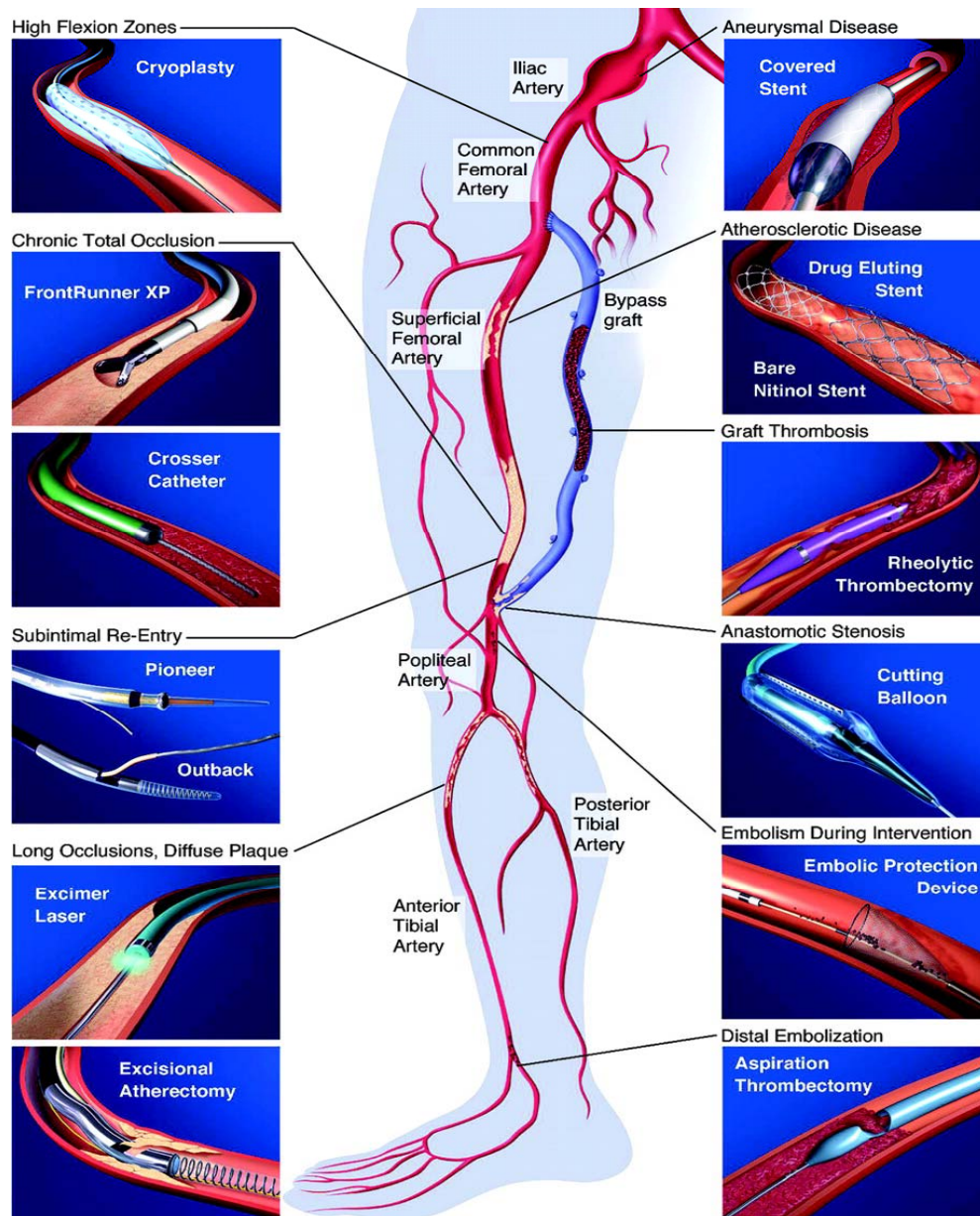


# **Determinants of Procedural Success and Patency following Subintimal Angioplasty in Patients with TASC C and D Femoropopliteal Arterial Disease**

- **63 lesions in 54 consecutive patients suffering from limb ischemia (Fontaine IIB –IV).**
- **inclusion of peripheral artery disease**
  - **TASC C and D with occlusion above 10 cm**
  - **Exclude : Acute occlusion, short occlusion (<10cm),**
- **TASC C (n=13, 20.6%) or TASC D (n=50, 79.4%).**
- **Success rate: 59 of 63 lesions (93.6%)**
- **Primary patency rate at 12 months was 51.6%.**



# New technologies for lower extremity revascularization



- Drugs
- Subintimal Angioplasty
- Bare Stents
- **Covered stents**
- **Drug eluting Stents**
- **Drug eluting balloon**
- **Bioabsorbable Stents**
- Brachytherapy
- Cryoplasty
- Cutting balloon
- Photodynamic therapy
- Debulking -arterectomy

# Drug-Eluting and Bare Nitinol Stents for the Treatment of Atherosclerotic Lesions in the Superficial Femoral Artery: Long-term Results From the SIROCCO Trial

## Duplex Ultrasound In-Stent Restenosis Rates

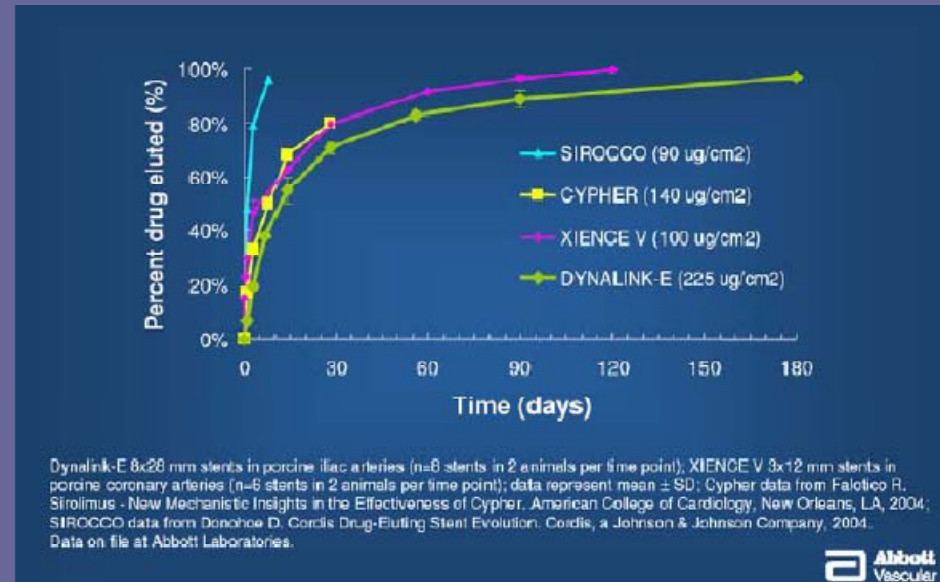
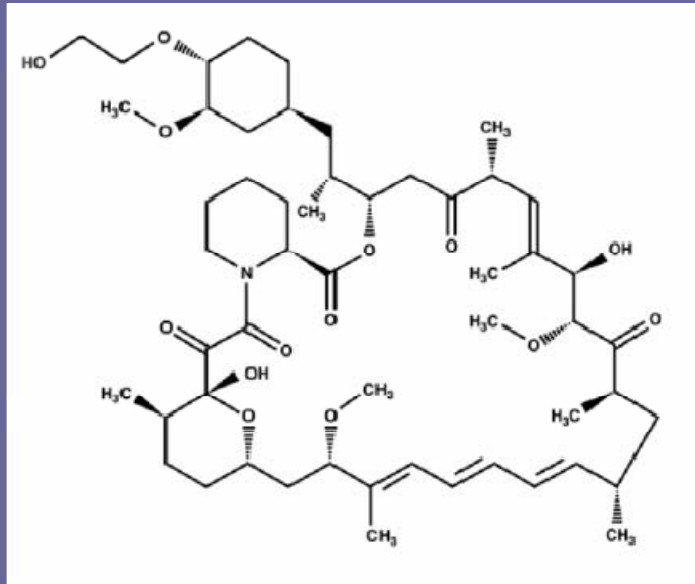
	Sirolimus Stent	Bare Stent
6 Months	4.8%; 0.6% to 16.2% (n=42)	4.5%; 0.6% to 15.5% (n=44)
9 Months	7.1%; 1.5% to 19.5% (n=42)	11.1%; 3.1% to 26.1% (n=36)
18 Months	18.4%; 7.7% to 34.3% (n=38)	12.8%; 4.3% to 27.4% (n=39)
24 Months	22.9%; 10.4% to 40.1% (n=35)	21.1%; 9.6% to 37.3% (n=38)

# STRIDES Study

**STRIDES** → Everolimus eluting Dynalink-E (Abbott Vascular)

**FIM:** Non-randomized European trial (100 pat<sup>s</sup>)

- Enrolled fempop lesions up to **17cm**
- Results to be awaited

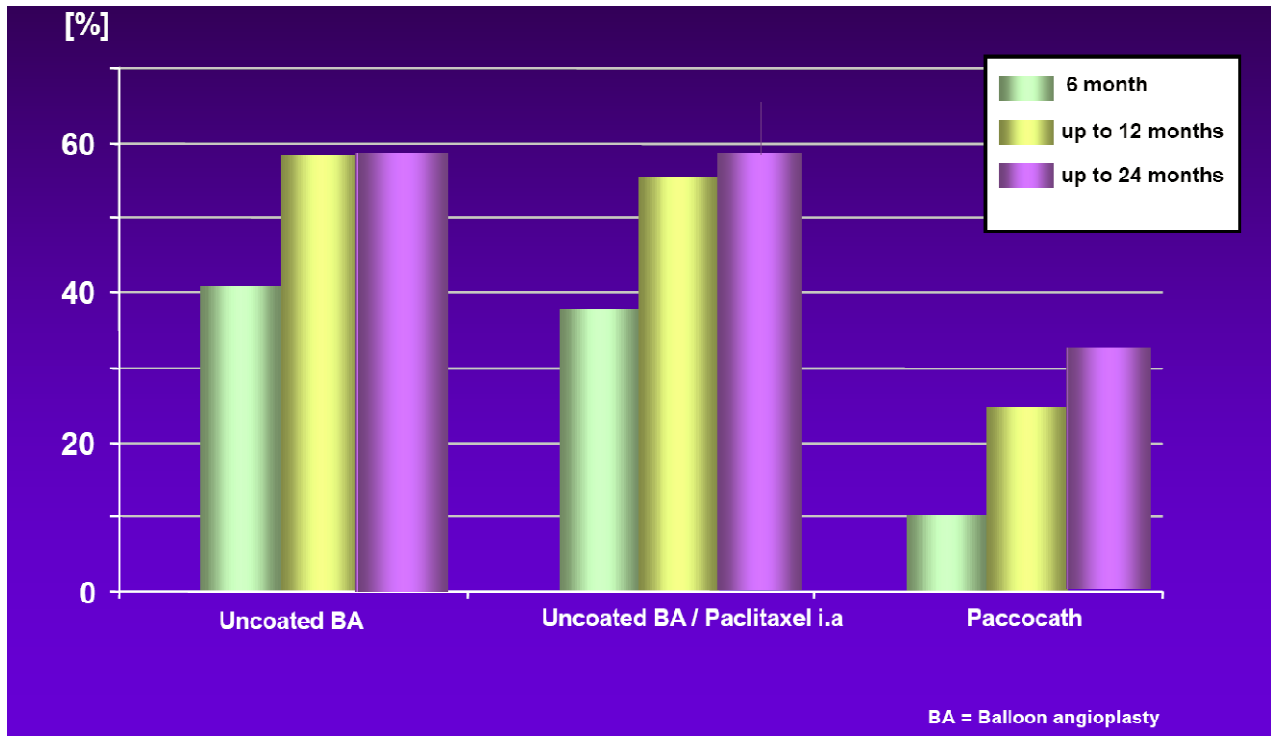


# **SFA Drug Eluting Stents - Issues to be Resolved**

- **Proper dose**
- **Ideal release kinetics**
- **Applying drug with or without a polymer to selfexpanding**
- **stents ( implanted in a dynamic environment)**
- **Stent fractures**
- **Costs**



# Is angioplasty with drug-coated balloon better than with regular balloons?



**First data: Better short-/midterm results**

**Currently: Possible indication only in few patients**

**Not in patients with complex/longdistance lesions**

# Randomized comparison of percutaneous Viabahn stent grafts vs prosthetic femoral-popliteal bypass in the treatment of SFA occlusive disease

*Kedora et al; J Vasc Surg 2007; 45:10-16*

Primary patency at 3, 6, 9, 12 months

stent graft 84% 82% 75.6% 73.5%

surgery 90% 81.8% 79.7% 74.2%

The mean total length of artery stented was 25.6 cm.

FU: ABI and color duplex sonography : 3, 6, 9, and 12 months

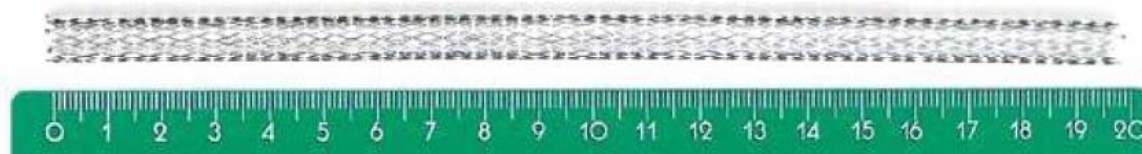
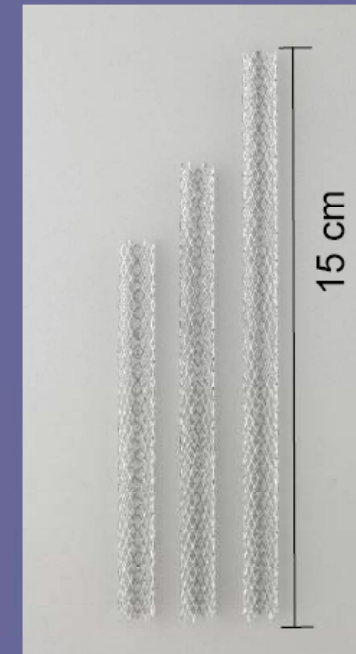
*McQuade et al; J Vasc Surg 2009; 49:109-15*

Similar primary patency at 24-months follow-up.

# Long stents = Improved results

- **Durability** : Prospective, non-randomized, controlled
  - **Protégé Everflex stent (ev3) = FIRST TRIAL WITH LONG STENTS**
    - Endpoints = Duplex based patency + Stent fractures

	Stent
Intention to treat	-
On treatment	151
<b>Lesion length</b>	<b>9.6cm</b>
<u>Single stent</u> in 93% of cases	
<u>150mm stent</u> in 47% of cases	
<b>12M patency (duplex)</b>	<b>72%</b>
<b>12M fracture rate</b>	<b>8%</b>



*Protégé Everflex (ev3) - up to 200mm in length*

# Atherectomy: SilverHawk Catheter

No proven benefits of  
Atherectomy over PTA

52 patients

42% de novo lesions

- 38% PTA restenosis

No proven benefits of  
Cutting balloon over regular PTA

- 27% for de novo lesions

- 41% for PTA restenosis

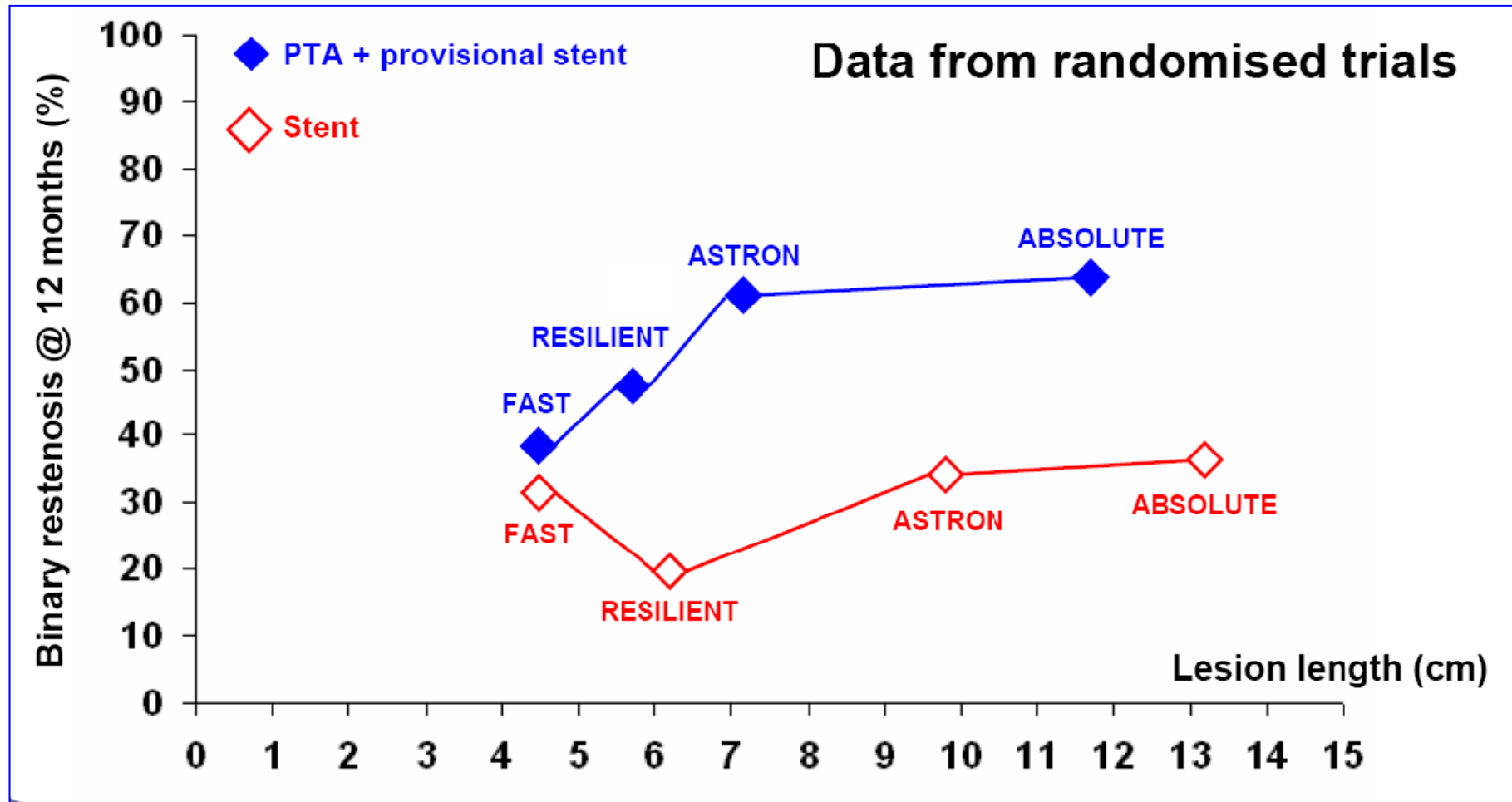
No proven benefits

For cryotherapy over PTA



# TASC A&B

## Effect of Primary Stenting



# TASC C & D : Bypass

**Primary patency** results in patients with above-knee vein bypasses after **5 yrs**

<b>AK-Prosth.</b> above-knee PTFE (n=1713)	<b>AK-Venous</b> above-knee vein (n=580)
<b>60.0%</b>	<b>81.1%</b>

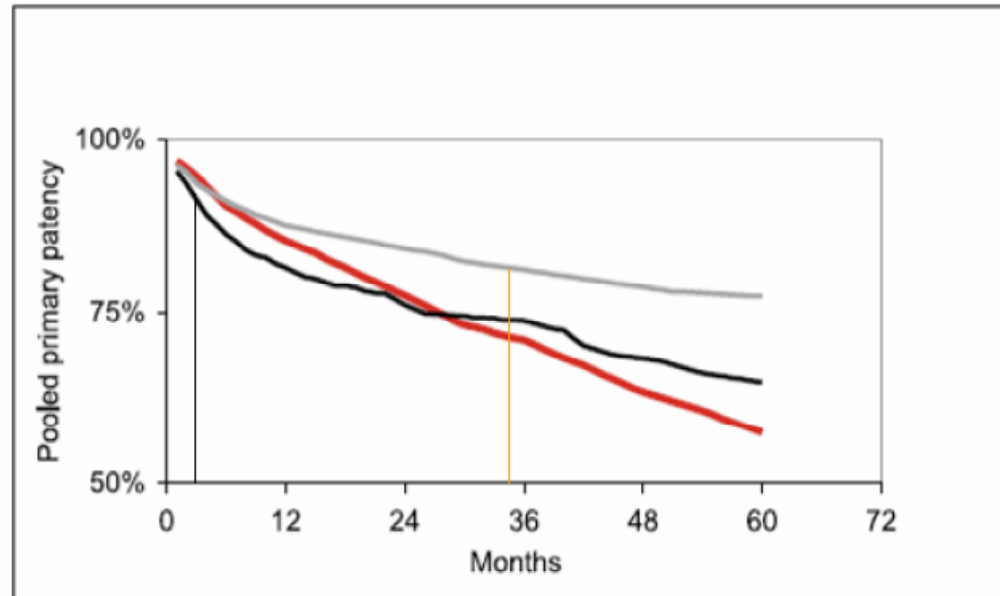


Fig 1. Meta-analysis C of primary patency for above-knee femoropopliteal polytetrafluoroethylene bypass grafts (AK-P; red line), above-knee femoropopliteal saphenous vein bypass grafts (AK-V; gray line), and below-knee saphenous vein bypass grafts (black line). The vertical line indicates when AK-V surpassed AK-P.

72/M Ulcer with necrosis at Lt. 3<sup>rd</sup> toe, tibial

ABI 0.45 / 0

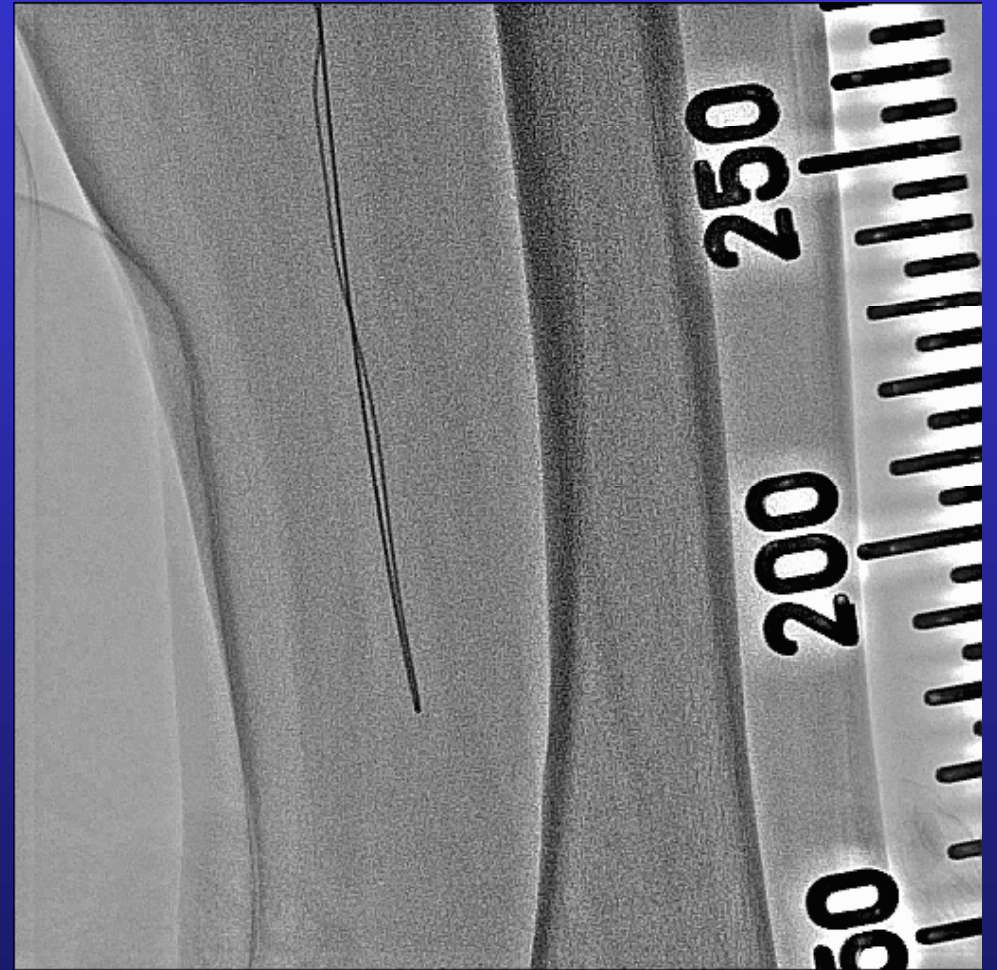


Total occlusion of Lt. EIA, SFA,  
popliteal artery



6F Balkin sheath  
Left/Right oblique view

# Subintimal Wiring



4F multipurpose catheter

0.014 angled Terumo wire



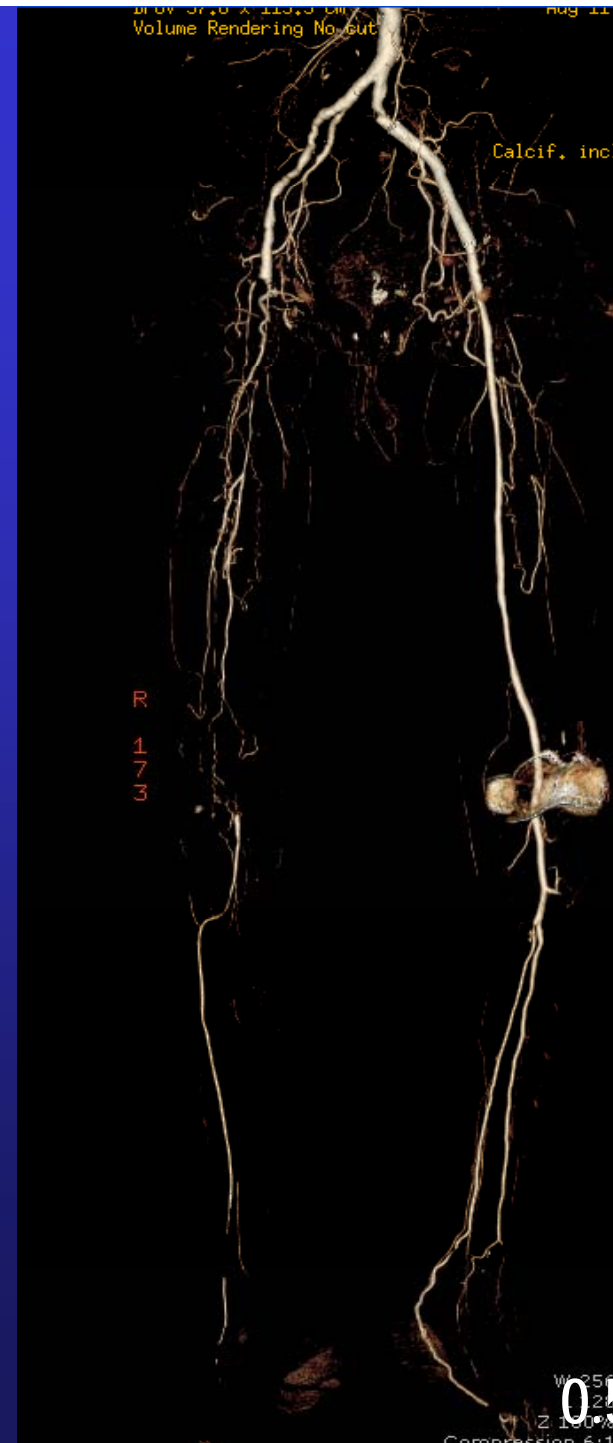
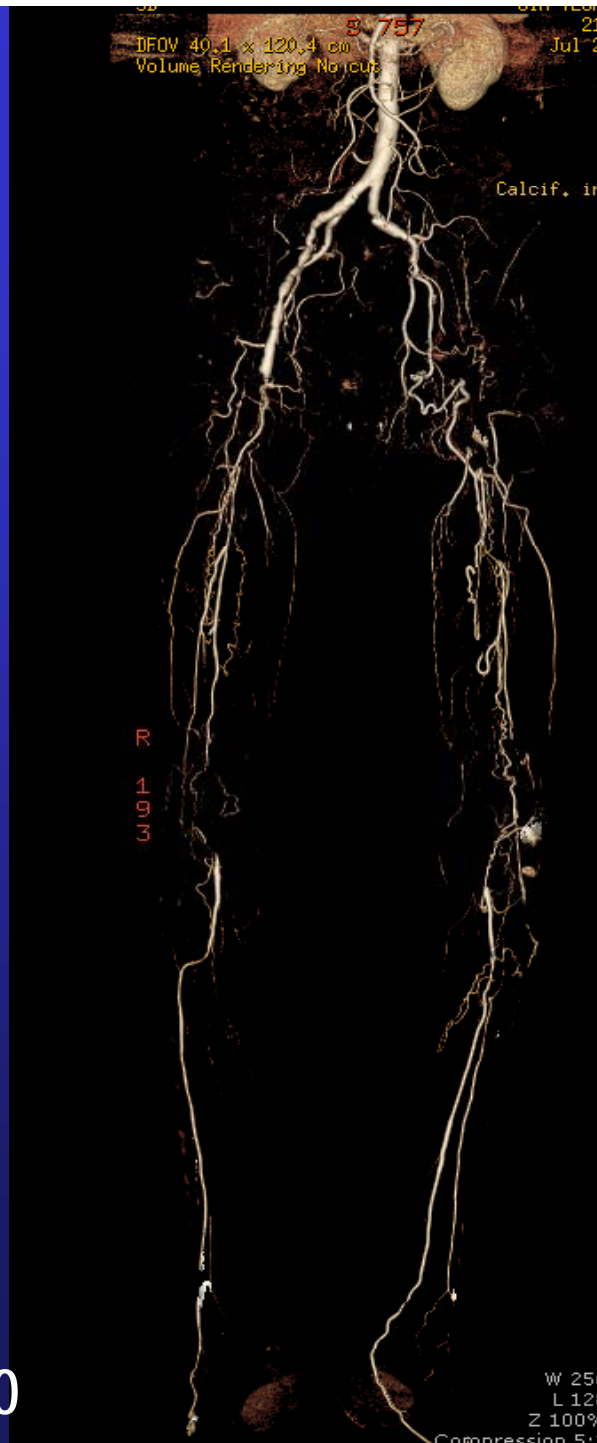
# Final angiogram



# Comparison of CT angio

good patency of Lt.  
EIA , SFA and  
popliteal artery with  
well distal run-off  
and not observed  
opacification of left  
ATA

0.45 / 0



0.55 / 0.95

# Conclusions

**1) Iliac intervention : Just do it !**

**2) TASC A & B: Primary stenting !!!**

**Bare Nitinol stents: established**

**Improvements by next generation stents**

**3) TASC C & D: Surgery ???,**

**but, Subintimal angioplasty with ...Long stent (DURABILITY) ??**

**DES(ZILVER PTX, other drug) ??**

**Covered stents ??**

**Drug eluting balloons ??**

**4) In-stent restenosis is still the Achilles heel of SFA stenting.**

**Further investigation needed for promising techniques**

# Improved the technique and device – not enough



New investigational devices (stent!!) might be expand endovascular possibilities to TASC C & D.

# What's Your Dream ?

나 혼자 꿈을 꾸면 그것은 한갓 꿈일뿐이다,  
하지만 우리 모두가 함께 꿈을 꾸면  
그것은 새로운 현실의 출발이다. (훈데르트 바서)

꿈은 이루어진다.

2002 6 22

Thanks for Your Attention !

# Expanding Catheter Therapeutics; Ilio-Femoral Artery Disease

김 원

경희 의대 순환기내과

# Procedural safeguards

- Use good sterile technique
- Always confirm back flow of blood from the catheter before injecting
- Inject a small amount of contrast to confirm catheter position before using the power injector
- Don't lose wire position especially during interventions
- Flush the sheath and catheter and wipe the wire frequently to avoid clots
- Control the wire when changing sheaths or exchanging catheters

# Case Presentation

21460745 79/M

C/C Lt.3<sup>rd</sup> toe necrosis & ant.tibial ulcer (O:1 weak ago)  
Claudication (O:1 year ago)

P/I 상기환자 07년 2월부터 claudication 있어 OPD F/U 중인 자로  
최근 약 1일주일 전부터 발생한 Lt. 3rd toe 의 necrosis 및  
ant.tibial ulcer 소견 보여 이에 대해 further evaluation 및  
treatment위해 OPD 통해 admission



P/H No known hx.of DM, hepatitis, HTN

Tb (+) (20년전)

09/1/29 local : sputum study

→ AFB stain 4+

TB-PCR : MTB + / NTM -

S/H Smoking : 20 pys

Alcohol : none

V/S BP : 110/50 mmHg

BT : 36.4 c

HR : 70회/min

RR : 20회/ min

# CTA lower extremity (HD #1)



ABI 0.97/0

# **Comparison intraluminal vs subintimal recanalization of the SFA**

- **In many interventions a subintimal passage is unavoidable.**
- **Comparison of the two modalities regarding patency rate is quite difficult or – currently – even impossible according to the data.**
- **Probably intentional subintimal angioplasty has a higher technical success rate.**