The Southern Association for Vascular Surgery

Lower Extremity Endovascular
Postgraduate Course - 2006

Superficial Femoral Artery Stents - Bare, Covered, or Drug-Coated – *"The Data and The HYPE"*

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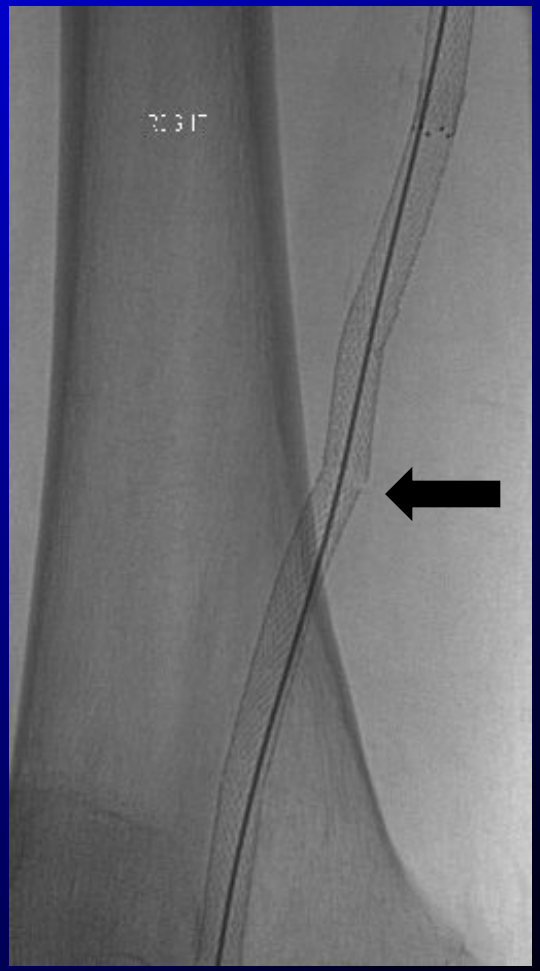
"The Most Common SFA Stents I've Seen"

"Failing"

"Occluded"

"Occluded-Fractured"



Role for SFA Stenting
- Opinions from the Literature -

- Justifiable for patients with critical limb ischemia or "high risk" for surgical bypass.
- To correct an anatomic/hemodynamic residual stenosis following balloon angioplasty
- As an adjunct with other procedures – subintimal angioplasty, athrectomy
- Inferior to surgical bypass for TASC C or D lesions

Contemporary results of angioplasty-based infrainguinal percutaneous interventions

James H. Black, III, MD, Glenn M. LaMuraglia, MD, Christopher J. Kwolek, MD, David C. Brewster, MD, Michael T. Watkins, MD, and Richard P. Cambria, MD, *Boston, Mass*

JVS - 2005

100 limbs in 95 consecutive patients
- 53% claudication
- only 1 stent implanted

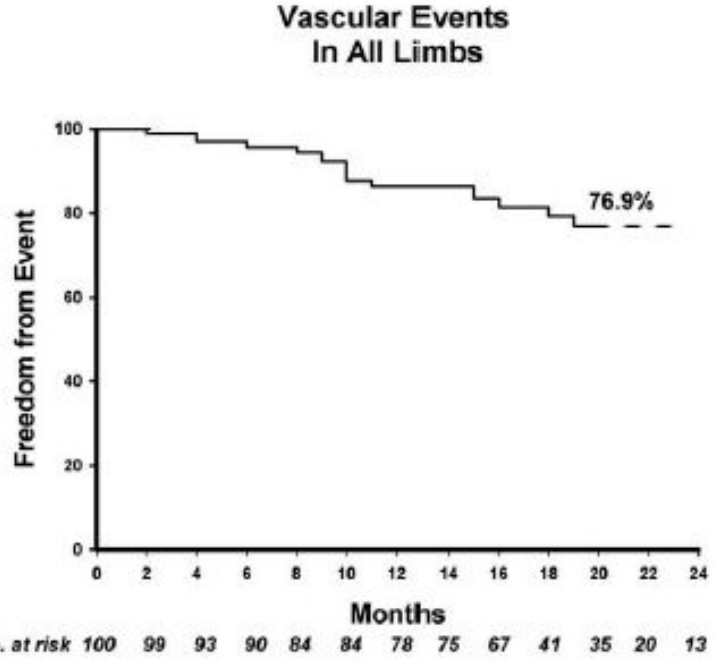


Fig 1. Cumulative freedom from vascular events in percutaneous transluminal angioplasty (PTA) limbs, including avoidance of clinical category decrement, need for another PTA, or need for surgical bypass or major amputation. *Dashed line* indicates SE >10%.

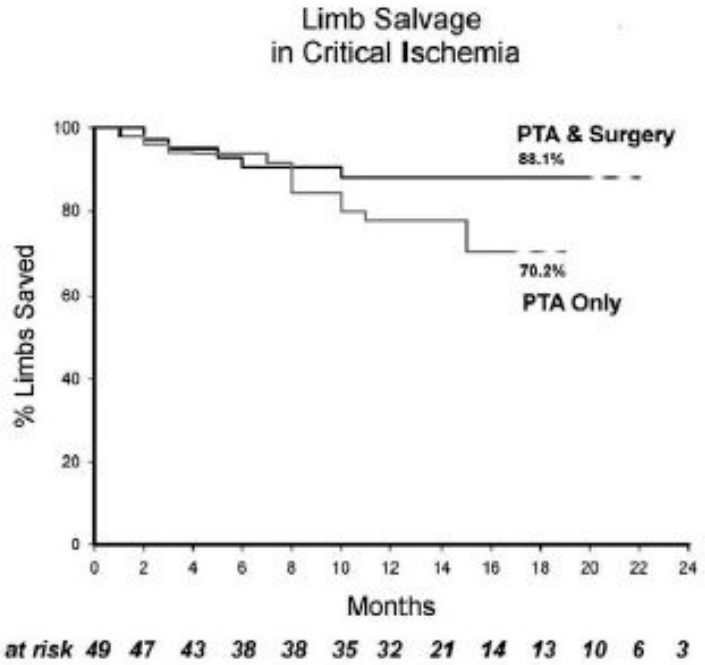


Fig 2. Kaplan-Meier life table analysis of limb salvage in patients with initial presentations of clinical ischemia. *Dashed line* indicates SE >10%. *PTA*, Percutaneous transluminal angioplasty.

Percutaneous angioplasty and stenting of the superficial femoral artery

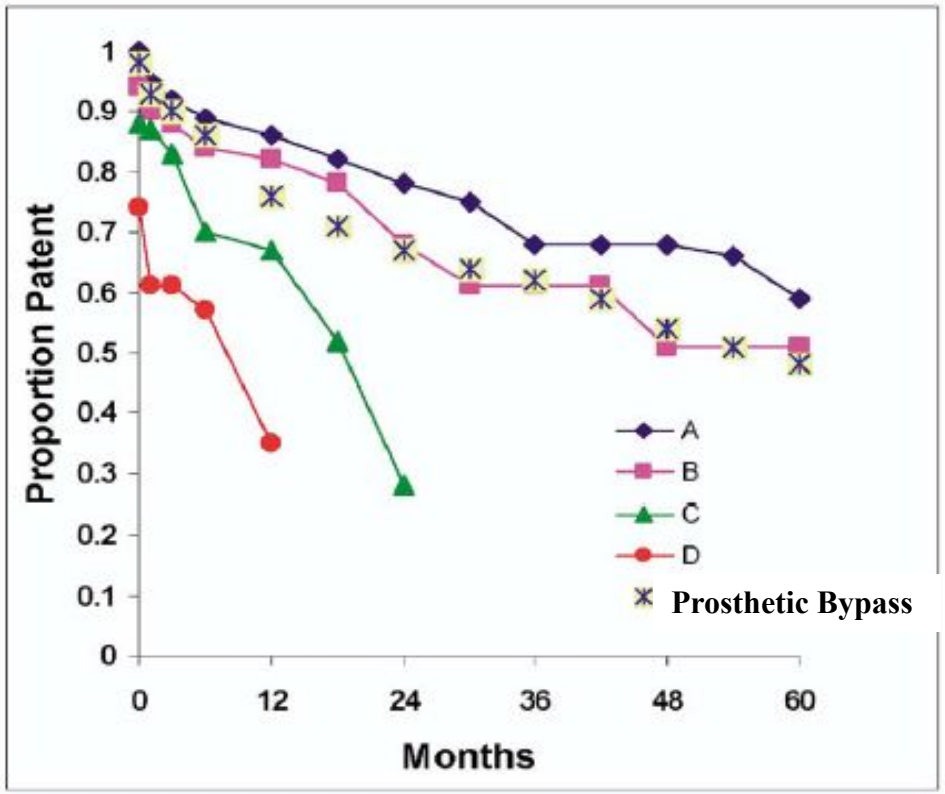
Scott M. Surowiec, MD,[a] Mark G. Davies, MD, PhD,[a,b] Shirley W. Eberly, MS,[c] Jeffrey M. Rhodes, MD,[a] Karl A. Illig, MD,[a] Cynthia K. Shortell, MD,[a] David E. Lee, MD,[b] David L. Waldman, MD, PhD,[a,b] and Richard M. Green, MD,[a] *Rochester, NY*

JVS - 2005

380 Limbs in 329 Patients:
- 67% male
- 66% claudication
- TASC lesions
  - A: 48%
  - B: 18%
  - C: 22%
  - D: 12%

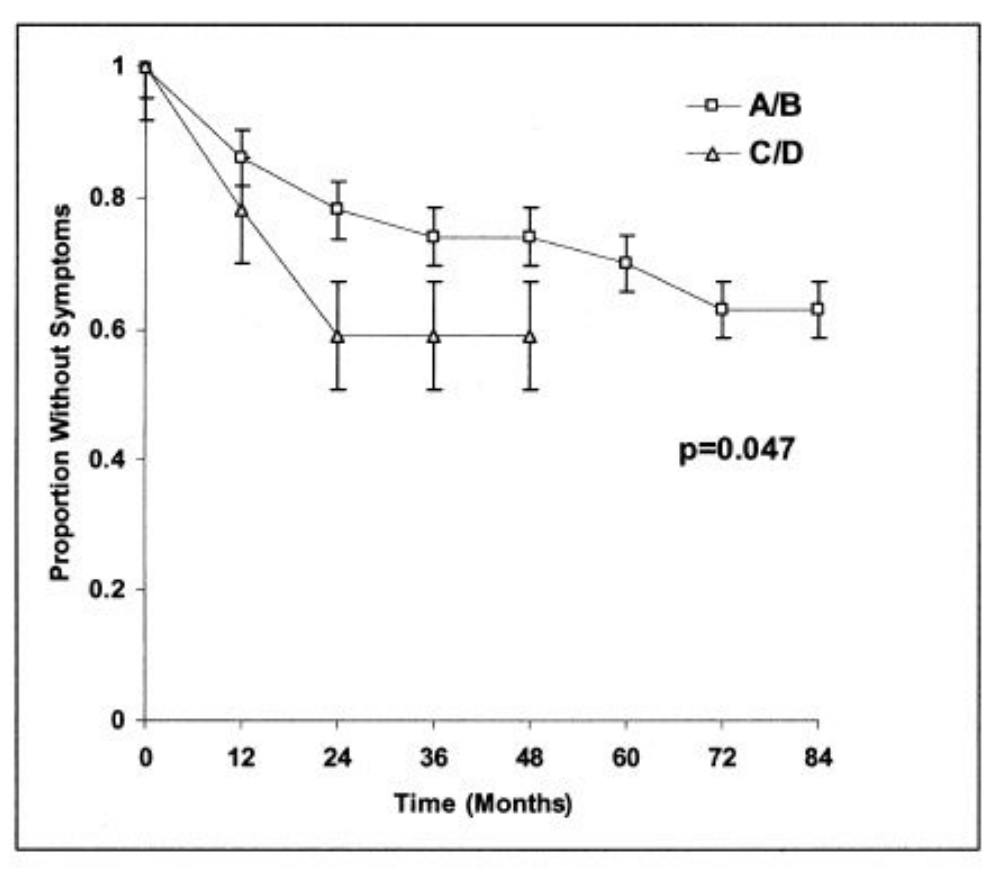
• Stents used in 37% of procedures

• Assisted primary patency not higher than primary patency



Lesion	0 Months	12 Months	24 Months	36 Months	48 Months	60 Months
A	180	100	64	43	31	17
B	83	26	10	7	5	5
C	69	16	2	1	0	
D	42	3	0			
P	350	180	129	97	70	50

Freedom from Symptoms after PTA/stenting

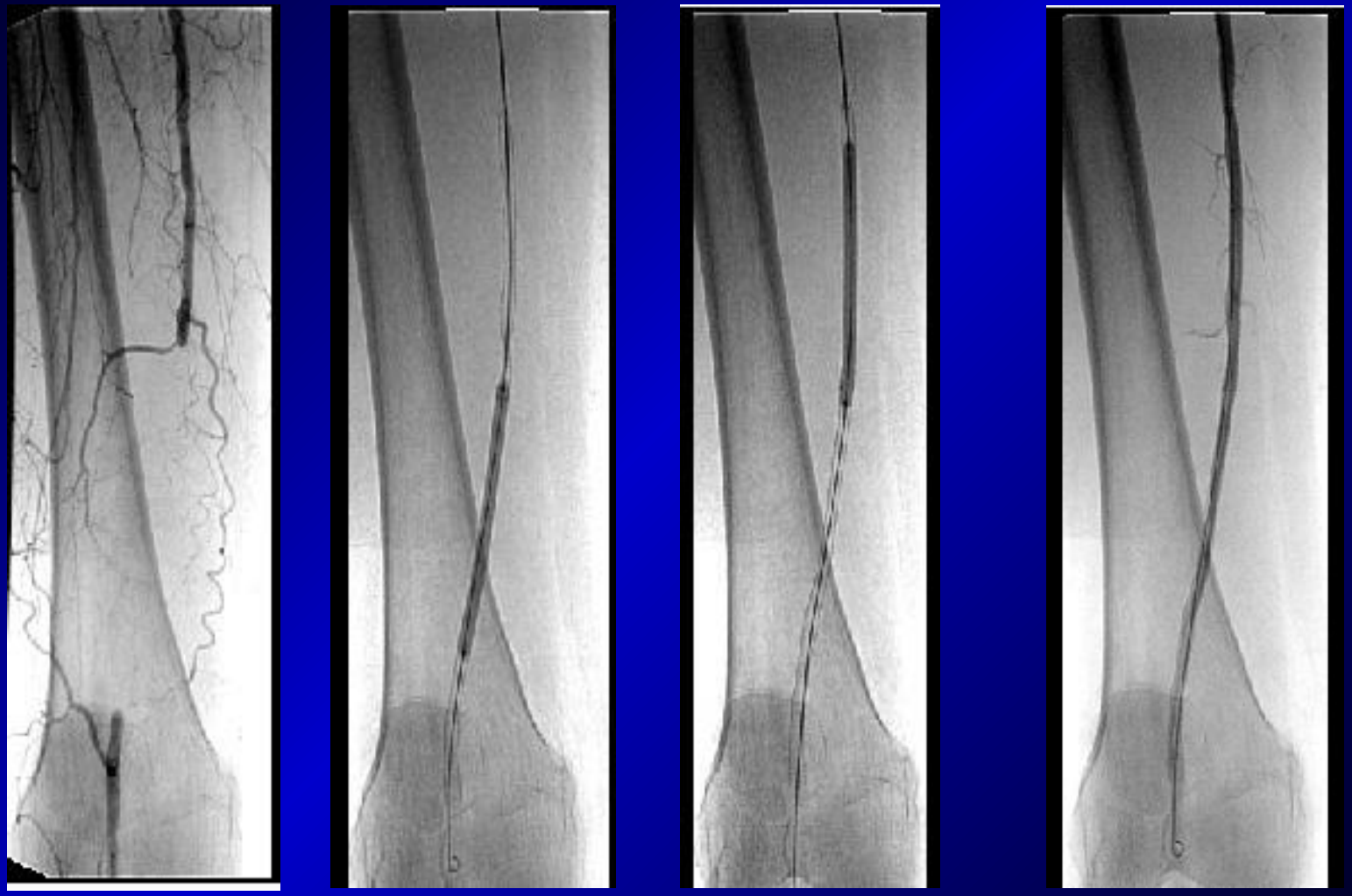


# at risk	0 months	12 months	24 months	36 months	48 months	60 months	72 months	84 months
A/B	297	155	108	61	47	36	16	8
C/D	144	56	8	1	1			

CONCLUSIONS:

- High procedural success
- Improved ABI
- Patency dependent on lesions type
- Patency of TASC A & B lesions treated by PTA/S was similar to prosthetic bypass

Primary Stenting Technique: TASC C - Occlusion

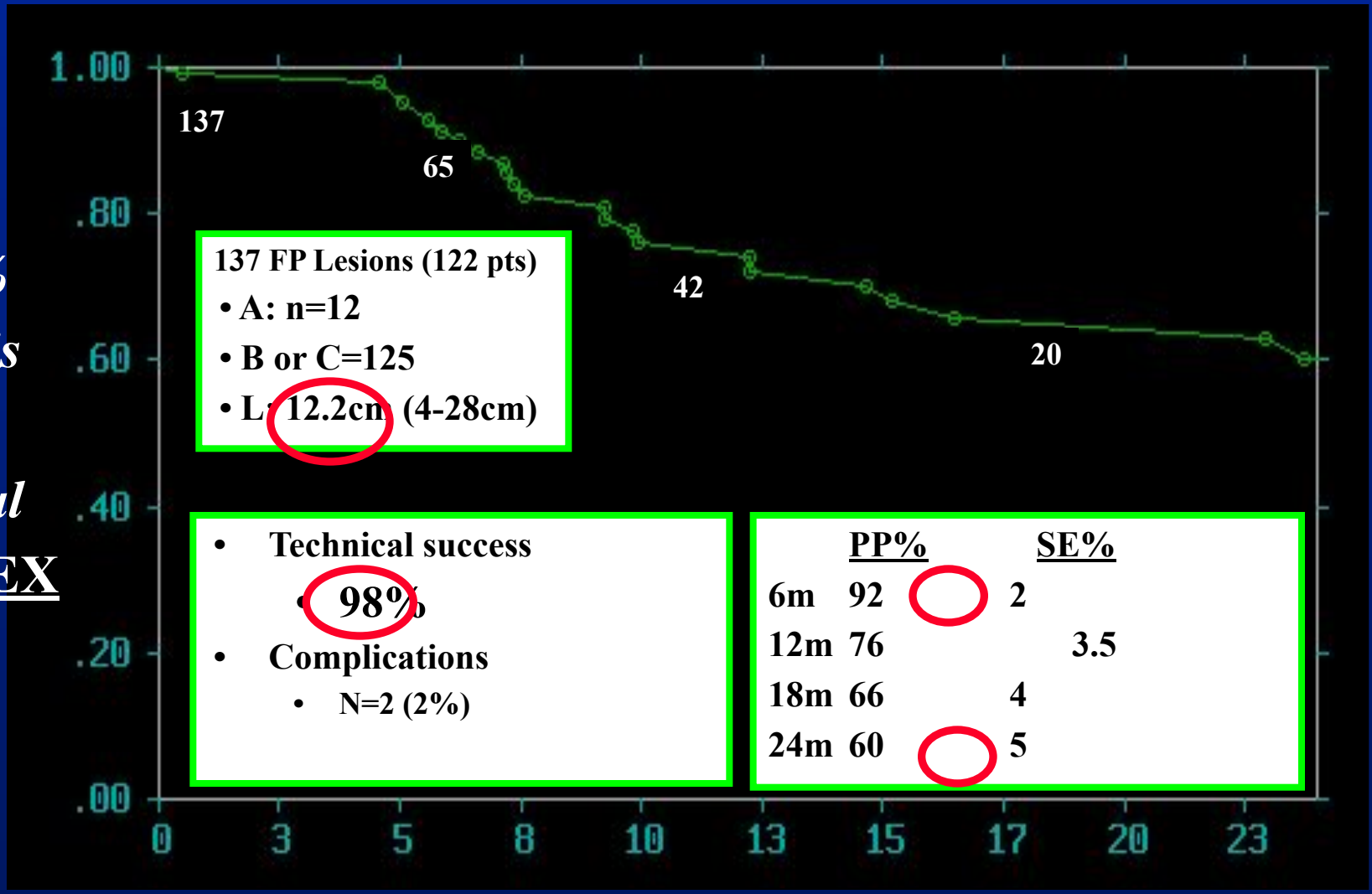


Mewissen MW. Self-Expanding nitinol stents in the FP segment: technique and mid-term results
Techniques in Vascular and Interventional Radiology. 7(1): 2-5, 2004 Mar

Self-Expanding Nitinol Stents in the FP Segment: Technique and Mid-term Results

50-99% Stenosis Free Survival

DUPLEX



Mewissen MW. Self-Expanding nitinol stents in the FP segment: technique and mid-term results *Techniques in Vascular and Interventional Radiology. 7(1): 2-5, 2004 Mar*

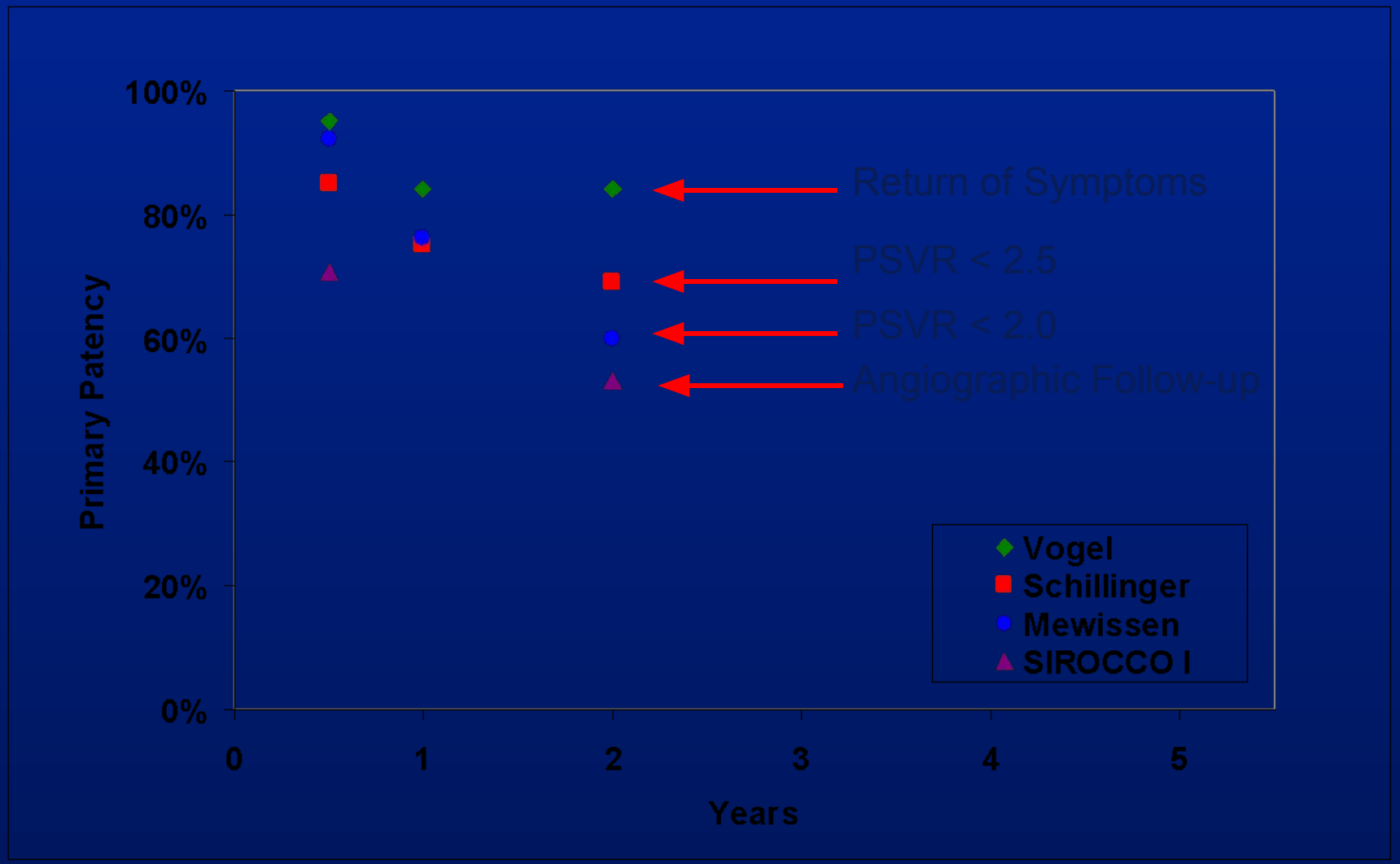
Self-Expanding Nitinol Stents in the FP Segment: Technique and Mid-term Results

Conclusions

- High Technical success, irrespective of TASC Grades
- Associated with clinical improvement
- Acute stent occlusion is rare (<1%)
- Excellent 6 mo. stenosis-free patency (92%)
- 76% and 60% primary hemodynamic patency at 1 and 2 years

Mewissen MW. Self-Expanding nitinol stents in the FP segment: technique and mid-term results
Techniques in Vascular and Interventional Radiology. 7(1): 2-5, 2004 Mar

Nitinol Stent Patency Based on Outcome Criteria



Nitinol Stent Primary Patency: All Data

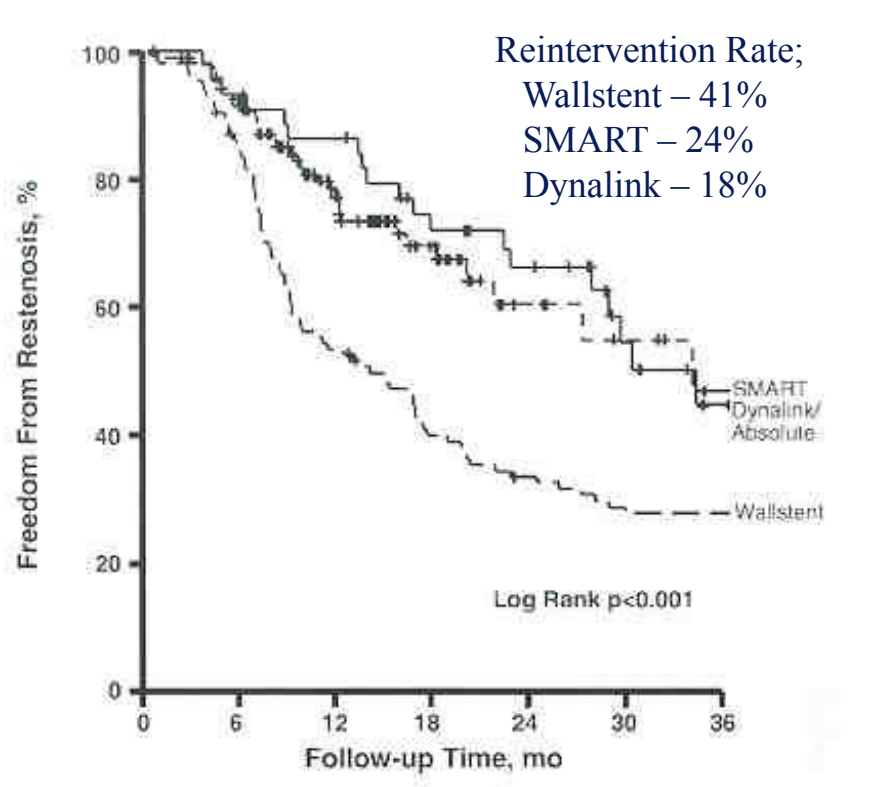
Author	Year	# limbs	length (cm)	Primary Patency (years) 0.5	0.75	1	1.5	2	3	4	5
Schillinger	2005		13	75%							
Kazemi	2005	69				76%					
Scheinert	2005	121	15.7			68%					
Ferreira	2005	63	15.7			67%					
BLASTER	2005	50			83%						
SIROCCO II	2005	28		92%	87%		82%				
Schillinger	2004	52	6	85%		75%		69%			
Haverizadeh	2004	163	17.8			61%					
Mewissen	2004	137	12.2	92%		76%		60%			
Vogel	2003	41	6.7	95%		84%		84%			
Peeters/Hendrix	2003	100	4.7			85%					
SIROCCO I	2002	18	8.5	71%				53%			
Jahnke	2002	40	3.6	97%		86%					
Henry	1996	45	4.5	89%		85%					
Weighted Average			11.6	90%	84%	74%		65%			

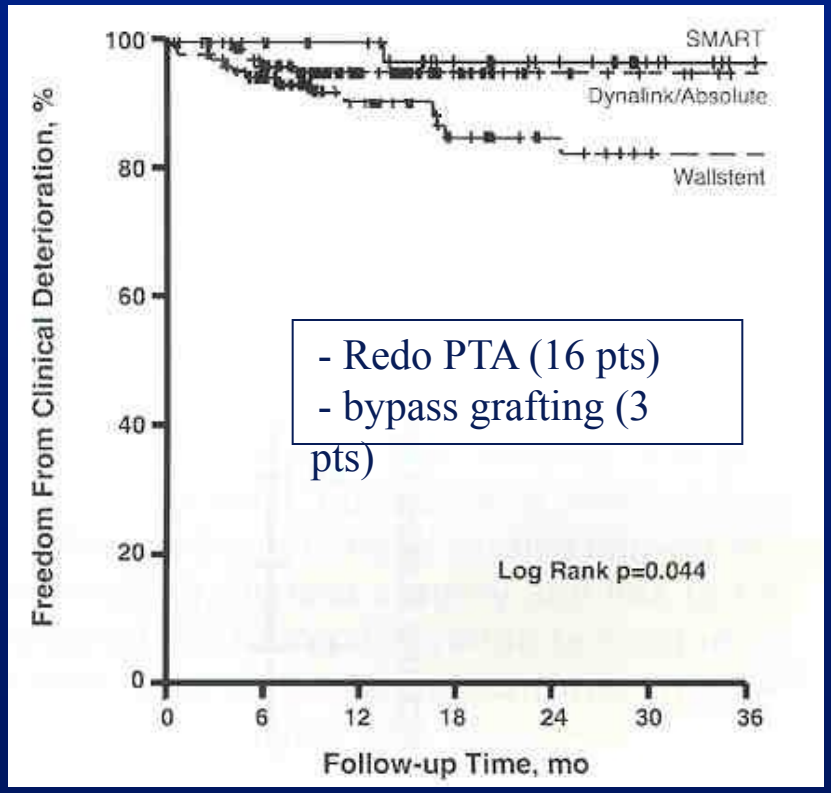
primary PTA alone: < 5CM 58% 51%

J Endovasc Therapy – 2005
Schlager et al - Vienna

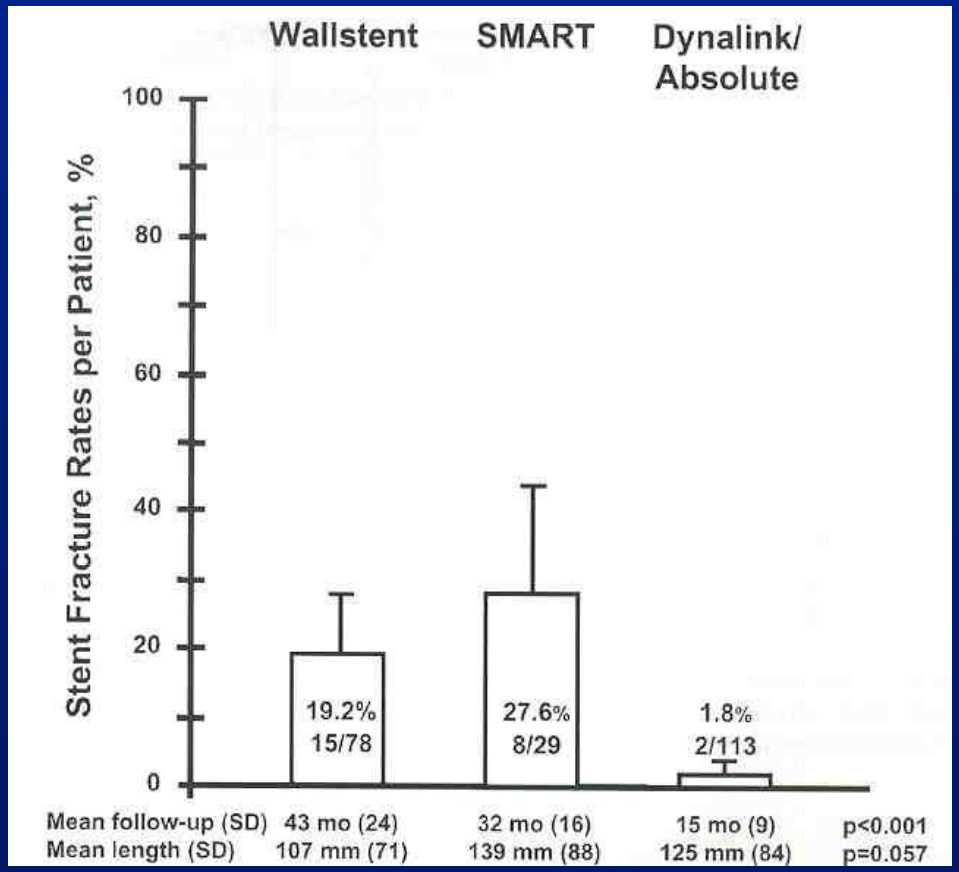
Nonrandomized Comparison of 3 SFA Stents

286 patients Rx: (1999-2004)
- 88% claudication
- stents (Wallstent, SMART, Dynalink) for suboptimal PTA
- mean stent length approx. 12 cm



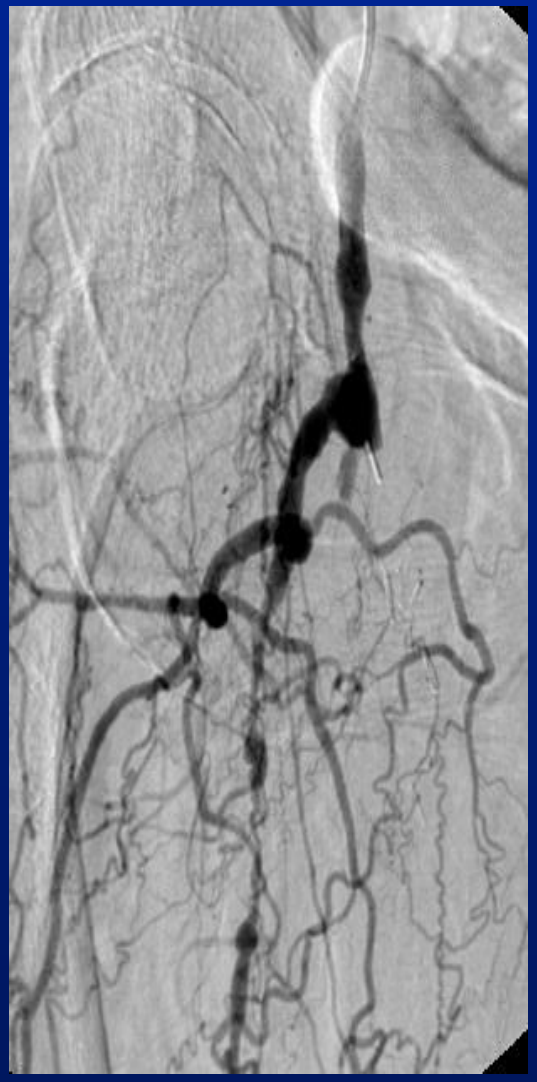


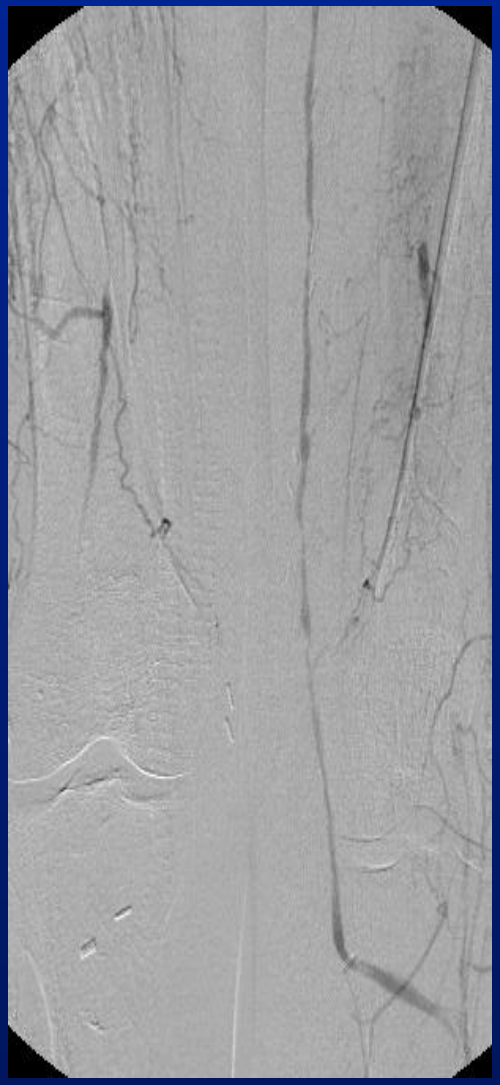
Incidence of Stent Fracture
- mean 15 mo. FU



Conclusions:
- nitinol stents outperformed Wallstents in SFA
- In-stent stenosis a common problem
- stent fracture related to length,stent type, and restenosis

Case Presentation – Stent Surveillance





01/04

76 YO IDDM

- **Non-healing Rt foot ulcer**
- **prior infra-inguinal Bypass**
- **prior CABG X 2**

Case Presentation

01/04

Outback Re-entry
Primary stenting



Case Presentation: PTA Surveillance

07/05

Duplex surveillance

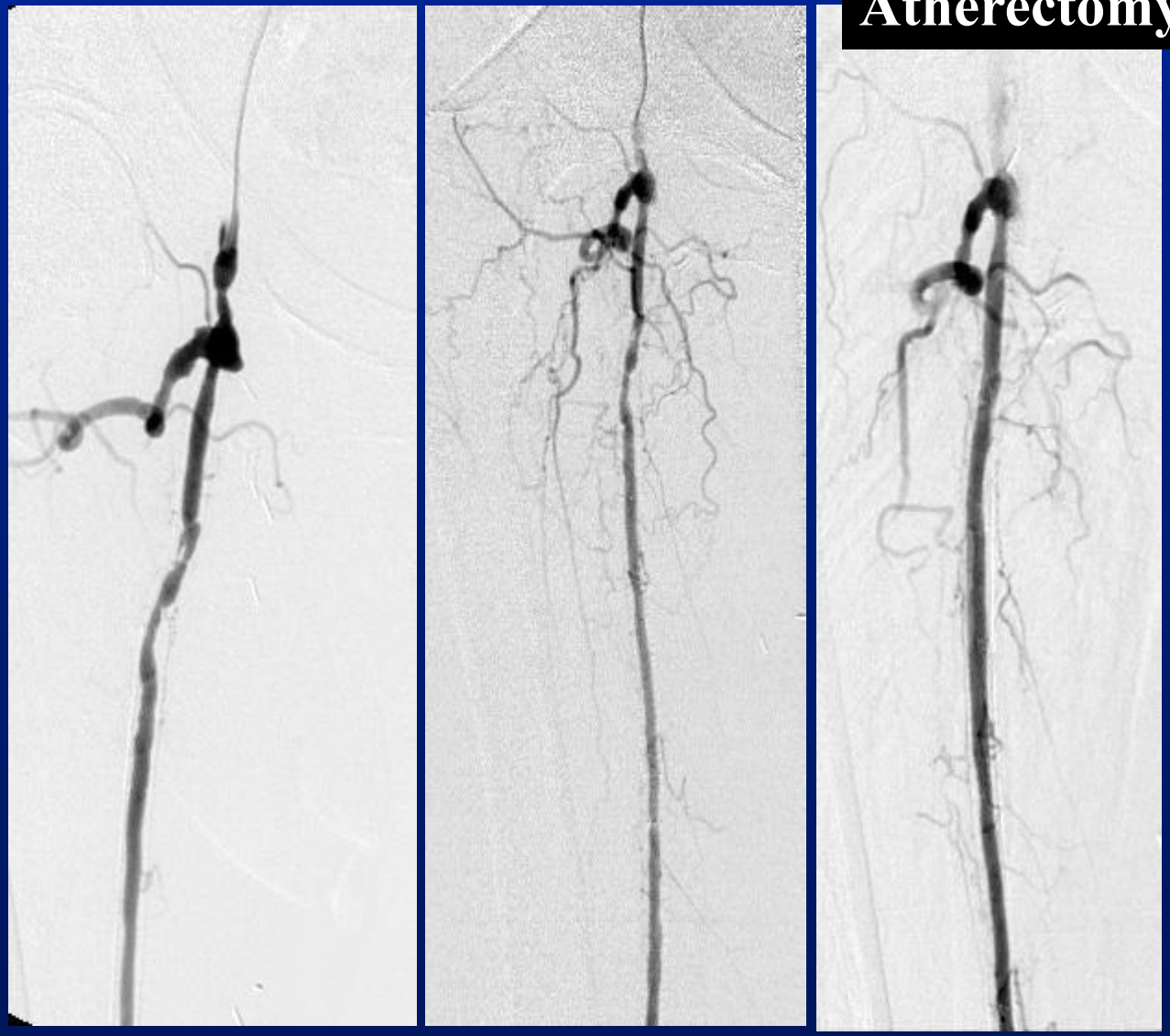
- **PSV > 300 cm/s**

In-stent stenosis

Asymptomatic

08/05

Atherectomy



Self-Expanding Nitinol Stents: Natural history in SFA

N=121	Primary Patency 12 Mo.	Stent FX X-Ray	FX /Stenosis
SMART *Cordis*	82%	15%	No
SelfX *Abbott*	44%	31%	Yes
Luminexx *Bard*	27%	52%	Yes

Scheinert at al. TCT

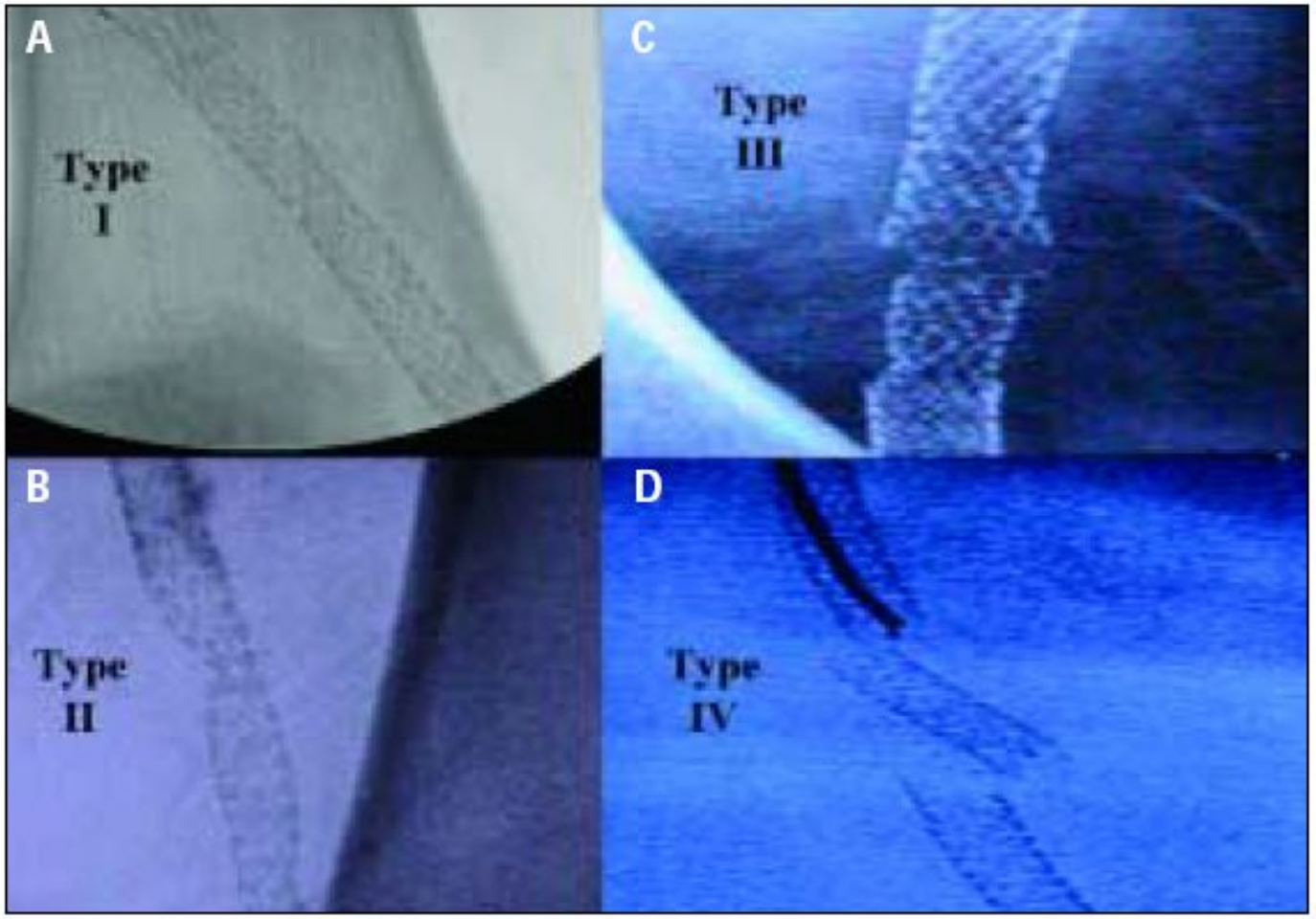


Figure 2. Nitinol stent fracture classification. Type I = a single strut fracture only (A). Type II = multiple single nitinol stent fractures that can occur at different sites (B). Type III = multiple nitinol stent fractures resulting in complete transverse linear fracture but without stent displacement (C). Type IV = a complete transverse linear type III fracture with stent displacement (D).

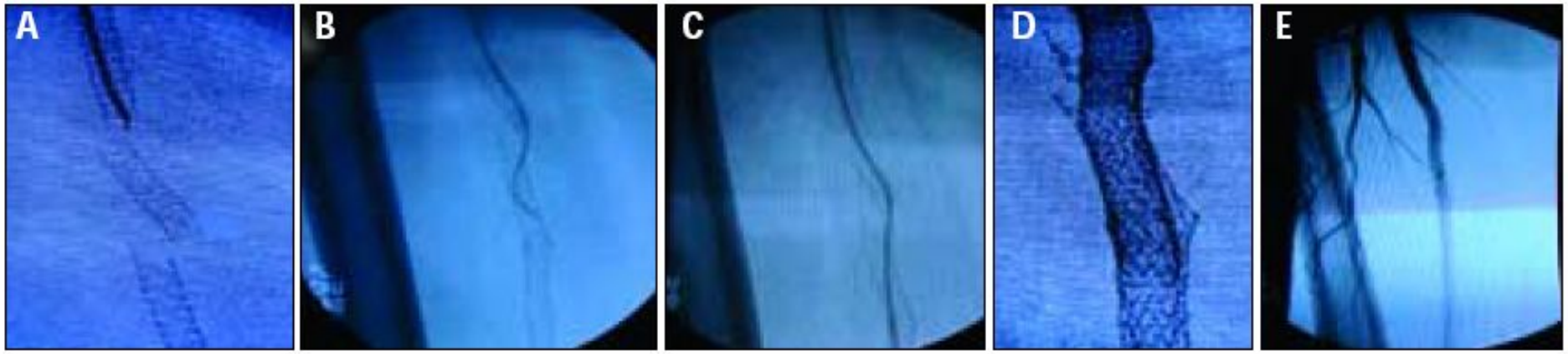


Figure 5. Symptomatic (occlusion) type IV nitinol stent fracture at 12 months after single SFA stent placement. This patient was a poor surgical candidate (A). All nitinol stent fracture elements are captured, realigned, and the occlusion crossed using a traditional Glidewire and 5-F angled Glide catheter (Terumo Medical Corporation, Somerset, NJ) (B, C). PTA and placement of a second nitinol stent (stent sandwich) were initially performed. Definitive endovascular treatment required a 6-mm Viabahn covered stent. Note the extraluminal migration of the nitinol stent fracture elements (D, E). The patient remained asymptomatic at 10 months.

TABLE 1. NITINOL STENT FRACTURE ANALYSIS BY CLINICAL OUTCOMES

Nitinol Stent Fracture Classification With Angiographic Stenosis

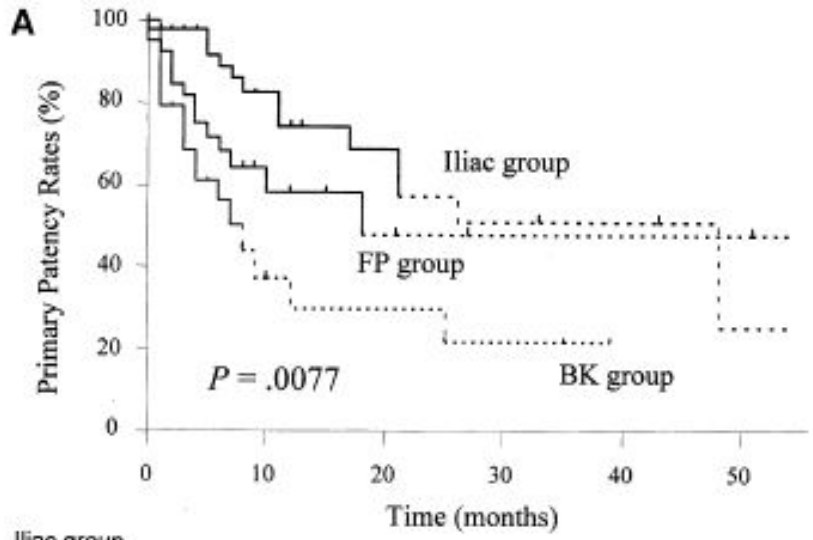
Classification	N = 72	%	<50%	>50%	Occlusion	Symptomatic (%)
I	27	37.5	10	15	2	7 (26)
II	32	44.4	6	21	5	15 (47)
III	11	15.2		7	4	9 (82)
IV	2	2.7			1	2 (100)*

**1 pseudoaneurysm.*

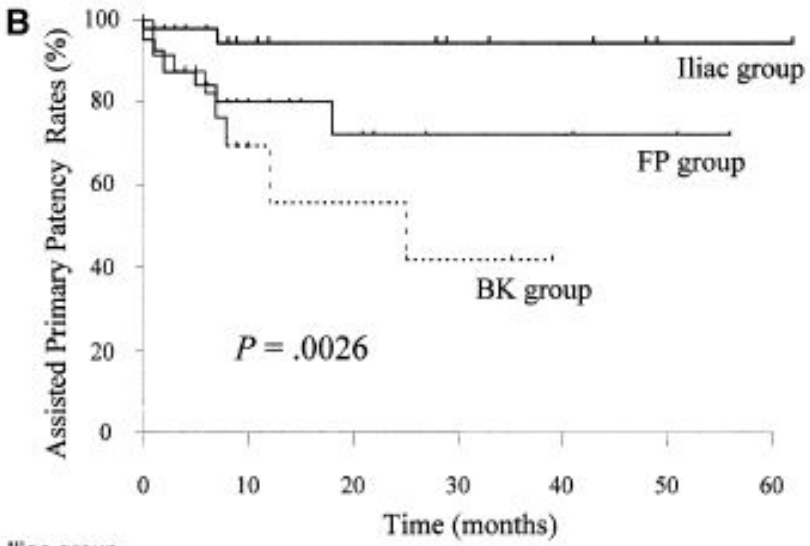
The effectiveness of percutaneous transluminal angioplasty for the treatment of critical limb ischemia: A 10-year experience

Toshifumi Kudo, MD, PhD, Fiona A. Chandra, and Samuel S. Ahn, MD, *Los Angeles, Calif*

Conclusions:
- PTA/stent has a role in CLI
- 77% 3-yr limb slavage
- duplex surveillance with re-PTA was effective



Iliac group						
At risk	45	21	12	5	4	1
S.E.	.021	.066	.091	.11	.11	.19
FP group						
At risk	41	11	4	2	2	2
S.E.	.024	.083	.012	.12	.12	.12
BK group						
At risk	52	6	4	2		
S.E.	.000	.10	.11	.11		

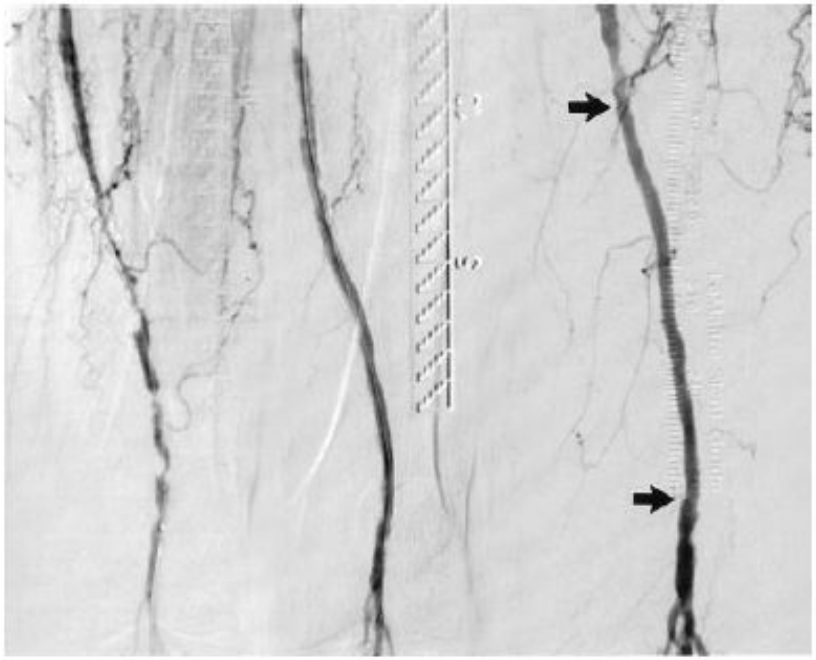


Iliac group							
At risk	45	20	15	9	8	4	4
S.E.	.021	.036	.036	.036	.036	.036	.036
FP group							
At risk	41	15	8	4	4	3	0
S.E.	.024	.068	.098	.098	.098	.098	
BK group							
At risk	52	7	4	2	0		
S.E.	.000	.10	.15	.16			

Sirolimus-Eluting Stents for the Treatment of Obstructive Superficial Femoral Artery Disease

Six-Month Results

Stephan H. Duda, MD; Benjamin Pusich, MD; Goetz Richter, MD; Peter Landwehr, MD; Vincent L. Oliva, MD; Alexander Tielbeek, MD; Benjamin Wiesinger, MD; Jan Bart Hak, PhD; Hans Tielemans; Gerhard Ziemer, MD; Ecatarina Cristea, MD; Alexandra Lansky, MD; Jean P. Bérégi, MD



Data for a 77-year-old patient with intermittent claudication. A, Intraarterial digital subtraction angiogram before treatment shows high-grade stenosis of the distal superficial femoral artery (length, 7 cm). B, After implantation of the sirolimus-eluting SMART nitinol stent, restoration of patency can be seen. C, After 6 months, no intimal hyperplasia is evident inside the stent or at the stent edges (arrows denote beginning and end of stent). There is mild restenosis proximal to the treated segment.

Scirocco II Trail

- 57 patients
- 59 lesions randomized
- Quantitiative angiography found no significant differences
- 6-mo follow-up

SFA Stents - Conclusions

- Better initial PTA results with nitinol stenting
- Mid-term patency similar due to in-stent stenosis
- Stent-graft patency may be better for long >15 cm lesions/occlusions
- Patency similar for drug-eluting stents (to date)
- No evidence that PTA-stenosis should be treated by routine stenting