

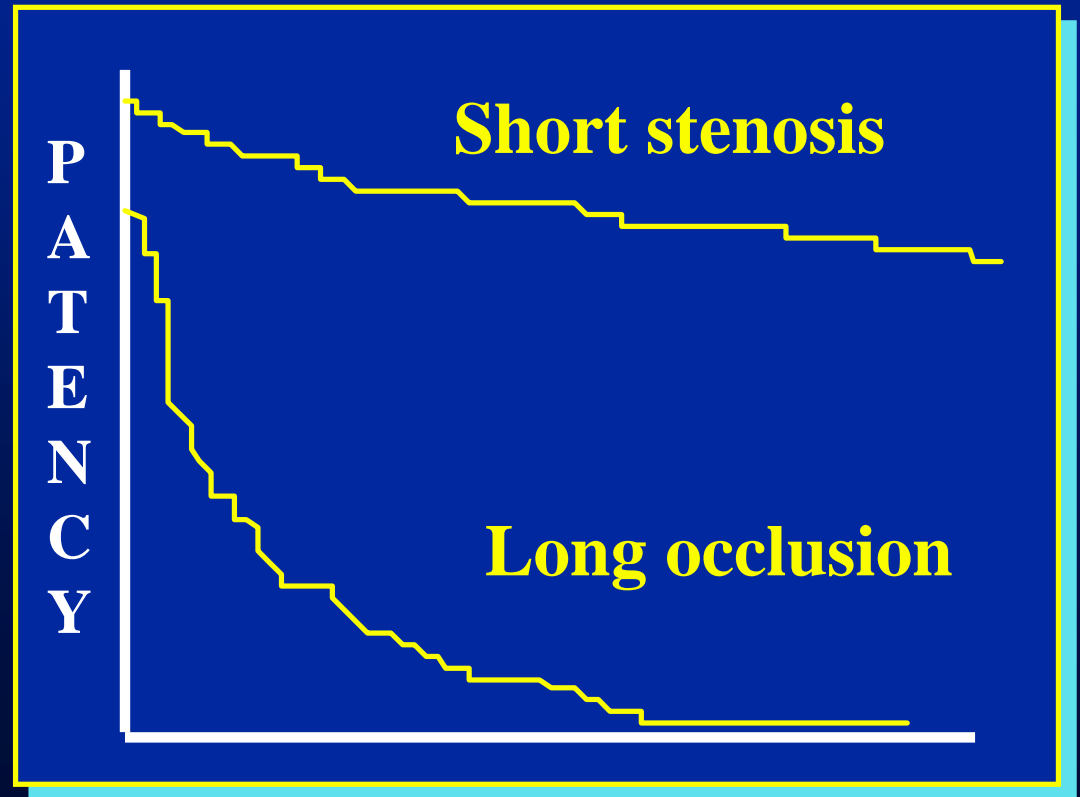
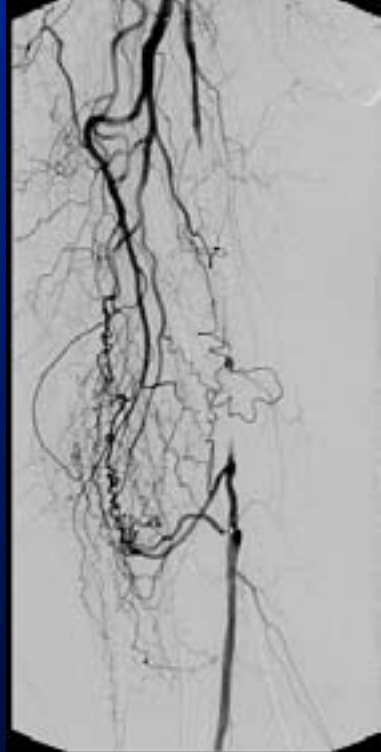
Is Primary Stenting in the SFA Indicated?

Mark W. Mewissen, M.D.

*Director, St Lukes Vascular Center
Milwaukee, WI*

Results of PTA in the FP arterial Segment

- LESION MORPHOLOGY**
- Technical success
 - Durability



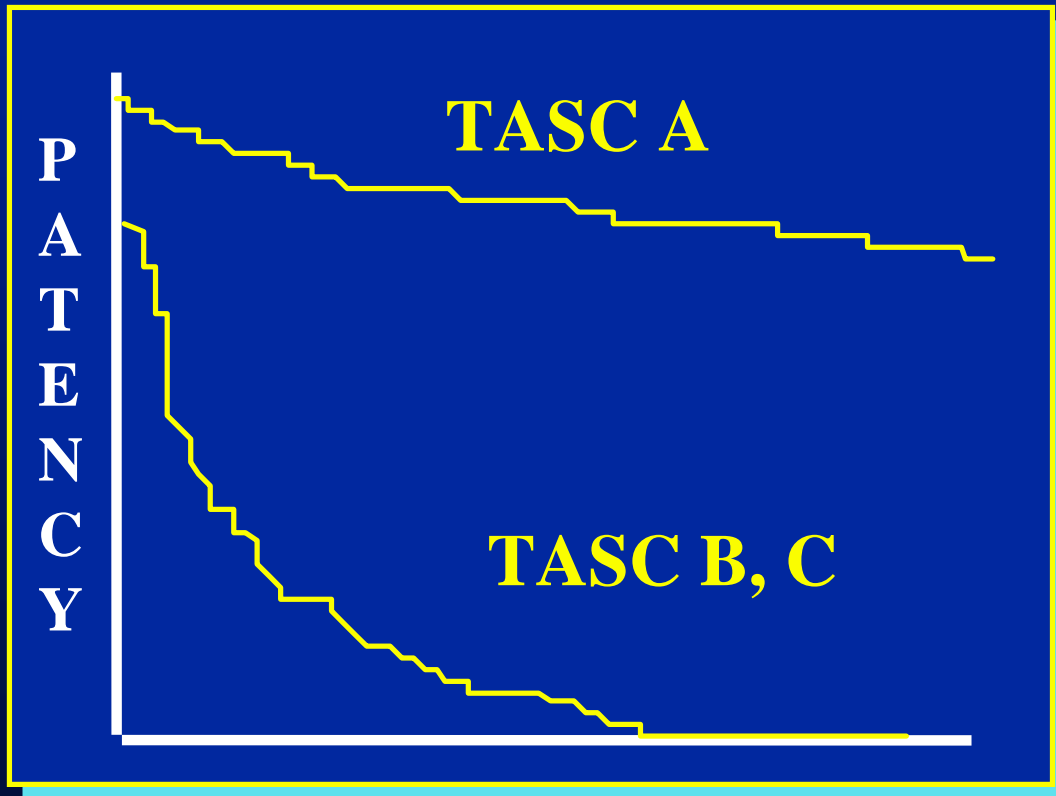
Morphological Stratification of FP Lesions

- TASC A
 - Single Stenosis < 3 cm
- TASC B
 - Single stenosis 3-10 cm not involving PA
 - Multiple lesions, each < 3 cm
 - Single or multiple lesions in the absence of continuous runoff to improve inflow for distal surgical bypass
- TASC C
 - Single Stenosis or occlusion > 5 cm
- TASC D
 - Complete common femoral artery or SFA occlusions or complete and proximal trifurcation occlusions

TASC Recommendation
JVS 2000

- Treatment of Choice for A and D Lesions
 - Endovascular procedure is the treatment of choice for type A lesions, and surgery for D lesions
- Treatment of Choice for B and C Lesions
 - More evidence is needed to make any firm recommendations about the best treatment for type B and C lesions

TASC A



TASC B, C



TASC Recommendation 36: FP Stenting in PAD

JVS 2000

- FP stenting as a primary approach to the interventional treatment of intermittent claudication or CLI is not indicated. Stents may have a limited role in salvage of acute PTA failures or complications.
-

- *Based on Limited data on BE Palmaz and WS*
- *No Data on newer SE Nitinol Stents*

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

Objectives

- Determine safety of FP primary stenting with SE Smart stent (J&J Cordis Endovascular) in patients with CLI and type B or C lesions
- Determine Hemodynamic Stent Patency
- Determine Predictors of stent hemodynamic failure

FP Primary Stenting

Materials and Methods

- From 1/16/99 to 01/15/2003
- 137 Limbs in 122 patients with Chronic Limb Ischemia
 - Males: 86 (72%); Females: 34 (28%)
- FP Primary stenting with Smart Stent
 - Contralateral approach: 7 F. Sheath (6 F. smart control)
 - 300 mg Plavix; 5,000 U IA Heparin /Angiomax
- F/U: 1 mo, 3 months, Q6 months
 - Doppler-derived Pressure measurements
 - Duplex scan
- Statistical Analysis
 - Life Table Methods

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

Technique: C Lesion

- 63 yo with claudication
- ABI
 - rest: 0.58
 - exercise: 0.2
- Long SFA stenosis
 - 22 cm

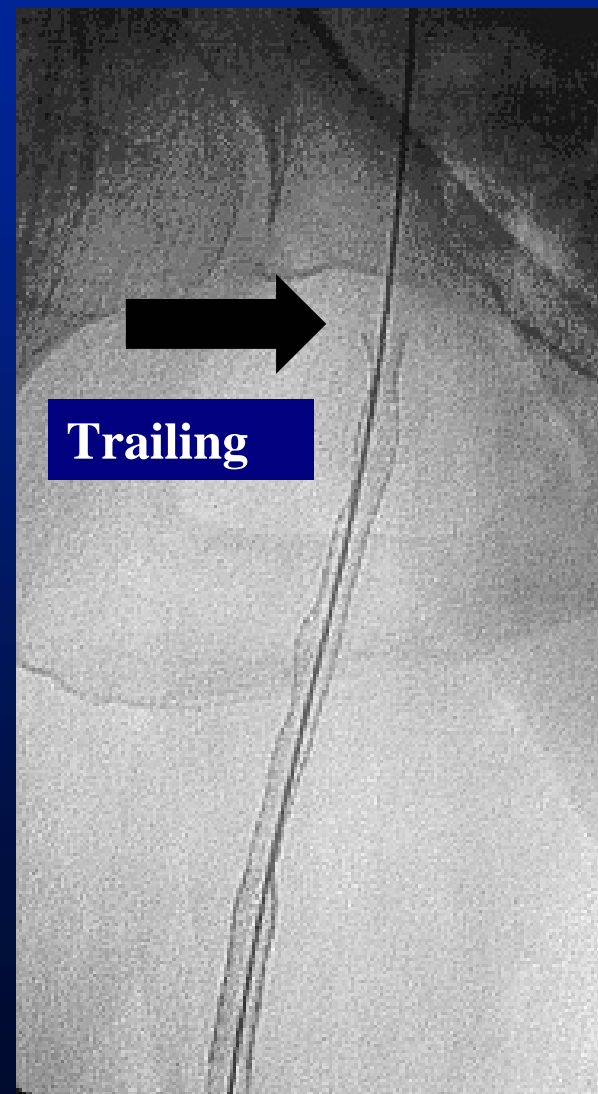


Mewissen MW. Self-Expanding nitinol stents in the FP segment: technique and mid-term results
Techniques in Vascular and Interventional Radiology. 7(1): 2-5, 2004 Mar

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

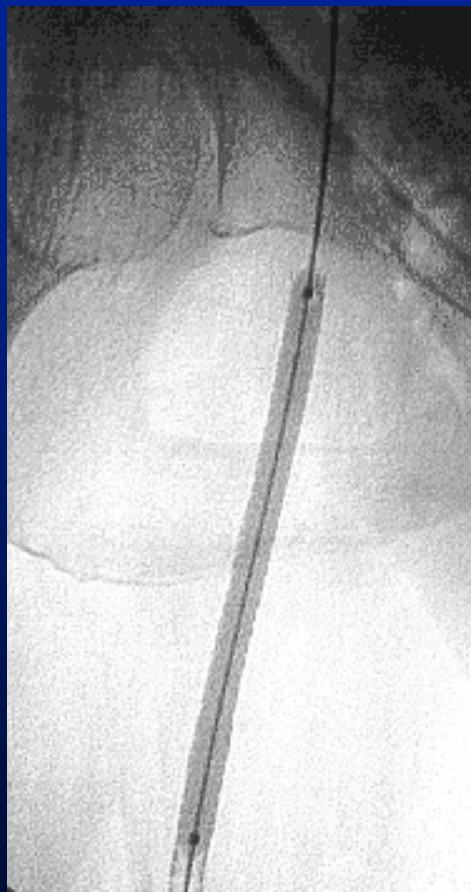
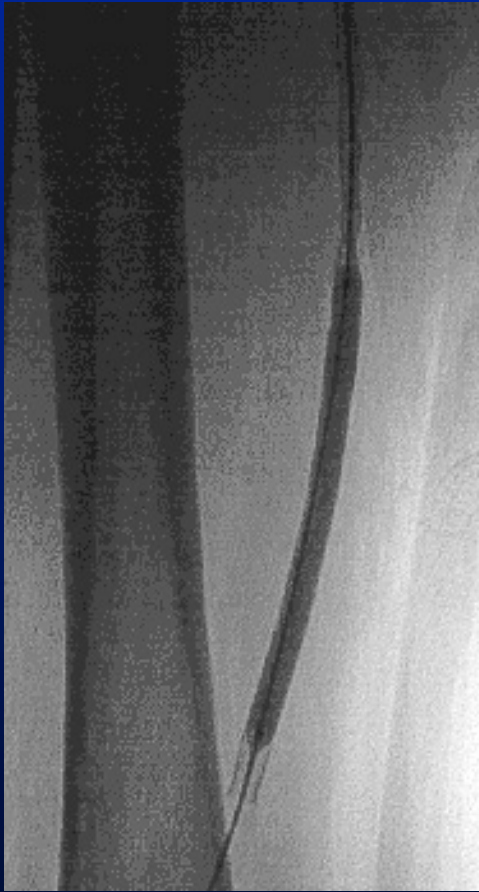
Technique: C Lesion

- 3 Smart stents
 - 8cm x 6mm



Technique: C Lesion

- Balloon PTA
 - 8cm x 6mm
- DO NOT DILATE STENT EDGES
- DILATE INSIDE THE STENTS



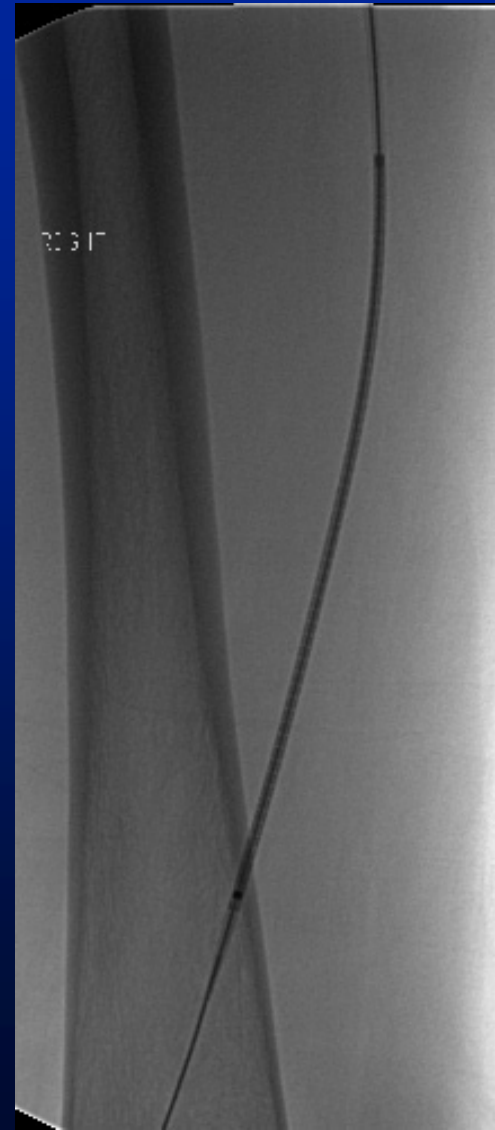
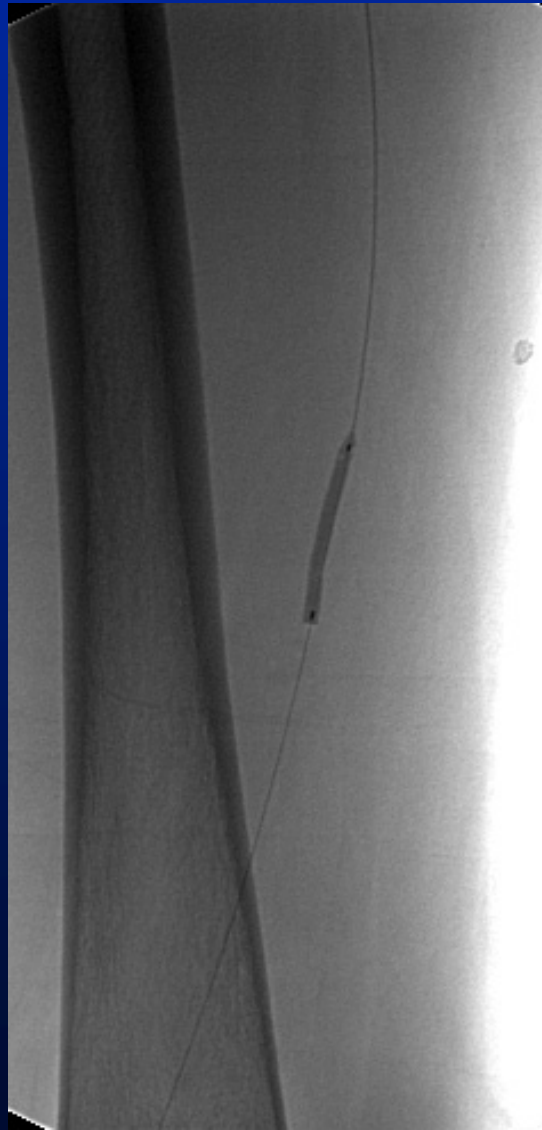
Mewissen MW. Self-Expanding nitinol stents in the FP segment: technique and mid-term results
Techniques in Vascular and Interventional Radiology. 7(1): 2-5, 2004 Mar

Technique: C Lesion-occlusion

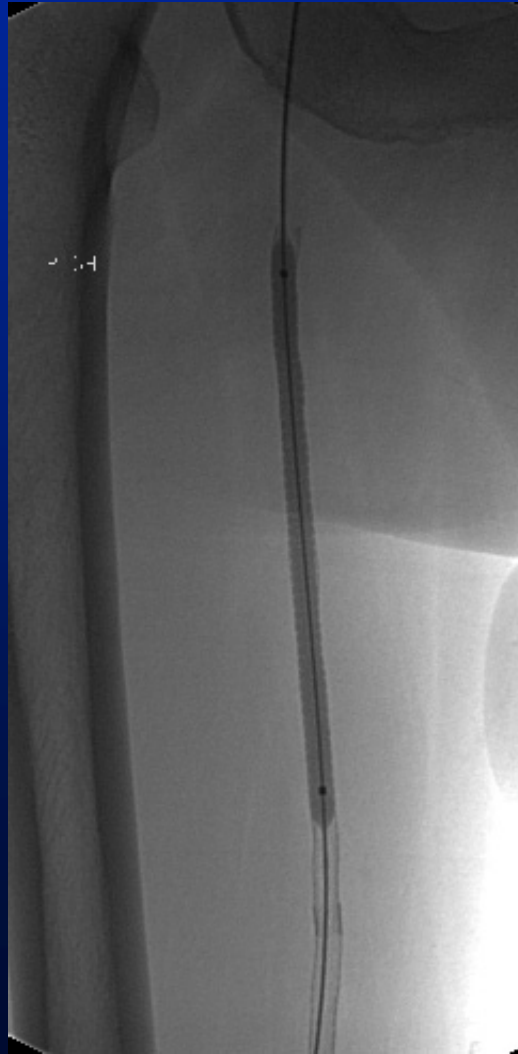
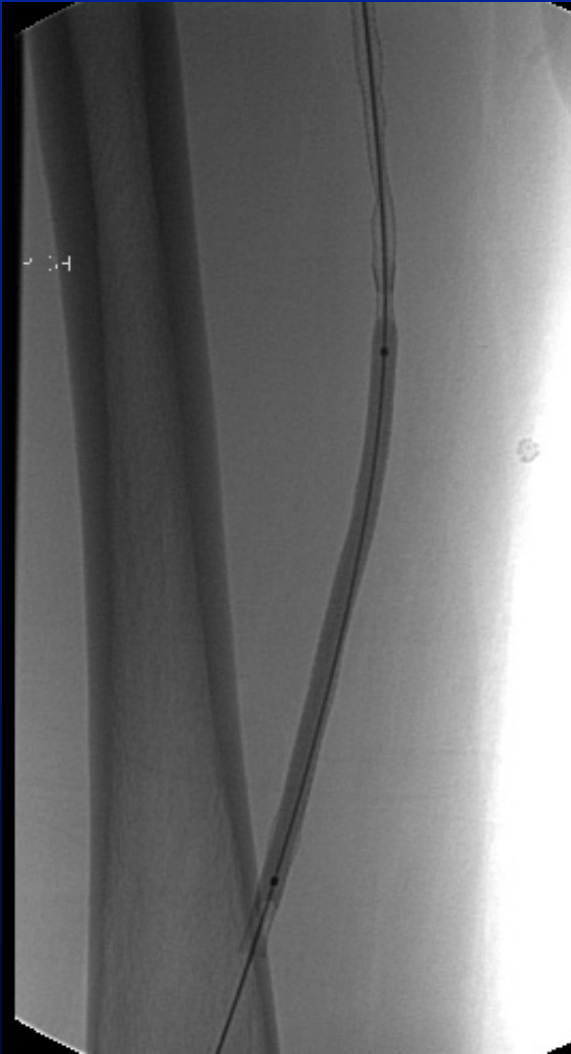


Mewissen MW. Self-Expanding nitinol stents in the FP segment: technique and mid-term results
Techniques in Vascular and Interventional Radiology. 7(1): 2-5, 2004 Mar

SFA Stenting: Technique



SFA Stenting: Technique



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

137 FP Lesions

- **A: n=12**
- **B or C=125**
 - **Occlusions: n=20**

Smart Stent

N=246 (1.8/Limb)

L: 12.2cm (4-28cm)

<10cm: 59 (43%)

>10cm: 78 (57%)

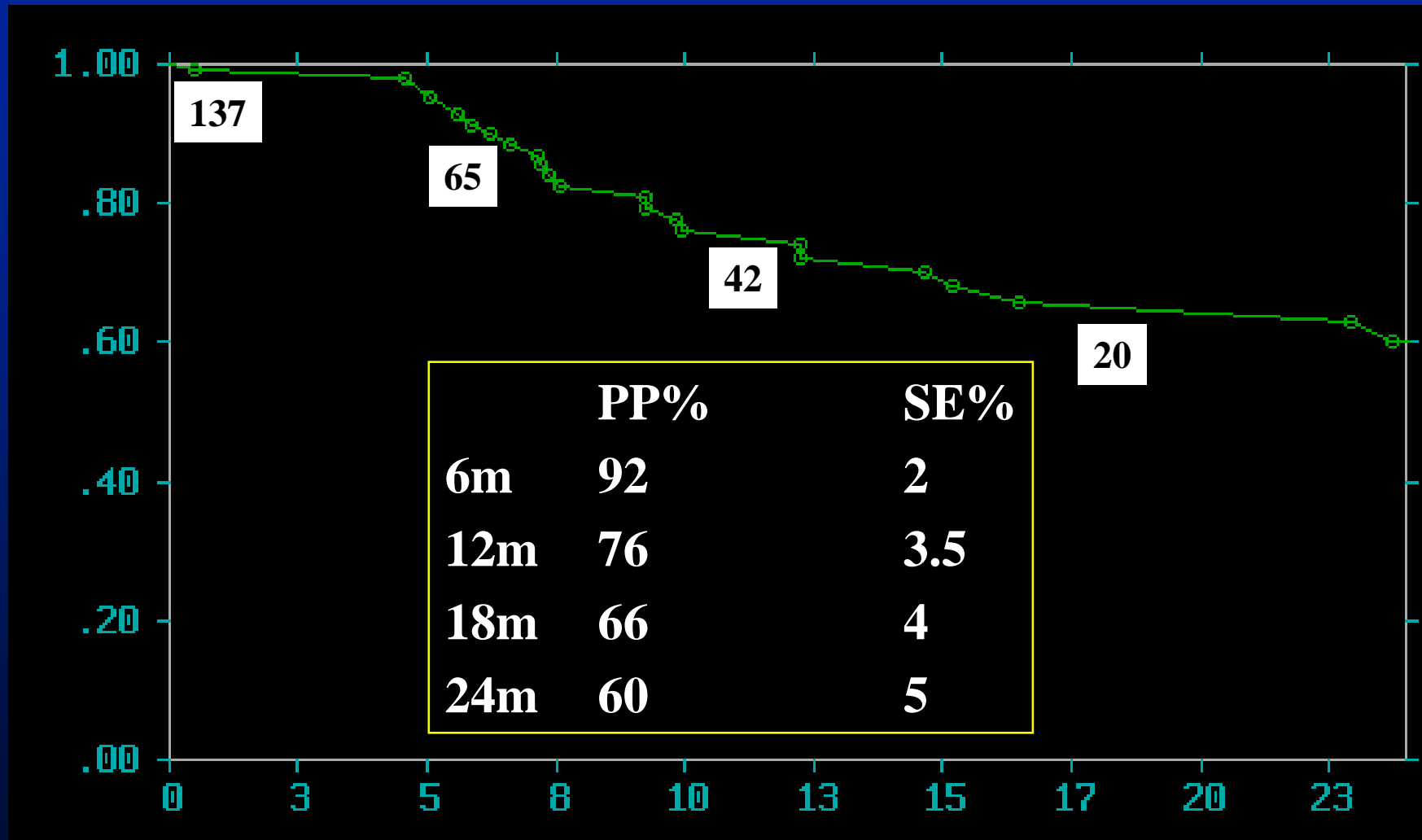
- **Technical success**
 - 98% (Failure in 2 long occlusions)
- **Complications**
 - N=2 (2%)
- **Acute (<30 D) occlusion: n=1**

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

- Mean Follow-up: 302 Days (1day-41months)
- # 50-99% stent stenoses: N=24
- Mean time to Hemodynamic stent failure (outcome event)
 - 290 Days
 - (14 days-24 months)

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

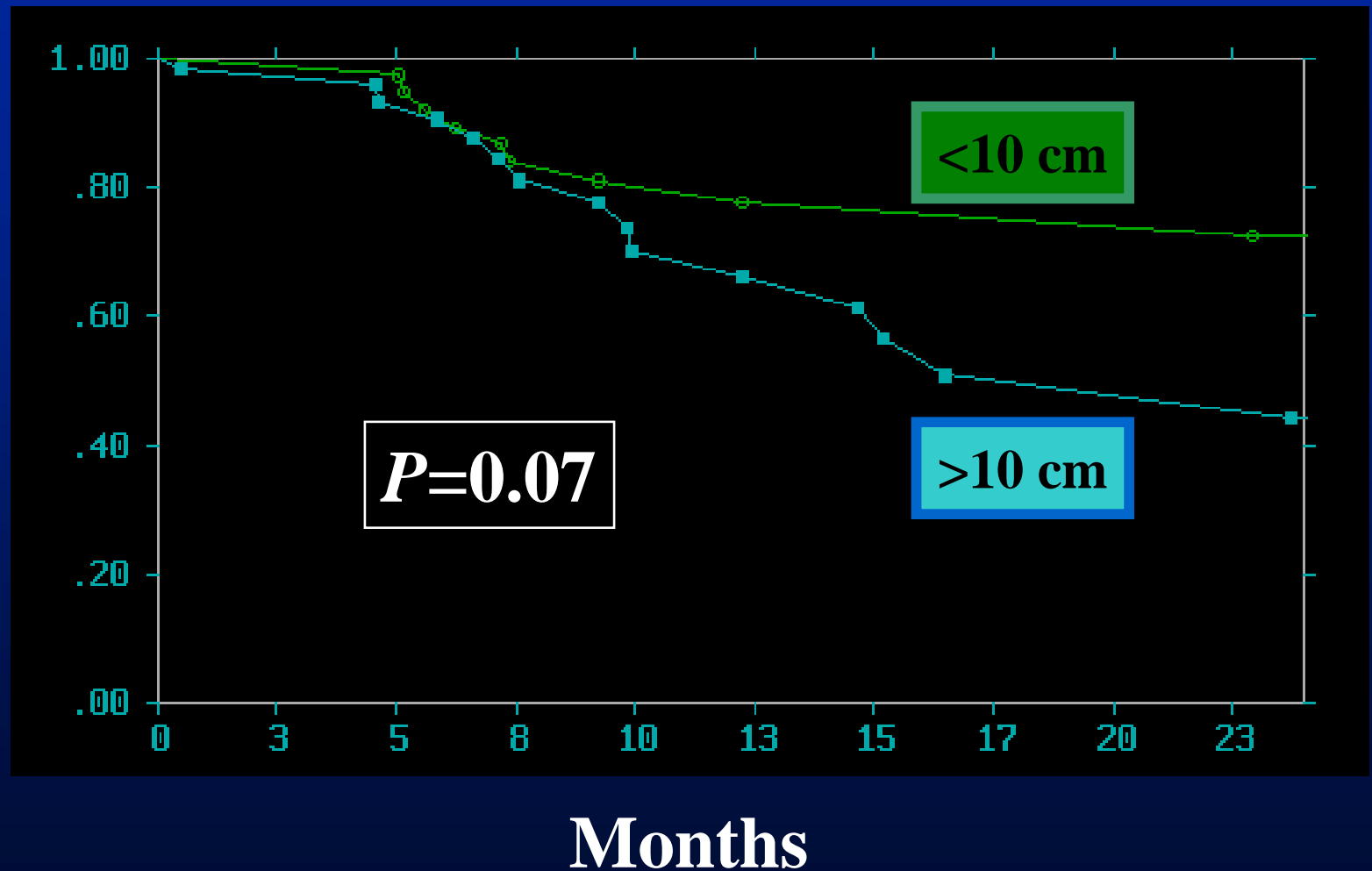
*50-99%
Stenosis
Free
Survival*



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: *Results*

*50-99%
Stenosis
Free
Survival*



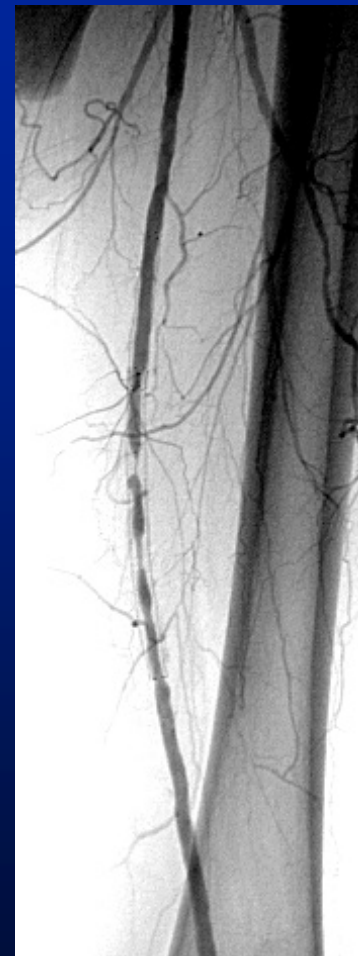
Mewissen MW. Self-Expanding nitinol stents in the FP segment: technique and mid-term results
Techniques in Vascular and Interventional Radiology. 7(1): 2-5, 2004 Mar

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

Conclusion

- High Technical success for all TASC Grades
- Safe
- Acute stent occlusion is rare (<1%)
- High 6 M hemodynamic patency (92%)
- 76% 1 year primary hemodynamic patency
- Lesion length may be a strong predictor of patency

Prevention of Myo-intimal Hyperplasia



Drug eluting STENTS?

SIROCCO SFA Stenting STUDY (European)

- **Design**: Double-blind, randomized, prospective study (sirolimus-eluting vs bare stent) in patients with obstructive superficial femoral artery (SFA) disease (>70%)
- **Primary endpoints**: Stent mean diameter via quantitative angiography determined within six months after stent placement.

<u>Sirocco I</u> (N=36)		<u>Sirocco II</u> (N=57)		Pooled Bare Stent
<u>Sirolimus</u> N=18	<u>Control</u> N=18	<u>Sirolimus</u> N=29	<u>Control</u> N=28	
<u>Slow</u> N=5	<u>Fast</u> N=13	<u>Slow</u> N=29		N=46
>70% stenosis 7-20 cm 4-20 cm occlusion		>70% stenosis 7-14.5 cm 4-14.5 cm occlusion		
8 cm Smart Stent Maximum: 3		8 cm Smart Stent Maximum: 2		

Sirocco 1: 6 months Angio

	<u>Sirolimus</u> N=16	<u>Control</u> N=17
Binary stenosis	0%	17.6% N=3

Not significant

Sirocco 1: 18 months Duplex

	<u>Sirolimus</u> N=14		<u>Control</u> N=17
	Slow (5)	fast (9)	
Binary restenosis	0%	33.3% N=3	24% N=4
T. Occ.	0%	0%	5.8% N=1
Stenosis/ occlusion	0%	33.3% N=3	29% N=5

Sirocco II: 6 months Angio

	<u>Sirolimus</u> N=24	<u>Control</u> N=26
Binary stenosis	0%	7.7% N=2

Not significant

Sirocco 2: 9 months duplex

	<u>Sirolimus</u> N=29	<u>Control</u> N=23
In Stent Binary restenosis	9.7% N=3	10.7% N=3
Occlusion	0%	3.6% N=1
Total	9.7% N=3	14.3% N=4

Not significant

Sirocco 1: 24 months

	<u>Sirolimus (14)</u>		<u>Control</u>
	Slow (5)	fast (9)	N=17
Binary restenosis	40% N=2	44% N=4	47.1% N=8
T. Occ.	0%	0%	5.8% N=1
Stenosis/ occlusion	40% N=2	44.4% N=4	52.9% N=5

Not significant

Sirocco 2: 18 months duplex

	<u>Sirolimus</u> N=29	<u>Control</u> N=28
In Stent Binary restenosis	20.7% N=6	14.3% N=4
Occlusion	0%	3.6% N=1
Total	20.7% N=6	17.9% N=5

Not significant

Pooled Bare Stent Data: Sirocco I and II

Binary ReStenosis rate by Duplex

	<u>9 months</u>	<u>18 months</u>	<u>24 months</u>
<u>S I and II</u> N=46	9.3%	22%	53%
<u>Mewissen</u> N=137	8%	34%	40%

Bilateral Lower Arterial Stenting Employing Reopro (BLASTER TRIAL)

- Purpose: To evaluate the feasibility of utilizing nitinol stents with and without intravenous abciximab for the treatment of femoral artery occlusive disease
- Primary endpoint: Primary restenosis by Duplex ultrasound

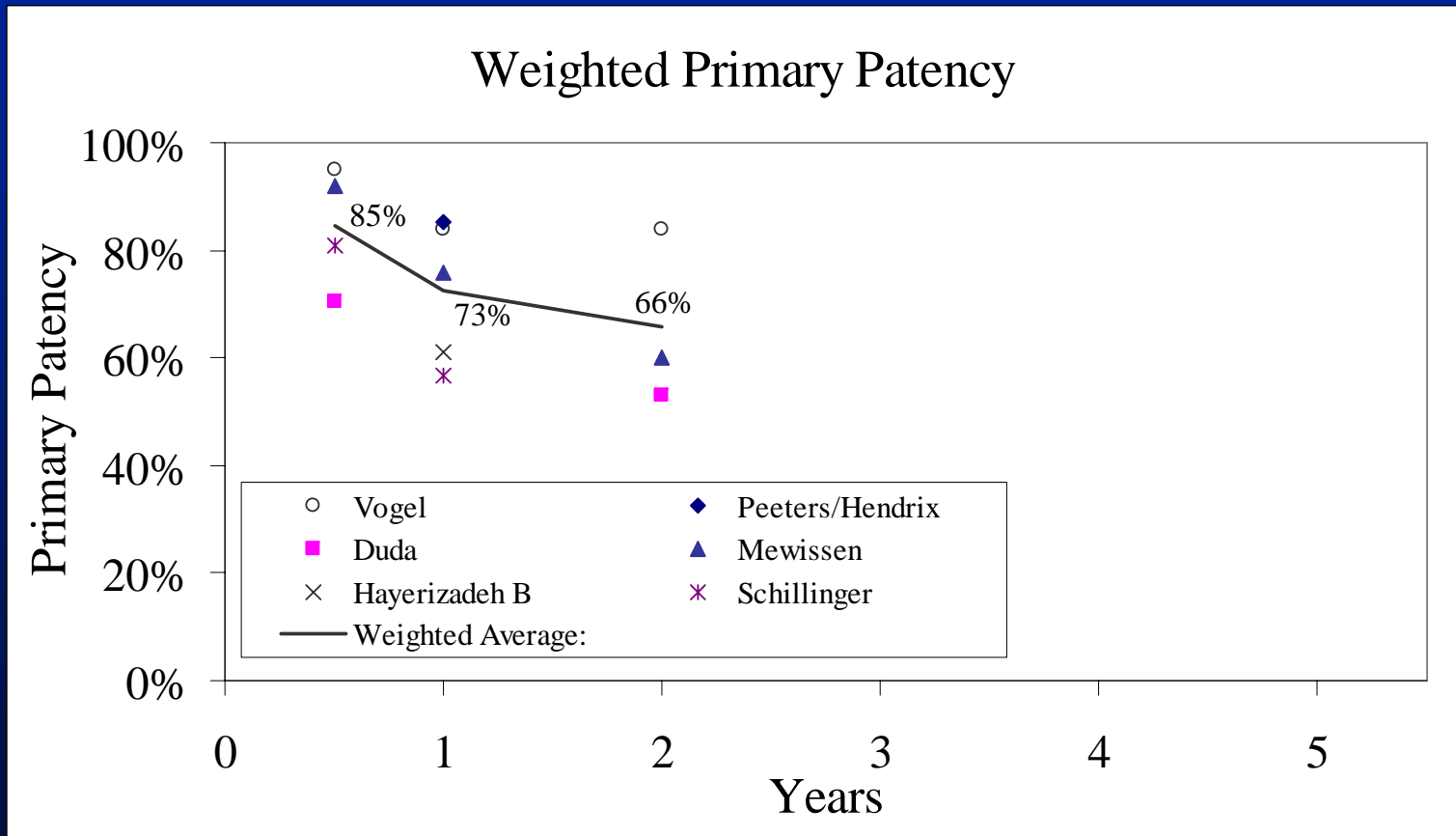
BLASTER Trial

- Study stopped at 50 patients due to concern of stent fractures seen in SCIROCCO
- Preliminary Results (5 U.S. CENTERS)
 - Technical Success = 100%
 - Average lesion length = 15.1cm (7 – 31cm)
 - Follow-up to date
 - 6 mo = 90%
 - 9 mo = 88%
 - 1 year = 82%

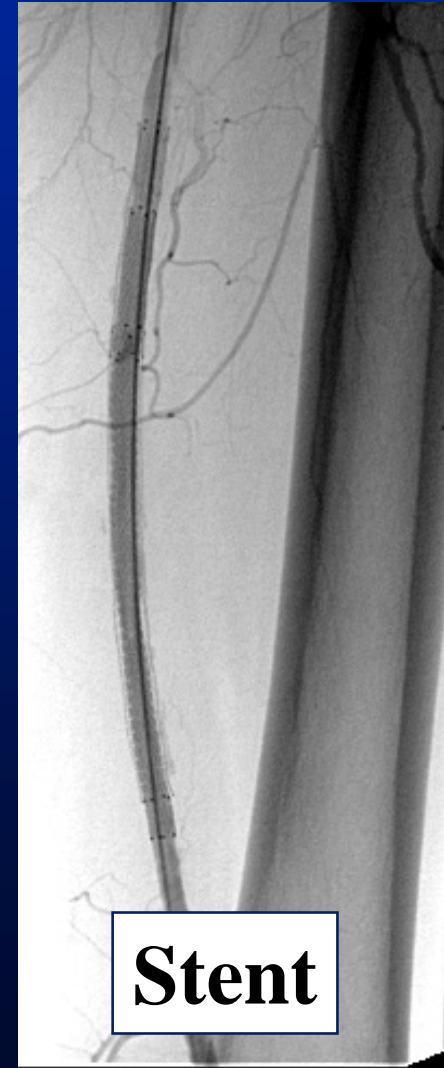
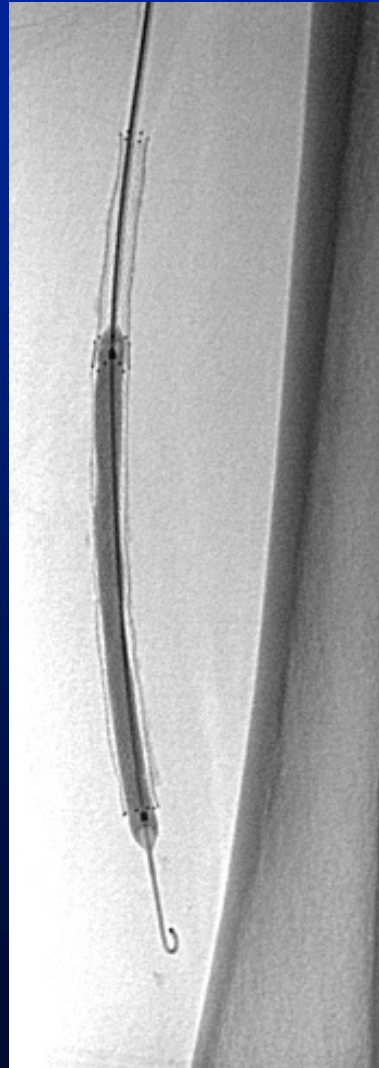
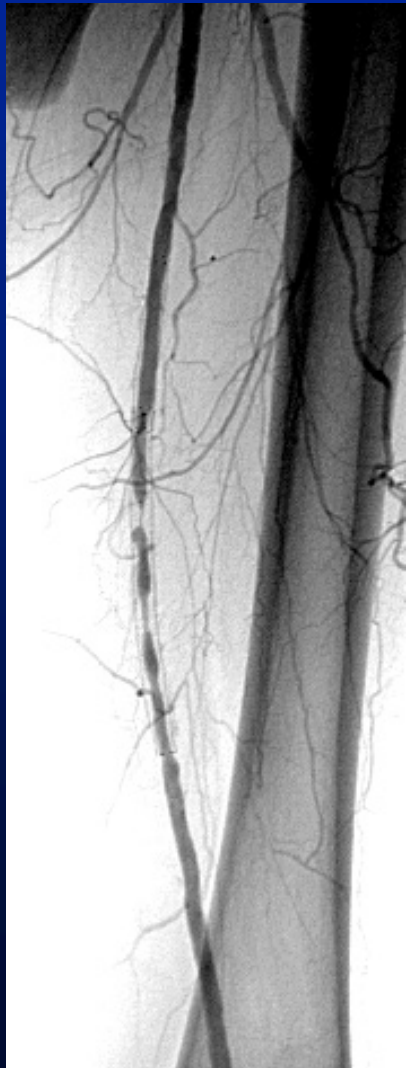
German Multicenter Experience

- Retrospective review, 3 centers
- 111 SFA Stenting procedures
 - SS: 76; WS: 35
- 6 months patency
 - SS: 82%
 - WS: 37%

Smart Stent Primary Patency: All Data



In Stent Stenosis



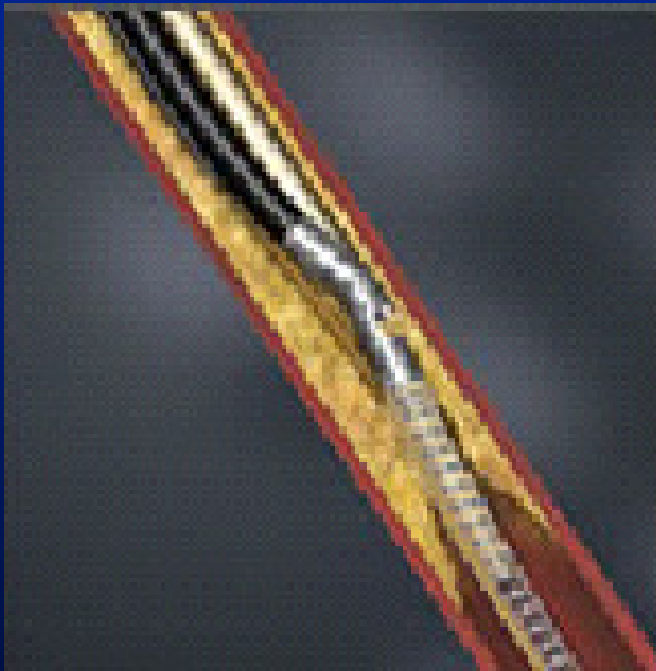
Stent

In Stent Stenosis

Cutting Balloon



In Stent Stenosis Silverhawk



6 F.
0.018

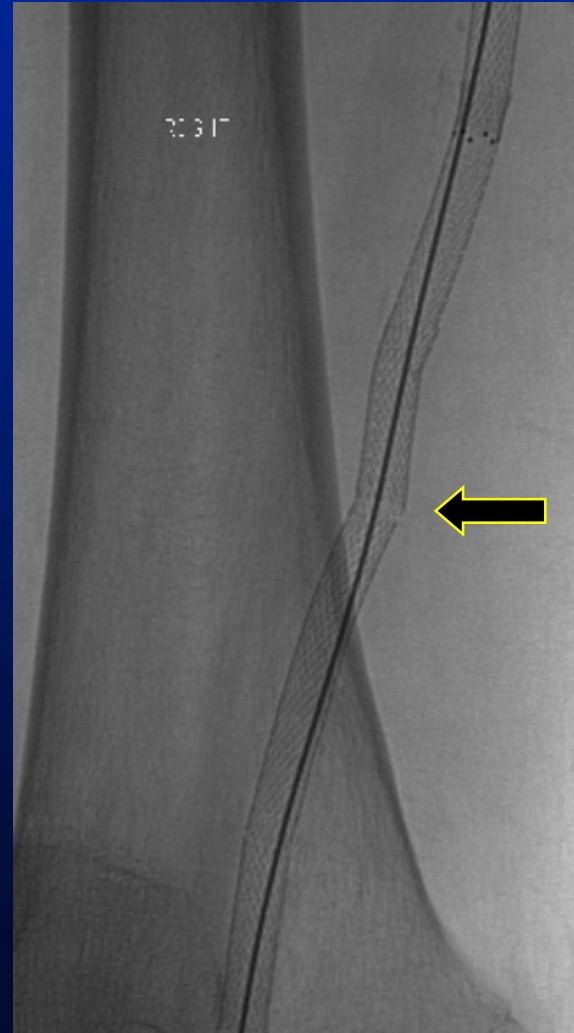
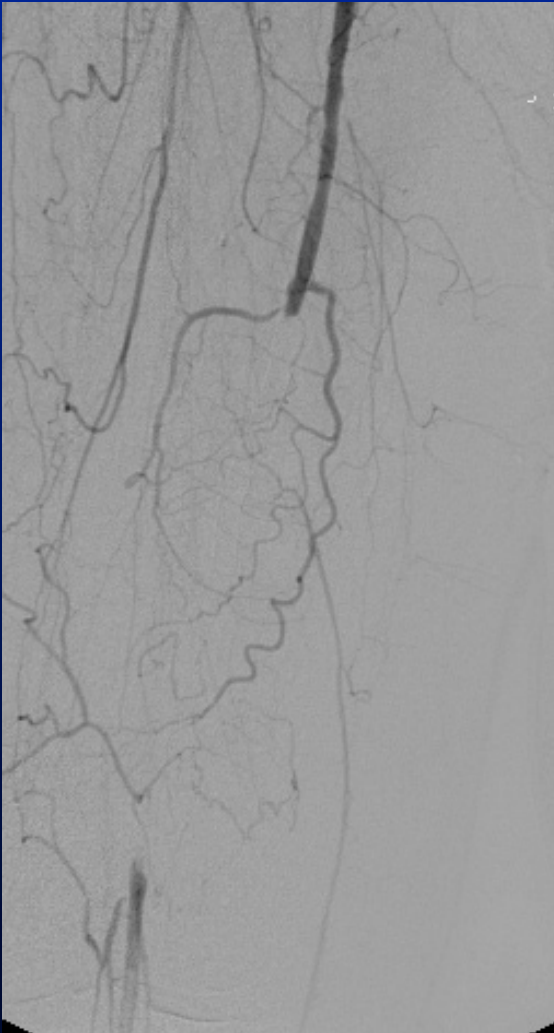


In Stent Stenosis

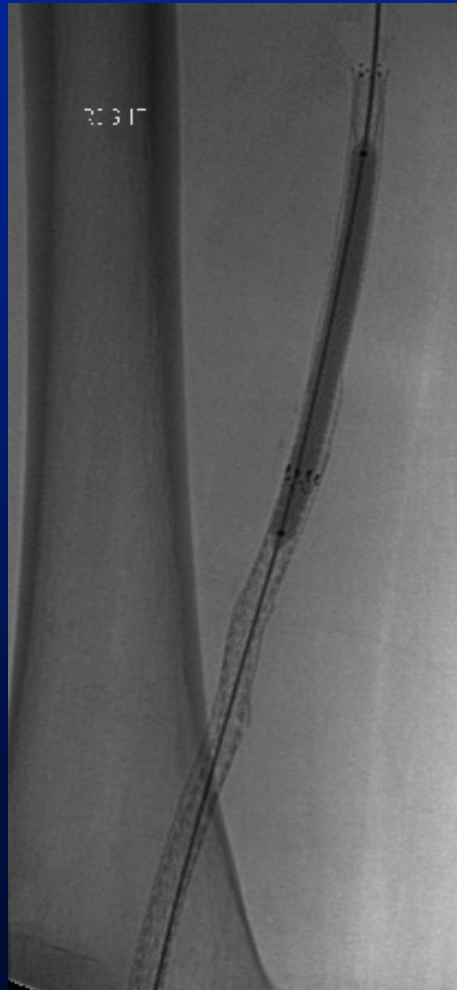
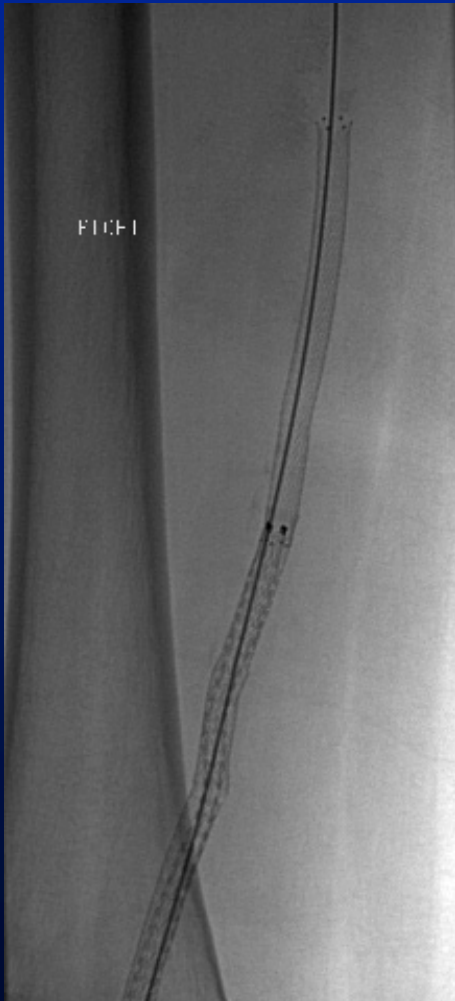
- PTA
- Cutting Balloon
- Stent
- Cryoplasty
- Brachytherapy
- Laser debuling
- Atherectomy
- Covered stent
 - Ansel et al: Endovascular Today: October 2004

Stent fracture

Recurrent Claudication (Progressive)



Stent fracture



SIROCCO I and II – Stent fracture

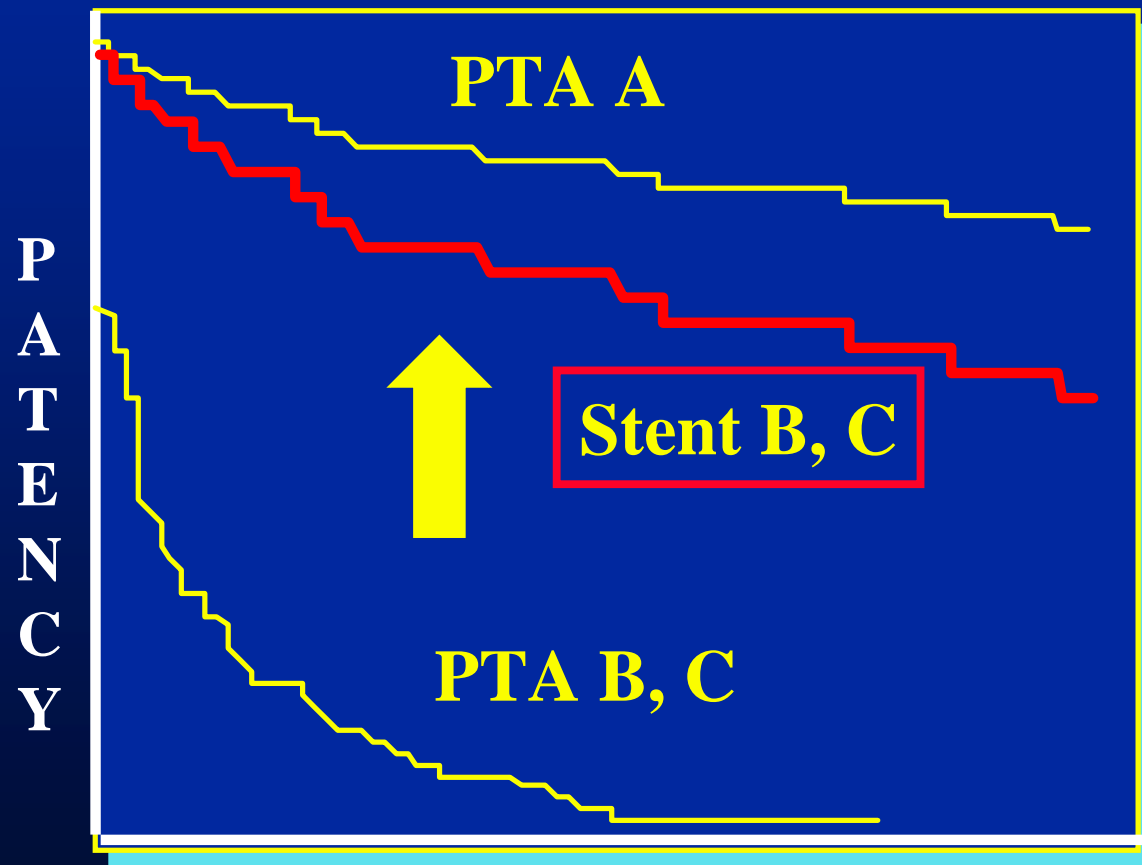
- SIROCCO I fracture rate was 24%
- 3 stent fractures observed in SIROCCO II (6% overall rate)
- No clinical events associated with stent fractures

Summary

- Nitinol stents are performing better than historic controls of PTA and Wallstent
- To date DES do not appear to significantly improve patency
- Clinical significance of stent fracture is not known

FP Primary Stenting: *CONCLUSION*

Patency **STENT** TASC B, C = Patency **PTA** TASC A



FP Primary Stenting:

CONCLUSION

- *TASC Recommendation 36*
 - FP stenting as a primary approach to the interventional treatment of intermittent claudication or CLI is not indicated. Stents may have a limited role in salvage of acute PTA failures or complications.

May Need To Be Revisited