Treatment of Femoropopliteal Disease

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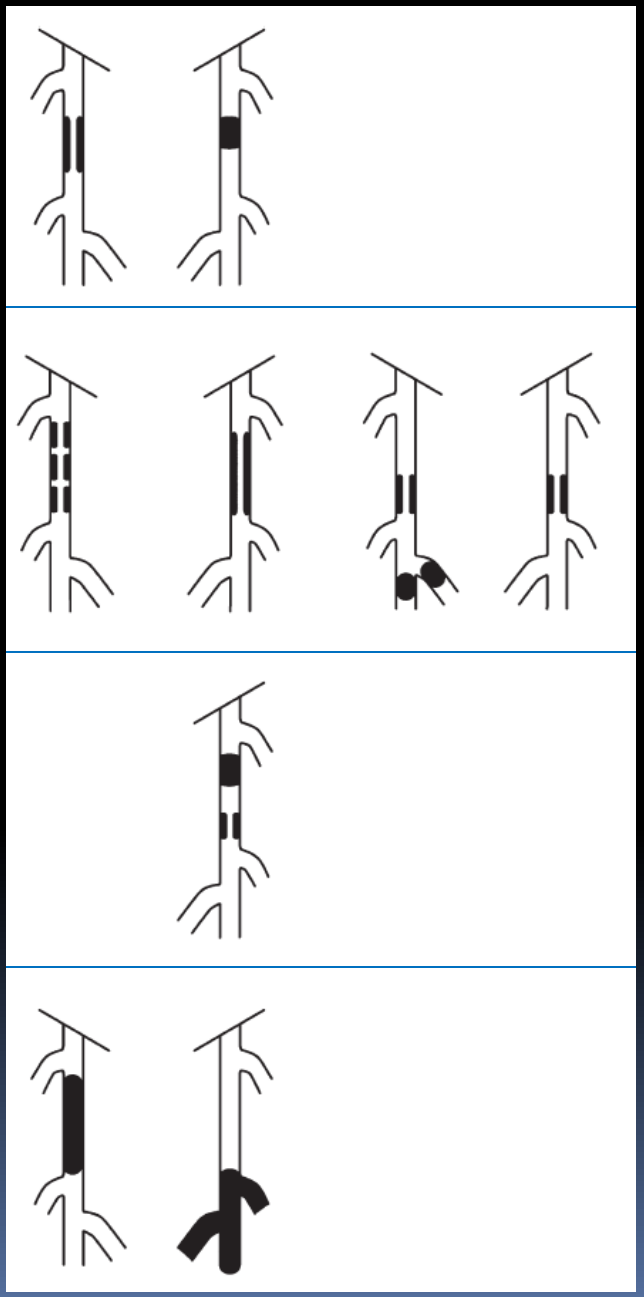
TASC II Classification: Femoropopliteal Lesions

Type A:
- Single stenosis (≤10 cm)
- Single occlusion (≤5 cm)

Type B:
- Multiple lesions, each ≤5 cm
- Single lesion (≤15 cm) not involving popliteal artery below the knee
- Lesions in the absence of continuous tibial vessels
- Single popliteal stenosis

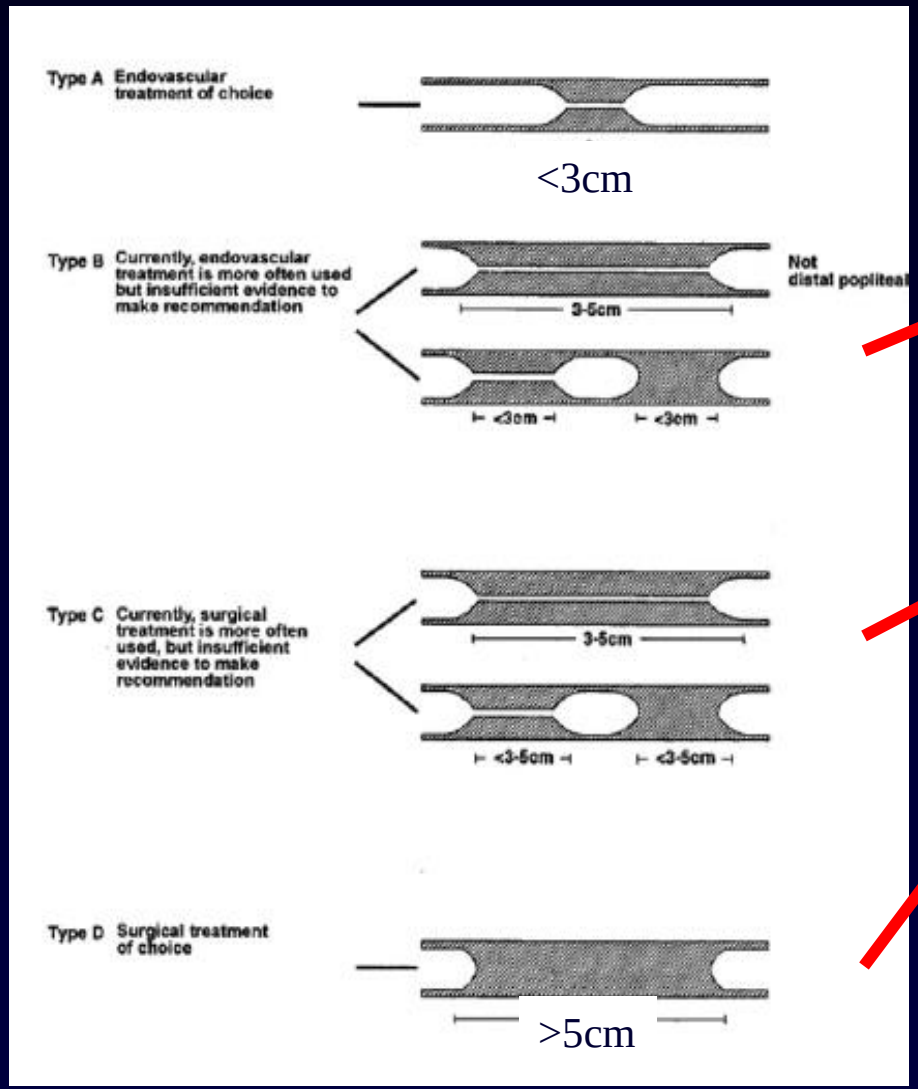
Type C:
- Multiple lesions (>15 cm) ± heavy calcification
- Recurrent lesions after two endovascular interventions

Type D:
- Chronic total occlusions of CFA or SFA (20 cm, involving the popliteal artery)
- Chronic total occlusion of popliteal artery & proximal trifurcation vessels

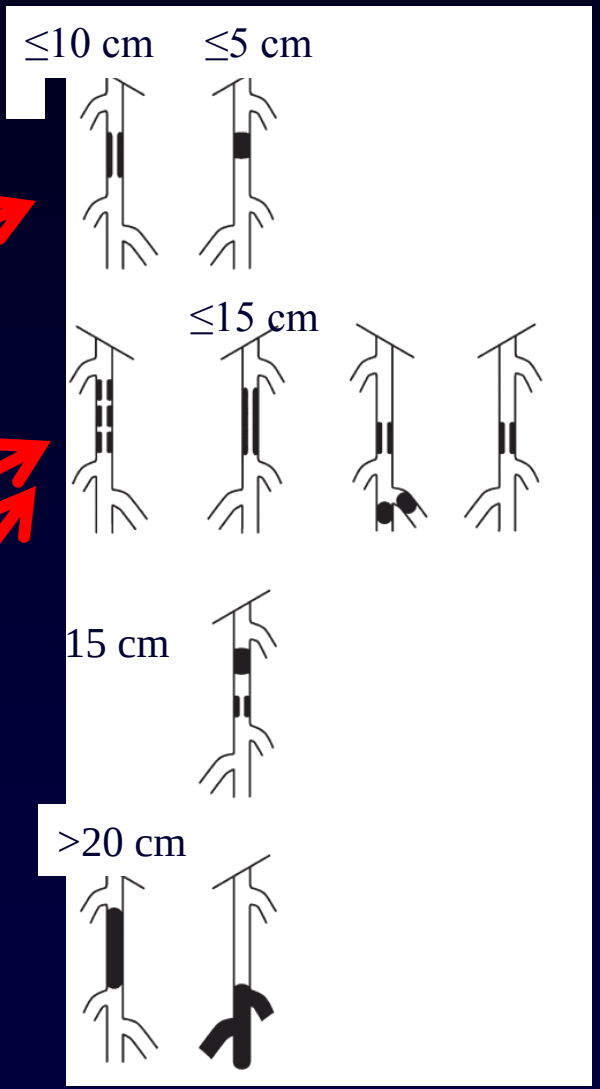


TASC Classification: Femoropopliteal disease

TASC I 2000



TASC II 2007



Conventional PTA with stenting in SFA

	Stenosis	Length	Primary patency (1 yr)
White et al.	47%	3.7 cm	75%
Henry et al.	33%	3.8 cm	81%
Martin et al.	35%	5.7 cm	61%
Saproval et al.	90%	6.2 cm	49%
Rousseau et al.	30%	6.2 cm	68%
Bergeron et al.	57%	7.6 cm	81%
Do-Dai-Do et al.	100%	8.6 cm	59%
Zollikofer et al.	80%	13.5 cm	29%
Gray et al.	89%	16.5 cm	22%
Totals	62%	8.0 cm	58%

Nitinol Stent vs. Balloon Angioplasty

Nitinol Stent Implantation Versus Percutaneous Transluminal Angioplasty in Superficial Femoral Artery Lesions u

The Femoral

Hans Krankenberg, MD; Michael Schlüt
Dierk Scheinert, MD; Karl-Ludwig Schulte
Gunnar Tepe, MD; Bernhard Reimers, M

Nitinol stent vs Balloon

Mean leasion length: 45 mm

Restenosis rate : 31.7% vs. 38.6%

TLR: 14.9% vs. 18.3% (p=ns)

Background—Endoluminal treatment of superfi
was designed to investigate the impact of niti
of 10 cm on restenosis and clinical outcomes

Methods and Results—Two hundred forty-four patients (168 men; 66±9 years) with a single superficial femoral artery lesion and chronic limb ischemia were randomized to implantation of a single Bard Luminexx 3 stent (123 patients) or stand-alone percutaneous transluminal angioplasty (PTA) (121 patients). Mean lesion length was 45 mm. Technical success (residual stenosis <50% for PTA, <30% for stenting) was achieved in 96 patients assigned to PTA (79%) and 117 patients assigned to stenting (95%); 13 PTA group patients (11%) "crossed over" to stenting. At 1 year, the primary end point of ultrasound-assessed binary restenosis was reached in 39 of 101 PTA group patients (38.6%) and 32 of 101 stent group patients (31.7%; absolute treatment difference, −6.9%; 95% CI, −19.7% to 6.2%; P=0.377). Target lesion revascularization rates at 1 year were 18.3% and 14.9%, respectively (absolute treatment difference, −3.3%; 95% CI, −13.0% to 6.4%; P=0.595). No statistically significant difference between treatment groups was observed at 12 months in the improvement by at least 1 Rutherford category of peripheral arterial disease.

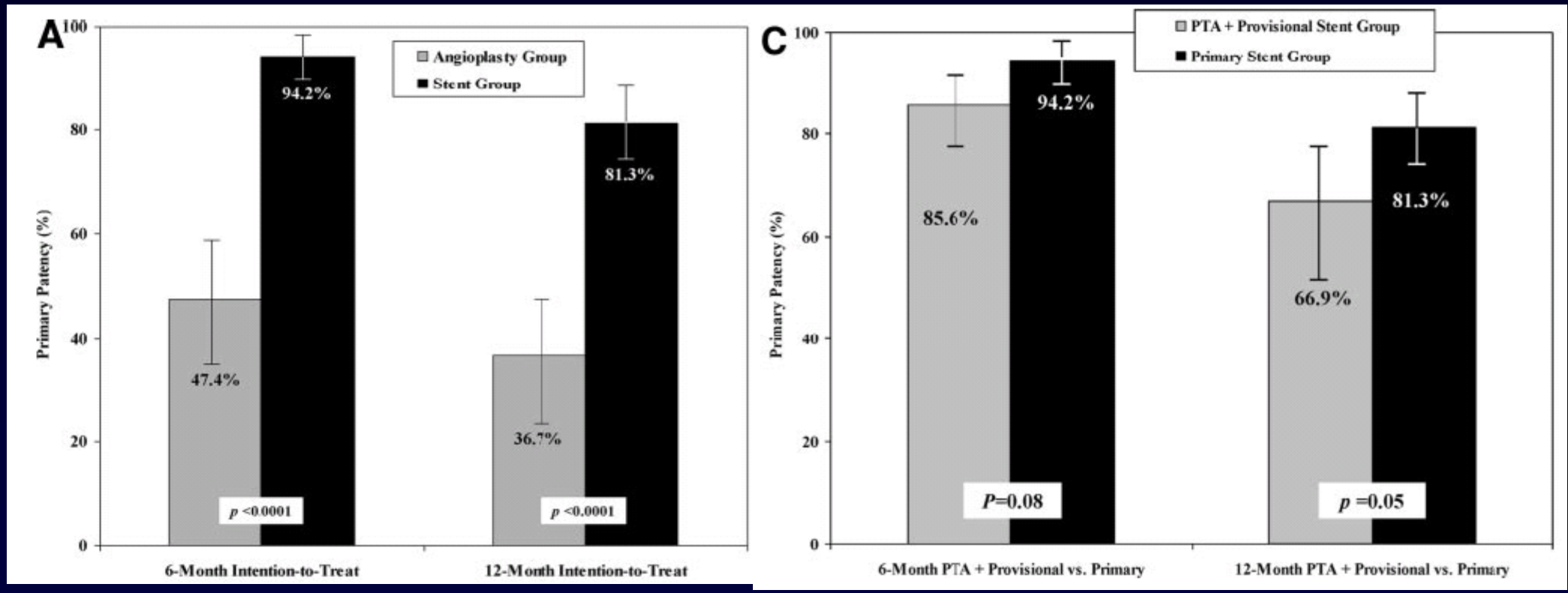
Conclusions—In the present study of patients with short superficial femoral artery lesions, the hypothesized absolute difference of 20% in binary restenosis at 1 year between the implantation of a single Luminexx nitinol stent and stand-alone PTA could not be demonstrated. A smaller difference requiring a larger trial might have been missed.
(*Circulation*. 2007;116:285-292.)

RESILIENT Trial: Nitinol Stent vs. POBA

N=206, mean length=71 mm

Balloon vs. Stent

Provisional vs. Primary Stenting



Laird JR. et al. Circ Cardiovasc Interv. 2010;3:267-276

Balloon Angioplasty versus Implantation of Nitinol Stents in the Superficial Femoral Artery

Martin Schillinger, M.D., Schila Sabeti, M.D., Christian Loewe, M.D., Petra Dick, M.D., Jasmin Amighi, M.D., Wolfgang Mlekusch, M.D., Oliver Schlager, M.D., Manfred Cejna, M.D., Johannes Lammer, M.D., and Erich Minar, M.D.

ABSTRACT

BACKGROUND

Because stent implantation for disease of the superficial femoral artery has been associated with high rates of late clinical failure, percutaneous transluminal angioplasty is preferred for endovascular treatment, and stenting is recommended only in the event of suboptimal technical results. We evaluated whether primary implantation of a self-expanding nitinol (nickel–titanium) stent yielded anatomical and clinical benefits superior to those afforded by percutaneous transluminal angioplasty with optional secondary stenting.

METHODS

We randomly assigned 104 patients who had severe claudication or chronic limb ischemia due to stenosis or occlusion of the superficial femoral artery to undergo primary stent implantation (51 patients) or angioplasty (53 patients). Restenosis and clinical outcomes were assessed at 6 and 12 months.

RESULTS

The mean (±SD) length of the treated segment was 132±71 mm in the stent group and 127±55 mm in the angioplasty group. Secondary stenting was performed in 17 of 53 patients (32 percent) in the angioplasty group, in most cases because of a suboptimal result after angioplasty. At 6 months, the rate of restenosis on angiography was 24 percent in the stent group and 43 percent in the angioplasty group ($P=0.05$); at 12 months the rates on duplex ultrasonography were 37 percent and 63 percent, respectively ($P=0.01$). Patients in the stent group were able to walk significantly farther on a treadmill at 6 and 12 months than those in the angioplasty group.

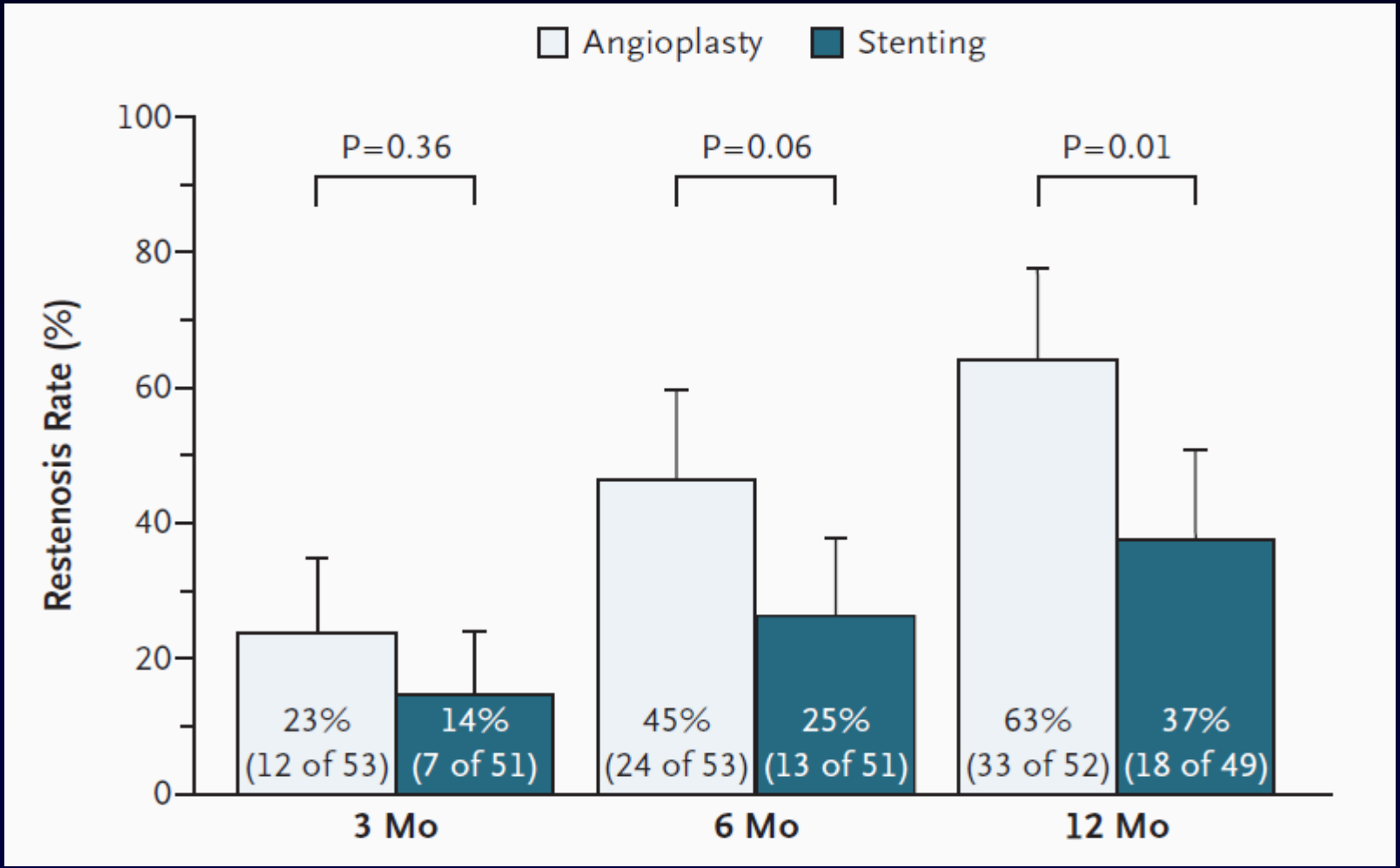
CONCLUSIONS

In the intermediate term, treatment of superficial-femoral-artery disease by primary implantation of a self-expanding nitinol stent yielded results that were superior to those with the currently recommended approach of balloon angioplasty with optional secondary stenting.

From the Departments of Angiology (M.S., S.S., P.D., J.A., W.M., O.S., E.M.) and Angiography and Interventional Radiology (C.L., M.C., J.L.), Medical University of Vienna, Vienna. Address reprint requests to Dr. Schillinger at the Department of Internal Medicine II, Division of Angiology, Vienna General Hospital, Medical University, Waehringer Guertel 18-20, Vienna A-1090, Austria, or at martin.schillinger@meduniwien.ac.at.

N Engl J Med 2006;354:1879-88.

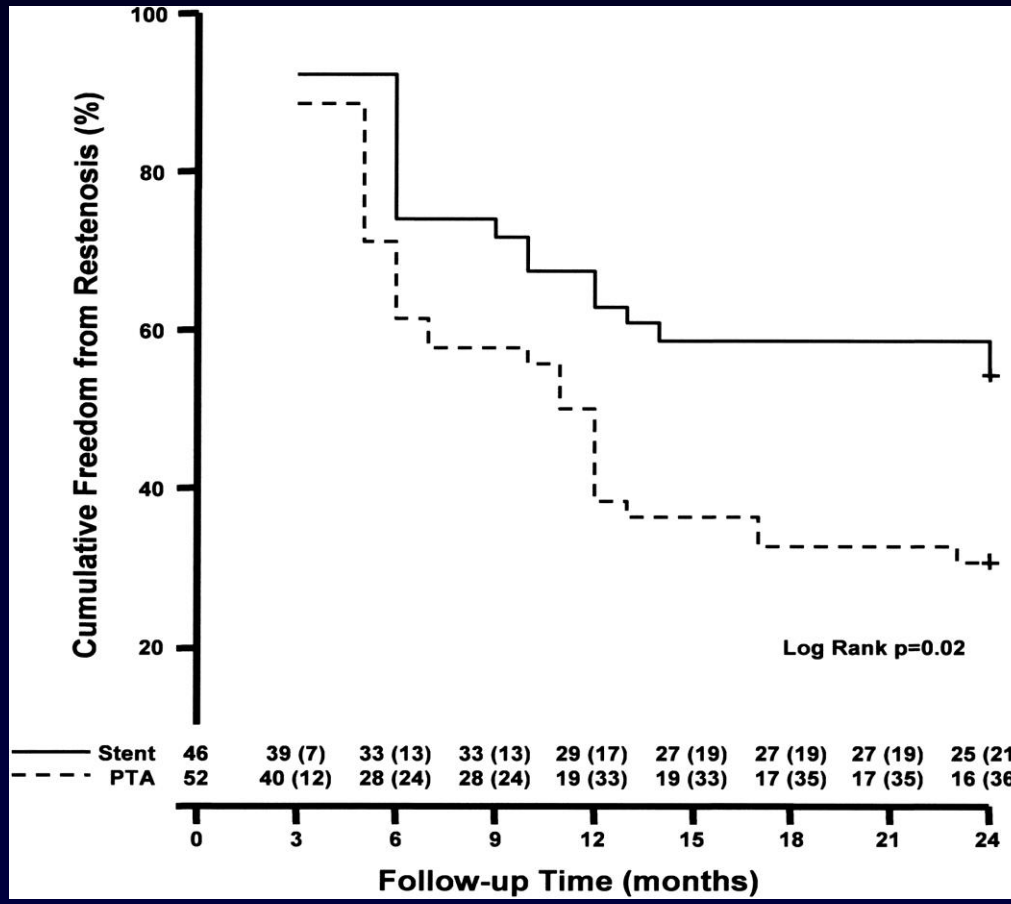
ABSOLUTE Trial
Nitinol-stent vs. Balloon Angioplasty



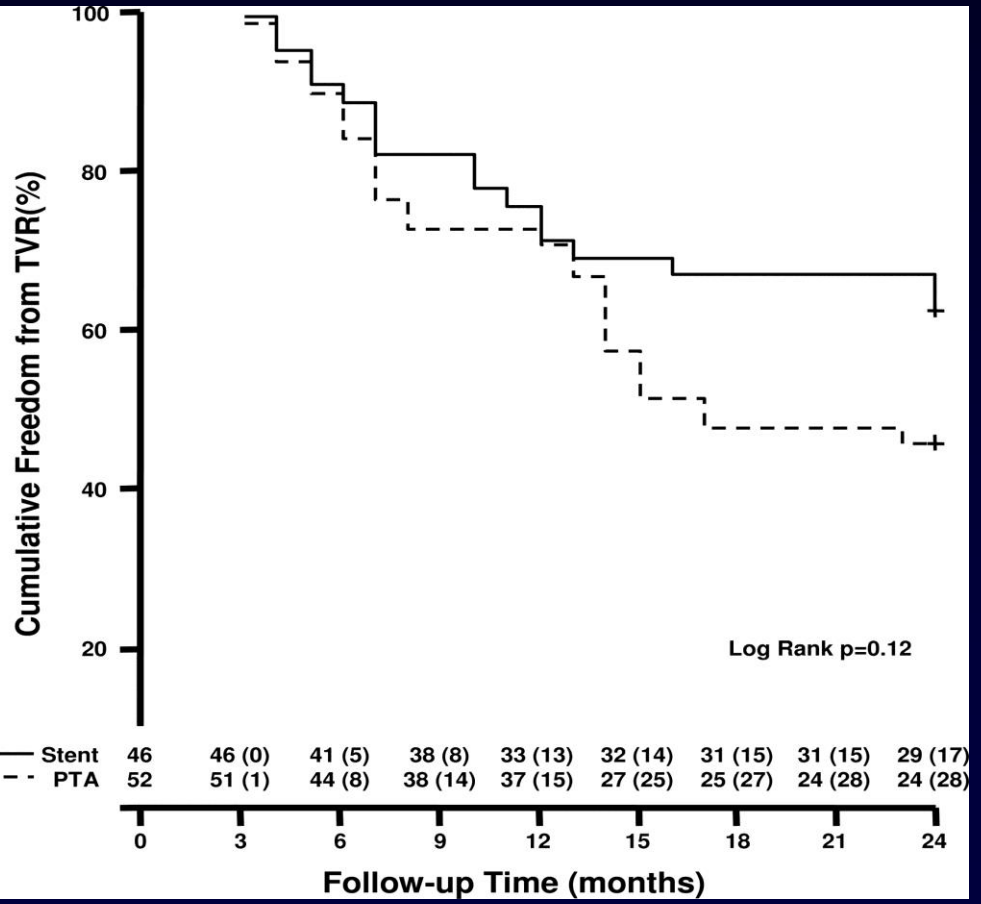
Schillinger M et al. N Engl J Med 2006;354:1879-88

ABSOLUTE trial
2 year outcome

Restenosis-free Survival



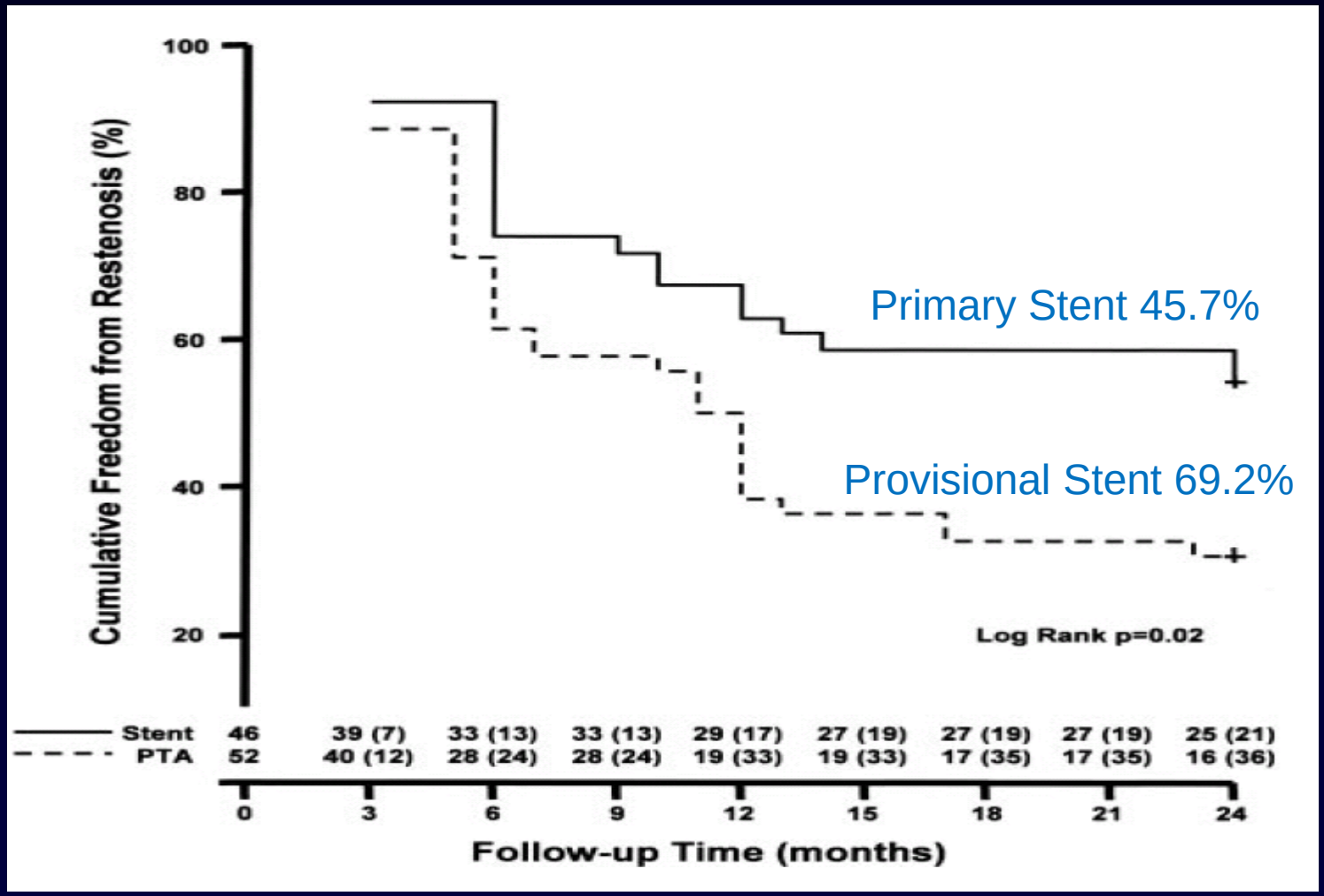
TVR-free Survival



Schillinger M et al. N Engl J Med 2006;354:1879-88

Primary vs. Provisional stenting

N=108
Mean length ~100mm



Schillinger M. et al. Circulation. 2007;115:2745-2749

DES vs BMS in SFA stenting

SIROCCO II
Baseline Lesion Characteristics

	Sirolimus (n=29)	Control (n=28)	P-value
Thrombus (%)	3.6	0	
Mod./sev. calcif. (%)	44.8	32.3	0.42
Total Occlusion (%)	75.9	57.1	0.17
Lesion Length (mm)	86.5 ± 36.6	76.3 ± 45.7	0.39
RVD (mm)	4.92 ± 0.77	4.61 ± 0.72	0.12
Pre - % DS	95.8 ± 7.82	89.1 ± 14.8	0.09*

*Wilcoxon rank sum test

SIROCCO II
Binary Restenosis Rate

	6M	9M	18M	24M	36M	48M
Sirolimus restenosis rate	3.8% (1/26)	7.7% (2/26)	15.4% (4/26)	29.2% (7/24)	31.8% (7/22)	42.1% (8/19)
Bare metal restenosis rate	0% (0/26)	11.5% (3/26)	20.0% (5/25)	20.0% (5/25)	33.3% (7/21)	41.2% (7/17)
Total restenosis rate	1.9% (1/52)	9.6% (5/52)	17.6% (9/51)	24.5% (12/49)	32.6% (14/43)	41.7% (15/36)

SIROCCO II
Target Lesion Revascularization

	6M	9M	18M	24M	36M	48M
Sirolimus TLR rate	0% (0/29)	3.4% (1/29)	3.4% (1/29)	6.9% (2/29)	17.2% (5/29)	20.7% (6/29)
Bare metal TLR rate	0% (0/28)	3.6% (1/28)	14.3% (4/28)	14.3% (4/28)	21.4% (6/28)	21.4% (6/28)
Total TLR rate	0% (0/57)	3.5% (2/57)	8.8% (5/57)	10.5% (6/57)	19.3% (11/57)	21.1% (12/57)

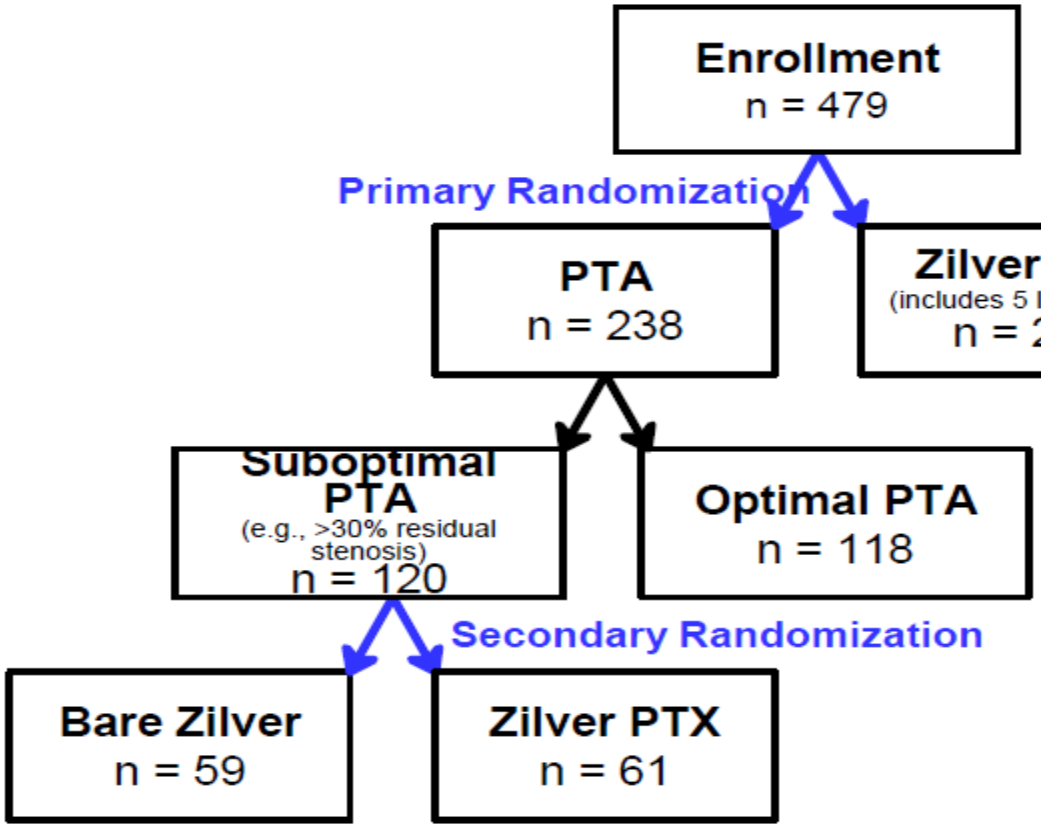
Zilver PTX: Registry Data

N=794

Subgroup	Freedom from TLR 6 months	Freedom from TLR 12 months
Overall	96%	88%
TASC C and D	95%	84%
De novo	97%	93%
Restenosis (all)	95%	79%
Restenosis (not ISR)	96%	83%
In-stent Restenosis (ISR)	94%	76%
≤ 7cm lesions	98%	94%
> 7 to 14 cm lesions	95%	88%
> 14 cm lesions	93%	75%
Occlusions	95%	85%
Stenosis	97%	90%
Similar to Randomized Study (≤ 14cm, no ISR)	98%	95%

Zilver PTX Randomized trial

Clinical Trial Design



Imaging Core Laboratories

- **Angiography and X-ray**: Brigham and Women's Hospital Angiographic Core Laboratory
- **Duplex Ultrasonography**: VasCore, Massachusetts General Hospital
- **IVUS**: Intravascular Ultrasoun

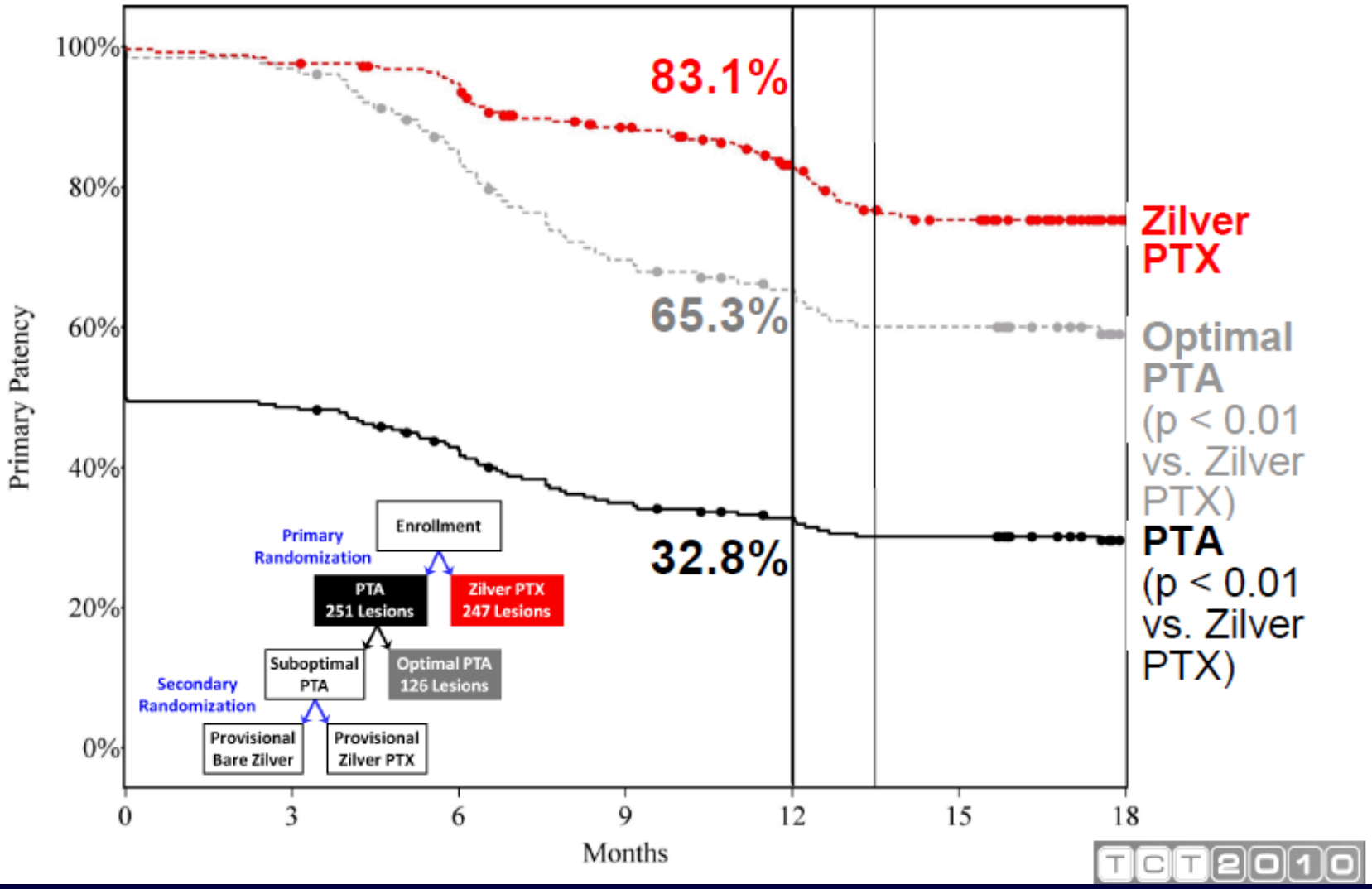
TCT 2010

Baseline Lesion Characteristics

		PTA	Zilver PTX	*P*-value
Lesions		251	247	
Normal-to-normal lesion length (mm)		63 ± 41	66 ± 39	0.35
Stenosed lesion length (mm)[1,2]		53 ± 40	54 ± 41	0.76
Diameter stenosis (%)[1]		78 ± 17	80 ± 17	0.44
Total occlusions		25%	30%	0.20
***De novo* lesions**		94%	95%	0.69
Lesion calcification[1]	**None**	5%	2%	< 0.01*
	Little	38%	26%	
	Moderate	22%	35%	
	Severe	35%	37%	

[1] Angiographic core lab assessment
[2] Region with > 20% diameter stenosis
*Statistically significant

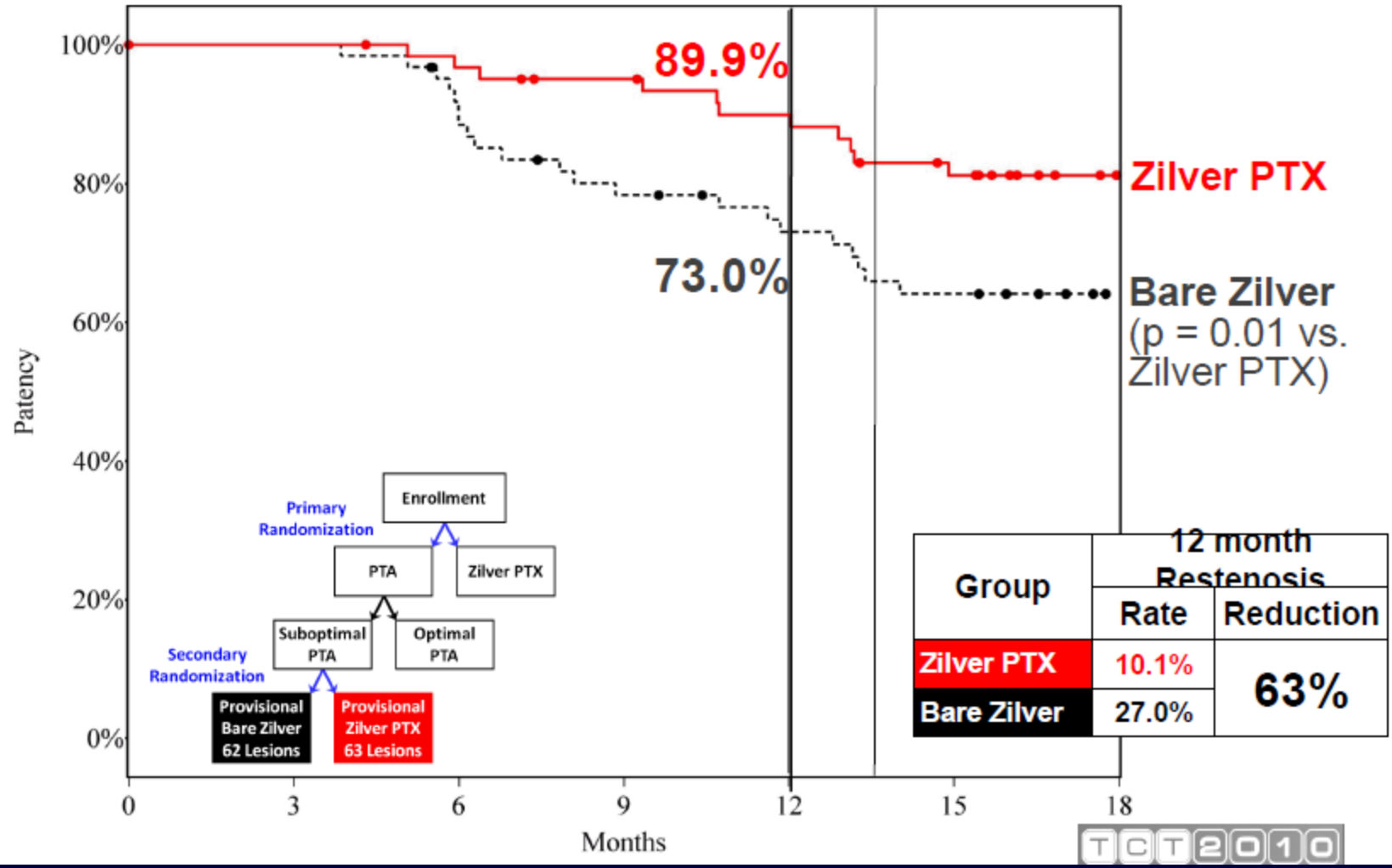
Effectiveness Endpoint
Primary Patency (PSVR < 2.0)



TCT2010

Patency (PSVR < 2.0) **for Zilver PTX vs. BMS**

Is the drug effect significant?



Group	12 month Restenosis	
	Rate	Reduction
Zilver PTX	10.1%	63%
Bare Zilver	27.0%	

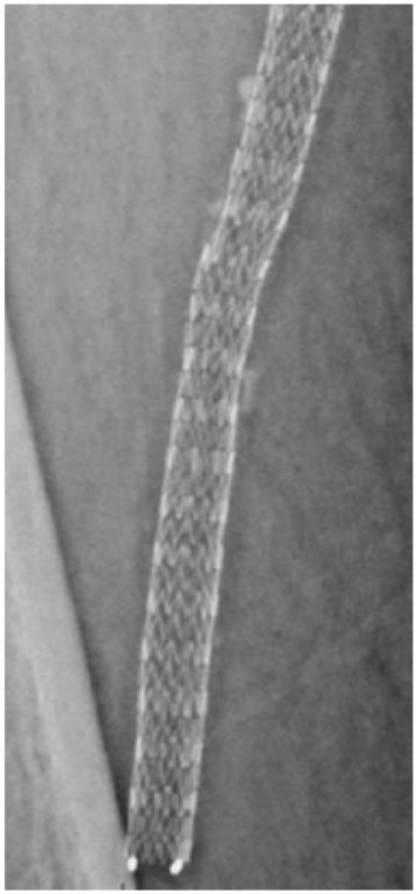
TCT2010

Low Stent Fracture Rate

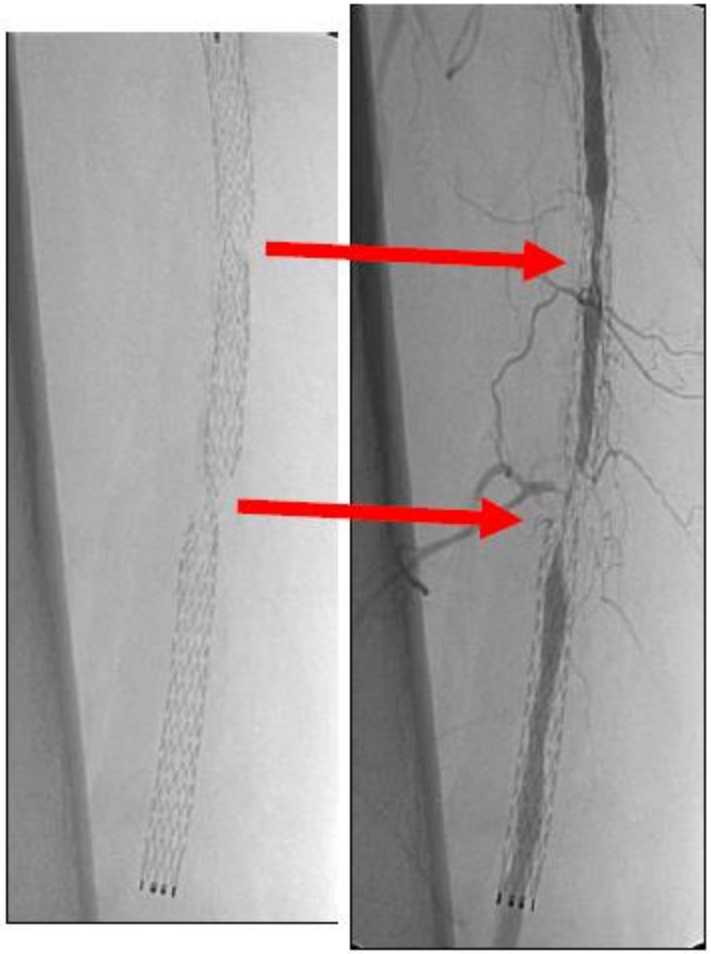
Number of Stents Implanted	% of Lesions (n = 900)	% of Patients (n = 787)
1	50%	40%
2	22%	25%
3	13%	16%
4	14%	17%
> 4	1%	2%
Average	1.9 stents per lesion	2.2 stents per patient

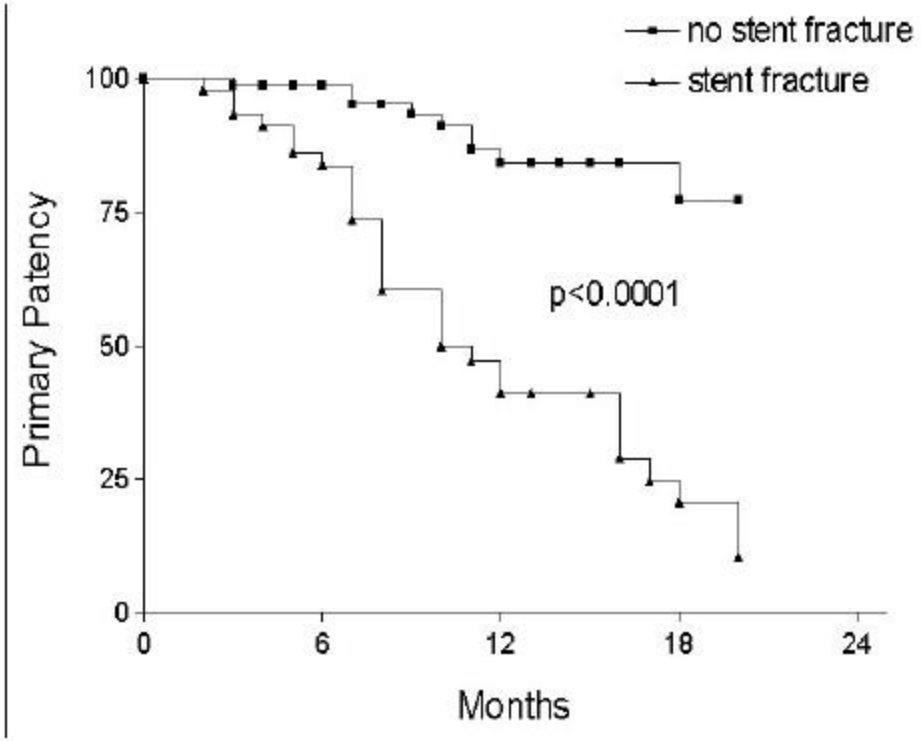
- 1,432 stents visualized at 12 months
- 22 confirmed stent fractures

1.5% stent fracture rate through 12 months



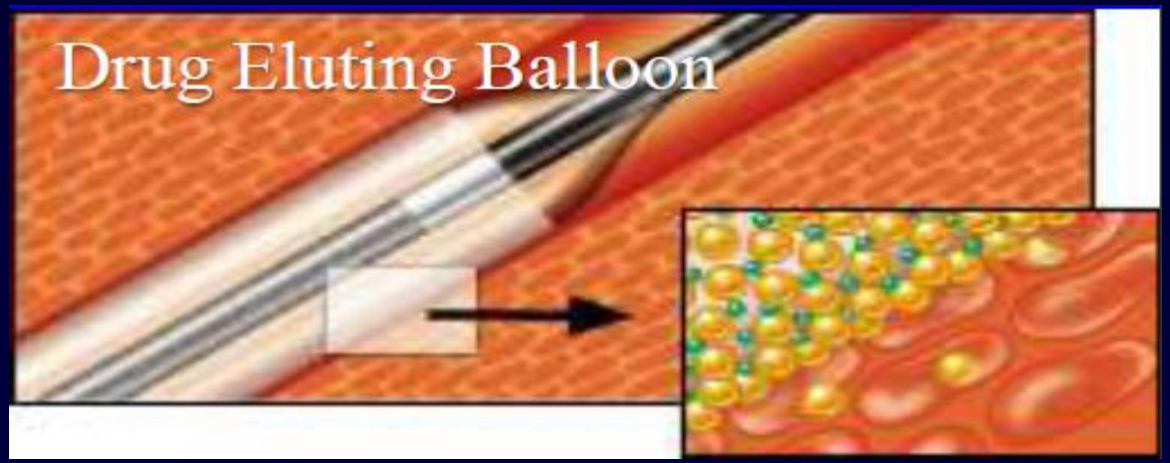
Stent Fracture and Restenosis in SFA





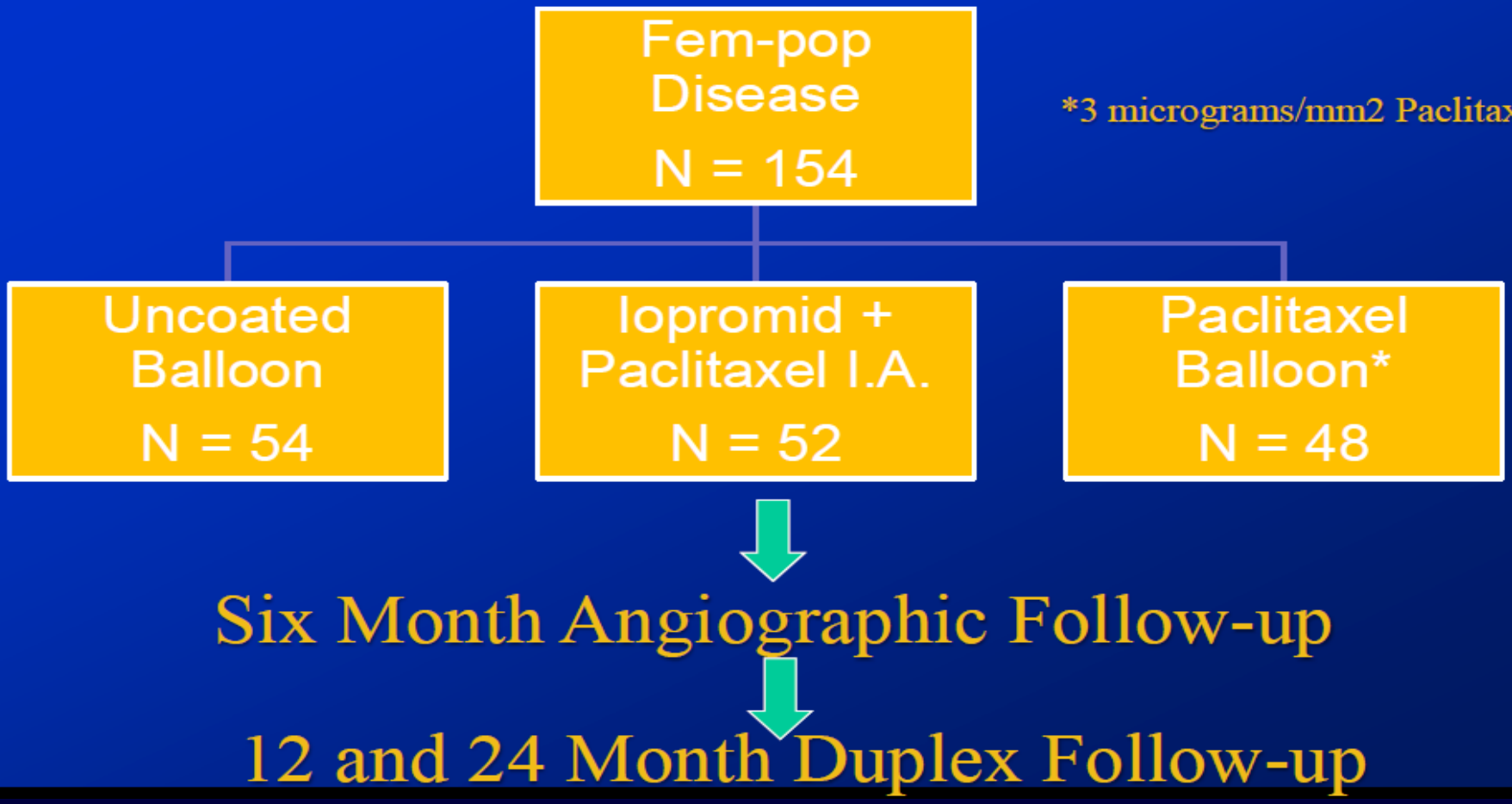
Scheinert D. et al, JACC 2005

Drug coated balloon in SFA lesion



THUNDER Trial

Study Design



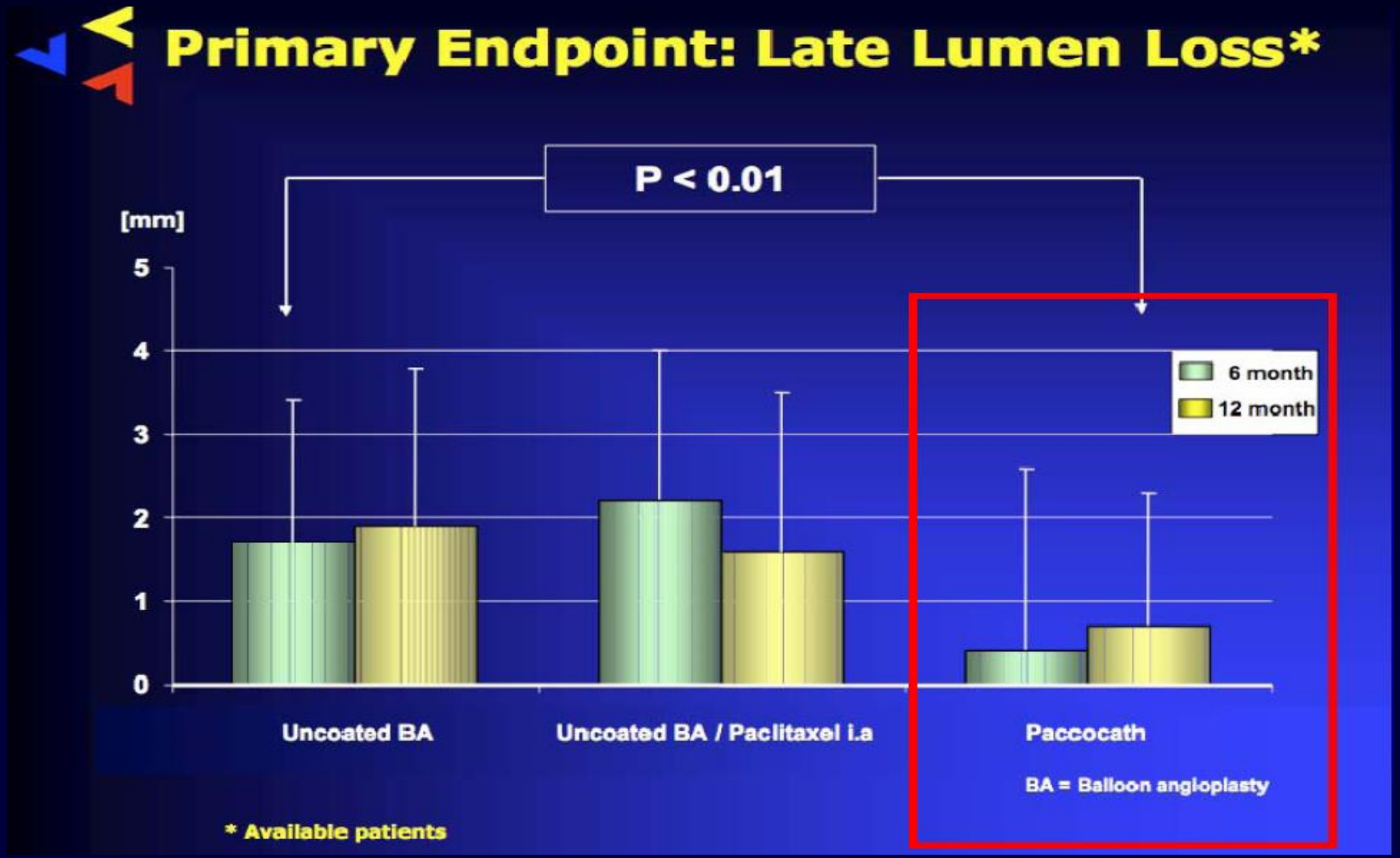
FemPac trial
: Drug coated balloon in FP lesion

Preinterventional Angiographic findings	Uncoated Balloon Group	Paclitaxel-Coated Balloon Group	p-value
Reference diameter(mm)	5.0/4.7-5.6(41)	5.2/4.9-6.2(43)	0.23
Total occlusion, n(%)	8/42(19)	6/45(13)	0.56
Degree of stenosis, %	85/80-90(42)	85/75-90(45)	0.55

Values are median/25th-75th percentile(n)
or number of patients/total number of patients

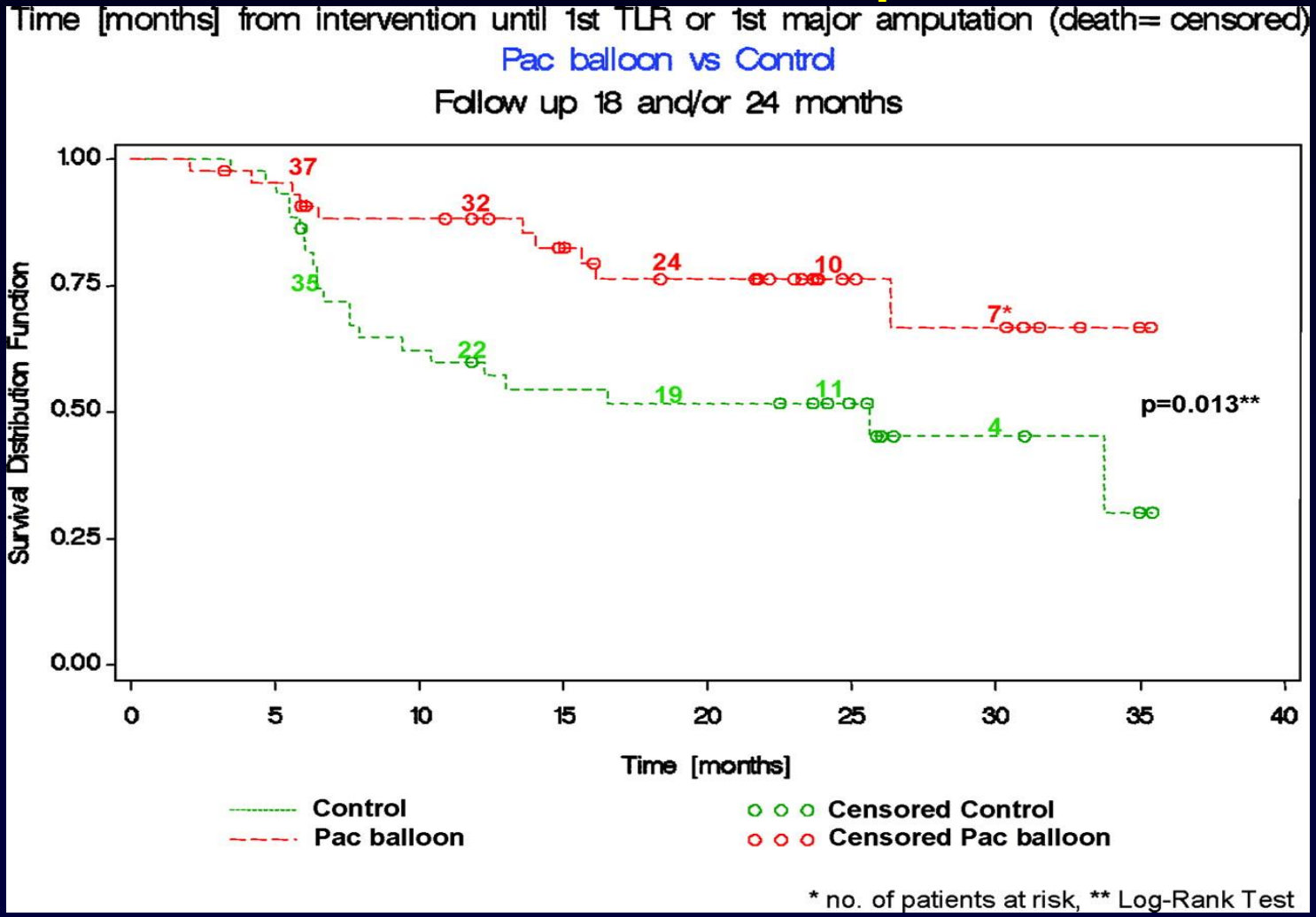
Werk, M. et al. Circulation 2008;118:1358-1365

THUNDER Trial
: Drug coated balloon in SFA lesion



FemPac trial

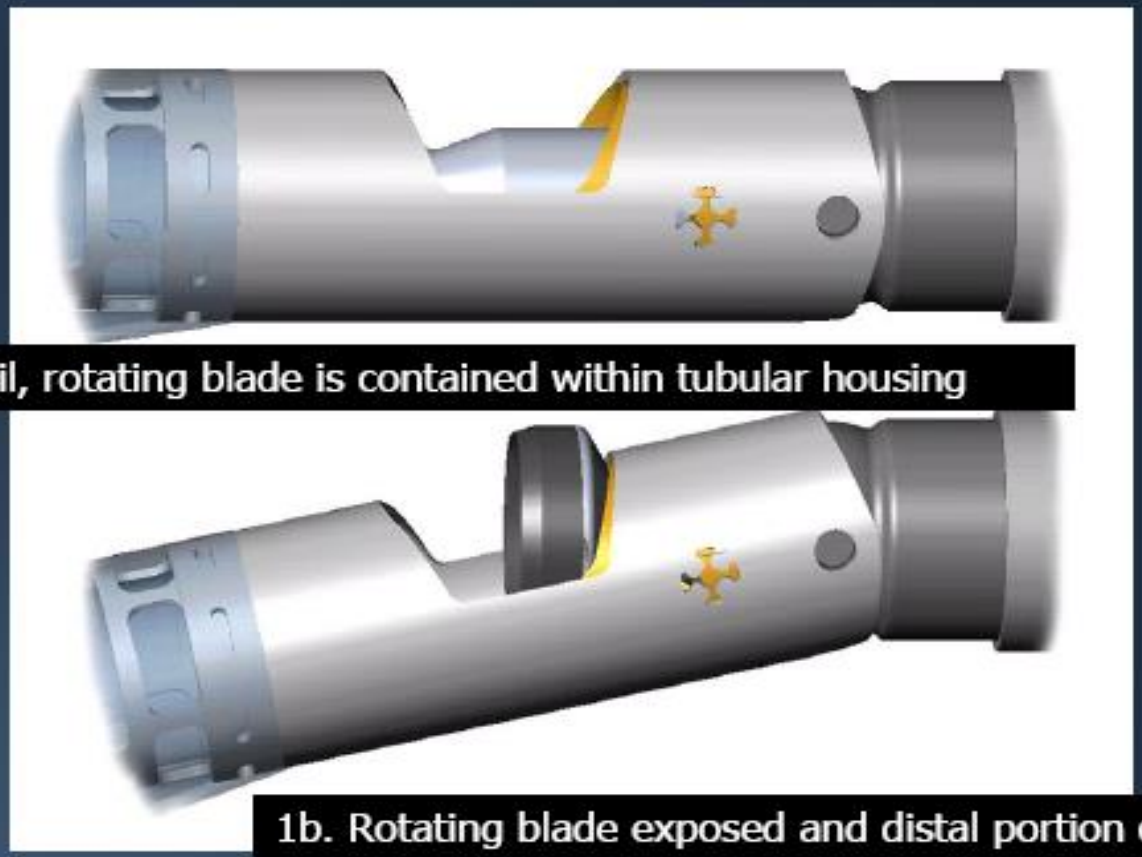
Survival distribution function up to 24 months



Werk, M. et al. Circulation 2008;118:1358-1365

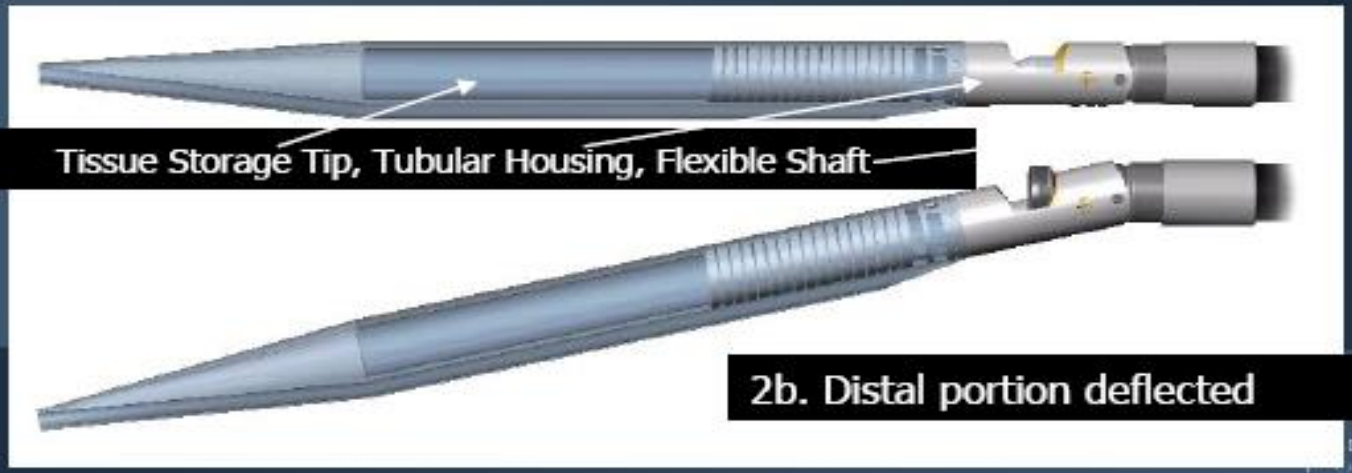
Atherectomy in SFA lesion

20 YEARS OF INNOVATION TCT 2008



1a. Cutting Assembly Detail, rotating blade is contained within tubular housing

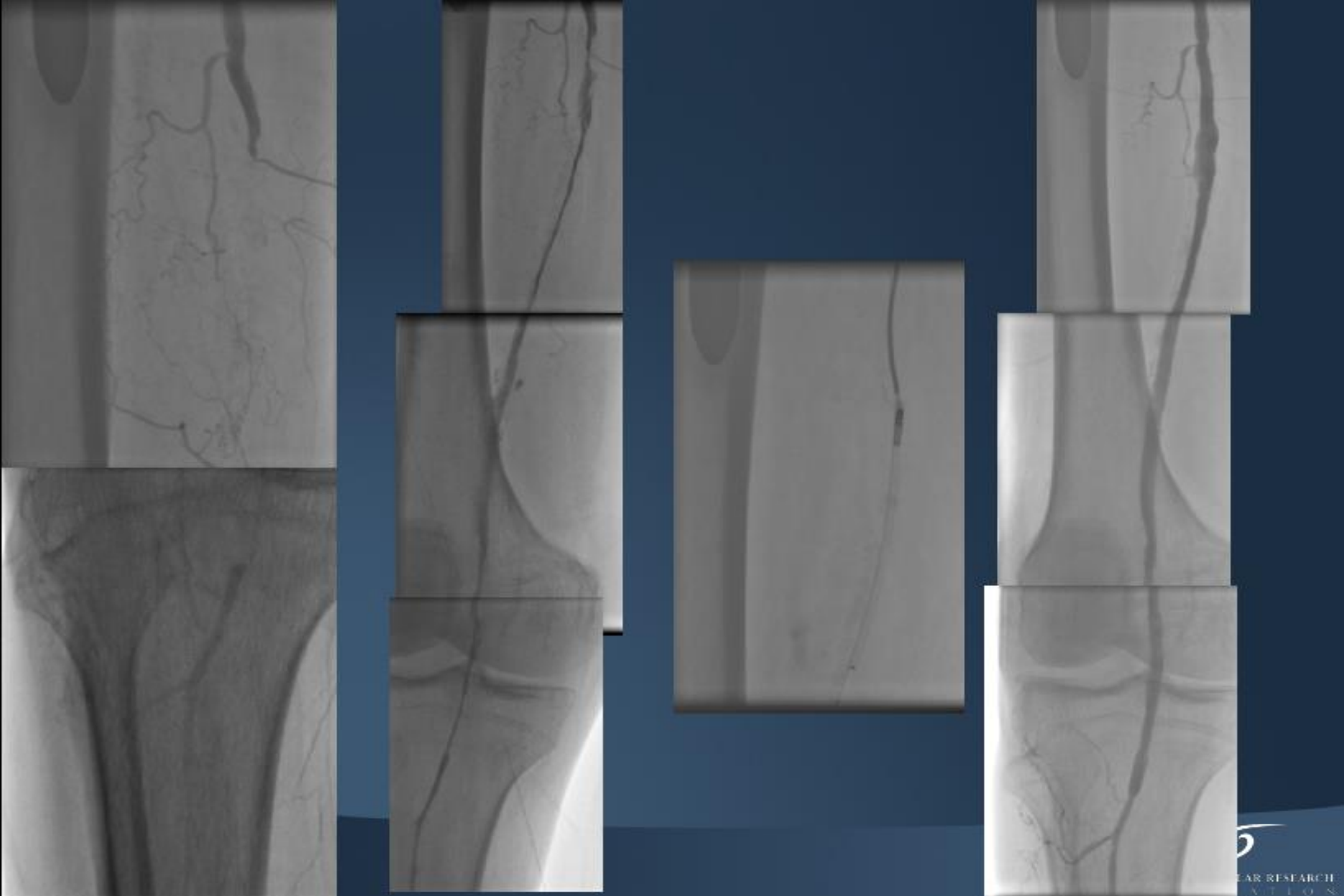
1b. Rotating blade exposed and distal portion of housing deflected



2a. Catheter Distal Detail

2b. Distal portion deflected

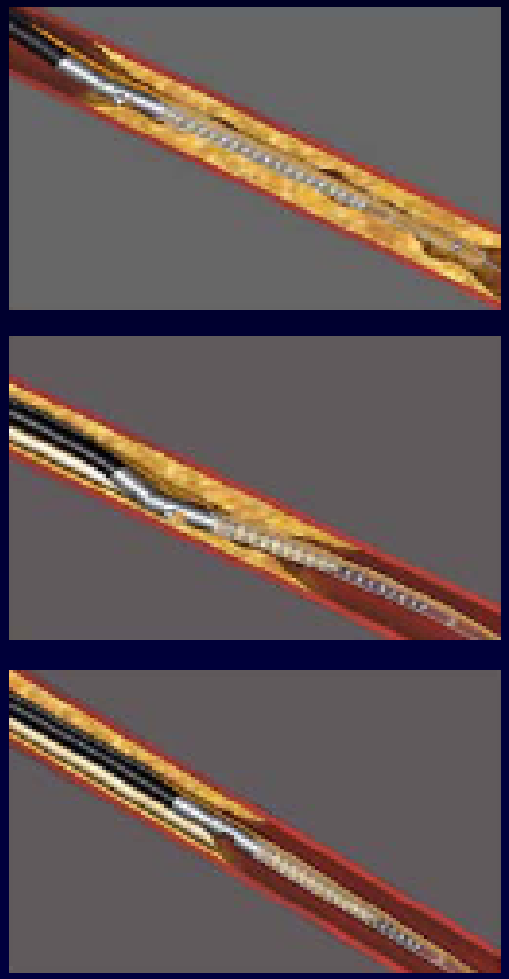
CARDIOVASCULAR RESEARCH FOUNDATION



Silverhawk for Femoro-popliteal Lesions

- Prospective single center study
- Rutherford 2-5
- 84 patients (100limbs), 131 lesions

- De novo lesions : 45
- Restenosis in a native artery : 43
- In-stent restenosis : 43



Zeller et al. J Am Coll Cardiol. 2006;48(8):1573-8

Atherectomy Results in SFA lesion

Lesion type	De novo lesions	Restenosis in a native artery	In-stent restenosis
Lesion length(mm)	43±54	105±122	131±111
1° patency(12M)	84%	54%	54%
1° patency(18M)	73%	42%	49%
2° patency(12M)	100%	93%	91%
2° patency(18M)	89%	67%	79%

Duplex ratio definition = ≥ 2.5

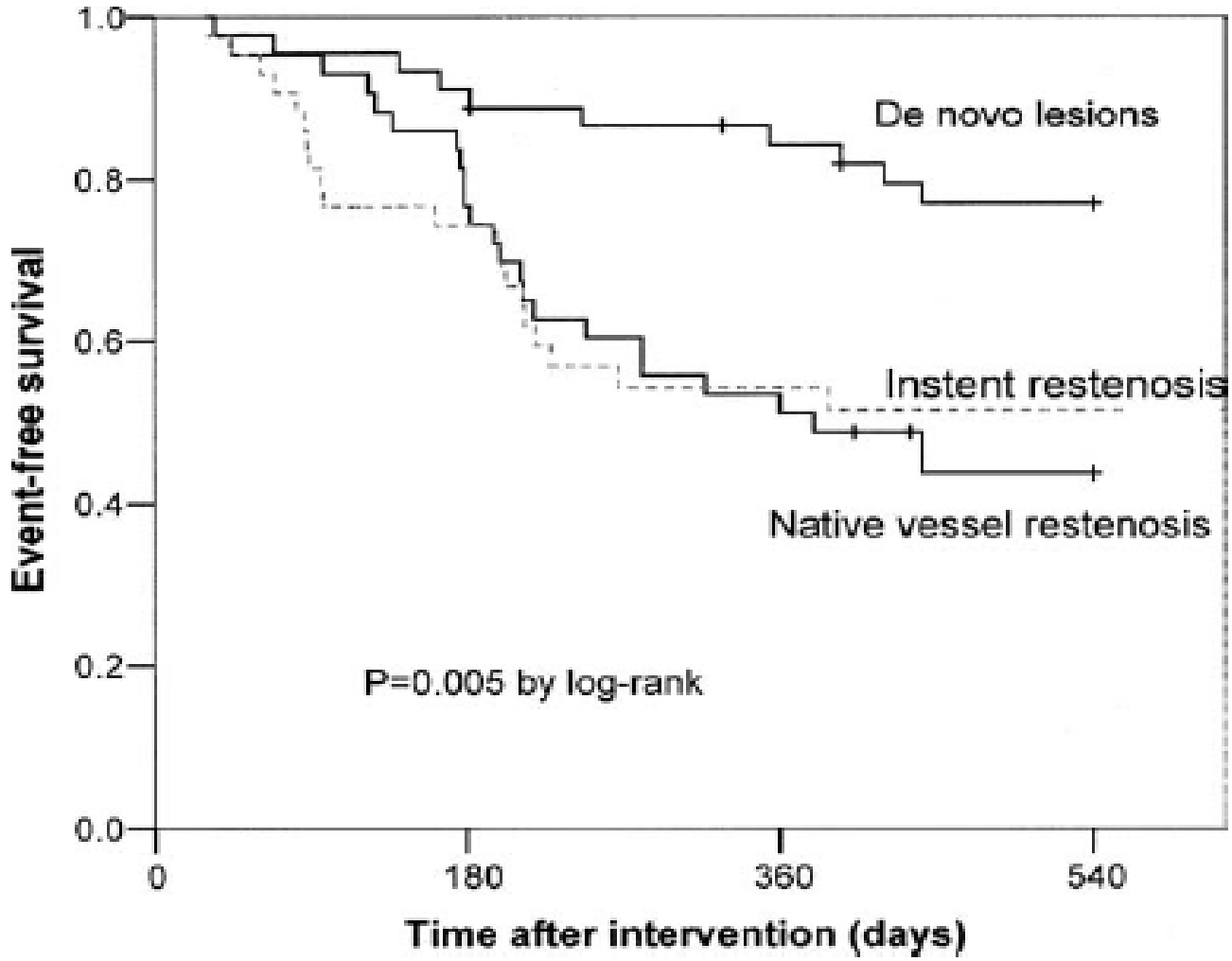
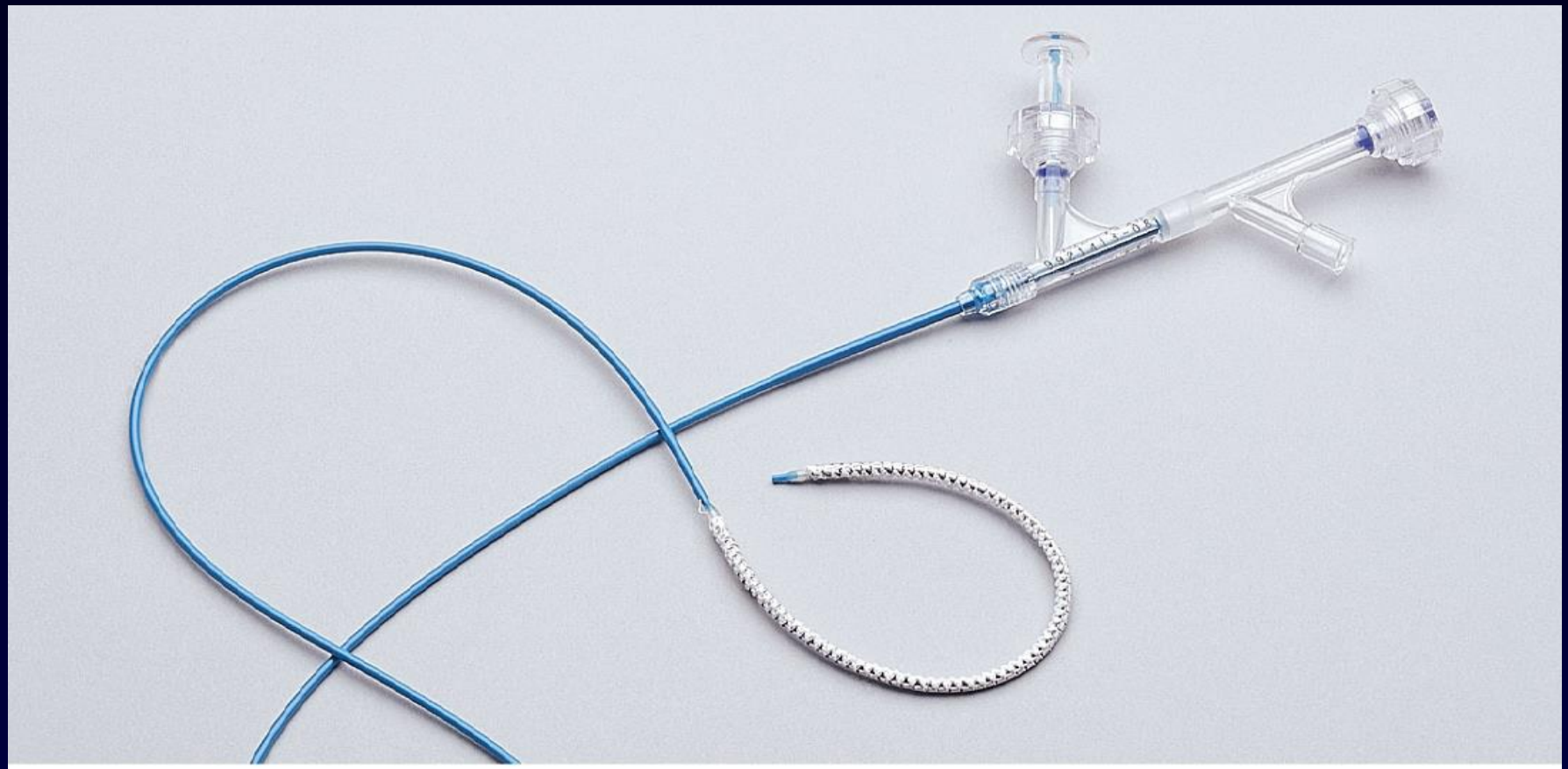


Figure 2. Kaplan-Meier event-free survival curves for survival without target vessel revascularization.

Stent-graft in SFA lesion

Stent-graft in SFA lesion



Stent-graft in SFA lesion
Hemobahn/Viabahn 5yr Results

- N=60 limbs (57 Pts)
- Ave lesion length 10.7 cm (3-34)
- Symptomatic class

  Claudication = 91%

  CLI = 9%
- ASA long term, Clopidogrel (3M)
- Surveillance 30 days, 6M, 12M

Fischer et al. J Endovasc Ther 2006;13:281-90

Stent-graft in SFA lesion Hemobahn/Viabahn 5yr Results

All patients(N=57)

- Patency 1yr

  Primary = 67%

  Secondary = 81%

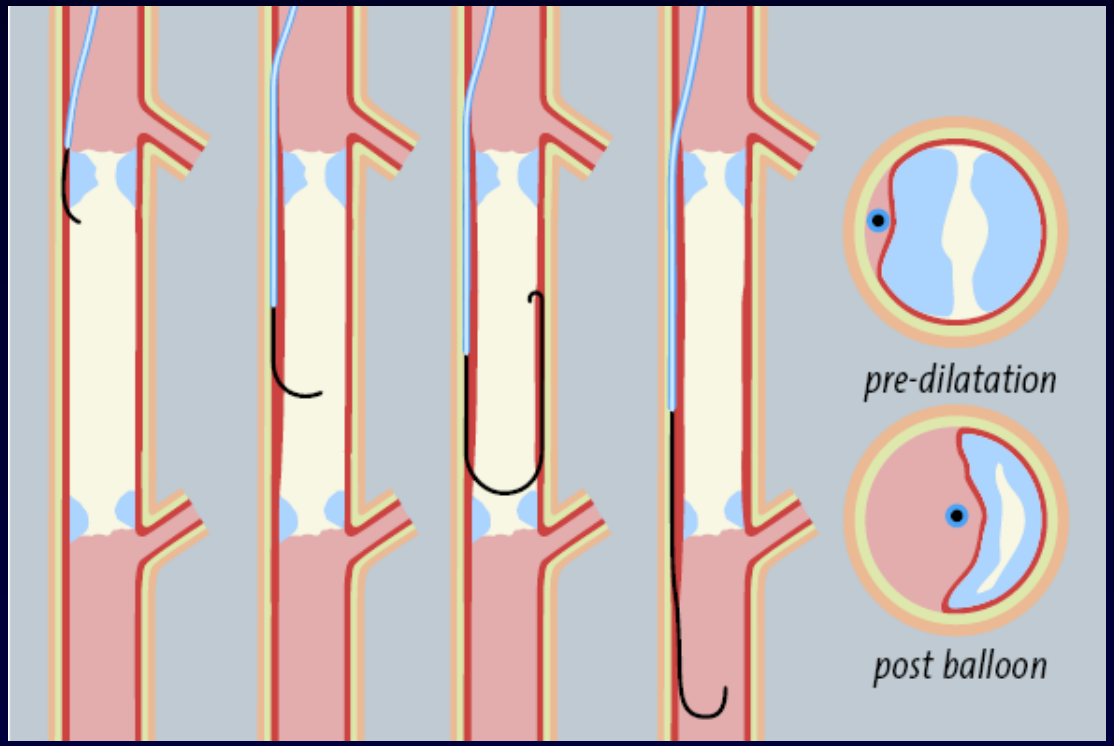
- Patency 5yr

  Primary = 45%

  Secondary = 69%

Fischer et al. J Endovasc Ther 2006;13:281-90

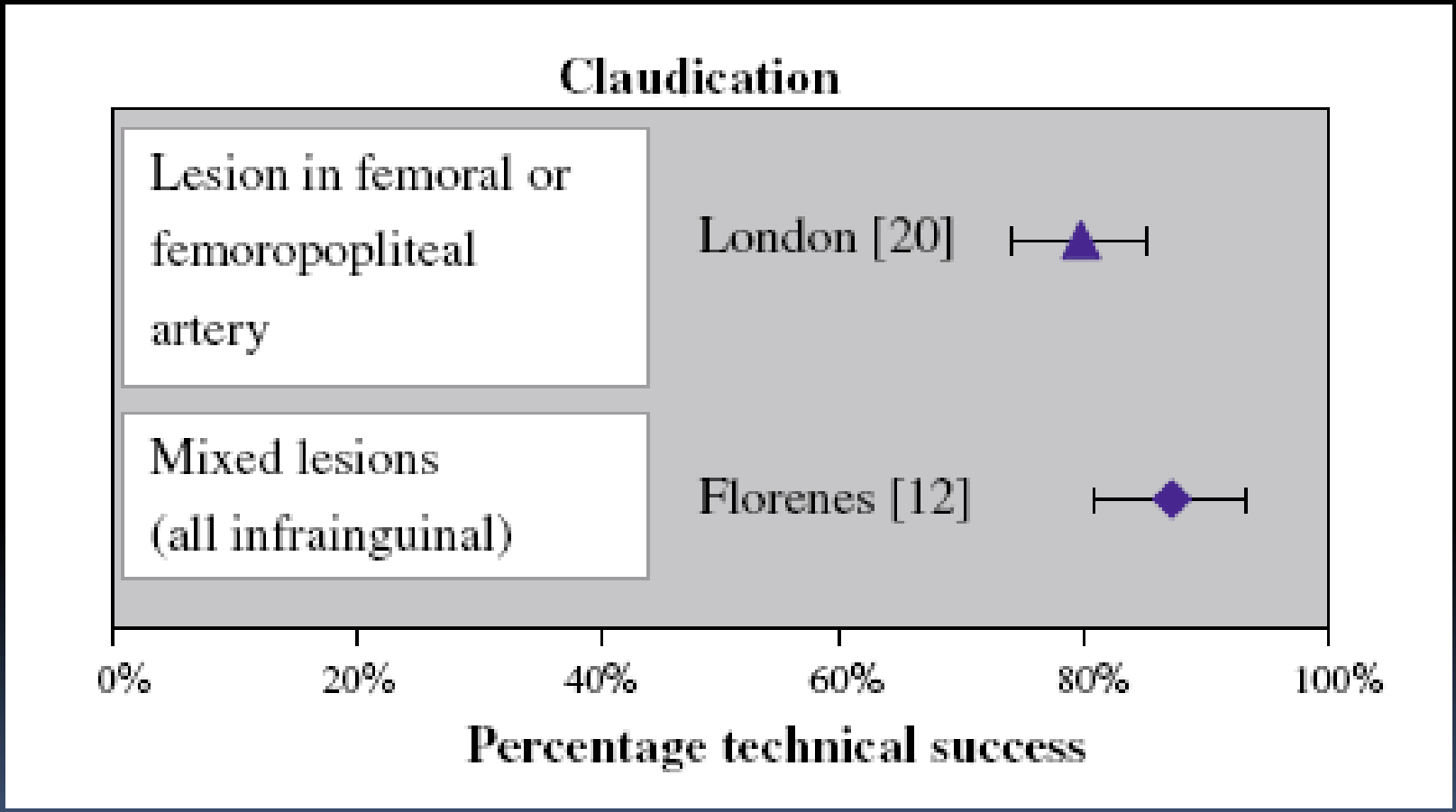
Improved Techniques and Devices for CTO in FemoropoIpiteal Lesions



Outback, Cordis

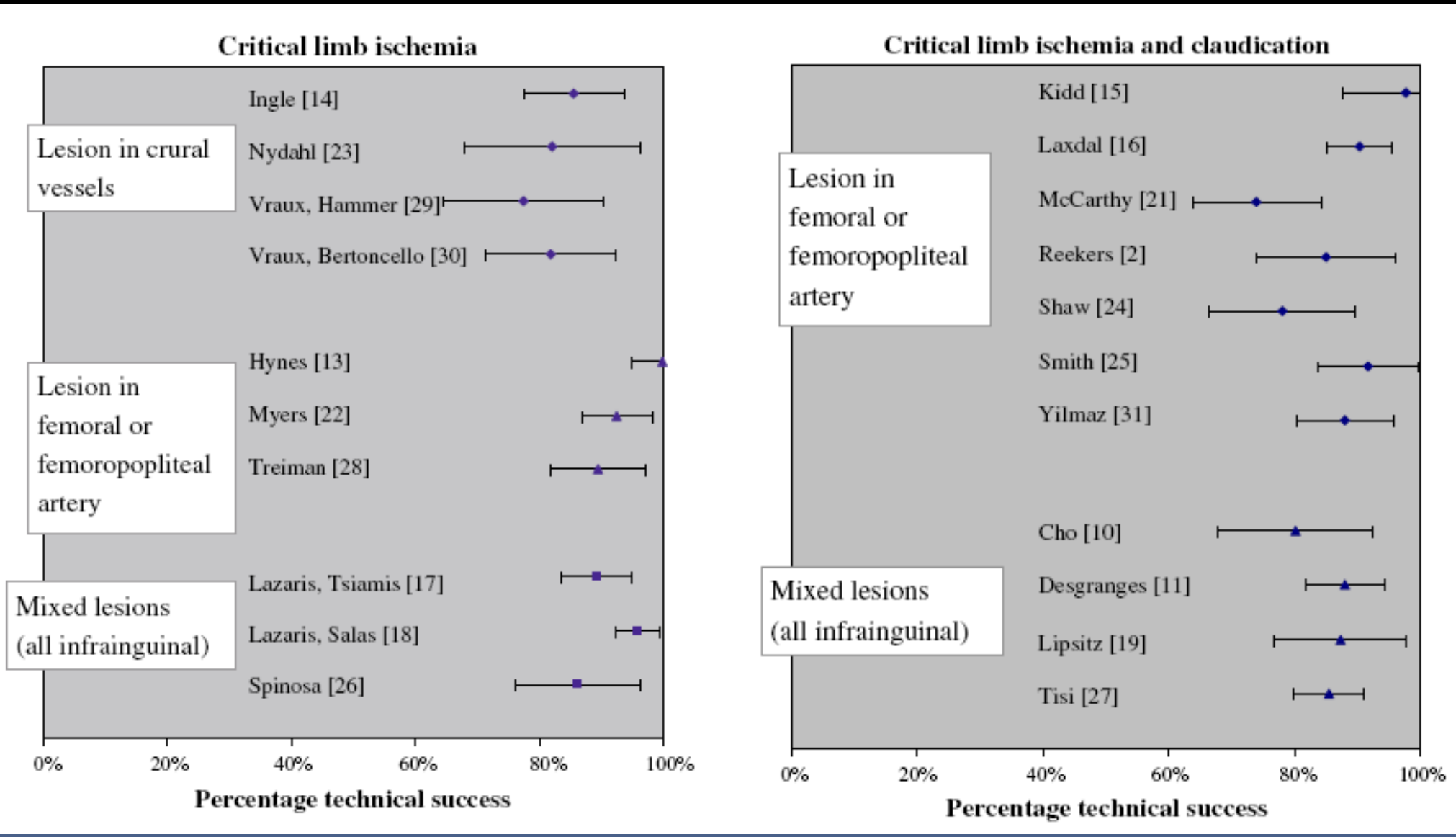
Pioneer, Medtronic

Technical Success of SIA in Patients With Claudication



Met R. et al. Cardiovasc Intervent Radiol 2008;31:687–697

Technical Success of SIA in CLI



Met R. et al. Cardiovasc Intervent Radiol 2008;31:687–697

Outcomes of SIA in Patients With Critical Limb Ischemia or Claudication

Table 6 Outcomes of studies reporting about patients with critical limb ischemia or intermittent claudication (mixed), subdivided according to location of lesion (femoral or femoropopliteal artery or mixed lesions, which are all infrainguinal)

Study	Statistical method	Clinical success (mo)	Complications	Primary patency (mo)	Primary assisted patency (mo)	Limb salvage (mo)	Survival (mo)
Lesion (mostly) in femoral or femoro-popliteal artery							
Kidd [15]	LTA	–	–	52% (12)[a]	–	100% (12)	98% (12)
Laxdal [16]	KMA	–	9/124 (7%)	–	37% (12)	90% (7)	–
McCarthy [21]	KMA	60% (8)	11/69 (16%)	51% (6)[a]	–	88% (8)	86% (6)
Reekers [2]	LTA	50% (12)	8/40 (20%)	59% (12)[a]	–	–	–
Shaw [24]	KMA	59% (6)	5/50 (10%)	57% (6)[a]	–	–	89% (6)
Smith [25]	KMA	–	7/47 (15%)	53% (12)[a]	–	–	–
Yilmaz [31]	KMA	–	10/67 (15%)	22% (12)[a]	57% (12)	–	100% (12)
Mixed lesions (all infrainguinal)							
Cho [10]	KMA	–	4/40 (10%)	44% (12)[b]	–	–	–
Desgranges [11]	LTA	–	17/100 (17%)	61% (24)[a]	69% (24)	78% (24)	85% (24)
Lipsitz [19]	LTA	68% (12)	3/39 (8%)	64% (12)[b]	–	92% (12)	–
Tisi [27]	LTA	–	26/158 (16%)	45% (1)[a]	–	–	–

Met R. et al. Cardiovasc Intervent Radiol 2008;31:687–697

Outcomes of SIA in Patients With Critical Limb Ischemia

Table 5 Outcomes of studies reporting about patients with critical limb ischemia, subdivided according to location of lesion (crural, femoral or femoropopliteal vessels or mixed, which are all infrainguinal)

Study	Statistical method	Clinical success (mo)	Complications	Primary patency (mo)	Primary assisted patency (mo)	Limb salvage (mo)	Survival (mo)
Lesion (mostly) in crural vessels							
Ingle [14]	KMA	–	9/70 (13%)	–	–	94% (12)	–
Nydahl [23]	KMA	56% (12)	3/28 (11%)	53% (12)[a]	–	85% (12)	–
Vraux & Hammer [29]	KMA	68% (12)	5/40 (13%)	56% (12)[b]	–	81% (12)	78% (12)
Vraux & Bertoncello [30]	KMA	63% (12)	7/50 (14%)	46% (12)[b]	–	87% (12)	65% (12)
Lesion (mostly) in femoral or femoropopliteal artery							
Hynes [13]	LTA	–	6/74 (8%)	–	–	–	–
Myers [22]	KMA	–	2/82 (2%)	74% (3)[a]	87% (3)	–	–
Treiman [28]	KMA	–	4/29 (14%)	64% (24)[b]	–	80% (24)	50% (24)
Mixed lesions (all infrainguinal)							
Lazaris & Tsiamis [17]	KMA	69% (24)	14/112 (13%)	–	–	88% (12)	–
Lazaris & Salas [18]	KMA	–	–	50% (12)[b]	–	92% (12)	87% (12)
Spinosa [26]	KMA	–	4/40 (10%)	–	–	66% (12)	71% (12)

Met R. et al. Cardiovasc Intervent Radiol 2008;31:687–697

Improved Technical Success and Midterm Patency With Subintimal Angioplasty Compared to Intraluminal Angioplasty in Long Femoropopliteal Occlusions

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Purpose: To compare the efficacy of subintimal angioplasty combined with primary stenting to intraluminal angioplasty with stenting for revascularization of long (>10 cm) femoropopliteal arterial occlusions.

Methods: Baseline characteristics and outcomes of 52 patients (40 men; mean age 65.6±9.7 years) with superficial femoral artery (SFA) occlusions in 61 limbs (mean occlusion length 22.7±9.9 cm) treated with subintimal angioplasty and primary stenting were compared with a 54-patient control group (46 men; mean age 64.8±8.2 years) from our registry database who had intraluminal angioplasty with stenting in 60 limbs (mean occlusion length 22.0±8.5 cm).

Results: All baseline clinical and angiographic characteristics showed no differences. In all patients, at least 1 self-expanding nitinol stent was implanted. Subintimal angioplasty was successful in 58 (95.1%) of 61 limbs, whereas technical success for the conventional approach was 86.7% (52/60 limbs; p=0.11). In both groups, there were no major complications requiring surgery. Primary patency at 12 months for successful cases was 76.4% for subintimal angioplasty and 59.2% for conventional angioplasty (p=0.06); on an intention-to-treat basis, including technical failures, the rates were 72.4% and 50.9%, respectively (p=0.02).

Conclusion: Subintimal angioplasty combined with stenting was feasible, with a high technical success rate and better short and midterm results for revascularization of long femoropopliteal occlusions than the conventional intraluminal approach.

J Endovasc Ther 2007;14:374–381

Baseline Characteristics

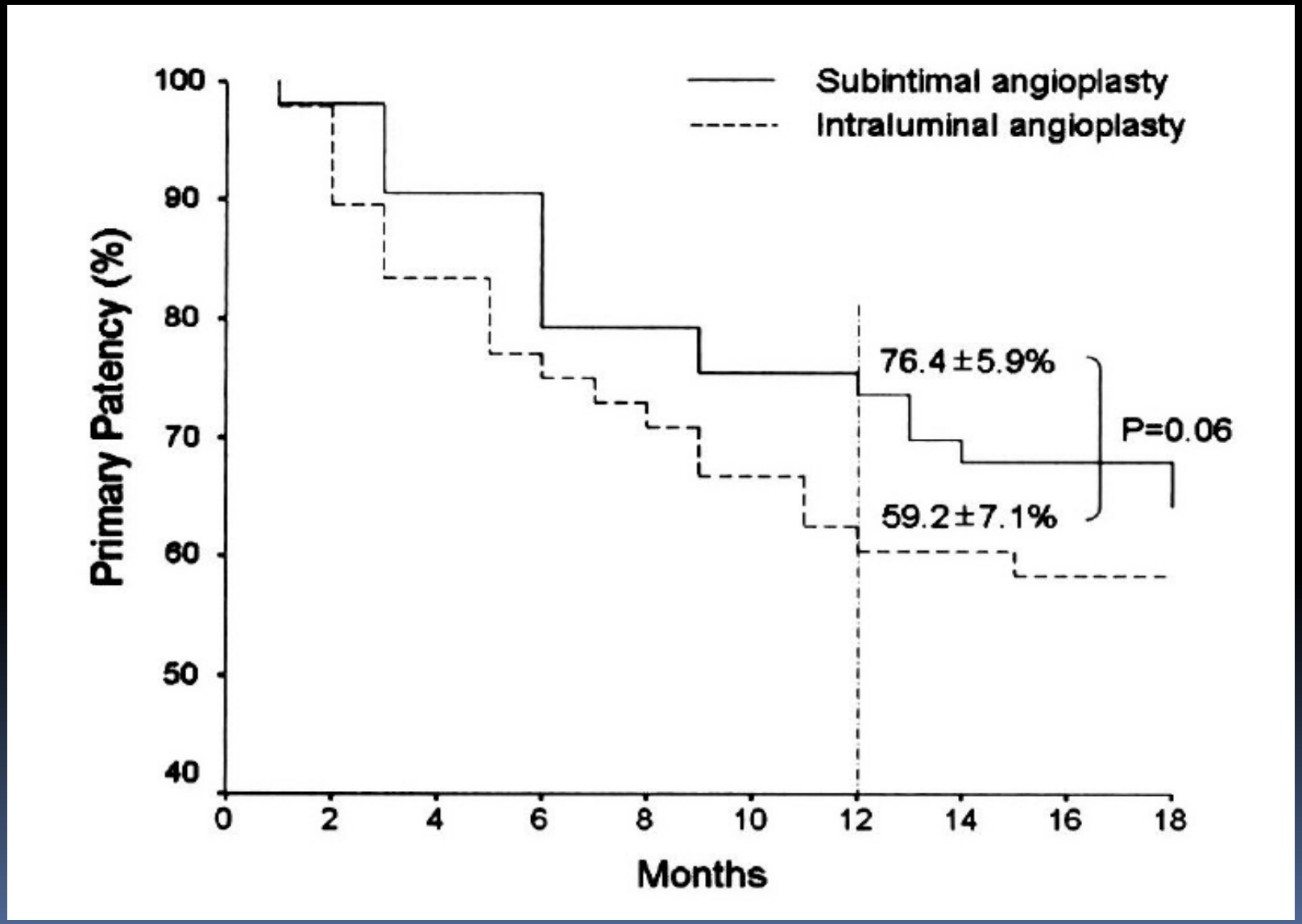
	Subintimal	Intraluminal	p
Patients	54	53	
Limbs	62	60	
Age, years	65.7±9.1	65.1±8.9	ns
Male, n (%)	40 (74.1)	42 (79.2)	ns
DM, n (%)	35 (64.8)	35 (66.0)	ns
HTN, n (%)	38 (70.3)	39 (73.6)	ns
Smoking, n (%)	26 (48.1)	24 (45.3)	ns
CAD, n (%)	34 (63.0)	32 (60.4)	ns

Procedural Outcome

	Subintimal	Intraluminal	p
Occlusion length (cm)	22.5 ± 6.5	20.8 ± 11.3	ns
Technical success	95.2%	86.7%	ns
GW passage Failure (n)	3	5	
Major complications*	0	0	ns
No. of stents	1.08 ± 0.27	1.22 ± 0.49	ns
Stent diameter (mm)	8.0 ± 1.1	7.8 ± 1.3	ns
Stent length (mm)	76.5 ± 6.7	80.4 ± 12.3	ns
Post-PTA ABI	0.79 ± 0.21	0.81 ± 0.19	ns

** Requiring surgical treatment*

Primary Patency



Failed cases

- Subintimal angioplasty

  => 1 of 3 failed cases: below knee amputation

  => 7 of 14 occluded limbs: re-PTA (2 limbs later OP)

- Intraluminal angioplasty

  => 2 of 8 failed caes: below knee amputation

  => 9 of 17 cases occluded limbs: re-PTA

  => 1 of 17 cases occluded limbs: OP

Efficacy of Subintimal Angioplasty/Stent Implantation for Long, Multisegmental Lower Limb Occlusive Lesions in Patients Unsuitable for Surgery

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Purpose: To investigate the feasibility and clinical outcomes of subintimal angioplasty combined with stent implantation in patients with long, multisegmental occlusive lesions unsuitable for surgical treatment.

Methods: Between 2003 and 2005, 30 patients (23 men; mean age 68 years, range 49–82) with severe claudication (Rutherford category 3, n=12) or critical limb ischemia (CLI; Rutherford category 4 or 5, n=18) underwent subintimal angioplasty with primary stenting for long (mean 28±11 cm) total occlusion in the lower limb arteries. Bypass surgery was considered unsuitable owing to inappropriate anatomy or poor distal runoff in 14 (47%) patients, severe coronary artery disease 14 (47%), or poor general condition in 2 (6%).

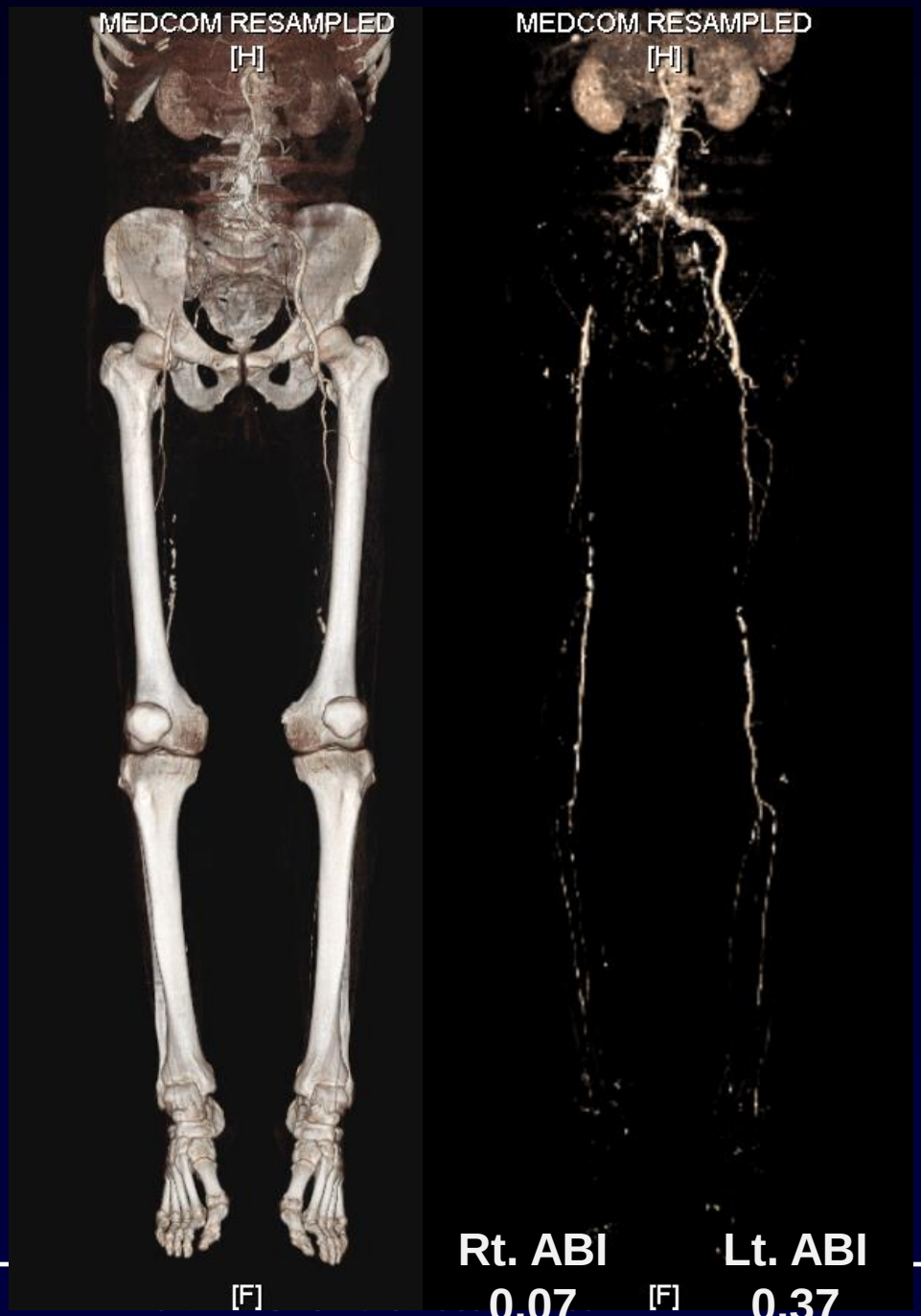
Results: Technical success was achieved in 27 (90%) of 30 cases. The 3 technical failures were due to inability to advance the wire, to re-enter the distal lumen, and vessel rupture, respectively. Three (10%) complications occurred (1 perforation, 2 hematomas) but did not require surgery. After a mean follow-up of 13±7 months (range 3–28), 10 (37%) cases of restenosis were found in 27 patients. At 12 months, the primary patency rate was 52%, and the limb salvage rate was 83%.

Conclusion: Combined use of subintimal angioplasty and stent implantation was performed safely, with a relatively high success rate and acceptable intermediate-term clinical outcomes in patients with multisegmental, long occlusions of the lower limb arteries. Therefore, this strategy can be considered an option for symptomatic relief and limb salvage in patients unsuitable for bypass surgery due to various reasons.

J Endovasc Ther 2006;13:514–521

Baseline Characteristics: (n=30)

Age, y	68±8 (49–82)
Men	23 (77%)
Comorbidities	
Coronary artery disease	20 (67%)
Hypertension	13 (43%)
Diabetes	16 (53%)
Smoking	18 (60%)
Rutherford classification	
Grade I category 3	12 (40%)
Grade II category 4	9 (30%)
Grade III category 5	9 (30%)
Lesion length, cm	28±10 (15–55)
Target lesion	
Iliofemoral	11 (37%)
Femoropopliteal	11 (37%)
Femoropopliteal/tibioperoneal	8 (26%)
TASC type D	30 (100%)
Patent tibioperoneal arteries	
0–1	14 (47%)
2	11 (37%)
3	5 (16%)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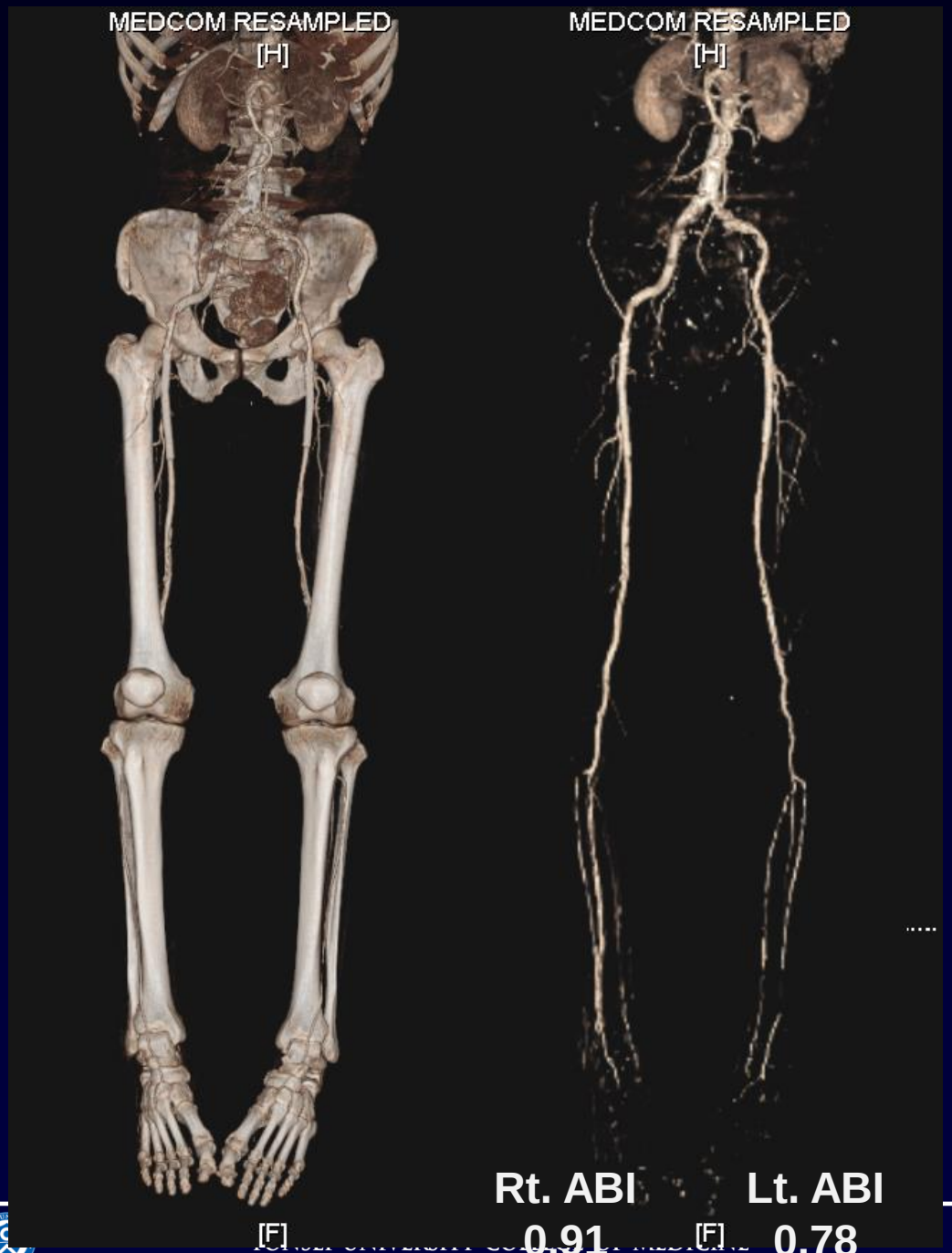
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Rt. ABI
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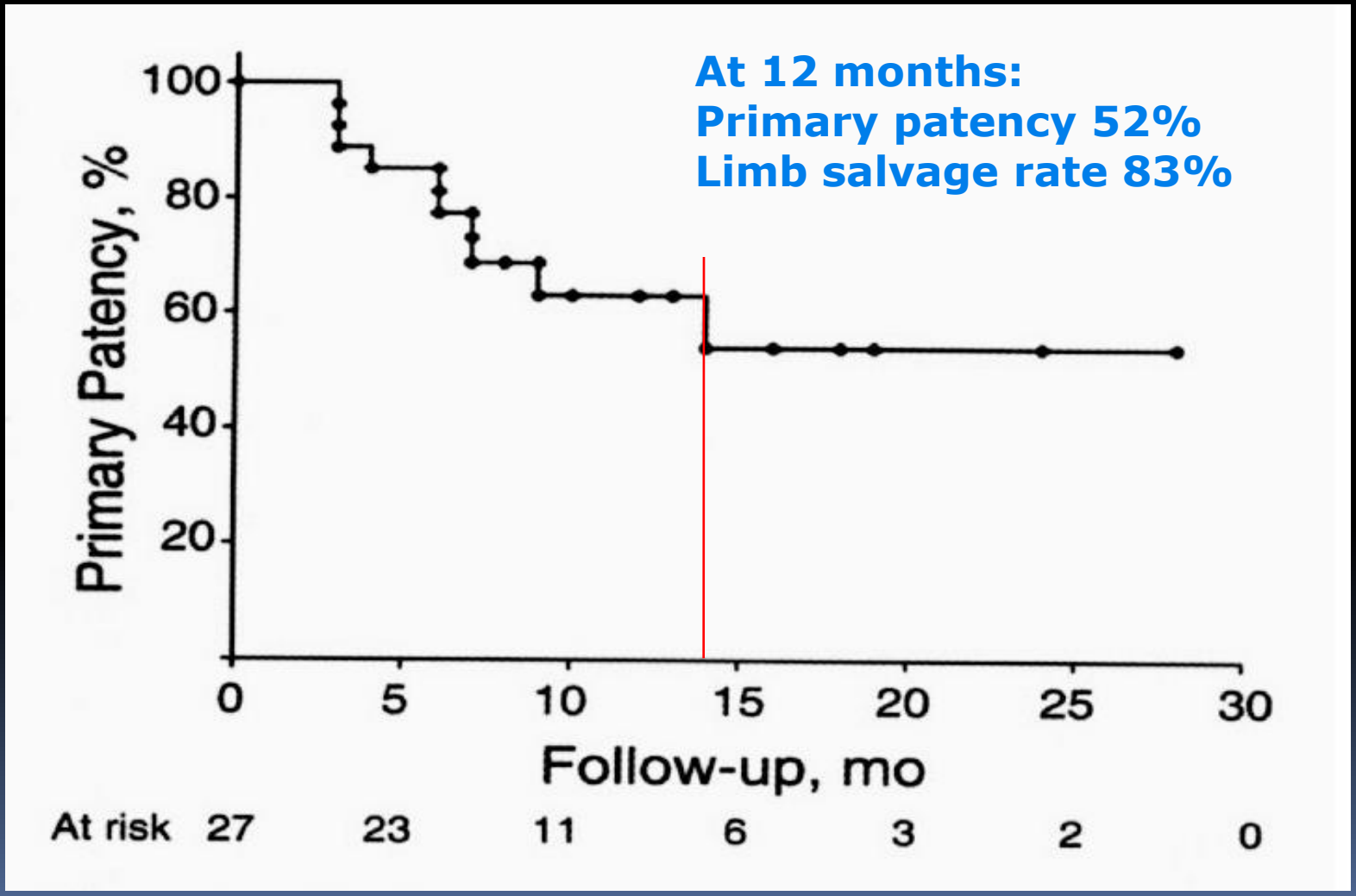
Immediate Results

Success Rate	**28 / 32 (87.5 %)**
Complication*	**3 / 32 (9 %)**
Stent length	**80 mm (Range 60-100 mm)**
ABI, pre-intervention	**0.40 (range, 0.09-0.71)**
ABI, post-intervention	**0.82 (range, 0.44-1.13)**
Limb salvage rate	**2 / 11 (83%)**

** 1 perforation, 2 hematomas: no surgery required*

Primary Patency



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Thank You for Your Attention!

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