Infrapopliteal intervention

Anatomic Challenges infrapopliteal disease

- Atherosclerotic disease confined to the infrapopliteal arteries may be asymptomatic due to the excellent collateral network between tibial arteries
- One patent tibial artery is often sufficient to keep a patient free from ischaemic symptoms
- When these patients present with CLI they often have severe, extensive three-vessel disease and only 20–30% have a simple, focal lesion with good distal run-off

Anatomic Challenges infrapopliteal disease

- Patients are usually elderly with several comorbidities, such as diabetes and coronary artery disease, which increases the surgical risk
- Femorodistal and pedal bypass surgery is technically demanding and associated with a 1.8–6% perioperative mortality

Classification of disease
*T*ransatl*A*ntic inter*S*ociety *C*onsensus document

Preferred Treatment

- Group A consists of single stenoses shorter than 1 cm. **PTA**
- Group B consists of multiple focal (<1 cm) stenoses of tibial trifurcation.
- Group D consists of occlusions longer than 2 cm and diffusely diseased tibial vessels **Surgery**

However, due to the improvements in equipment and technique, endovascular therapy is now considered a feasible option in groups C–D. In addition the presence of co-morbid conditions and operator skills should be considered when making the final decision.

Why?

PTA for intrapopliteal lesions

- The highest likelihood of coronary heart disease in patients with infrapopliteal disease.
- PTA is a low-risk and minimally invasive procedure, which rarely compromises a later surgical procedure, and at the same time preserves the saphenous vein for future coronary or lower extremity distal bypass surgery.
- The total intervention time of infrapopliteal PTA (less than 2 h), is shorter than time of surgery (4h)
- Avoids general anaesthesia and shorteer the hospital stay, compared with surgical treatment.
- Repeat PTA, unlike repeat surgical bypass operations, can be easily performed in case of restenosis.

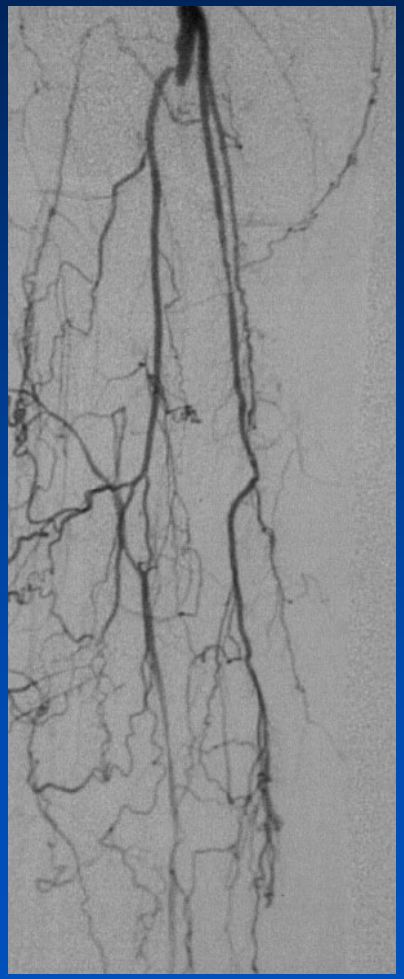
How do you treat ?
intrapopliteal lesions

- In those with significant medical co-morbidities
- Absence of suitable veins to act as conduits for bypass,
- Inadequate sites for distal anastamosis

  -No angiographically visible tibial vessels,

  -Vessels ≤ 1 mm in diameter,

  -Diffusely diseased vessels



Indication

PTA for intrapopliteal lesions

- Critical limb ischemia
- Moderate to severe claudication (debate)
- Prevention of proximal PTA or bypass failure

Critical limb ischemia

Clinical description	Fontaine class	Rutherford category	ABI	Symptom
Asymptomatic	I	0	0.85-1	none
Mild claudication	IIa	1	0.5-0.8	Walking distance>200m
Moderate claudication	IIb	2	0.5-0.8	Walking distance=100-200m
Severe claudication	IIb	3	0.5-0.8	Walking distance<100m
Ischemic rest pain	III	4	<0.5	Resting pain
Minor tissue loss	IV	5	<0.5	Minor tissue loss (ulceration)
Major tissue loss	IV	6	<0.5	Major tissue loss (gangrene)

Critical limb ischemia

- High cardiovascular mortality rate (46% at 5 years)
- 25% amputation rate despite attempts at revascularization.
- Patients with CLI undergoing successful revascularization survive longer and have an increased quality of life compared with patients who have an amputation
- Therefore, restoration of adequate blood supply to the foot should be attempted whenever possible in all these patients.
- Even if amputation cannot be avoided, infrapopliteal PTA may allow a lesser amputation in patients who would otherwise have needed a major amputation

Moderate to severe claudication

Clinical description	Fontaine class	Rutherford category	ABI	Symptom
Asy		0	0.85-1	none
Mild	a	1	0.5-0.8	Walking distance>200m
Mod	b	2	0.5-0.8	Walking distance=100-200m
Seve	b	3	0.5-0.8	Walking distance<100m
Isch	I	4	<0.5	Resting pain
Min	V	5	<0.5	Minor tissue loss (ulceration)
Maj	V	6	<0.5	Major tissue loss (gangrene)

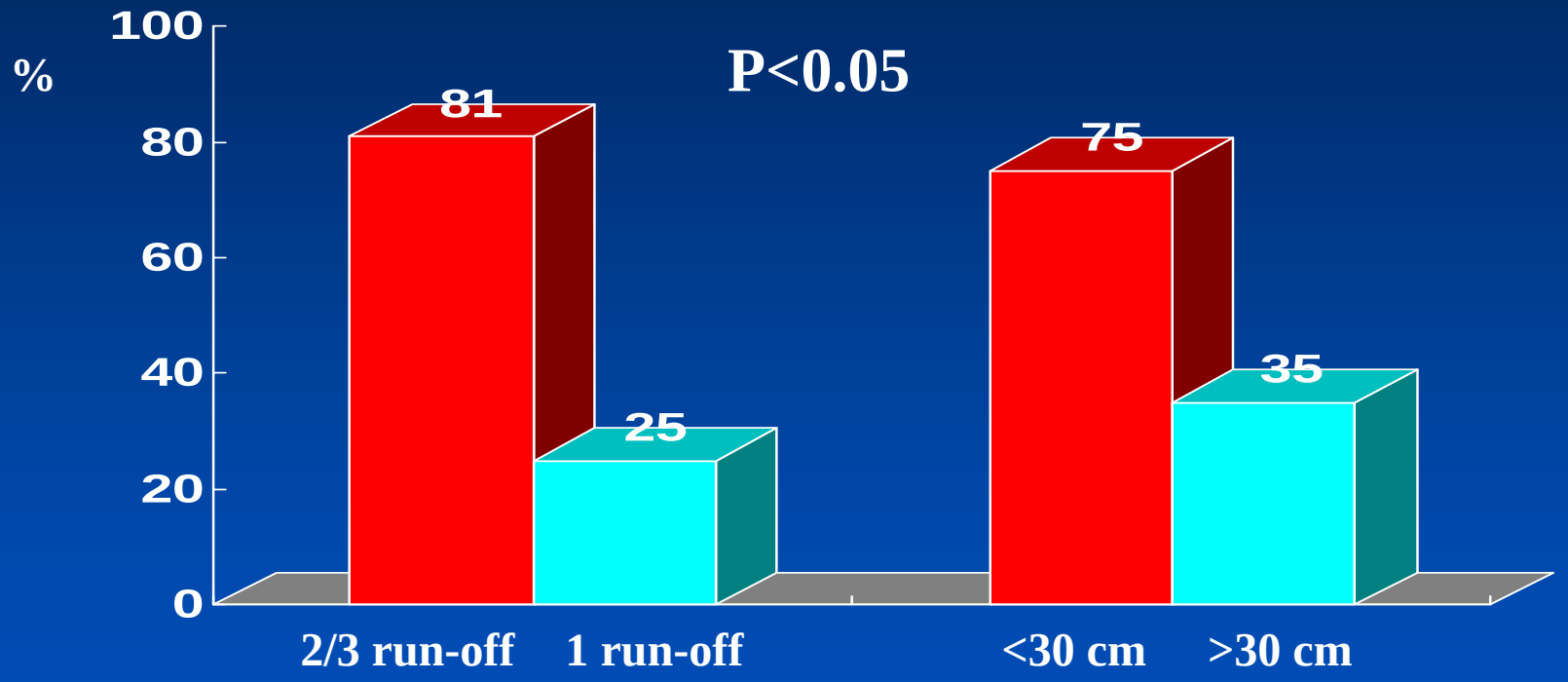
- PTA is recommended in simple lesion with moderate to severe claudication

Prevention of proximal PTA or bypass failure

- PTA is effective in treating graft stenosis
- Distal run-off influences long-term patency rates after femoropopliteal PTA or bypass surgery; patients with 2–3 patent vessels have significantly better long-term patency rates after femoropopliteal PTA than patients with 0–1 patent calf arteries.

Subintimal Angioplasty: factor affecting primary patency sfter SFA intervention

N=51, primary patency at 12 Mo:50%



Run-off vessels	0.30 (0.11-0.87)
Length of occlusion (cm)	1.02 (1.00-1.04)

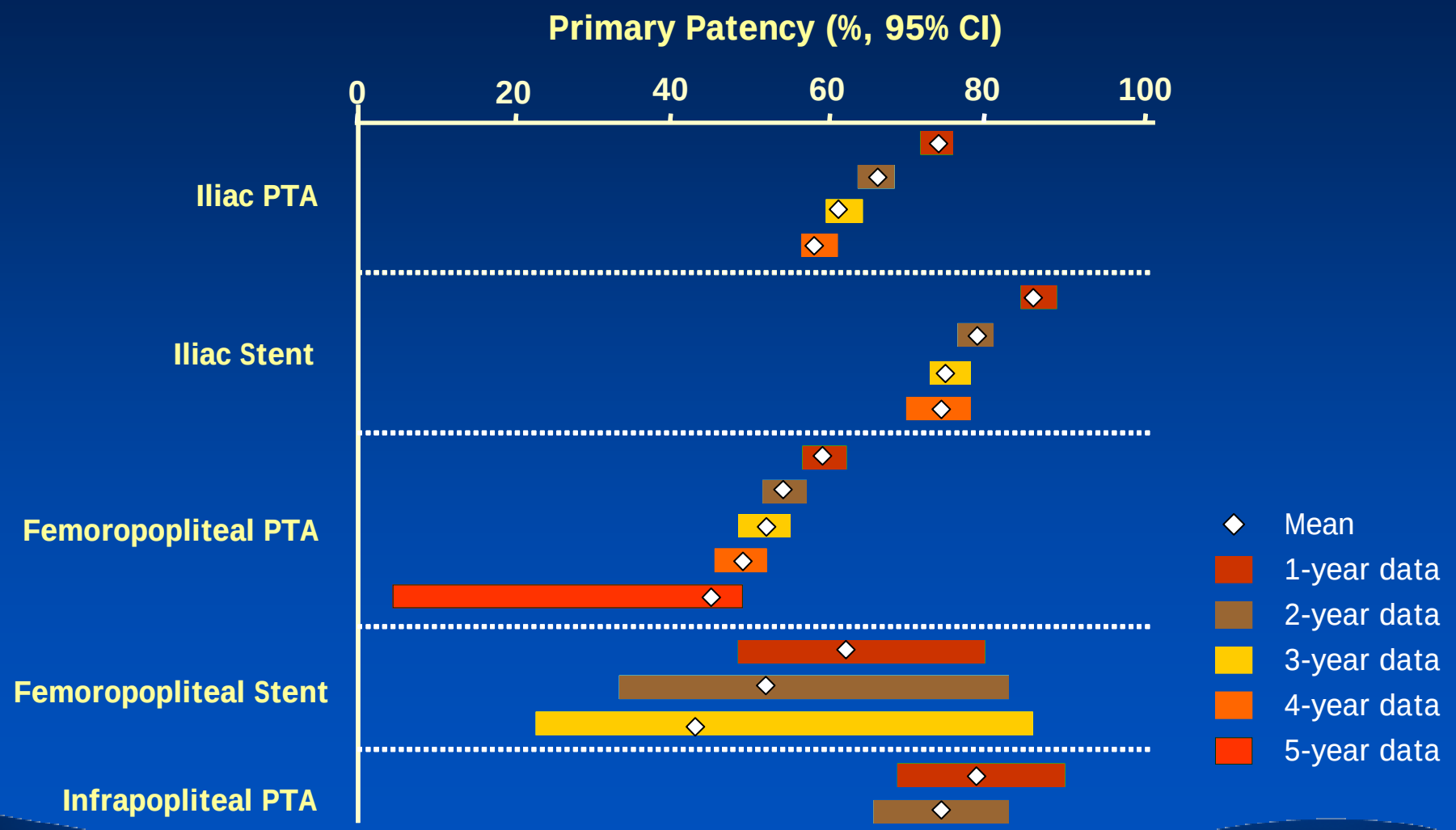
Lazaris AM et al. Eur J Vasc Endovasc Surg 2006; 32: 668-674

RESULTS of PTA

Technical success

- The technical success rates of infrapopliteal angioplasty range between 78% and 100%.
- Occlusion length >10 cm is an adverse factor both for technical success and patency.

Durability of Endovascular Procedures



Hirsch AT, et al. *J Am Coll Cardiol*. 2006;47(6):e1-e192.

Results of Tibioperoneal Angioplasty

Author	Year	No. of Limbs	Patency Rate (%)	Limb Salvage(%)	F/U (mos)
Bakal	1990	43	86	67	24
Schwarten	1991	112	97	83	24
Bull	1992	168	80	85	26
Wagner	1993	158	94	88	17
Durham	1994	14	N/A	77	17
Varty	1995	40	68	77	24

Fraser SCA. Radiology 1996;200:33-43

Results of Tibioperoneal Angioplasty

- 215 patients/266 limbs
  - 60% with lifestyle limiting intermittent claudication
  - 40% with critical limb ischemia
- Successful Revascularization in 91% of lesions (408/449 lesions)
- Five Year Follow-Up
  - Need for surgical revascularization---8%
  - Above-Knee Amputation---2%
  - Below-Knee Amputation---7%
  - Transmetatarsal Amputation---9%
  - **Survival---56%**

Dorros G. Unpublished Data

Discrepancy between primary patency and clinical success

- Primary patency rates for PTA vary widely
  - 13% to 81% at 1 year
  - 48% to 78% at 2 years.

- The limb salvage rate for PTA
  - 77% to 89% at 1 year
  - 94% at 3 years (one report).

- The limb salvage rate for surgery
  - 81% to 88% at 1 year
  - 88 at 2 years.
  - 80 at 3 years.

Discrepancy between primary patency and clinical success

- This feature is more prominent in patients with tissue loss, especially with ulcers, than in those with rest pain.
- Ulcer healing reduces the oxygen demand and as a consequence less blood flow is generally required to maintain tissue integrity compared with the amount required for initial ulcer healing.
- Collaterals may therefore be sufficient to preserve tissue integrity if there is no further injury.

Factors Influencing the Patency of Infrapopliteal Artery after PTA

- Diabetes: lower rate of limb salvage & ulcer healing.
- Renal insufficiency
- Elevated lipoprotein (a)
- Presence of ulcer or gangrene
- Lack of angiographic improvement
- Extensive atherosclerotic disease

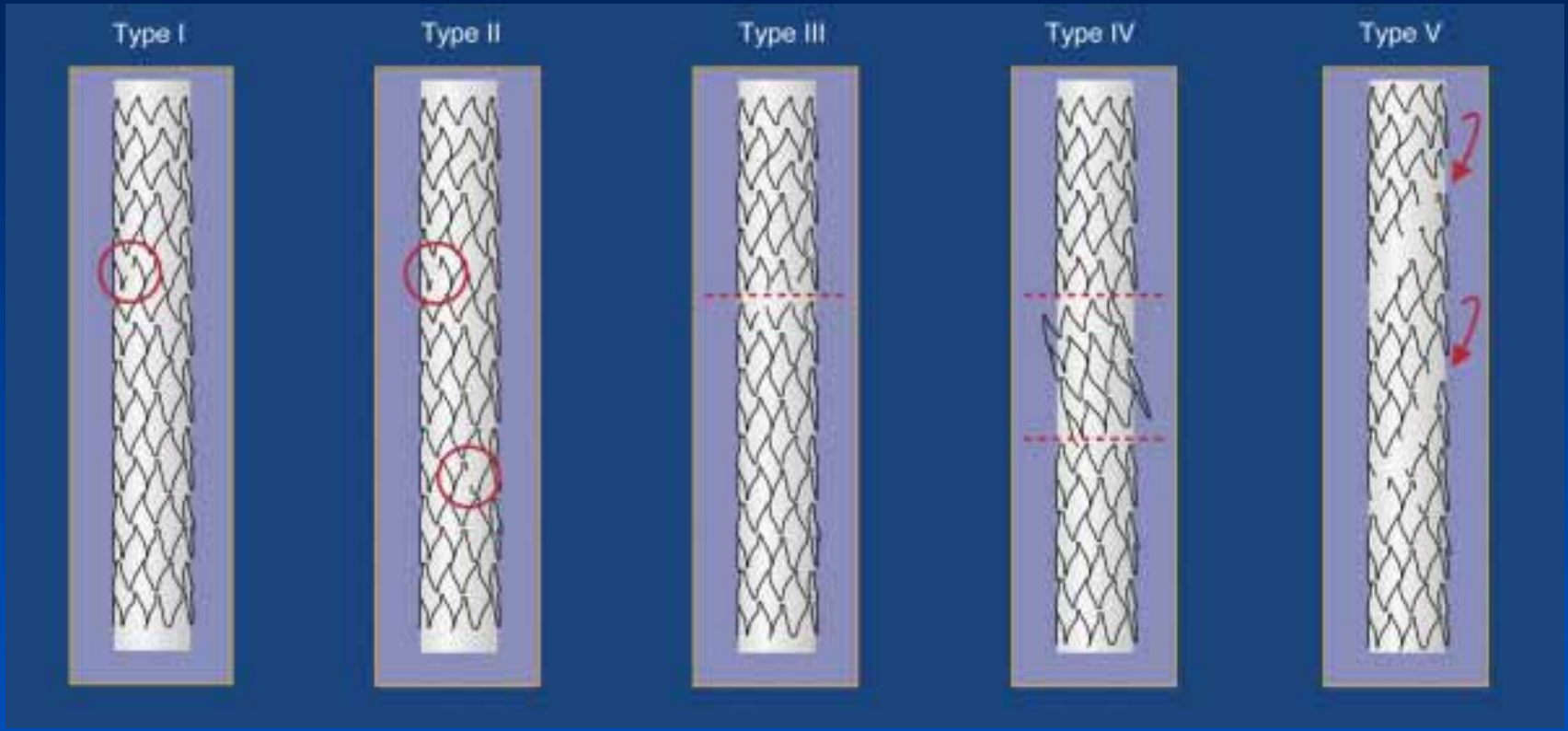
Complications of PTA

- Complication rate : 2-6%
- Puncture site hematoma
- Acute arterial occlusions by spasm or dissection: (stent or liberal use of antispasmodics)
- Embolic occlusion: thrombolysis or thrombectomy
- Arterial perforations (3.7%): rarely require intervention
- 30-day mortality : 1.7% vs. bypass surgery :1.8-6%

Categories and definitions of Stent Fractures and Deformations

Compression	Stent deformity with luminal narrowing
Collapse	Complete compression of stent mesh
Type I	Fracture of 1 stent strut
Type II	Fracture of >1 stent strut
Type III	Complete separation of stent segments
Type IV	Separation and misalignment of stent segments
Type V	Spiral stent fracture

Categories of Stent Fractures



Catheter Cardiovasc Interv. 2007 Sep;70(3):460-2

Incidence, Anatomical Location, and Clinical Significance of Compression and Fractures in Infrapopliteal Balloon-Expandable metal Stents

- 63 patients who had previously been treated with angioplasty and infrapopliteal stenting.
- 84 limbs, 191 lesions, 369 balloon-expandable coronary stents

Anatomical location of infrapopliteal balloon-expandable stents

	Upper	Mid	Distal	Total
Tibioperoneal		34 (9.2%)		34 (9.2%)
Anterior tibial	89 (24.1%)	46 (12.5%)	60 (16.3%)	195 (52.8%)
Posterior tibial	27 (7.3%)	17 (4.6%)	19 (5.1%)	63 (17.1%)
Peroneal	47 (12.7%)	23 (6.2%)	7 (1.9%)	77 (20.9%)
				369 (100%)

J ENDOVASC THER 2009;16:15-22

- Single fracture and most of the compression events occurred in the **distal third of the ATA.**

Fractures and Deformations of Infrapopliteal Balloon-Expandable Stents
Anatomical incidence and Clinical implications

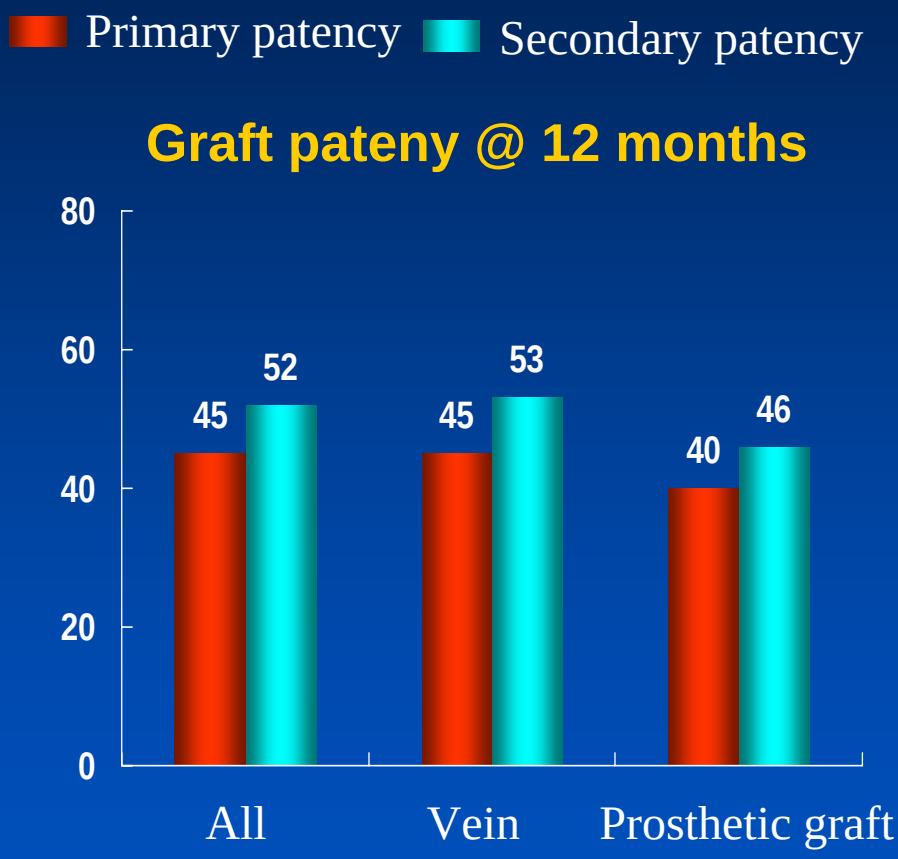
Event	Stent Material	Artery	Location	Angiography
Fracture IV	Stainless steel	Anterior tibial	Lower	Reocclusion
Compression	Stainless steel	Anterior tibial	Upper	Restenosis>50%
Compression	Stainless steel	Anterior tibial	Lower	Restenosis>50%
Collapse	Cobalt-chromium	Anterior tibial	Lower	Reocclusion
Compression	Stainless steel	Anterior tibial	Lower	Reocclusion
Compression	Stainless steel	Anterior tibial	Lower	Reocclusion
Collapse	Cobalt-chromium	Anterior tibial	Lower	Reocclusion
Compression	Stainless steel	Anterior tibial	Lower	Reocclusion
Compression	Cobalt-chromium	Anterior tibial	Lower	Reocclusion
Compression	Stainless steel	Anterior tibial	Lower	Restenosis>50%
Compression	Stainless steel	Anterior tibial	Lower	Restenosis>50%
Compression	Stainless steel	Posterior tibial	Lower	Restenosis>50%

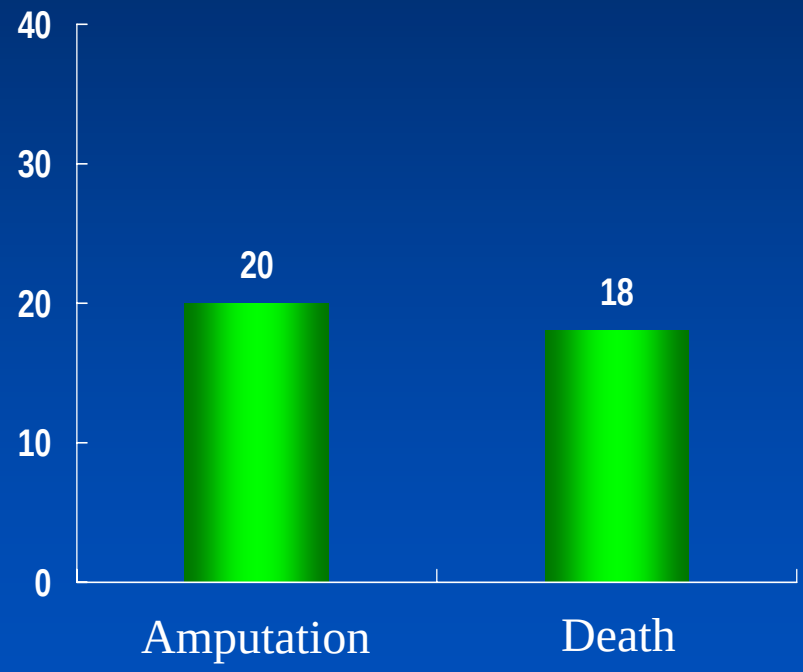
J ENDOVASC THER 2009;16:15-22

RESULTS of Surgery

Result of bypass surgery

Total population: 517 patients

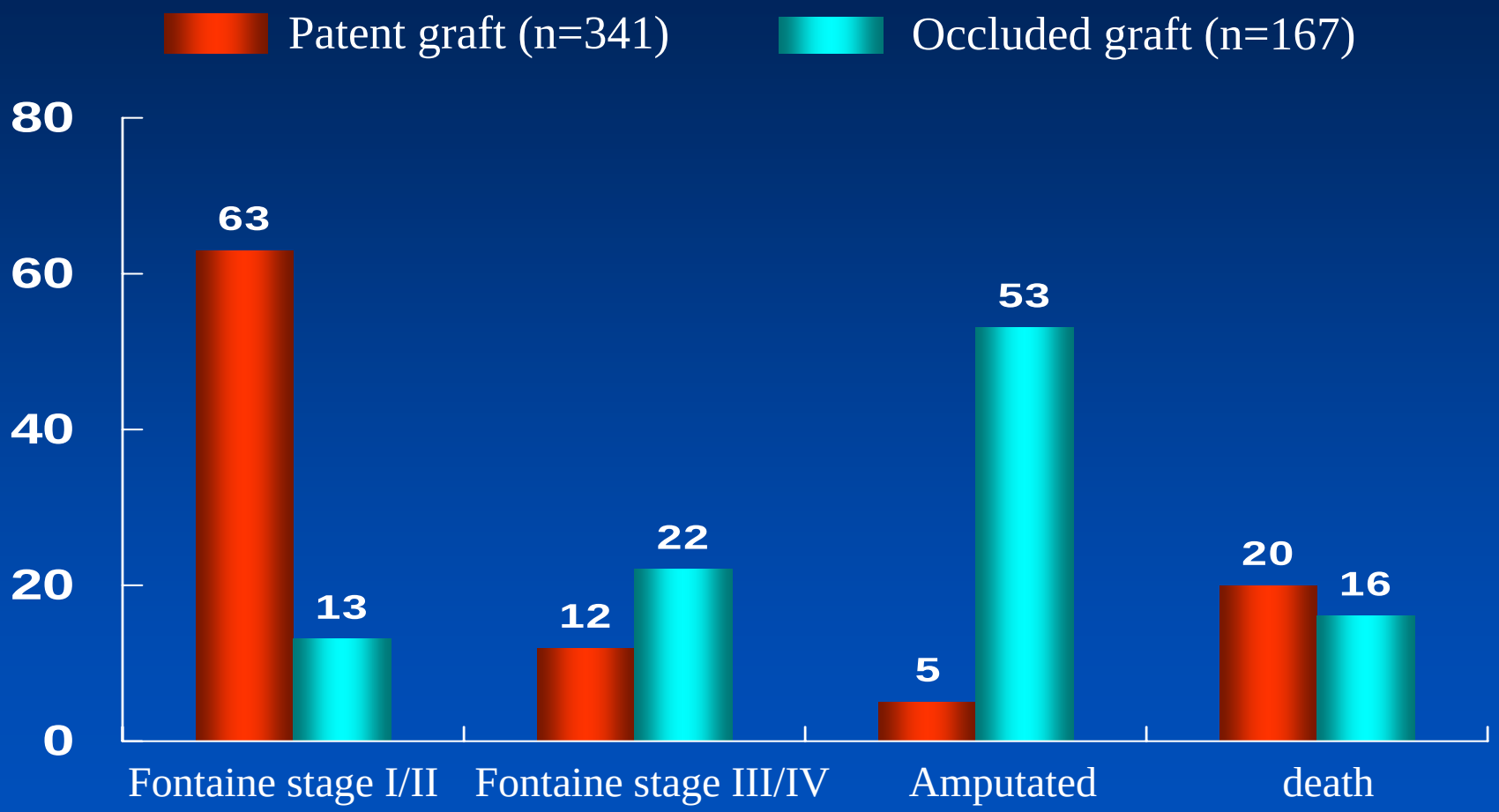




Eur J Vasc Endovasc Surg 1999;17:77–83

Patent vs. occluded graft

Clinical outcomes @ 12 months

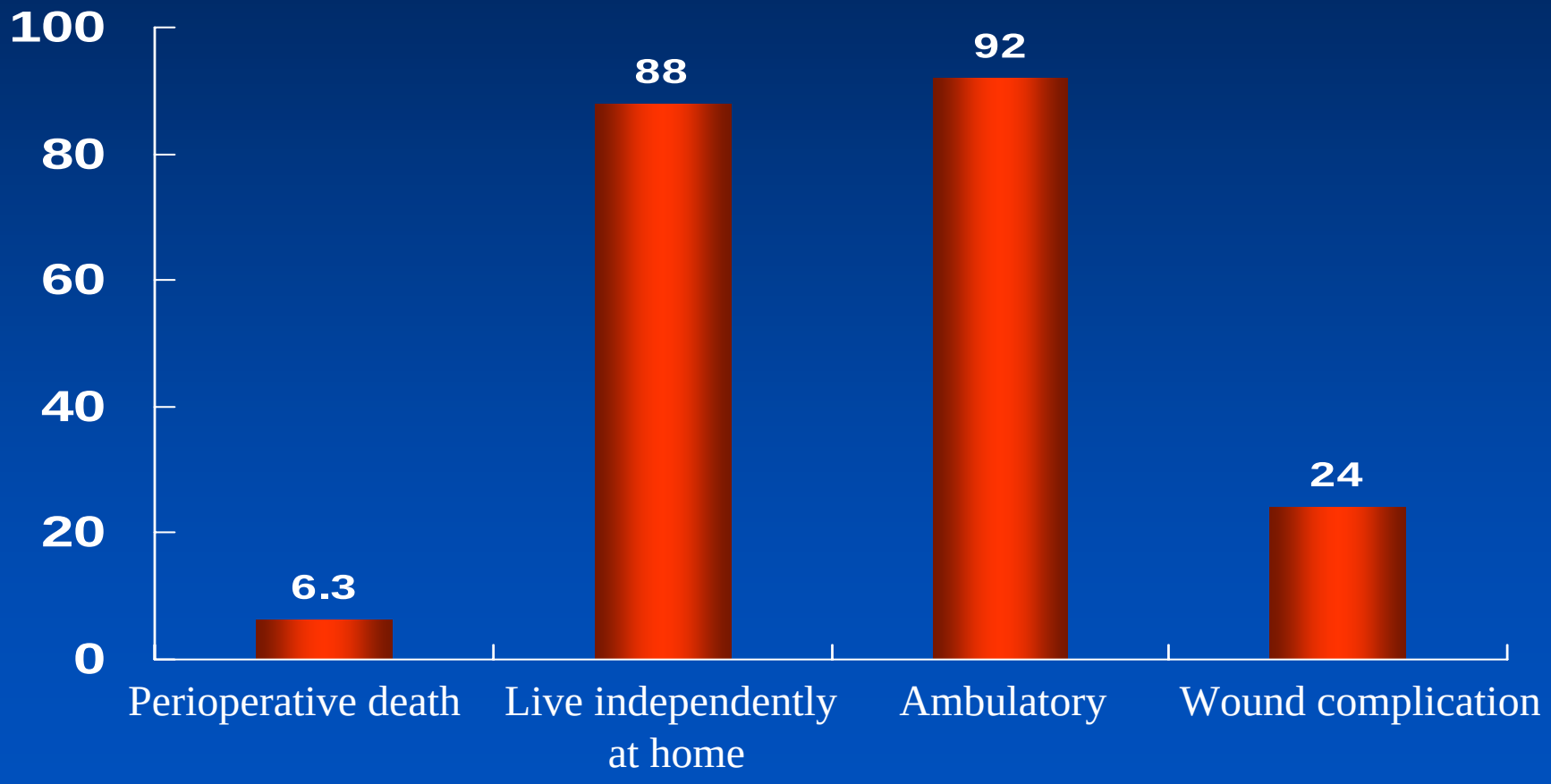


Eur J Vasc Endovasc Surg 1999;17:77–83

Early clinical outcomes after surgery

Total population: 112 patients

Wound (operative and ischemic) healing : a mean of 4.2 months, and
22% had not achieved complete wound healing at the time of last FU or death.

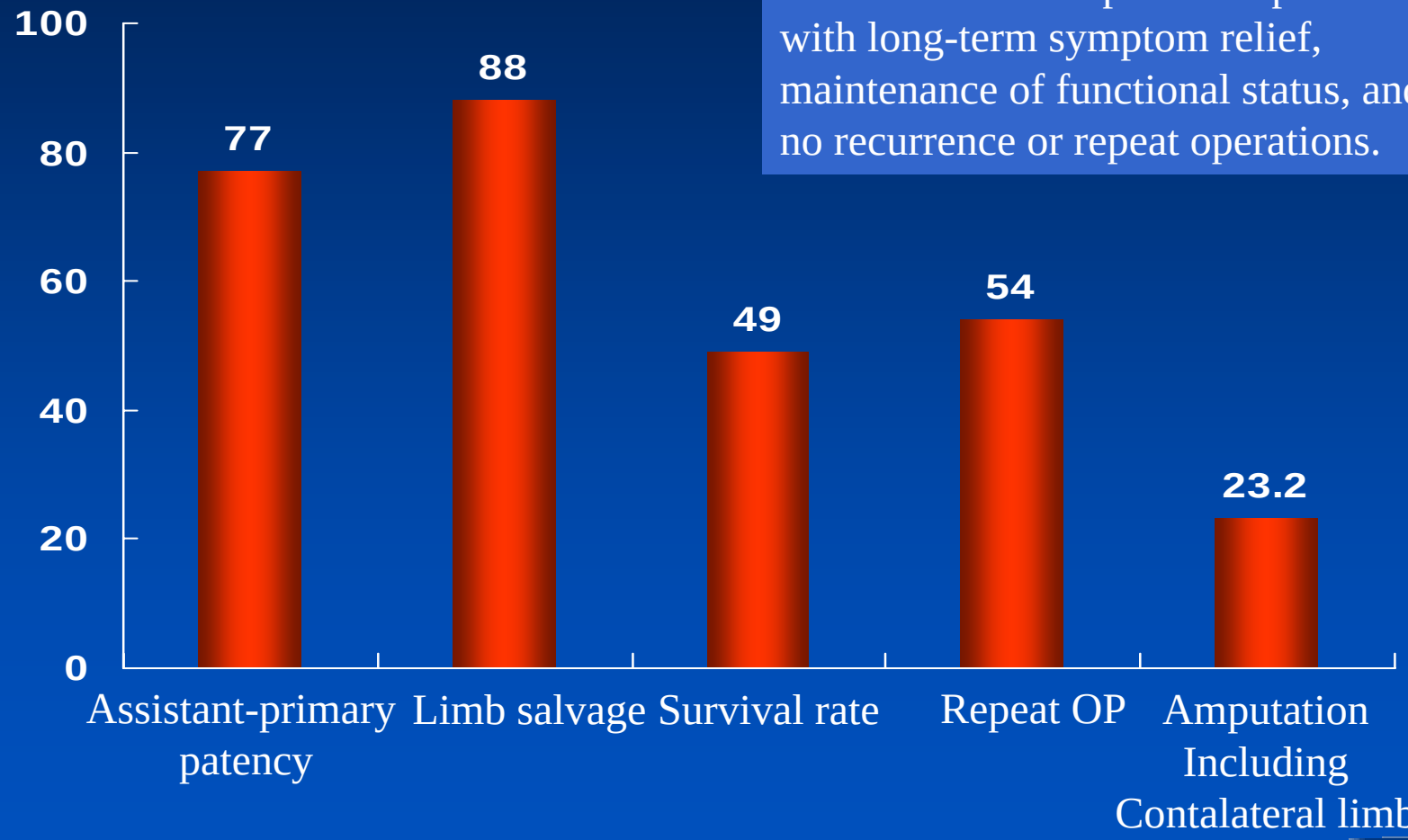


J Vasc Surg. 1998;27:256-63

Long-term outcomes

Clinical outcomes @ 5 years

Only 14.3% achieved the ideal surgical result of an uncomplicated operation with long-term symptom relief, maintenance of functional status, and no recurrence or repeat operations.



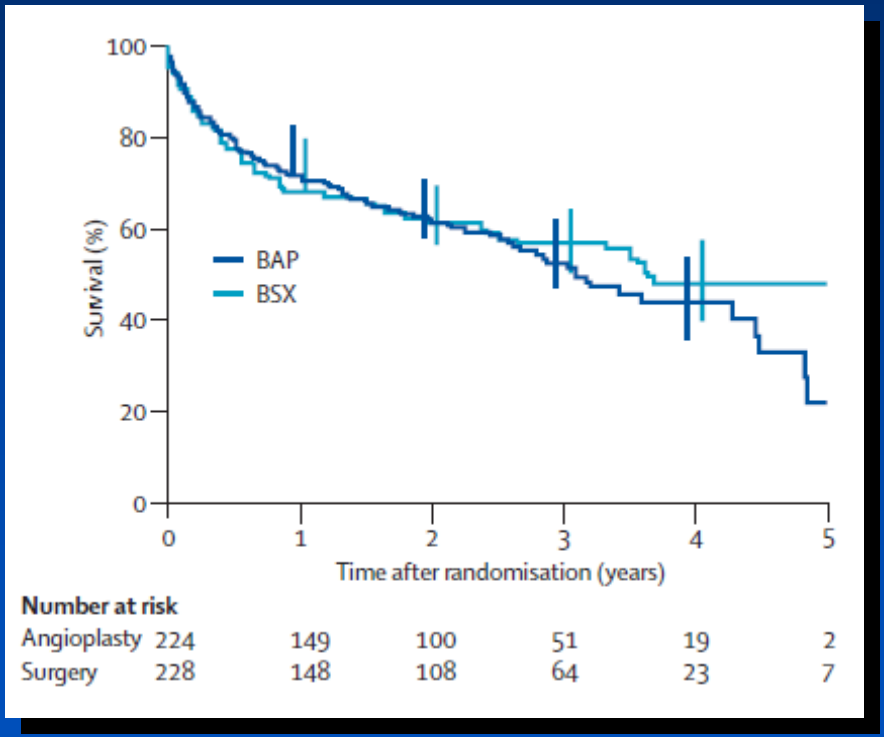
J Vasc Surg. 1998;27:256-63

BASIL trial

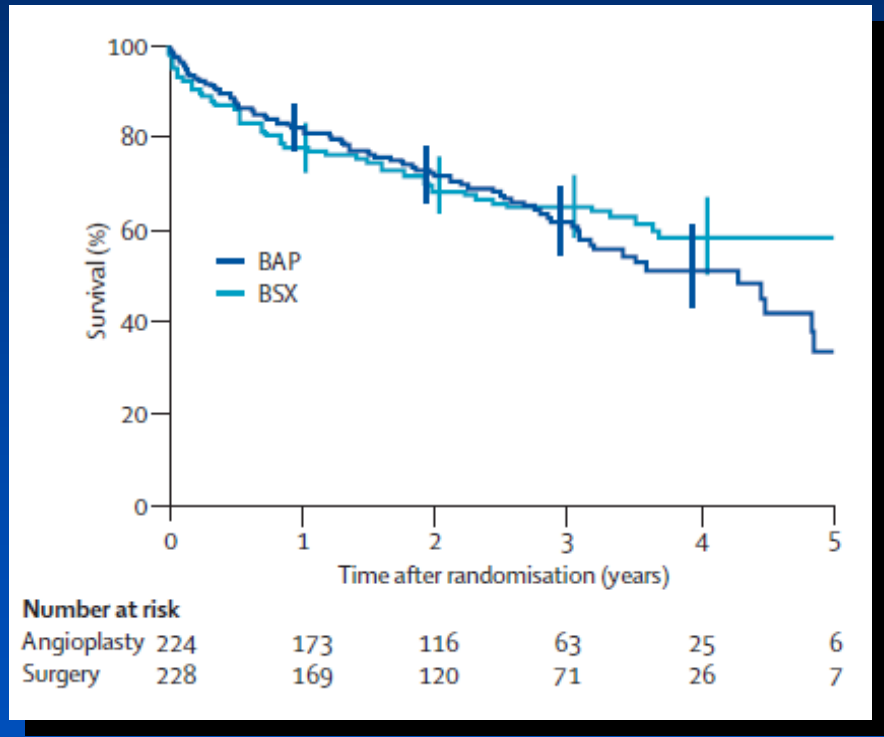
(Multicenter randomized trial for infrainguinal severe ischemia)

Surgery vs. Balloon angioplsty

Amputation-free survival



Mortality-free survival



Lancet. 2005;366:1925-34

New approach

68yo Male with Diabetic Foot

- Hypertension, Long standing diabetes
- DM ESRD on HD

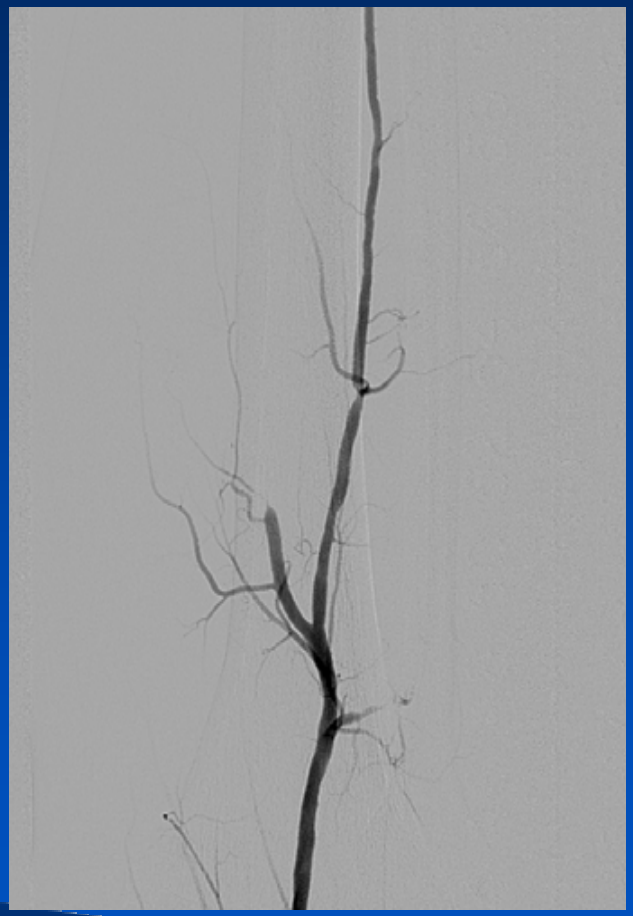
First Treatment

Before

After

However, Incomplete wound healing and Restenosis Occurred and We need more than balloon…

Three months later



2nd Treatment

New approach

- Laser angioplasty
- Cutting balloon.
- Coated stent
- Drug-eluting stents
- Absorbable metal stent

New approach

- Laser angioplasty
- Cutting balloon.
- Coated stent
- Drug-eluting stent
- Absorbable metal stent

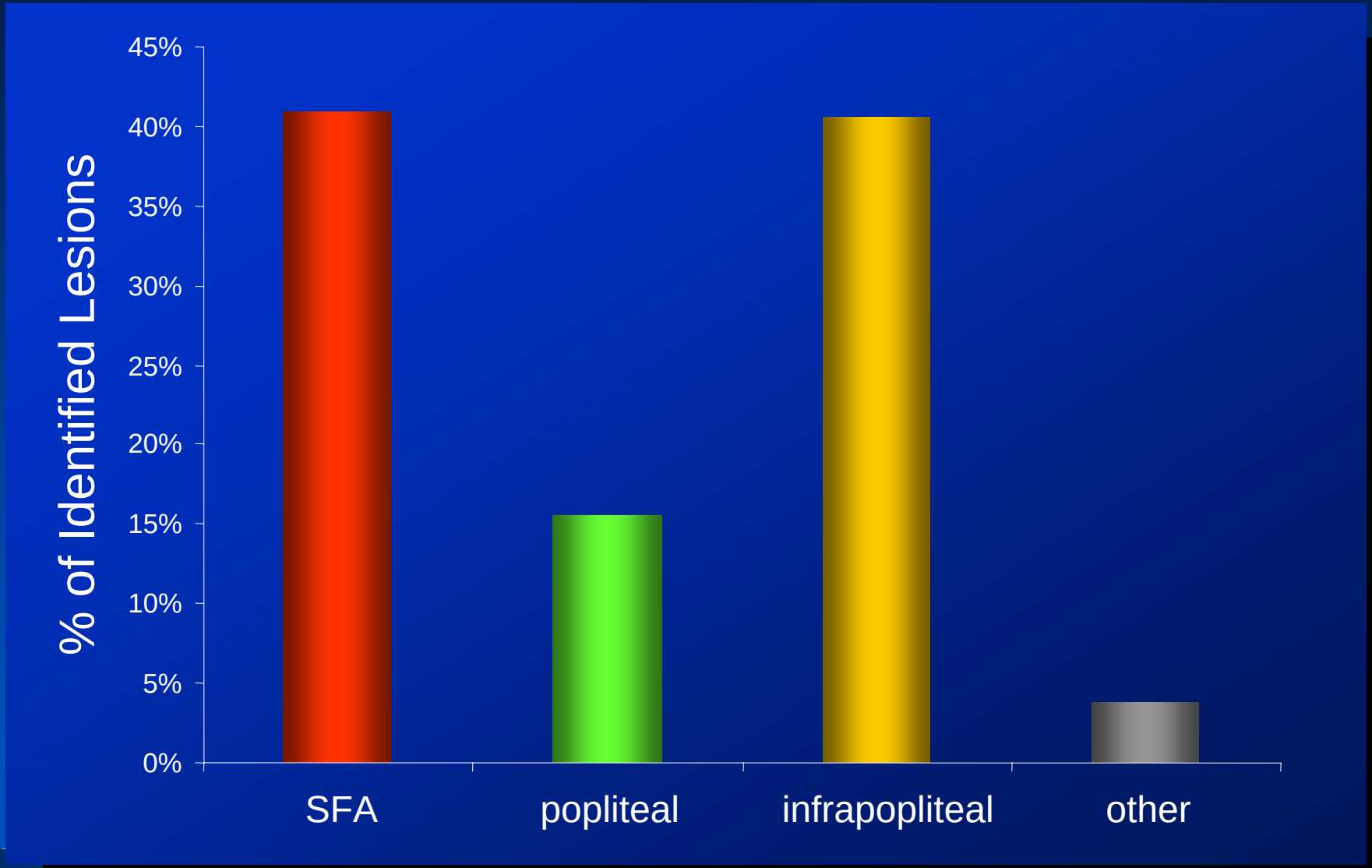
Laser Angioplasty for Critical Limb Ischemia

Results of the LACI Phase 2 Clinical Trial

LACI Phase 2 Registry

- **Prospective, multi-center study**
- **Patients with CLI**
  - Rutherford Category 4-6
  - poor surgical candidates
- **Treatment:** ELA of SFA, popliteal and/or infrapopliteal arteries, with adjunctive PTA and optional stenting
- **Primary Endpoint**: limb salvage at 6 months
  - freedom from amputation at or above the ankle

Vascular Lesion Locations



Angiographic Results

Visual assessment

		%DS			
Location	n*	Baseline	Post-laser	Final	Stented
SFA	280	91%	56%	16%	61%
Popliteal	37	94%	53%	14%	38%
Infrapopliteal	89	92%	53%	24%	16%

*n = number of treated lesions

- Laser provided about half of the net luminal gain
- Stenting was performed preferentially in larger vessels
- Below the knee, final %DS was slightly higher

Adjudicated SAEs

	In-hospital	All Follow-up	Total
Death	0	15	15
Major amputation	2	9	11
Nonfatal MI or Stroke	0	2	2
Reintervention	1	23	24
Hematoma w/ surgery	1	0	1
Acute limb ischemia	0	1	1
Perforation w/ surgery	0	0	0
Bypass	0	3	3
Endarterectomy	0	1	1

48 (33%) of patients experienced ≥1 SAE

6-Month Results

Total enrollment	155 limbs
death	17
lost to follow-up	11
Reached 6-month follow-up	127
Major amputation among survivors	9
Survival with limb salvage	118/127 = 93%

Main Endpoints

per-patient basis

	LACI	Control	p
Surgical intervention*	2%	34%	<.001
At 6 months:			
Died	10%	13%	ns
Survived with:			
Limb salvage	93%	87%	ns
Persistent CLI	34%	31%	ns

* bypass or endarterectomy

New approach

- Laser angioplasty
- Cutting balloon.
- Coated stent
- Drug-eluting stents
- Absorbable metal stent

Cutting balloons

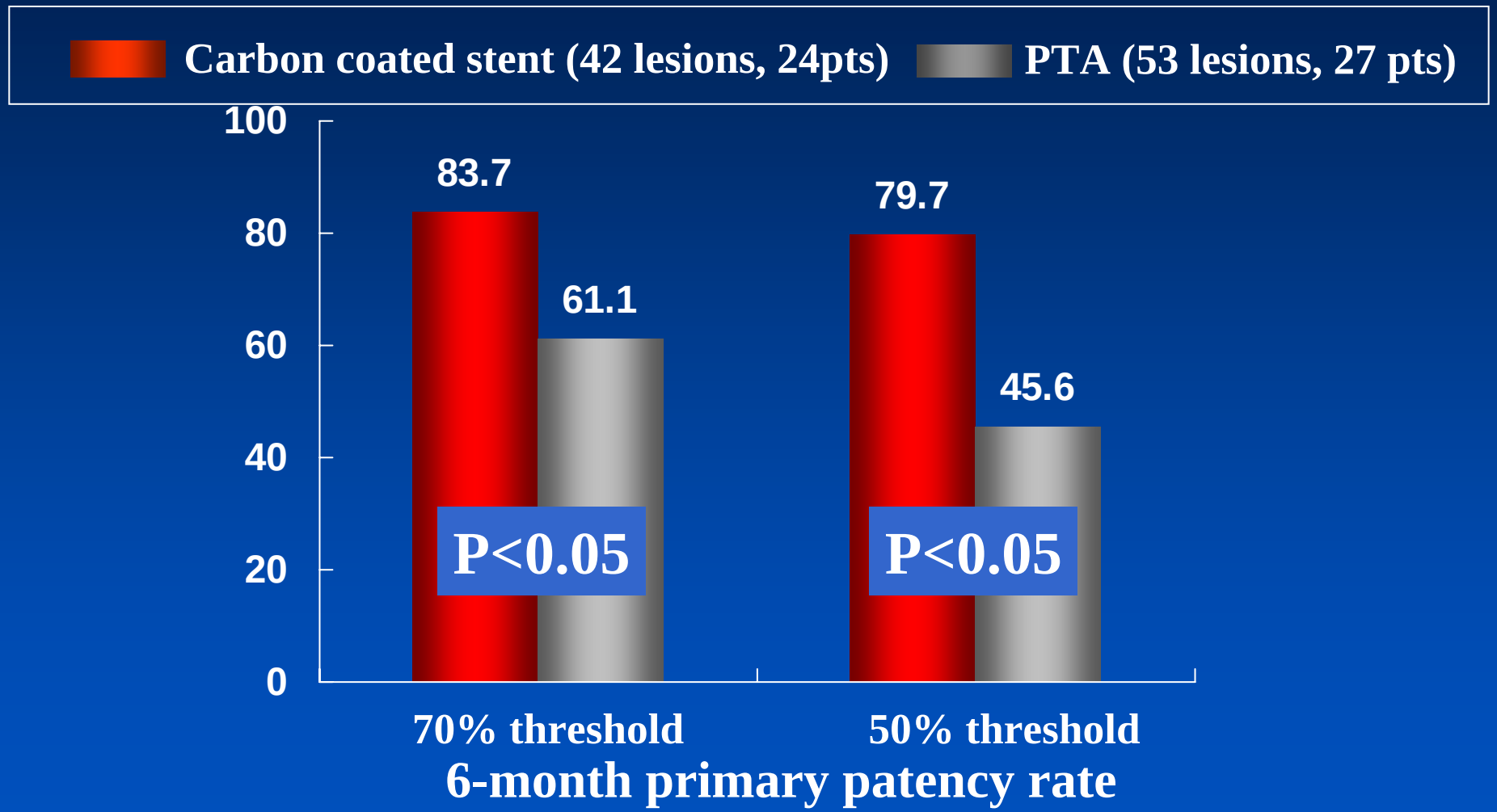
- Although application of this technique in peripheral arteries is still limited, it appears that it is effective in the treatment of esistant femorodistal bypass stenoses and complex infrapopliteal obstructions such as ostial and bifurcational lesions

New approach

- Laser angioplasty
- Cutting balloon.
- Coated stent
- Drug-eluting stents
- Absorbable metal stent

Carbofilm coated stents vs. PTA

Prospective randomized trial



Cardiovasc Intervent Radiol. 2006;29:29-38

New approach

- Laser angioplasty
- Cutting balloon.
- Coated stent
- Drug-eluting stents
- Absorbable metal stent

SiroBTK study with SES

30 patients, 62 arteries, 106 SES

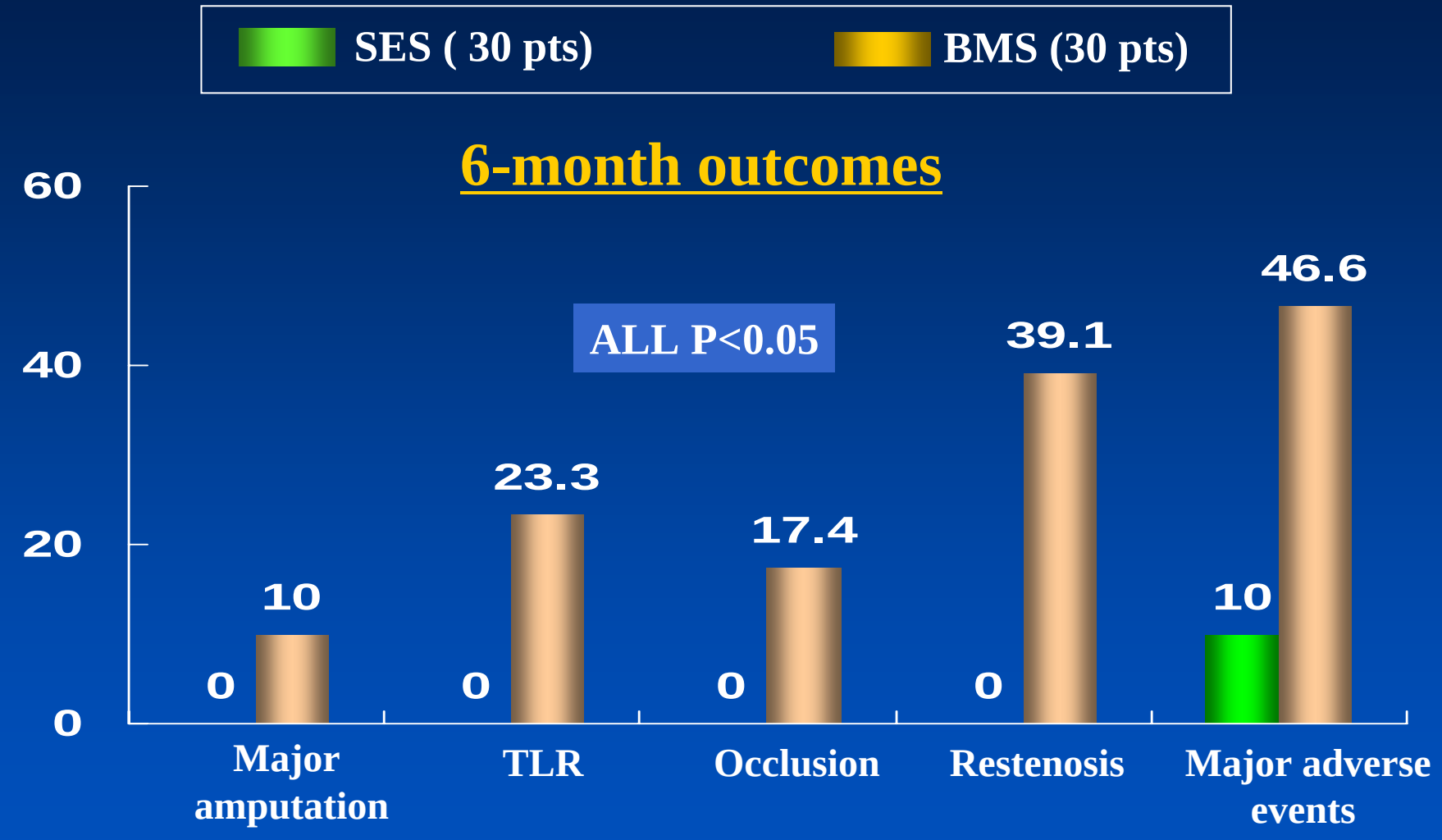
Primary endpoint: clinical improvement and healing of ulcer @ 1 & 7.7 months

- Angiographic and procedural success : 100%.
- 7 months outcomes

- Amputatiton 1 toe in one patient and 1 mid-foot in another.
- **Limb salvage : 100% of patients.**
- Death : two cardiac deaths unrelated to CLI
- Three recurrent homolateral claudication.
- **Mid-term clinical improvement : 100%**
- **Primary patency: 97% (56 patent arteries on 58 arteries).**

J Endovasc Ther. 2007;14:241-50.

SES vs. BMS

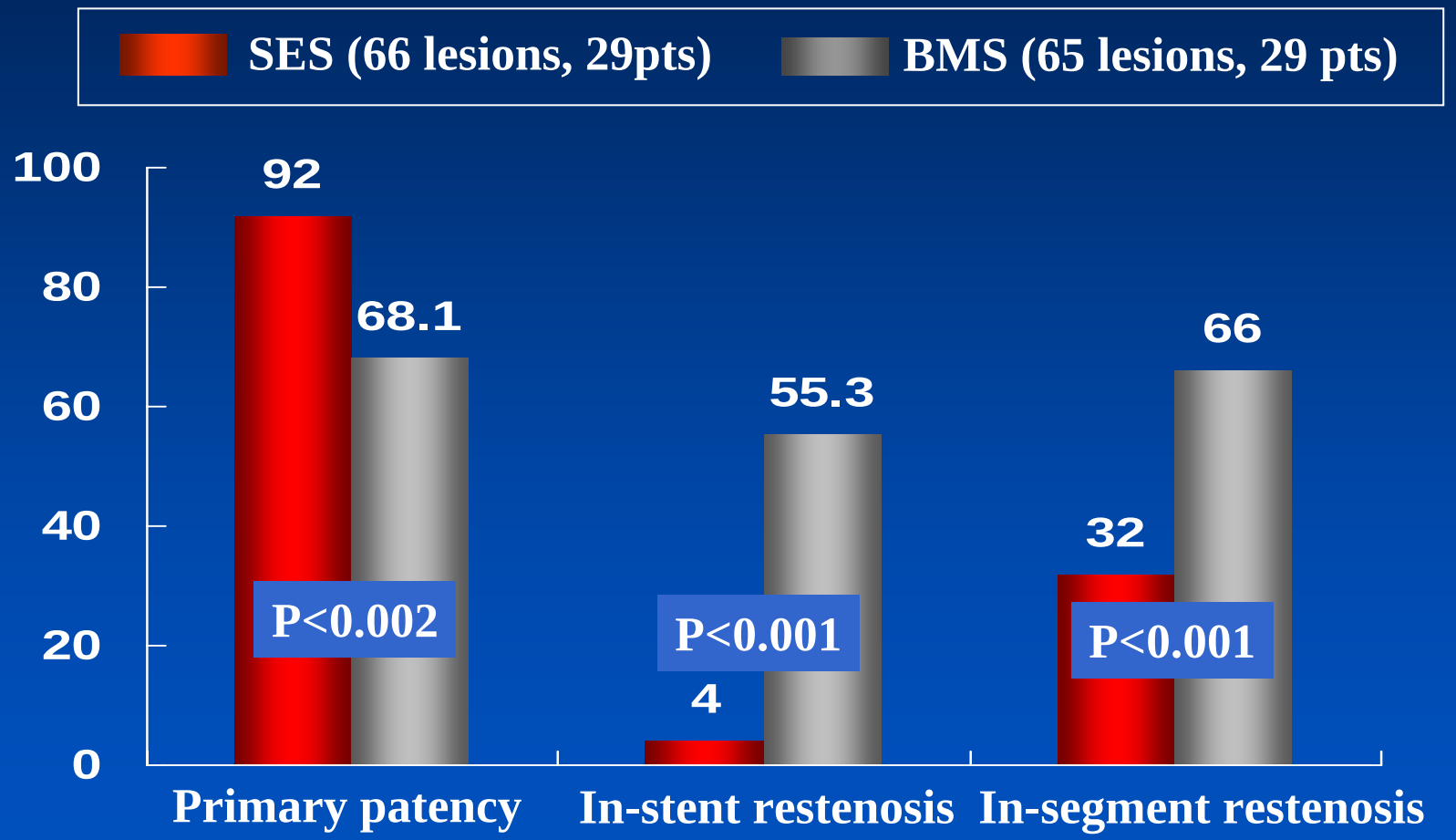


Eurointervention 2006;2:169–174.

SES vs. BMS for CLI

SES (29 pts) vs. BMS (29 pts) for bailout use

Endpoint: 1-year angiographic and clinical outcome

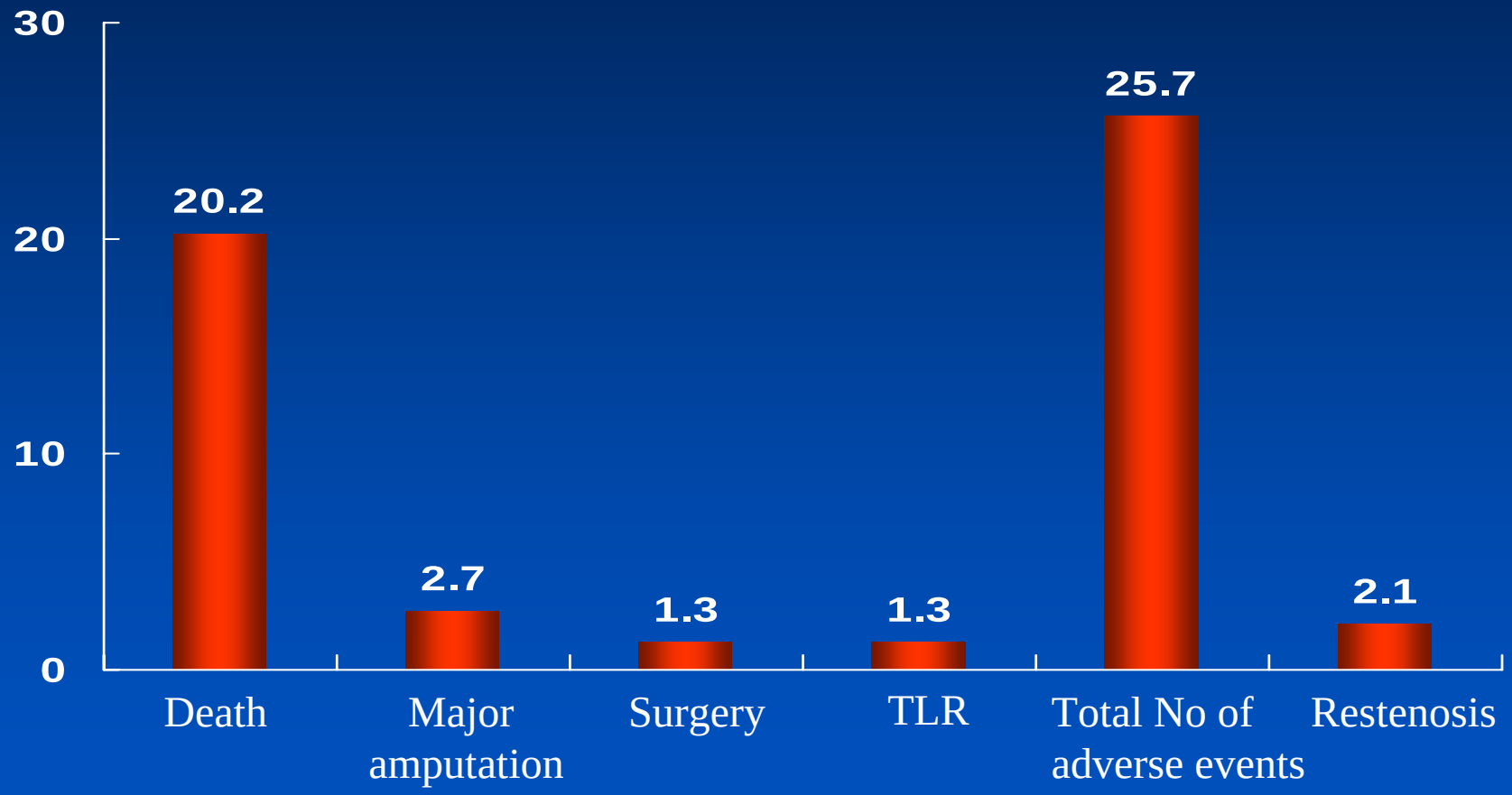


J Endovasc Ther 2005;12:685–95.

BTK SES registry

Prospective nonrandomized single center registry

SES for Sxmatic focal infrepopliteal obstruction (n=74 pts)

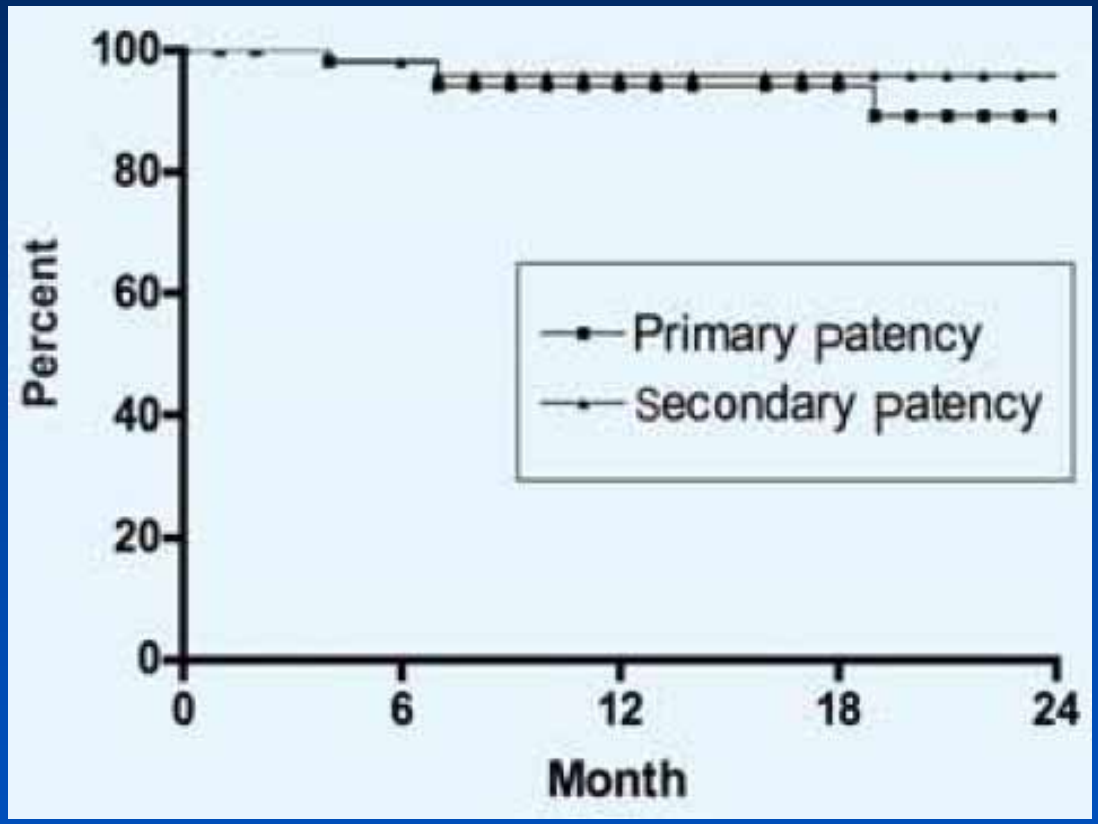


Endovascular today 2007;August.71-74

BTK SES registry

Prospective nonrandomized single center registry

SES for Sxmatic focal infrepopliteal obstruction (n=74 pts)



Patency at 24 months

Primary: 89.2%

Secondary: 95.9%

Endovascular today 2007;August.71-74

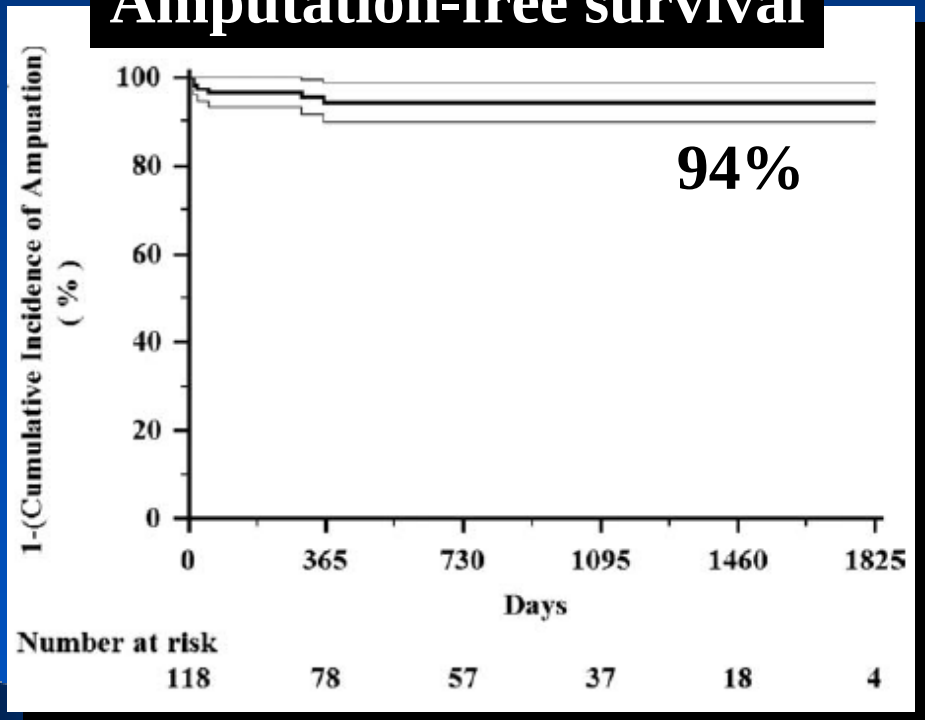
PaRADISE trial

(PReventing Amputation using Drug-elutIng StEnt)

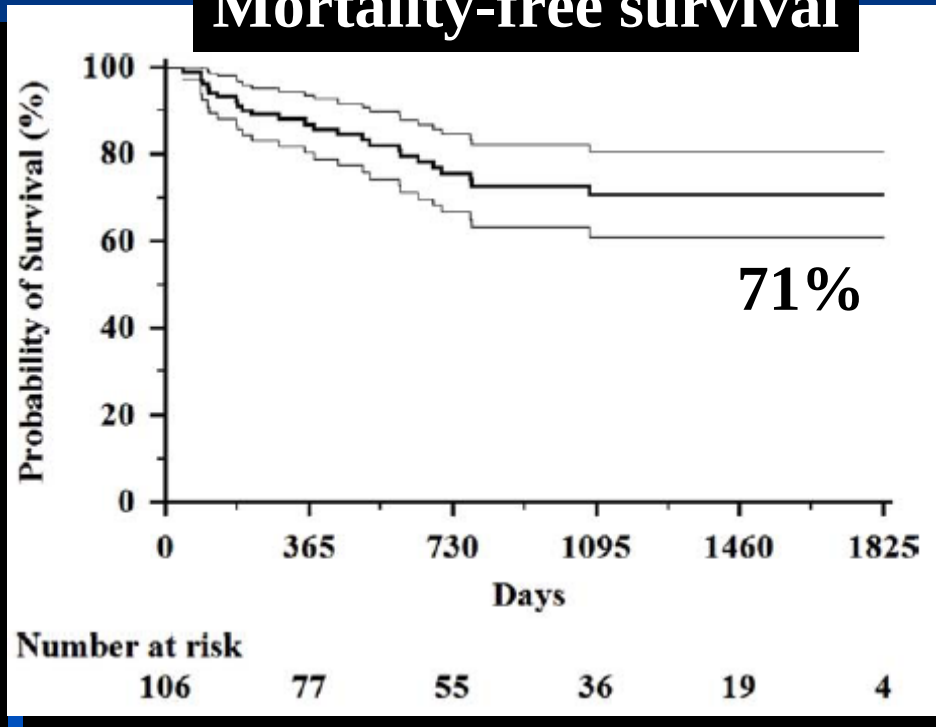
Critical limb ischemia (106 pts, 108 limbs, SES 83%, PES 17%)

- Stent number/limb: 1.9±0.9, Stent length : 60±13 mm
- Target limb revascularization: 15%
- Angiographic restenosis: 12% (follow-up rate 35%)

Amputation-free survival



Mortality-free survival

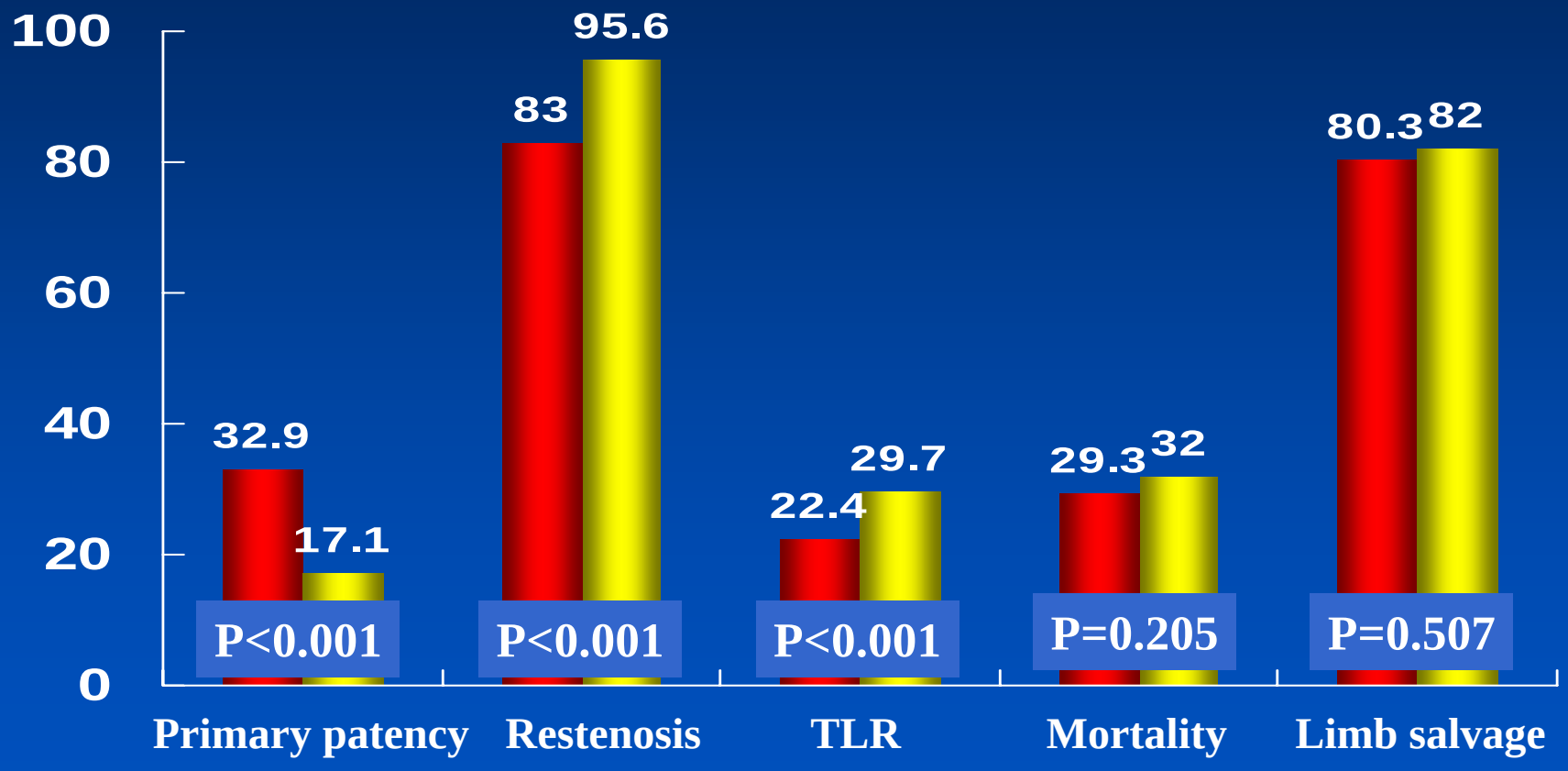


Feiring AJ et al. J Am Coll Cardiol. 2010;55:1580-9

SES vs. BMS

SES (75 limb, 153 lesions) BMS (47 limb, 77 lesions)

3-year outcomes



Siablis D et al. J Vasc Interv Radiol 2009; 20:1141–1150

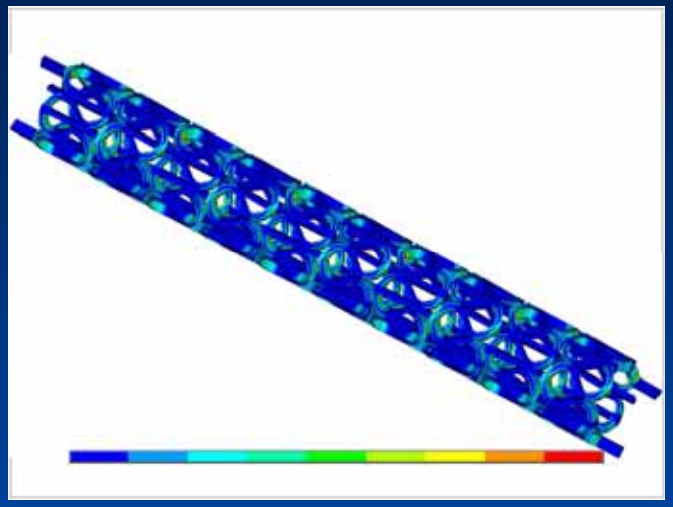
On-going trial

Study	Test device	Control	Number
Drug-eluting balloon			
PICCOLO	PEB	Balloon	114
Drug-eluting stent			
ACHILESS	Cypher select	Balloon	200
DESTINY	Xience V	Vision (BMS)	140
YUKON	SES (Yukon)	Stent (Yukon)	130

New approach

- Laser angioplasty
- Cutting balloon.
- Coated stent
- Drug-eluting stents
- Absorbable metal stent

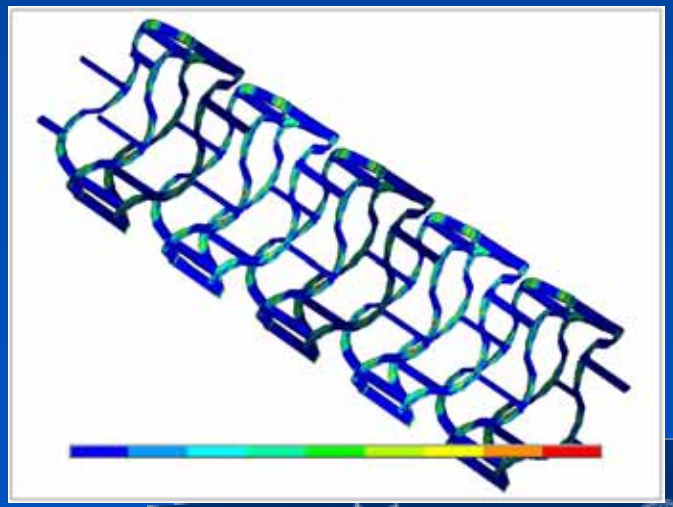
Absorbable Magnesium Stent



FEA: Crimped state

Recoil	~ 5%
Foreshortening	< 5%

* Investigational device only - not for sale -



FEA: Fully expanded state

Clinical Results

BEST-BTK

First in Man experience with the Biotronik absorbablE metal StenT Below The Knee

- 20 CLI patients (Rutherford 4-5) with BTK pathology
- Implants performed between December ‘03 – January ‘04

Patient demographics (n=20)

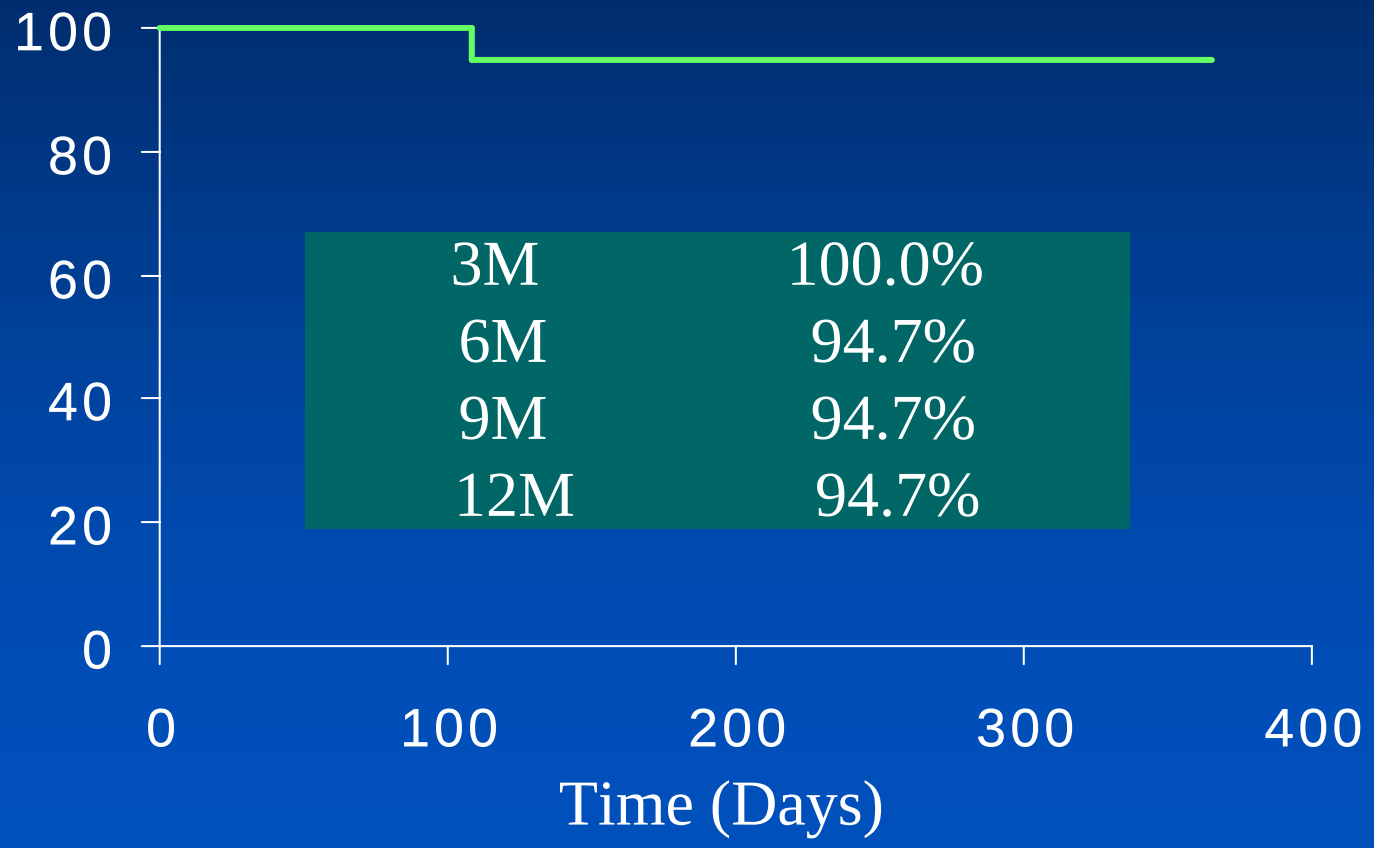
Male	10	50%
Female	10	50%
Average age	76 yrs (59 - 96)	
Clinical vascular status		
- Rutherford Class IV	9	45%
- Rutherford Class V	11	55%

Lesion description (n=20)

Average lesion length	11 mm	(2 mm - 20 mm)	
Average vessel diameter	2.7mm	(2.5 mm - 3 mm)	
Average stenosis	84 %	(75% - 95%)	
Dissection		0	0%
Ulceration		1	5%
Thrombus		3	15%
Calcification		14	70%

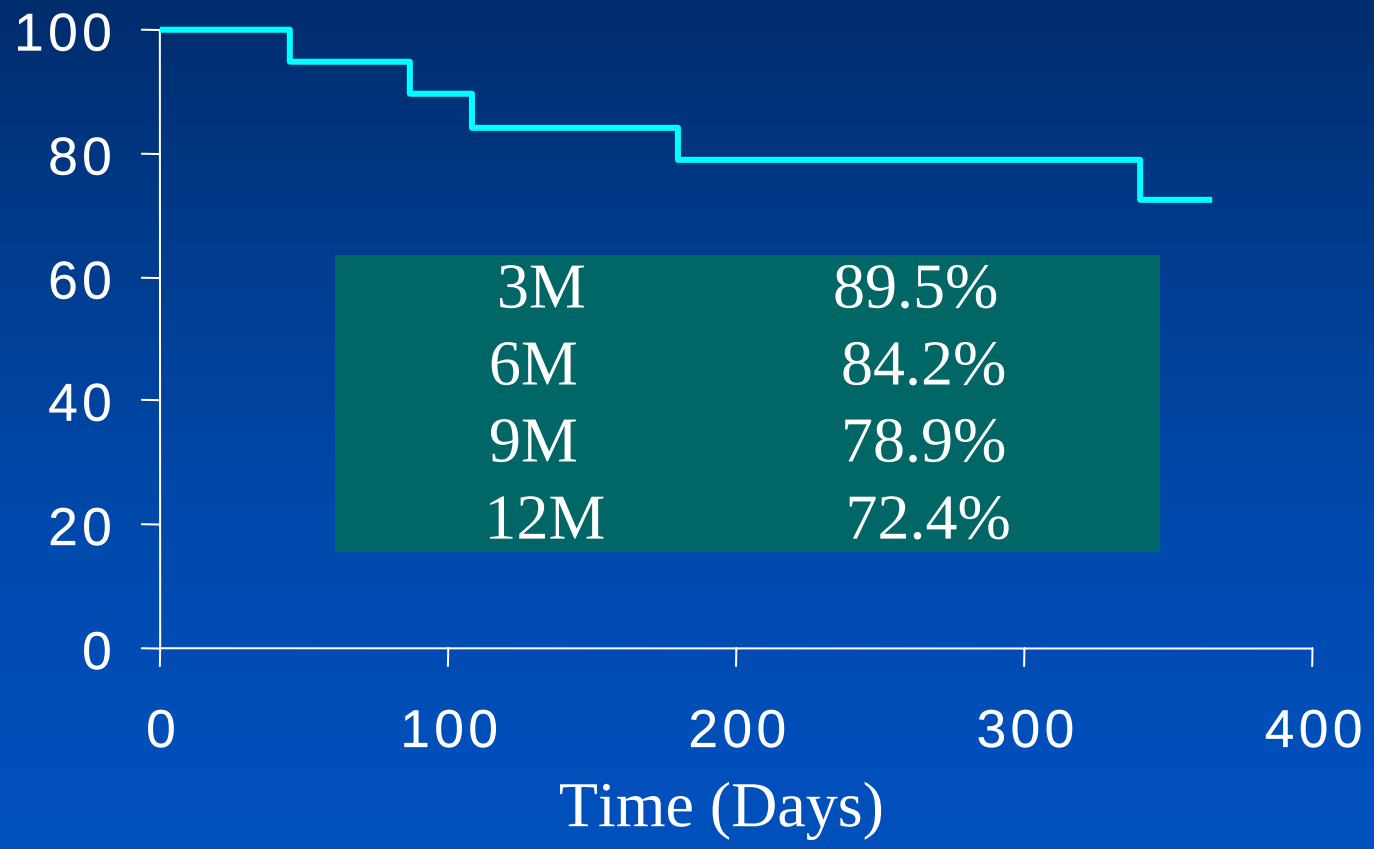
Limb Salvage After One Year

Limb Salvage Rate



High Patency Rate

Primary Clinical Patency



Conclusions I

- PTA is the preferred treatment strategy in patients with infrapopliteal occlusive disease who typically present with critical limb ischemia.
- With tremendous improvements in interventional devices and techniques, long and multiple stenotic and occlusive lesions can be treated successfully with PTA
- PTA carries a lower morbidity and mortality compared with surgery and would be considered as the first treatment option in all patients with critical limb ischemia who would otherwise be offered distal bypass surgery or amputation, as failure rarely precludes surgery.

Conclusions II

- Clinical success is superior to angiographic patency and repeat angioplasty can be performed if there is recurrence of ischaemic symptoms and signs.
- SESs have a consistent and profound effect on the reduction of reobstructions after endovascular procedures.
- while there is growing familiarity and acceptance of DESs in endovascular procedures to treat BTK lesions, we should be considered against the fact that there was no randomized clinical trial data comparing DESs with the current BTK interventional standard of PTA.