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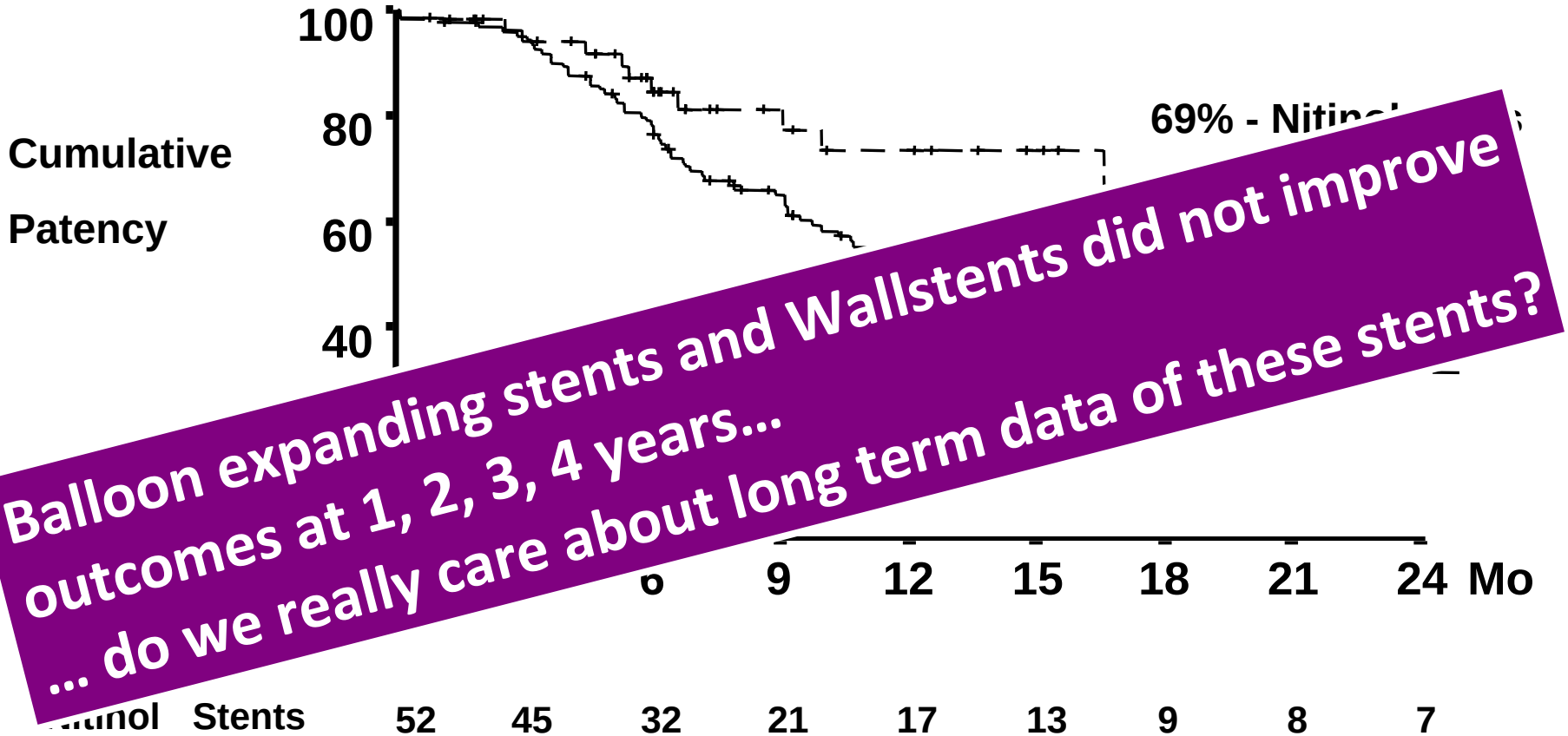
SFA long term results

Martin Schillinger

Long Term Results

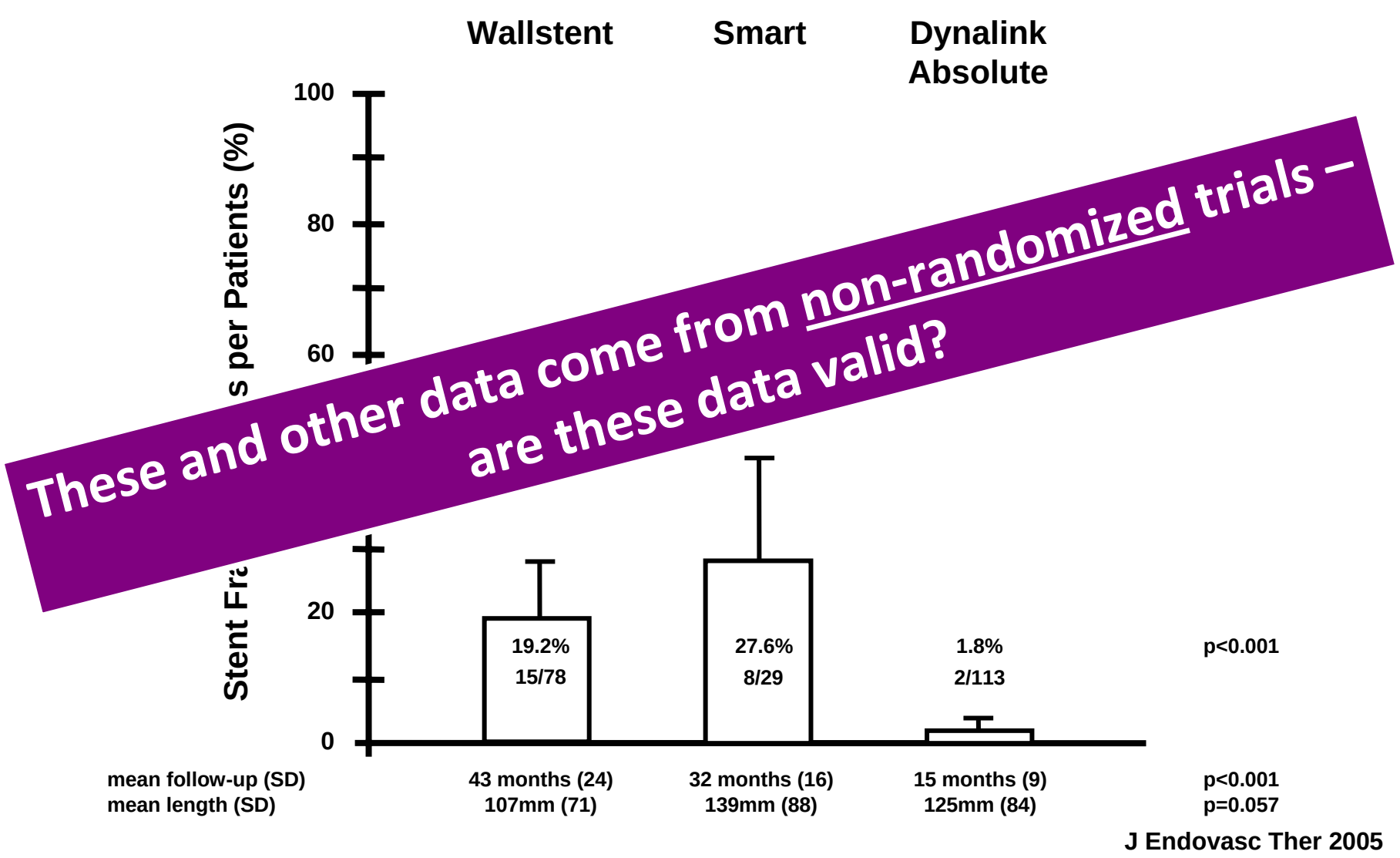


Balloon expanding stents and Wallstents did not improve outcomes at 1, 2, 3, 4 years…
… do we really care about long term data of these stents?

Nitinol	Stents	52	45	32	21	17	13	9	8	7
	Wallstents	123	113	91	69	53	38	33	28	25

Radiology 2004

Long Term Results



These and other data come from non-randomized trials – are these data valid?

Long Term Results ???

20 years… not available

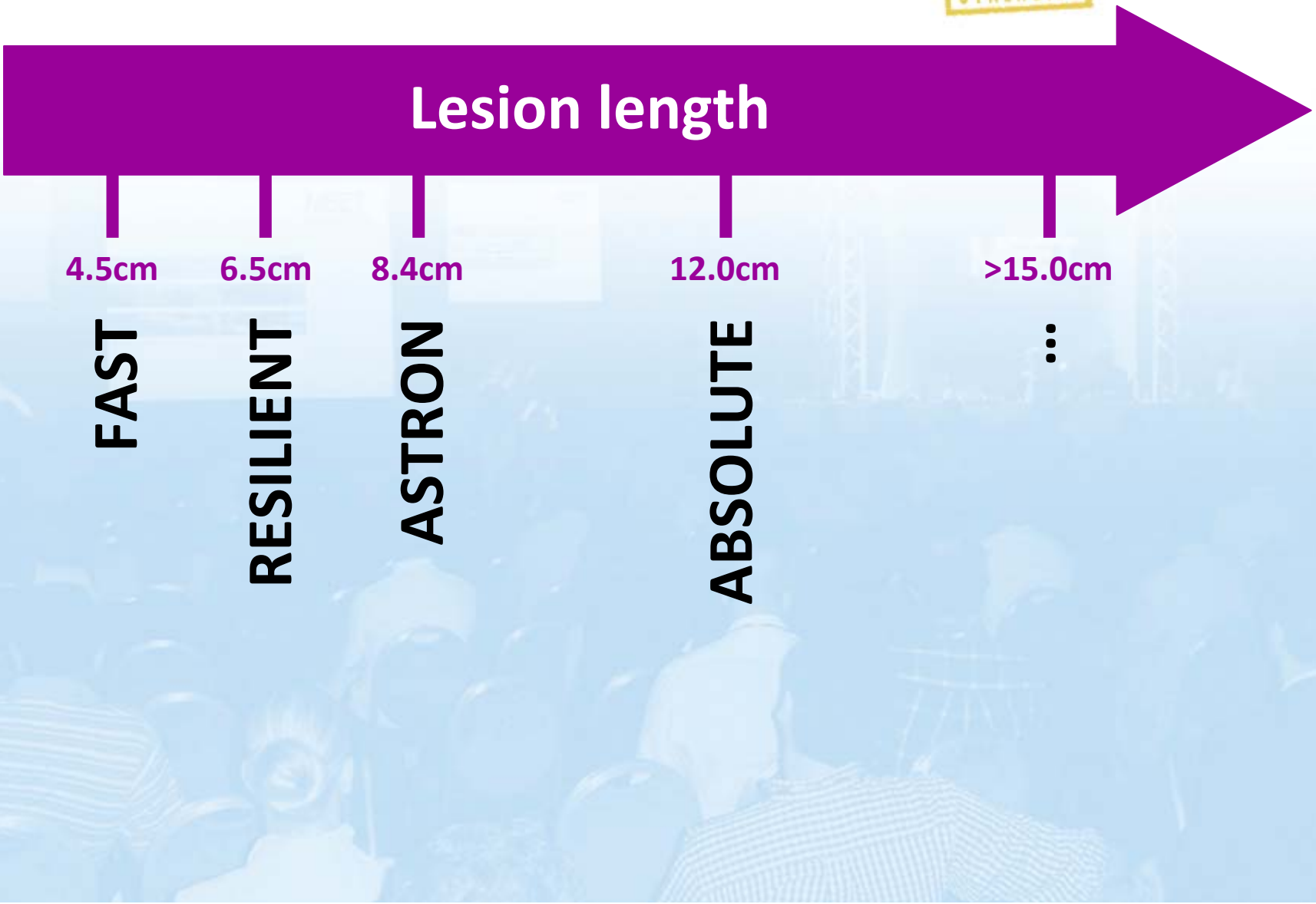
10 years… Palmaz st

stents – non RCTs

years… Nitinol stents – RCTs

Valid „long term“ data from RCTs are available only up to 2 years

Evidence from randomised trials



FAST Trial
Baseline Characteristics

Lesion length

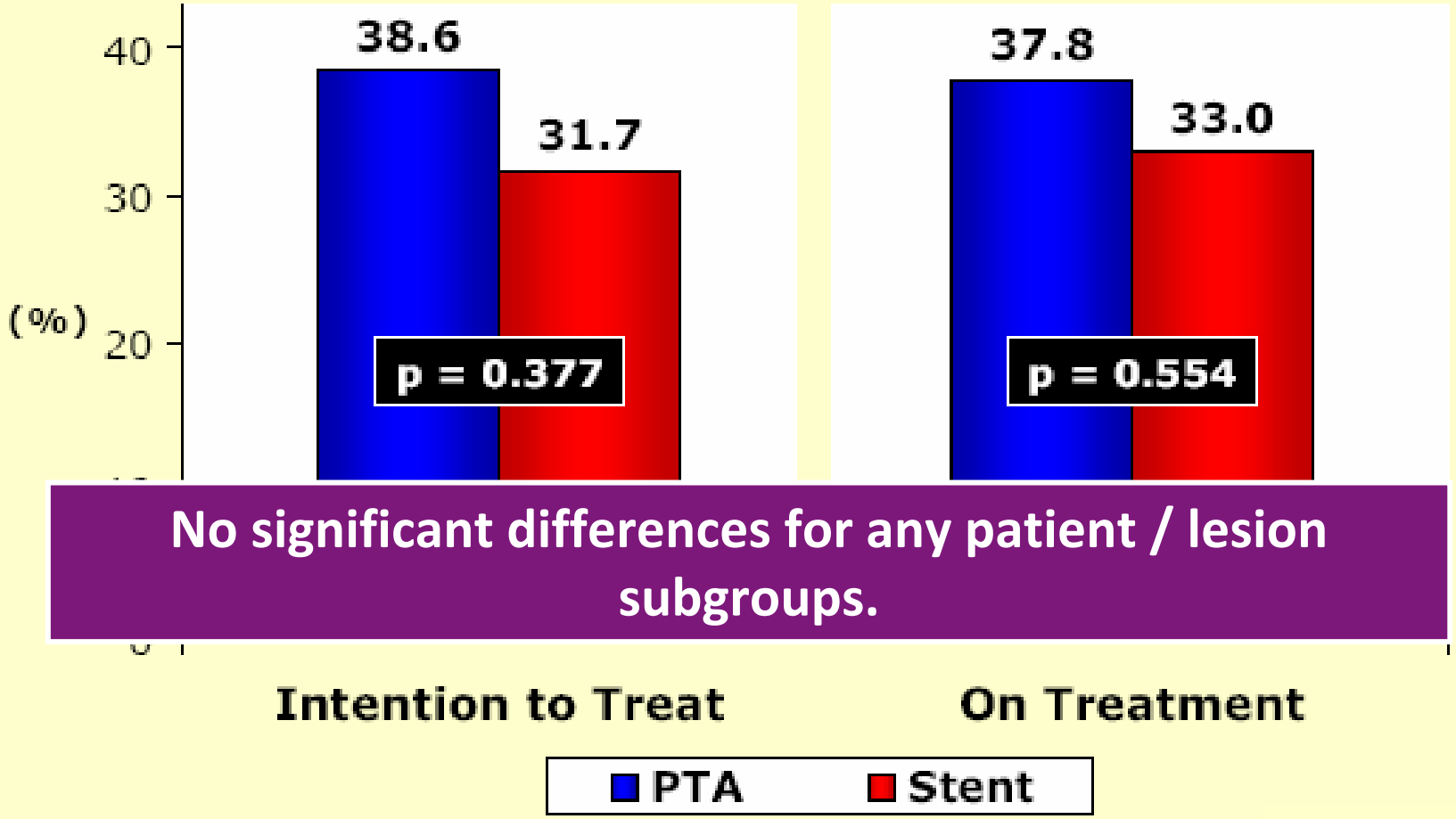
4.5cm

- n=244
- PTA (n=121) vs. primary stenting (n=123)
- Rutherford stages 2 to 5
- de-novo lesions
- mean lesion length 4.5 cm (range 1 to 10cm)
- 1/4 chronic total occlusions
- Luminexx nitinol stent (Bard)

Krankenberg H et al. *Circulation.* 2007;116:285-292

FAST
12-Month Results

- Binary Restenosis (**1ry EP**)

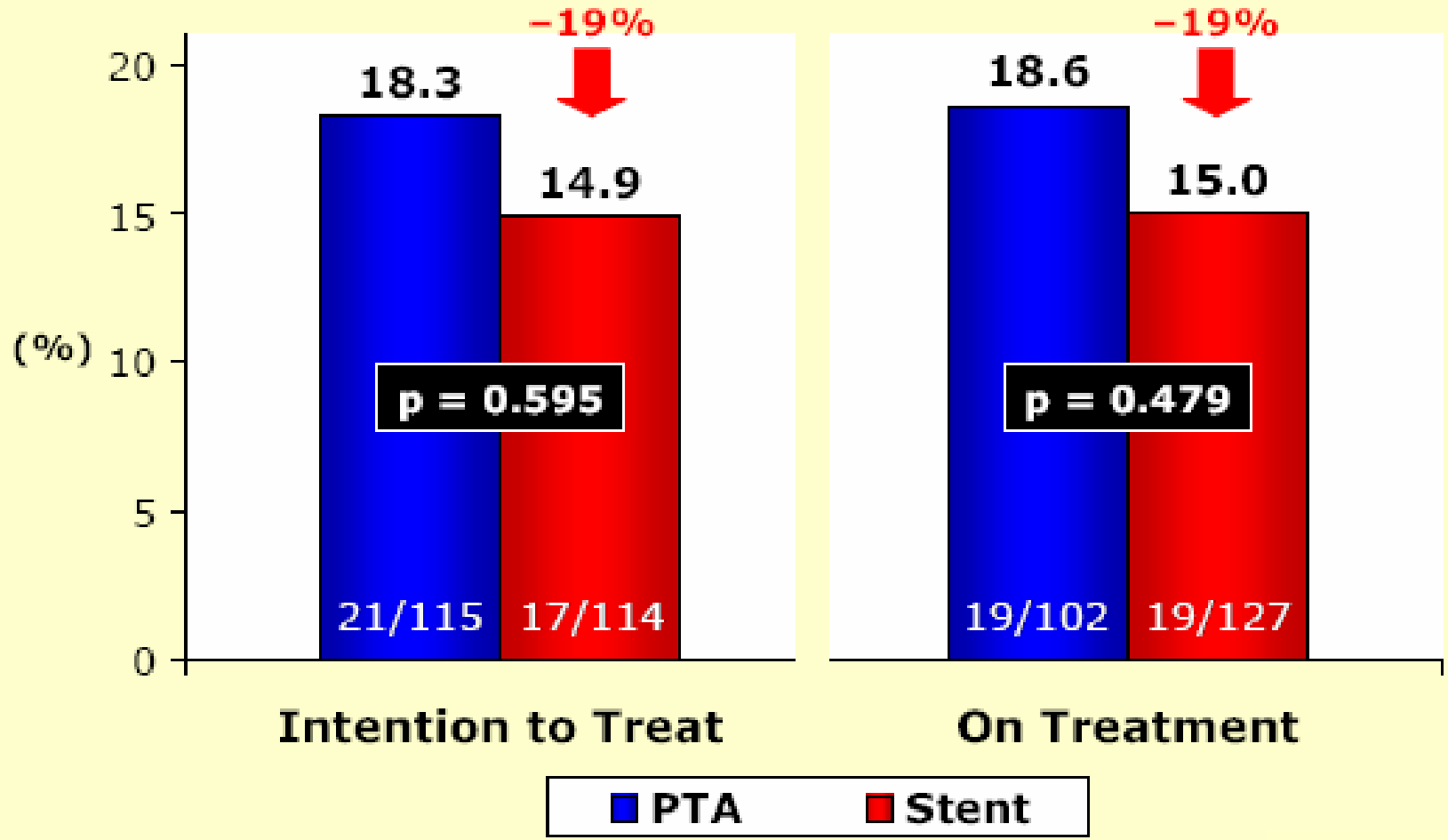


No significant differences for any patient / lesion subgroups.

Krankenberg H et al. *Circulation.* 2007;116:285-292

FAST
12-Month Results

- Target Lesion Revascularizations



Krankenberg H et al. *Circulation.* 2007;116:285-292

Conclusions
FAST

- In patients with a mean lesion length around 4 cm, primary stenting using the Luminexx Nitinol Stent did not improve morphological or clinical outcome at 12 months follow-up.

- Subgroup analysis did not show a significant benefit of the Luminexx Stent for any lesion or patient subgroup.

Krankenberg H et al. *Circulation.* 2007;116:285-292

RESILIENT Trial
Baseline characteristics

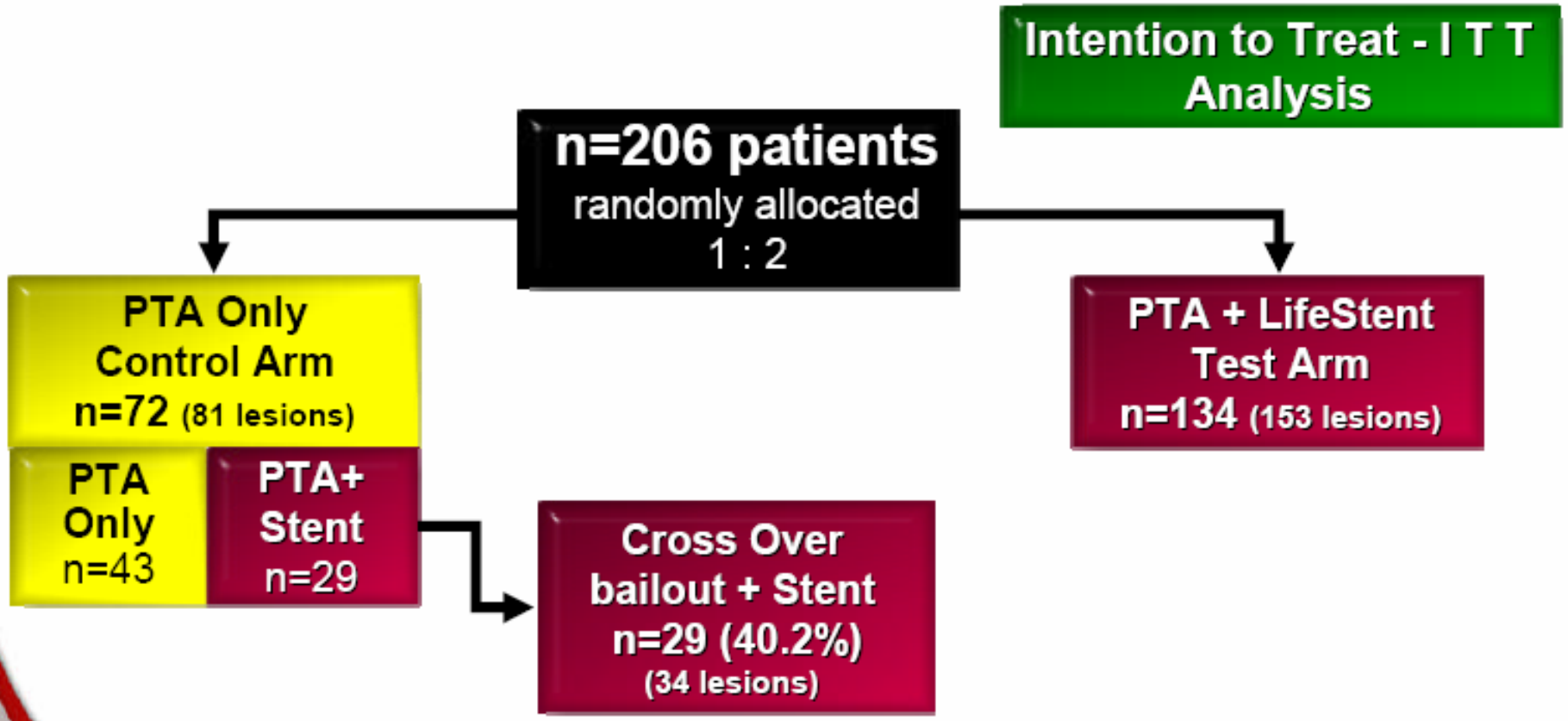
Lesion length

6.5cm

- n=206
- PTA (n=72) vs. primary stenting (n=134)
- Rutherford stages 1 to 3
- mean lesion length 6.5 cm (range <15cm)
- 1/5 chronic total occlusions
- Life Stent (Edwards)

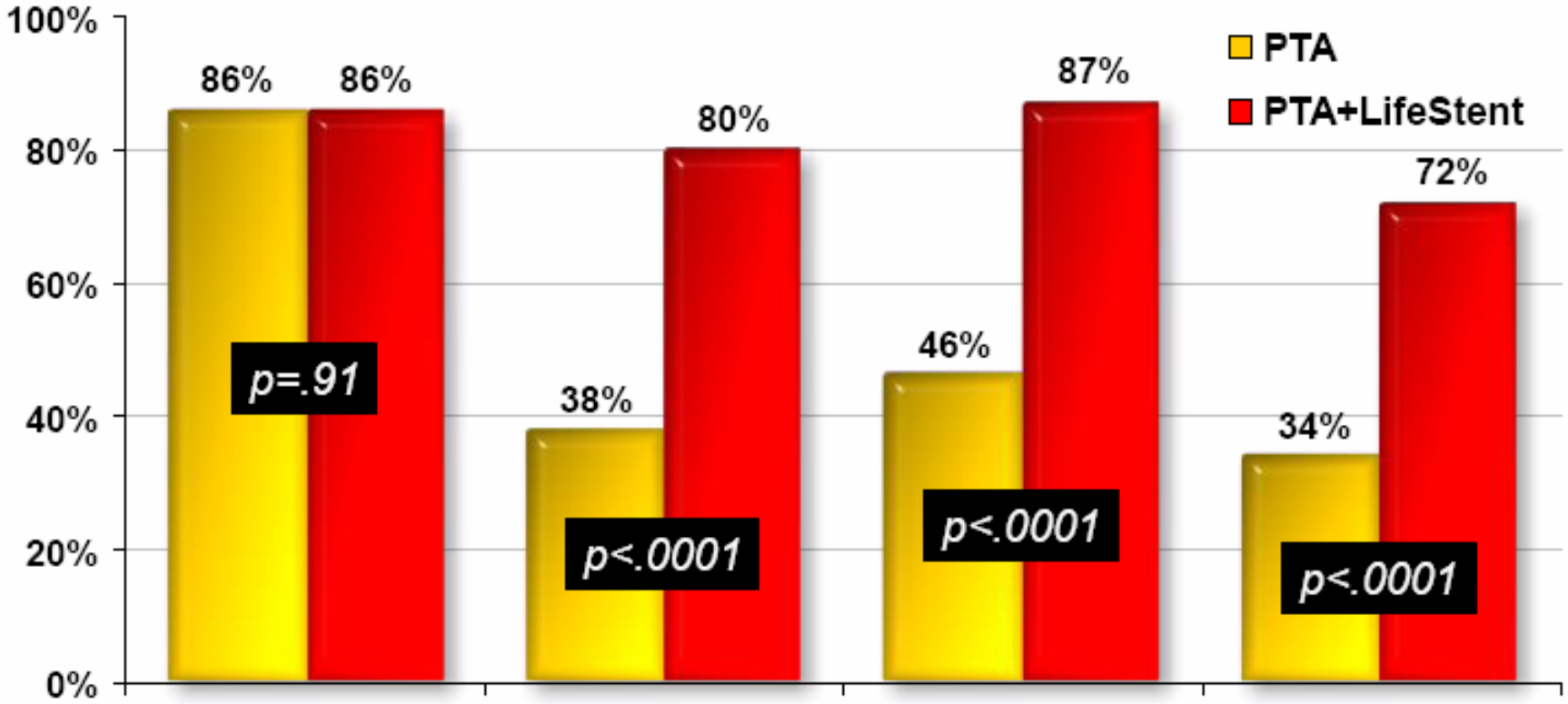
Katzen B et al. *TCT.* 2007

Actual Enrollment Pattern



THE RESILIENT TRIAL

12-Month Results



BUT: 40.2% patients in the PTA group underwent bail-out stenting and were included as PTA-failures at day 0!

*Data from Kaplan-Meier Survival Analysis

THE RESILIENT TRIAL

Conclusions RESILIENT

- In patients with a mean lesion length around 6 cm, primary stenting using the Lifestent improved morphological and clinical outcome compared to PTA alone.

- BUT: It remains unclear, whether primary stenting was superior compared to provisional stenting (PTA plus bail-out stenting) in these patients.

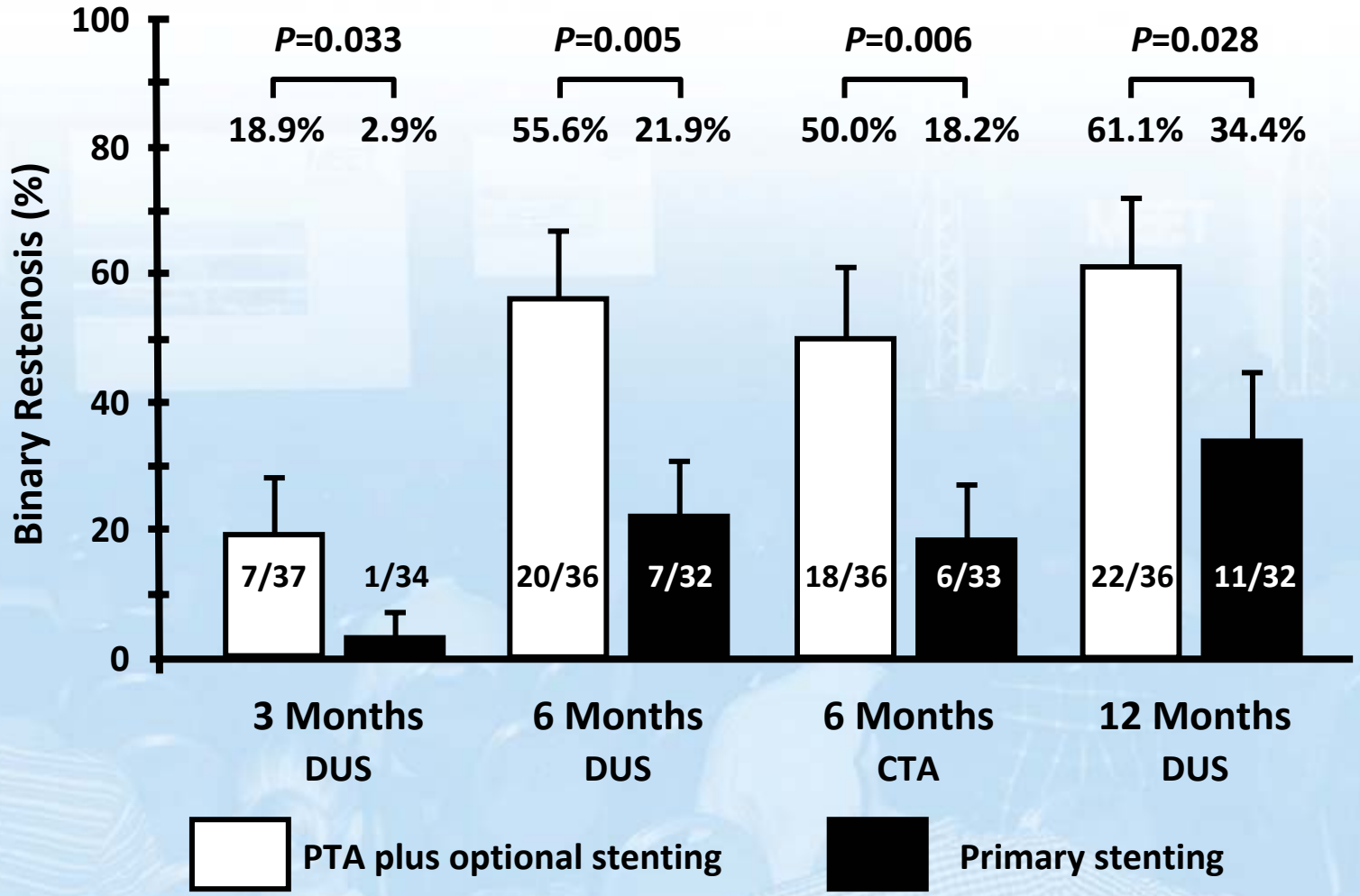
Katzen B et al. *TCT.* 2007

ASTRON Trial
Baseline characteristics

- n=73
- PTA plus optional stenting (n=39) vs. primary stenting (n=34)
- Rutherford stages 2 to 5
- de-novo and restenotic lesions
- mean treated length 8.4 cm (range 3 to 25cm)
- 1/3 chronic total occlusions
- Devices: Astron Stent (Biotronik)

Schillinger M et al.

ASTRON Trial – Restenosis rates until 12 months



Schillinger M et al.

Conclusions ASTRON

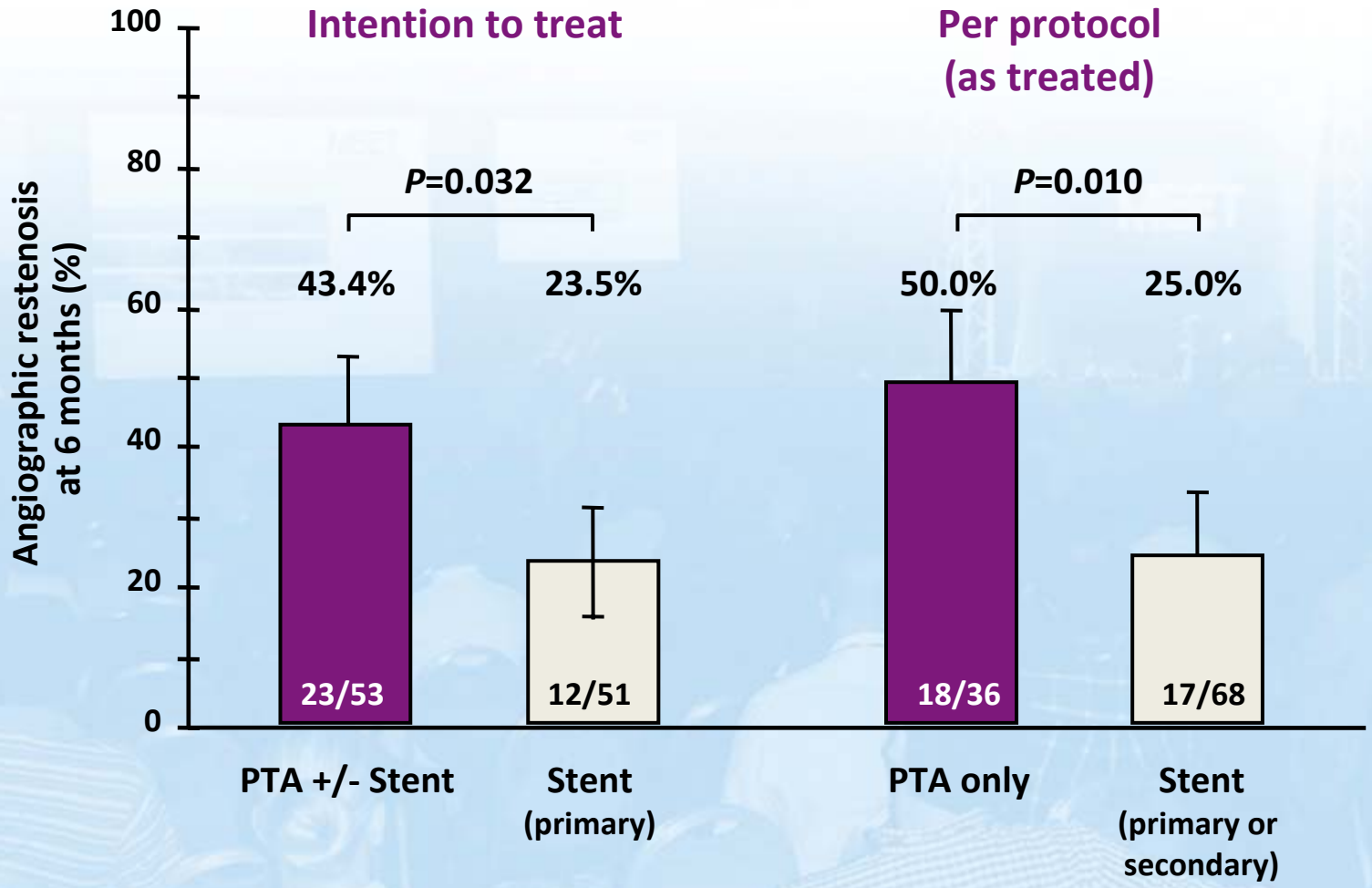
- In patients with a mean treated length around 8 cm, primary stenting using the Astron Nitinol Stent improved morphological and clinical outcome compared to PTA with optional stenting.

ABSOLUTE Trial
Baseline Characteristics

- n=104
- PTA plus optional stenting (n=53) vs. primary stenting (n=51)
- Rutherford stages 2 to 5
- de-novo and restenotic lesions
- mean treated length 12.0 cm (range 3 to 33cm)
- 1/3 chronic total occlusions
- Devices: Dynlink / Absolute Stents (Abbott Vascular)

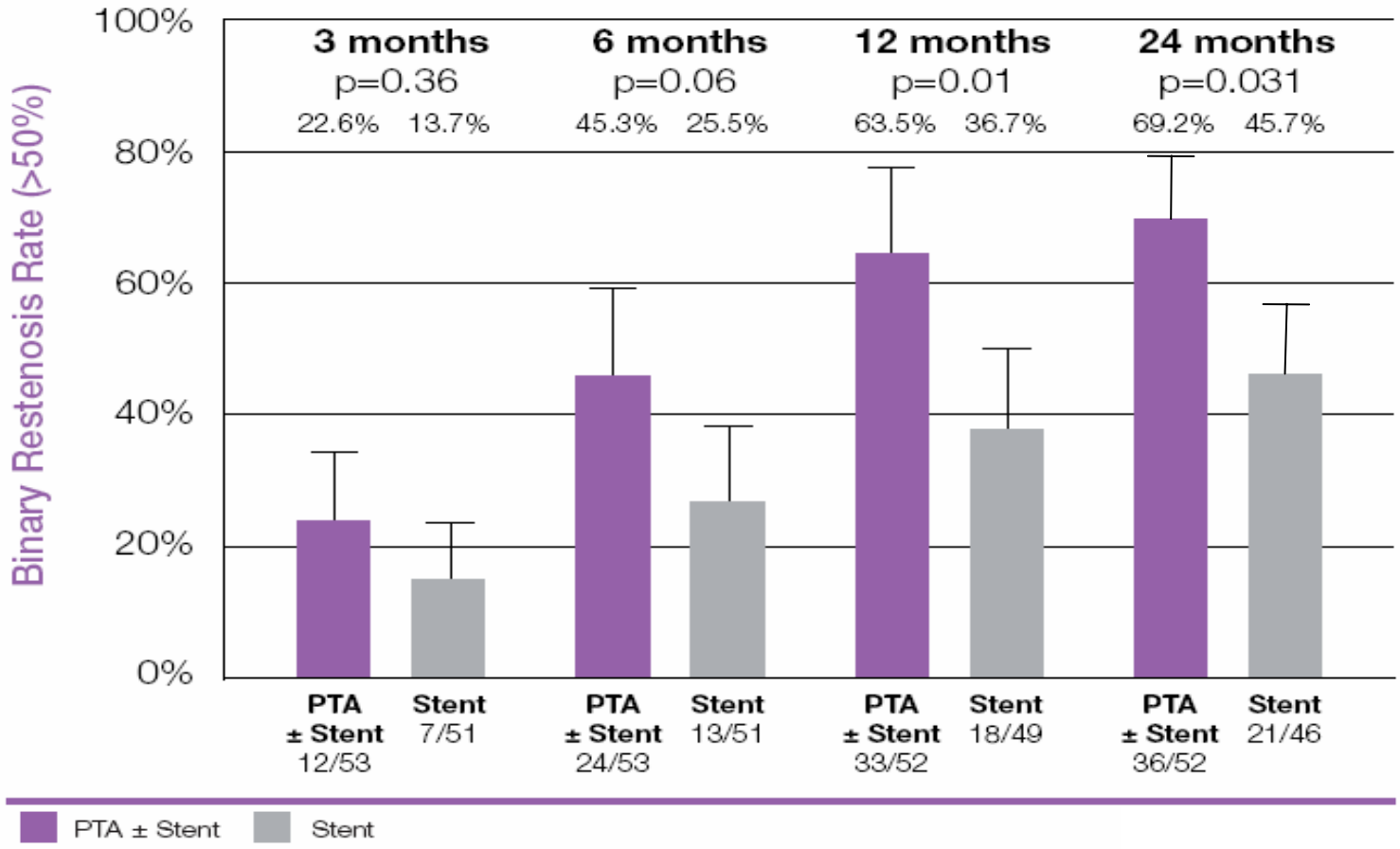
Schillinger M et al. *N Engl J Med.* 2006;354:1879-1888

ABSOLUTE Trial - 6 month angiographic restenosis



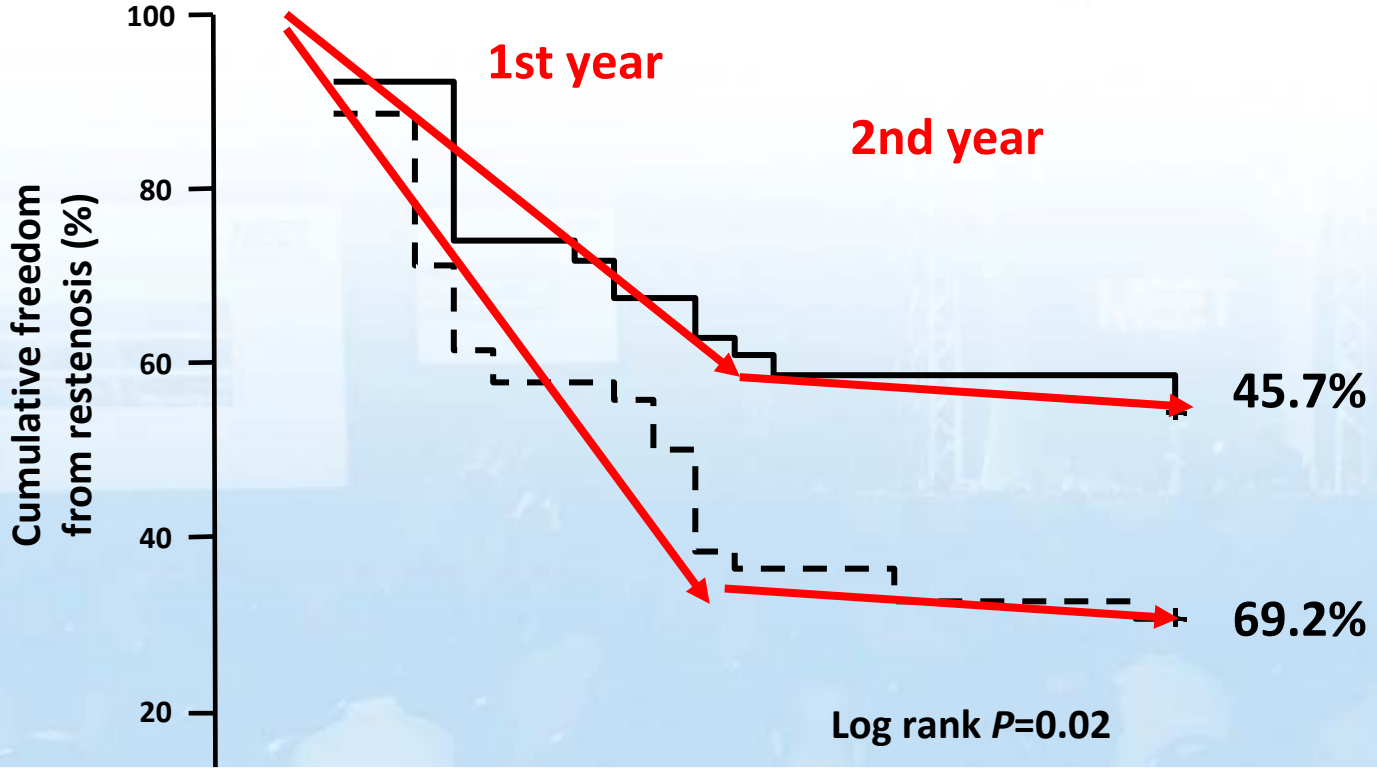
Schillinger M et al. *N Engl J Med.* 2006;354:1879-1888

ABSOLUTE Trial – Restenosis rates until 2 years



Schillinger M et al. *N Engl J Med.* 2006;354:1879-1888 *Circulation*. 2007;115:2745-2749

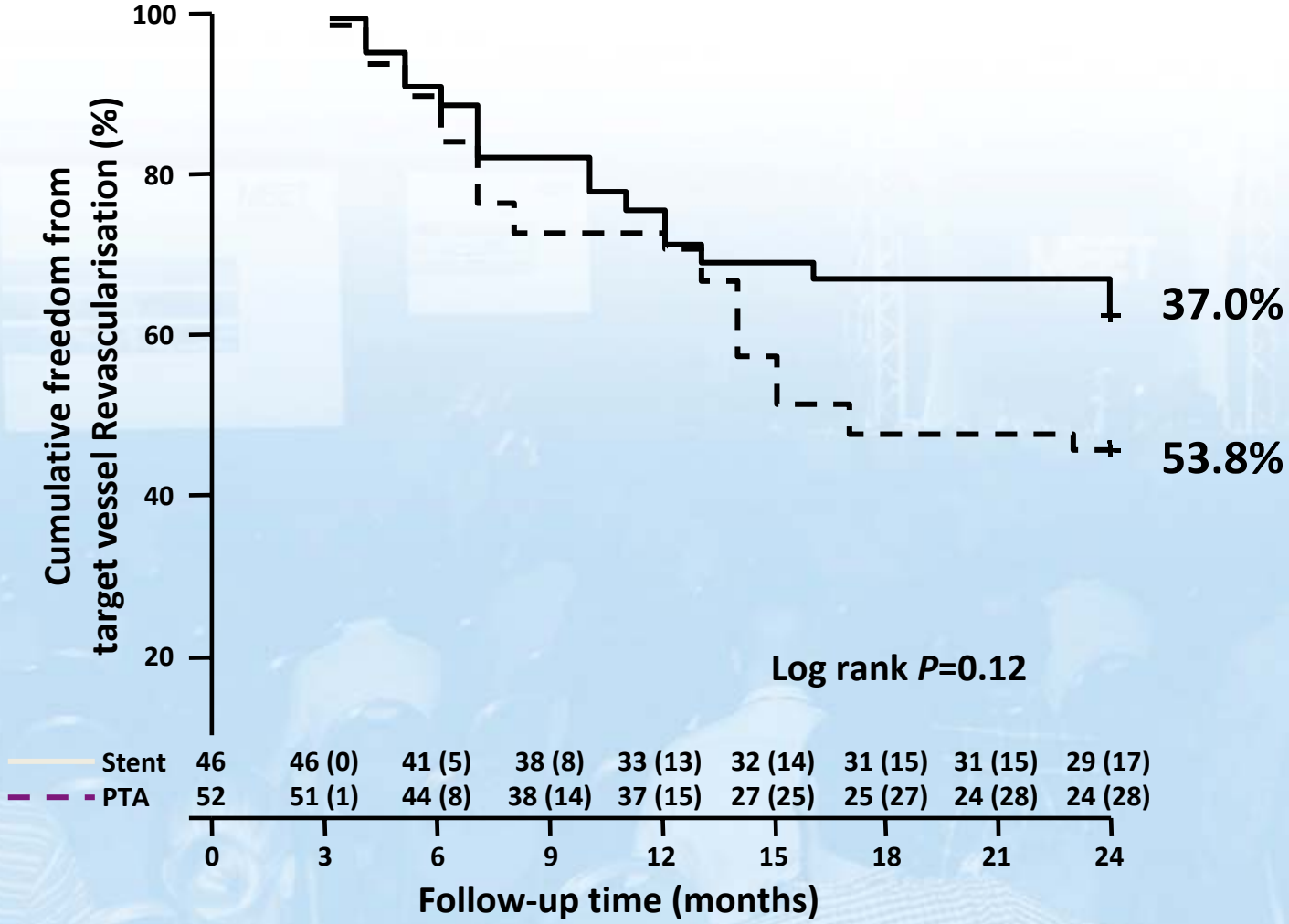
ABSOLUTE Trial - Pattern of Restenosis until 24 months



- Sustained benefit of nitinol stents @ 2-year follow-up
- No 'catch-up' phenomenon
- Restenosis later than 12 months was rare

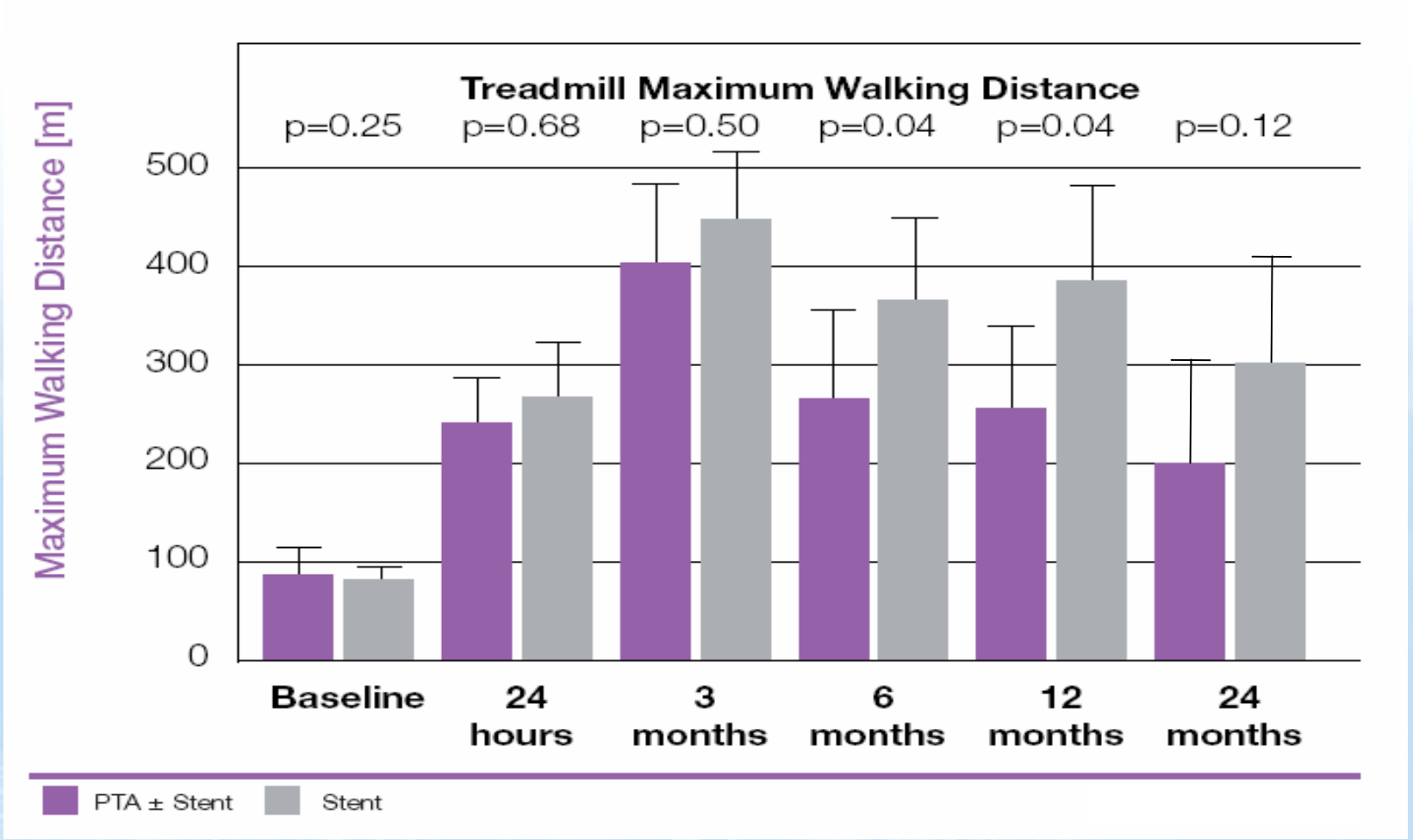
Schillinger M et al. *N Engl J Med.* 2006;354:1879-1888 *Circulation*. 2007;115:2745-2749

ABSOLUTE Trial
Clinically driven TVR



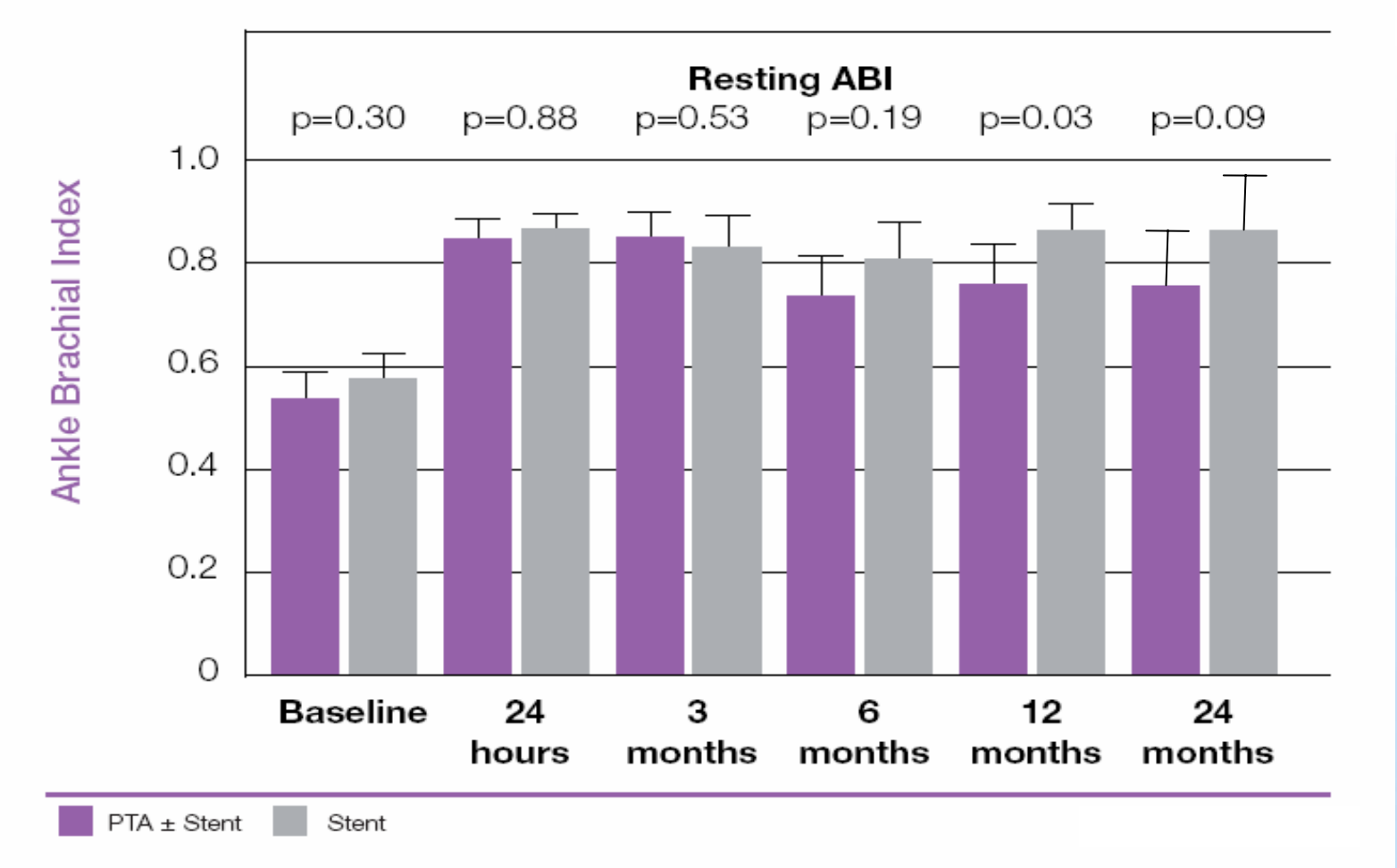
Schillinger M et al. *N Engl J Med.* 2006;354:1879-1888 *Circulation*. 2007;115:2745-2749

ABSOLUTE Trial
Walking capacity



Schillinger M et al. *N Engl J Med.* 2006;354:1879-1888 *Circulation*. 2007;115:2745-2749

ABSOLUTE Trial
Haemodynamic outcome

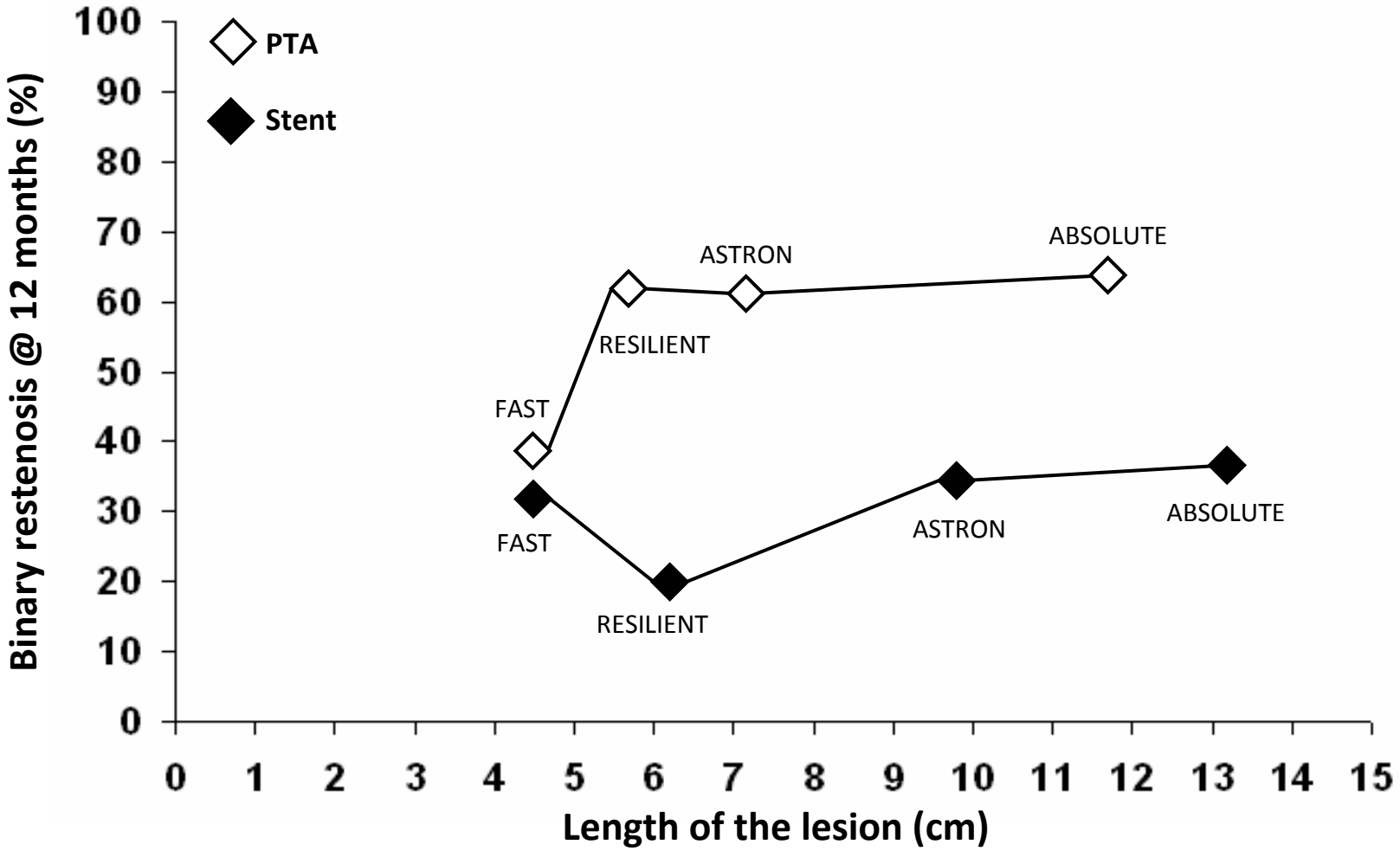


Schillinger M et al. *N Engl J Med.* 2006;354:1879-1888 *Circulation*. 2007;115:2745-2749

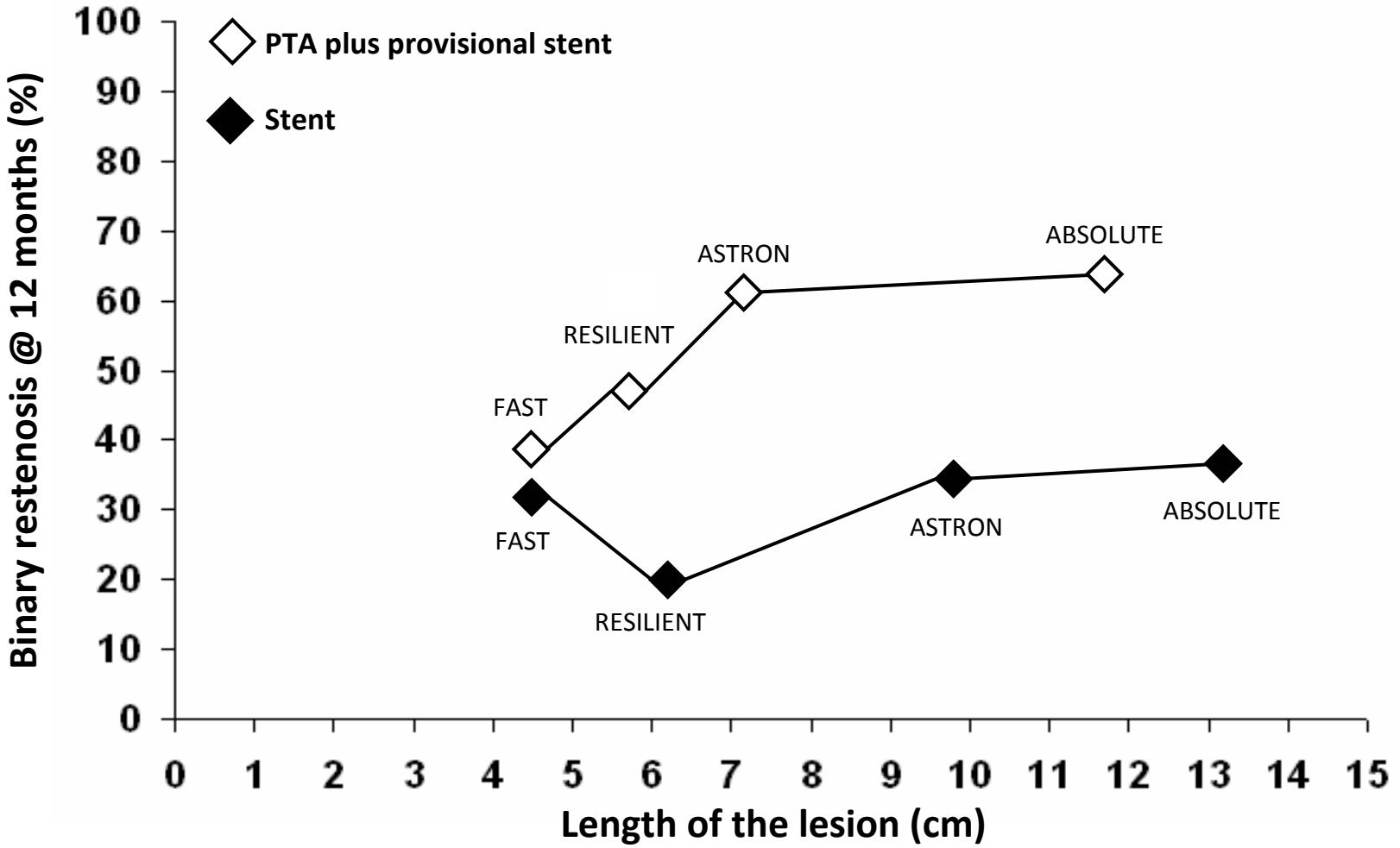
ABSOLUTE Trial Conclusion

- Primary stenting with the ABSOLUTE nitinol stent improved primary patency rates and clinical outcomes until 24 months, when compared with balloon angioplasty with optional stenting in lesions with a mean treated length of 12 cm.

12 mo restenosis vs. lesion length: Data from randomised trials



12 mo restenosis vs. lesion length: Data from randomised trials



Primary stenting in patients…

… with long/complex lesions

FAST – RESILIENT – ASTRON – ABSOLUTE

… with restenosis after prior PTA

even Wallstents were better than repeat PTA

… when an optimal primary result is crucial (CLI)

because ulcer healing rather than long-term patency counts

CLI, critical limb ischaemia

Long Term Problems: Which stents should we use?

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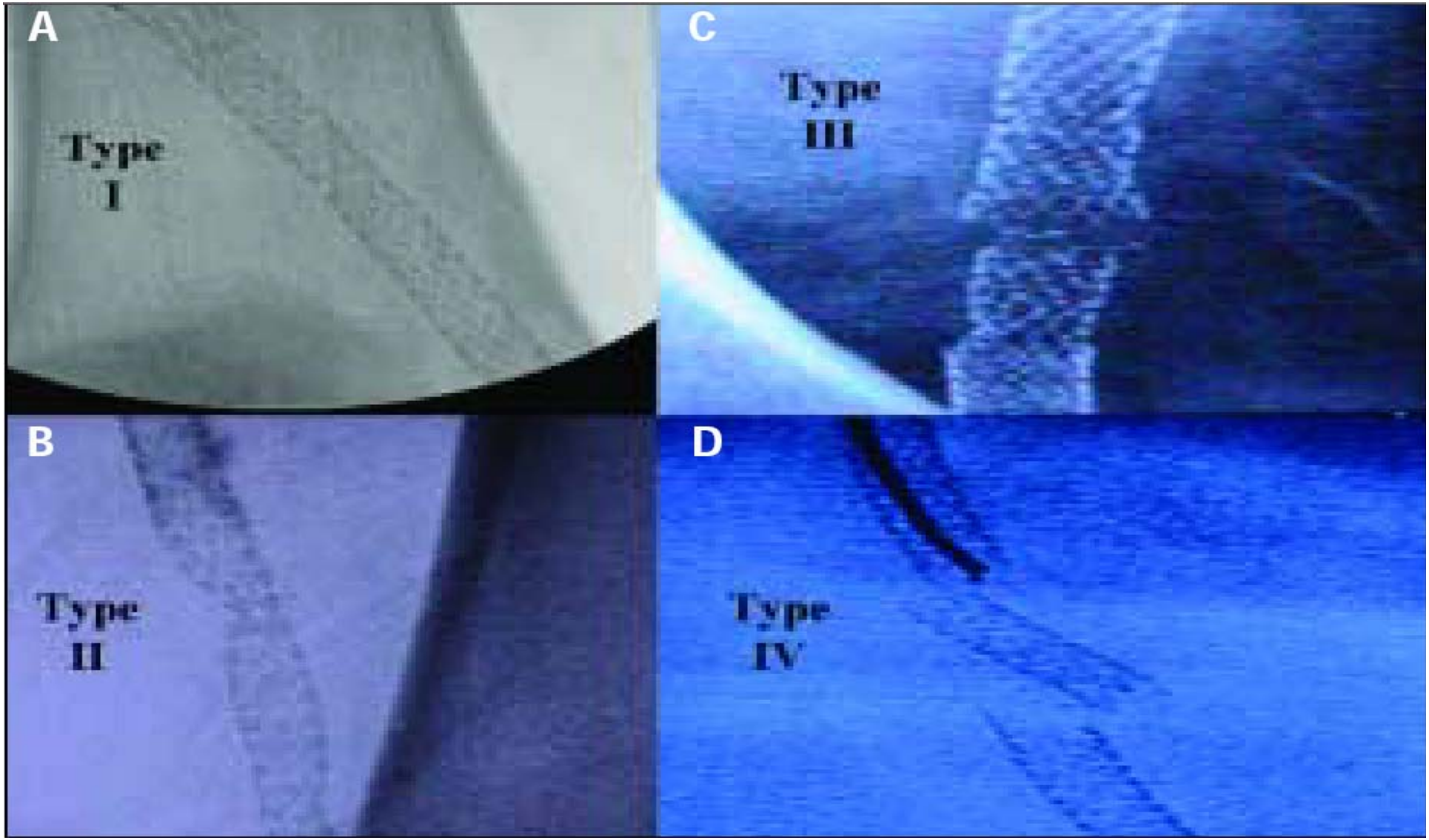

Fracture rates in the context: Data from randomised trials

	SIROCCO I	SIROCCO II	ABSOLUTE	FAST	RESILIENT
6 months	19%	9%	1.5%	–	2.2%
12 months	31%	11%	1.5%	12%	2.9%
Length	85 mm	82 mm	124 mm	45mm	65mm

Factors that determine fracture rates:

- **– Length of the lesion**
- **– Type of stent**
- **– Fracture rates beyond 12 months?**

Unresolved long term problems of SFA stenting

- How to treat instent restenosis?
- How to handle stent fractures?

Treating the SFA in 2008:
in the Absence of Long-Term Data

- Why should we stent the SFA?
  - Symptomatic SFA disease is usually long and complex: the best results in this indication are obtained with stents
- Do current data support the use of primary nitinol stenting?
  - Currently liberal ‘stenting on indication’
- Which stents should we use?
  - Stents with approved low restenosis and low fracture rates from randomised trials

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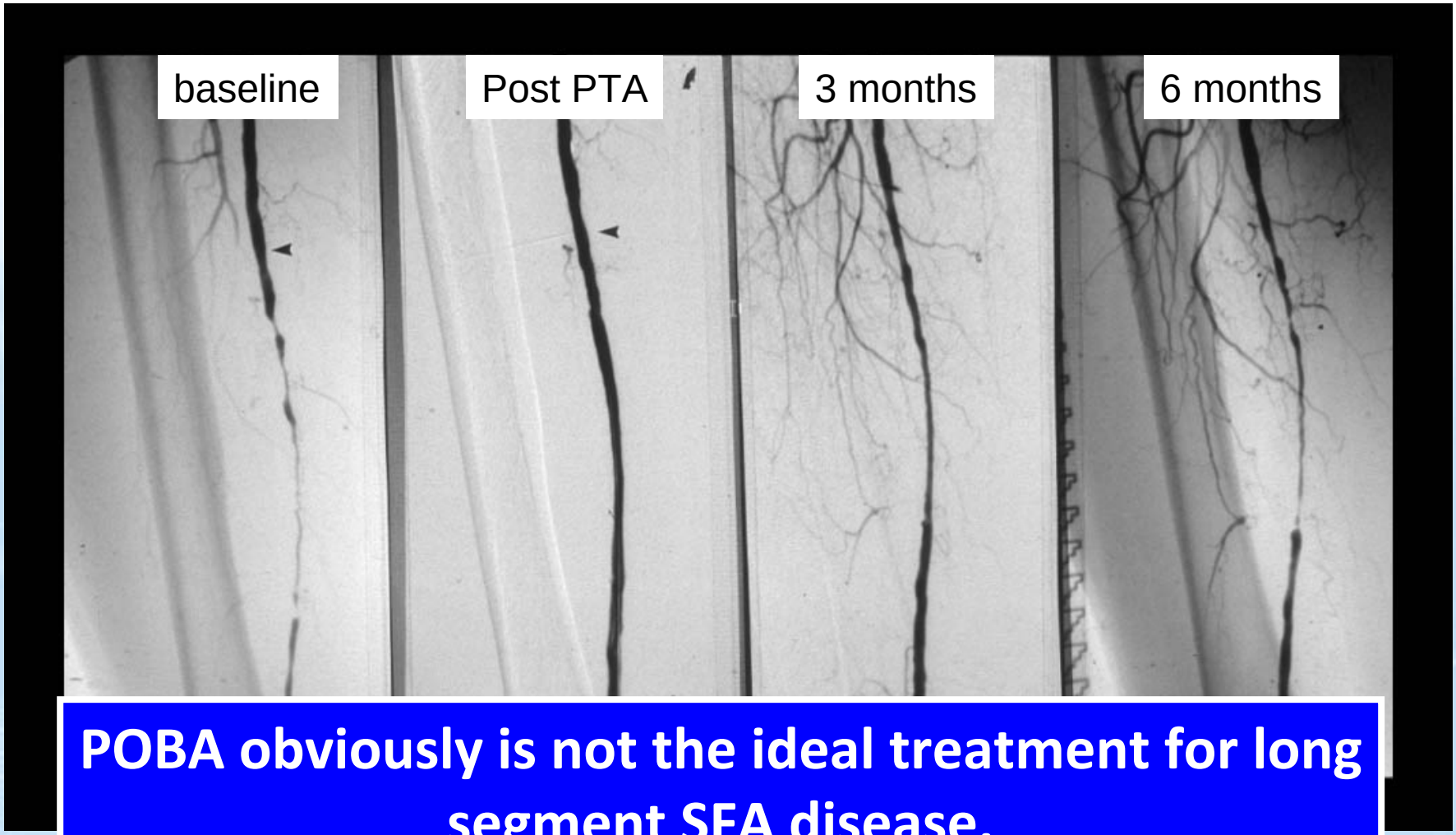
The future of interventional therapy for superficial femoral artery disease

The Future…
is not:



POBA obviously is not the ideal treatment for long segment SFA disease.

The Future…

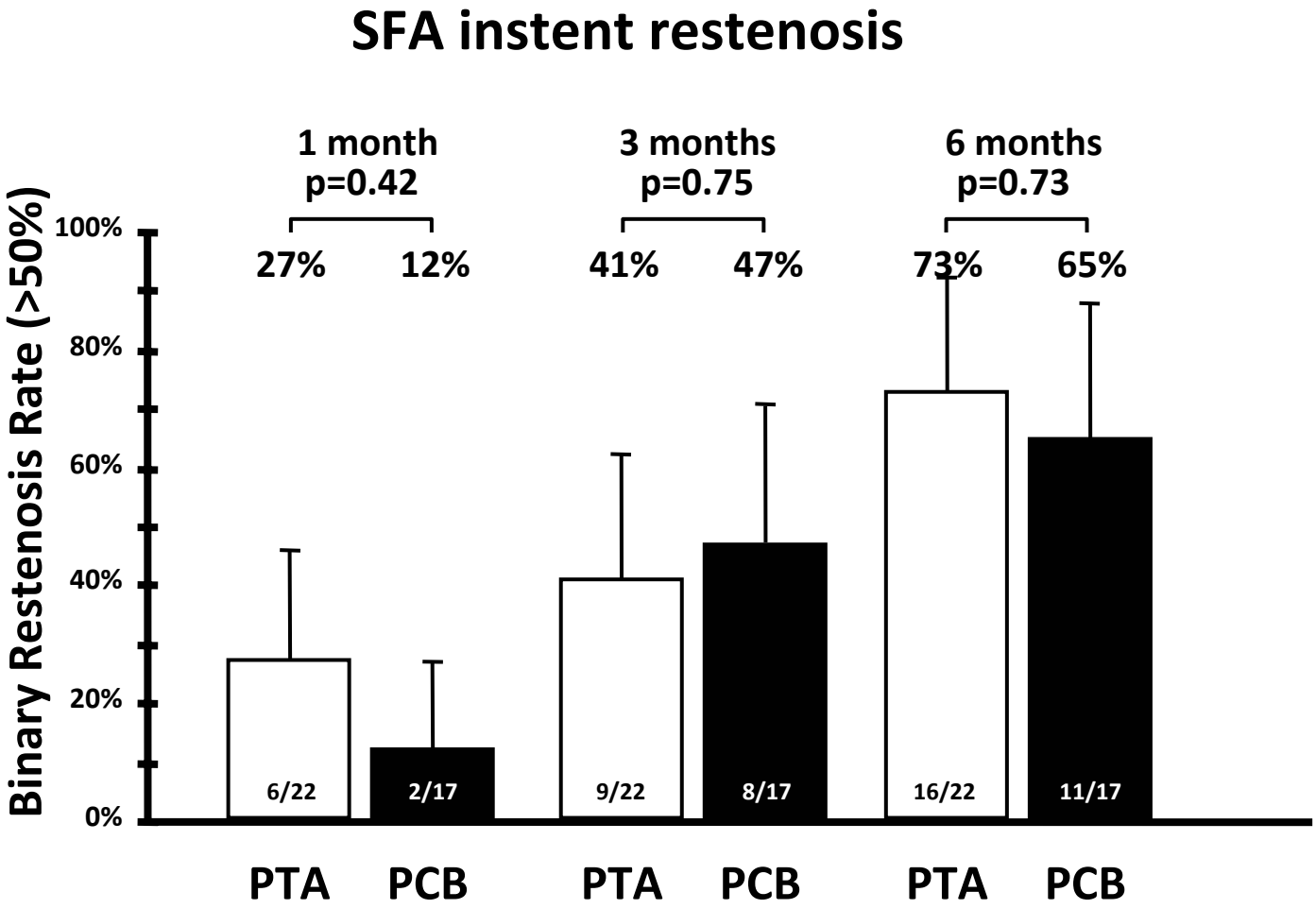
Cryoplasty

Cutting balloon
Atherectomy

Laser

Technically feasible, but even non-randomized studies are not convincing…
…there are very good reasons why RCT are not initiated for these devices.

The Future…
is not:



Dick P et al. Radiology 2008

The Future…

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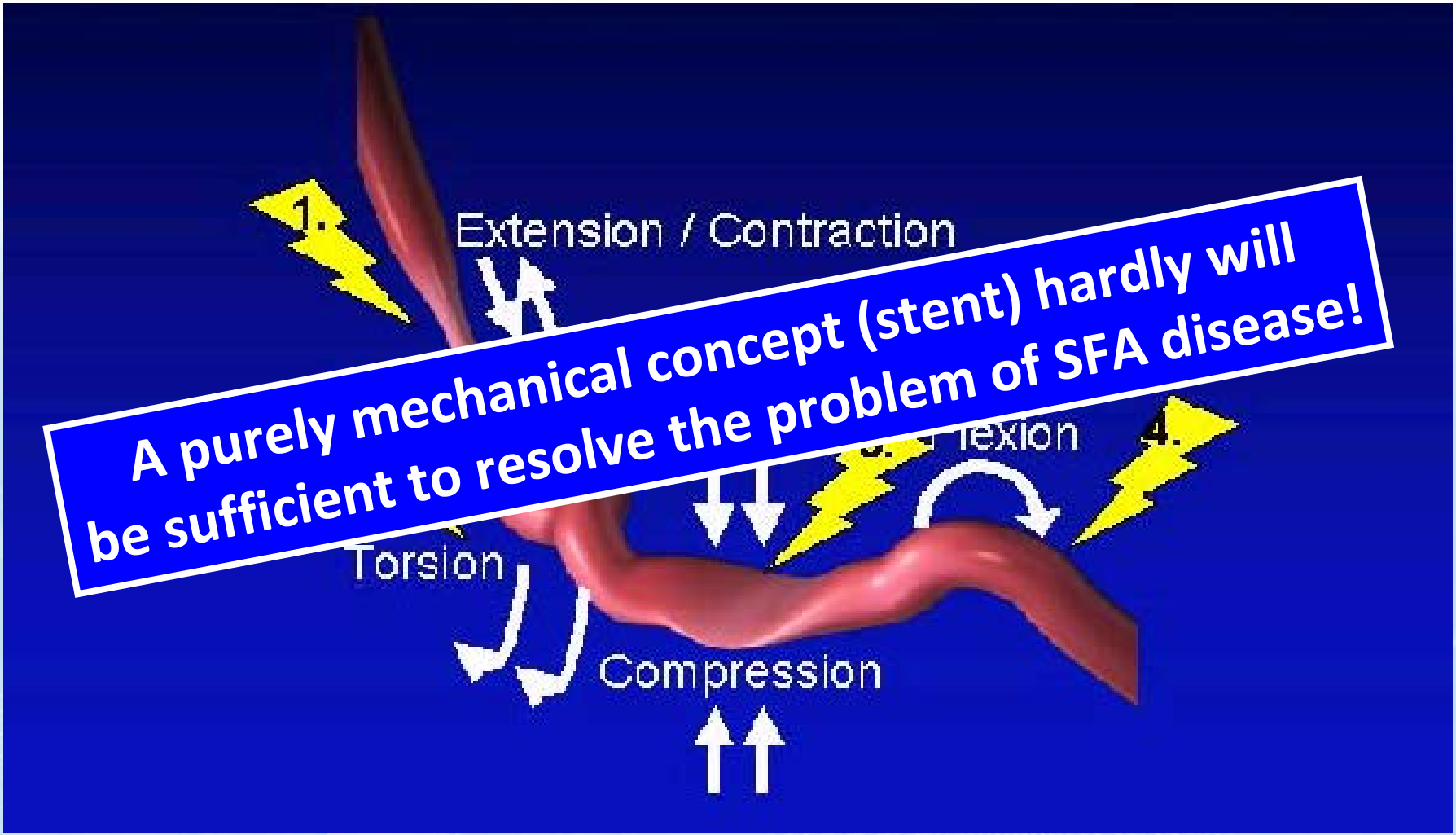
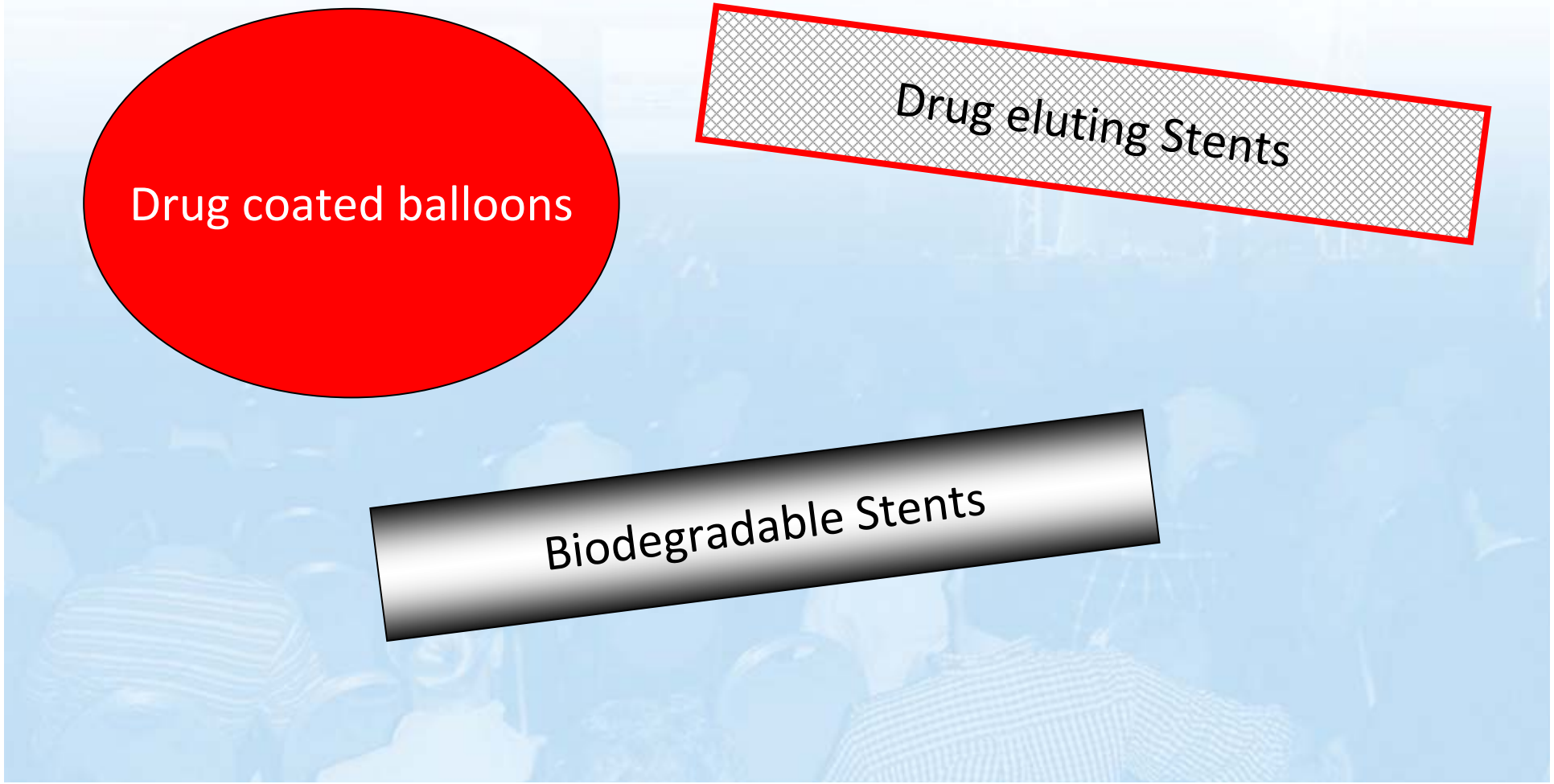


Promising Concepts – for the near future



Drug eluting balloons – THUNDER Trial

- n=154 randomized to three groups:
  - Paclitaxel coated balloon (n=48)
  - Standard balloon (n=54)
  - Paclitaxel disolved in contrast medium (n=52)
- Endpoints:
  - Late lumen loss by angiography at 6 months
  - TLR until 24 months

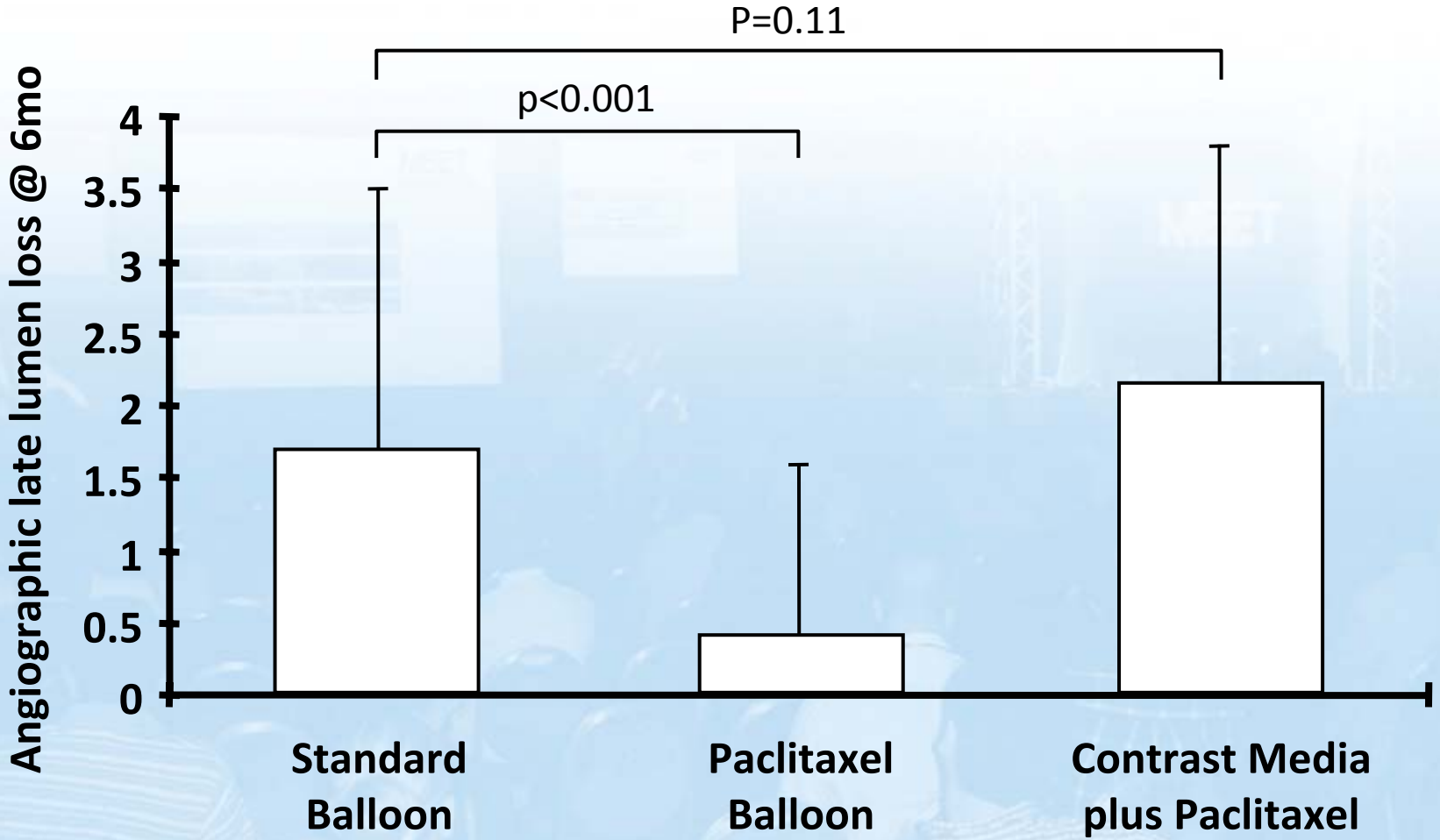
Tepe et al. N Engl J Med. 2008;358:689-699

Drug eluting balloons – THUNDER Trial

- claudication or critical limb ischemia (mean ABI 0.5)
- mean age 68 years
- 49% diabetics
- 27% chronic total occlusions
- 36% restenotic lesions
- mean leasion length 7.4cm

Tepe et al. N Engl J Med. 2008;358:689-699

Drug eluting balloons – THUNDER Trial



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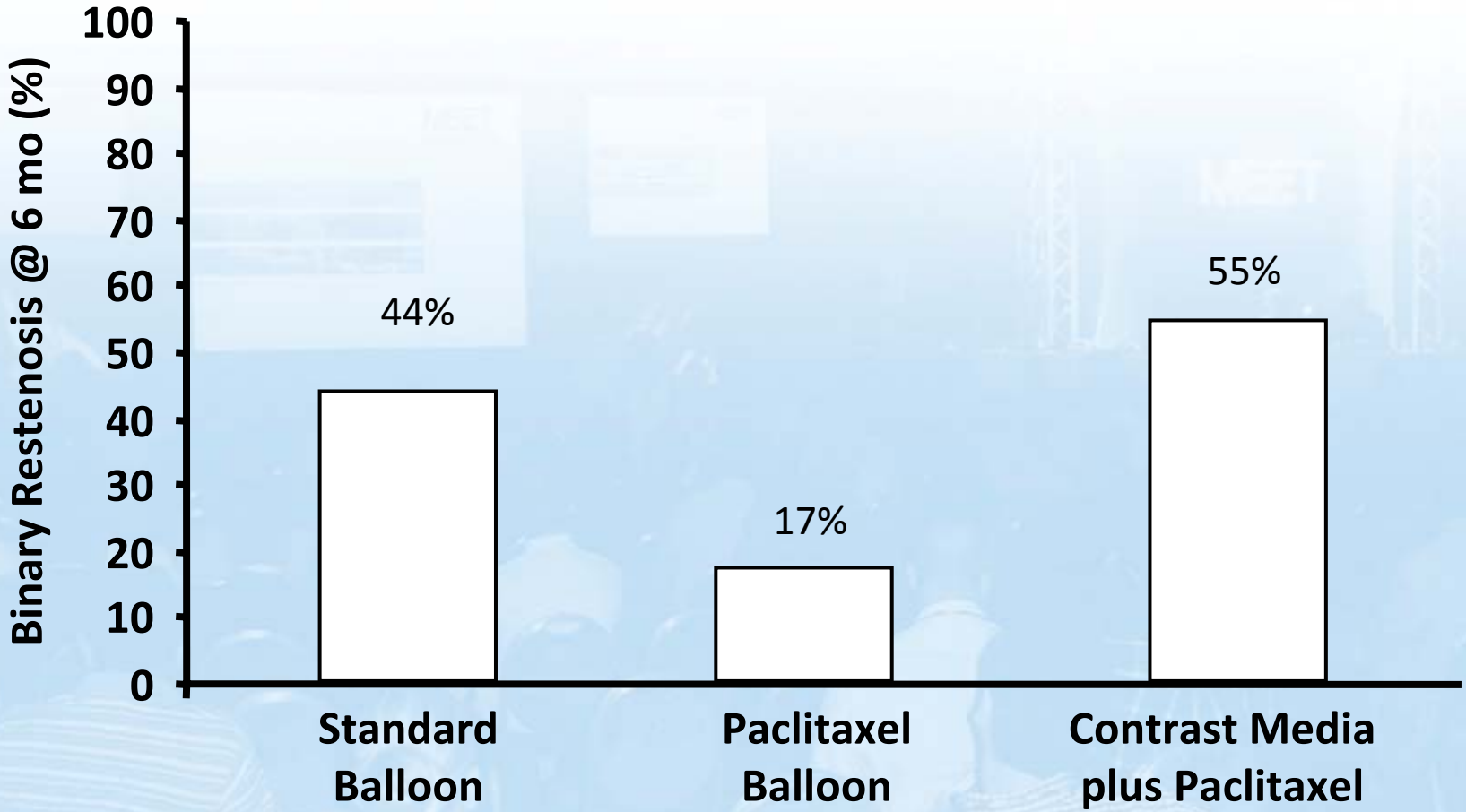
Drug eluting balloons – THUNDER Trial



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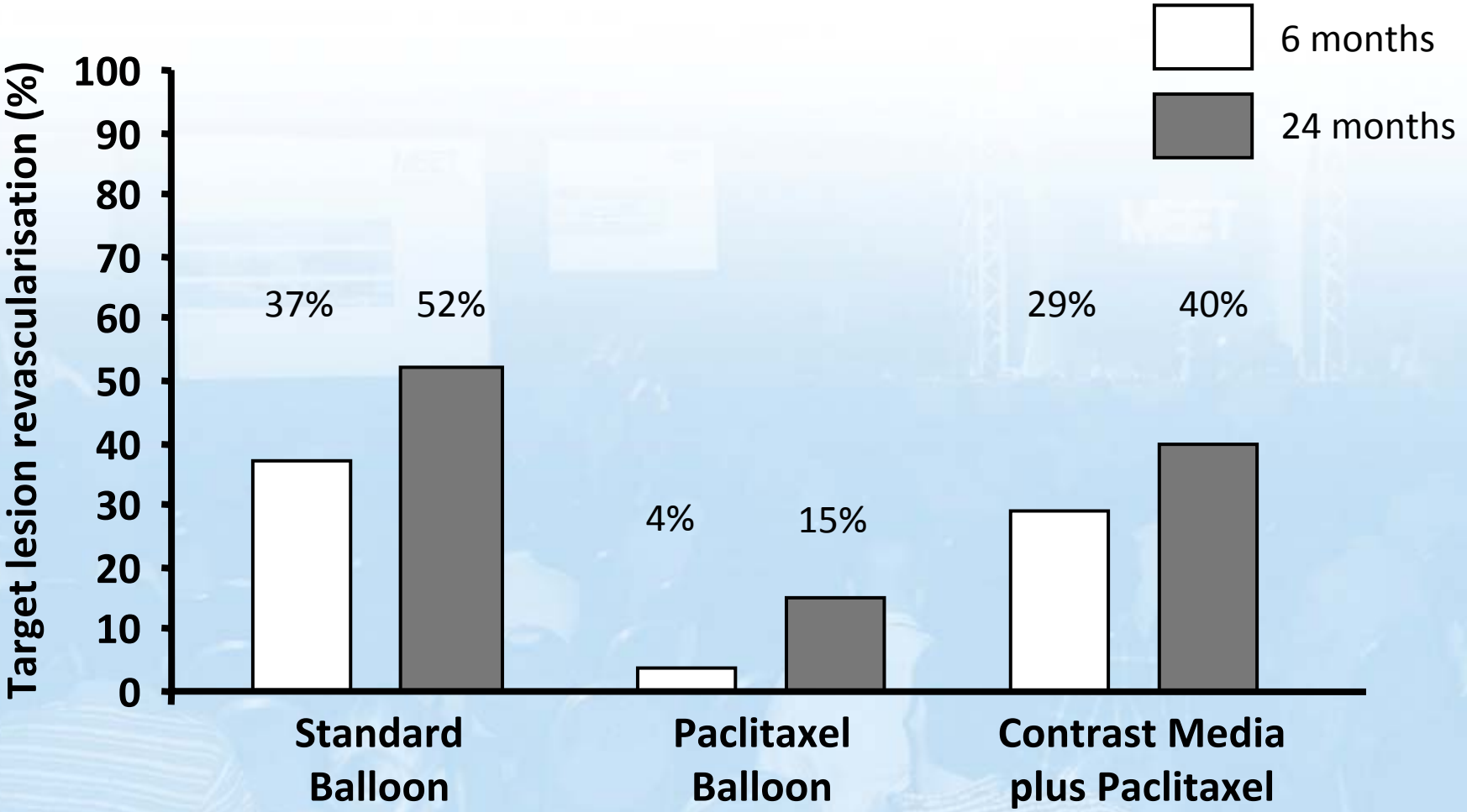
Drug eluting balloons – THUNDER Trial



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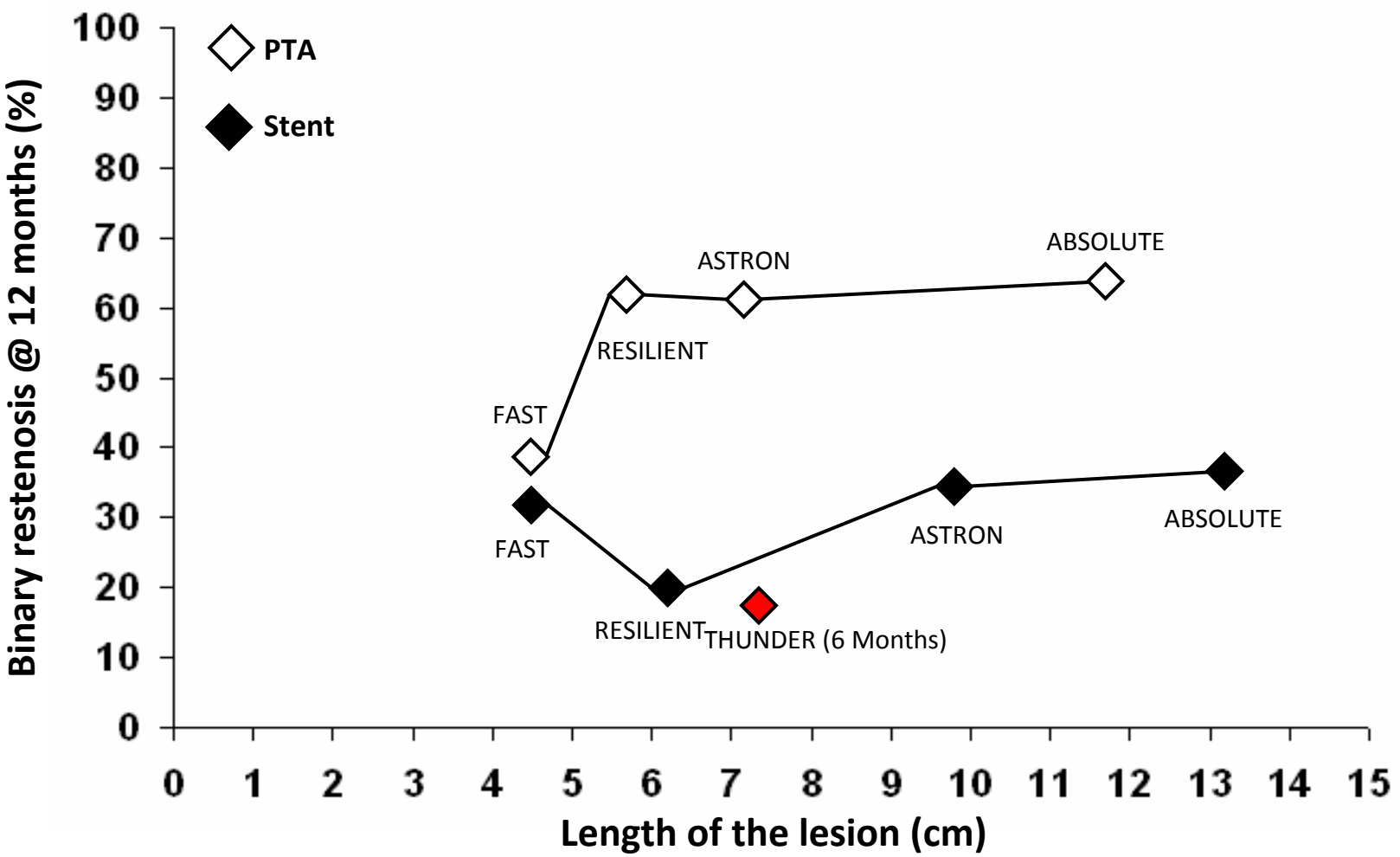
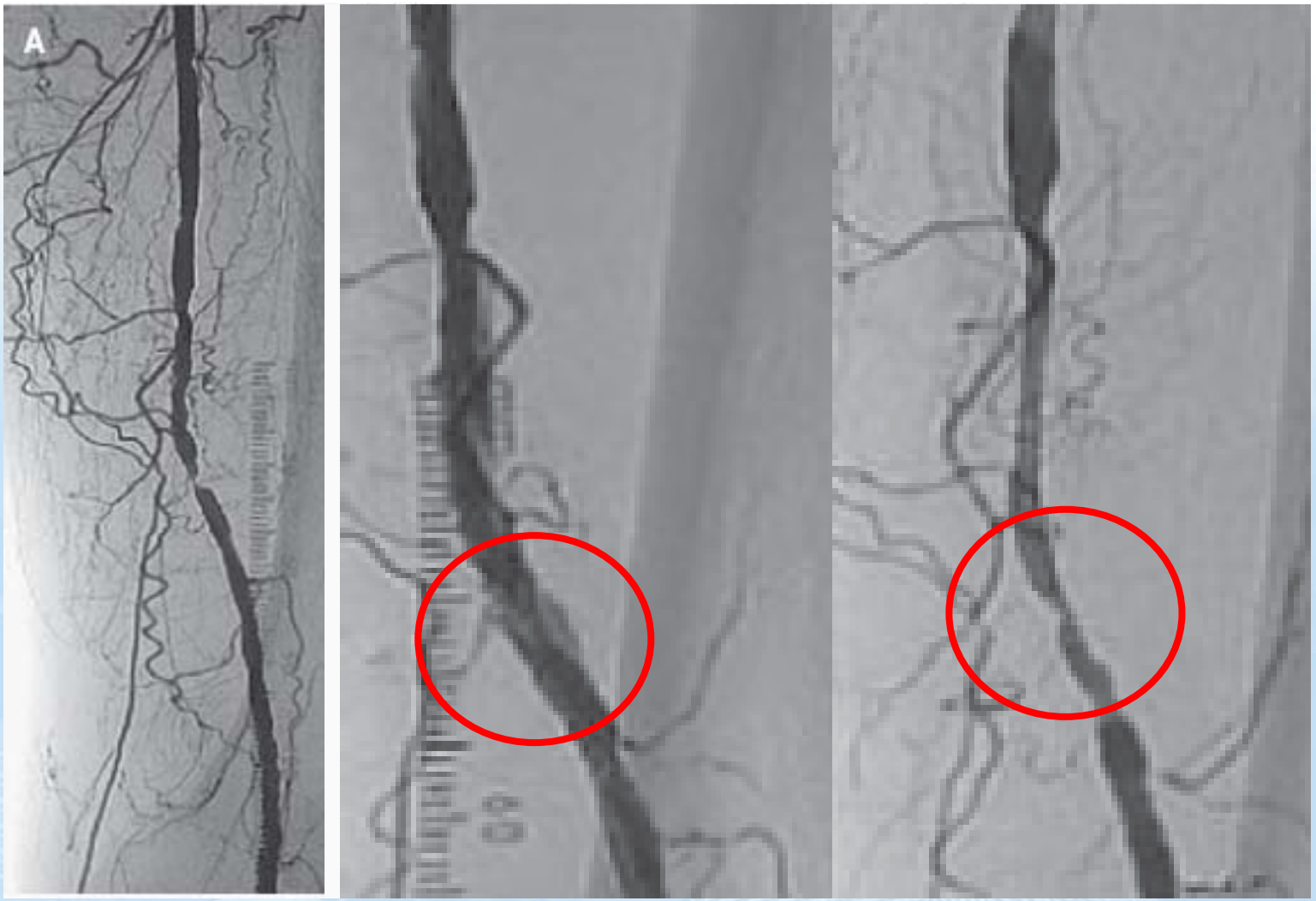
Restenosis vs. lesion length: Data from randomised trials



Drug eluting balloons – THUNDER Trial



Tepe et al. N Engl J Med. 2008;358:689-699

Drug eluting balloons

Drug eluting balloon technology may improve restenosis rates in short- to medium-length SFA lesions.

However, the problems of residual stenosis and elastic recoil remain unresolved.

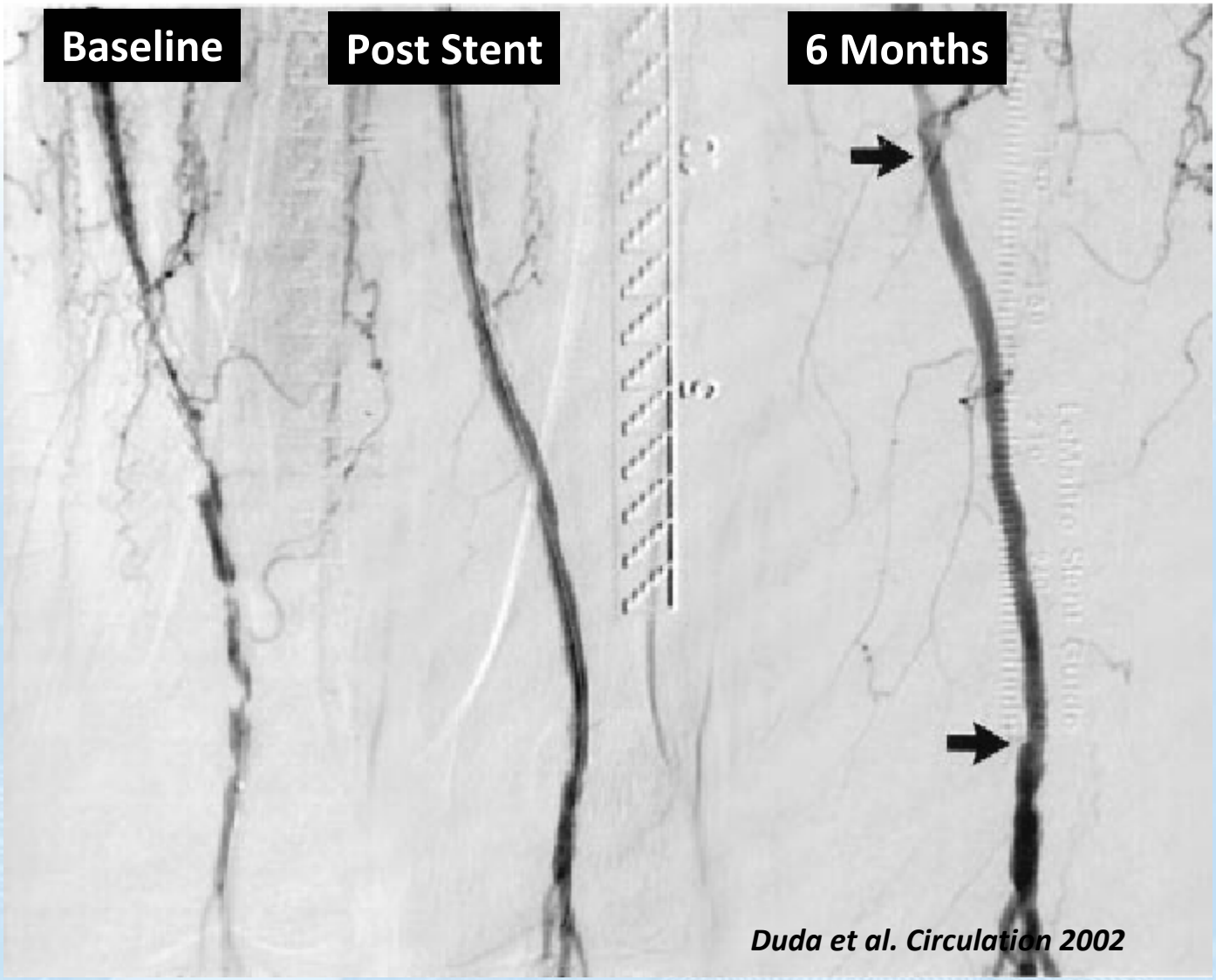
Drug-eluting Stents

30 days after coronary stenting (pigs)

Bare metal stent

DES (Sirolimus)

Drug-eluting Stents

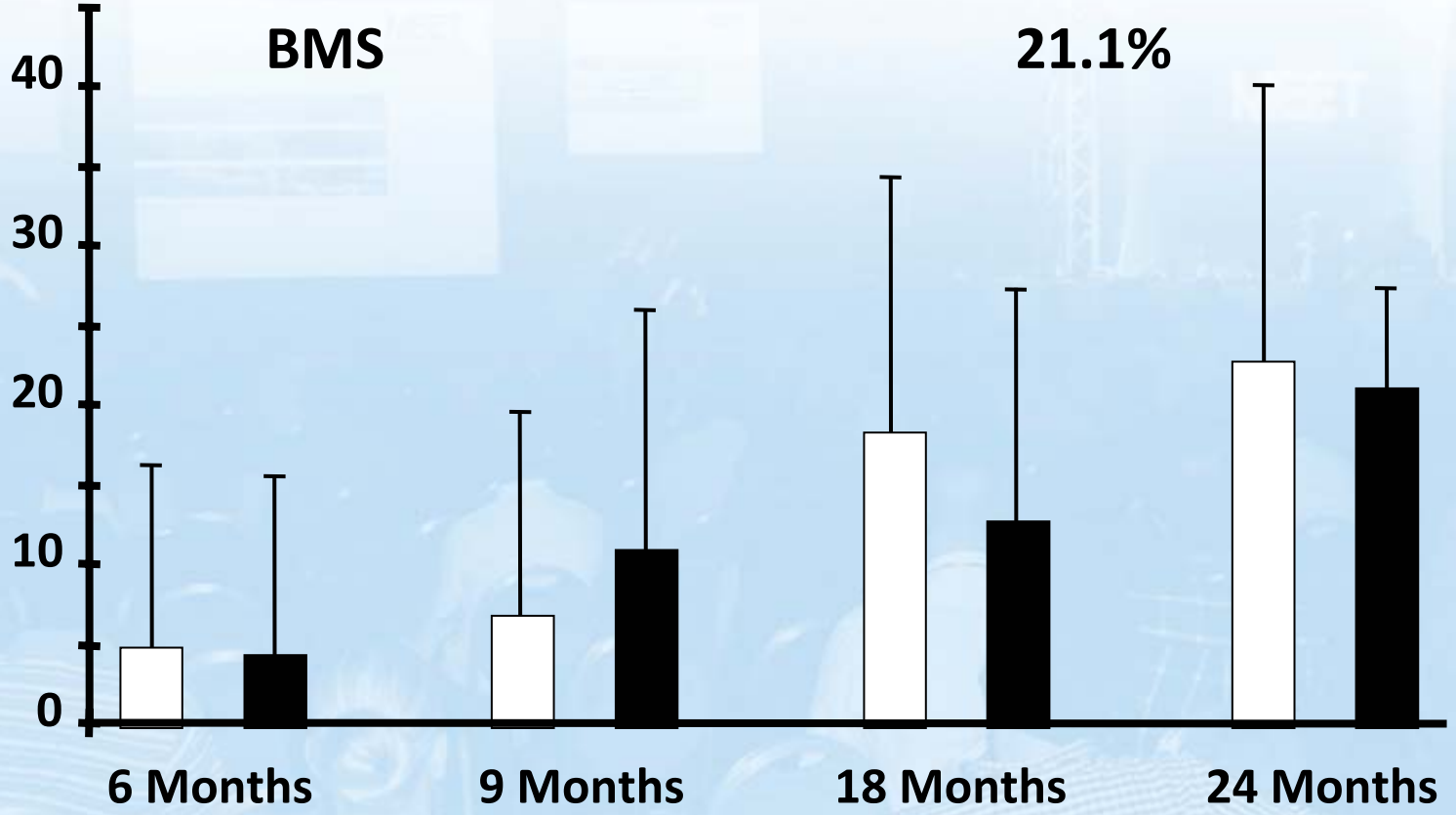


Duda et al. Circulation 2002

SIROCCO I + II –
Follow-up until 2 Years

Restenosis at 2 years:

DES	**22.9%**
BMS	**21.1%**



Duda et. al JEVT 2006

Drug-eluting Stents – critical issues

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- choice of drug: -limus family vs. paclitaxel
- duration of drug-delivery
- polymeric vs. non-polymeric stent platform
- dosage of delivered drug
- carrier platform (stent fractures!)

Drug-eluting Stents – ongoing trials

Zilver-PTX

- paclitaxel
- stent platform
- nitinol

STRIDES

- ease kinetics
- polymeric stent platform
- nitinol

After the drug is released, DES remains a purely mechanical concept, will this be sufficient to resolve the problem of SFA disease in the long-term?

Biodegradable Stents – critical issues

- choice of material: Mg-alloy vs. polymeric materials
- problematic mechanical properties:
  - limited radial strength
  - limited flexibility
  - investigational products are all balloon expanding
- duration until stent desintegration / complete degradation
- vessel wall reaction to degradation process
- with vs. without drug coating
- coronary and BTK data are disappointing

The Future of SFA Treatment

1. next generation bare Nitinol stents
   – minimized fracture rates
   – optimized radial strength
   – short term restenosis < 1 year will remain the problem

2. Drug eluting Nitinol stents
   – based on latest generation nitinol BMS
   – postpone restenosis to > 1 year

3. Biodegradable (drug eluting) stents
   – resolve mechanical problems?
   – resolve restenosis?

4. Pro-healing technologies??