BARE METAL STENTS FULFILL THEIR GOALS

Mr Adriano Sala Tenna BSc, MBChB, AFRCSEd
Specialty Trainee, Vascular Surgery
Dr Sumaira Macdonald MBChB (Comm.), FRCP, FRCR, PhD,
Consultant Vascular Radiologist & Honorary Clinical Senior Lecturer,
Freeman Hospital, Newcastle, UK

FACULTY DISCLOSURE

- ADRIANO SALA TENNA
- I HAVE NO FINANCIAL RELATIONSHIPS TO DISCLOSE

- CACVS 2013

INTRODUCTION

- Explore level 1 evidence of benefit over "standard" therapy
- Highlight shortfalls
- Consider future directions

GOALS

- Achieve patency
- Maintain patency
- Avoid mechanical failure

ACHIEVEMENT AND MAINTENANCE OF PATENCY

ANGIOPLASTY VS STENTING FOR SFA LESIONS

Cochrane Database of Systematic Reviews 2009

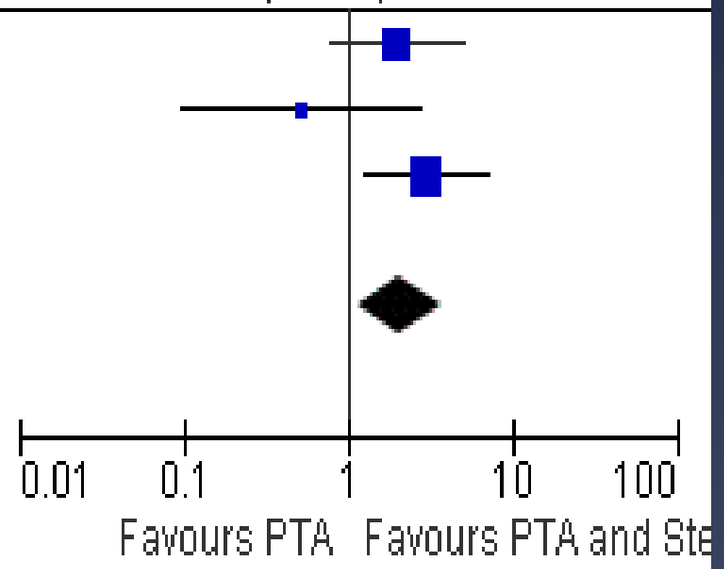
- Becquemin 2003
- Cejna 2001
- Grimm 2001
- Grenacher 2004
- FAST Trial
- Vienna ABSOLUTE Trial
- Vroegindeweij 1997
- Zdanowski 1999

PTA vs STENTING
6 month angiographic patency

Study or Subgroup	PTA and Stent Events	Total	PTA Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Cejna 2001	38	45	42	58	40.0%	1.99 [0.78, 5.04]
Grenacher 2004	24	28	24	26	12.2%	0.52 [0.10, 2.79]
Vienna Absolute Trial	51	68	18	36	47.8%	3.03 [1.29, 7.10]
Total (95% CI)		**141**		**120**	**100.0%**	**2.06 [1.15, 3.72]**
Total events	113		84			

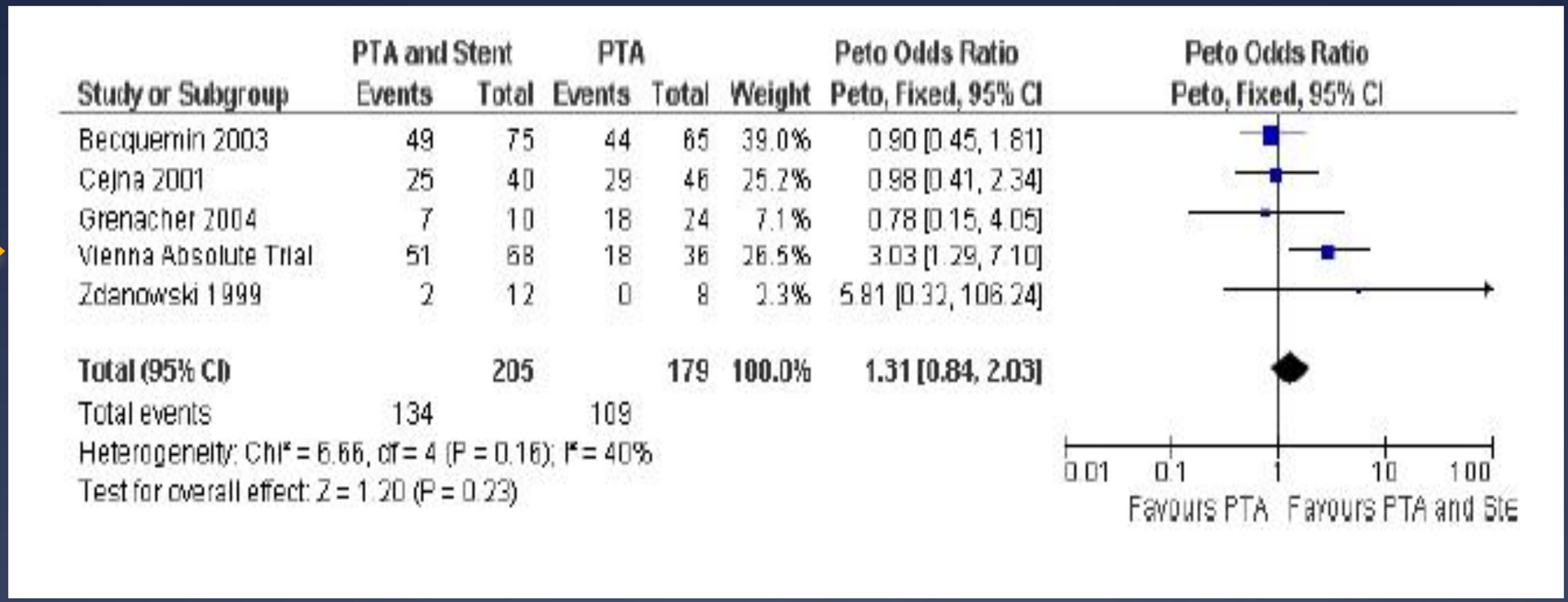
Heterogeneity: Chi² = 3.37, df = 2 (P = 0.19); I² = 41%

Test for overall effect: Z = 2.41 (P = 0.02)



Angioplasty versus stenting for superficial femoral artery lesions. Cochrane Database of Systematic Reviews, Issue 4, 2009
Twine CP, Coulson J, Shandall A, McLain AD.
DOI: 10.1002/14651858.CD006767.pub2

PTA vs STENTING
12 month angiographic patency



Study or Subgroup	PTA and Stent Events	Total	PTA Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Becquemin 2003	49	75	44	65	39.0%	0.90 [0.45, 1.81]
Cejna 2001	25	40	29	46	25.2%	0.98 [0.41, 2.34]
Grenacher 2004	7	10	18	24	7.1%	0.78 [0.15, 4.05]
Vienna Absolute Trial	51	68	18	36	26.5%	3.03 [1.29, 7.10]
Zdanowski 1999	2	12	0	8	2.3%	5.81 [0.32, 106.24]
Total (95% CI)		**205**		**179**	**100.0%**	**1.31 [0.84, 2.03]**
Total events	134		109			

Heterogeneity: Chi² = 6.66, df = 4 (P = 0.16); I² = 40%
Test for overall effect: Z = 1.20 (P = 0.23)

Peto Odds Ratio
Peto, Fixed, 95% CI

0.01 0.1 1 10 100
Favours PTA Favours PTA and Ste

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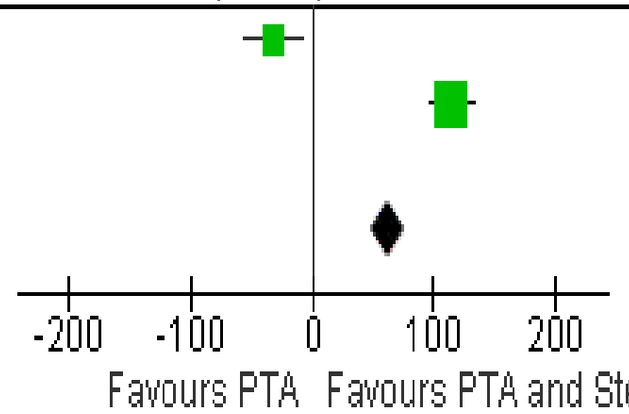
PTA vs STENTING
12 month walking distance

Study or Subgroup	PTA and Stent Mean	SD	Total	PTA Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
FAST Trial	20	62	61	52	79	75	35.7%	-32.00 [-55.70, -8.30]
Vienna Absolute Trial	295	51	51	180	40	53	64.3%	115.00 [97.34, 132.66]
Total (95% CI)			**112**			**128**	**100.0%**	**62.52 [48.36, 76.68]**

Heterogeneity: Chi² = 95.02, df = 1 (P < 0.00001); I² = 99%

Test for overall effect: Z = 8.65 (P < 0.00001)



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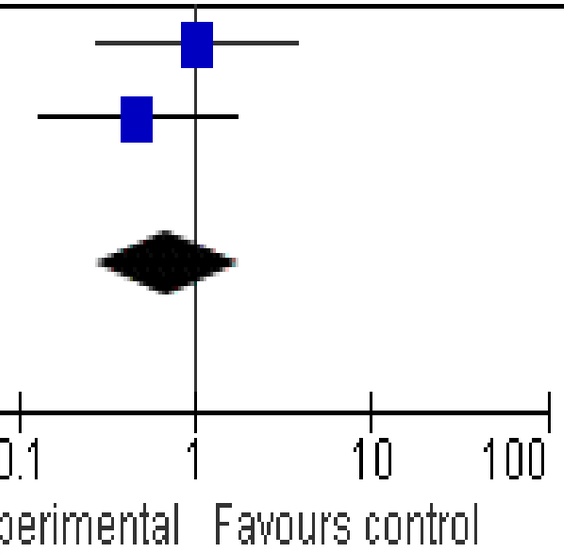
PTA vs STENTING
24 month angiographic patency

Study or Subgroup	PTA and Stent Events	Total	PTA Events	Total	Weight	Peto Odds Ratio Peto, Fixed, 95% CI
Cejna 2001	8	15	11	21	49.7%	1.04 [0.28, 3.84]
Grenacher 2004	7	15	15	23	50.3%	0.48 [0.13, 1.75]
Total (95% CI)		**30**		**44**	**100.0%**	**0.70 [0.28, 1.76]**
Total events	15		26			
Heterogeneity: Chi² = 0.68, df = 1 (P = 0.41); I² = 0%						
Test for overall effect: Z = 0.75 (P = 0.45)						



Stent PTA

Angioplasty versus stenting for superficial femoral artery lesions.
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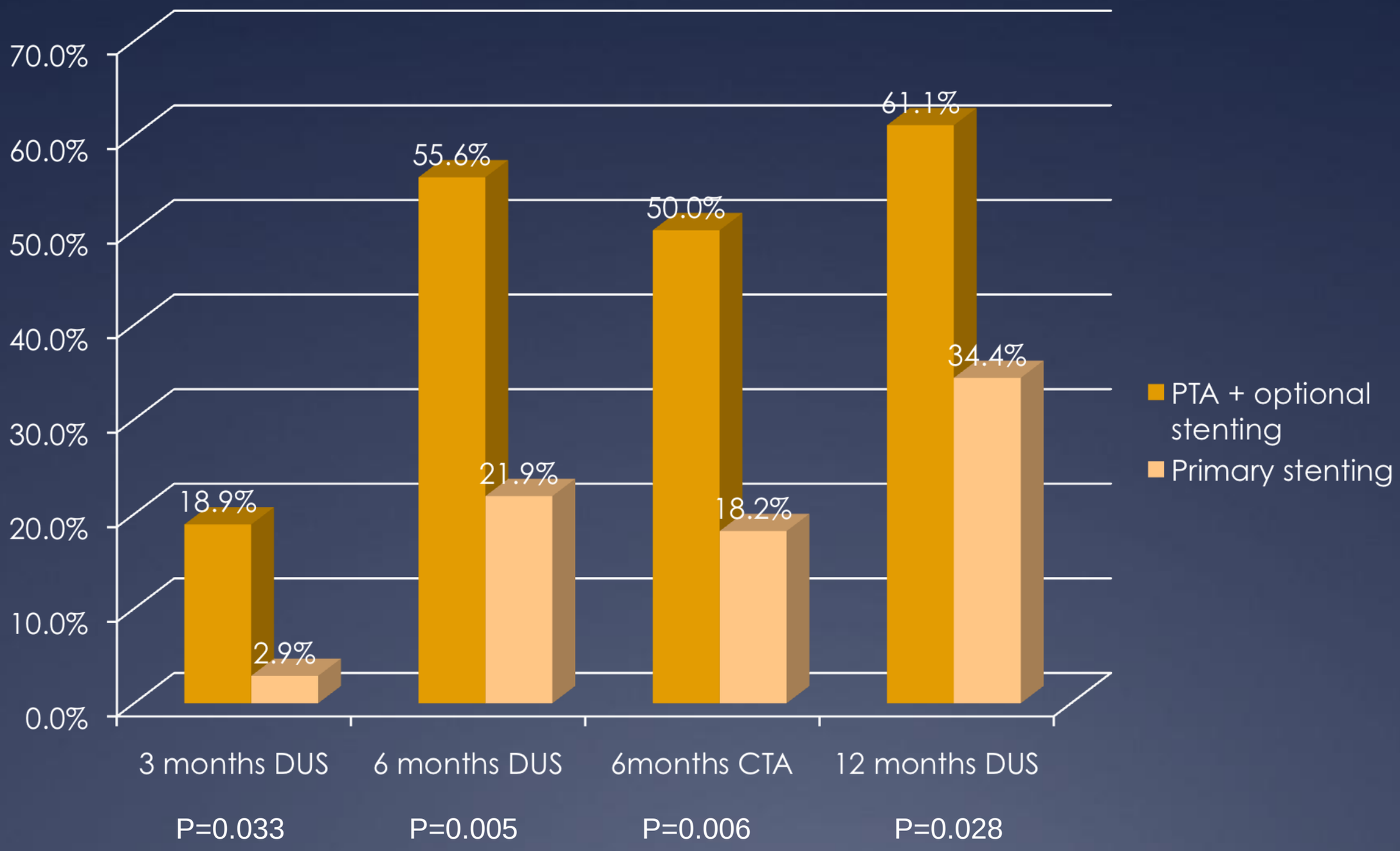
2ND GENERATION DEDICATED NITINOL STENTS

- ASTRON Trial – Biotronic Stent
- RESILIENT TRIAL – Bard LifeStent

ASTRON Trial

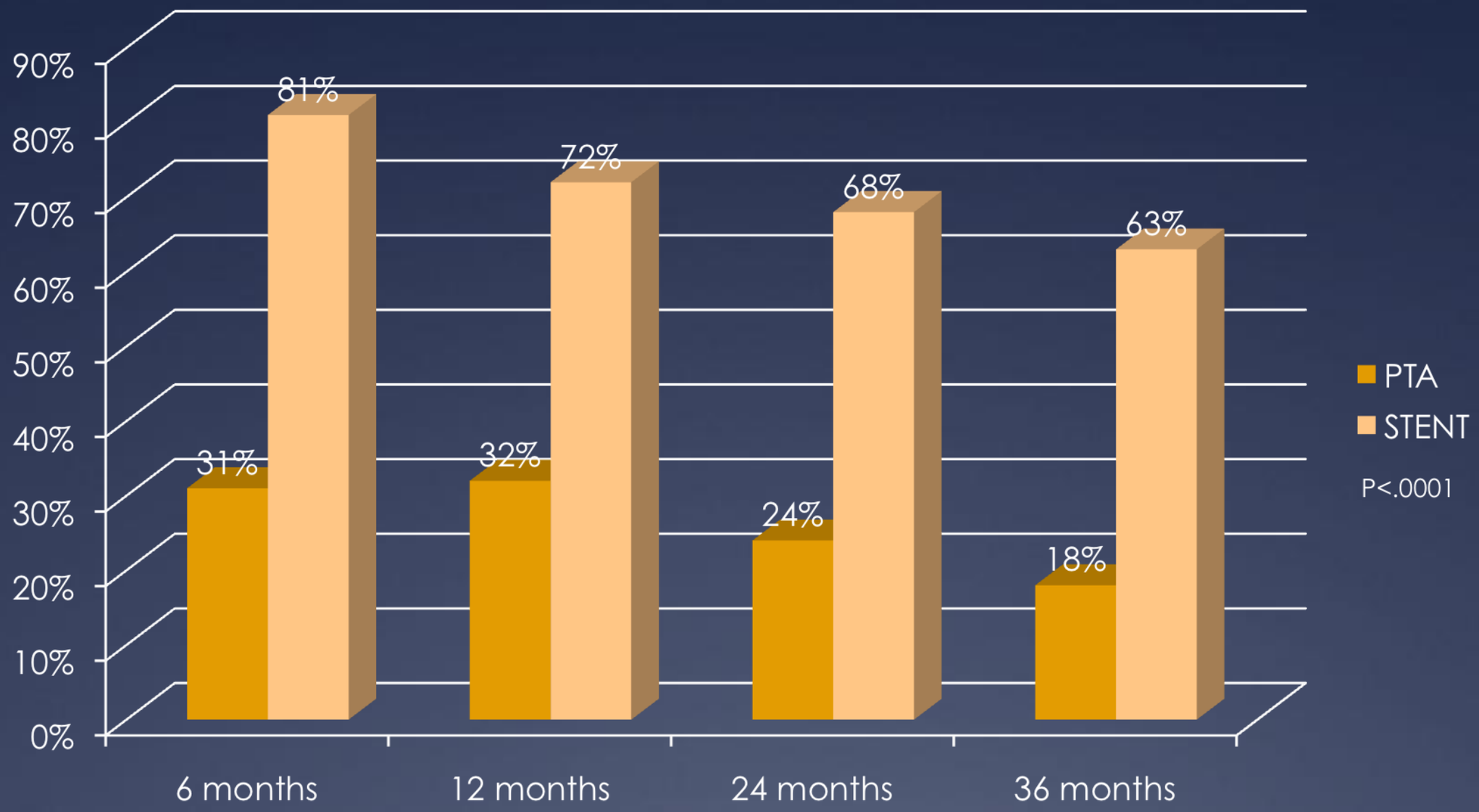
Mean treated length 8.4cm (3 – 25cm)

Binary restenosis



RESILIENT Trial

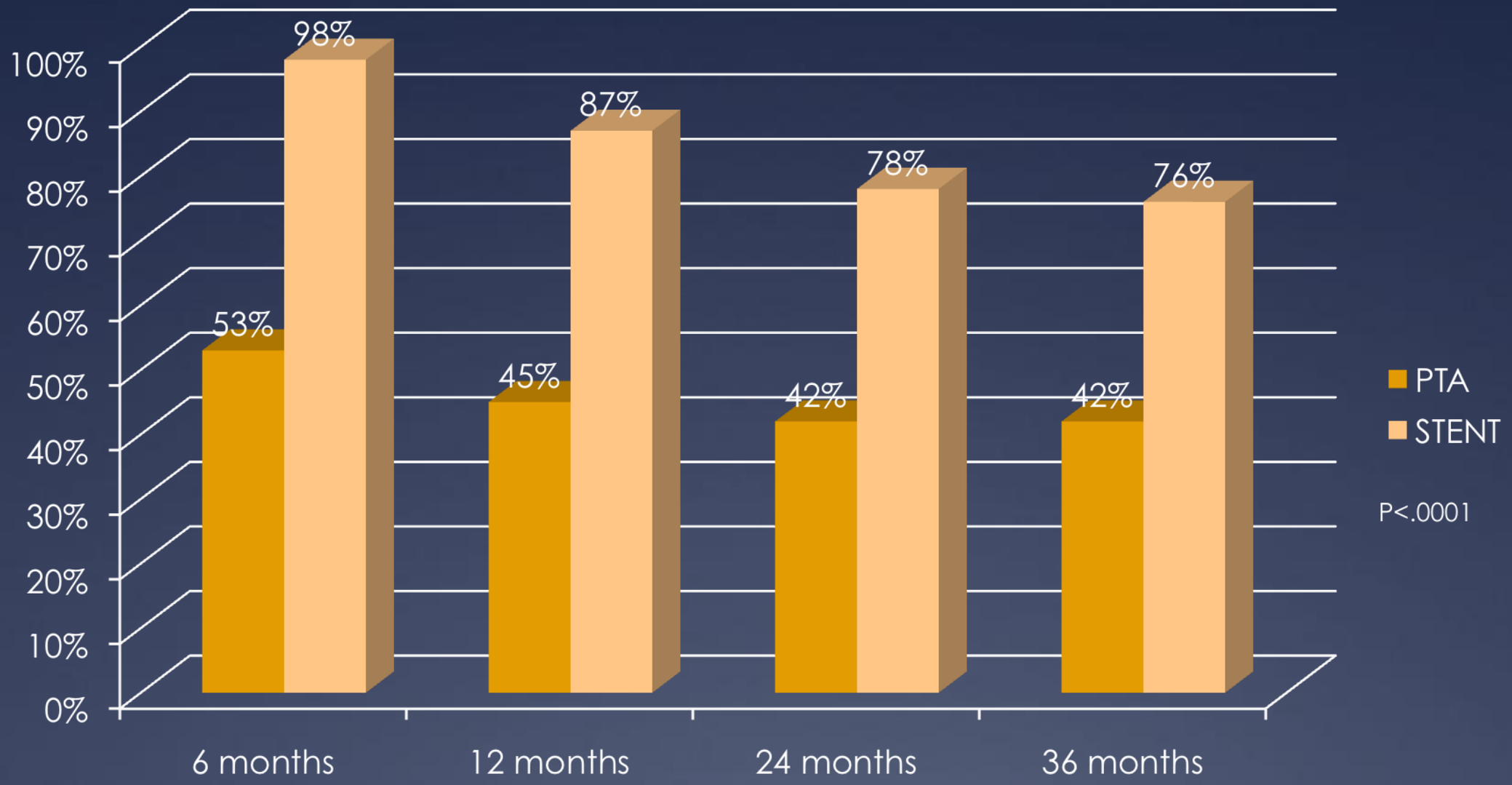
Clinical success 3yr data. Mean length 6.5cm (<15cm)



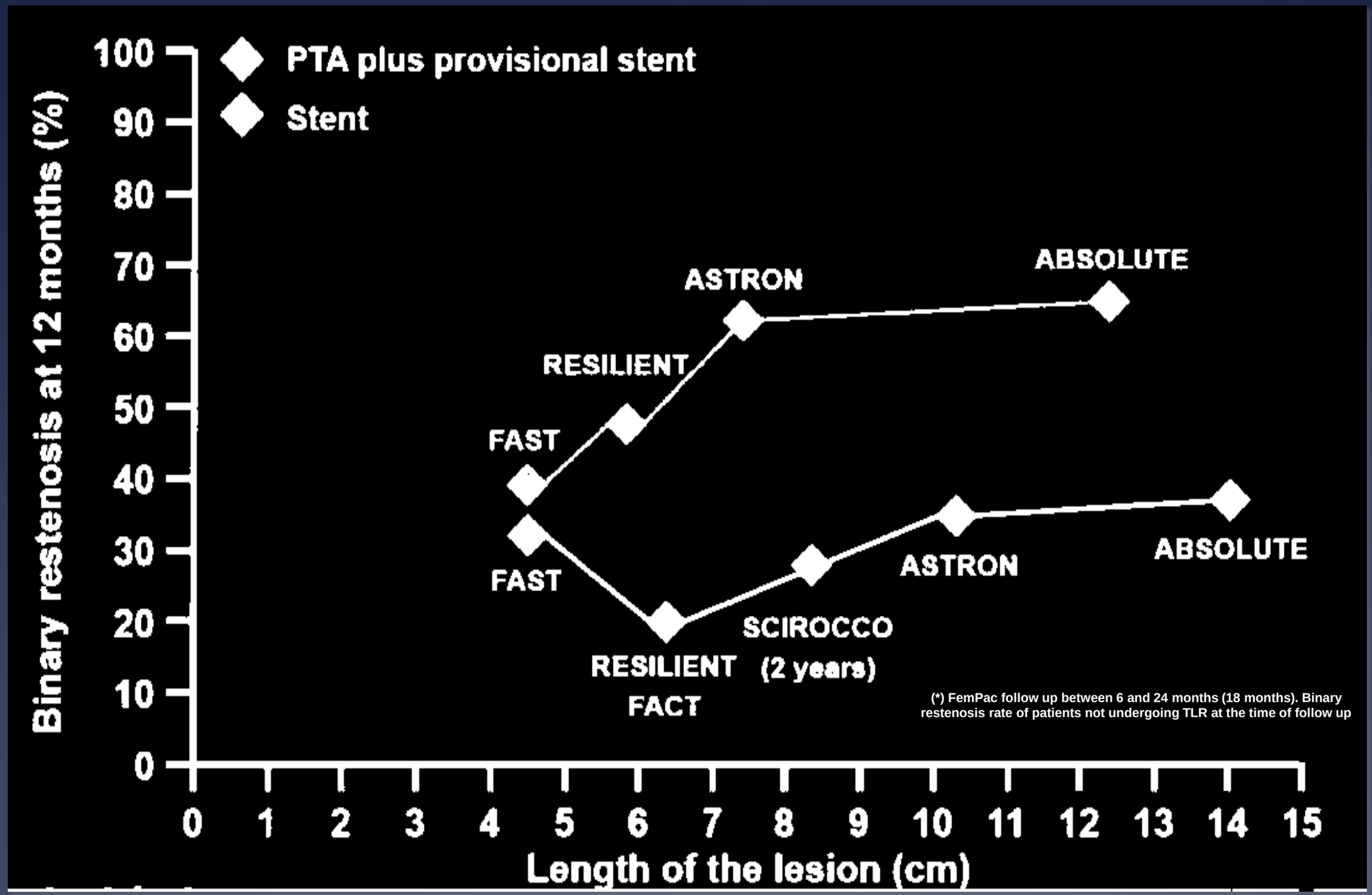
An improvement in baseline symptoms by at least one Rutherford category and sustained through follow-up

RESILIENT Trial

Freedom from TLR - 3yr data



CLINICAL STUDY RESULTS



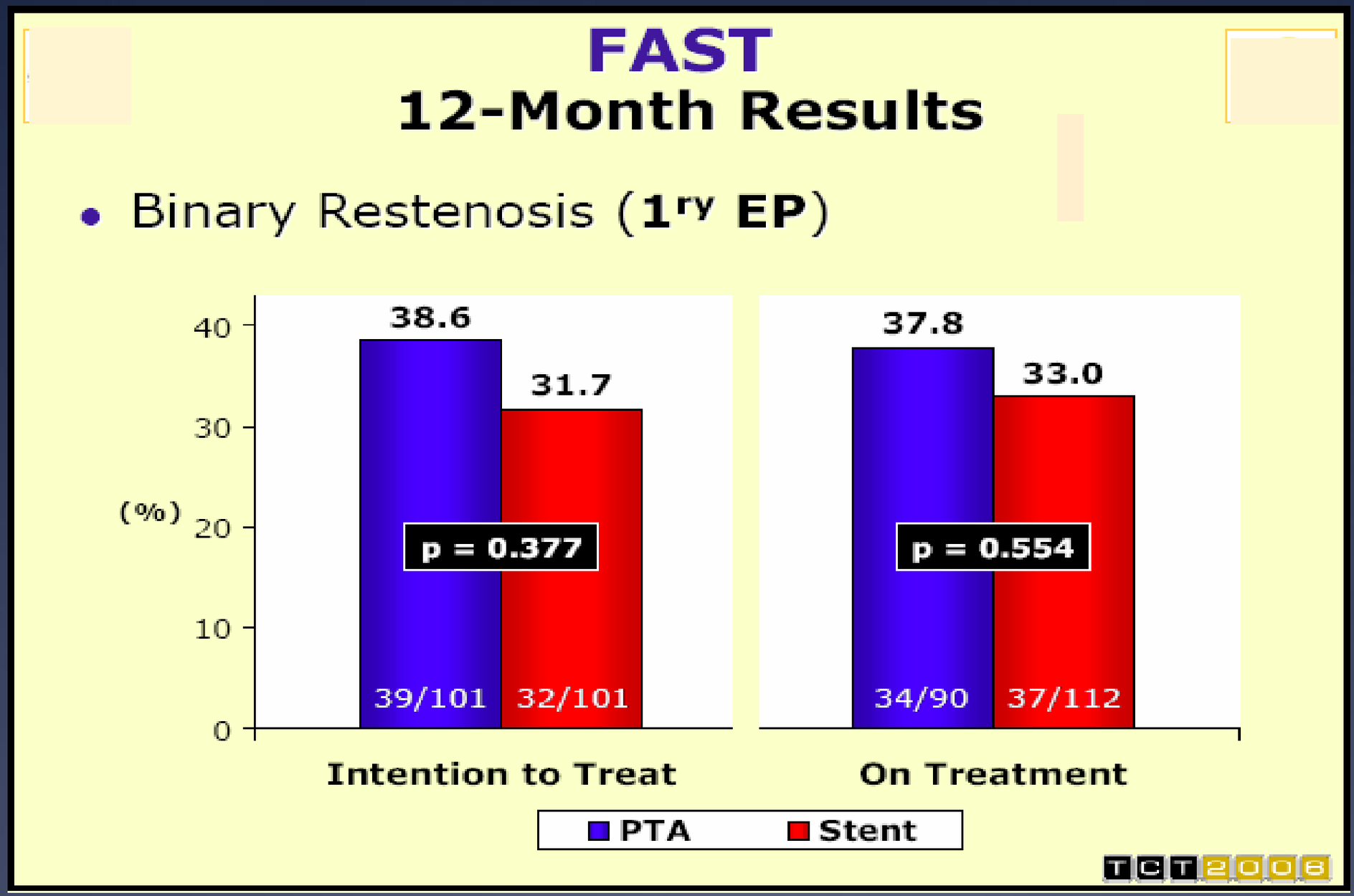
(*) FemPac follow up between 6 and 24 months (18 months). Binary restenosis rate of patients not undergoing TLR at the time of follow up

FAST Trial

- Mean length treated 4.5cm (1-10cm)
- Luminexx nitinol stent (Bard)
- Underpowered for low rates of PTA restenosis
- Short lesions best treated with PTA

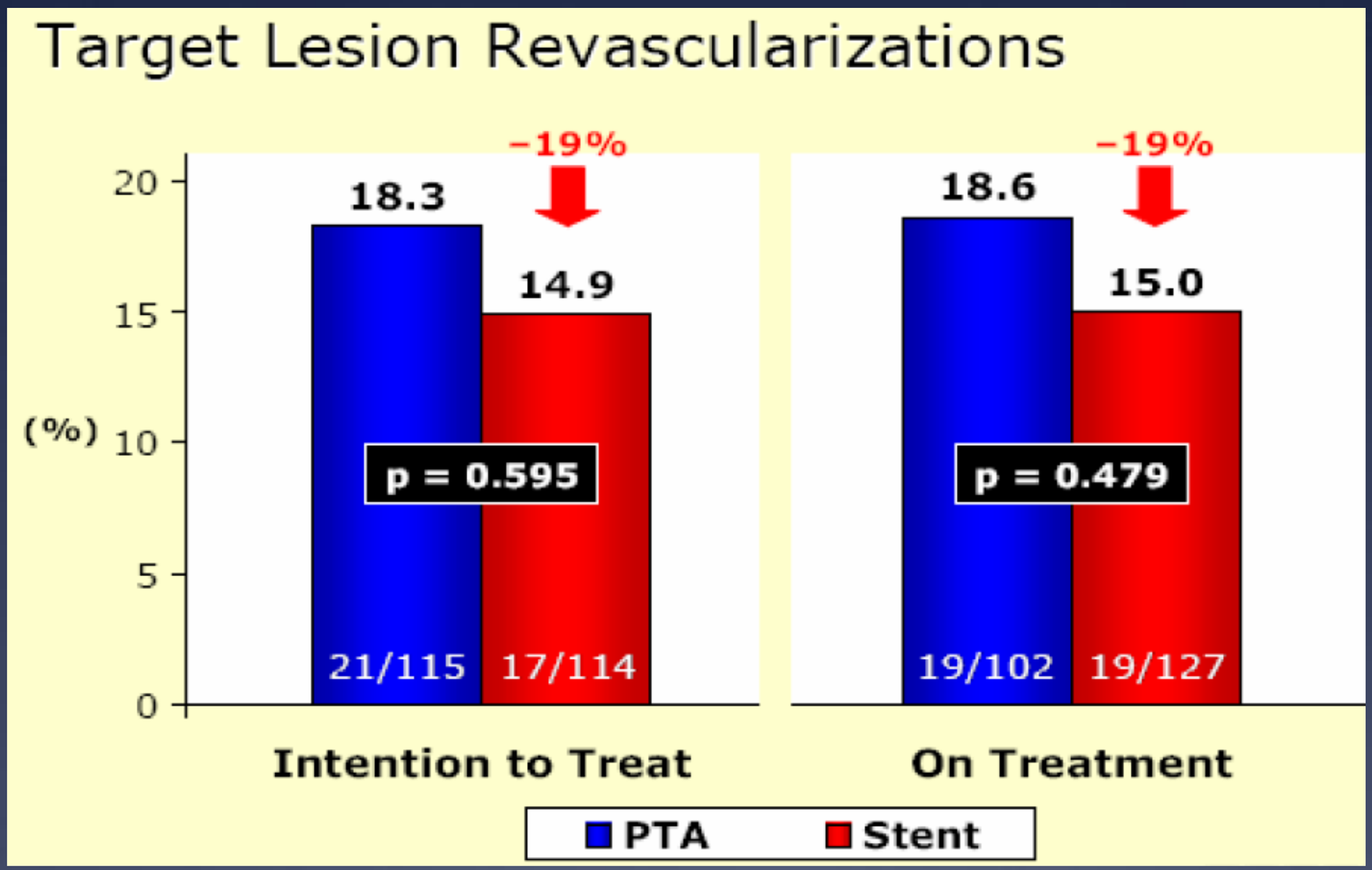
FAST Trial

Primary endpoint Binary restenosis >50%



FAST Trial

Primary endpoint Binary restenosis >50%



No difference in morphological and clinical outcome at 12 months

SHORTFALLS

STENT FRACTURE

SFA stent fracture rates – 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%
18 months	-	-	-	-	4.1%
length	85mm	82mm	124mm	45mm	65mm

Fracture rate determined by length of lesion and type of stent

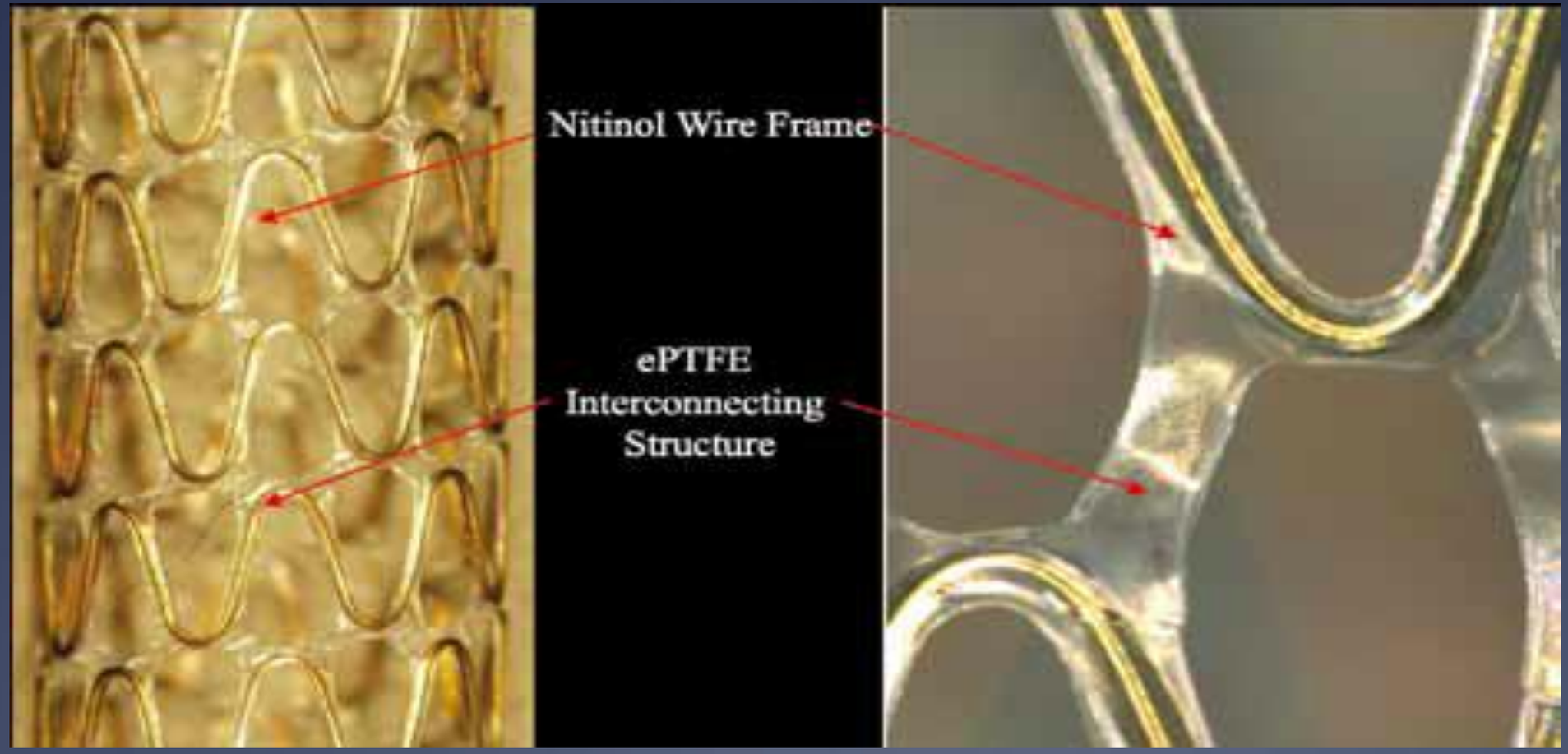
FUTURE DIRECTIONS

TECHNICAL CONSIDERATIONS

- Stent overlap zones rigid and prone to subsequent fracture – long stents have potential utility in the SFA
- Deployment must be without stretch or tension. A molecular stretch of ≥ 7% causes microfractures which predisposes to stent fractures at 6/12

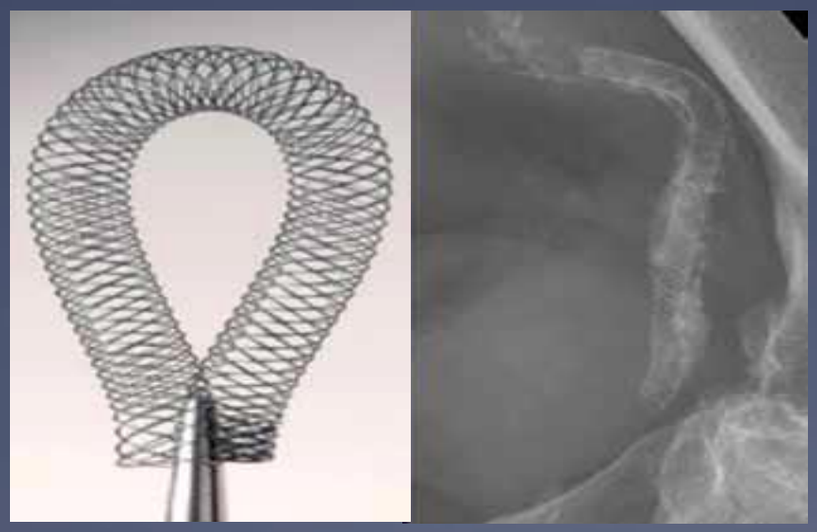
3rd GENERATION STENTS

- TIGRIS stent (Gore) – greater flexibility and less elongation during deployment
- LMWT heparin to reduce thrombosis



3rd GENERATION STENTS

- Supera stent interwoven closed cell nitinol wires (6 pairs). Increased radial force and crush resistance.
  - Freedom from restenosis on DUS 85% at 12 months and 76% at 24 months. No stent fractures despite deployment at sites of significant flexion.
  - Data suggest lower rates of stent fracture – SUPERB Registry



FUTURE DIRECTIONS

- Newer generation stents
  - Increased flexibility and reduced fracture rates
- Drug eluting stents – Zilver PTX
- Alternative therapies

CONCLUSION

- Current generation dedicated bare metal stents in SFA fulfill their goals
- Achieve and maintain patency (up to 3 ys in RCT's) over "standard" therapy
- Still problems with fracture rate and instent stenosis