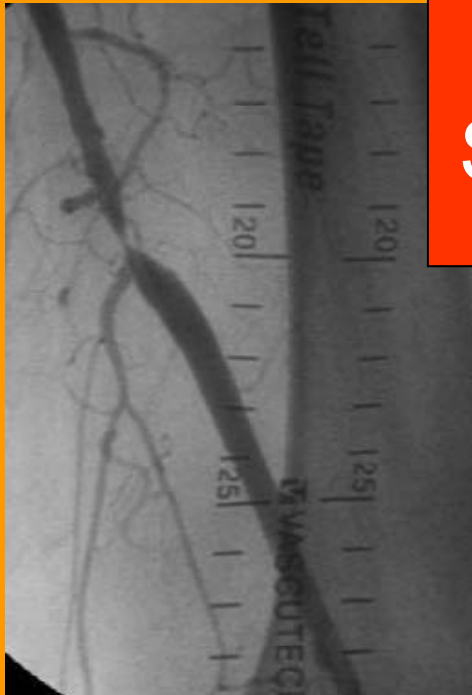


Evolving Horizon:

Drug-coated Balloons
Drug-coated Stents
in
Superficial Femoral Artery Disease



Mark W. Burket, MD
University of Toledo Medical Center

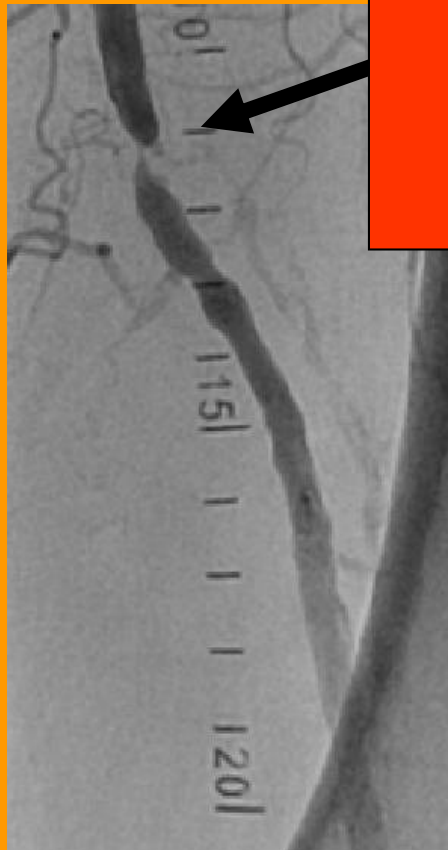




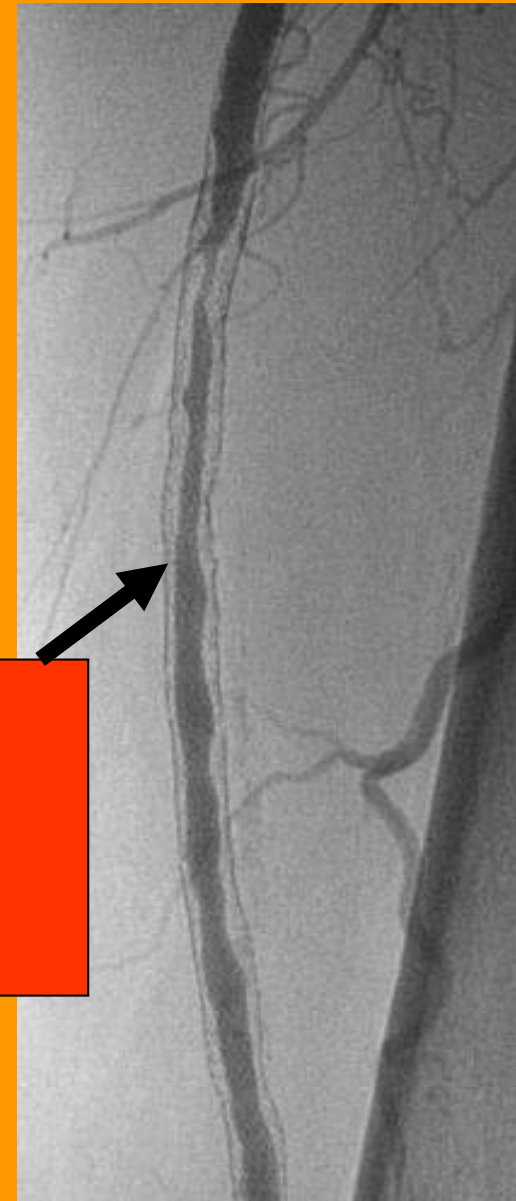
The New Game

- In which country do you practice?
- What is your budget?
- Can the patient comply with prolonged thienopyridine use?
- What is this person's risk of restenosis?
- What treatment combination(s) make sense?

Not all SFA disease is the same



Discrete lesion
Predictably good result
Inexpensive procedure
Reasonably durable



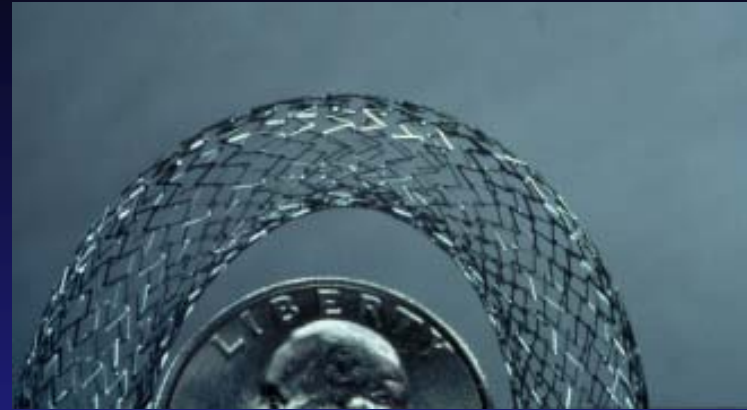
Diffuse in-stent restenosis
Expensive procedure
Questionable durability

The Big Question in Percutaneous SFA Treatment

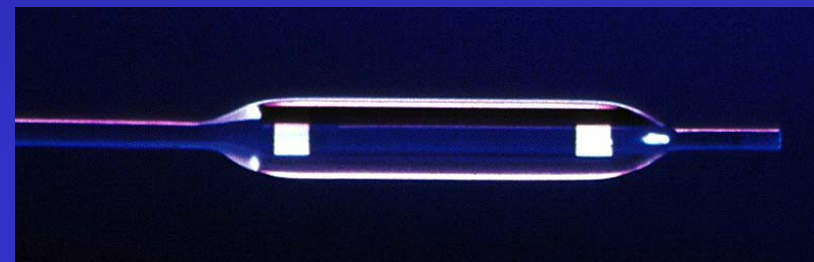
How can I keep it open?

Nitinol Stents

to reduce restenosis



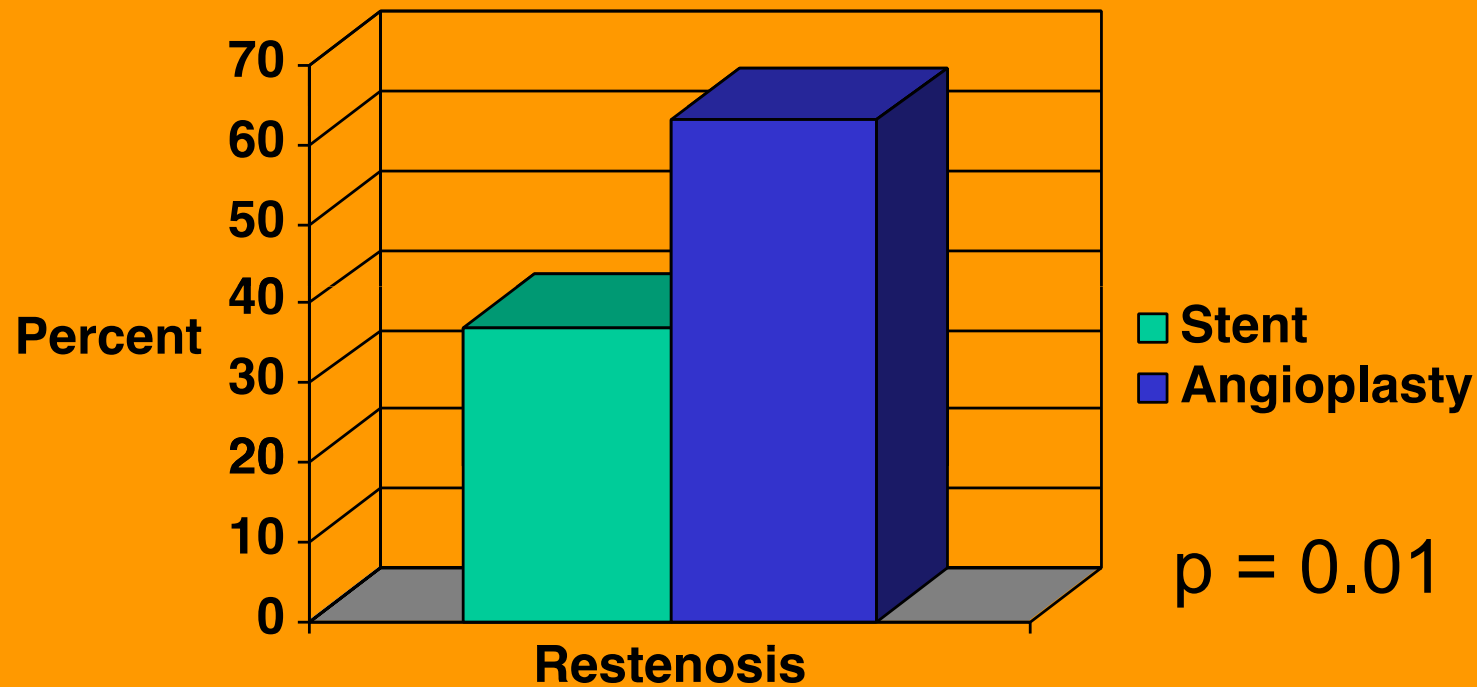
- Prospective series with nitinol encouraging
- Schillinger randomized 104 patients
 - 51 primary stent (Dynalink or Absolute)
 - 53 angioplasty



Martin JVIR 1995;6:843

Schilinger N Engl J Med 2006;354:1879

12 Month Restenosis by Duplex



Benefit also in FAST and RESILIENT

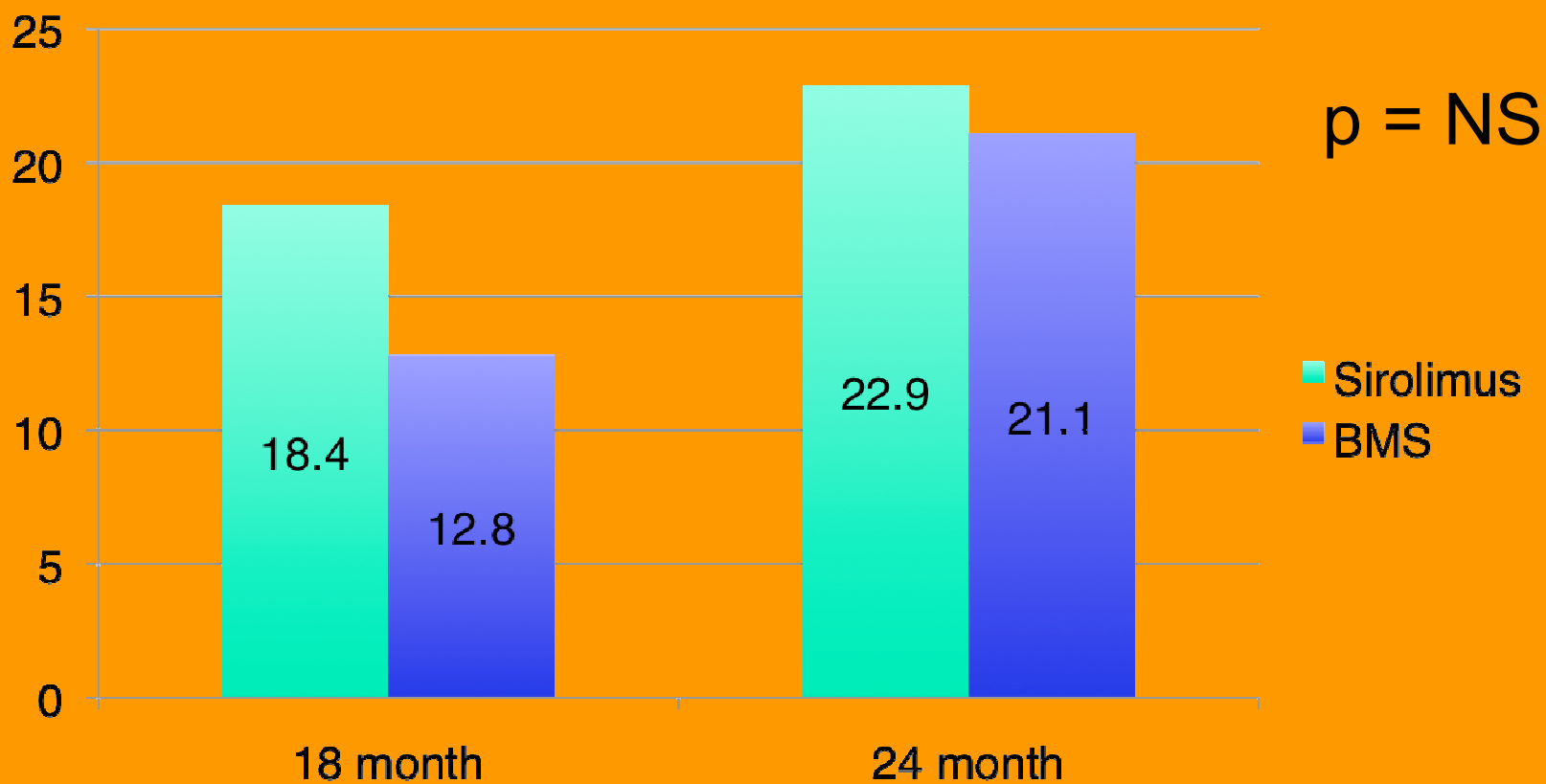
Drug Eluting Stent Disappointments

- SIROCCO
 - SMART + polymer + sirolimus
- STRIDES
 - Dynalink-E + polymer + everolimus

SIROCCO

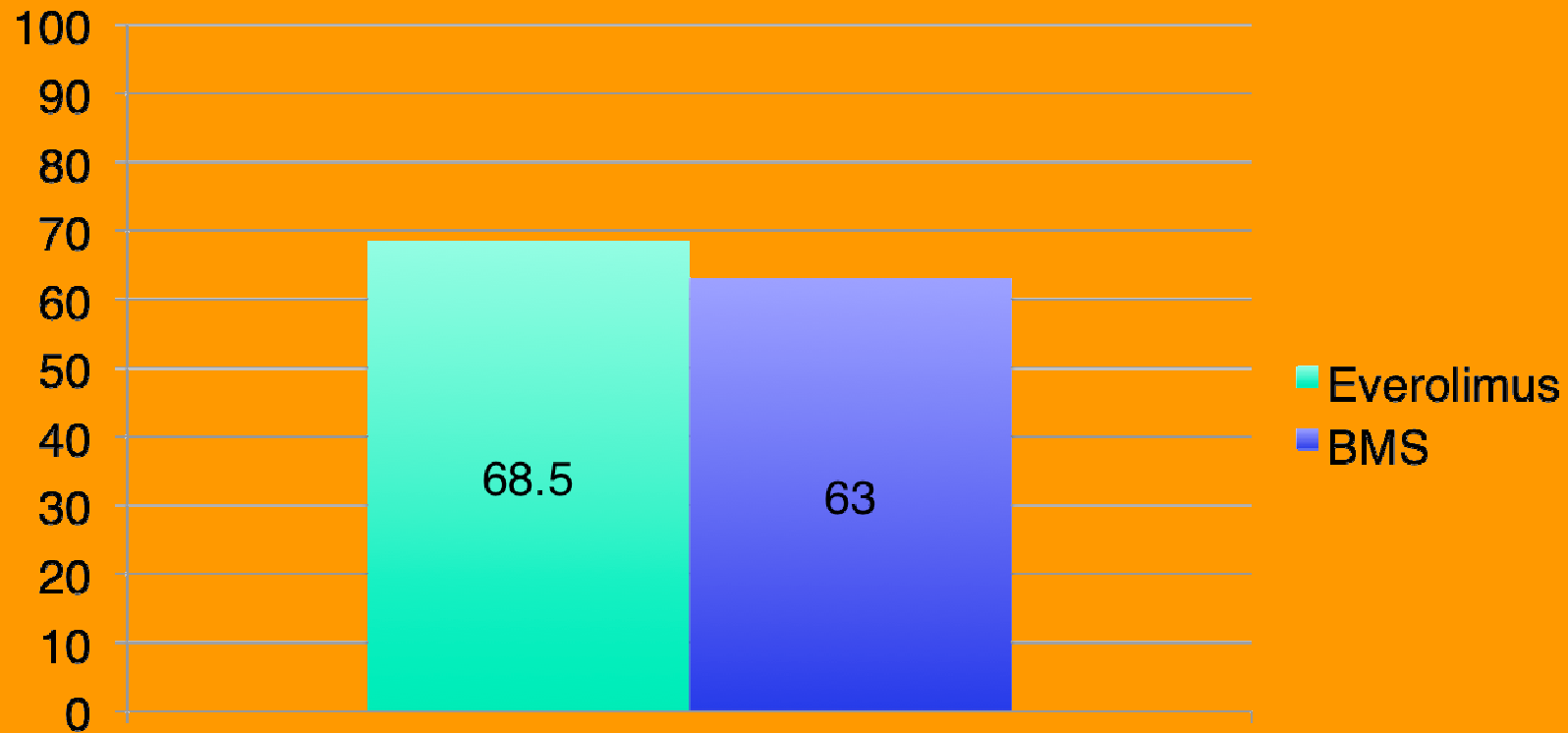
In-stent Restenosis

(by duplex ultrasound)



STRIDES

12 Month Patency
(duplex ultrasound)

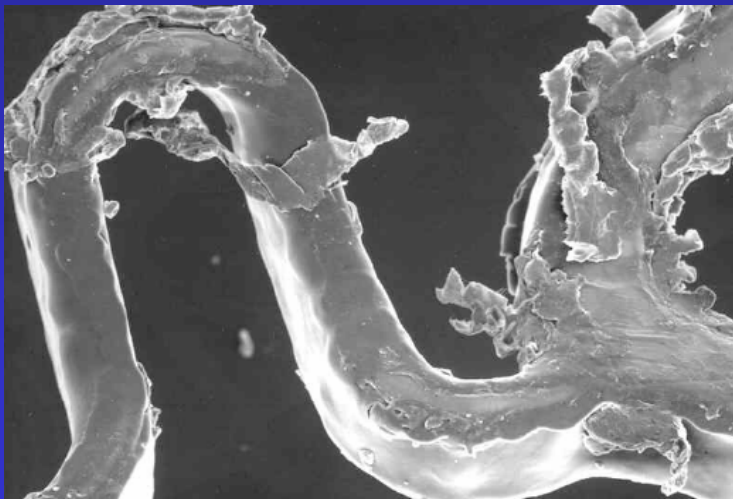
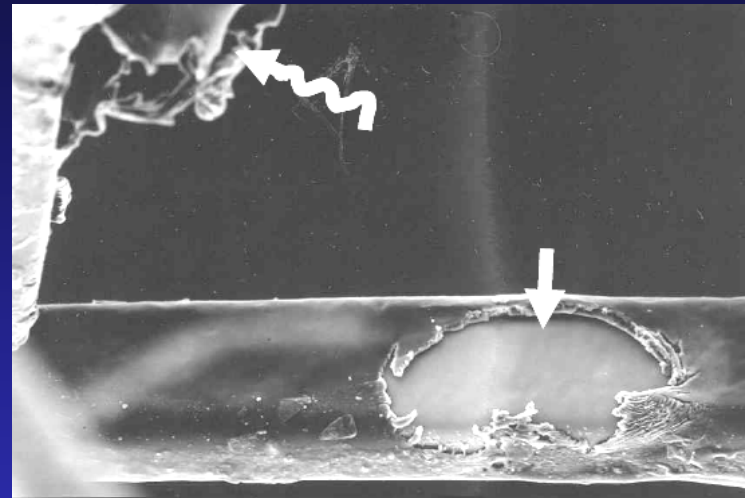
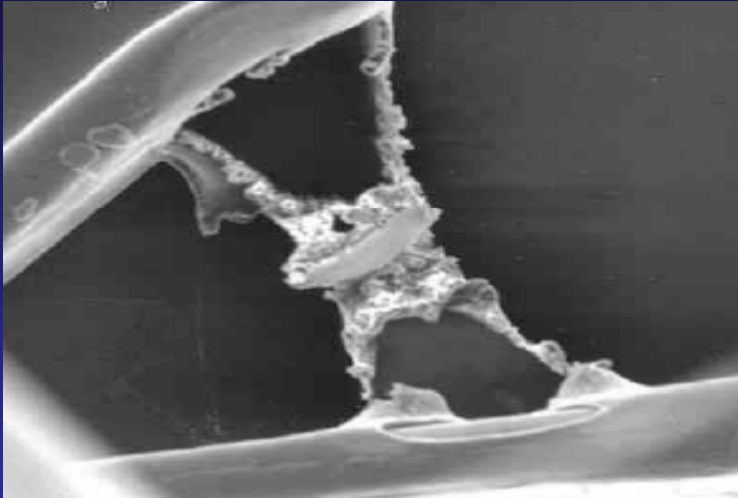


SIROCCO and STRIDES

what went wrong?

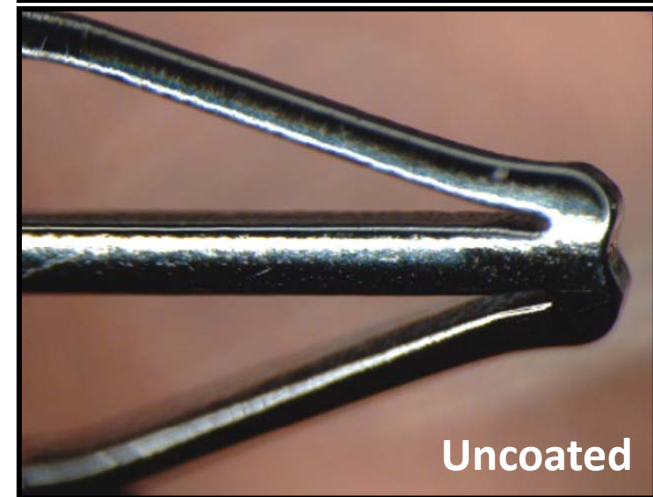
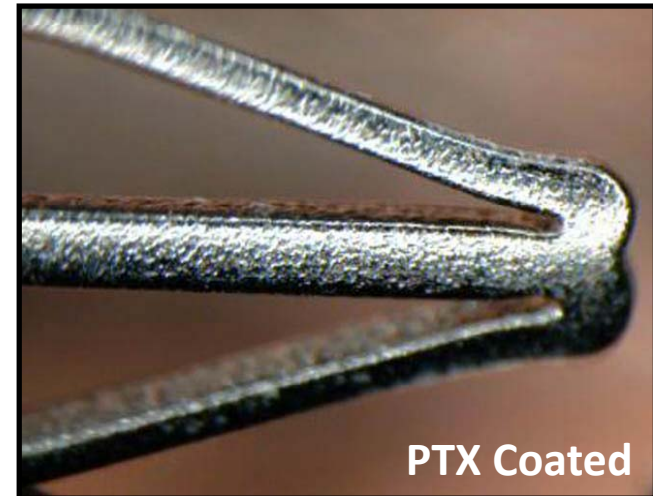
- “imus” drugs?
- Wrong elution rate?
- Wrong dose?
- Wrong stent?
- Polymer?

Polymer Breakdown



Zilver[®] PTX[®] Drug-Eluting Stent

- Designed for the SFA
- Drug coating: paclitaxel only
 - No polymer or binder
 - 3 $\mu\text{g}/\text{mm}^2$ dose density



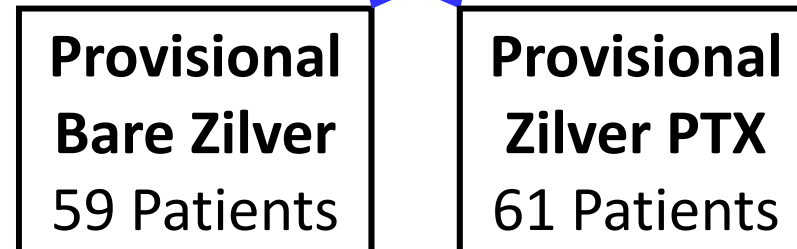
Randomized Clinical Trial Design

* Failed PTA = Acute PTA

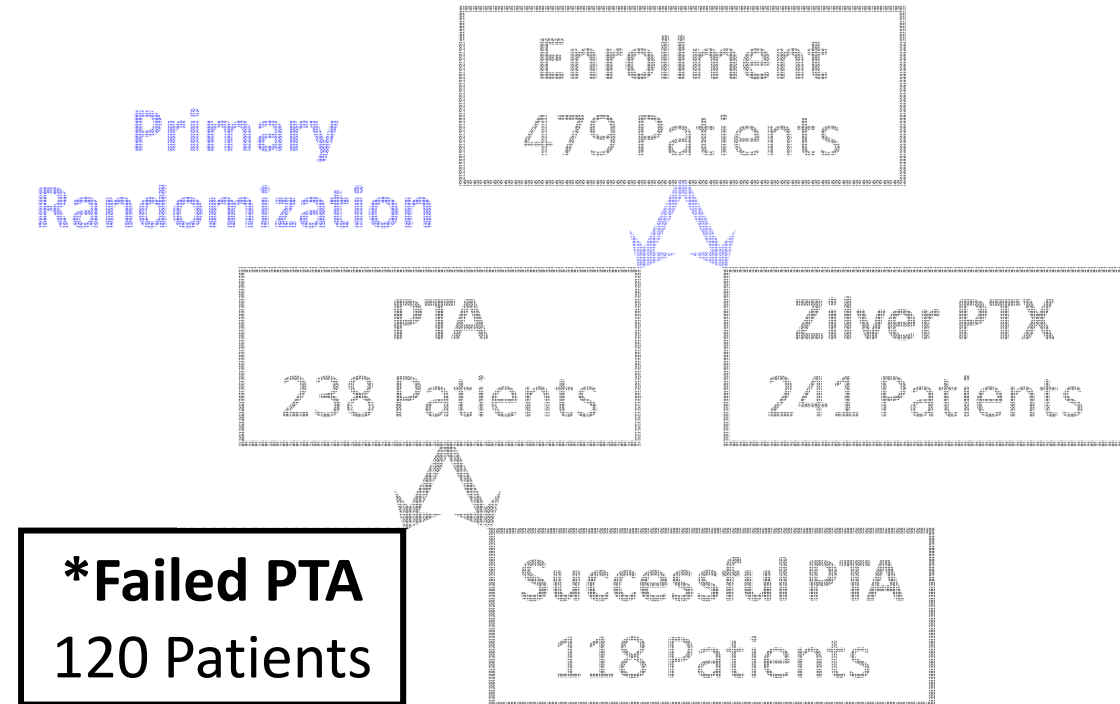
Failure Due to:

- ≥ 30 %DS (including persistent, flow-limiting dissection) on arteriography
- OR -
- ≥ 5 mmHg mean trans-stenotic pressure gradient

Secondary Randomization

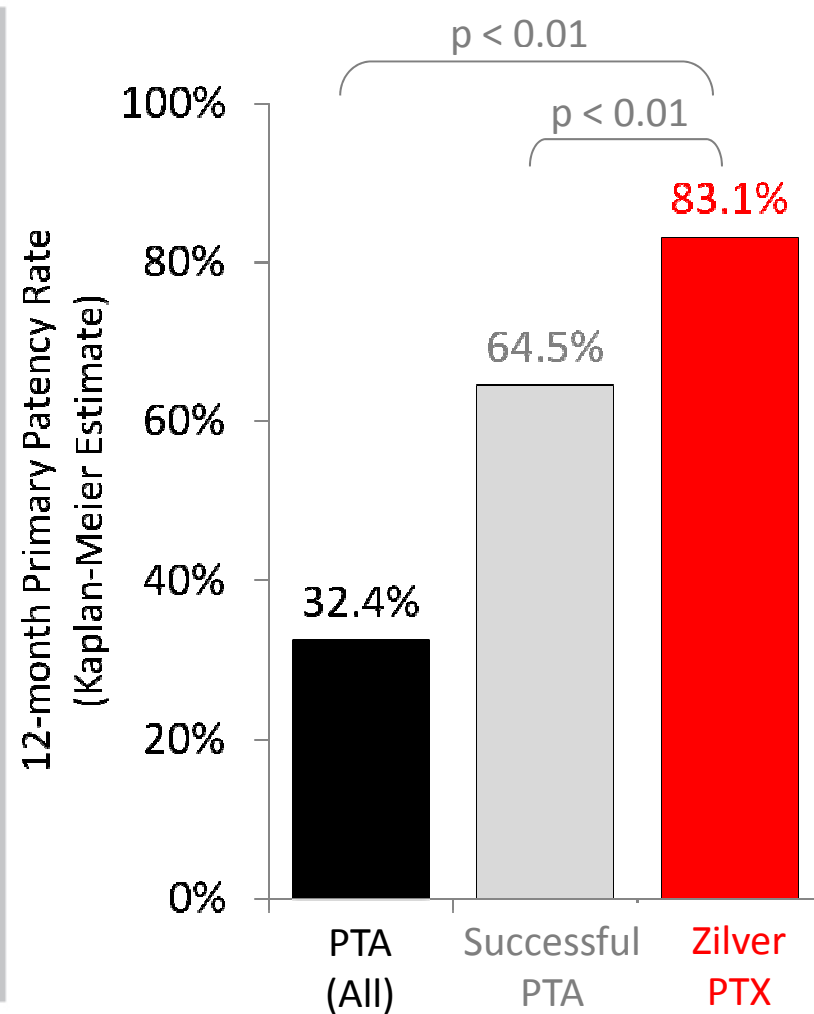
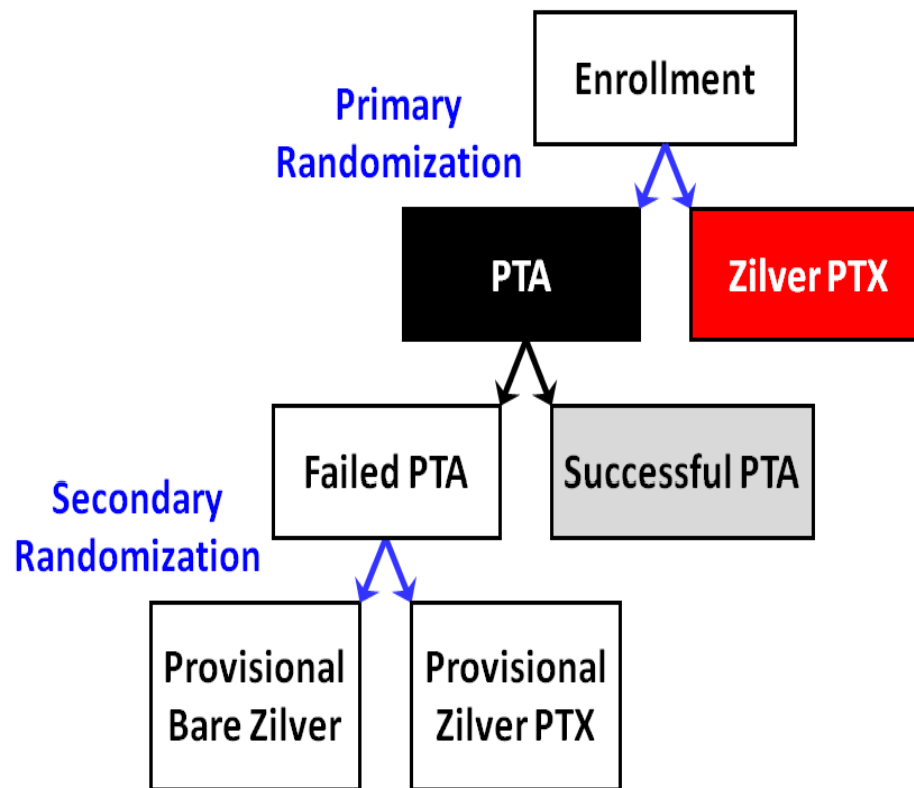


Primary Randomization



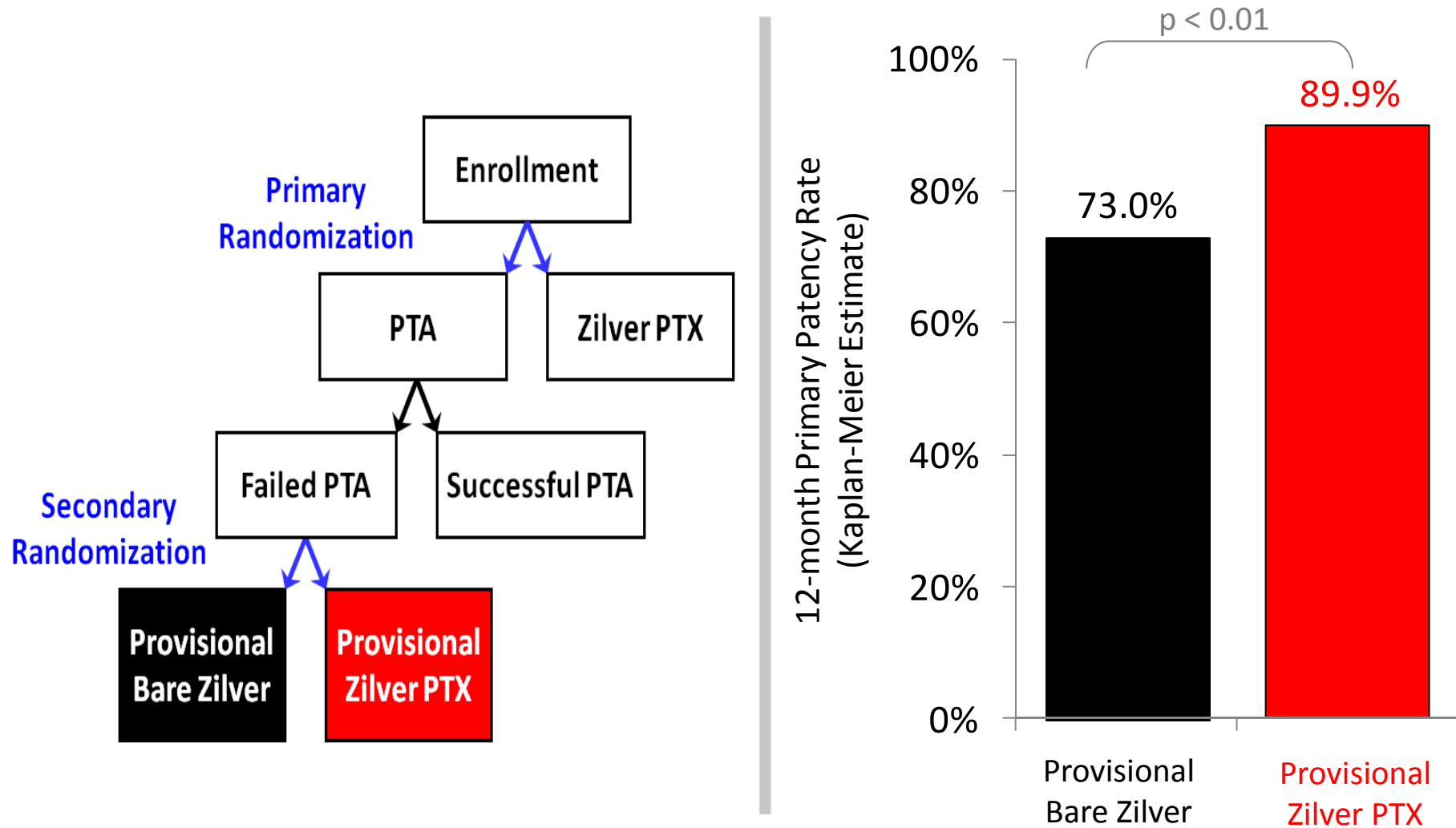
12-Month Effectiveness

Primary Patency (PSVR < 2.0): Zilver PTX vs. PTA



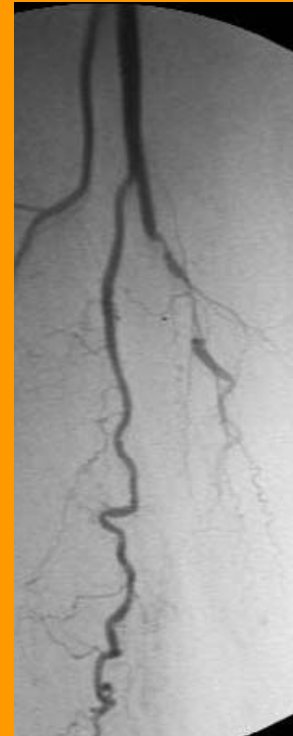
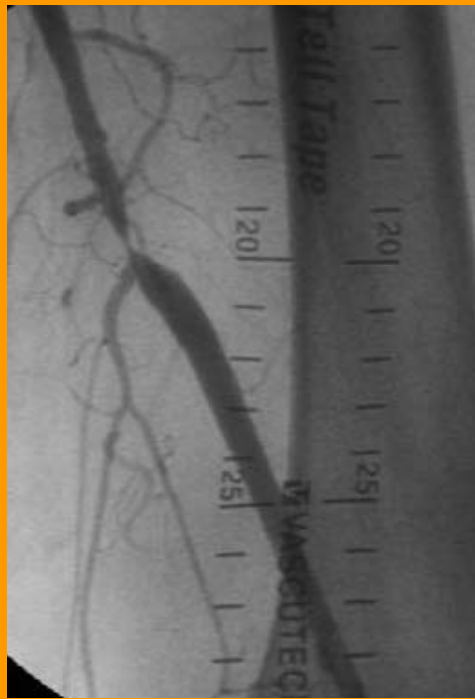
12-Month Paclitaxel Effect

Patency (PSVR < 2.0): Provisional Zilver PTX vs. BMS



Zilver PTX Registry

Real World SFA Disease



Zilver PTX Single-Arm Registry

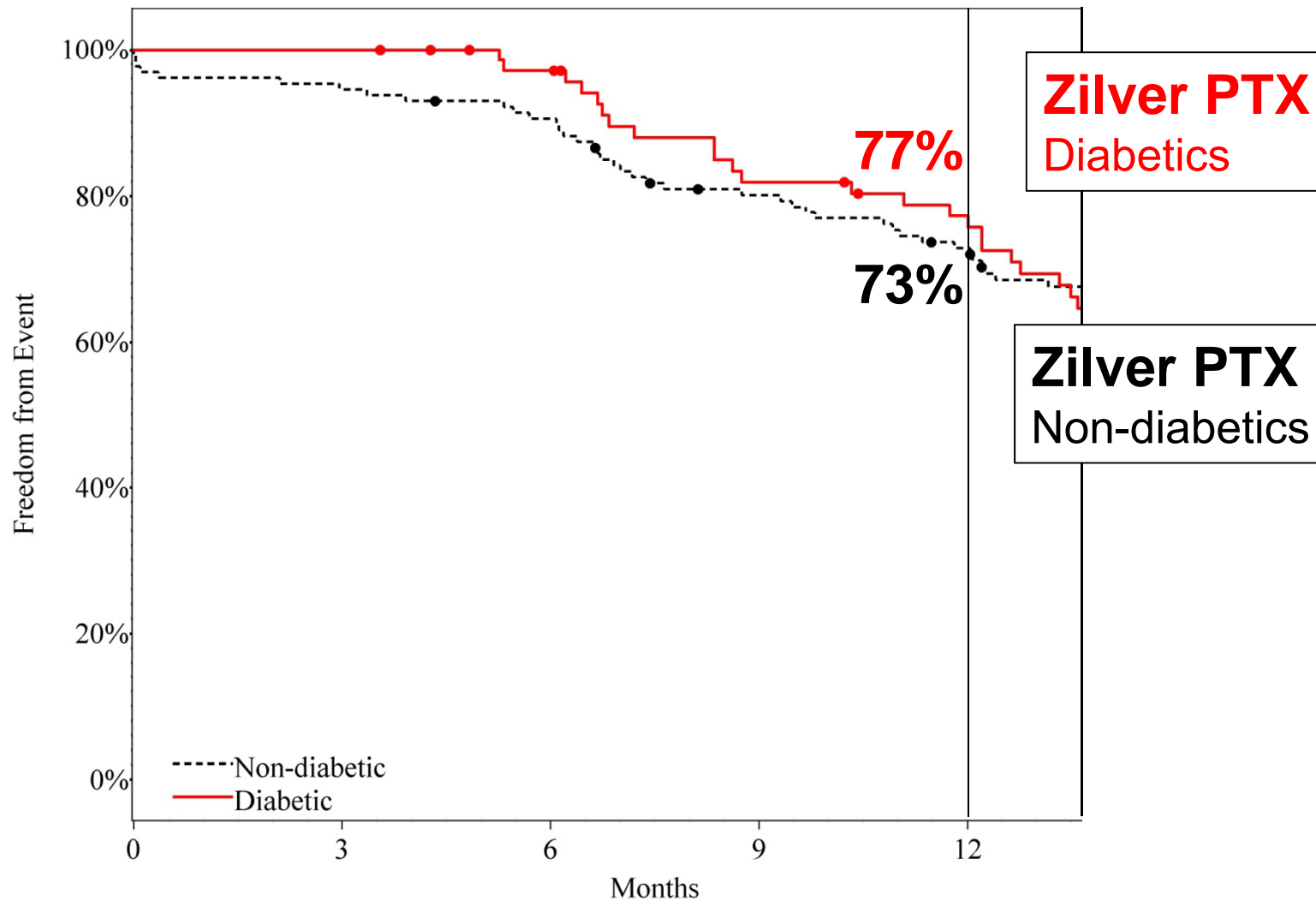
- **No lesion length limit**
- **Up to 4 stents per patient**
- **Included restenosis, including in-stent restenosis**
- **Prospective, nonrandomized, multinational**

Baseline Lesion Characteristics

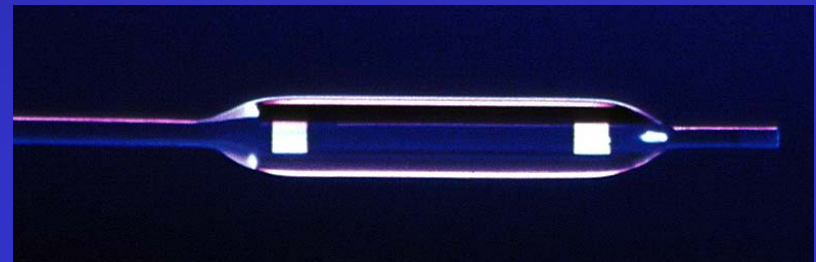
Lesions		900
Lesion length (mm)		100 ± 82
Diameter stenosis		85 ± 16%
TASC 2000 class	A	26%
	B	29%
	C	25%
	D	14%
Lesions > 7 cm		48%
Lesions > 15 cm		22%
Total occlusions		38%
Restenosis (all)		24%
In-stent restenosis (ISR)		14%

Zilver PTX in long lesions (> 15 cm)

Primary Patency (PSVR < 2.5)



Is the stent really necessary?



New England Journal, February 14, 2008

Gunnar Tepe, MD

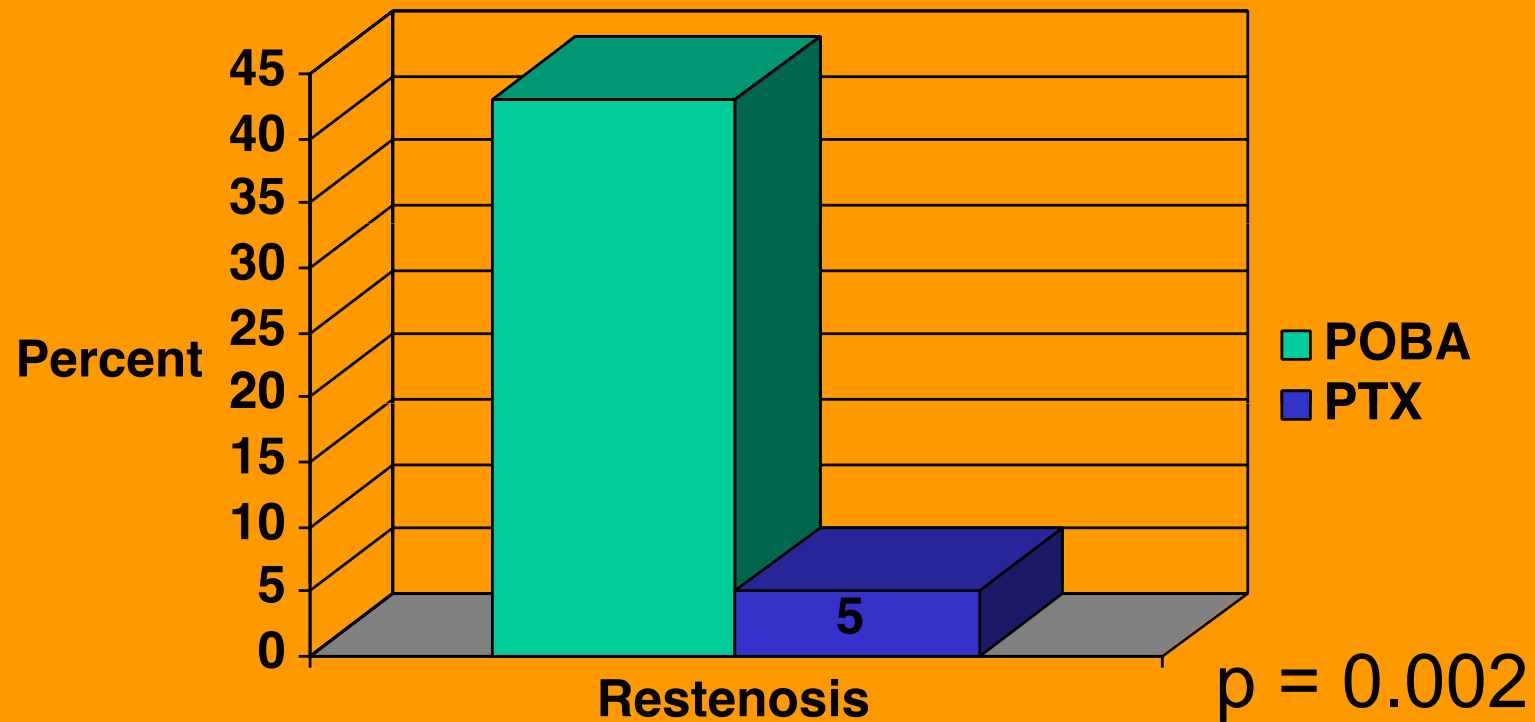
- Hypothesis: short-term exposure to paclitaxel can inhibit cell growth
- 2004: PTX coated balloon reduces ISR in porcine model
- 2006: 52 patients with coronary ISR randomized to POBA vs PTX coated balloon

Scheller Circulation 2004;110:810

Scheller N Engl J Med 2006;355:2113

6 Month Binary Restenosis

(second restenosis in coronary ISR)



Scheller N Engl J Med 2006;355:2113

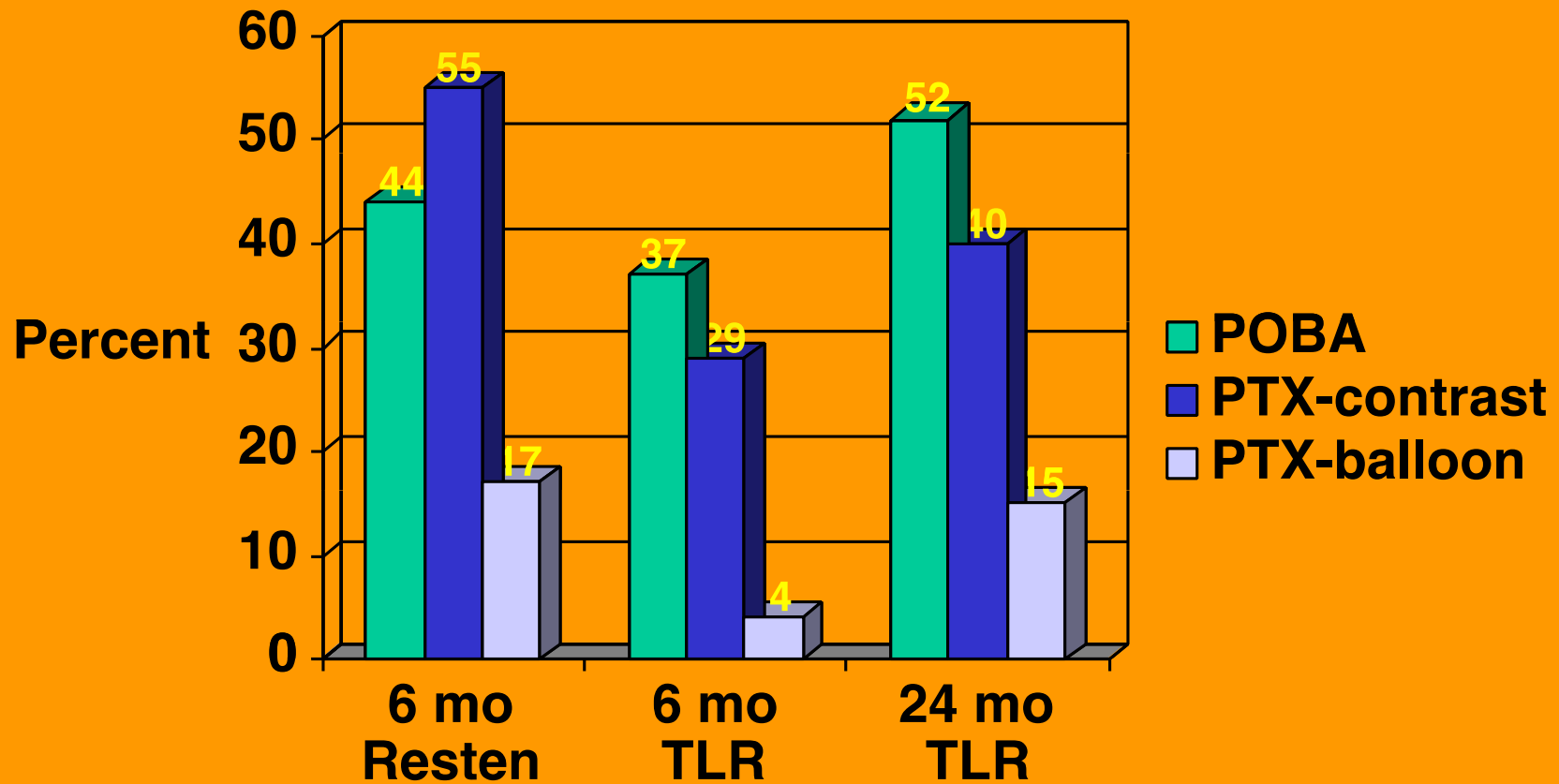
New England Journal, February 14, 2008

Gunnar Tepe, MD

- 154 patients with femoropopliteal disease
- 3 arm study
 - POBA without PTX
 - PTX in contrast medium
 - PTX coated balloons
- Balloons coated with 3 μg per sq mm

Tepe N Engl J Med 2008;358:689

Outcomes After PTX Treatment





Pre Post 6 Mo
 PTA

Pre Post 6 Mo
 PTA

Tepe N Engl J Med 2008;358:689-99

Paclitaxel Coated Balloons

- Commercially available in Europe
- Clinical trial site selection in US
 - LEVANT 2 (Lutonix)
 - RIVER (Medrad Interventional)

A More Complex Chess Game

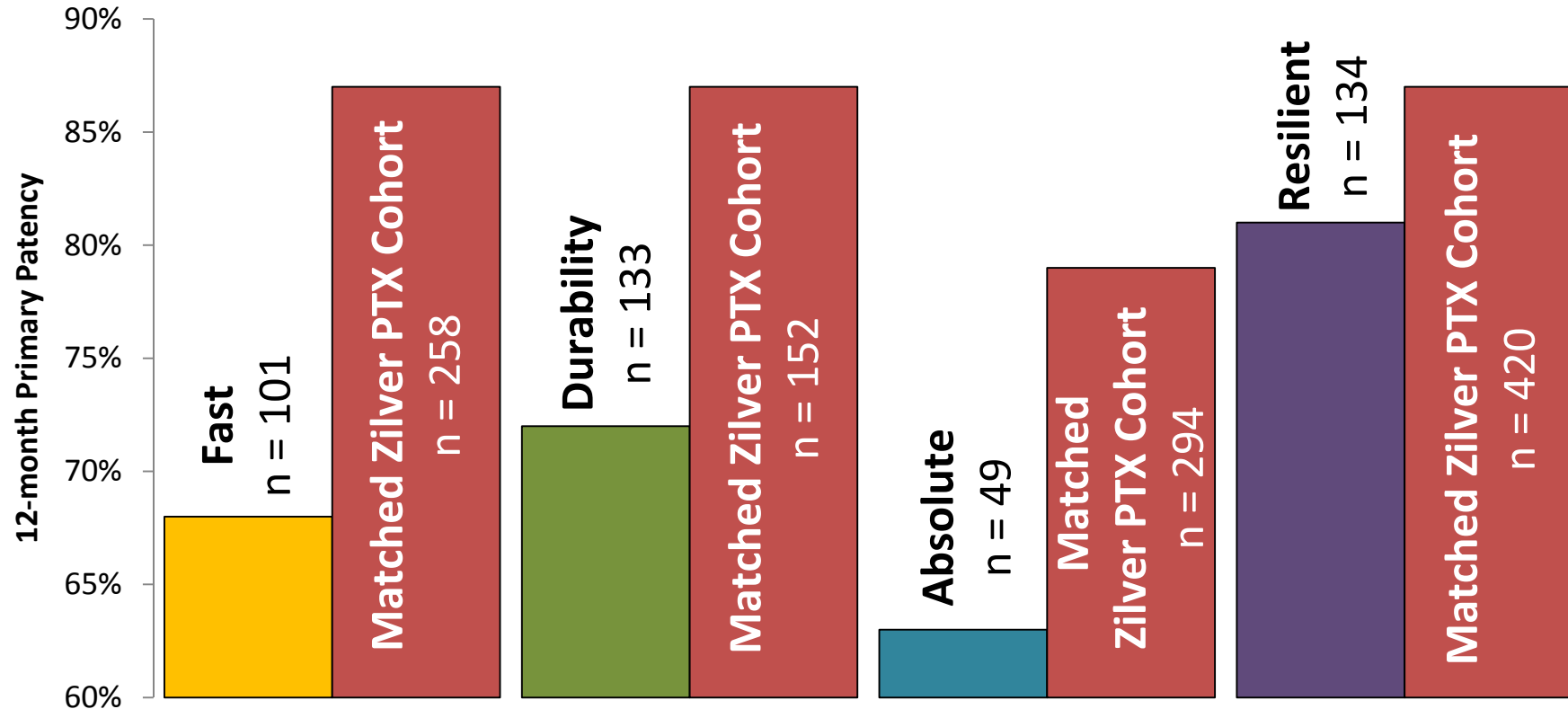
- Simple lesions: POBA
- Thienopyridine contraindications
 - POBA or bare nitinol stent
- Moderate disease
 - POBA with provisional PTX stent
 - PTX balloon with provisional bare nitinol stent
- Diffuse disease, restenosis
 - PTX stent(s)
 - PTX balloon with provisional stent
 - Mix of PTX treatment and POBA





Zilver PTX Patency Compared to BMS

Matched Zilver PTX Cohort: matched inclusion/exclusion criteria and PSVR threshold for each published study



Zilver PTX stenting increases 12-month patency rates relative to BMS published literature