Now and the Future: Endovascular Interventions

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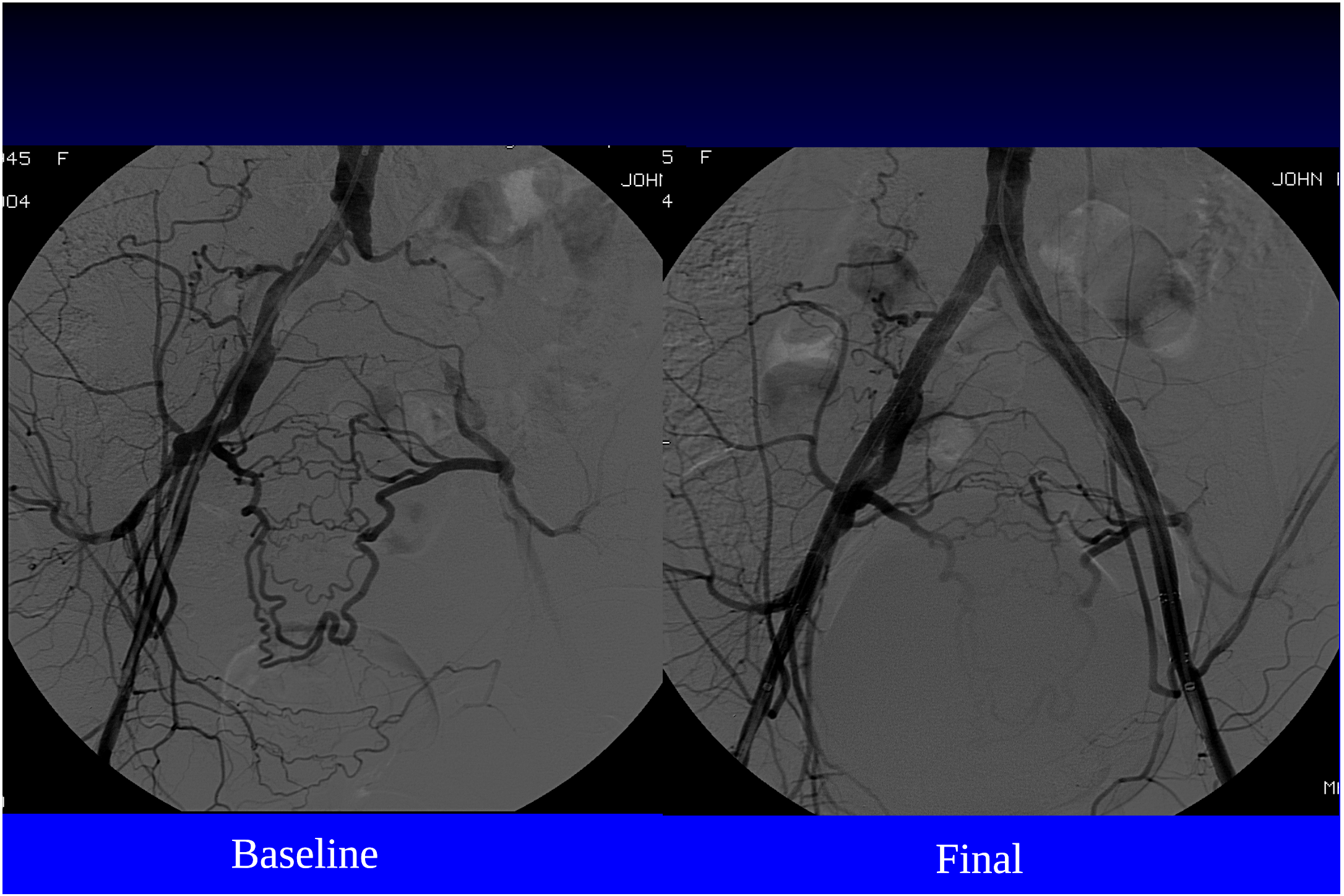
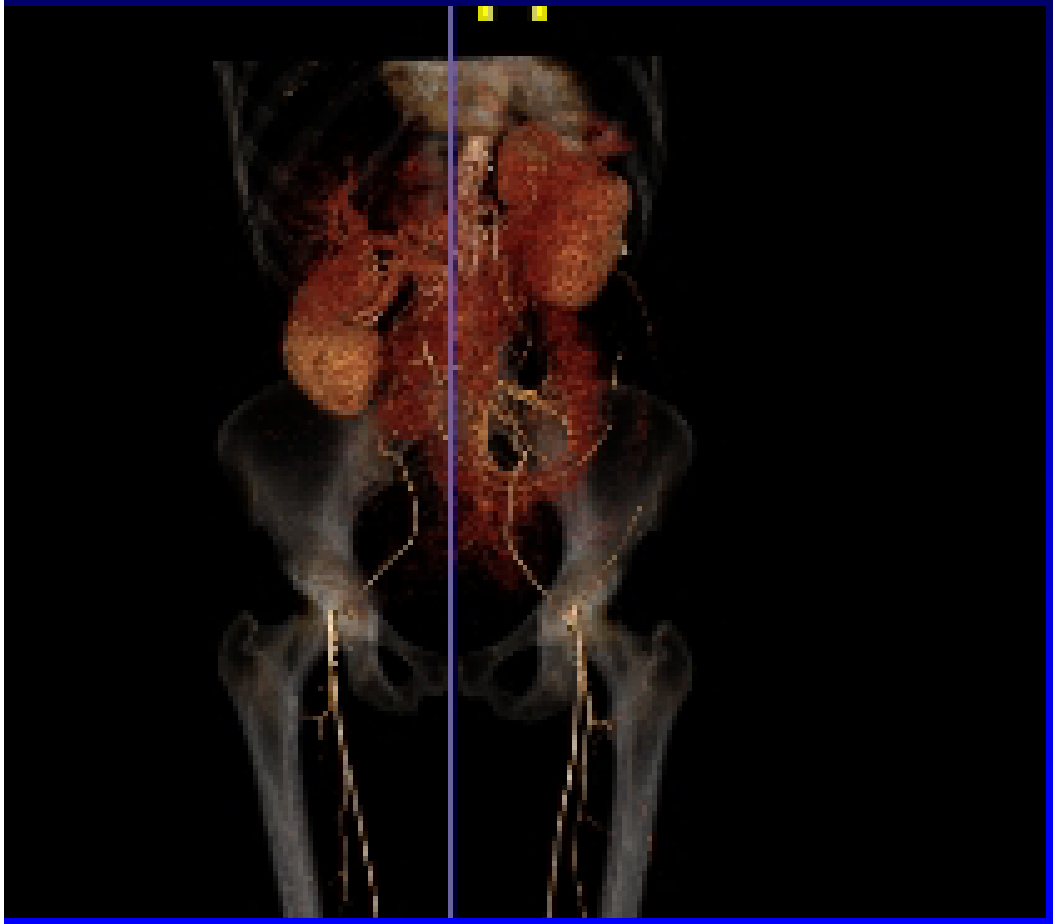
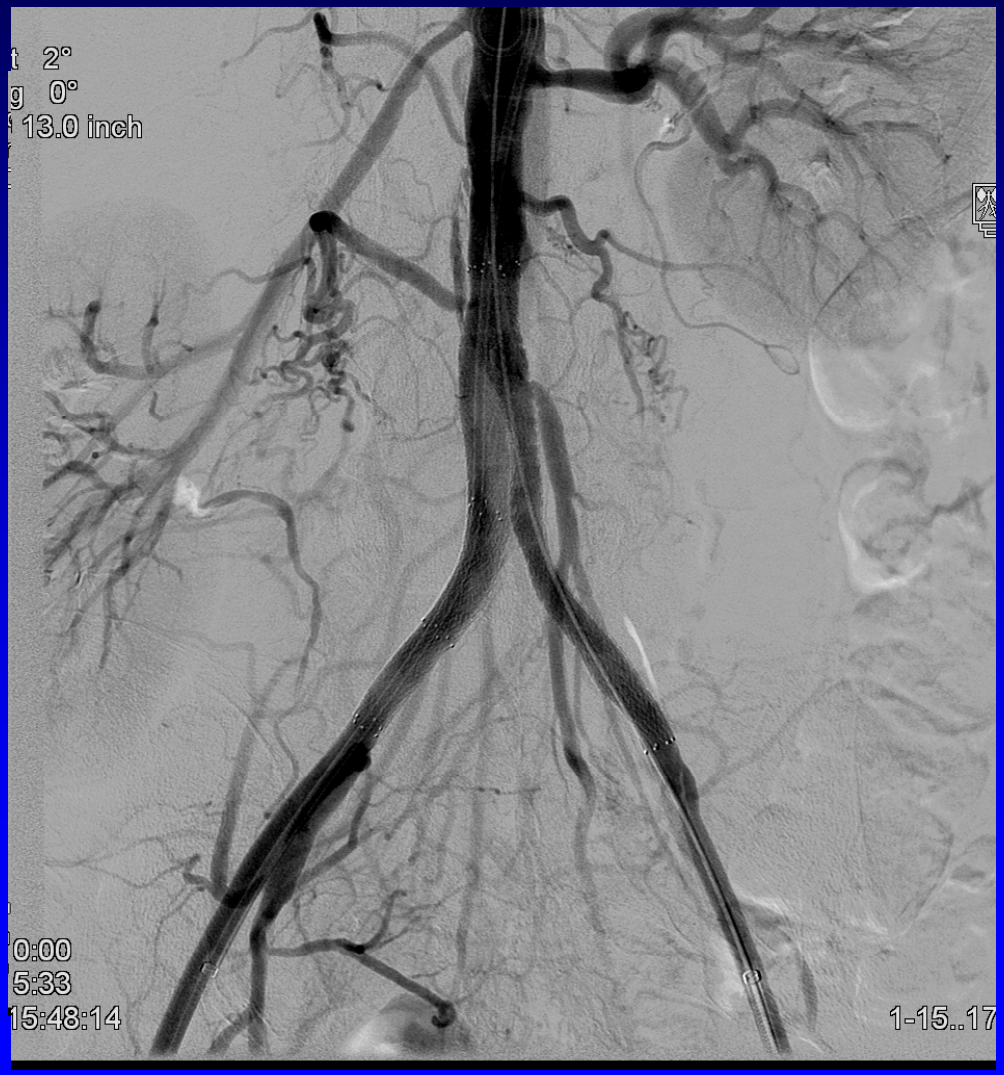
Aortoiliac Intervention Now

- High procedural success rates (> 95%)
- Effective CTO devices (reentry devices)
- Good medium and long-term results:
  - One-year primary patency > 90%
  - Three-year primary patency > 75%
- Challenges:
  - TASC D disease
  - Complex bifurcation disease
  - Combined iliac and common femoral disease


Baseline
Final

Infrarenal Aortic Occlusion

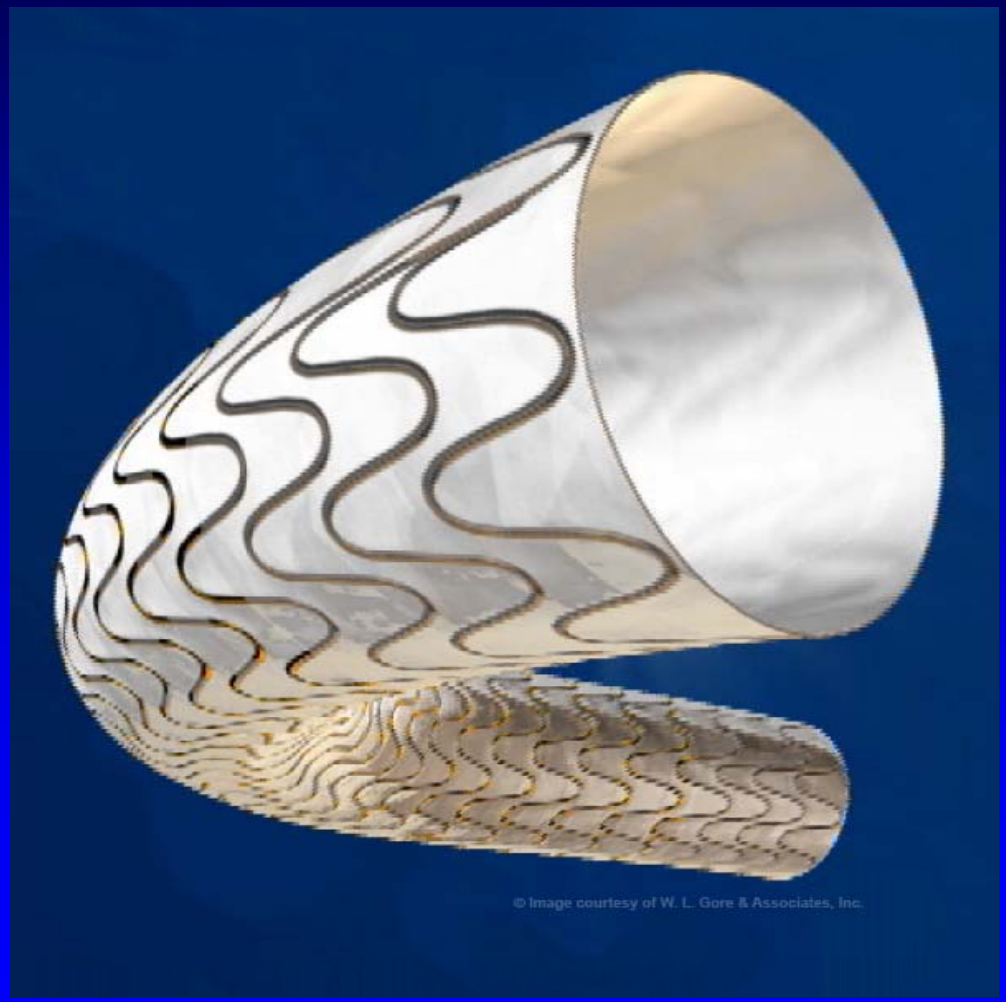




Aortoiliac Intervention
The Future

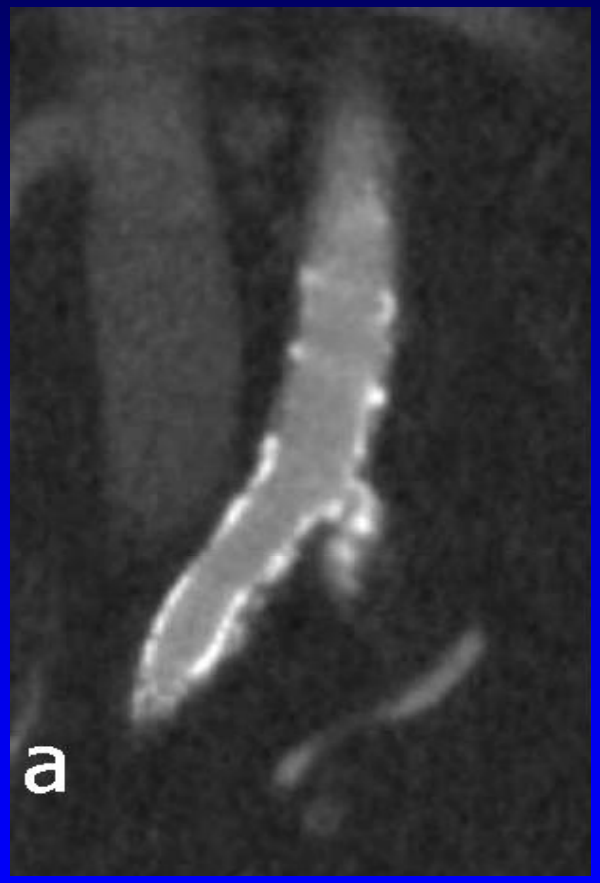
- Expanded role for covered stents?
- Drug eluting stents?
- Drug eluting balloons?
- Intraluminal CTO devices?

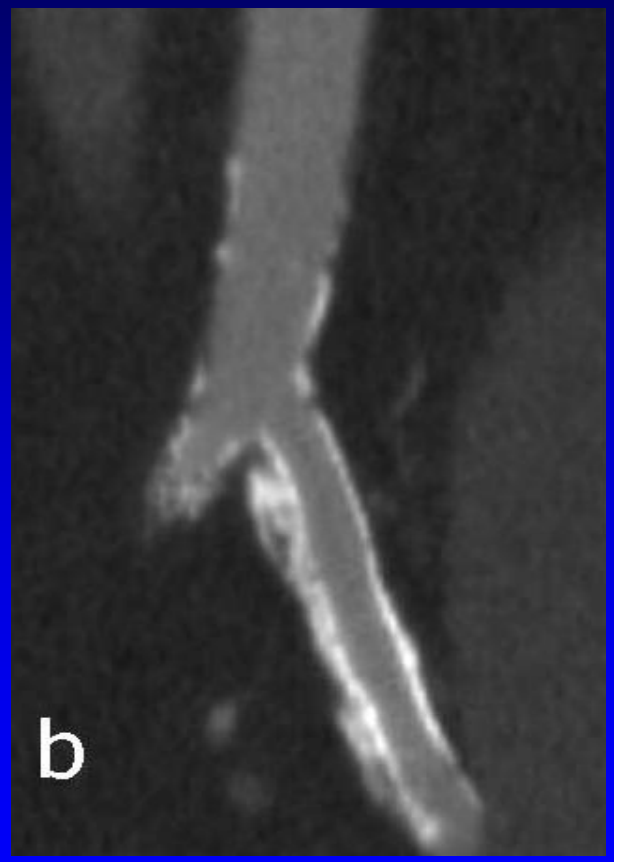
Expanded Role for Covered Stents?



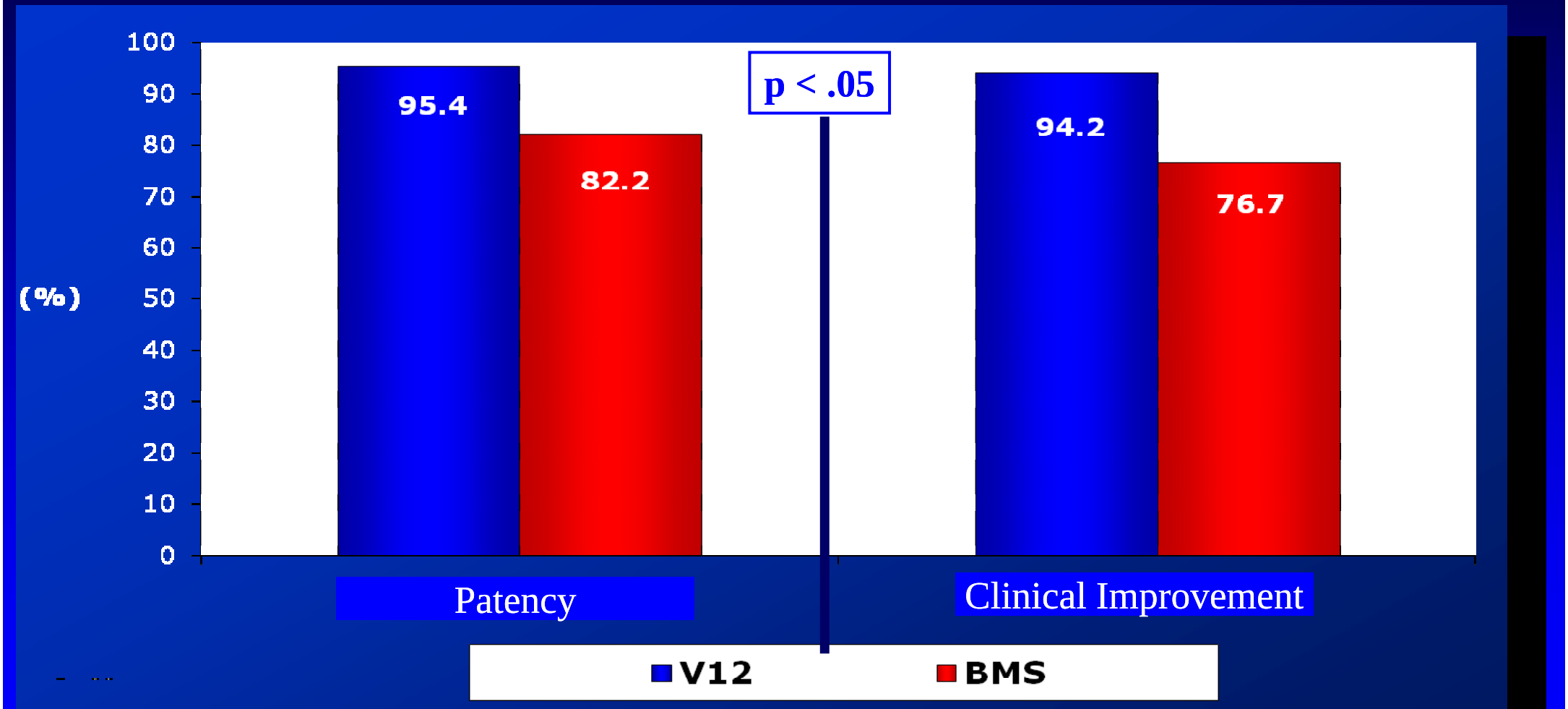
Bare Metal Stents

Covered stents



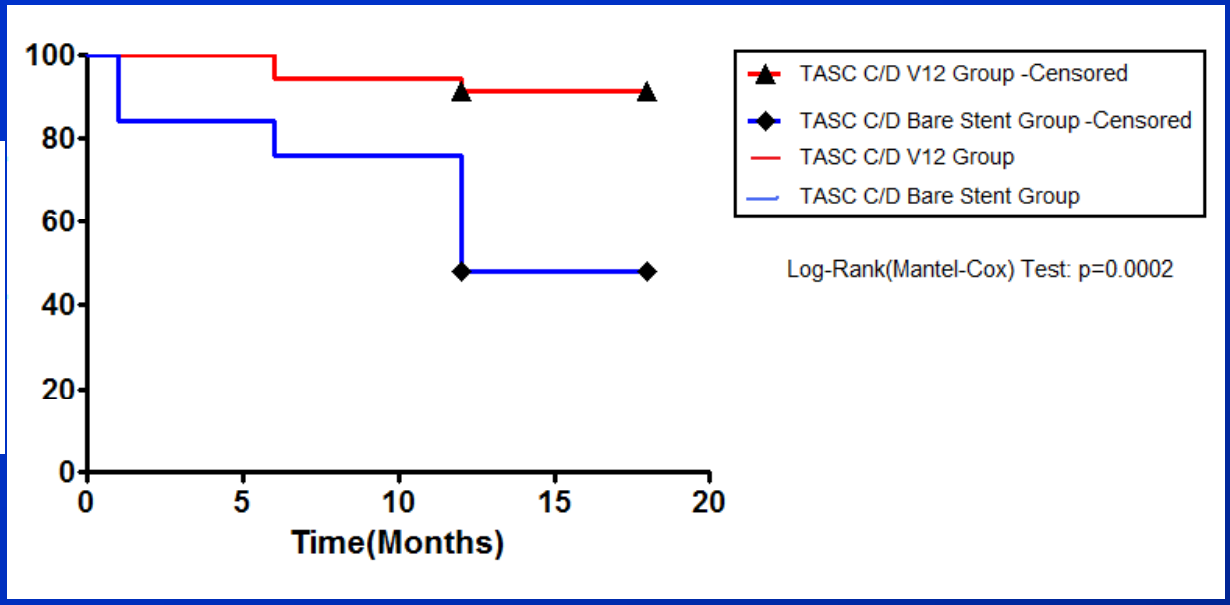


COBEST:
18-Month Results

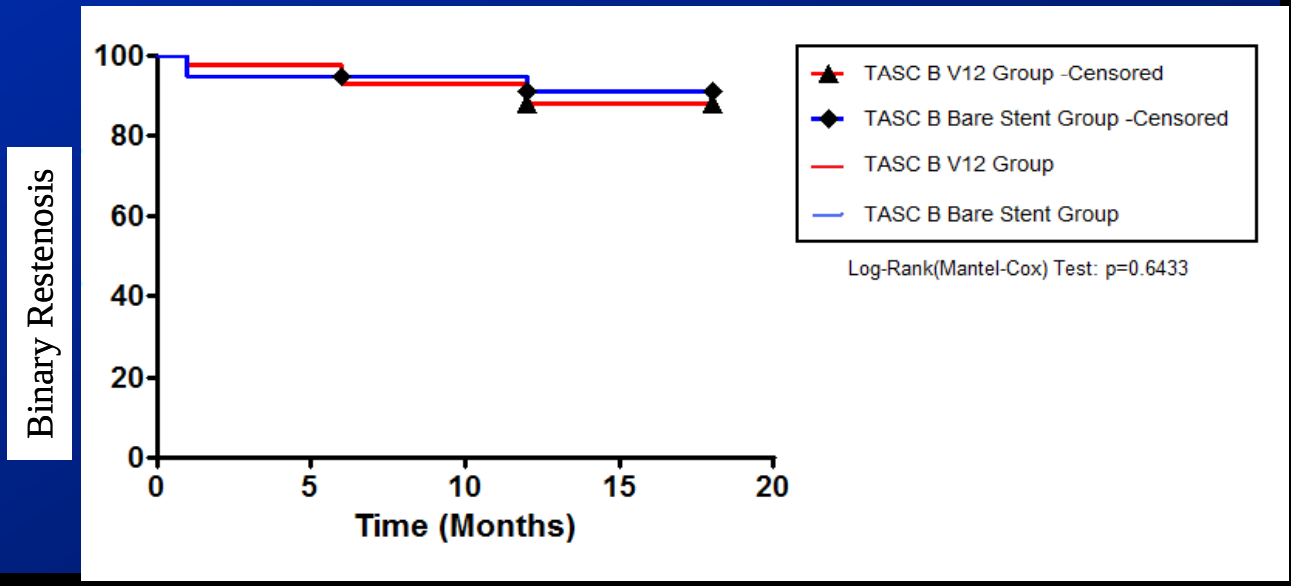


Comparing patency and clinical improvement between V12 group and BMS group (Kruskal-Wallis test p < .05)

Cox adjusted plots stratified for the type of stent used according to the TASC C/D group



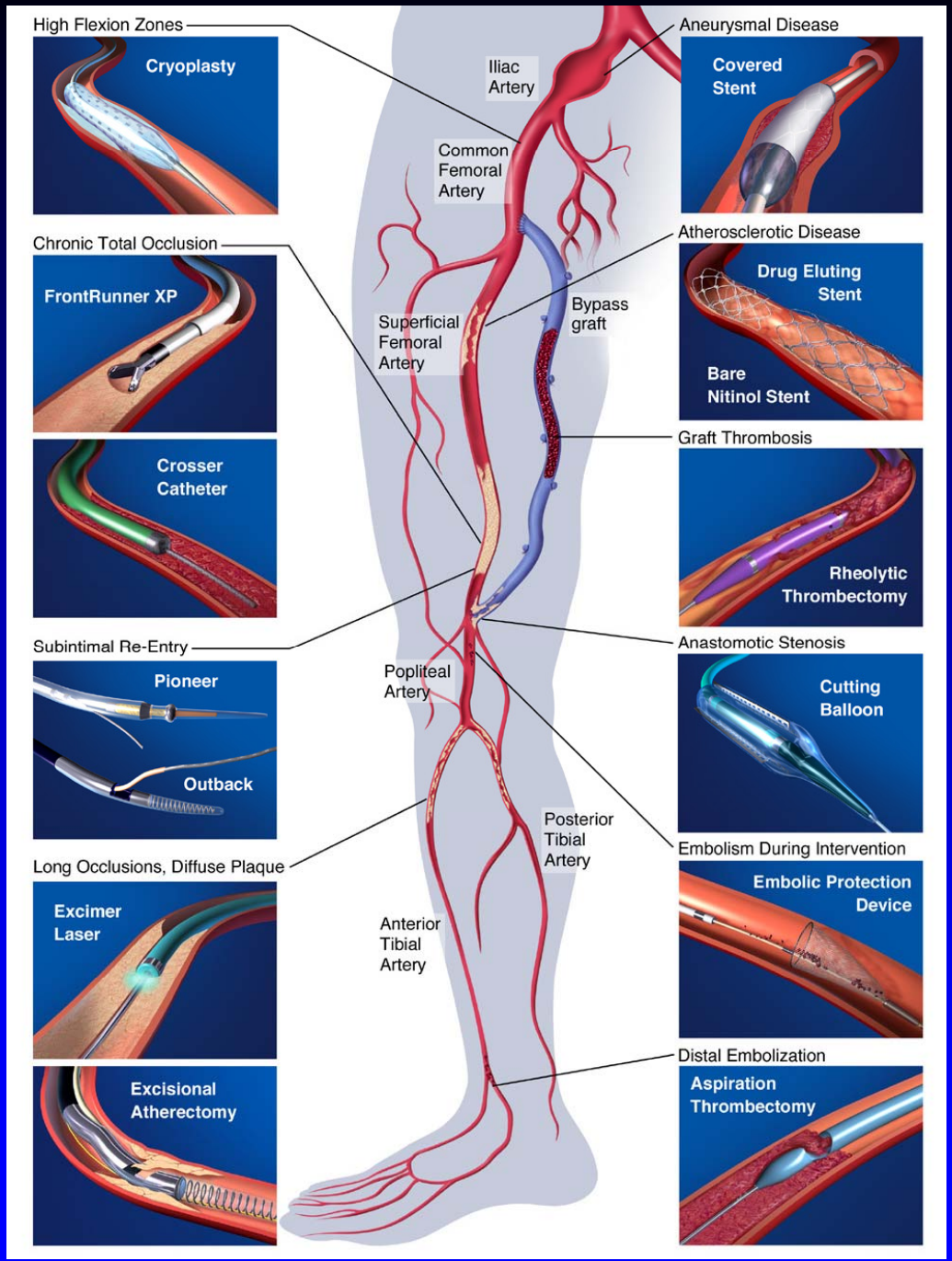
Cox adjusted plots stratified for the type of stent used according to the TASC B group



Femoropopliteal Intervention Now

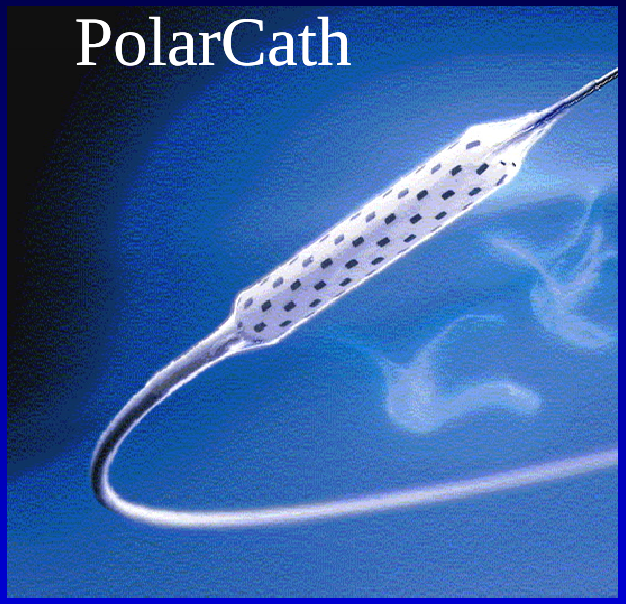
- High procedural success rates (>90%)
- A multitude of devices (balloons, atherectomy devices, stents)
- Numerous CTO devices (reentry and “intraluminal”)
- Adequate short and medium term results for moderate length (<15 cm) lesions
- Poor results with longer lesions and diffuse disease

The Search for Something that Actually Works



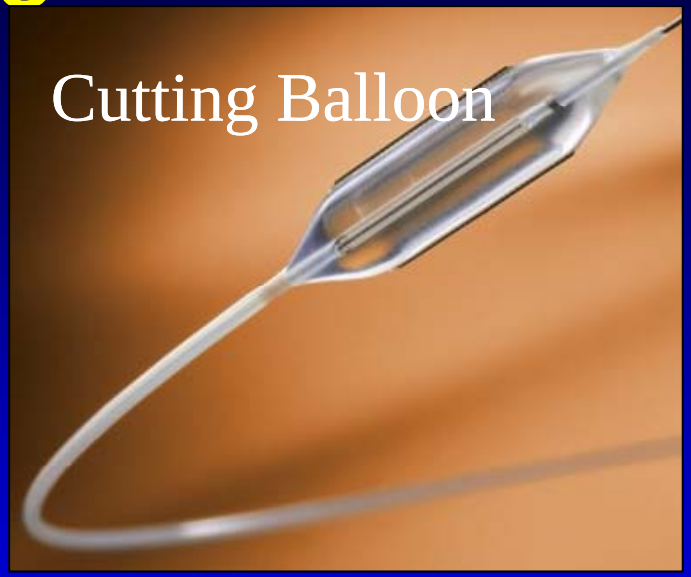
The Crowded Landscape
Balloon Technologies

PolarCath

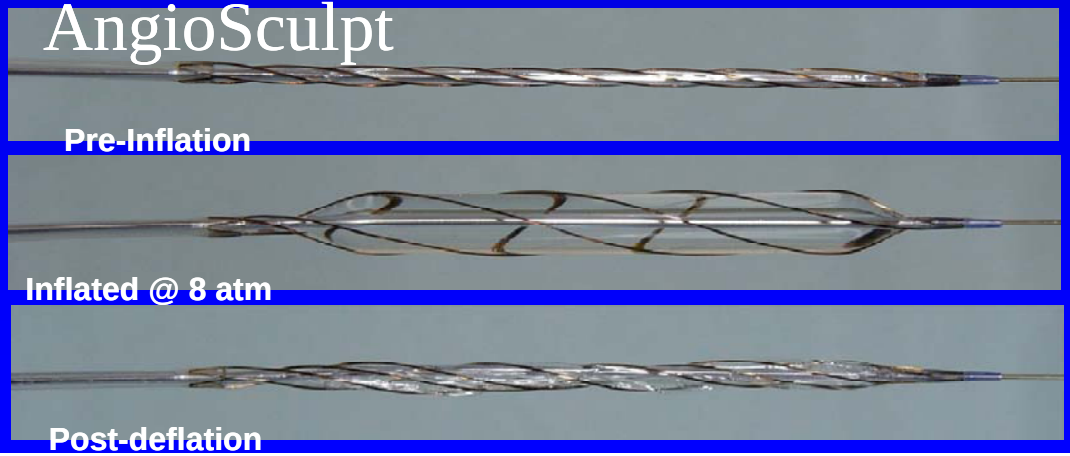


Minnow

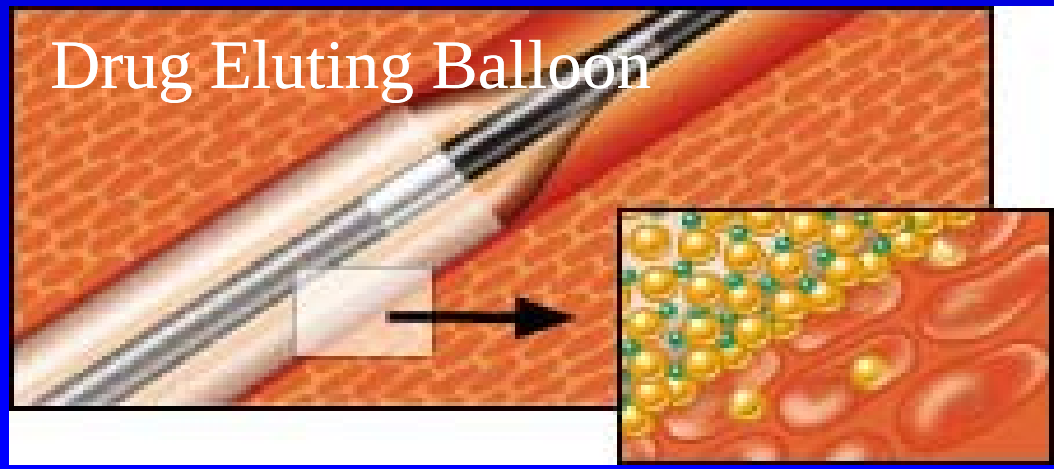
Cutting Balloon



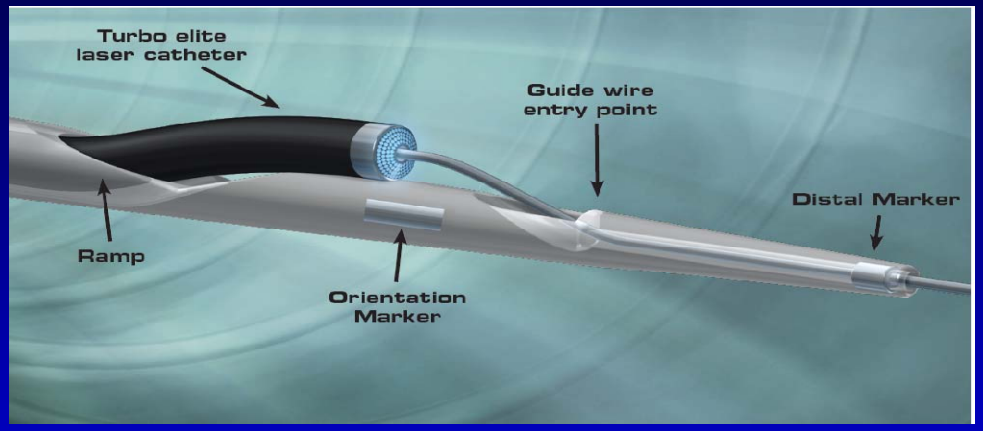
AngioSculpt

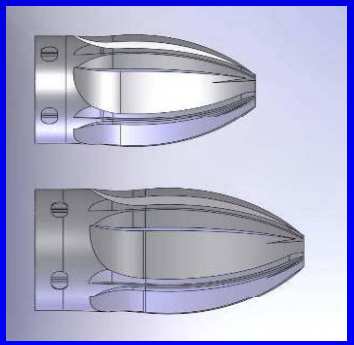


Drug Eluting Balloon

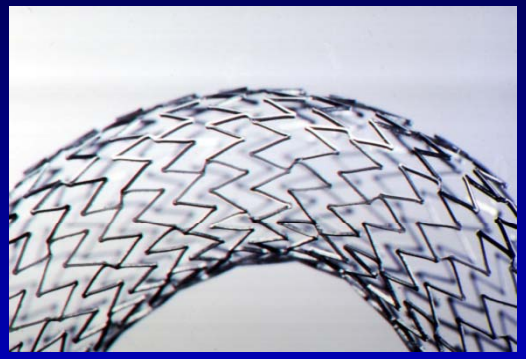


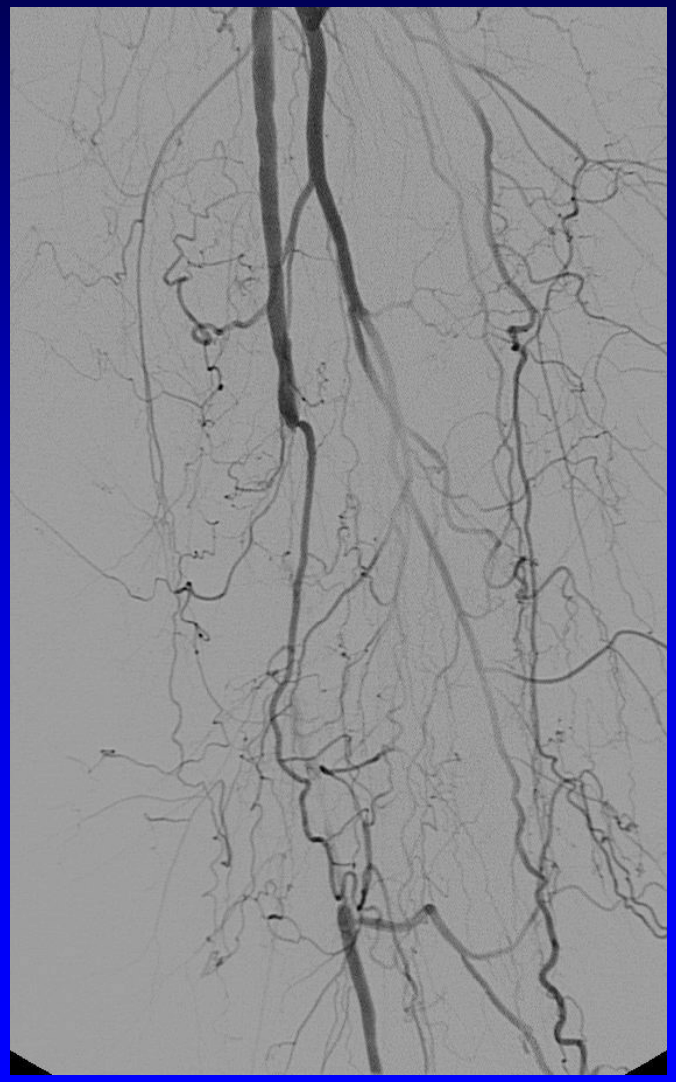
The Crowded Landscape Atherectomy Devices

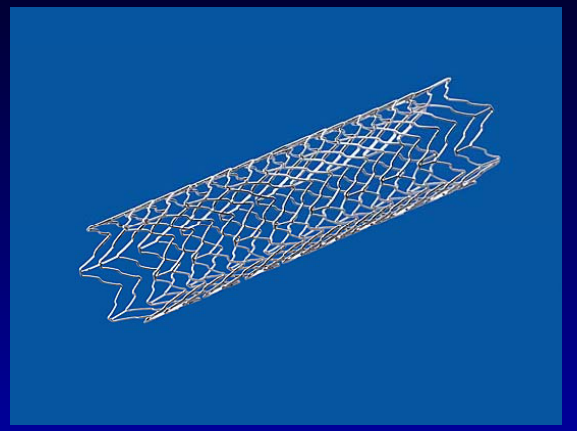




The Crowded Landscape
Nitinol Stents



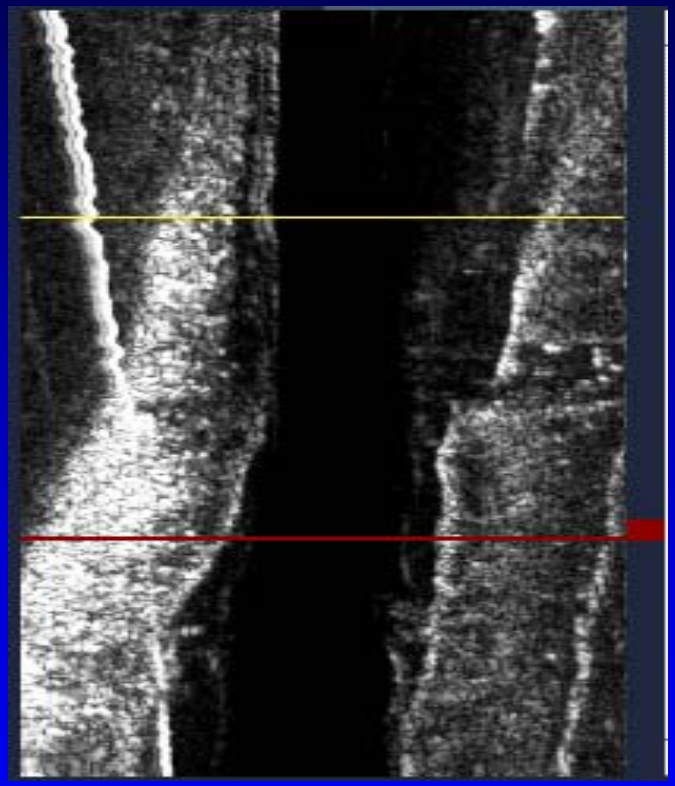




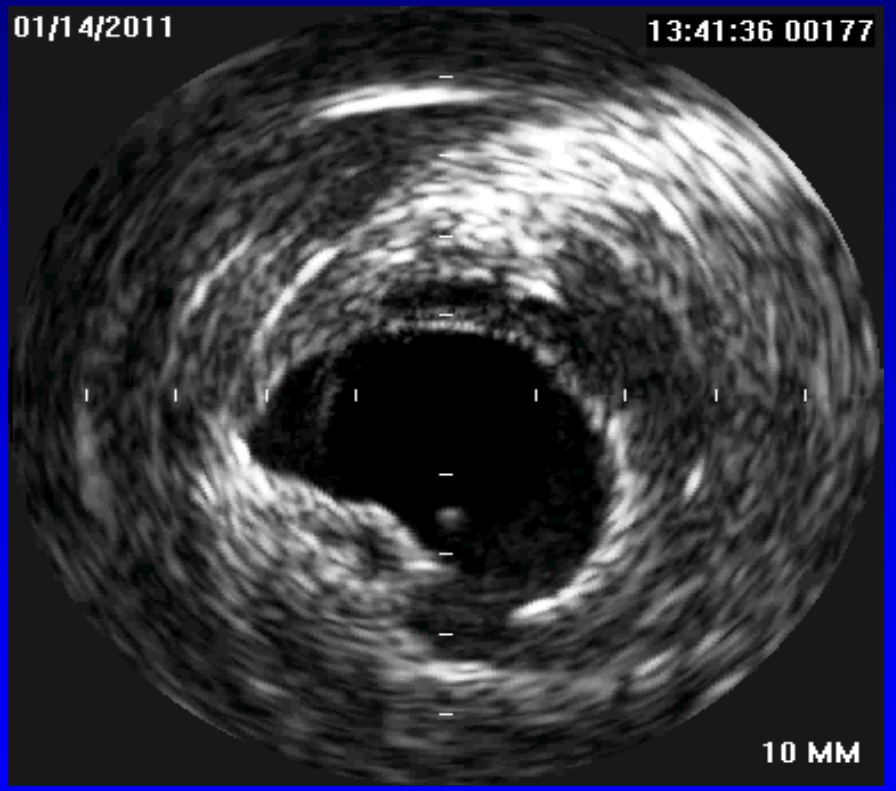
Femoropopliteal Intervention
The Future

- Image guided atherectomy
- Better stents
- Drug eluting balloons
- Drug eluting stents (stent)
- Atherectomy followed by DEB
- Bioresorbable vascular scaffold

IVUS Guided Atherectomy

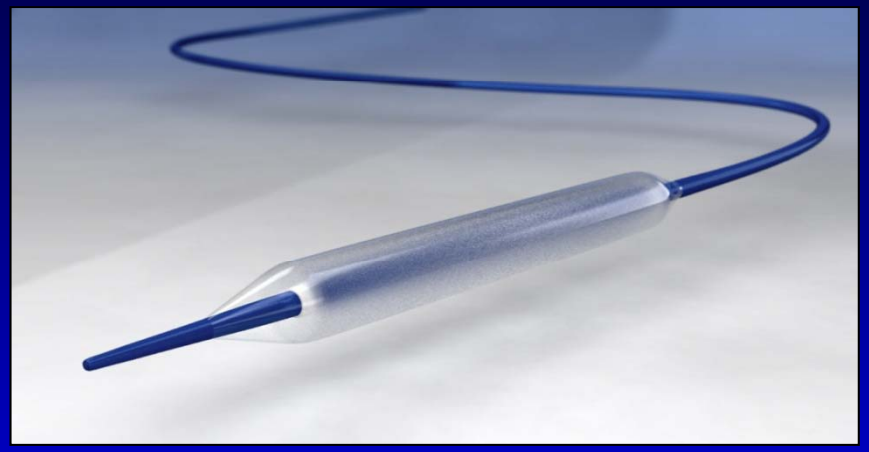


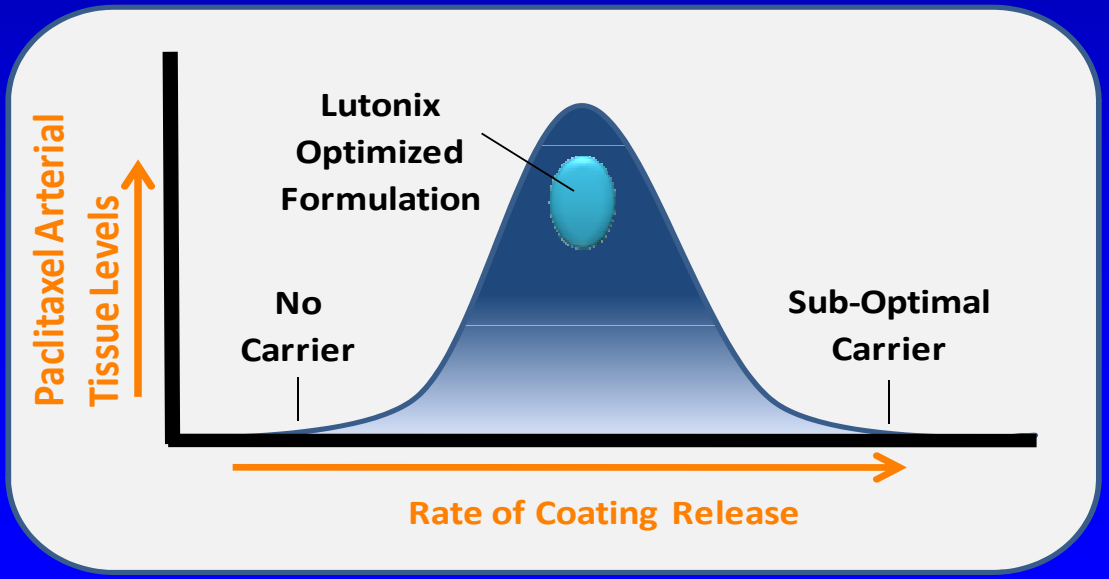
IVUS Guided Atherectomy



Drugs and Devices!!

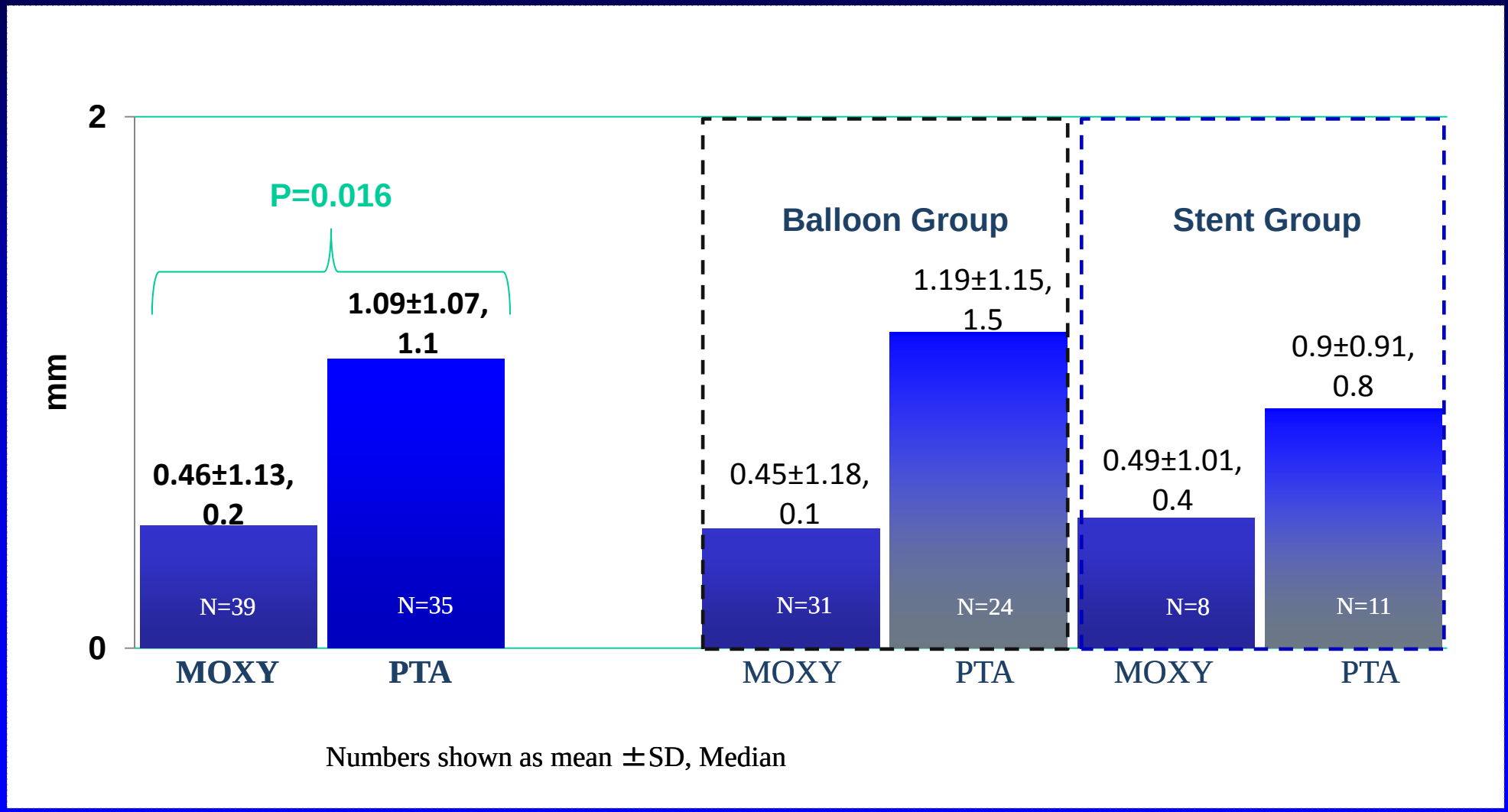
Lutonix Technology overview





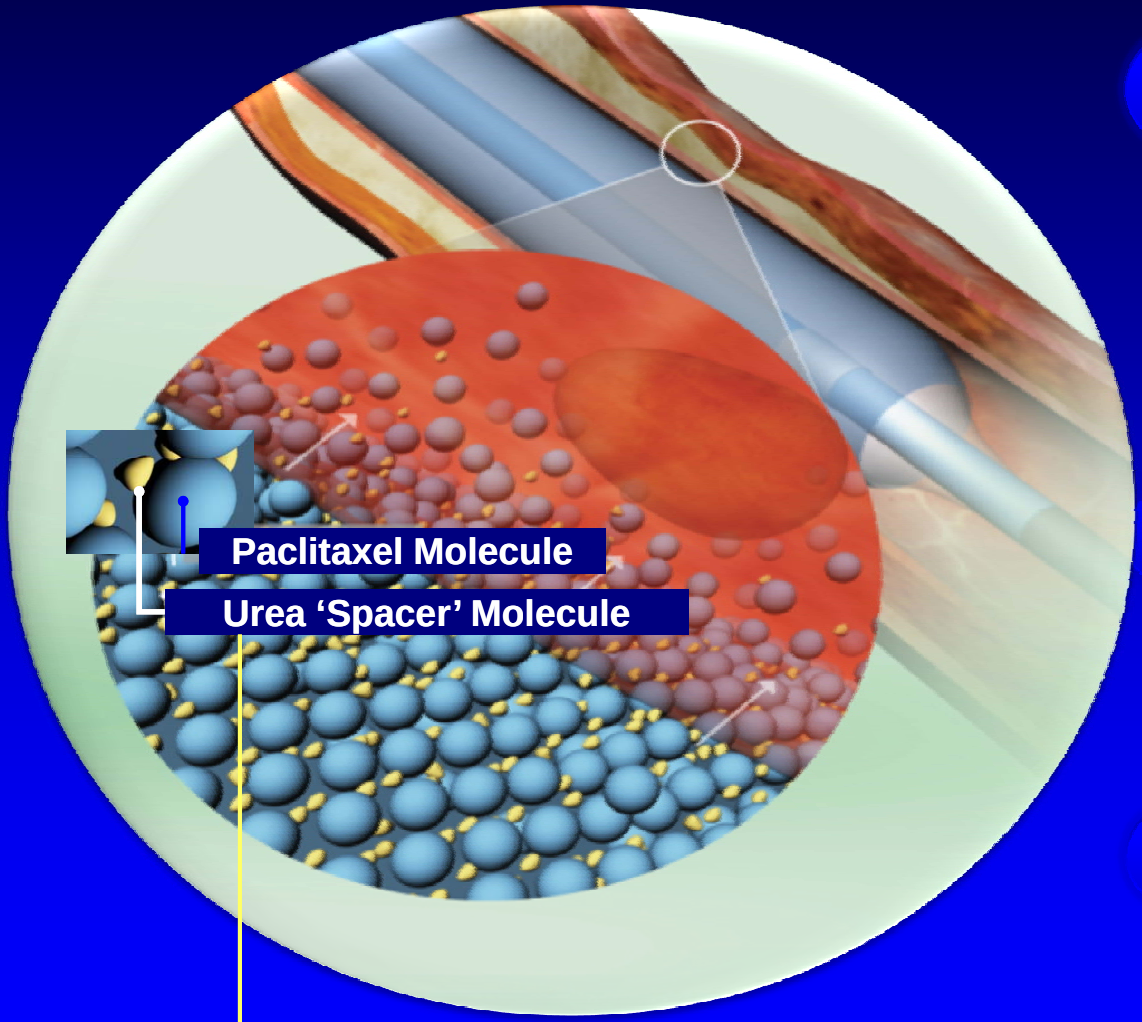
- Low drug-load balloon with 2µg per mm^2 of paclitaxel
- Hydrophilic, transfer-efficient drug carrier from IV-approved list
- Formulation designed to optimize drug *retention* during transit and drug *uptake* during inflation
- Robust, uniform coating

LEVANT I Late Lumen Loss at 6M



Numbers shown as mean ±SD, Median

IN.PACT Drug Eluting Balloon with FreePac™ Coating Technology



3 Approved Peripheral DEBs

Used to safely and effectively treat thousands of patients since 2009

IN.PACT Amphirion - BtK

IN.PACT Admiral - SFA/Pop

IN.PACT Pacific - SFA/Pop

FreePac ™ Coating

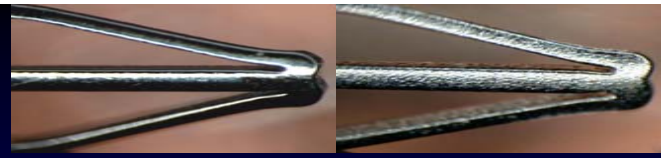
Delivery to vessel wall within 30-60 seconds

Antirestenotic protection for 28 days

Clinical Program

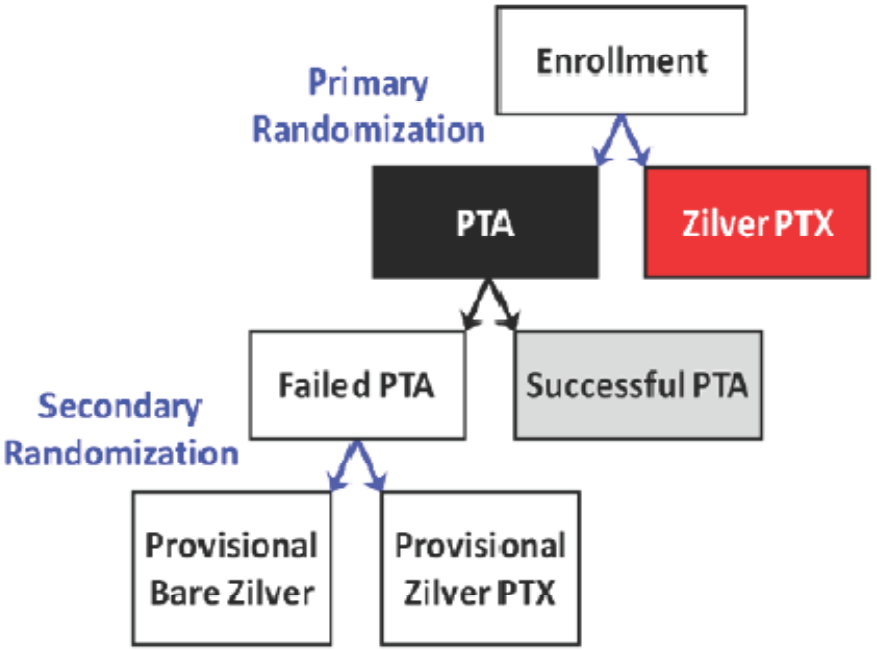
11 peripheral clinical studies underway

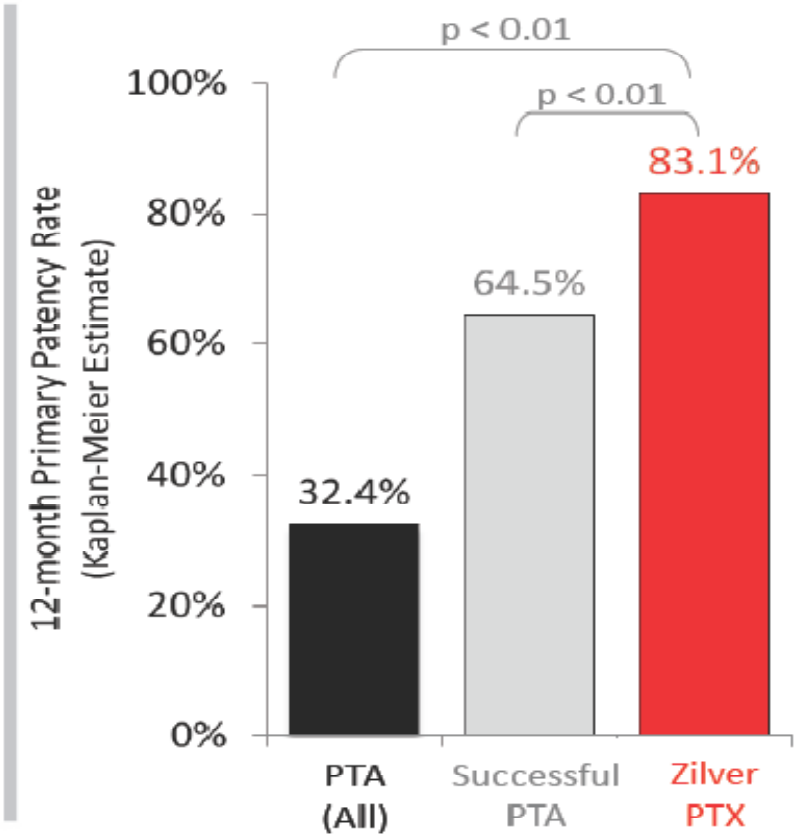
What About DES?

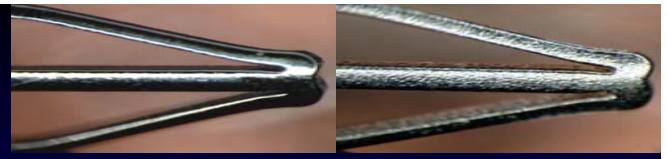


12-Month Effectiveness

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

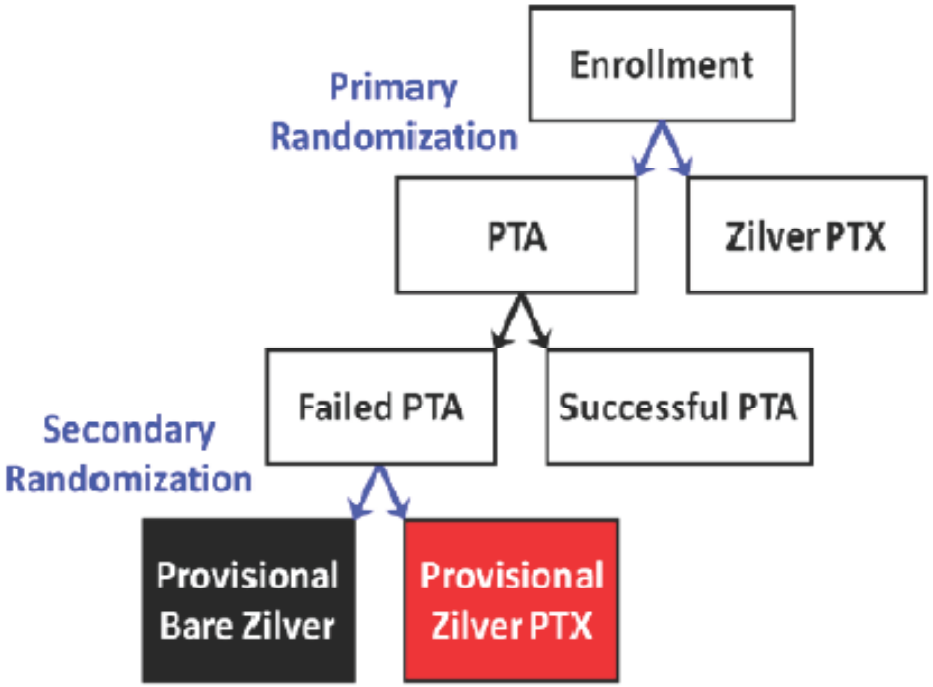


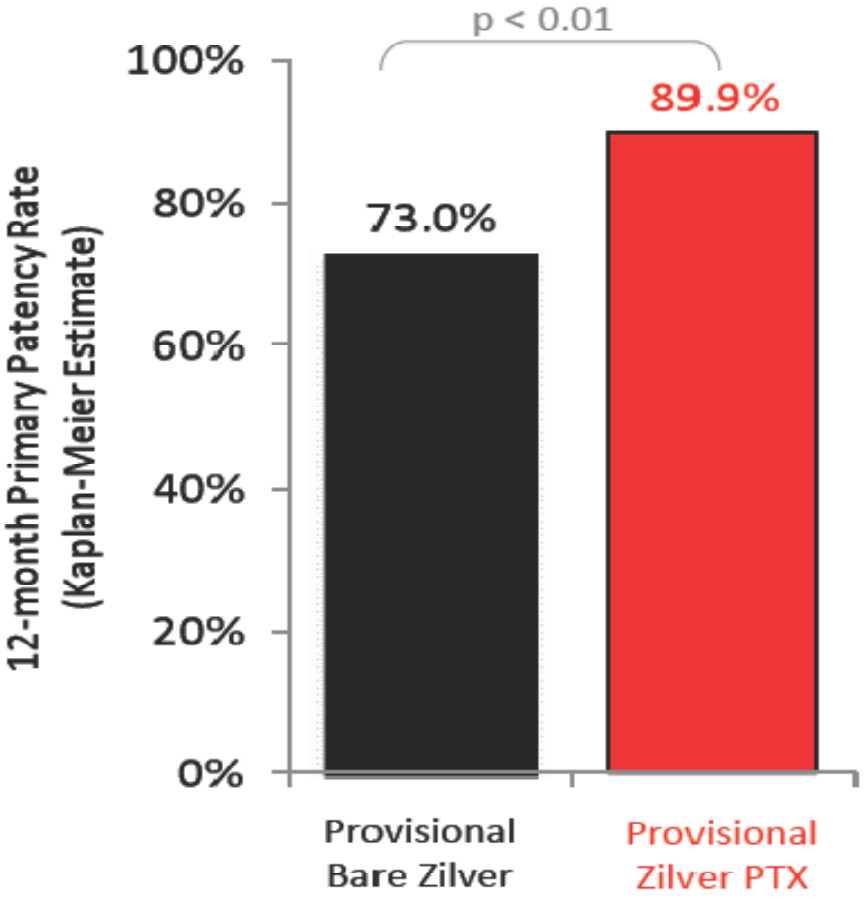


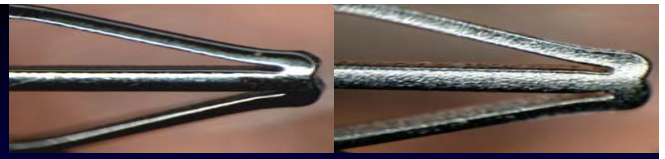


12-Month Paclitaxel Effect

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

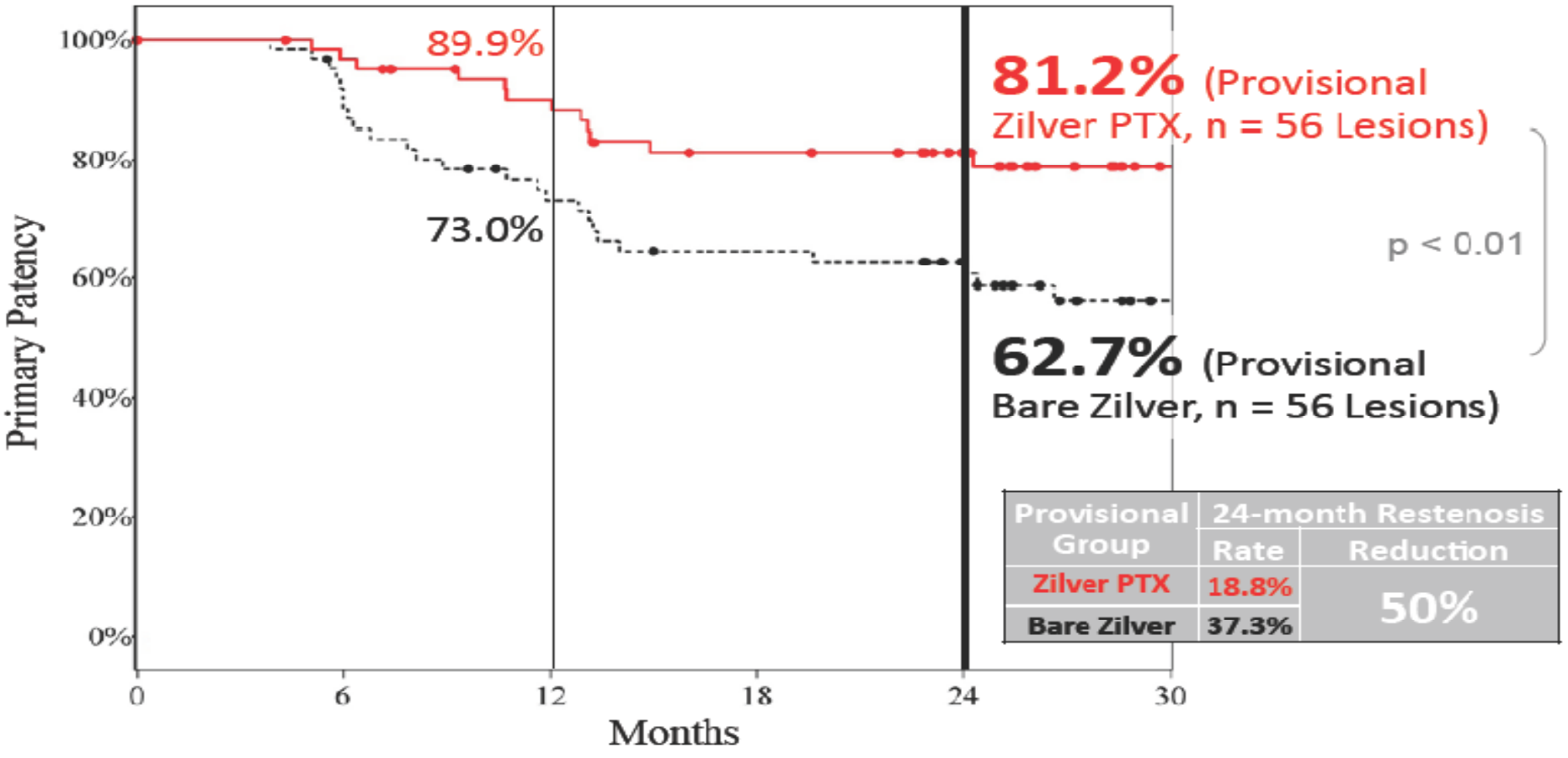






24-Month Paclitaxel Effect

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



Provisional Group	24-month Restenosis Rate	Reduction
Zilver PTX	18.8%	50%
Bare Zilver	37.3%	

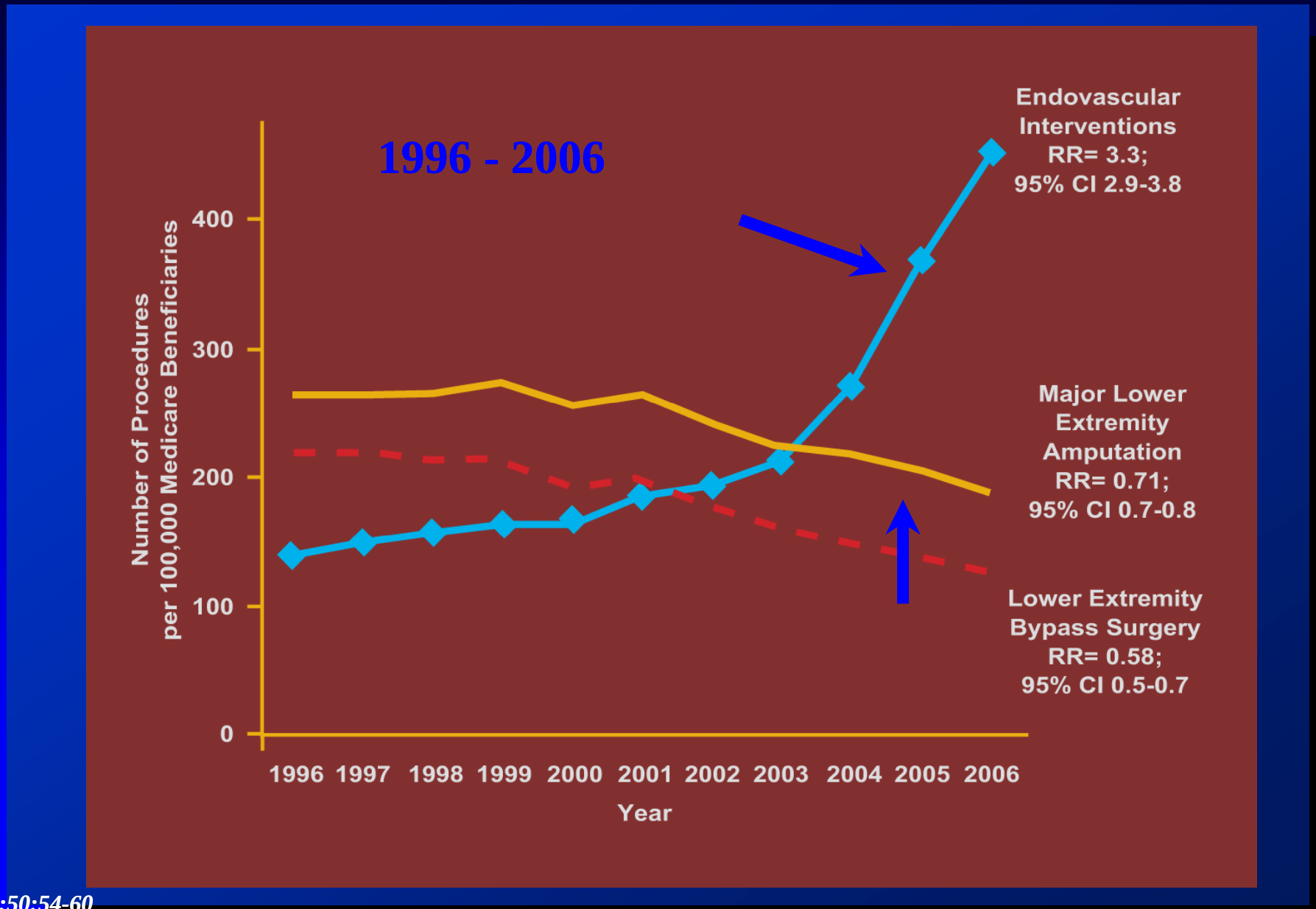
Infrapopliteal Intervention Now

- High procedural success (>90%)
- Comparable limb salvage rates to surgery (>80% at one year)
- High restenosis rates (not linked to limb loss in short-term)
- Creative revascularization techniques

Creative Techniques for Limb Salvage

- Distal and multivessel intervention
- Pedal and tibial access
- Advanced CTO techniques
- Recanalization through collaterals
- Plantar arch recanalization

The Good News



J Vasc Surg 2009;50:54-60

Infrapopliteal DEB
Leipzig Experience

- 109 limbs treated in 104 patients
- Mean lesion length 17.6 cm
- 3 month angiographic follow-up:
  - Restenosis > 50%: 19.1%**
  - Total occlusion: 8.3%
- 12 month limb salvage rate: 95.6%

**Angiographic restenosis with POBA in a similar patient cohort with similar lesion lengths at the same institution: 69%

Infrapopliteal Drug-Eluting Stents

- Cypher and XIENCE V stents have CE-mark for below knee
- 4 Investigator initiated trials have shown safety and clinical benefit of DES vs. BMS
  - 6 mo binary restenosis 0-4% vs 55-57%
- Stent fracture/crush appears to be a rare event

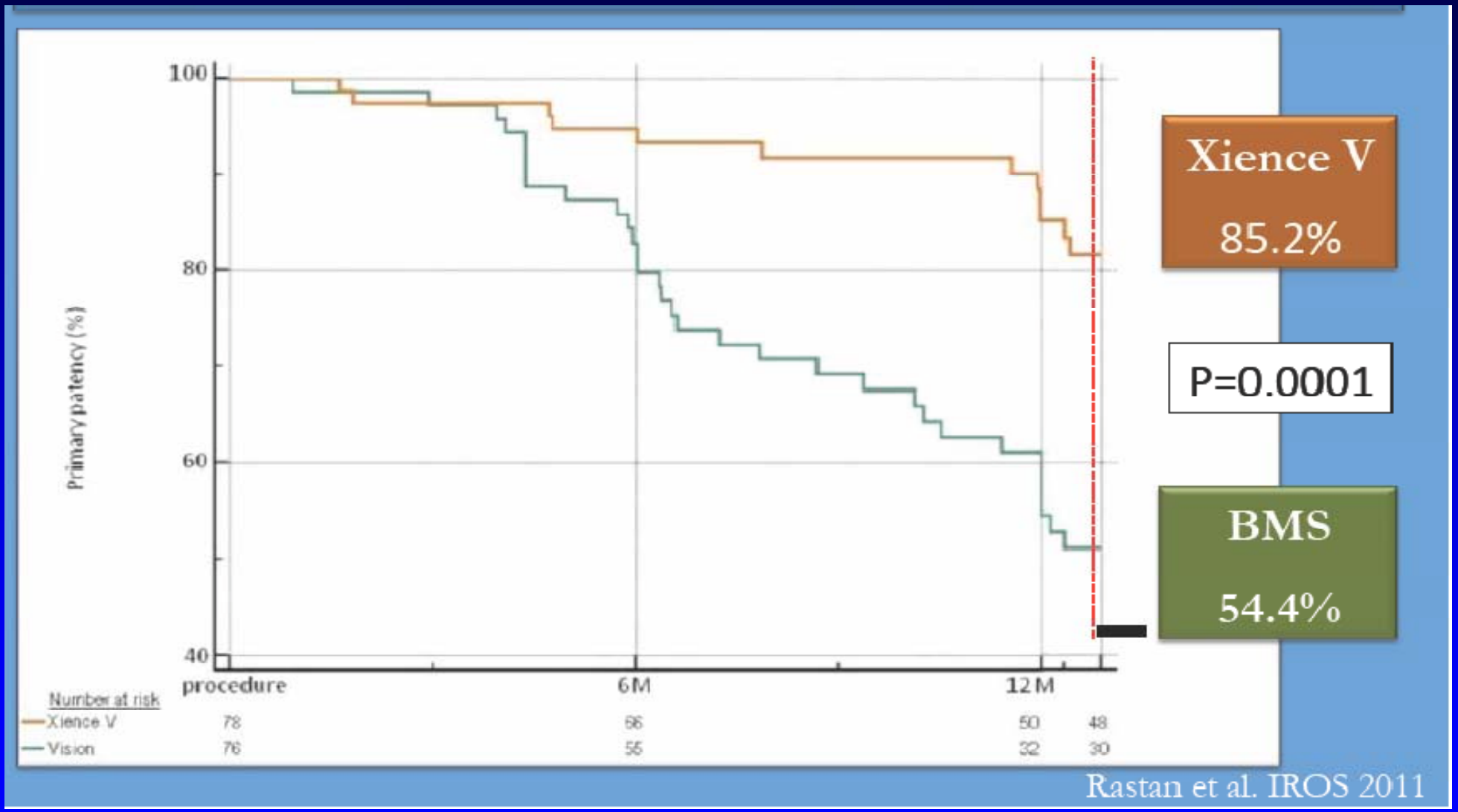
Siablis. J Endovasc Ther 2005;12:685.

Scheinert. EuroIntv 2006;2:169.

Bosiers. J Cardiovasc Surg 2006;47:171.

Commeau. Cath Cardiovasc Intc 2006;68:793.

DESTINY Trial
12 Month Primary Patency



Endovascular Interventions Exciting Developments

- Renal Denervation for resistant HTN, Insulin resistance, CHF
- Low profile EVAR devices
- Expanded indications for carotid stenting
- Endovascular approaches to erectile dysfunction
- Stem cell therapies