Drug-Eluting Stent In Lower Extremity Intervention: Changed Landscape in the Current Practice?

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Drug-Eluting Stent In Lower Extremity Intervention: Changed Landscape in the Current Practice?

Definitely!!

Remaining Questions

- How much will it change going forward?
- How soon will changes take place?
- What will be the interplay of stents with other technologies?

Why Will It Change?

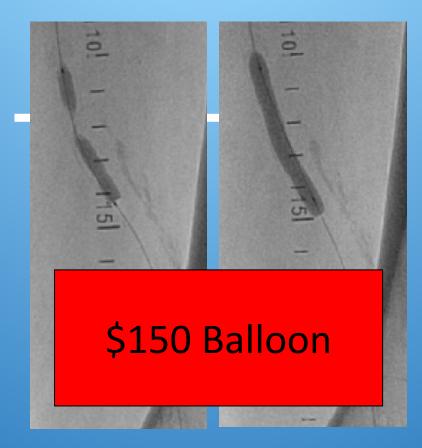
- Restenosis after femoropopliteal intervention is common
- Treatment of femoropopliteal restenosis is complex and costly
- Drug eluting stents effectively:
 - Prevent restenosis
 - Treat it after it occurs

The First Cut Is the Cheapest

- Initial procedures: simplest, cheapest, shortest treated region
- Subsequent procedures: increased:
 - Complexity
 - Duration
 - Radiation
 - Equipment expense
 - Encroachment on surgical anastomotic sites
 - Risk of additional intervention

Cheap Has Become Pretty Cheap!!



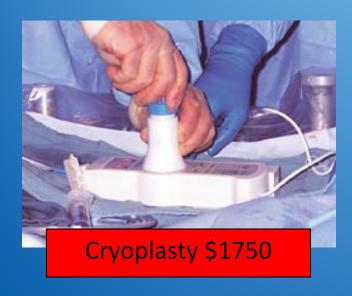


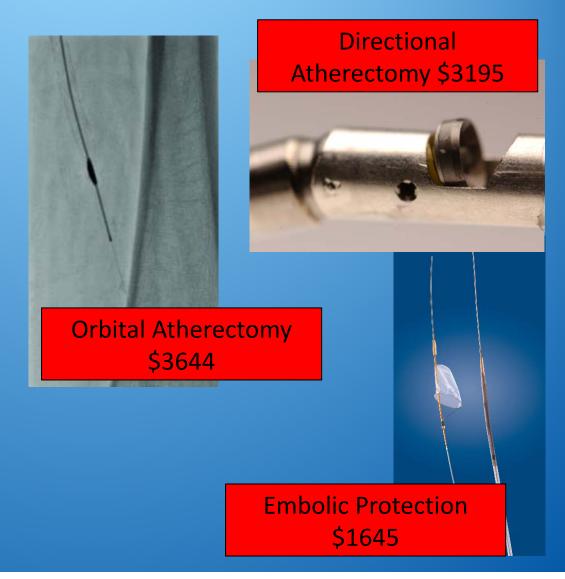


Everything Else Has BecomePretty Expensive!!

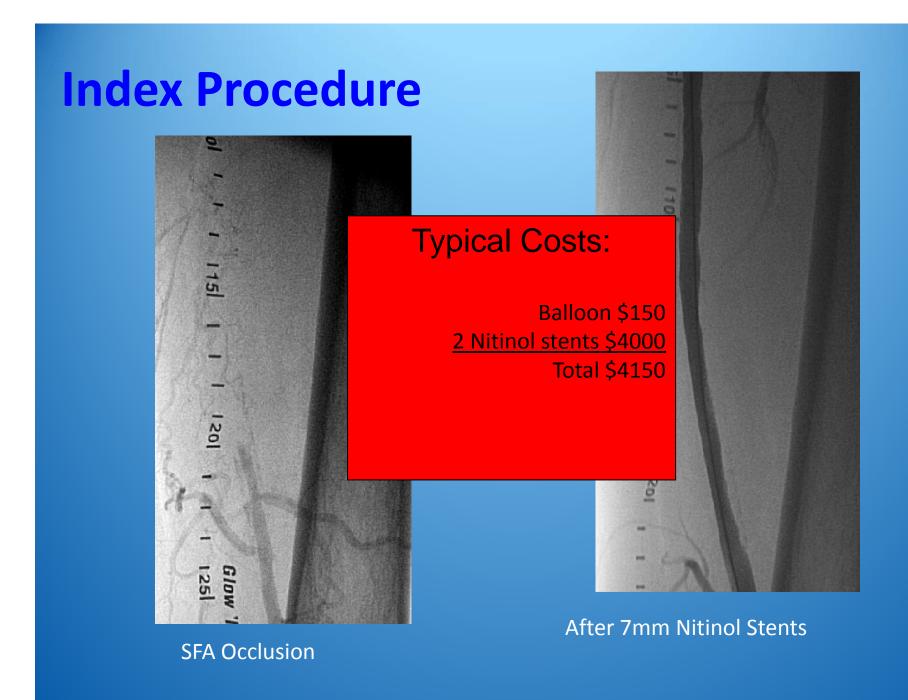


Nitinol Stent \$1400





Prices based on actual cost to cardiovascular laboratories in Toledo, OH







Laser \$2400

Embolic Protection Device \$1600

Balloon \$150

2 PTFE Stent Grafts \$6100

Additional stent \$1100

Total \$11350

Equipment Cost Increase 270%!!

In-stent Restenosis

Laser

PTFE Stent Graft

The "Cascade" of Procedures

- 2008: SFA angioplasty in clinical trial
- At 5 months: nitinol stents for restenosis
- 5 months later: additional nitinol stent

•	8	Actual Hospital Cost	Overhead	Total
•	2	\$11,035	\$6,747	\$17,782

Venous jemoro-populasi pypass

Total Hospital Costs
3 interventions (after index)
\$32,000

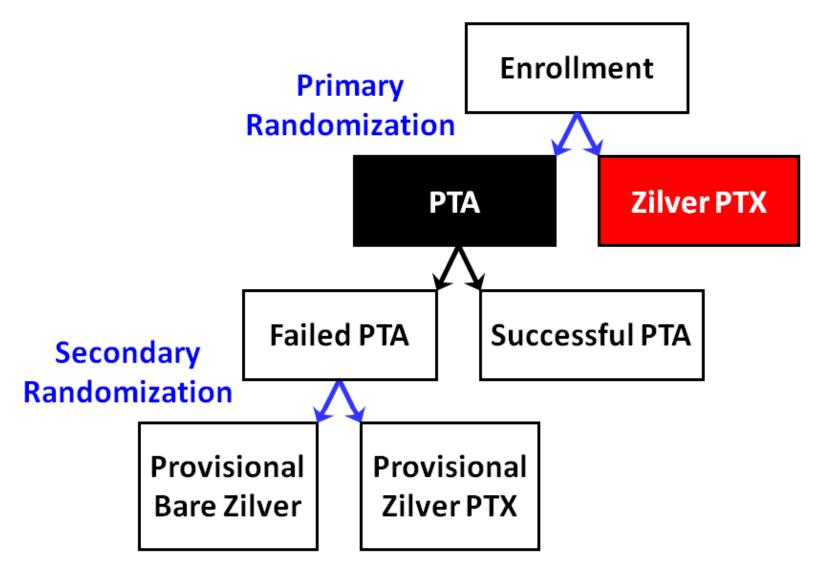
Zilver PTX Clinical Trials





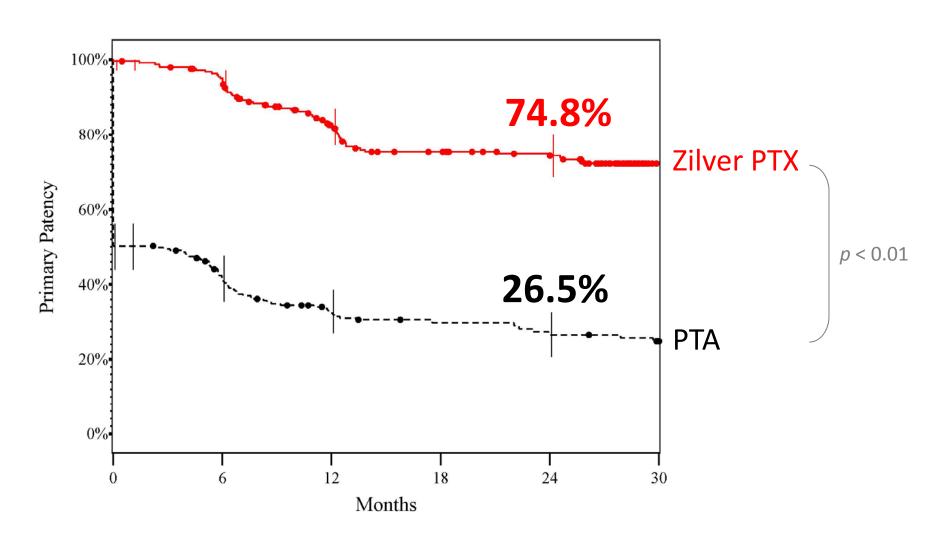
- Randomized trial
 - Paclitaxel coated stent vs. balloon angioplasty
 - Provisional stenting for PTA failures
- Nonrandomized registry
 - "All comers"
 - Much more complex anatomy

Zilver PTX Study Design



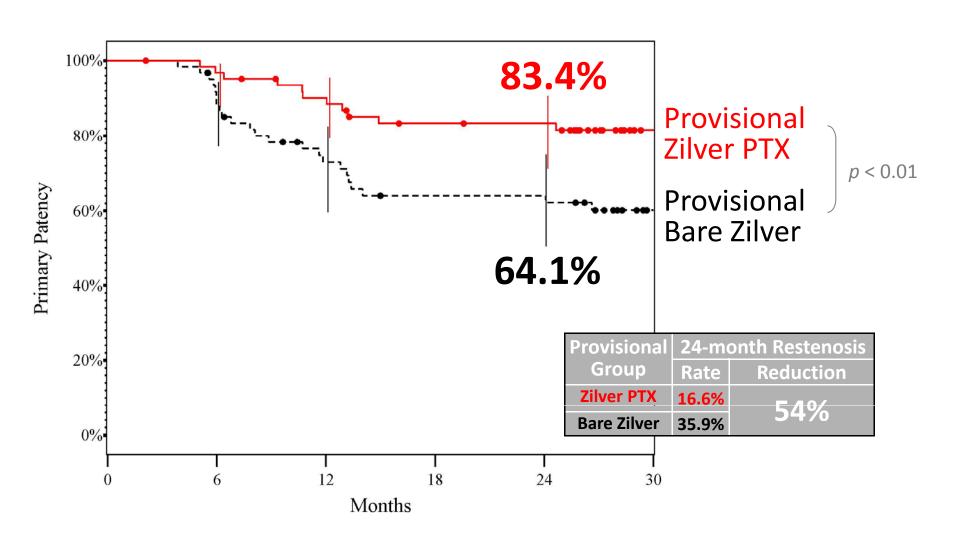
24-Month Effectiveness

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



Proven Drug Effect at 24-Months

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

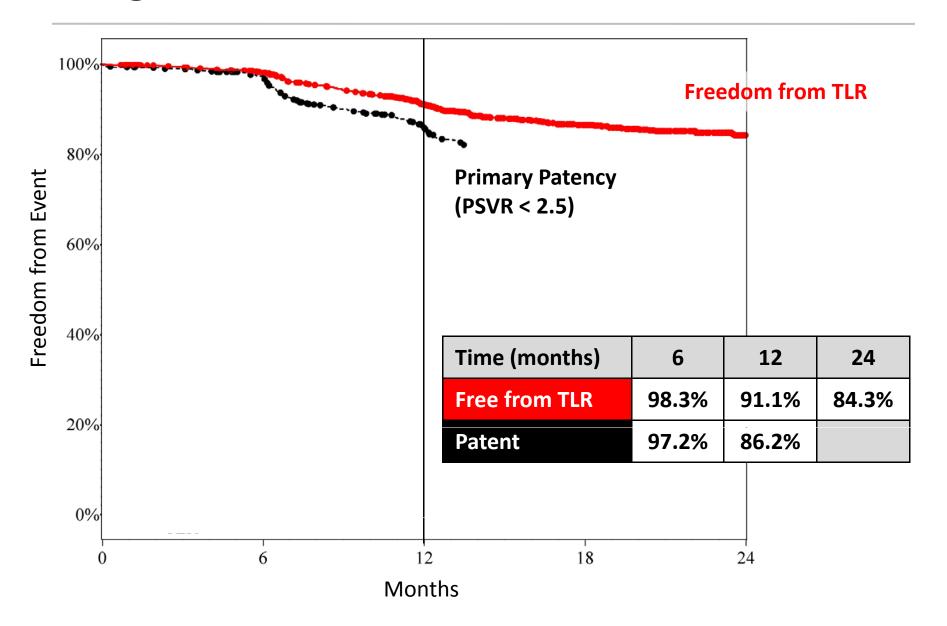


Zilver PTX Registry

Baseline Lesion Characteristics

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

Long-term Effectiveness

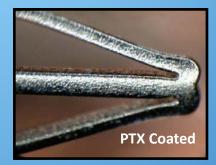




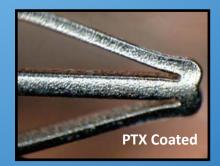
limitless possibilities















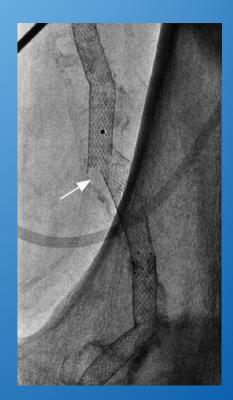
Why Doesn't Everyone Receive Drug-Eluting Therapies?

- Technical
- Financial
- Governmental
- Health care delivery system

Technical Barriers



- Lag between clinical trial devices and best commercially available stents
- Likely first US approval:
 - 6 french delivery system
 - 80 mm maximum stent length
- More stents = more potential for fractures

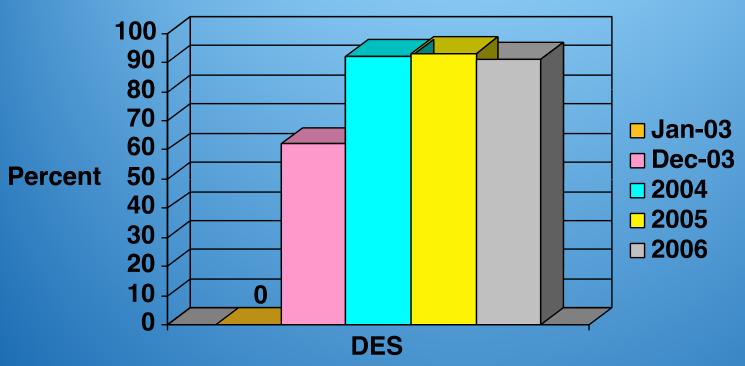


Financial Barriers



- Each paclitaxel-coated stent costs more
- Cost is multiplied in longer lesions

Does the Country Matter? Coronary Drug Eluting Stent Adoption: US



Average cost: DES \$2287 BMS \$850

Governmental Barriers

Status of Zilver PTX

- CE Mark 2009
- Japanese approval 2012
- Korea: approved but not reimbursed
- US: "approvable", but not approved



Health Care Delivery System Barriers

Incentives are not aligned!



- Insurers
 - Derive benefit from drug eluting technology
 - Have no involvement with purchase decisions
- Hospitals
 - Pay more for drug eluting technology
 - Lose revenue (through fewer restenosis cases)
- Physicians
 - Lose revenue (through fewer restenosis cases)

Summary

- Femoropopliteal restenosis is common and costly
- DES effectively prevent and treat restenosis
- Creative combinations
- Eventual role depends on technical, financial, and governmental factors