

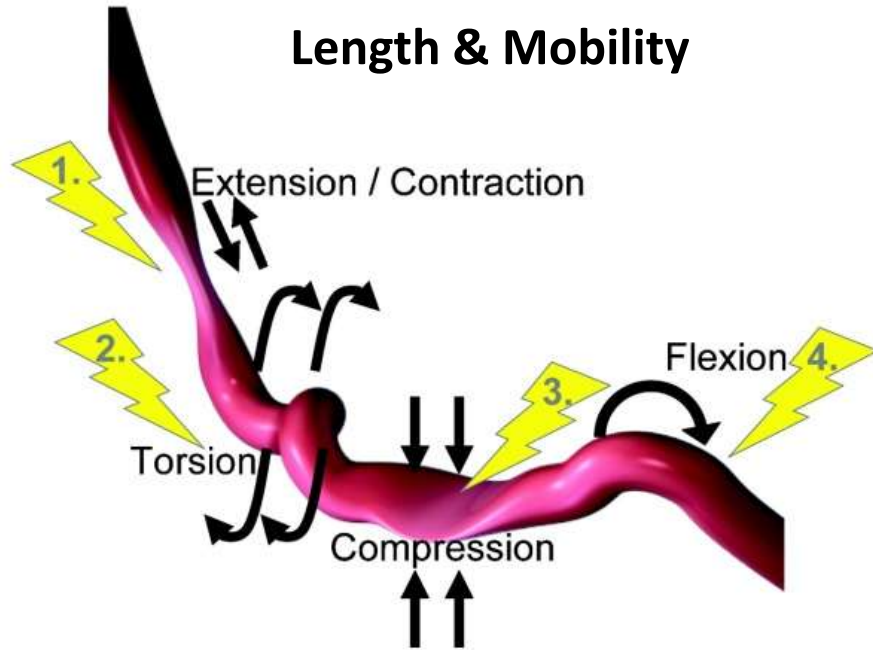


My Practice with Zilver PTX

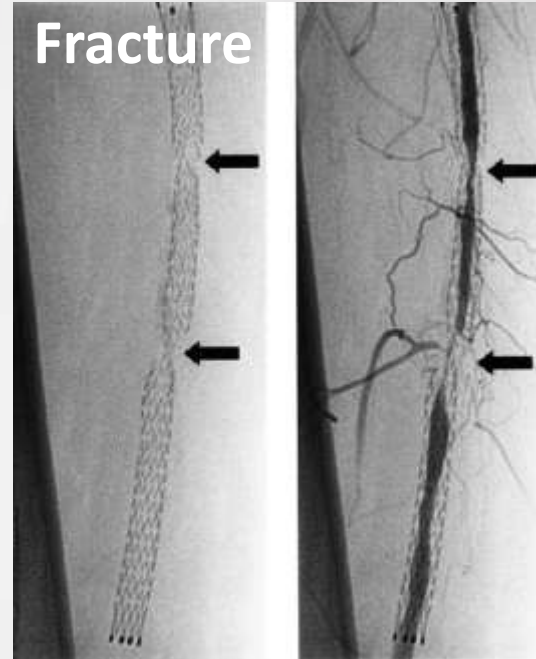
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Challenges & Limitations of SFA Interventions

Length & Mobility



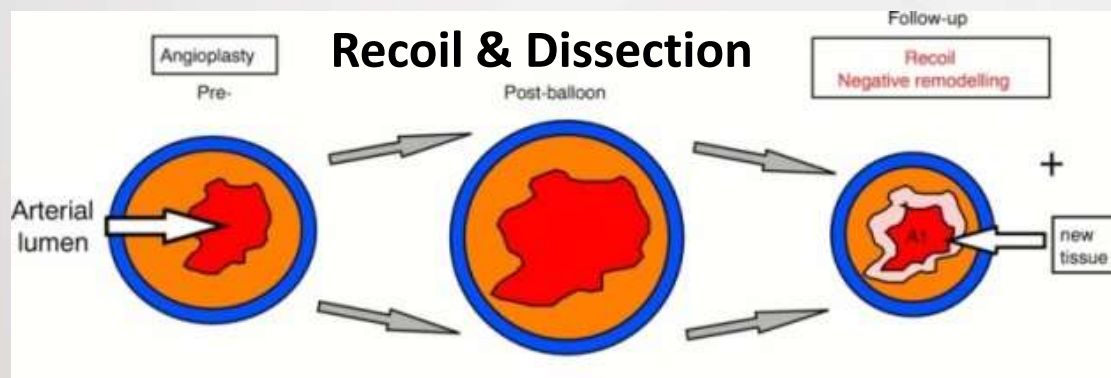
Fracture



ISR difficult to treat



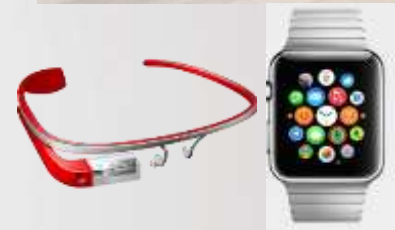
Recoil & Dissection



My SFA Intervention Wish List



- ☐ Easy to perform or deliver
- ☐ High procedural success
- ☐ Safe
- ☐ Long term efficacy vs. PTA & BMS
 - ☐ Complex lesions (Long, Ca++, CTO, ISR)
 - ☐ Patency
 - ☐ Clinical benefit
- ☐ Preserve future treatment options
- ☐ Cost effective



Drug Eluting Evolution



- ~100% DES in coronary intervention
 - 1st (2002) \Rightarrow 4th Generation (now)
- Zilver PTX is the 1st & only DES for SFA (since 2009)

CE Mark
7F Avail. in HK

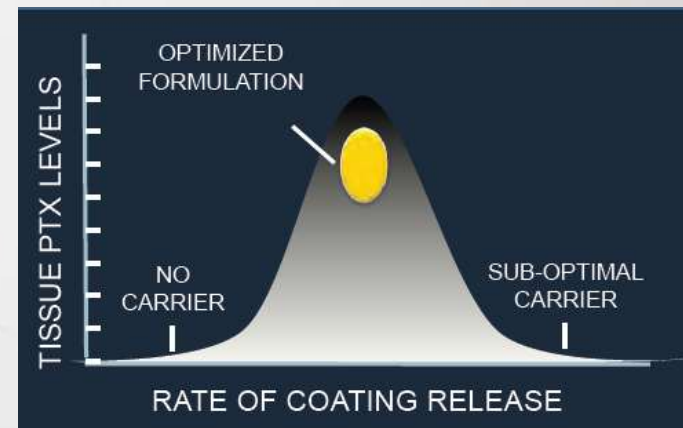
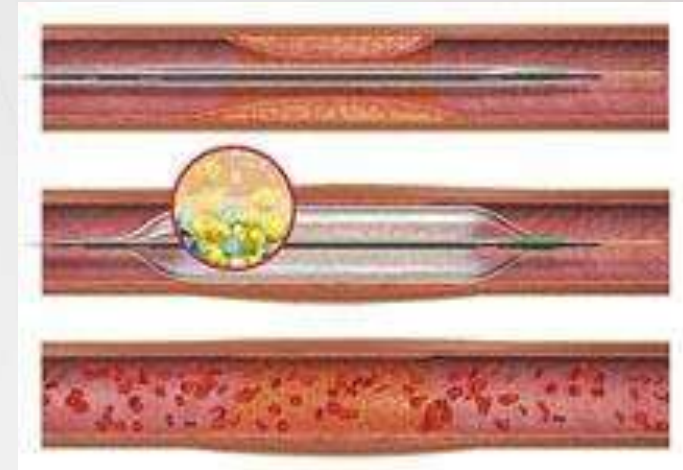
6F Avail. in HK (Jan)
USFDA approval (Nov)

6F Cogwheel
Avail. in HK (May)



Drug Coated Balloons as Well

- Paclitaxel
- Promising RCT outcomes for simple lesions vs. PTA
- Lack long term data on complex lesions
- Not all DCB the same because of different expedient
- Unpredictable drug delivery
- “Nothing left behind” vs. stents
- Same limitations as PTA
 - Dissections & recoils
 - Bail out stenting



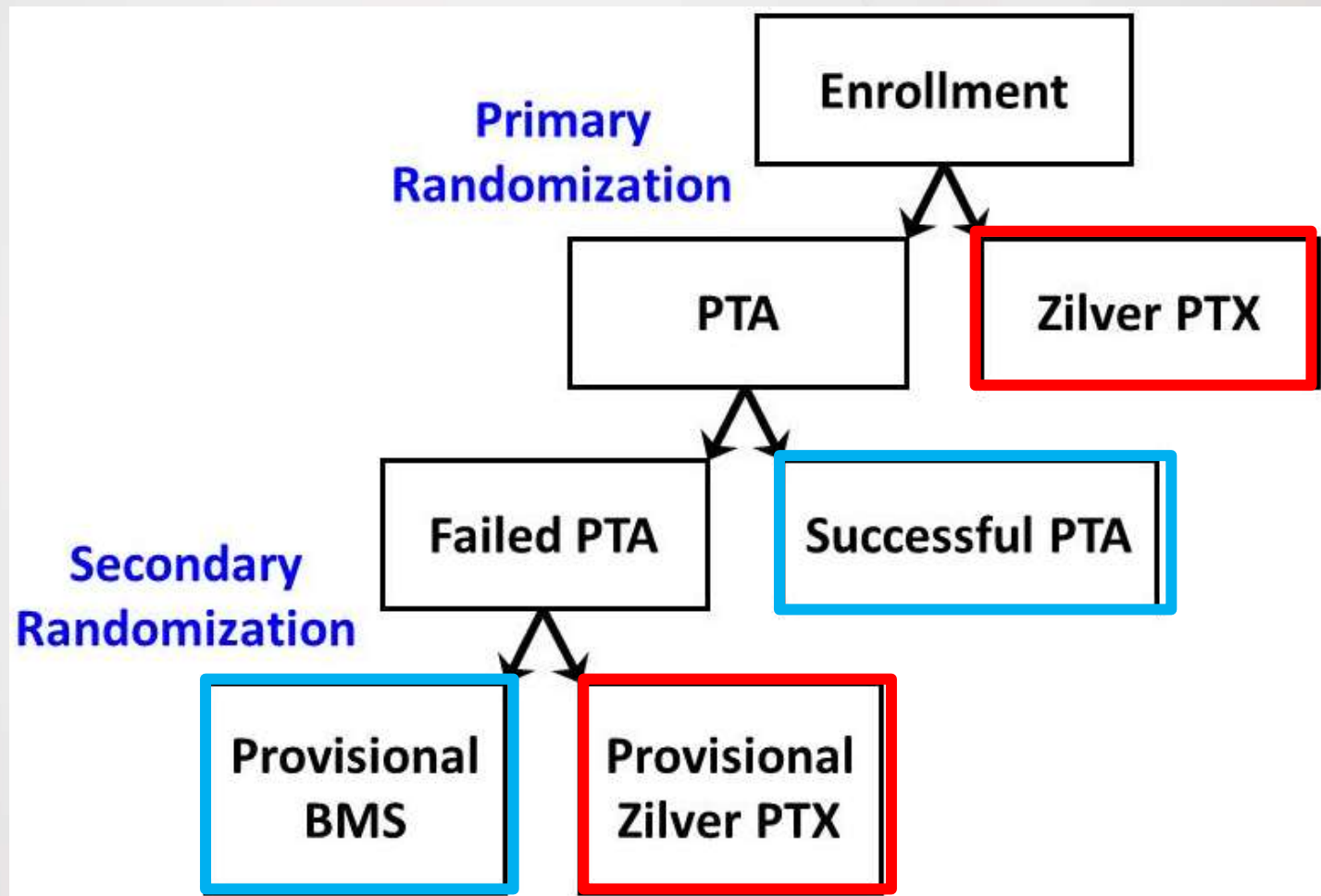
Is Stenting Still Necessary with DCB?



- Longer & more complex the lesion, more often a stent is required to treat residual stenosis & flow limiting dissection after balloon angioplasty
 - 20-50% TASC A-B lesions
 - 50-100% TASC C-D lesions
- Similar after DCB

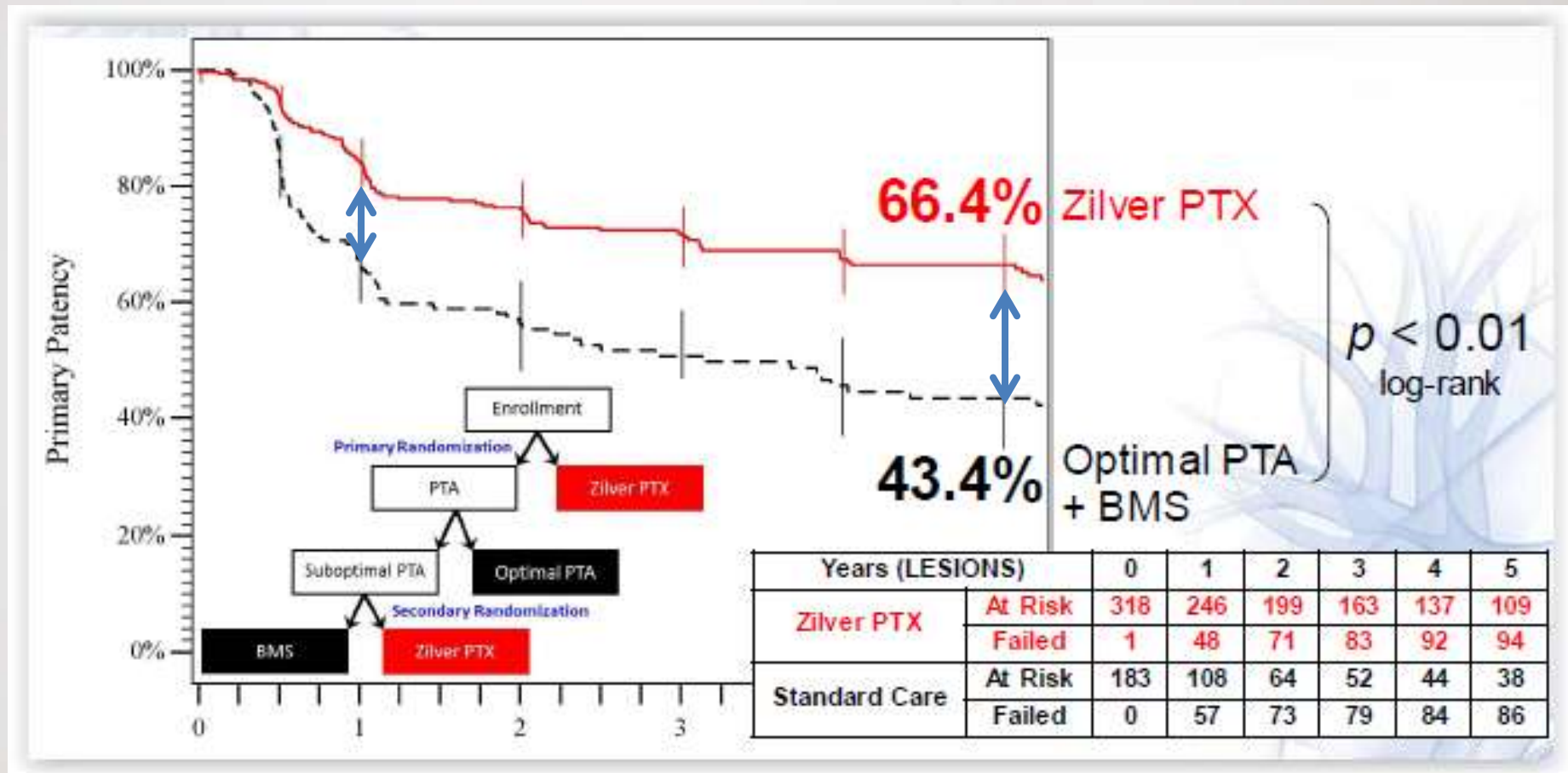
Trial	Trial Type	Lesion Length	Incidence of “Bail Out” stenting
THUNDER	DEB	7.5cm	4%
In.Pact SFA	DEB	8.9cm	7.3%
Advance PTX	DEB	10.5cm	29%
Schmidt A et al.	DEB	24cm	23.3%
Micari A et al.	DEB	7.6cm	12.3%
Zilver PTX RCT	DES	9.7cm	50%

Zilver PTX RCT Design



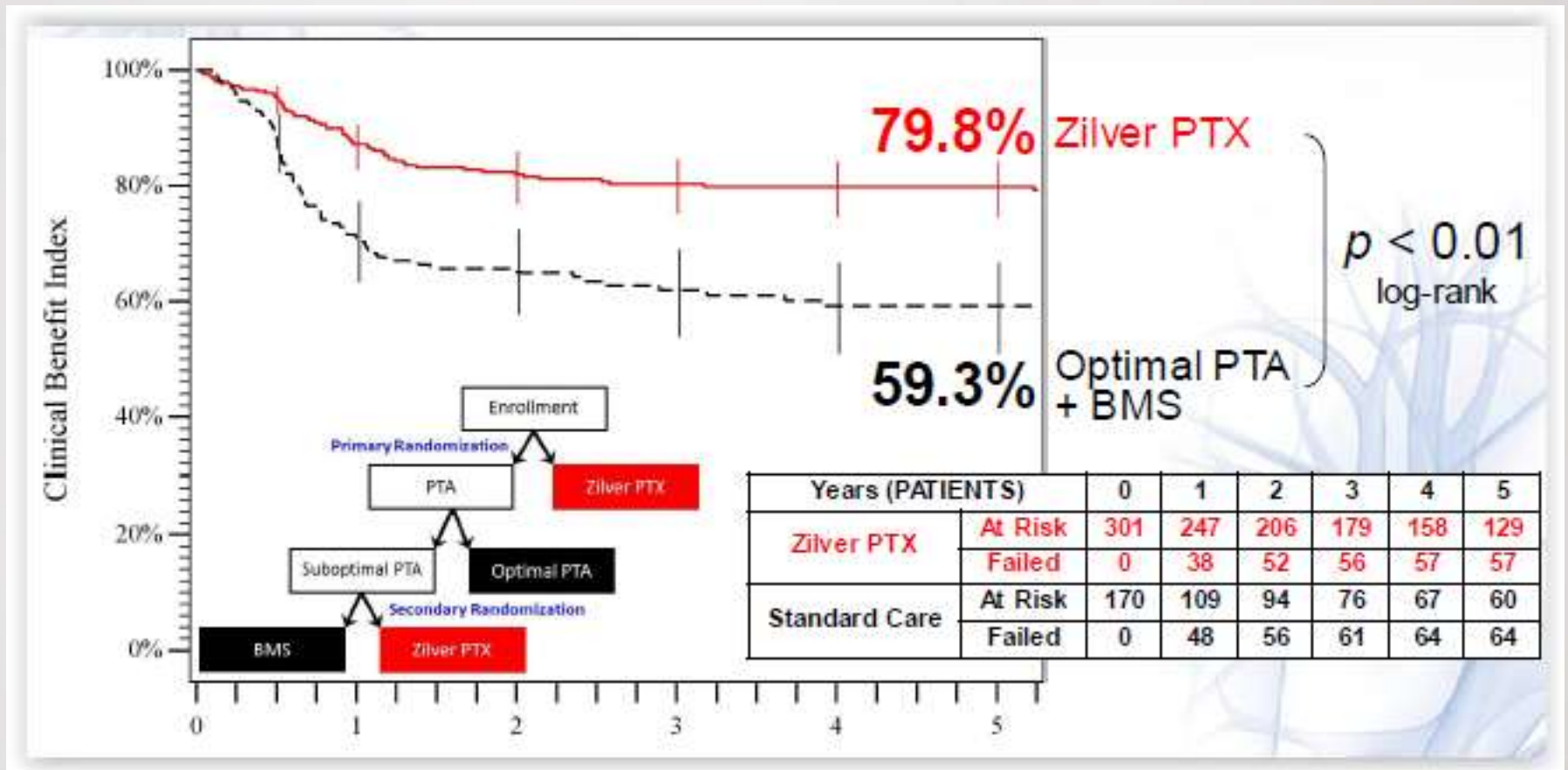
5 Year Primary Patency

Zilver PTX vs. Standard of Care



- 41% reduction in restenosis compared to standard of care
- From year 1 to 5, relative separation increased 35%

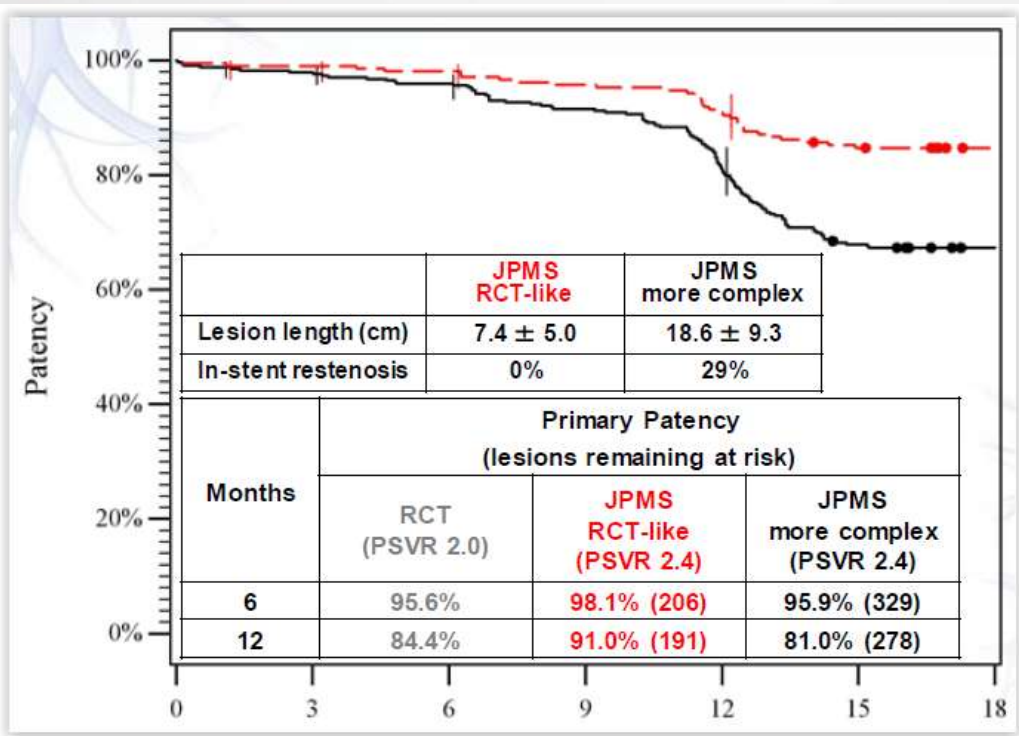
5 Year Clinical Benefit Index Zilver PTX vs. Standard of Care



- Zilver PTX superior rate of freedom from persistent or worsening claudication, rest pain, ulcer or tissue loss

‘Real World’ Complex Lesions (Japan PMS)

	Zilver PTX RCT	JPMS RCT-like	JPMS more complex	p-value*
Lesions	247	378	703	
Lesion length (cm)	6.6 ± 3.9	7.4 ± 5.0	18.6 ± 9.3	< 0.001
Diameter stenosis (%)	80 ± 17	89 ± 12	93 ± 9	< 0.001
Total occlusions	33%	28%	49%	< 0.001
In-stent restenosis	0%	0%	29%	< 0.001

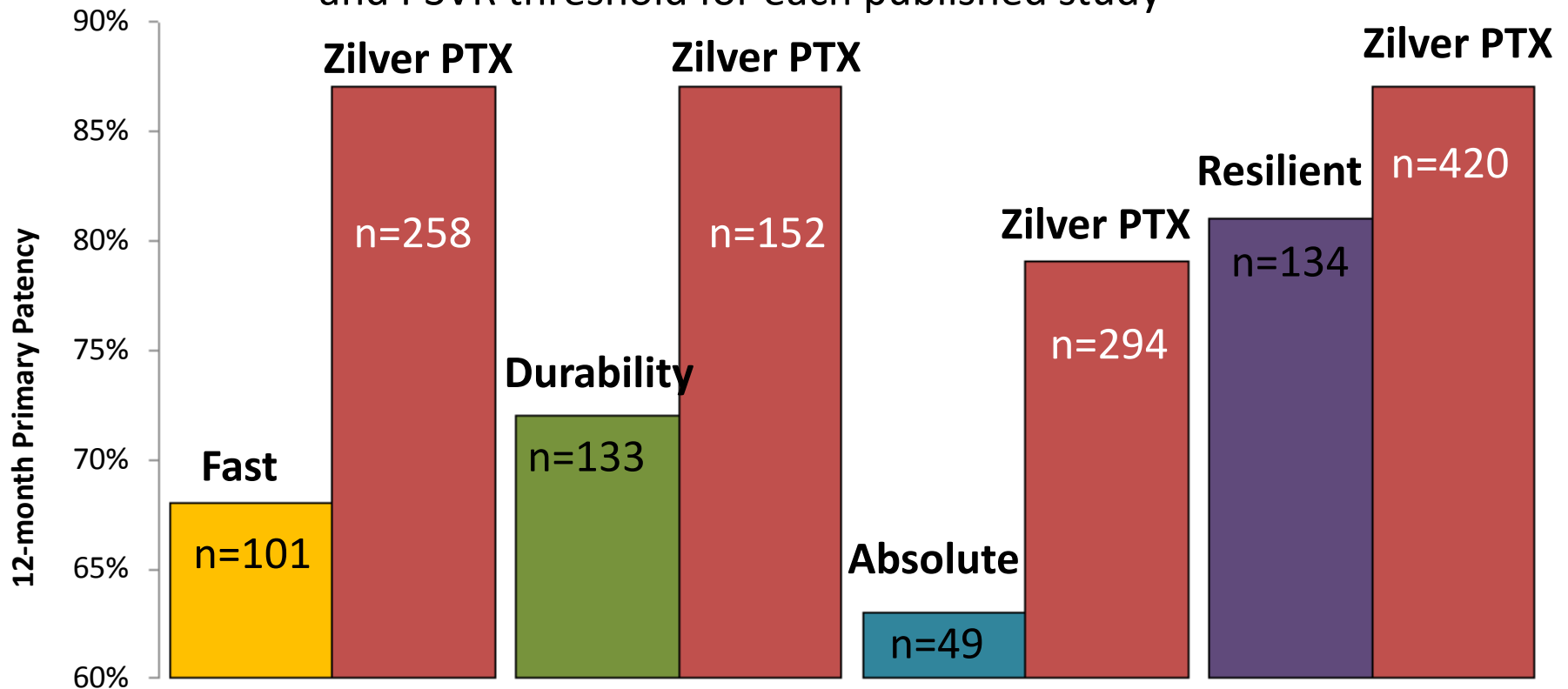


- Consistency between RCT & JPMS RCT-like lesions
- Primary patency lower in more complex lesions as expected

	RCT	SAS	Japan PMS
Fracture Rate	0.9%	1.5%	1.6%
Number of Stents Evaluated	470	1889	1066

Zilver PTX Patency Compared to BMS

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



Zilver PTX has higher 12-month patency rates relative to BMS published literature

Meta-Analysis of Drug-Eluting Balloon Angioplasty and Drug-Eluting Stent Placement for Infrainguinal Peripheral Arterial Disease

ABSTRACT

Purpose: To perform a meta-analysis of randomized controlled trials (RCTs) of drug-eluting balloon (DEB) angioplasty and drug-eluting stents (DESs) for infrainguinal peripheral arterial disease.

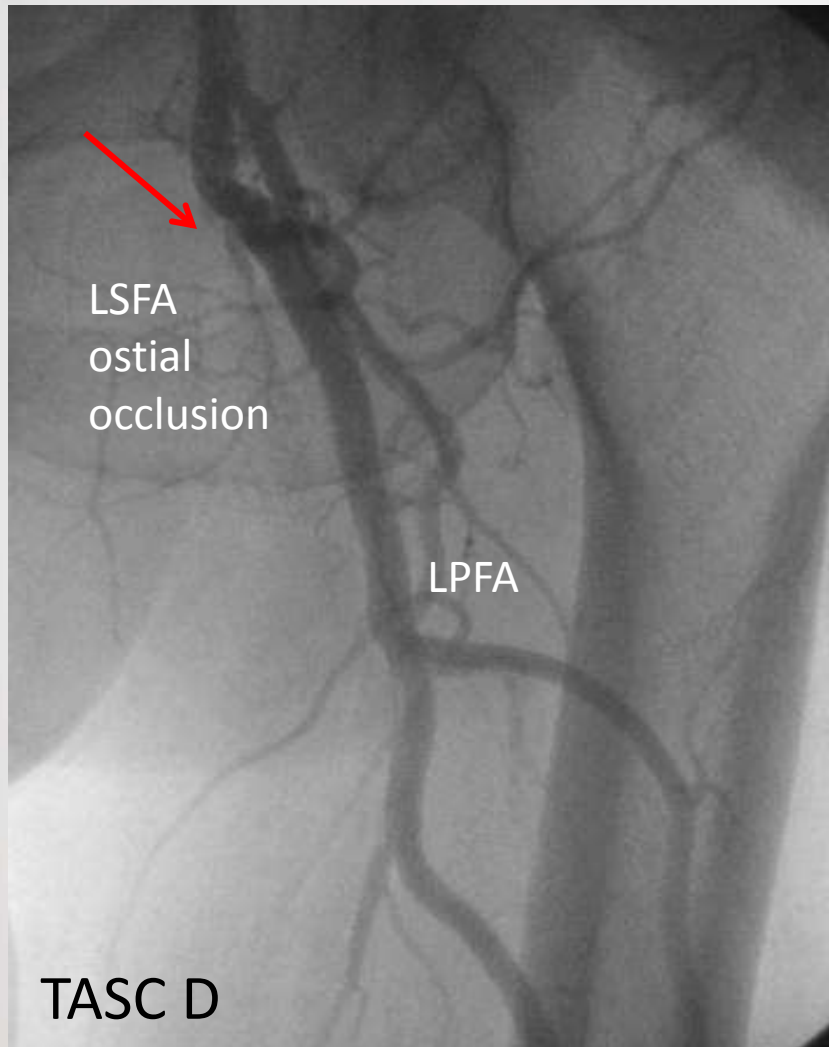
Materials and Methods: Systematic searches were performed for all relevant RCTs.

Results: Eight RCTs for DEB angioplasty and 12 RCTs for a DES in peripheral arterial disease were identified. Meta-analysis demonstrated statistically significant superiority of DEB over plain balloon angioplasty of femoral-popliteal disease for late lumen loss, restenosis, and target lesion revascularization, with no benefit in major amputation or mortality. Statistically significant superiority of DEB over percutaneous transluminal angioplasty (PTA) was demonstrated for infrapopliteal disease for restenosis and target lesion revascularization. Drug-eluting stents showed statistically significant superiority over bare metal stents (BMSs) of femoral-popliteal disease for late lumen loss and restenosis, with no benefit in mortality or amputation. Drug-eluting stents showed statistically significant superiority over BMSs of infrapopliteal disease restenosis and target lesion revascularization, with no benefit in amputation or mortality.

Conclusions: Drug-eluting balloon angioplasty and DESs demonstrated superior outcomes compared to PTA and BMS, with no difference in amputation or mortality.

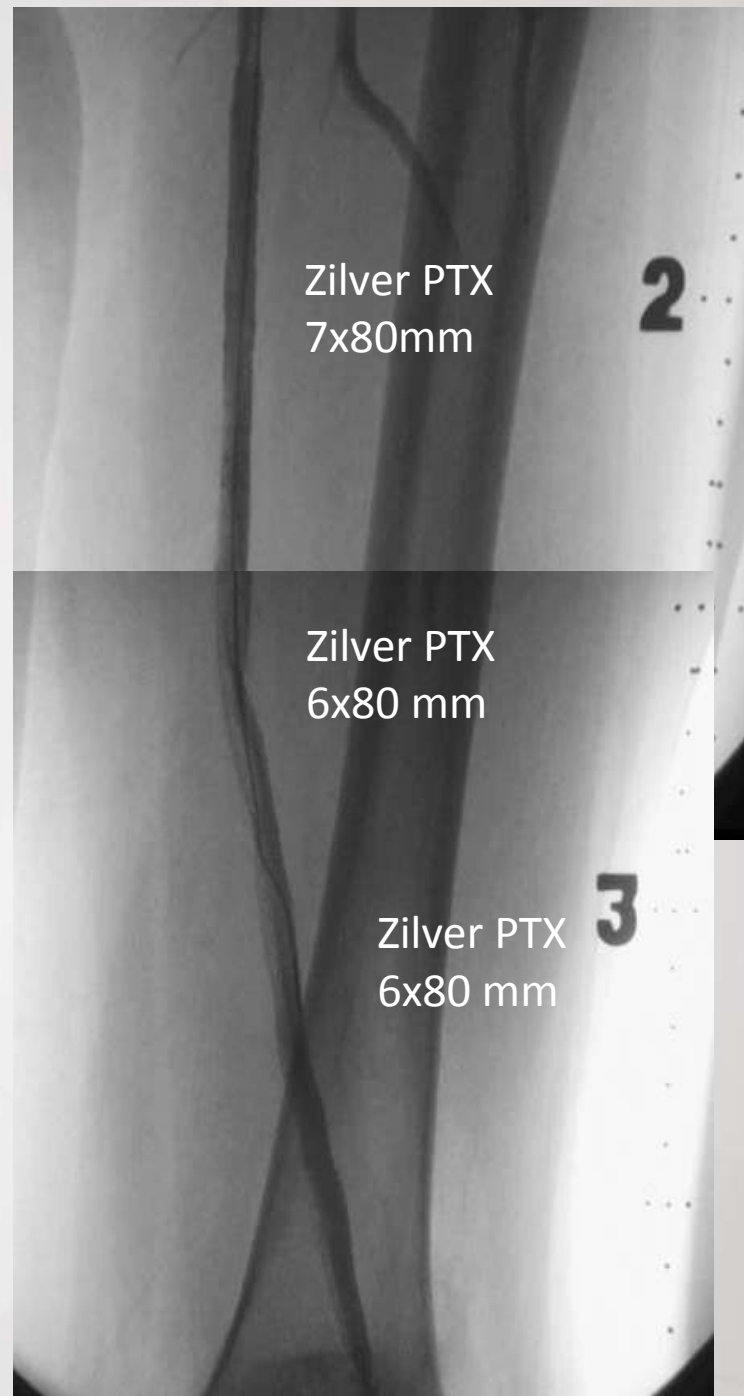
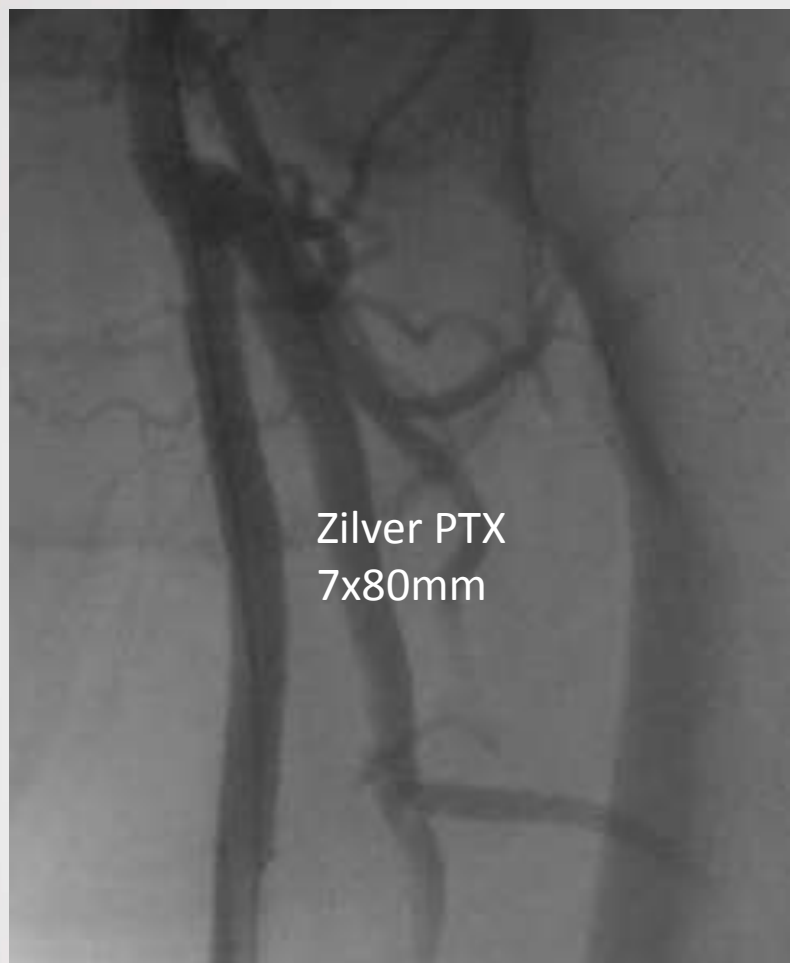
One of My Early PTX Case:

78F, DM, claudication (RC 3), ABI 0.65



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7F Zilver PTX system

12 months re-angio: No fracture
RC 1, ABI 1.01

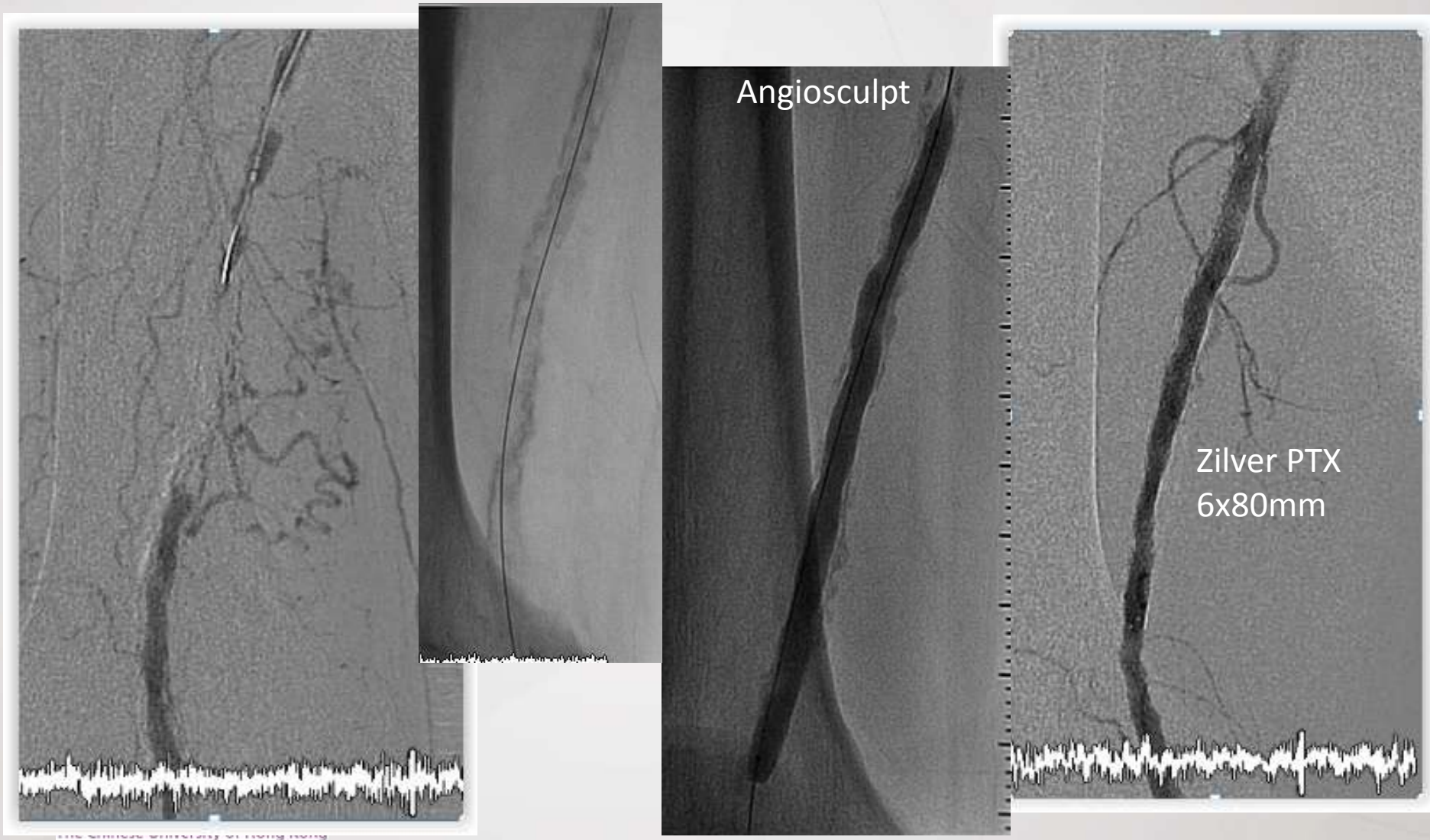


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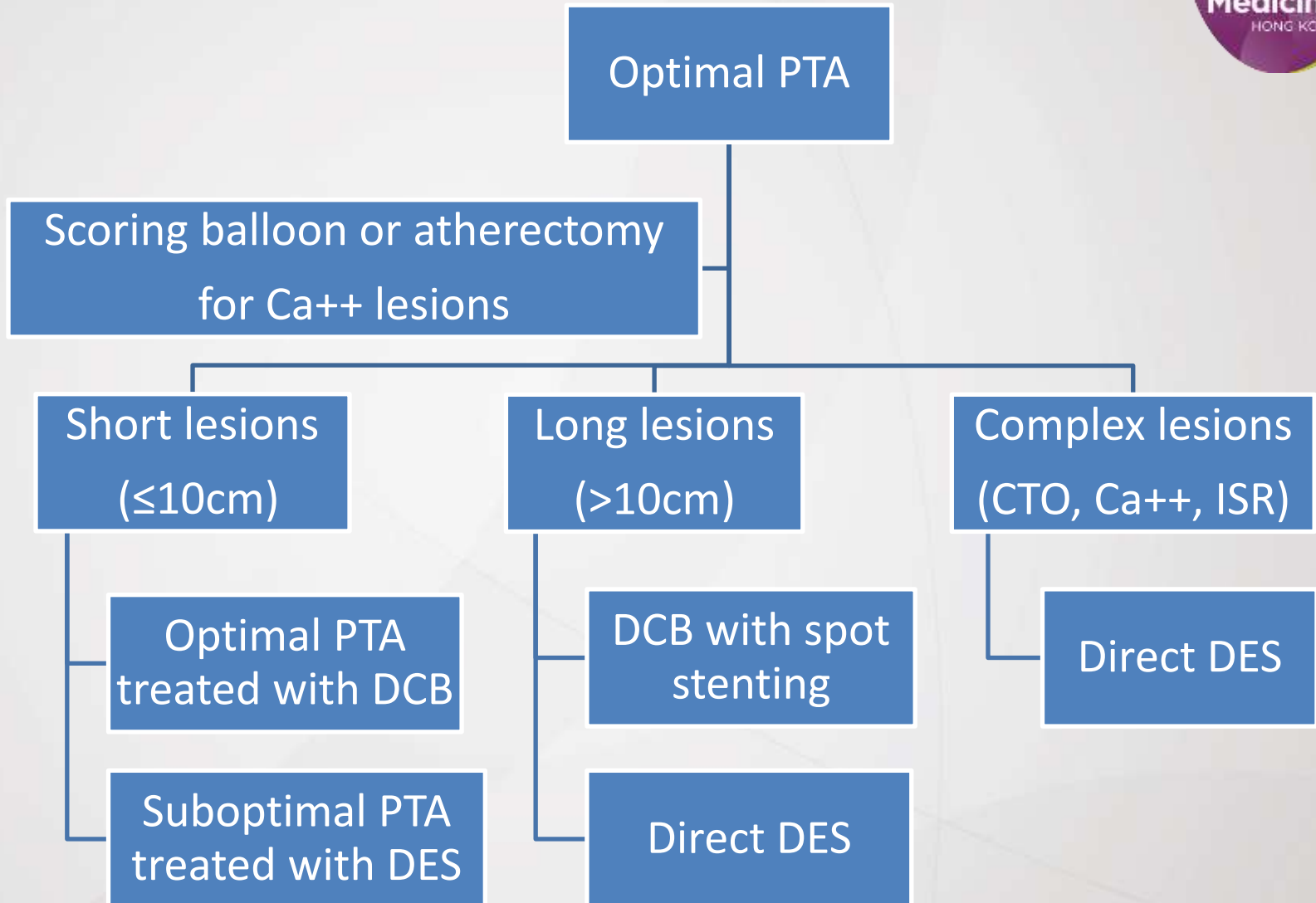
4 year clinical follow-up:
RC 1, ABI 0.91



Calcified Chronic Total Occlusion



My Drug-eluting Strategy for SFA



Who is Paying for the DES?



- DES/DCB not reimbursed in HK
- 30-50% incremental cost for PTX vs. BMS
 - Reasonable
 - Much lower premium than coronary DES vs. BMS
- Patient willingness-to-pay for peripheral intervention is lower than coronary
- Is PTX a cost effective strategy?



Why Drug-Eluting Stents Are Cost Effective in the Superficial Femoral Artery

The importance of cost effectiveness in health care is accelerating. Implanting drug-eluting stents in the superficial femoral artery may offer a safe, effective, and economically valuable solution.

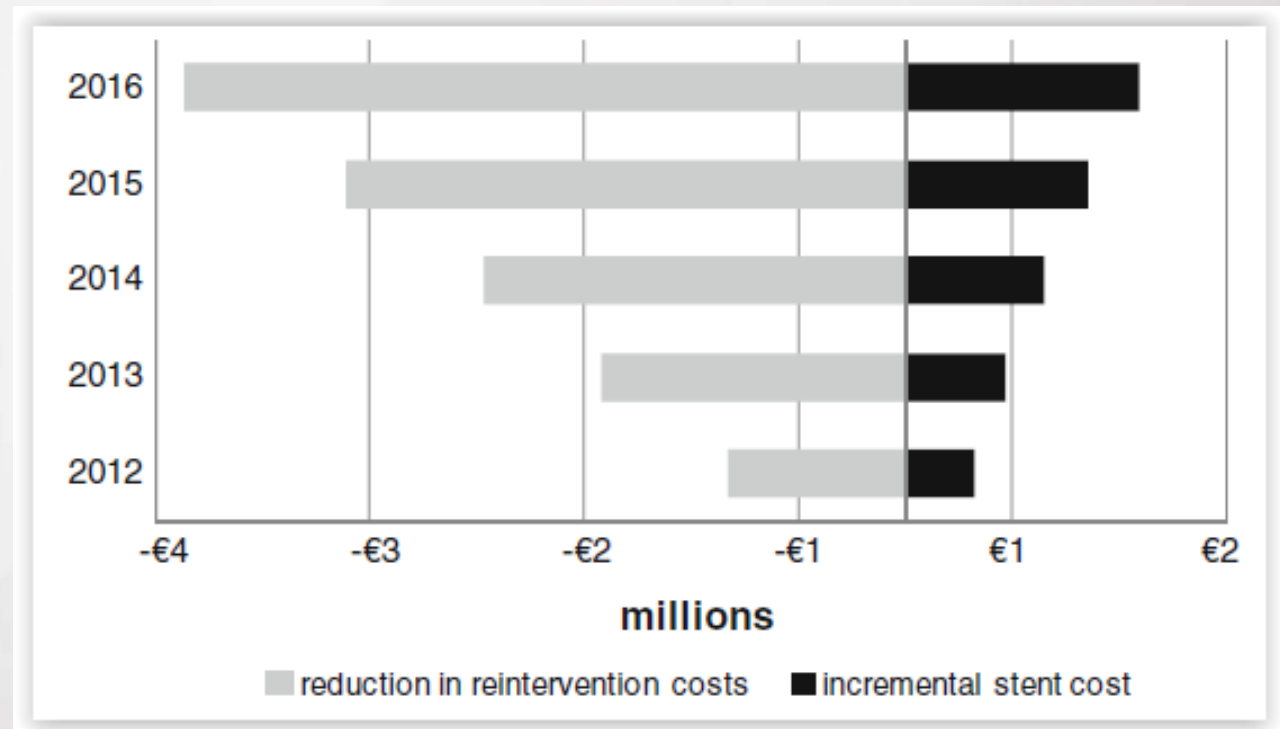
BY MARK W. BURKET, MD

“For a relatively modest increase in purchase price,
extremely expensive follow-up care
may potentially be avoided.”

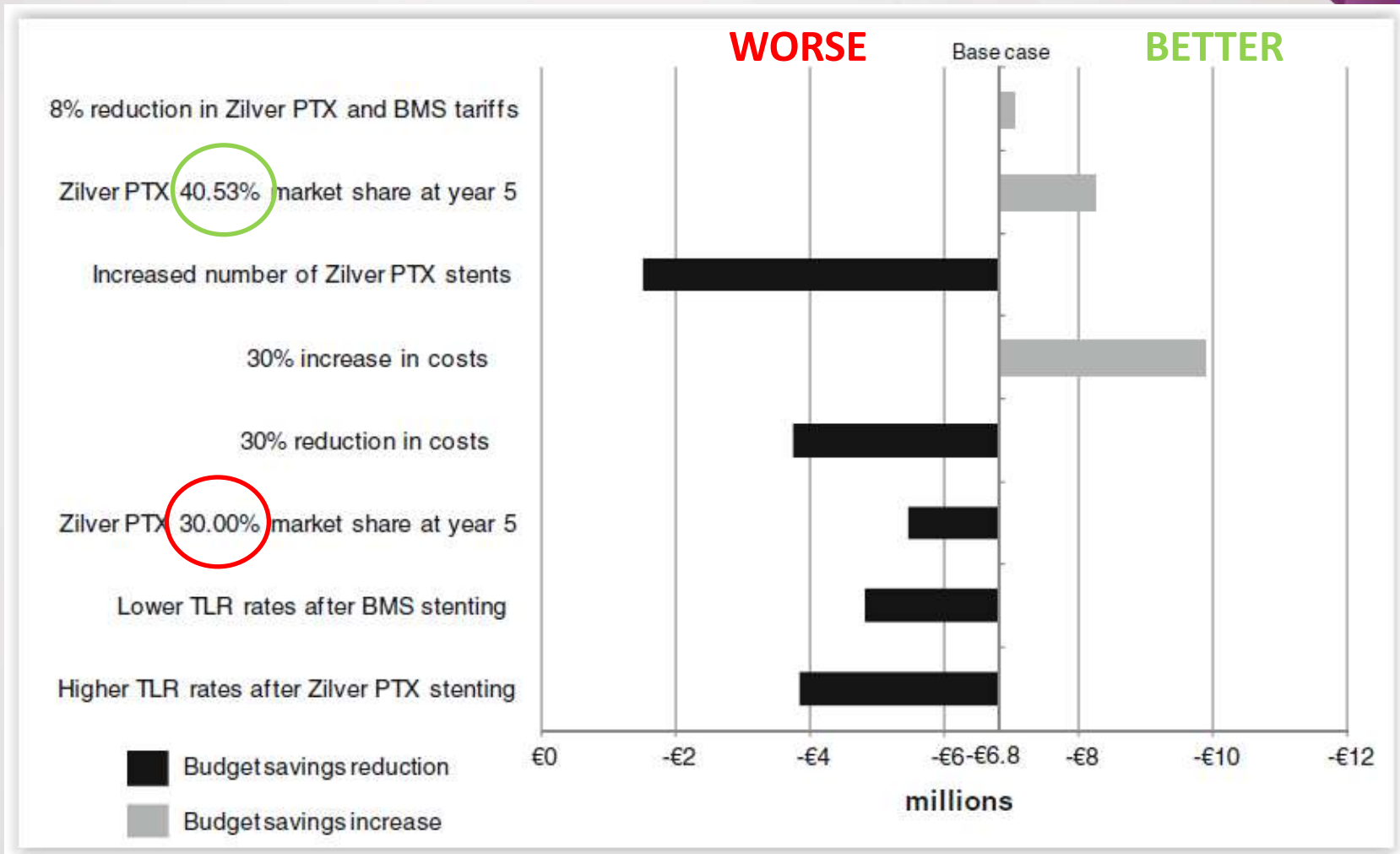


A Budget Impact Model for Paclitaxel-eluting Stent in Femoropopliteal Disease in France

- Systematic adoption of Zilver PTX results in cumulative 5-year cost saving
- Increased stent costs offset by reduced re-intervention costs



Sensitivity Analysis



Zilver PTX & My SFA Intervention Wish List



- ☑ New cogwheel delivery easy to perform
- ☑ High procedural success with stents
- ☑ Safe: low fracture rate
- ☑ Sustained efficacy up to 5 years
 - ☑ Complex 'real world' type C/D lesions
 - ☑ Superior patency vs. BMS
 - ☑ Sustained clinical benefit
- ☒ Preserve future treatment options
 - ☑ Focal ISR may be easier to treat
- ☑ Potential long term cost saving with increased use of DES

Thank You



VS.

