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# Below the Knee Stenting: DES vs. BVS

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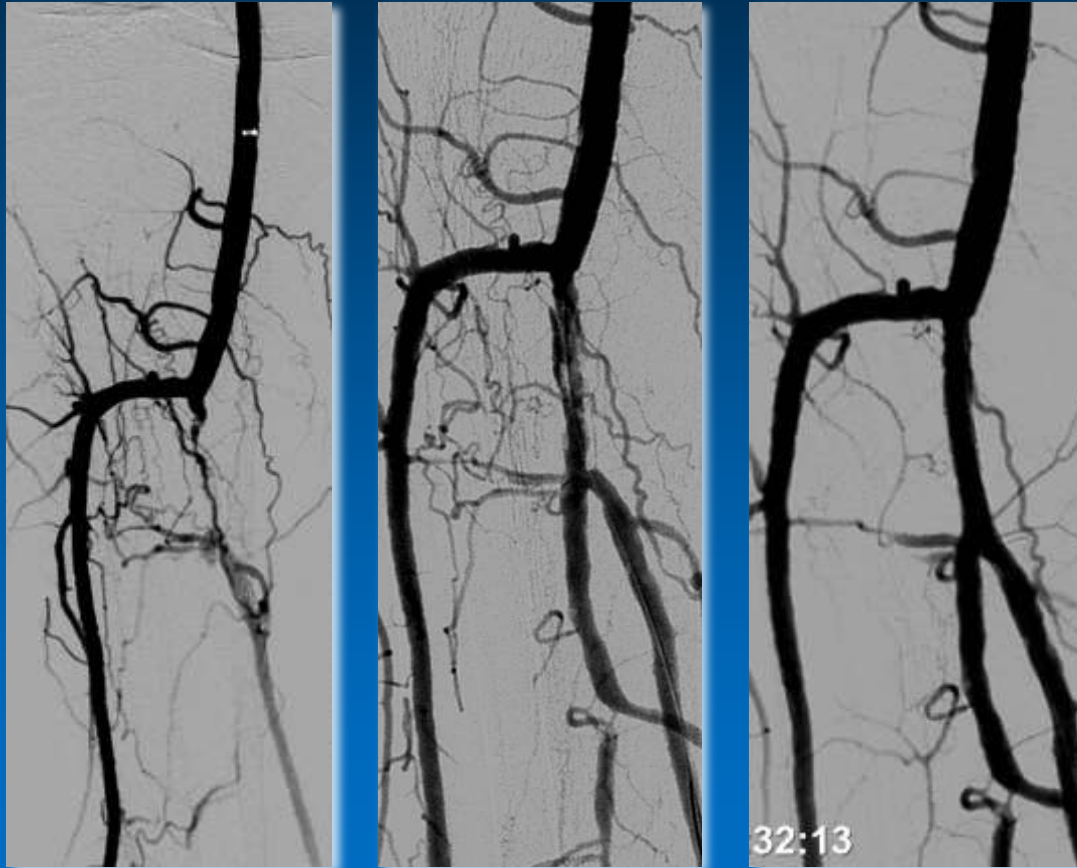
## *Disclosure Information*

Abbott Vascular C, P, SB  
Ablative Solutions EI  
Boston Scientific AB, C, EI, P, SB  
Cook Medical, Inc. C, P  
Cordis Endovascular C  
MedAlliance AB, EI  
Medtronic Vascular C, P  
Omeros Corp, EI  
QT Vascular, EI  
Transverse Medical AB, EI, SO  
Vatrix Medical AB, EI  
W.L. Gore C, P

AB: Advisory Board  
C: Consulting Relationship  
EI: Equity Interest  
GS: Grant Support  
P: Proctor or Training Course Sponsorships  
SB: Speakers Bureau  
SE: Spouse Employee  
SO: Stock Options or Positions

# Is DES the Standard for BTK Interventions?

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Pre

Post-PTA

Post-Stent

TPT-occlusion right leg – CLI

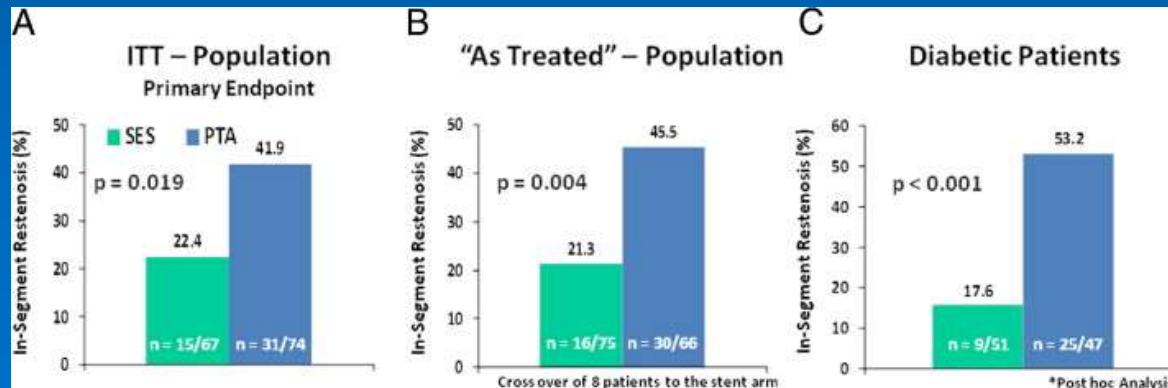
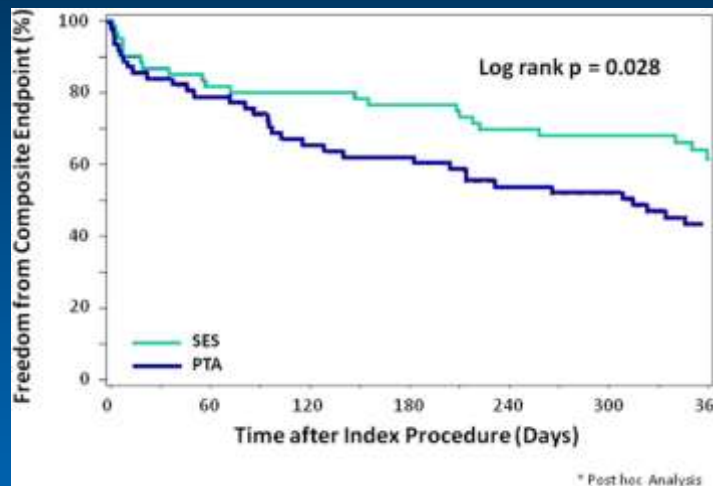
# Short Lesion BTK DES

## Summary of Single Center Results

	Pts	Les	Treatment	Primary Patency %	Limb Salvage %
<b>Bosiers</b> Cardiovasc Interv Radiol 2008	57	75	<b>PTA</b>	40% @1yr	92.4 @ 6M
<b>Bosiers</b> EuroIntervention 2007	50	62	<b>Bare metal stents</b>	62.8 @ 12M	89.3 @ 12M
<b>Siablis</b> J Endovasc Ther 2007	29	65		40-60% @1yr	100 @ 12M
<b>Rand</b> Cardiovasc Interv Radiol 2006	24	42		83.7 @ 6M	95.0 @ 6M
<b>Commeau</b> Cardiovasc Interv Radiol 2006	30	62		97 @ 7.7M	100 @ 7.7M
<b>Siablis</b> J Endovasc Ther 2007	29	66	<b>Sirolimus DES</b>	80-85% @1yr	96.0 @ 12M
<b>Scheinert</b> EuroIntervention 2006	30	30		100 @ 6M	-

# ACHILLES Trial

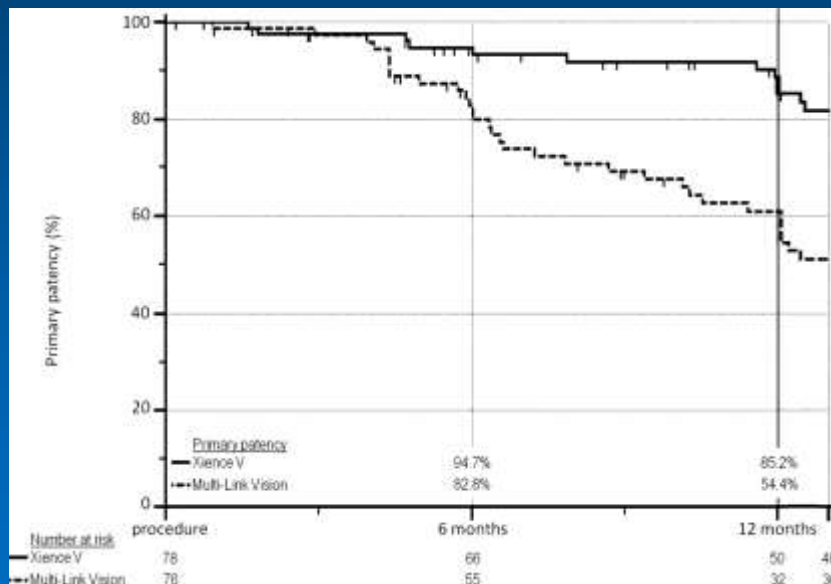
Randomized trial of Cypher Select DES vs. PTA in BTK (N=200 pts)



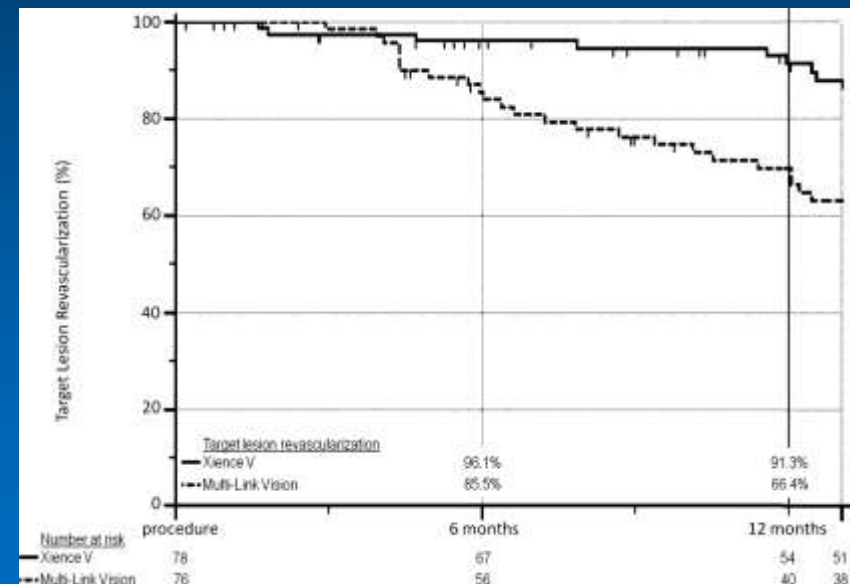
# DESTINY Trial 12-month Outcomes

## MultiLink Vision vs Xience V

### Primary Patency



### Freedom from TLR



# YUKON BTK

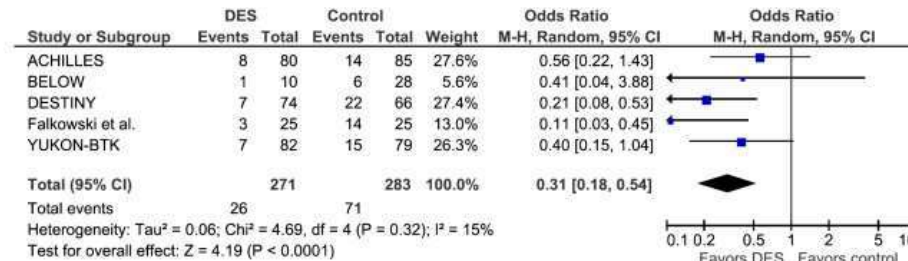
## YUKON-BTK Trial

- 161 patients at 4 sites in Germany
- Primary patency 80.6% vs. 55.6% at 1 year
- MACE events (incl. TLR) lower at 3 years

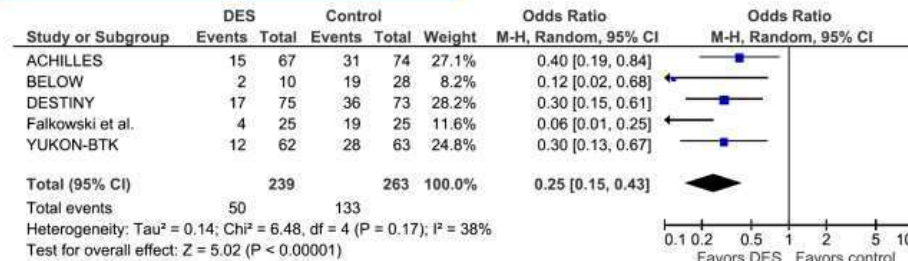


# Meta-analysis of BTK DES Trials

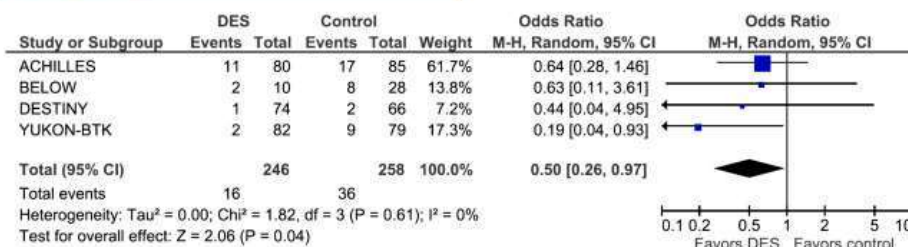
## A Target lesion revascularization



## B Restenosis



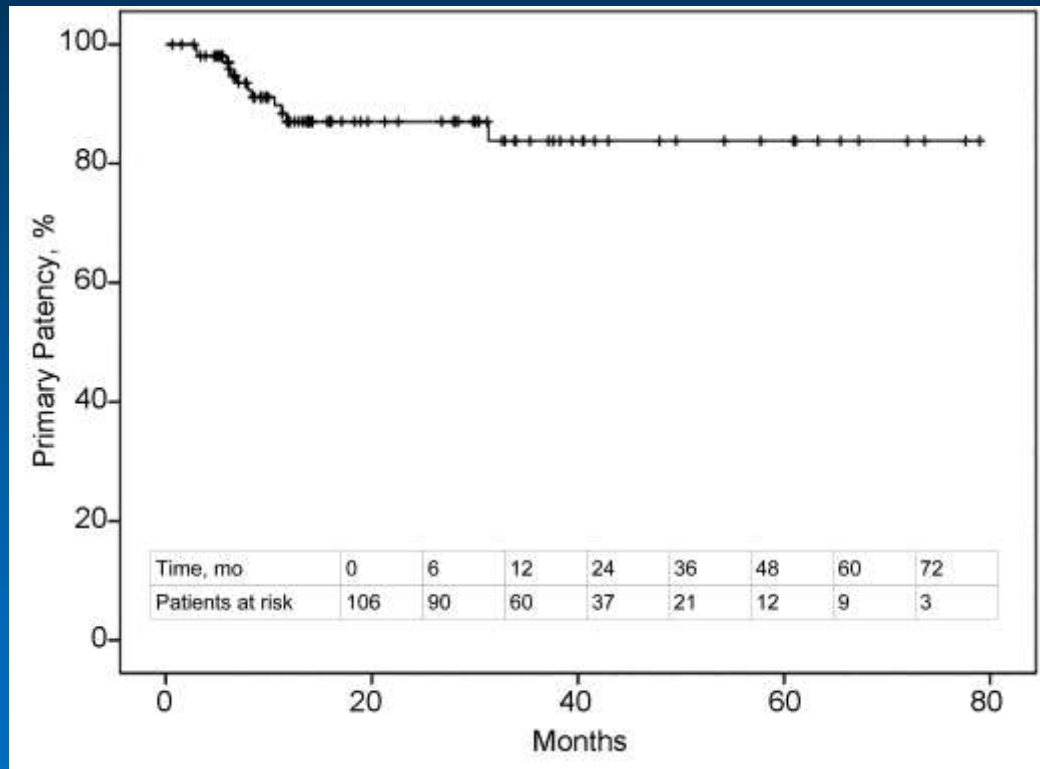
## C Amputation





# Long-term Results of Cypher DES BTK

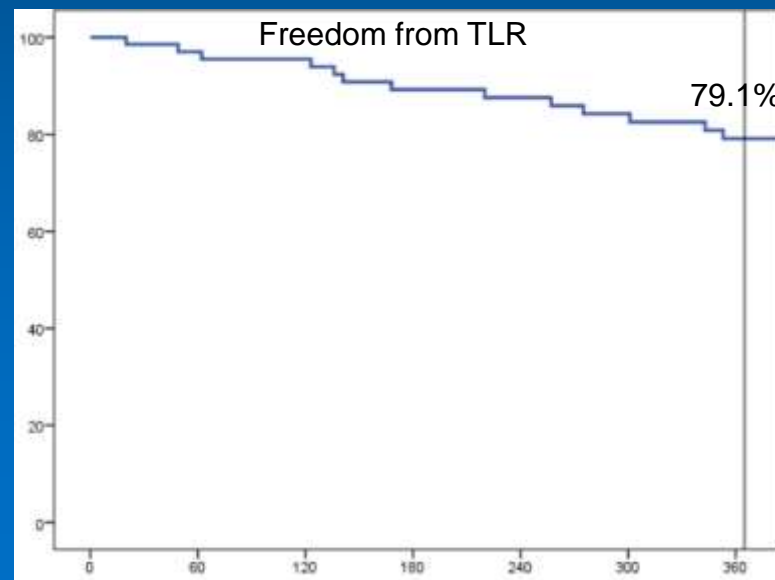
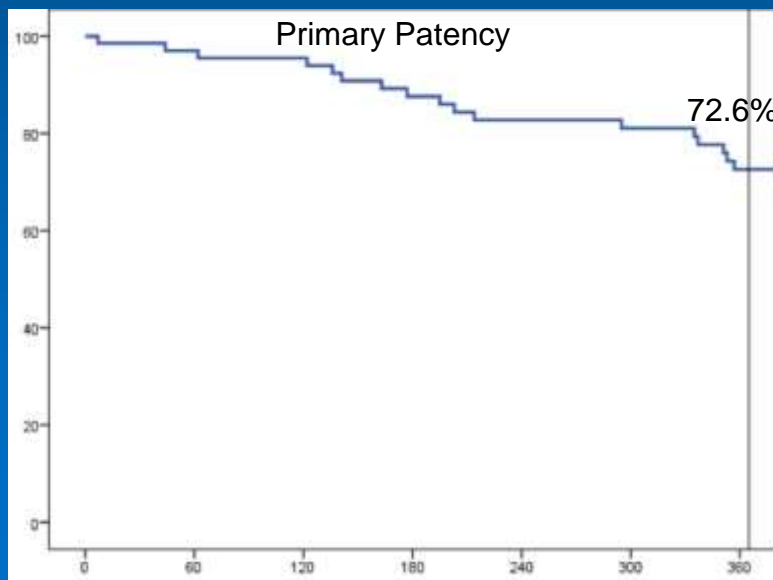
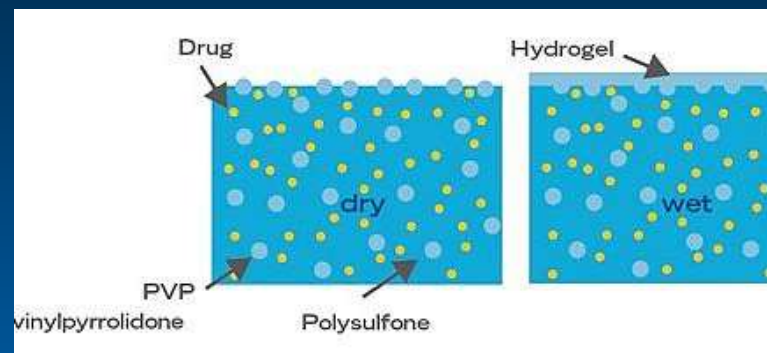
Retrospective single center study of 158 patients



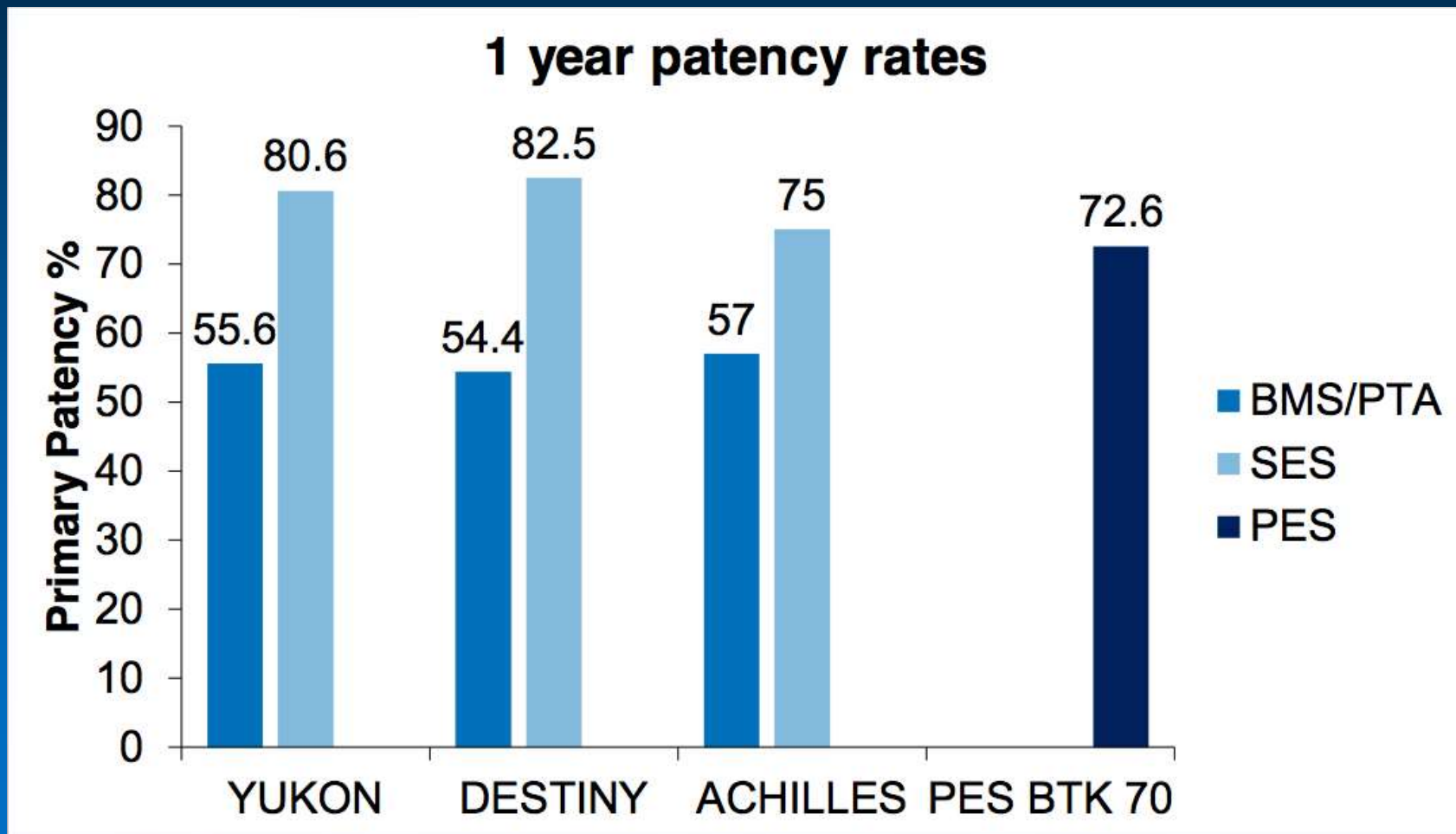
Primary patency 97.0% at 6 months, 87.0% at 12 months, and 83.8% at 60 months

# Stentsys BTK-70 Trial

- 70 pts with Rutherford IV-V CLI
- Paclitaxel eluting SES
- Mean lesion length 19.7 mm



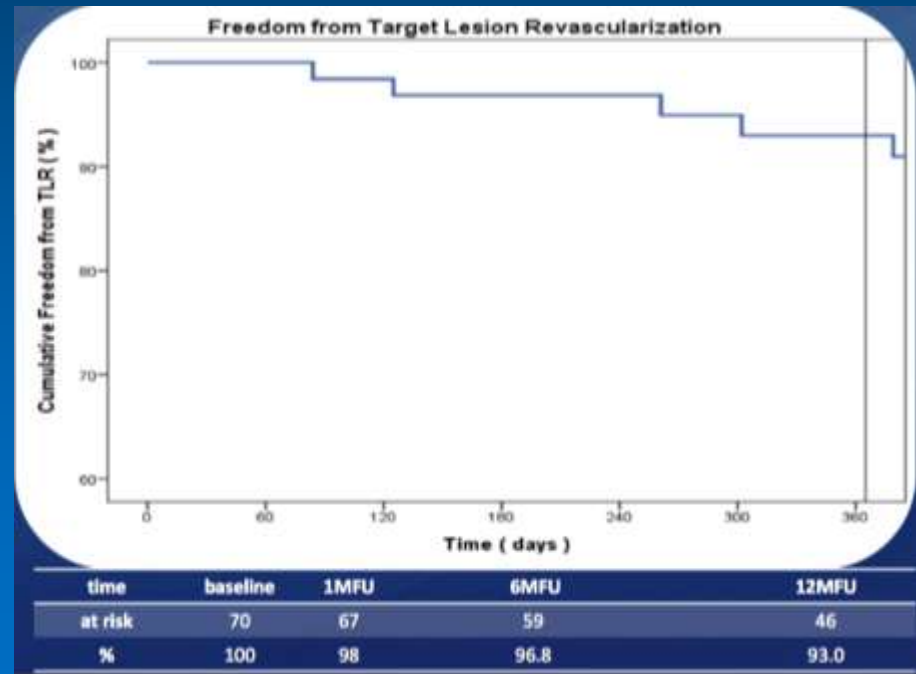
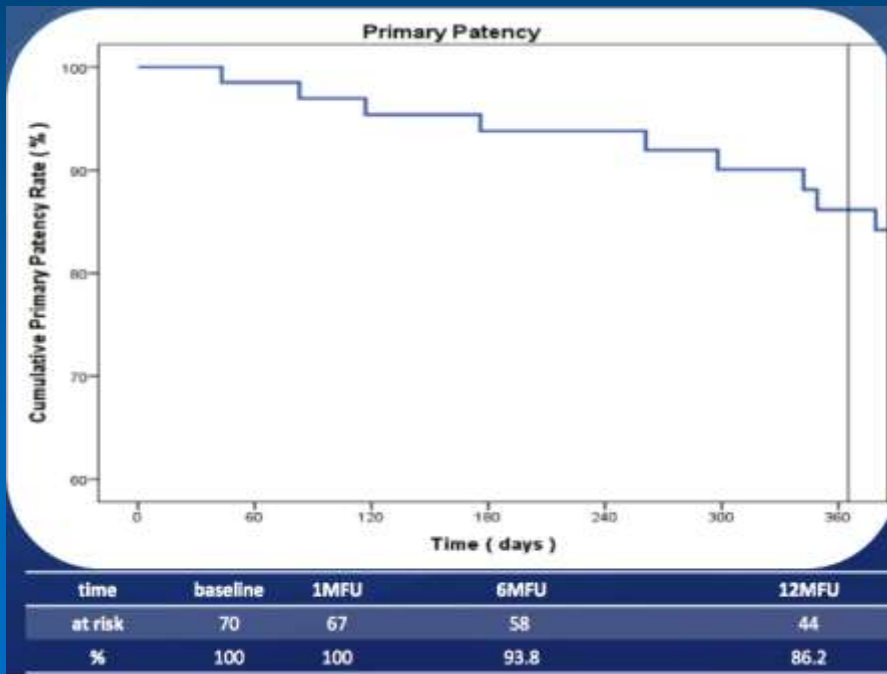
# Stentsys BTK-70 Trial



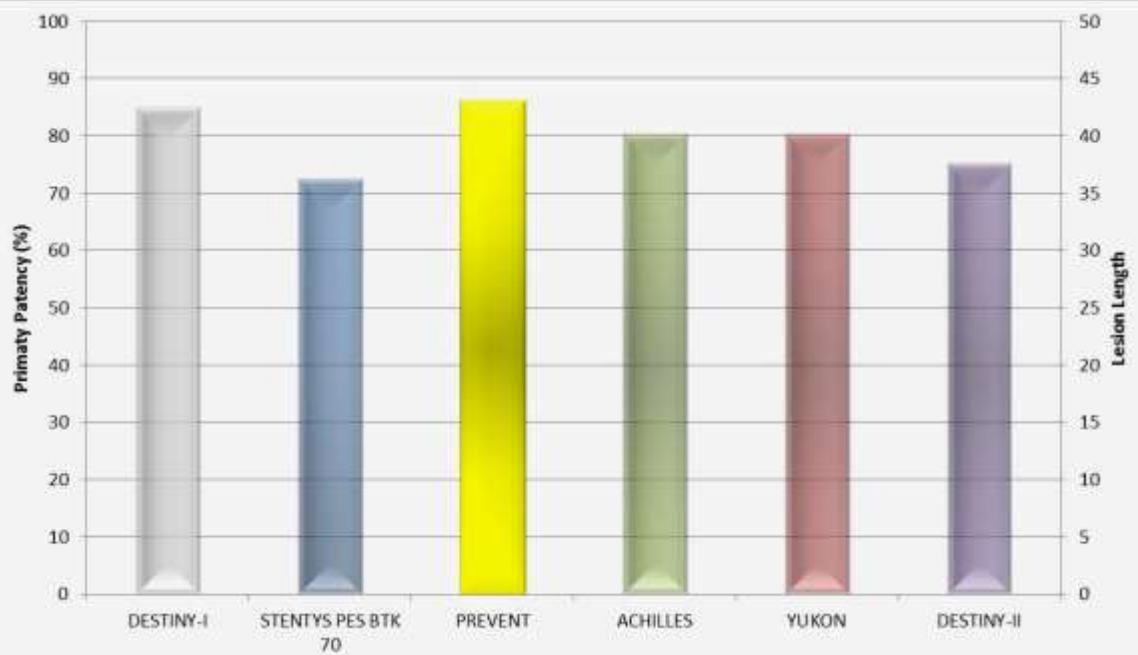
# PREVENT BTK Trial



- Promus Premier™ platform
- Prospective single arm study in 70 patients at 5 sites
- 12-mo primary patency 86.2%, TLR 7%



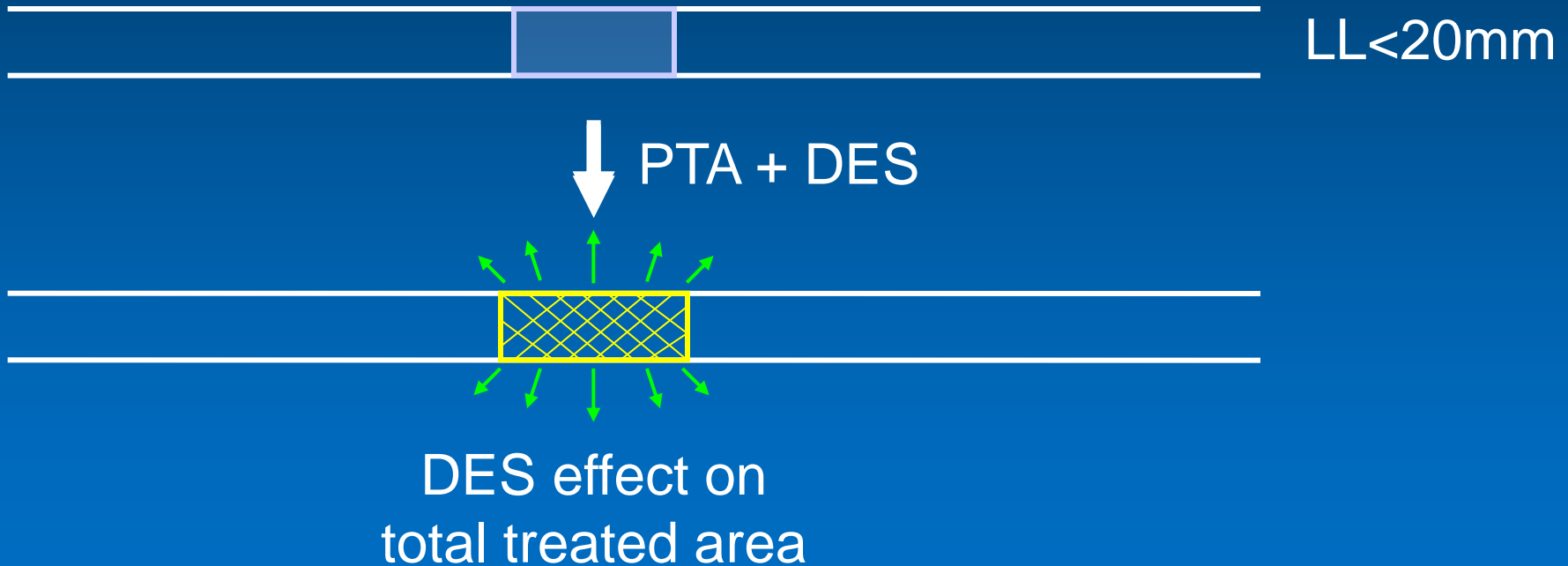
# 1-Year Primary Patency of BTK DES



	Primary Patency	Lesion Length
DESTINY-I	85.2	15.9
STENTYS	72.6	19.7
PREVENT	86.2	22.8
ACHILLES	80.6	26.9
YUKON	80.6	31.0
DESTINY-II	75.4	47.4

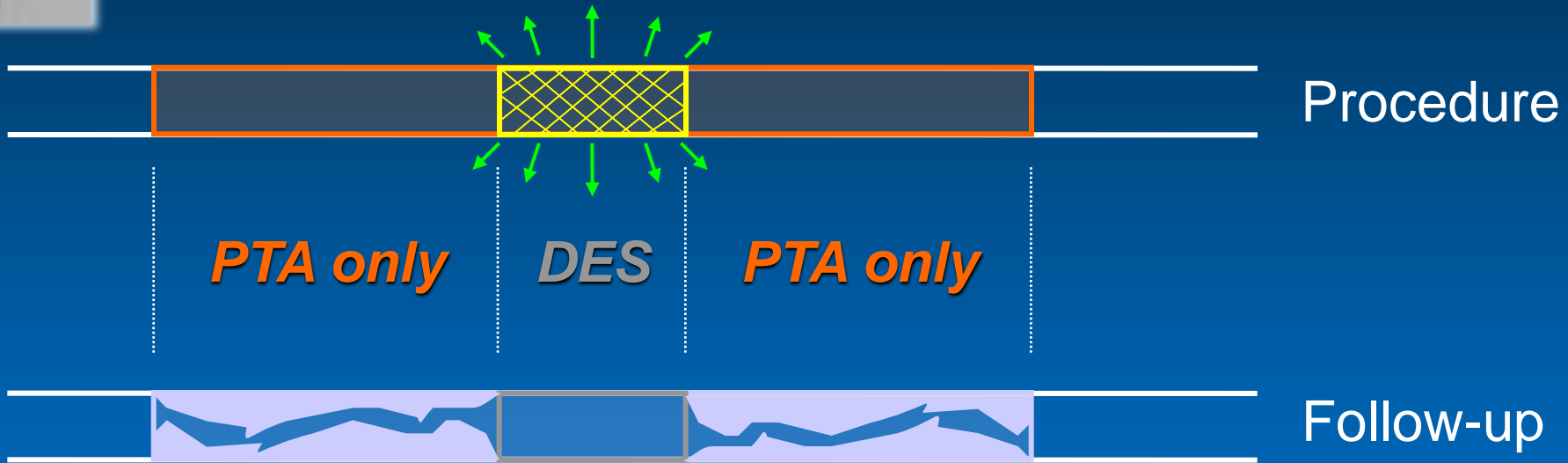
# Short Lesion BTK DES

## DES treatment principle



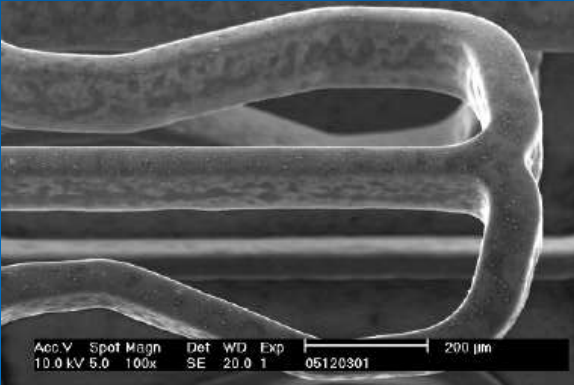
# Long Lesion BTK DES

DES for bail-out stenting in longer lesions



- Lesion length PTA  $46.0 \pm 50.0$  mm
- Lesion length stents  $25.5 \pm 12.2$  mm
- **Primary patency (12-month angiographic) 30.0%**

# Bioabsorbable Magnesium Stent



## Theoretical model

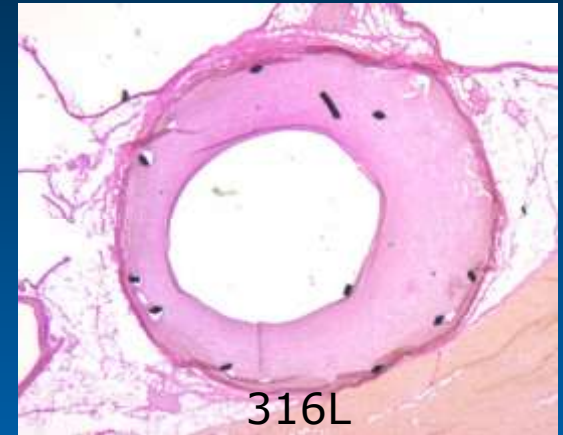
Magnesium



Magnesium  
Hydroxide

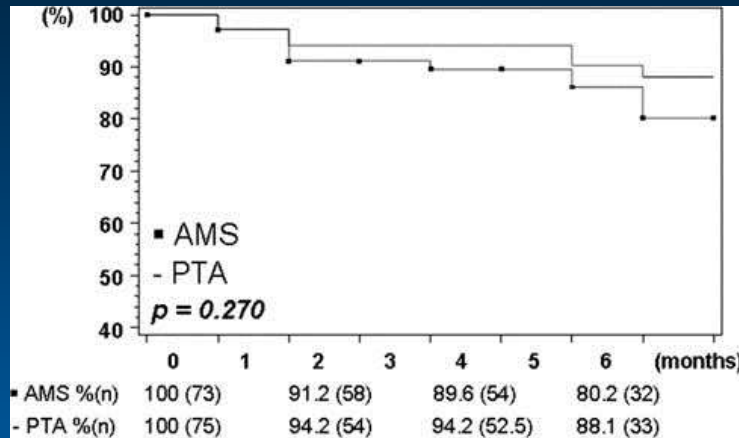


Soft calcium compounds  
Calcium phosphate  
Hydroxyl apatite

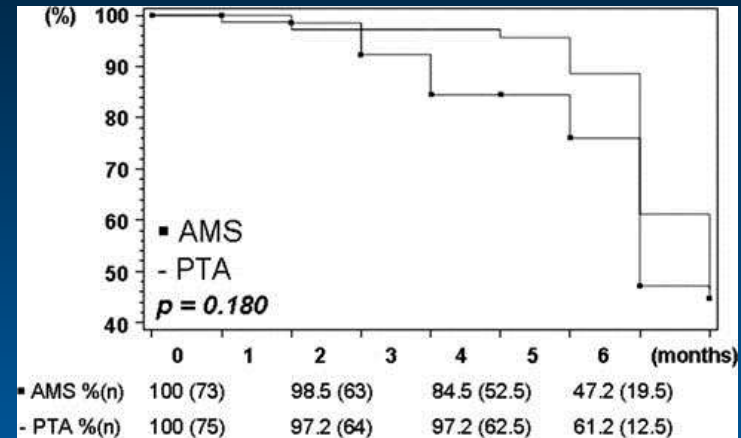




# INSIGHT Peripheral AMS Trial 6 Month Results



Duplex Patency

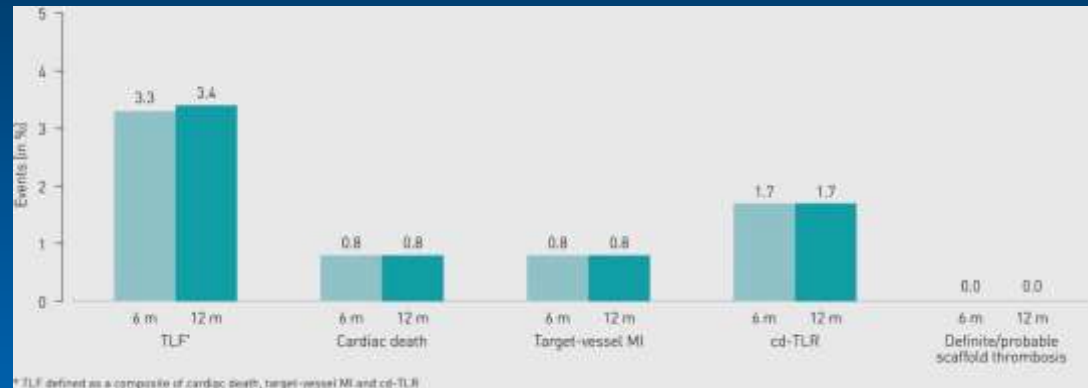


Angiographic Patency

	PTA	AMS
Number of Patients	57	60
Number of Lesions	75	74
Lesion Length (mm)	12.0±5.0	10.6±4.9
<b>Primary Patency QVA @ 6 M (%)</b>	<b>61.2</b>	<b>47.2</b>
Limb Salvage QVA @ 6 M (%)	92.4	87.6

# Magmaris BIOSOLVE II Trial 12 Month Results

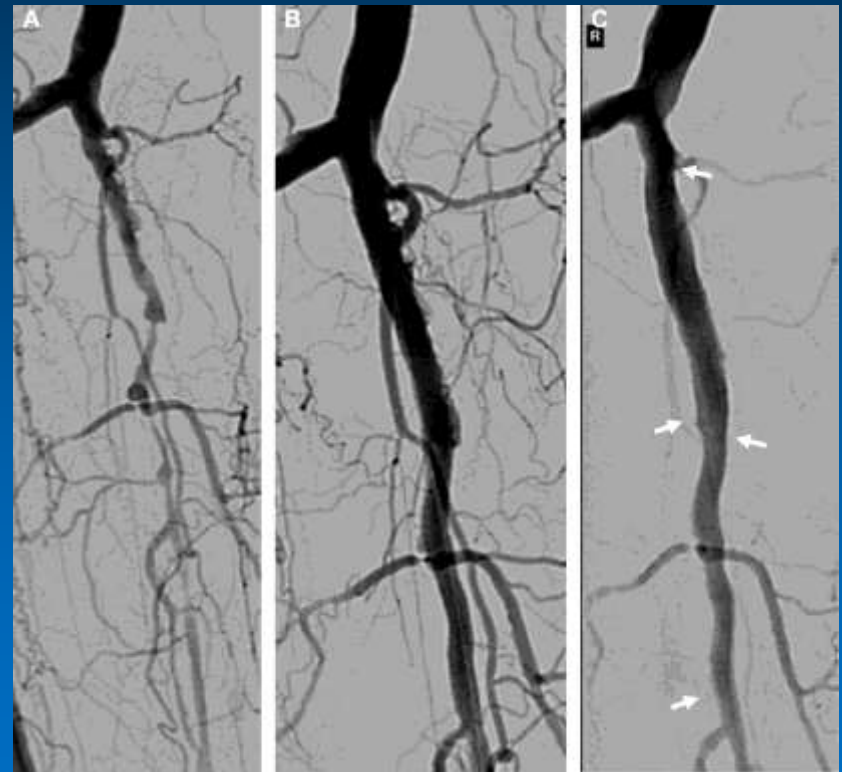
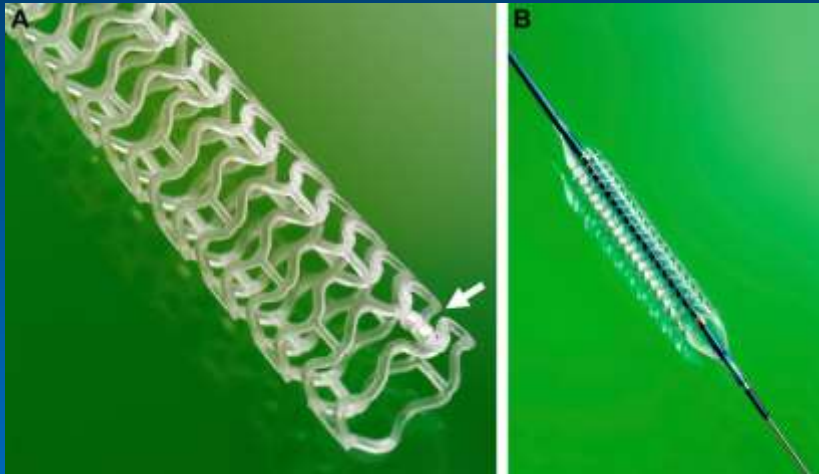
123 patients with up to 2 de novo lesions  
in 2 separate coronary arteries



- Late lumen loss 0.27 mm
- TLF rate 3.4%
- No scaffold thrombosis at 12 months
- Vasomotion present in 80% of patients at 6 and 12 months

# ABSORB BTK DES

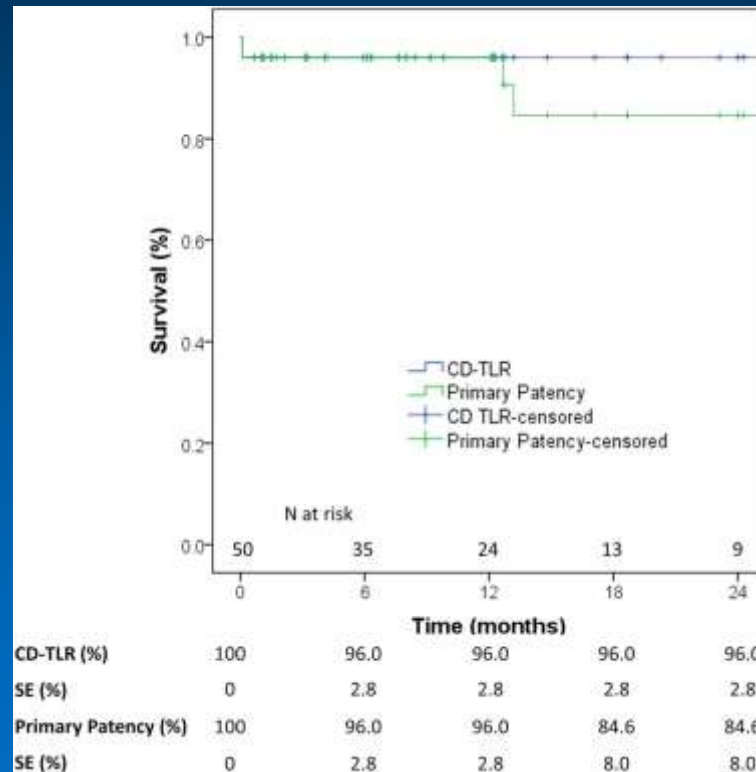
## ABSORB BVS BTK Trial



43 lesions with mean lesion length  $19.2 \pm 11.6$  mm

# ABSORB BTK DES

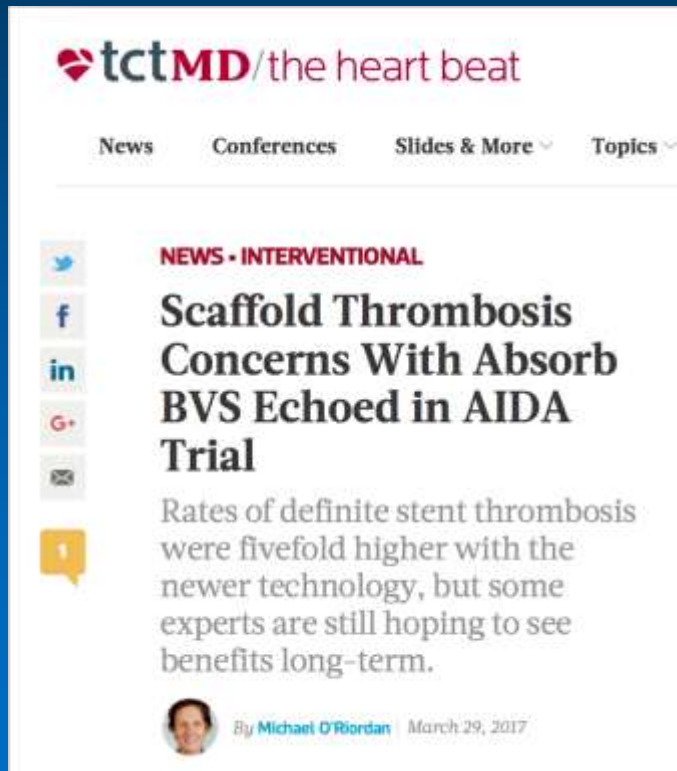
## ABSORB BVS BTK Trial



Primary patency 96% at 12 mo and 84.6% at 24 mo  
TLR 4% at 12 and 24 mo.

# ABSORB BTK DES

## Stent Thrombosis in ABSORB II and AIDA Trials



tctMD/the heart beat

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NEWS • INTERVENTIONAL

Scaffold Thrombosis Concerns With Absorb BVS Echoed in AIDA Trial

Rates of definite stent thrombosis were fivefold higher with the newer technology, but some experts are still hoping to see benefits long-term.

By Michael O'Riordan March 29, 2017

This screenshot shows a news article on the tctMD website. The article is titled "Scaffold Thrombosis Concerns With Absorb BVS Echoed in AIDA Trial" and is categorized as "NEWS • INTERVENTIONAL". The text states that rates of definite stent thrombosis were fivefold higher with the newer technology, but some experts are still hoping to see benefits long-term. The article is authored by Michael O'Riordan and dated March 29, 2017. Social media sharing icons for Twitter, Facebook, LinkedIn, Google+, and Email are visible on the left side of the article.



tctMD/the heart beat

News Conferences Slides & More Topics

NEWS • INTERVENTIONAL

Absorb BVS Use Restricted in Europe

The CE Mark approval remains in place, but only centers participating in formal registries should be using the bioresorbable device for now.

By Michael O'Riordan April 06, 2017

This screenshot shows a news article on the tctMD website. The article is titled "Absorb BVS Use Restricted in Europe" and is categorized as "NEWS • INTERVENTIONAL". The text states that the CE Mark approval remains in place, but only centers participating in formal registries should be using the bioresorbable device for now. The article is authored by Michael O'Riordan and dated April 06, 2017. Social media sharing icons for Twitter, Facebook, LinkedIn, Google+, and Email are visible on the left side of the article.

# Endovascular DES Conclusions

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1. Short lesion DES with sirolimus and everolimus has been proven to be superior to BMS in tibial-peroneal lesions.
2. There is currently no role for DES as bail-out for failed PTA in long lesions until we have more scientific evidence of its benefit.
3. The potential for a self-expanding DES for tibial-peroneal applications is obvious (Stentsys SES)
4. Bioabsorbable DES has even more potential for endovascular applications, but long term safety and effectiveness need to be established.