NITINOL STENTING SHOULD BE THE FIRST CHOICE IN SFA TREATMENT

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Disclosure of Interest

Speaker name: Aljoscha Rastan

I have the following potential conflicts of interest to report:

- [X] Consulting/Lecture Fees

  →Medtronic, Abbott Vascular, Terumo, Boston Scientfic
- [ ] Employment in industry
- [ ] Shareholder in a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

Case Study

Clinical Data:

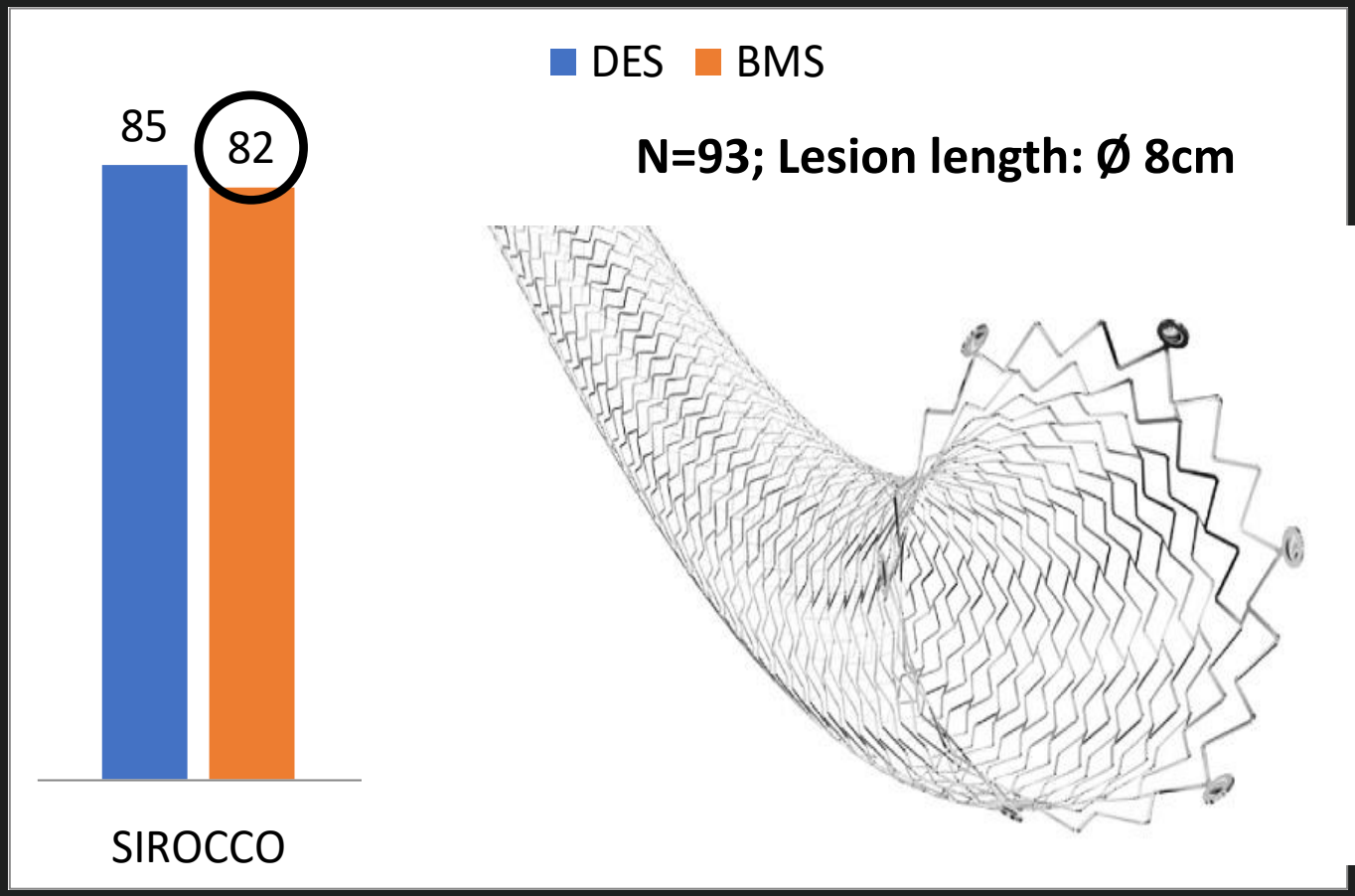
- Male, 82y
- Claudication Rutherford-Becker class 3 (walking capacity 150m)
- CVR: Hypertension, tobacco use, hypercholesterolemia
- Coronary heart disease, (DE-) stenting of the LAD in 2002
- COPD
- Renal failure

Baseline Examinations

- ABI at rest (left/right): 0.6/1.1
- Duplex ultrasound: Calcified occlusion left SFA.

“Which therapy option should I choose?”

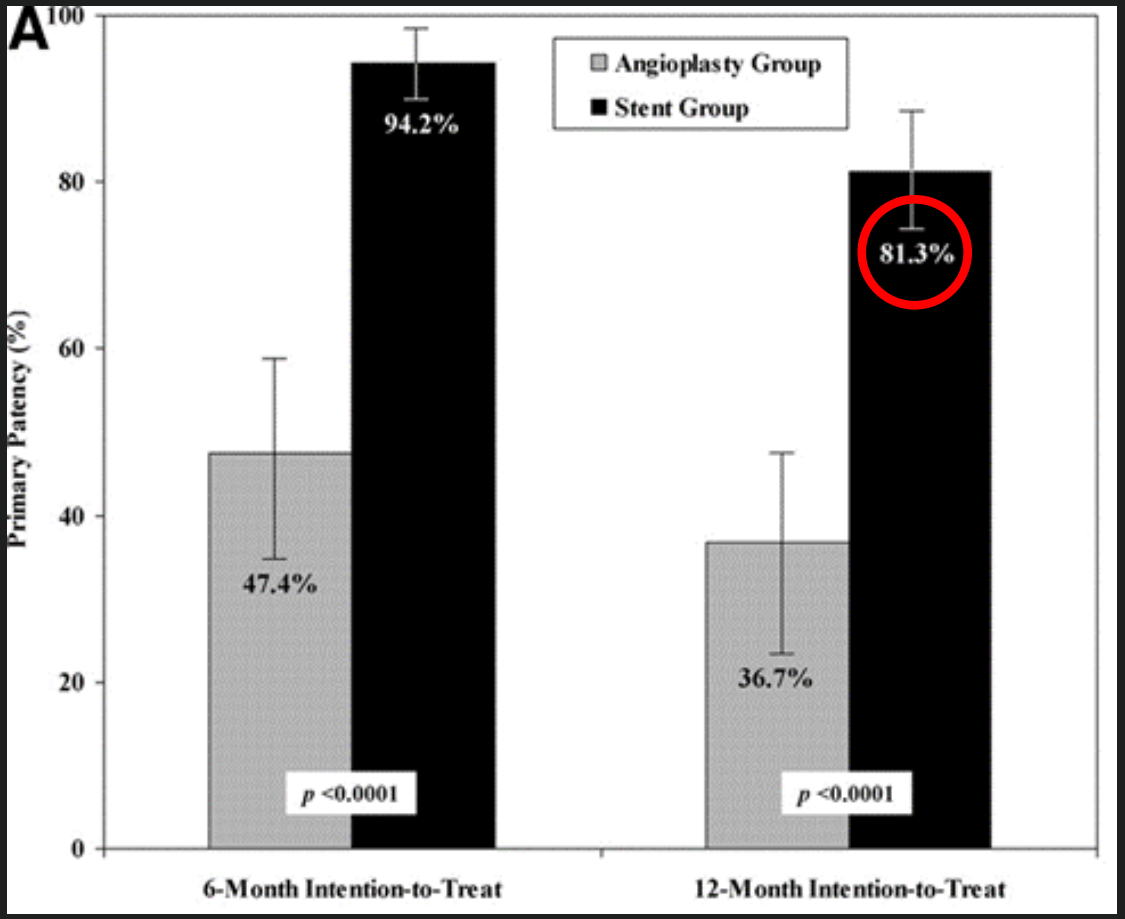
SIROCCO Trial: Primary Patency at 1-Year

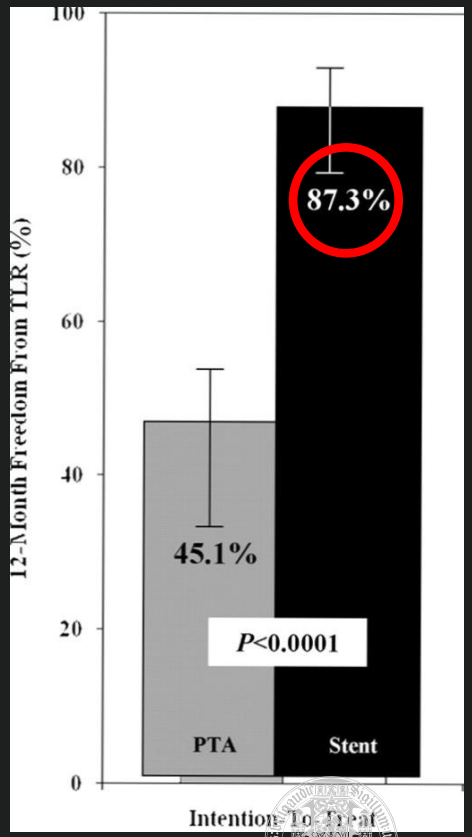


Duda SH et al. J Endovasc Ther 2006

RESILIANT TRIAL: PRIMARY PATENCY AND TLR AT 1-YEAR

Multi-center, randomized trial: N=204; Lesion length: Ø 7cm





John R. Laird et al. Circ Cardiovasc Interv. 2010;3:267-276

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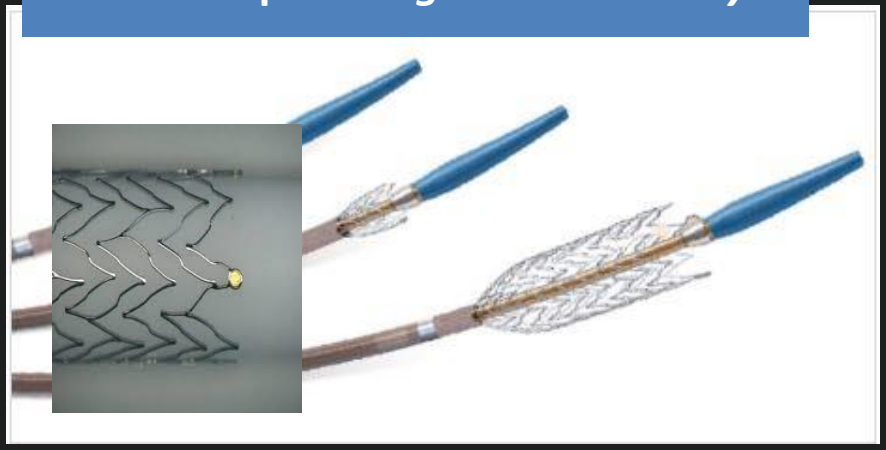
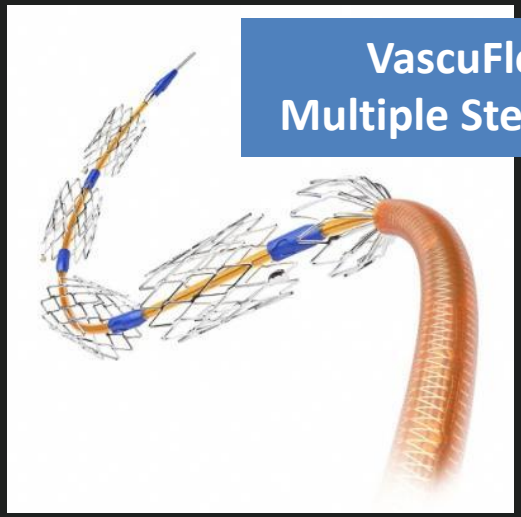
STENTING OF THE SFA

DEDICATED STENTS

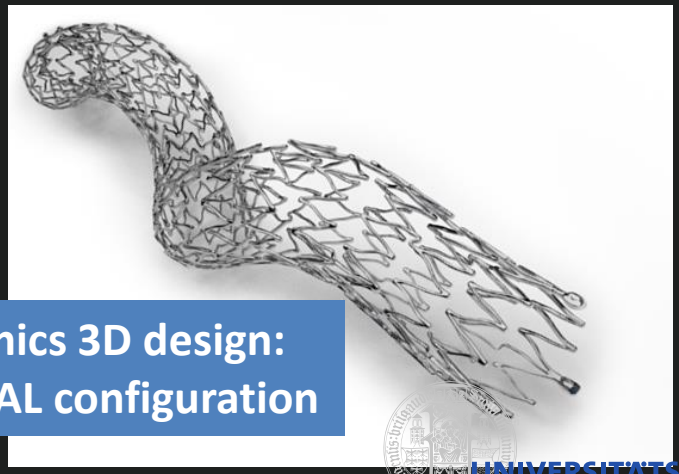
Supera Vascular Stent
Interwoven Nitinol Design

MISAGO New Generation Stent
with unique *Design & RX Delivery*





VascuFlex® Multi-LOC
Multiple Stent Delivery System



Unique BioMimics 3D design:
Connectors SPIRAL configuration

One-year outcomes of the U.S. and Japanese regulatory trial of the Misago stent for treatment of superficial femoral artery disease (OSPREY study)

Takao Ohki, MD,[a] John F. Angle, MD,[b] Hiroyoshi Yokoi, MD,[c] Michael R. Jaff, DO,[d] Jeffrey Popma, MD,[e] Guy Piegari, MD,[f] and Yuji Kanaoka, MD,[a] for the OSPREY investigators, *Tokyo and Fukuoka, Japan;*

Table I. Baseline characteristics of patients

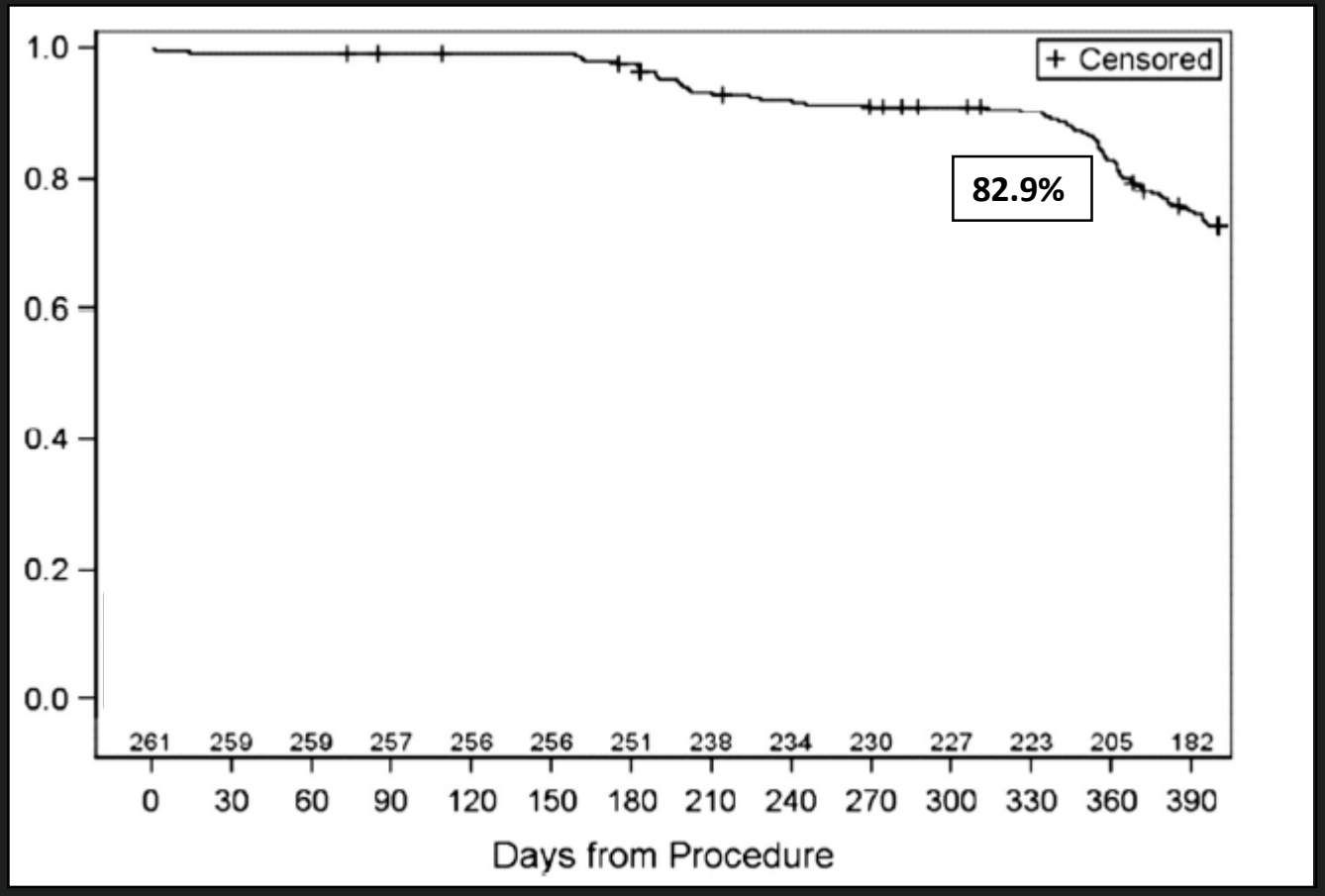
No. of patients	261
Age, years, mean ± SD	69.3 ± 10.0
Gender, male	64.8 (169/261)
Race/ethnicity	
White	69.0 (180/261)
Asian	23.0 (60/261)
Black	6.9 (18/261)
Hispanic	1.1 (3/261)
Previous vascular interventions	35.2 (92/261)
Diabetes mellitus	47.9 (125/261)
Arterial hypertension treated with medication	85.1 (222/261)
Hyperlipidemia	87.0 (227/261)
Smoking history	
Yes, current	42.1 (110/261)
Yes, previous	40.6 (106/261)
No	15.7 (41/261)
Unknown	1.5 (4/261)
Amputations	1.1 (3/261)
Rutherford classification	
0	0.00 (0/261)
1	0.00 (0/261)
2	48.30 (126/261)
3	47.10 (123/261)
4	4.60 (12/261)
5	0.00 (0/261)
6	0.00 (0/261)
ABI, mean ± SD	0.7 ± 0.1

Table II. Baseline characteristics of lesions

Location	
Left	49.0 (128/261)
Right	51.0 (133/261)
Arterial segment	
Proximal SFA	12.3 (32/261)
Middle SFA	53.6 (140/261)
Distal SFA	33.3 (87/261)
Other	0.8 (2/261)
Lesion length, mm	83.8 ± 41.3

Ohki et al. JVS 2016

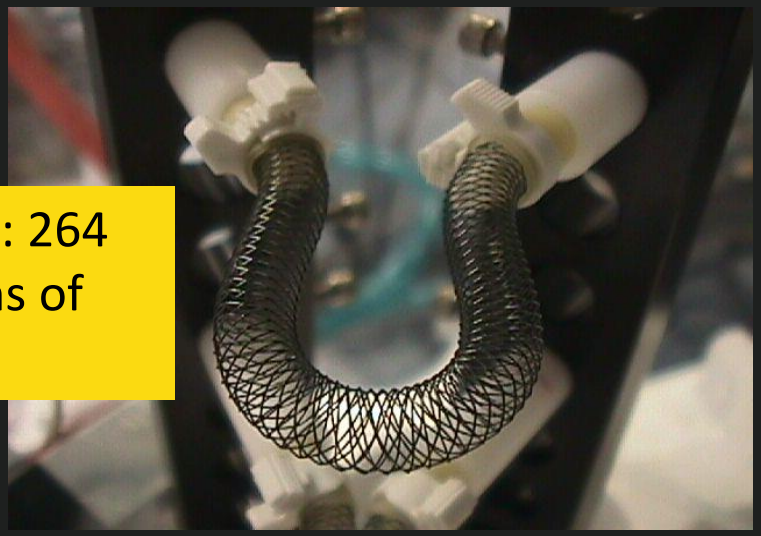
OSPREY Study: KM Primary Patency at 1-Year



Primary patency was considered lost if stent occluded, TLR, or PSVR ≥ 2.5 was met.

Ohki et al. JVS 2016

The SUPERB Trial



Prospective, multi-center, single-arm trial: 264 patients with de novo or restenotic lesions of the superficial femoral or PPA.

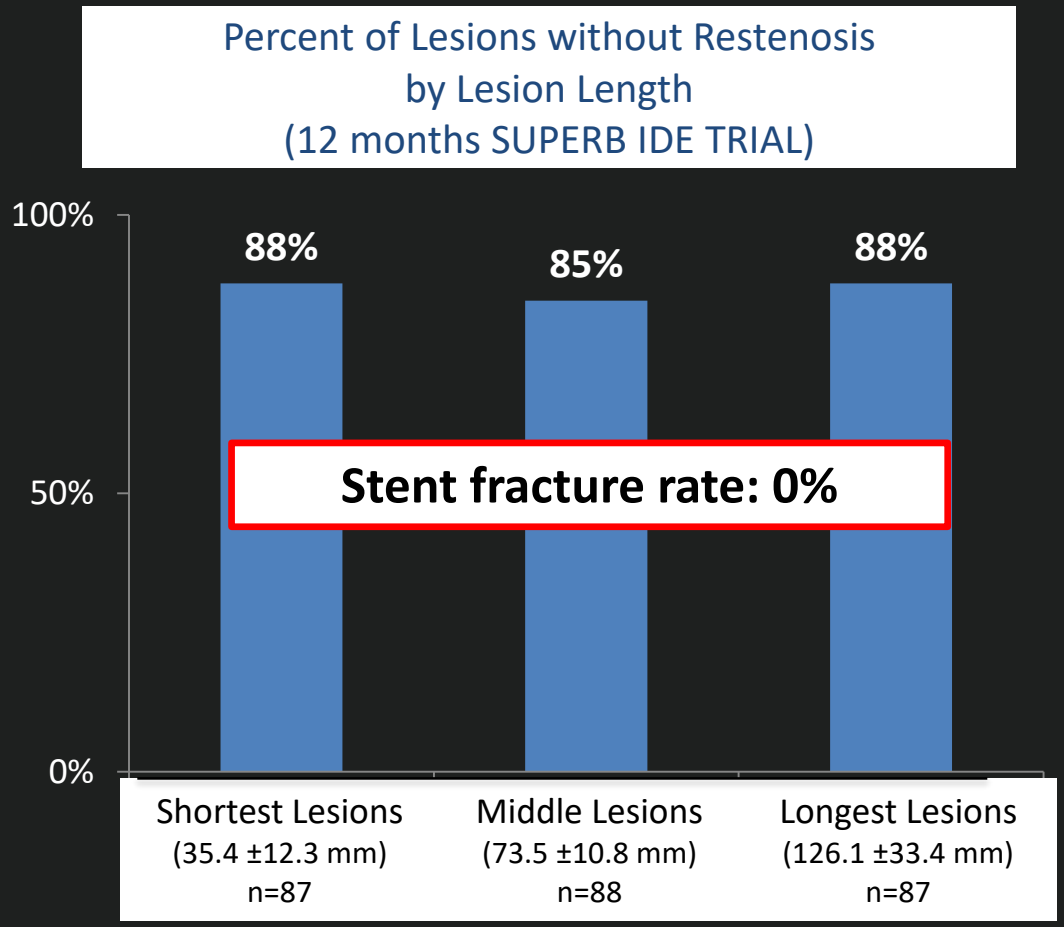
Freedom from death, TLR, or amputation at 30 days: 99.2%.

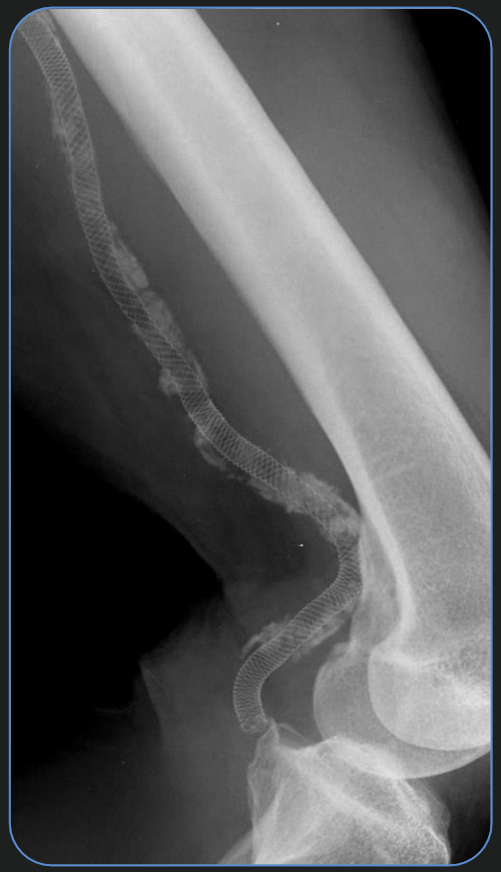
Improvement by at least 1 Rutherford-Becker category: 88.7%.

"The Supera stent provides high primary patency rate, absence of stent fracture, significant improvements in functional quality-of-life measures."

Garcia L., et al. Circ Cardiovasc Interv. 2015

SUPERB: 1-Year Results Across Lesion Lengths





Garcia L., et al. Circ Cardiovasc Interv. 2015

MIMICS-2

1st Presentation of One-Year Results

MIMICS-2 Study

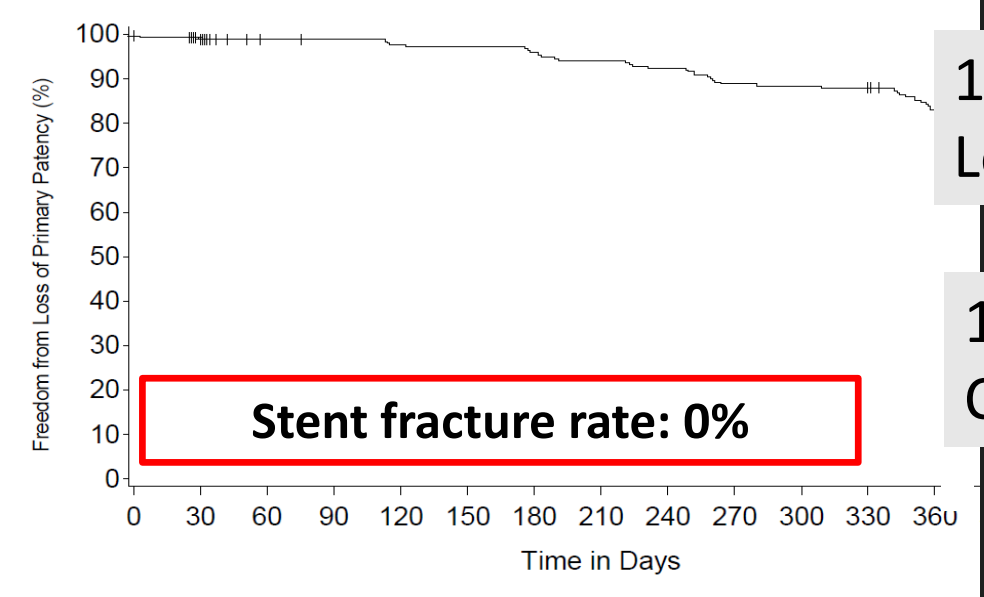
Baseline Angiography and QVA

Core Laboratory Data		N= 271 Subjects
Reference Vessel Diameter (mm)	Mean ± SD	5.2 ± 0.9 (269/271)
Lesion Type[1]	De novo	100% (271/271)
Lesion Location in Femoropopliteal Artery	Prox	11.5% (31/270)
	Mid	48.1% (130/270)
	Distal	40.4% (109/270)
Diameter Stenosis (%)	Mean ± SD	77.8 ± 18.3 (269/271)
Lesion Length (mm)	Mean ± SD	81.2 ± 38.4 (269/271)
Total Occlusion (%)		30.0 (81/270)
Calcification (%)	None - Mild	54.1 (146/270)
	Moderate - Severe	45.9 (124/270)
Run-off (%) - 1 or more patent tibial artery (<50% stenosis)		98.8 (237/240)

[1] *Investigator-reported*

MIMICS-2 Study

Kaplan-Meier Survival Analysis



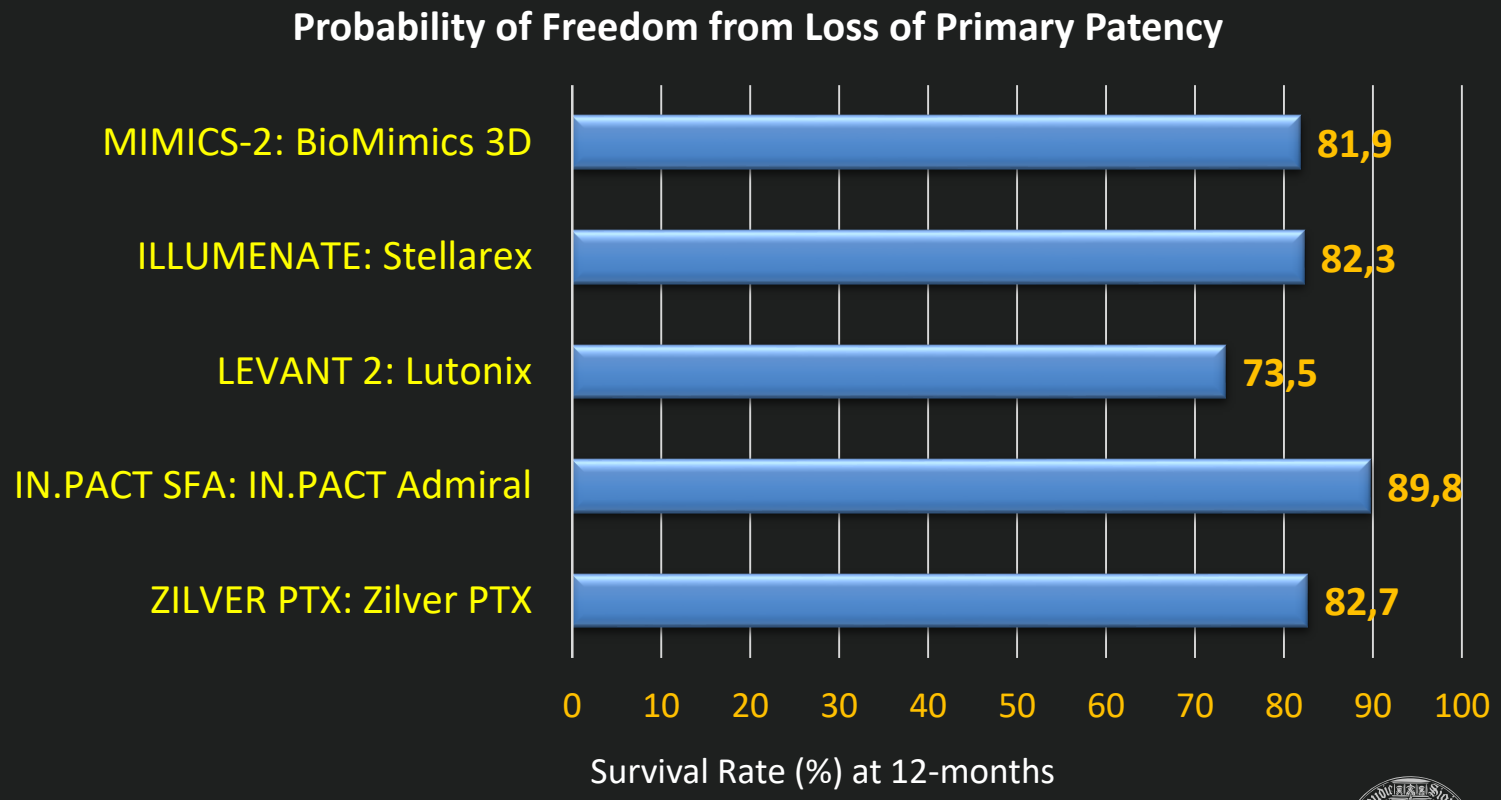
12-Month Freedom from Loss of PP: **81.9%**

12-Month Freedom from CDTLR: **88.4%**

Time (days)	0-0	1-30	31-60	61-120	121-180	181-240	241-300	301-360	361-365
# at risk	271	258	248	244	240	231	221	202	199
# subjects with events	0	3	0	3	4	9	10	13	3
# censored	0	10	10	1	0	0	0	6	0
Event-free % (cumulative)	100%	98.9%	98.9%	97.7%	96.1%	92.5%	88.5%	83.1%	**81.9%**
SE	0.0%	0.6%	0.6%	0.9%	1.2%	1.7%	2.0%	2.4%	2.4%

Comparative Kaplan-Meier Analyses

Alternative Strategies to Prevent Restenosis:
Natural Swirling Flow vs. Antiproliferative Drug



In-Stent Restenosis?

It´s the time for “Plan B”!

Drug-Eluting Balloon for Treatment of Superficial Femoral Artery In-Stent Restenosis

Eugenio Stabile, MD, PHD, Vittorio Virga, MD, Luigi Salemme, MD, Angelo Cioppa, MD, Vittorio Ambrosini, MD, Giovanni Sorropago, MD, Tullio Tesorio, MD, Linda Cota, MD, Grigore Popusoi, MD, Armando Pucciarelli, MD, Giancarlo Biamino, MD, Paolo Rubino, MD

Mercogliano, Italy

Table 1 Patient Clinical Characteristics

Male	32 (82.1)
Age (yrs)	65.9 ± 9.6
Diabetes (%)	19 (48.7)
Hypertension (%)	
Hypercholesterol	
Smoking history	
eGFR <30 (ml/n	
Rutherford class	
BTK patent vesse	
≥2	
1	

Stent length, mm	150 (95–262.5)
Lesion length, mm	82.9 ± 78.9
Pre-dilation balloon diameter, mm	5 (4.5–5)
	120 (80–120)
	6 (5–6)
	2 (1–2)
	160 (120–250)
	4 (10.3)
	4 (10.3)
	39 (100)

N = 39. Values are n (%) or mean ± SD.
BTK = below-the-knee; eGFR = estimated glomerular filtration rate.

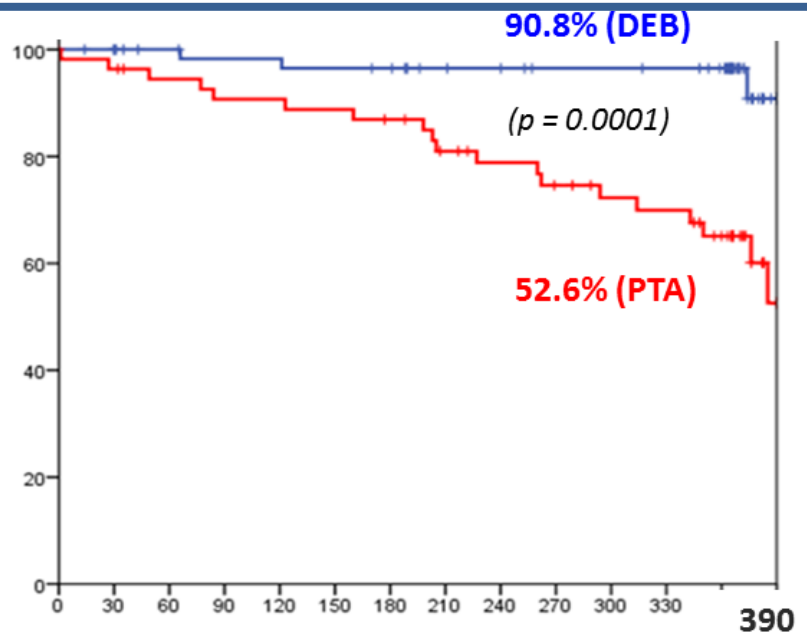
12 months Primary patency: 92.1%
Secondary patency: 100%
Ankle-brachial index improvement: P<0.05
Rutherford-class improvement from baseline P<0.05

Stabile et al. J Am Coll Cardiol 2012

FAIR-TRIAL

Prospective, randomized, multi-center trial: 119 Patients;
Mean ISR Lesion length: 8.2 ±6.8cm

Freedom from CD-TLR: 90.8% (DCB) vs. 52.6% (PTA; p=0.0001)



12-month freedom from TLR

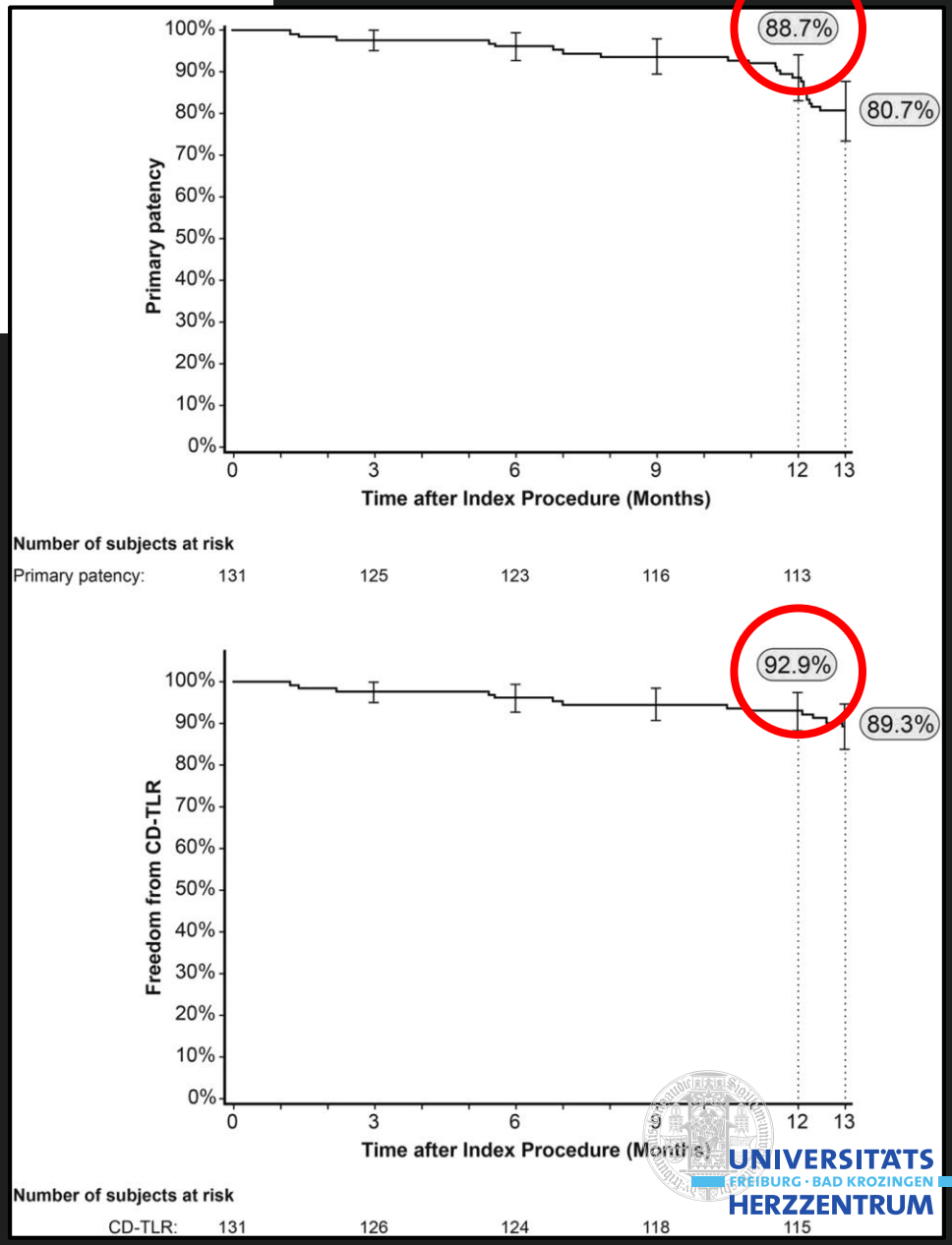
Krankenberg et al. Circ. 2015

Drug-Coated Balloon Treatment for Femoropopliteal Artery Disease

The In.PACT Global Study De Novo In-Stent Restenosis Imaging Cohort

A total of 131 subjects with 149 ISR lesions included.

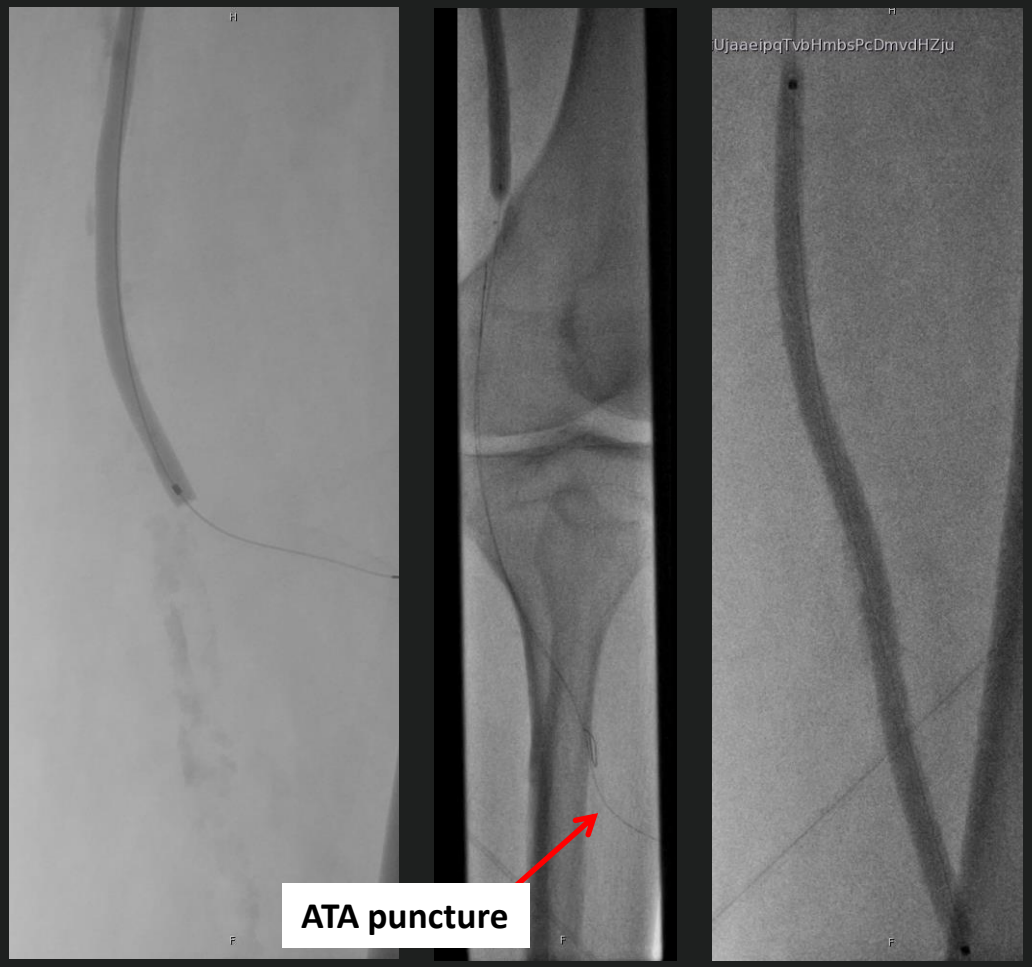
- **Mean lesion length:** 17.17 ±10.47cm.
- **Procedural success:** 99.3% (n = 148 of 149) of lesions
- **Clinical success:** 98.5% (n = 129 of 131) of subjects.
- **Provisional stenting:** 13.4% (n = 20 of 149) of lesions.



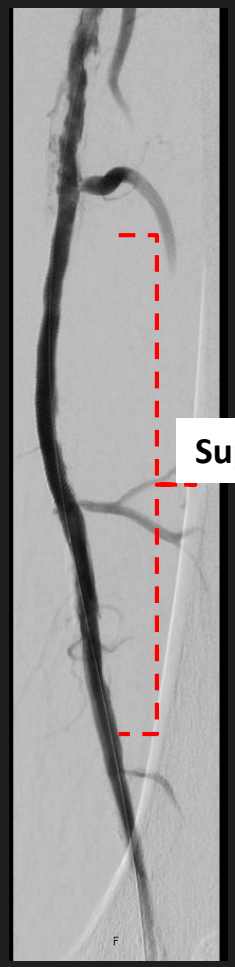
M. Brodmann et al. JACC Intv. 2017

Case Study

Procedural Images



Final Angiogram



Conclusion

- **Nitinol stents, DCB´s, and DES provide comparable 12 months results in the SFA.**
- **In case of restenosis an evidence-based therapy with DCB´s is available for patients after stenting.**
- **The real potential of drug-eluting technologies lies in their effectiveness in restenosis therapy.**

→Stenting should be the first choice in SFA treatment.