To Reduce Injury In Post Balloon PTA Dissections: The Value Of Stents, Tacks, Etc

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Disclosure

Speaker name:

Michael Lichtenberg

I have the following potential conflicts of interest to report:

- ☒ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ I do not have any potential conflict of interest

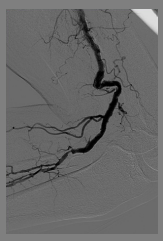
Background
Mandate of Endovascular Devices

2 Targets:

1. **Make it Open**
2. **Keep it Open**

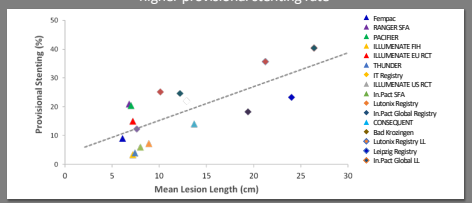
- **Target 1) necessary but not sufficient to Target 2)**
- **Measure of success of Target 1 (lumen size, stability, ± presence of dissections) may influence degree of success in target**

"Jailing" the natural behaviour



Stents used in DCB Studies

Longer mean lesion length in DCB studies correlates with higher provisional stenting rate

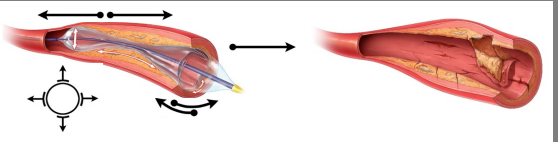


Provisional Stenting in Randomized Controlled Trials may not be representative of actual stenting in studies due to study design

Results from different trials are not directly comparable. Information provided for educational purposes.

FEMPAC- Werk Mat al. Circulation 2008;
RANGER SFA-Bausback et al. J Endovasc Ther 2017;
PACIFIER- Werk et al. Circ Cardiovasc Interv 2012;
THUNDER- Tepe G et al. N Engl J Med 2015;
IT Registry- Micari A et al. J Am Coll Cardiol Intv 2012;
IN.PACT SFA- Tepe et al. Circulation 2015;
Lutonix Registry- Thieme M, et al. JACC Cardiovasc Interv. 2017; 10(15);
CONSEQUENT- Tepe et al. Cardiovasc Intervent Radiol 2017;
Bad Krozingen- Zeller T et al. J Endovasc Therapy 2016;
Leipzig Registry- Schmidt A, et al. JACC Cardiovasc Interv. 2016;
In.PACT Global Registry- Ansel G. TCT 2016;
ILLUMENATE FIH- Schroeder H et al. Catheter Cardiovasc Interv
ILLUMENATE EU RCT- Schroeder et al. Circulation 2017;
ILLUMENATE US RCT- Krishnan et al. Circulation 2017;

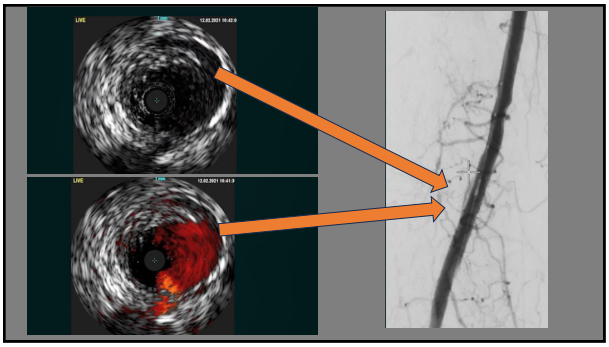
Dissection: Mechanism of Action for Angioplasty



Lesions with dissections have a **TLR rate 3.5 times higher** than lesions without dissection[1]

Current tools for dissection repair (stents) have limitations

[1] Kobayashi, Intervent Cardiol Clin 2017;



Dissections Occur Frequently…

- Dissection is a result of plaque disruption during angioplasty
- DCB is not a stand-alone therapy in mechanically challenging SFA/popliteal lesions:
  - CTO
  - Lesions >15 cm

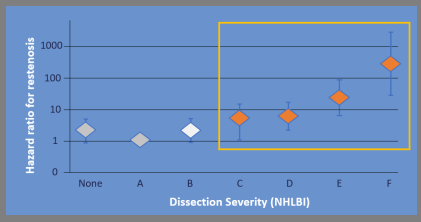
Study	Dissection Rate
PACIFIER	47.4% PTA 73.5% DCB
THUNDER	56%
LEVANT 2	72.3% PTA 63.7% DCB

DCB Registry	Dissection/Stent Rate
Lutonix® Global Registry[1]	34.3% in lesions 140 – 500mm (35.7% stent rate)
IN.PACT® Global Registry[1]	62% in lesions ≥ 15cm (40.4% stent rate)

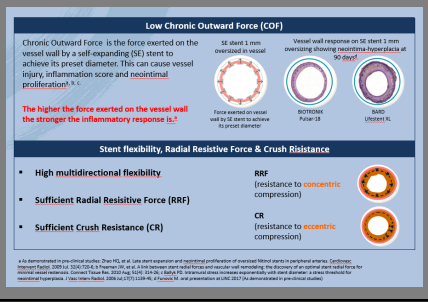
Dissections Impact Clinical Outcomes

[1]Fujihara, *J Endovasc Ther* 2017

Risk for restenosis **increases** with dissection severity



STENTS



MIMICS3D European Registry: Comparison of KM freedom from CDTLR with and without DCB

	BioMimics 3D *with* DCB	BioMimics 3D *without* DCB
1 Year	91.4%	88.7%
2 Year	81.5%	83.1%
3 Year	76.4%	79.6%

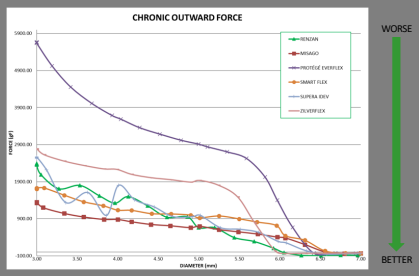
No statistical difference in CDTLR between DCB and no-DCB cohorts

Data on file at Venous Medical

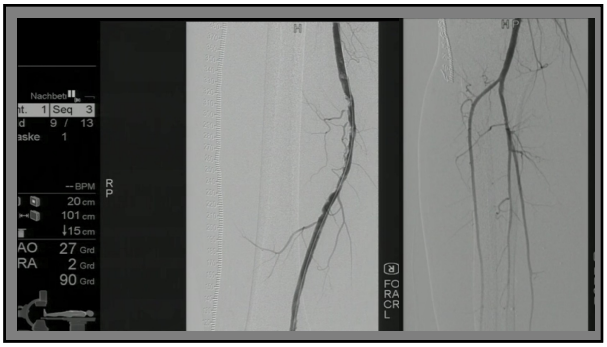
Renzan Concept

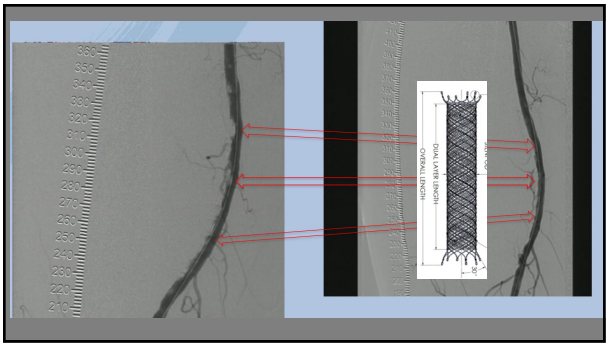
- Dual Layer Stent for Superior Femoral (SFA) and Popliteal Arteries
- Leverage Micromesh Protection Dual Layer Stent and Delivery System Design from Roadsaver
- Design for High Radial Strength, Low Chronic Outward Force
- Designed for Improved Fracture Resistance and Durability
- Braided Design for Superior Flexibility and Adaptation to FemPop Arteries

Chronic Outward Force Comparison



Data on file at MicroVention. TR17-120 ,TR16-272. Renzan stent (n=30), Supera stent (n=5), Other brand stents (n=2)





Study design DISSECT-DISSECTion®

Klinikum Hochsauerland

Study Design	Retrospective/Prospective, single-arm, single-center study with follow-up investigations at 30 days, 6 months, 12 months. Up to 26 subjects will be enrolled at Hochsauerland-Klinikum, Karolinen-Hospital Arnsberg.
Primary Efficacy Endpoint	Patency rate of target vessel at 12 months. Patency defined as freedom from occluded target lesions (flow) verified by duplex ultrasound without re-intervention
Primary Safety Endpoint	Composite Safety: Freedom from major adverse limb events (MALE) and/or perioperative death (POD) at 30-days *Major Adverse Limb Event is defined as the composite of either major amputation or major re-intervention through 30 days of the index procedure. Major re-intervention is defined as creation of a new surgical bypass graft, the use of thrombectomy or thrombolysis or a major surgical graft revision such as a jump graft or an interposition graft*

Objective

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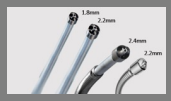
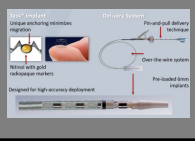
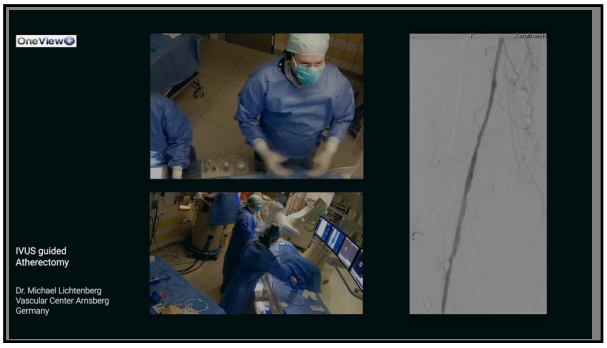
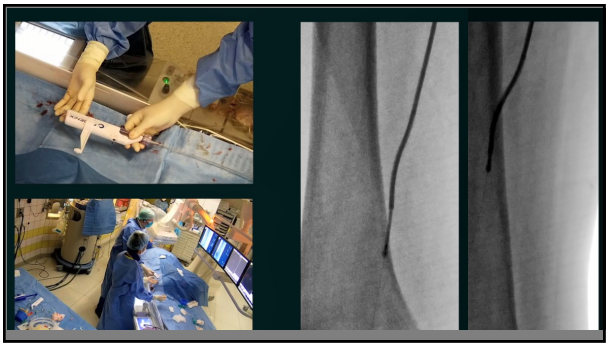
The purpose of this single-arm, exploratory study was to investigate if a lesion preparation strategy with Atherectomy plus DCB before Intact Tack usage for dissection repair in patients with PAD Rutherford Stage 3-5 and mild/moderate/severe calcium can improve outcomes including patency and limb salvage and evaluate safety and performance of the combination therapy.



+ DCB +







Baseline patient & lesion characteristics

Patients	N=26
Age, years	72.46 ± 9.32
Male	12 (46.2%)
Hypertension	24 (92.3%)
Hyperlipidemia	19 (73.1%)
Diabetes Mellitus	10 (38.5%)
Smoker (n=18)	
Current	10 (38.5%)
Previous	8 (30.8%)
Coronary artery disease	4 (15.4%)
History of PAD	14 (53.8%)
Renal insufficiency	6 (23.1%)
Rutherford category	
2	0 (0%)
3	20 (76.9%)
4	2 (7.7%)
5	4 (15.4%)
ABI	0.67 ± 0.14

Target lesions	
Lesion location	
SFA proximal	3 (11.6%)
SFA mid	2 (7.7%)
SFA distal	11 (42.0%)
Popliteal proximal	5 (19.0%)
Popliteal mid	4 (15.3%)
Popliteal distal	1 (4.0%)
Cumulative lesion length, mm	188.6 ± 36.5
Reference vessel diameter, mm	5.4 ± 0.6
Diameter stenosis, %	91.0 ± 9.4
Calcification	
None	11 (42.3%)
Mild	8 (31.0%)
Moderate	4 (15.3%)
Severe	3 (11.6%)
Total occlusion	5 (19.2%)

Procedure characteristics & outcomes

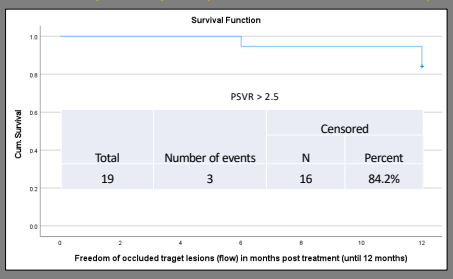
Procedural characteristics	
Atherectomy (Phoenix)	
DCB per lesion	
Total inflated length, mm	
Balloon/ artery ratio	
Maximum pressure, atm	8.0 ± ..
Inflation time/balloon, min	2.2 ± 0.7
Number dissection per patient	1.76
Dissection Typ	
A	20%
B	35%
C	45%
Tacks used (mean)	3.13 (1-10)
Due to dissection Typ A/B	0%
Due to dissection (>Type C)	100%

Procedural outcomes	
Device success*	26 (100%)
Technical success **	26 (100%)
Procedural success ***	26 (100%)

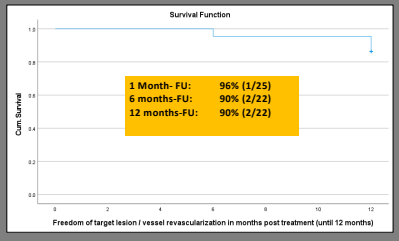
BAIL OUT STENT RATE
0%

≤30% RS post- Intact tack usage
...on after appropriate vessel
...ny kind of ballooning (POBA
and/or DCB) ...assessme
Patency Success = ...of a ≤30% RS following vessel preparation requesting Athe... ...and dissection repair with Intact Tacks as determined by visual assessment
***Procedural success** = achievement of a ≤30% RS at the end of the procedure without MAEs as determined by visual assessment (irrespective of any pre- or postadjunctive therapy, incl. stents).

Patency analysis (DISSECT-DISSECTion®)

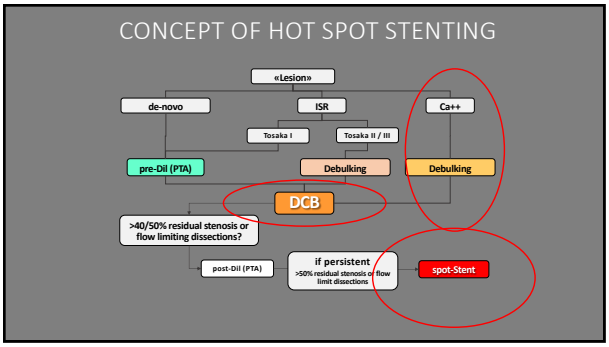


Freedom from revascularization (fTLR)
DISSECT-DISSECTion®



Rutherford category
DISSECT-DISSECTion®

		Pre-intervention	6 months FU	12 months FU
N	Valid	26	25	21
	Missing	0	1	5
Mean		3.3846	1.0000	.7143
Median		3.0000	1.0000	1.0000
Std.-Deviation		.75243	1.25831	.64365
Minimum		3.00	.00	.00
Maximum		5.00	5.00	2.00
Percentile	25	3.0000	.0000	.0000
	75	3.2500	1.0000	1.0000


CONCEPT OF HOT SPOT STENTING
«Lesion»
de-novo
ISR
Ca++
Tosaka I
Tosaka II / III
pre-Dil (PTA)
Debulking
Debulking
DCB
>40/50% residual stenosis or flow limiting dissections?
post-Dil (PTA)
if persistent
>50% residual stenosis or flow limit dissections
spot-Stent


Global Algorithm for the Endovascular Treatment of Chronic Femoropopliteal Lesions
An Interdisciplinary Expert Opinion Statement.
2 = strong recommendation
1 = Weak recommendation
-1 = Weak Warning
-2 = Strong warning
. DCB
.BMS
S. Interwoven tents
H.DES
Covered stent
Mobile Segments: distal SFA & popliteal artery PACSS I-II (non-CTO) 2 -1 2 -1 -1
Mobile Segments: distal SFA & popliteal artery PACSS III-IV (non-CTO) 1 -1 2 -1 -1
Short <15 TASC A&B ; PACSS I-II; intraluminal & fibrotic lesions 2 1 1 1 -1
Short <15 TASC A&B ; PACSS I-II; fresh & organized thrombotic 2 1 -1 1 1
Short <15 TASC A&B; PACSS I-II; subintimal passage 2 1 2 2 -1
Short <15 TASC A&B ; PACSS III-IV;Diffuse calcification 1 1 2 1 -1
Short <15 TASC A&B ; PACSS III-IV; Eccentric calcification 1 1 2 1 -1
Short <15 TASC A&B ; PACSS III-IV subintimal passage 1 1 2 1 -1
Long >15 cm TASC C&D ; PACSS I-II; intraluminal passage 2 1 1 2 1
Long >15 cm TASC C&D; PACSS I-II; subintimal passage 2 1 2 2 1
Long >15 cm TASC C&D; PACSS III-IV; intraluminal passage 2 1 2 2 1
Long >15 cm TASC C&D ; PACSS III-IV; subintimal passage 1 1 2 1 1
Short ISR non-CTO ; Tosaka I 2 -1 -1 -1 1
Long ISR and stent occlusions; Tosaka II-III 2 -1 1 1 1