Update on Scaffolds and Tacks in PAD

Matthew T. Finn MD MSc

Cardiovascular Institute of the South

Houma, Louisiana

Cors at the Shore 2023

Disclosures

Consultant:
Akura medical
Truvic

Major Stockholder:

Speaker’s Bureau:
Janssen

Other Support:

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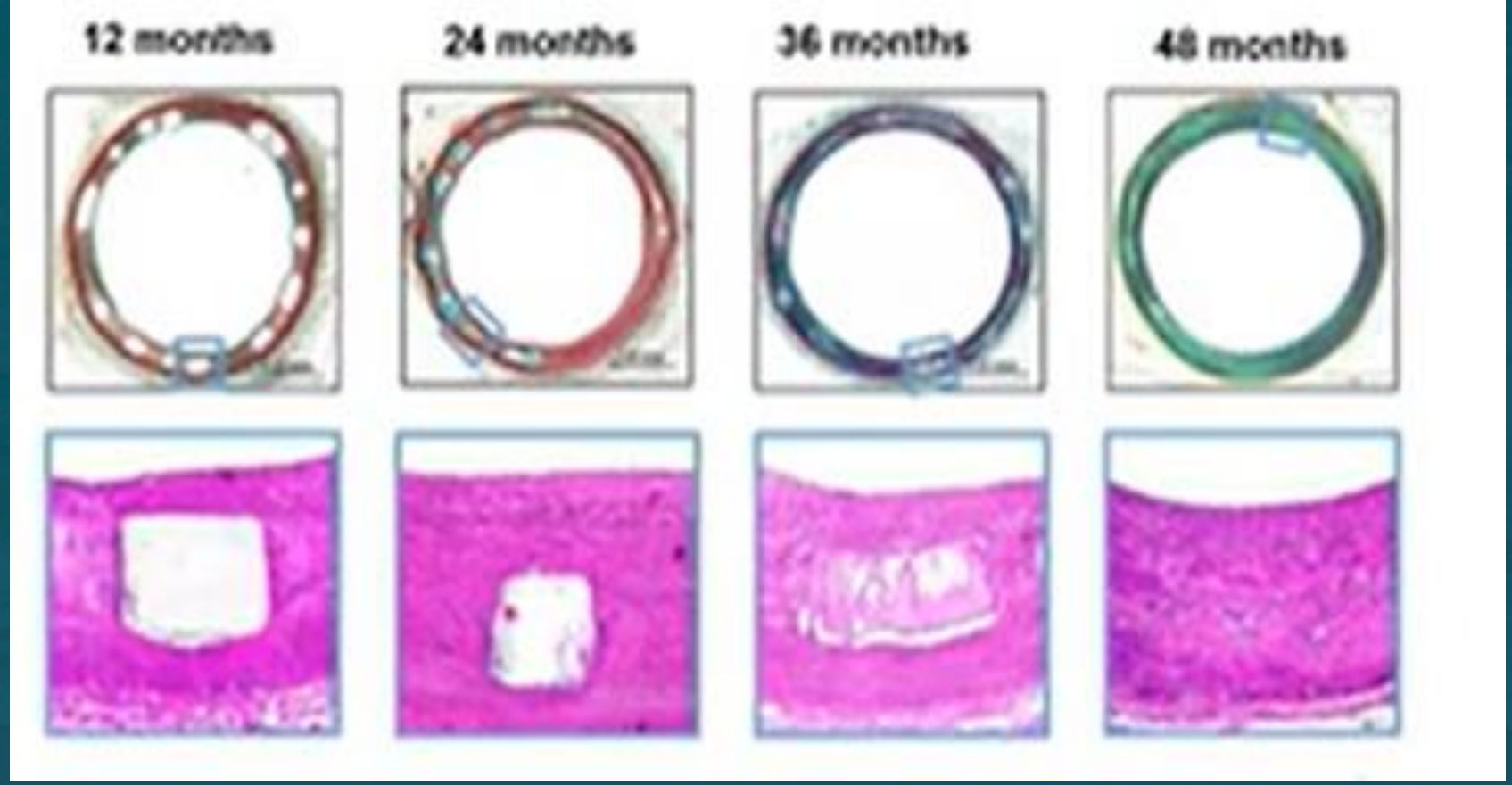
Bioabsorbable (BRS) and Drug Eluting Bioabsorbable Scaffold (DEBRS)

- Conceptual benefits:
  - Can treat some degree of elastic recoil
  - Can treat/seal dissection
  - Deliver drug for longer term anti-restenosis
  - More palatable to patients than having a permeant device implanted in their bodies

BVS structure

- BVS has structural backbone
  - Magnesium
  - Poly-lactide (PLLA)
- Over time (2-3 years) poly-lactide ester bonds are hydrolyzed and then small remaining particles are consumed by macrophages (phagocytosis)
- Remaining stent and polymer degraded to lactic acid and metabolized



3 years replaced by collagenous matrix

4 years nearly completely gone

Historical issues with BRS (lessons from cors)

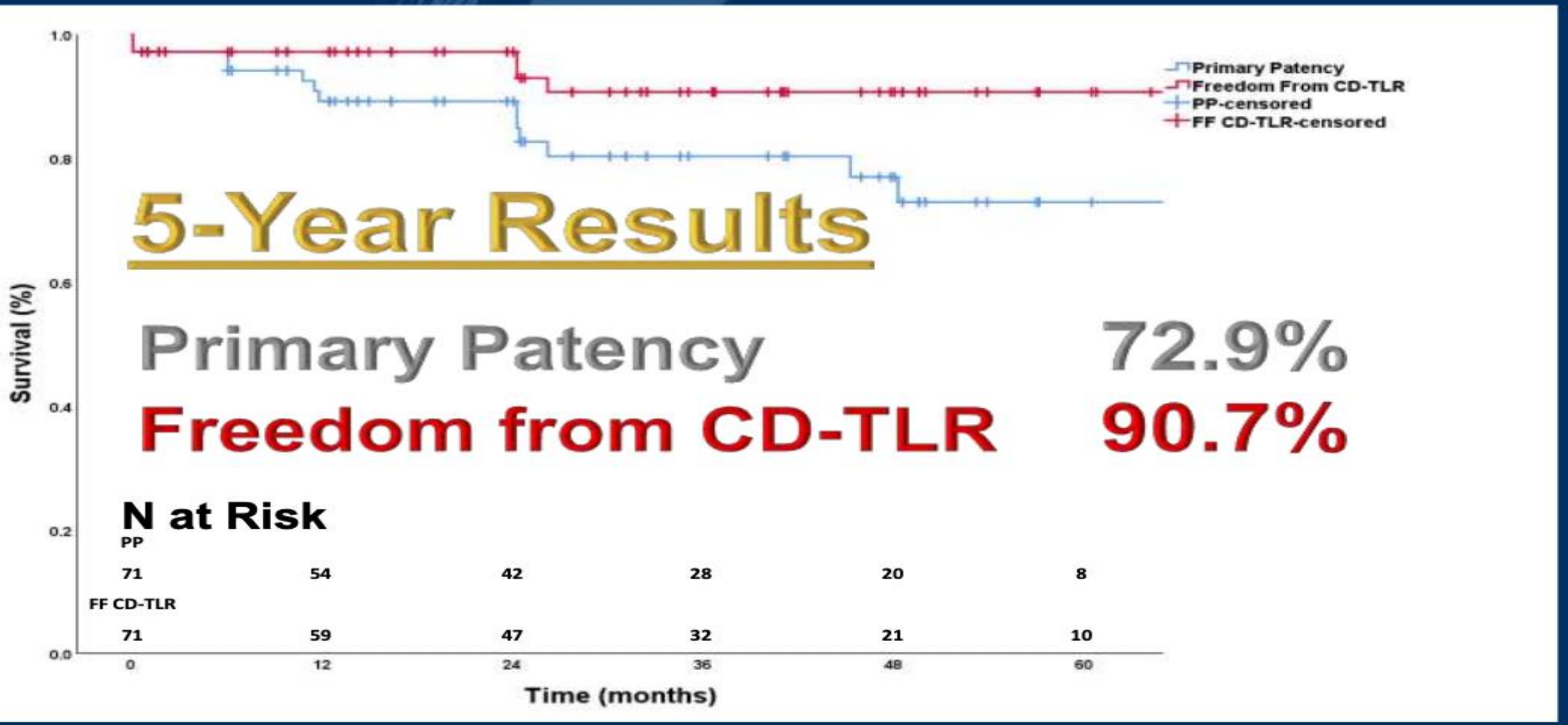
- Thicker struts were problematic (limiting luminal gain and increasing risk of early ISR)
- Decreased radial strength risks under-expansion → stent thrombosis
- ? Of prolonged structural integrity during resorption process

Historical issues with BRS (lessons from cors)

Iterative improvements in BRS/DEBRS and trial design

- Ensuring adequate vessel prep
- IVUS/OCT as key aspect of sizing and ensuring vessel prep
- Adequate vessel post dil (+0.5 mm of vessel size)
- Thinner struts (espirt BTK device from abbott: 99 um in similar design and thickness to current coronary DES)
- Utilization of DEBRS
- Prolonging DAPT to prevent stent thrombosis

Further data that BRS in the periphery has “legs”


Primary Patency
Freedom From CD-TLR
PP-censored
FF CD-TLR-censored
5-Year Results
Primary Patency 72.9%
Freedom from CD-TLR 90.7%
N at Risk
PP
71 54 42 28 20 8
FF CD-TLR
71 59 47 32 21 10
0 12 24 36 48 60
Time (months)
Survival (%)
1.0
0.8
0.6
0.4
0.2
0.0

Pooled Analysis of Three Studies

CONSECUTIVE PATIENTS TREATED WITH ABSORB AUGUST 2012–MAY 2017

INCLUSION:

- Rutherford Class 3-6 CLI
- *De novo* BTK lesions (distal popliteal or tibial arteries)
- Diameter between 2.5 and 4 mm

	NUMBER OF PATIENTS	NUMBER OF LIMBS/LESIONS	NUMBER OF SCAFFOLDS	FOLLOW-UP
Pooled analysis	121	161	71	2 years

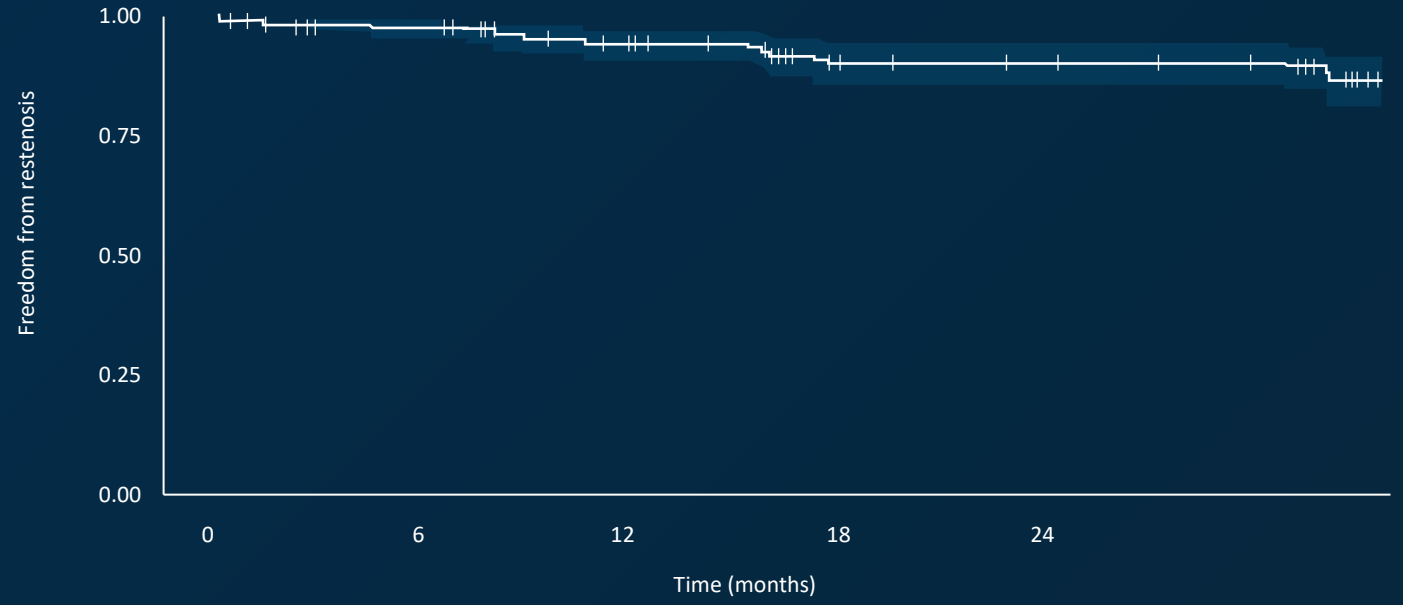
Huizing et al Vasc Med 2021 Apr;26(2):195-199

NCVH
New Cardiovascular Horizons

Pooled Analysis of Three Studies *(cont.)*

Primary Patency and TLR Outcomes

- **ABSORB IN THE BTK**



No. at risk	189	166	139	126	114
Freedom fm restenosis	100	97.3	91.7	90.3	86.6
Standard error	0	1.2	2.1	2.3	2.8

PRIMARY PATENCY	
@ 1y	91.7%
@ 2y	88.6%

FREEDOM FROM TLR	
@ 1y	97.2%
@ 2y	96.6%

Huizing et al Vasc Med 2021 Apr;26(2):195-199

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Pooled Analysis of Three Studies *(cont.)*

- **ABSORB IN THE BTK**

PATIENT CHARACTERISTICS	
Number of patients	121
Male	50%
Rutherford Score 3	16%
Rutherford Score 4	9%
Rutherford Score 5	55%
Rutherford Score 6	20%
Ischemic heart disease	47%
Hypertension	72%
Hyperlipidemia	69%
Smoking	31%
Diabetes	57%

LESION CHARACTERISTICS	
Lesions treated	161
Target lesion location:	
• Popliteal	4%
• Anterior tibial	25%
• Posterior tibial	24%
• Tibioperoneal trunk	29%
• Peroneal	18%
Target lesion length	21 mm (15-30 mm)
Degree of stenosis %	80 (80-95)
Total occlusion	22%
Calcified lesions	63%
No. of scaffolds deployed	189
Scaffold diameter	3.oo mm (3.0-3.5 mm)
Scaffold length	28 mm (18-28 mm)

Huizing et al Vasc Med 2021 Apr;26(2):195-199

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New Cardiovascular Horizons

LIFE-BTK Randomized Clinical Trial

Pivotal investigation of safety and efficacy for BTK treatment

Prospective, randomized multicenter,
US and OUS single-blind, trial
225 patients randomized
2:1 Esprit™ BTK vs. PTA

PRIMARY ENDPOINTS

SAFETY ENDPOINT @ 6 months:
MALE+POD

EFFICACY ENDPOINT @ 12 months:
Primary Patency + Limb Salvage

5-YEAR FOLLOW-UP

CAUTION: Investigational device. Limited by Federal law to investigational use only

New Cardiovascular Horizons

DRUG-ELUTING RESORBABLE SCAFFOLDS (DRS) BEING STUDIED AS POTENTIAL TREATMENT OPTION FOR LOWER LIMB DISEASE

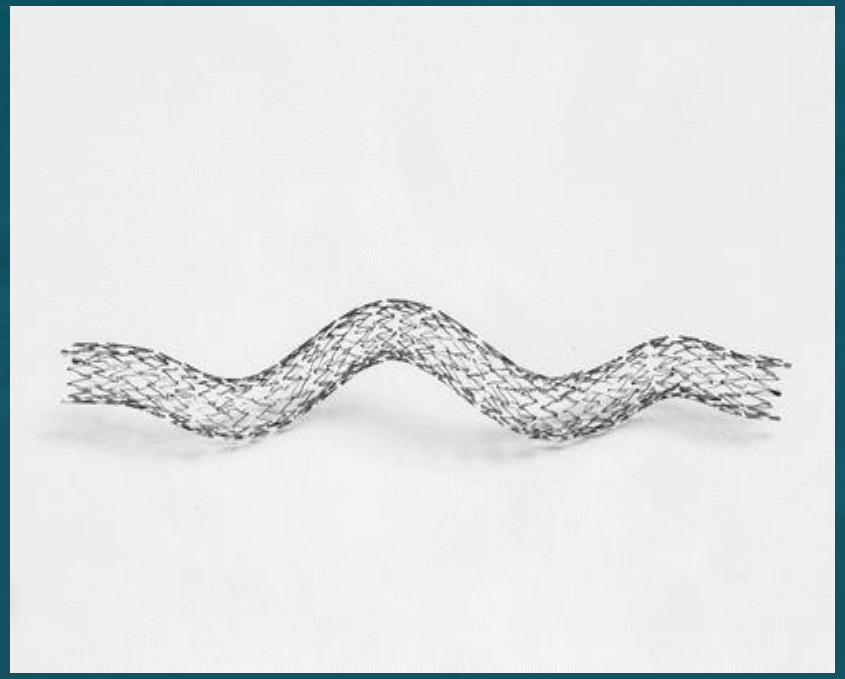
COMPANY	DEVICE	SCAFFOLD MATERIAL	DRUG	STATUS
Abbott	Esprit™ BTK	PLLA	Everolimus	LIFE-BTK RCT vs PTA (2:1) (N=261). CLTI. Enrollment complete
Biotronik	Magmaris™	Magnesium	Sirolimus	Completed 24mo fu for single center retrospective study (n=28)
Meril	MeRes™	PLLA	Sirolimus	CREDENCE BTK study. FIM. Multi-center (N=30). 12mo fu presented
Reva	Motiv™	Tyrocore™ (Tyrosine-Derived Polycarbonate)	Sirolimus	MOTIV RCT vs PTA (1:1) (n=292). Enrolling. (IDE) CE Mark. Post-market, multi-center, pilot BTK study (N=50) completed 12 mo fu
R3 Vascular *(prior Amaranth Medical)*	Magnitude	PLLA	Sirolimus	RESOLV-1. FIM multi-center study. (n=30). Enrolling
Lifetech Scientific	Lifetech IBS™	Iron	Sirolimus	GENIUS RCT vs PTA multi-center. (n=120). Enrolling
Efemoral Medical	Efemoral *with FlexStep Technology*	Unknown	Sirolimus	Enrolling Efemoral I. FIM single arm multi-center (n=100) for SFA

NCVH
New Cardiovascular Horizons

Other scaffolds of interest

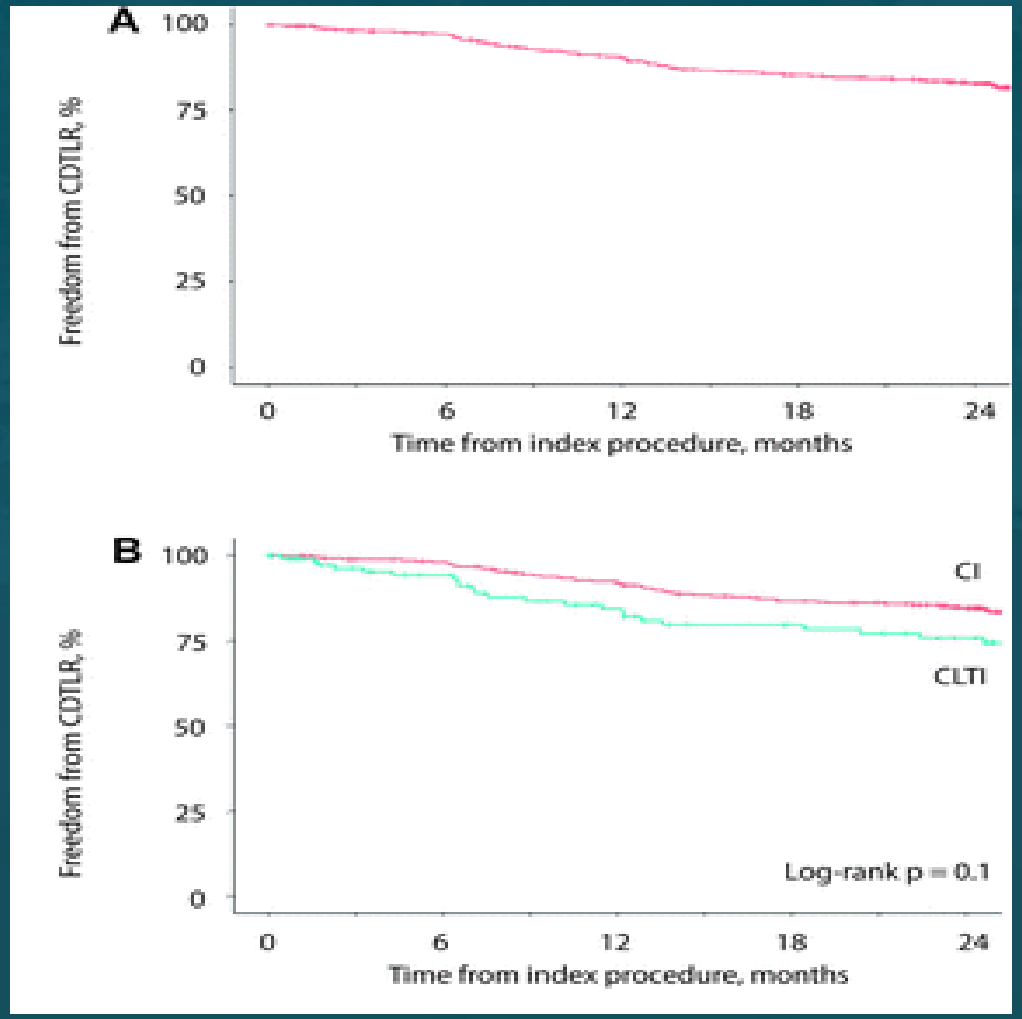
- Biomimics 3D
- Covered stents
  - Can be used for multiple indications
- Tacks

Biomimics stent



- impart swirling flow and to elevate wall shear stress which has been shown to prevent intimal hyperplasia and restenosis

Bio-mimics stent TLR 87.7and 78.6% at 12 and 24 months, respectively



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Update Covered stents for ISR –Relign Max

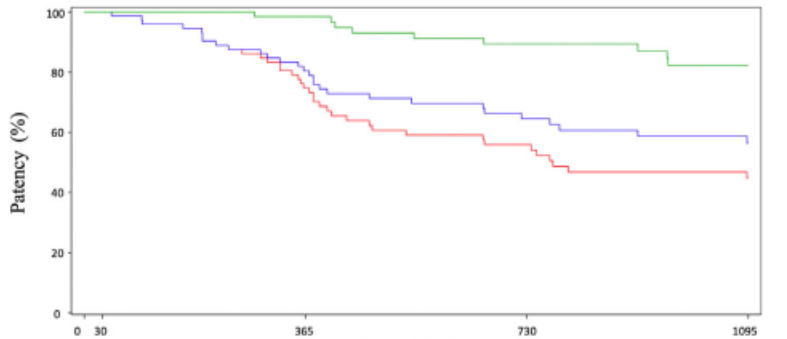
- Gore Viabahn - PTFE covered nitinol stents

JSCAI
The official journal of the Society for Cardiovascular Angiography & Interventions

Original Research

Three-Year Results of the GORE VIABAHN Endoprosthesis in the Superficial Femoral Artery for In-Stent Restenosis

Peter Soukas, MD[a,*], Matthew Becker, MD[b], Karl Stark, MD[c], Gunnar Tepe, MD[d], on behalf of the RELINE MAX Investigators



At risk, %, (95% CI)	Days (30)	Days (365)	Days (730)	Days (1095)
Secondary Patency	83, 100% (100-100%)	79, 98.4% (89.4-99.8%)	61, 89.4% (77.8-95.1%)	41, 82.3% (68.5-90.5%)
Primary Assisted Patency	83, 100% (100-100%)	80, 80.4% (69.2-87.9%)	55, 64.6% (51.8-74.8%)	34, 56.4% (42.9-67.9%)
Primary Patency	83, 100% (100-100%)	80, 74.7% (62.9-83.3%)	51, 55.9% (43.2-66.9%)	31, 44.7% (32.0-56.6%)

Freedom from target lesion revascularization was 84.8%, 74.6%, and 65.0% at 1, 2 and 3 years

Tack Endovascular System (4F) for BTK

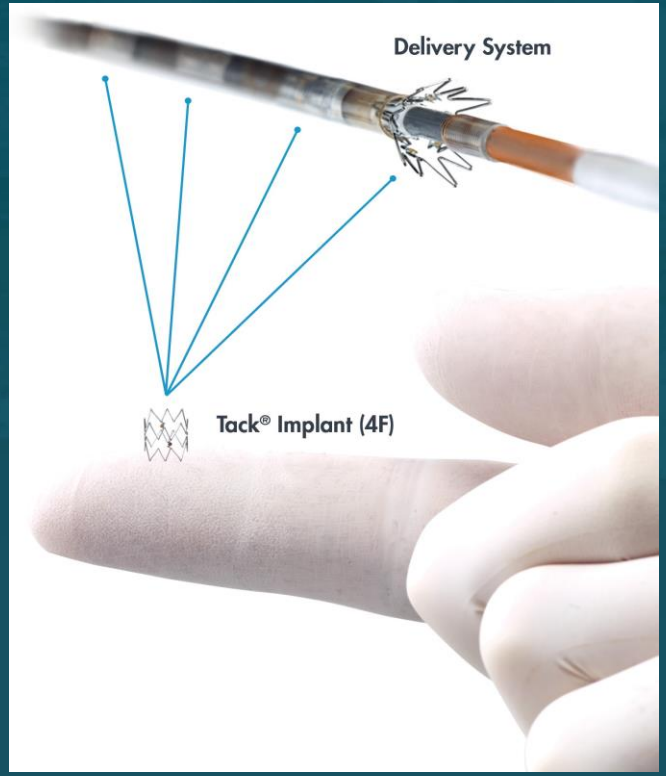
FDA approval April 2020

Tack implants

- Four pre-loaded nitinol implants
- 6mm deployed length
- Each implant self-sizes to tapering BTK anatomy
  - 1.5 – 4.5mm RVD

OTW delivery system

- 4F / .014”
- 150cm working length
- Accurate (≤1mm) deployment



INTENDED USE: The Tack Endovascular System (4F, 1.5-4.5mm) is intended for use in mid/distal popliteal, tibial and peroneal arteries, ranging in diameter from 1.5 mm to 4.5 mm, for the repair of post percutaneous transluminal balloon angioplasty (PTA) dissections.

CONTRAINDICATIONS: The Tack Endovascular System is contraindicated for the following: 1. Patients with residual stenosis in the treated segment equal to or greater than 30% after PTA. 2. Tortuous vascular anatomy significant enough to prevent safe introduction and [illegible] 3. Patients with a known hypersensitivity to nickel-titanium alloy (Nitinol). 4. Patients unable to receive standard medication used for interventional procedures such as anticoagulants, contrast agents and antiplatelet therapy.

Cors at the Shore 2020

Tack Endovascular System is CE Mark authorized under EC Directive 93/42/EEC.
[illegible] are registered trademarks of Intact Vascular, Inc. a Philips company.

TOBA II BTK Follow-Up Complete

Prospective, single-arm pivotal IDE study	
Population	Patients with **CLI** and angiographic evidence of a **dissection post-PTA requiring repair** in the mid/distal popliteal, tibial and/or peroneal arteries
Enrollment	**233** patients at 41 US, international sites
Primary Endpoints	▪ *Safety*: MALE + POD at 30d ▪ *Efficacy*: freedom from MALE at 6m + POD at 30d
Secondary Endpoints	▪ Tacked segment patency at 6 months (DUS flow/no flow) ▪ Target limb salvage at 6 months
Key Observational Endpoints	▪ Dissection resolution ▪ Freedom from CD-TLR ▪ Target limb salvage ▪ Amputation-free survival ▪ Changes from baseline: -Rutherford -Wound status -Quality of life

Enrollment (n=233)

6-m follow-up (n=199)
19 missed visit
7 died
8 withdrew

12-m follow-up (n=180)
24 missed visit
18 died (cumulative)
11 withdrew (cumulative)

24-m follow-up (n=143)
29 missed visit
43 died (cumulative)
18 withdrew (cumulative)

36-m follow-up (n=120)
11 missed visit
64 died (cumulative)
38 withdrew (cumulative)

MALE + POD: composite of all-cause death, above-ankle target limb amputation, or major re-intervention to the target lesion(s), defined as new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis

TOBA II BTK: Complex Patients and Lesions
(ITT Population)

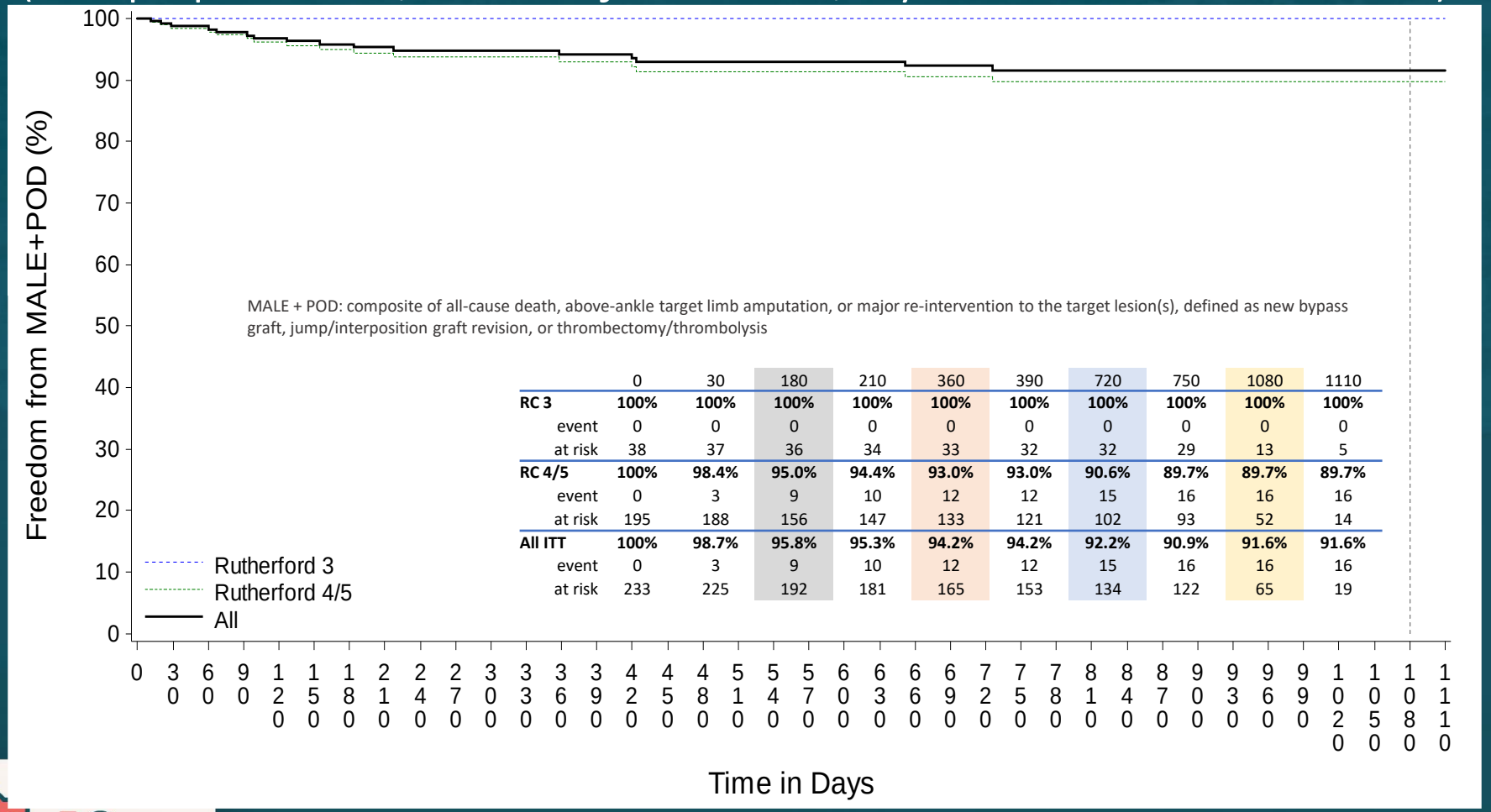
Patient characteristics		Mean ± SD (N) or % (n/N)
Age (y)		74.4 ± 10.0 (233)
Male Gender		67.4% (157/233)
Rutherford	3	16.3% (38/233)
	4	**33.5% (78/233)**
	5	**50.2% (117/233)**
TBI target limb		0.43 ± 0.23 (118)
Smoking History		62.2% (145/233)
Diabetes mellitus		**65.7% (153/233)**
Arterial hypertension		93.6% (218/233)
Coronary artery disease		56.1% (129/230)
	MI	22.0% (51/232)
	PCI / CABG	43.9% (101/230)
Chronic renal insufficiency		**24.6% (57/232)**

Lesion characteristics (core lab adjudicated)		Mean ± SD (N) or % (n/N)
RVD (mm)	Proximal	3.5 ± 1.0 (248)
	Distal	2.6 ± 0.7 (248)
Lesion length (mm)*	Baseline	80 ± 49 (248)
	PTA Treatment	**154 ± 110 (238)**
Pre-PTA DS%		85 ± 17 (248)
Total Occlusion		**47.6% (118/248)**
Calcium (PARC)	None/mild	64.1% (159/248)
	Moderate	18.1% (45/248)
	Severe	17.7% (44/248)
Distal Target Vessel	P2/P3	5.2% (13/248)
	TP Trunk	10.1% (25/248)
	Anterior tibial	41.5% (103/248)
	Posterior tibial	22.2% (55/248)
	Peroneal	21.4% (53/248)

*Site-reported baseline lesion length: 116 ± 100 (277)

36-Month Freedom from MALE + POD

(ITT population, CEC adjudicated, by baseline Rutherford)

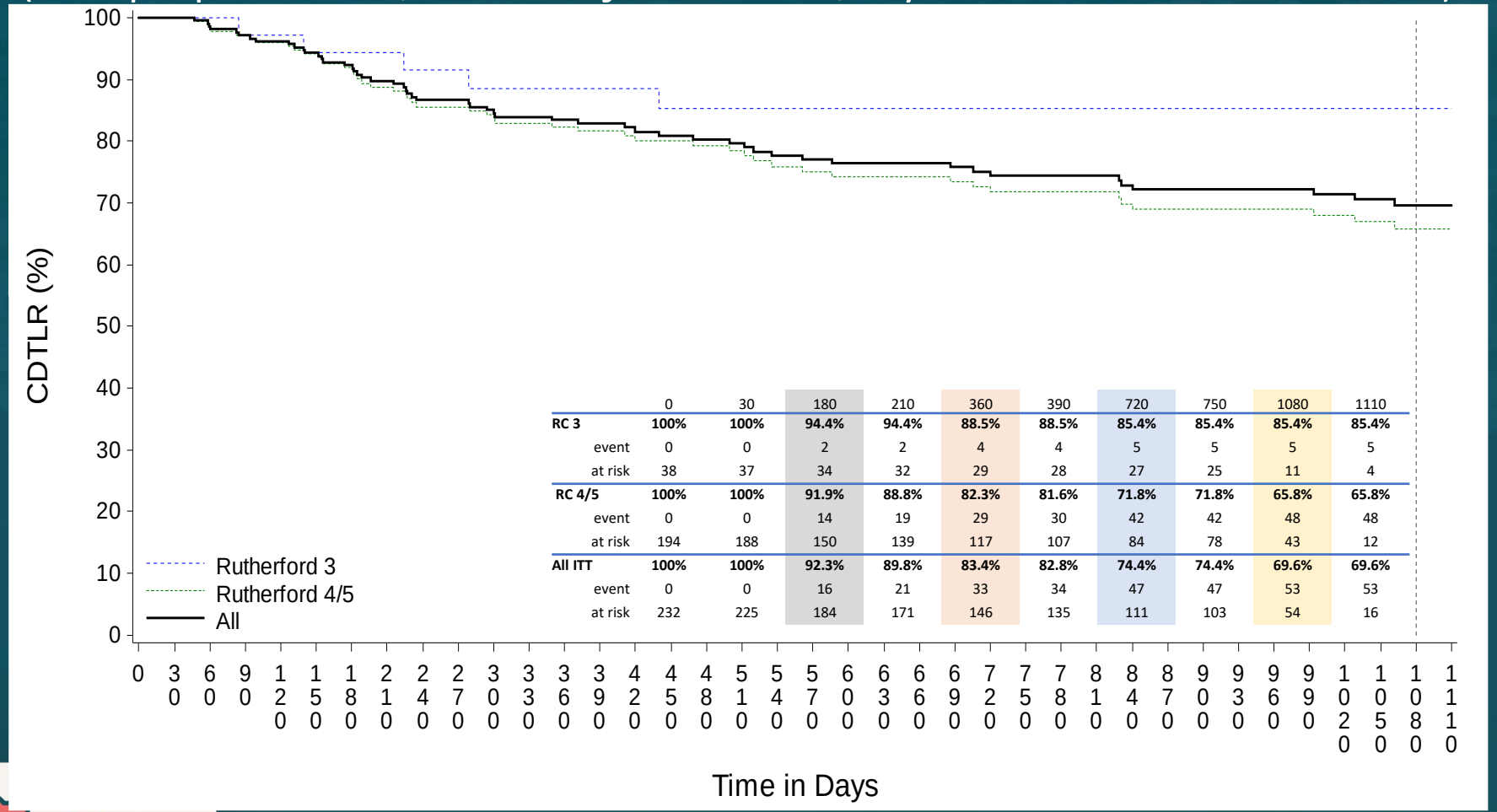


	0	30	180	210	360	390	720	750	1080	1110
RC 3	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**
event	0	0	0	0	0	0	0	0	0	0
at risk	38	37	36	34	33	32	32	29	13	5
RC 4/5	**100%**	**98.4%**	**95.0%**	**94.4%**	**93.0%**	**93.0%**	**90.6%**	**89.7%**	**89.7%**	**89.7%**
event	0	3	9	10	12	12	15	16	16	16
at risk	195	188	156	147	133	121	102	93	52	14
All ITT	**100%**	**98.7%**	**95.8%**	**95.3%**	**94.2%**	**94.2%**	**92.2%**	**90.9%**	**91.6%**	**91.6%**
event	0	3	9	10	12	12	15	16	16	16
at risk	233	225	192	181	165	153	134	122	65	19

89.7%
(CLI pts)

36-Month Freedom from CD-TLR

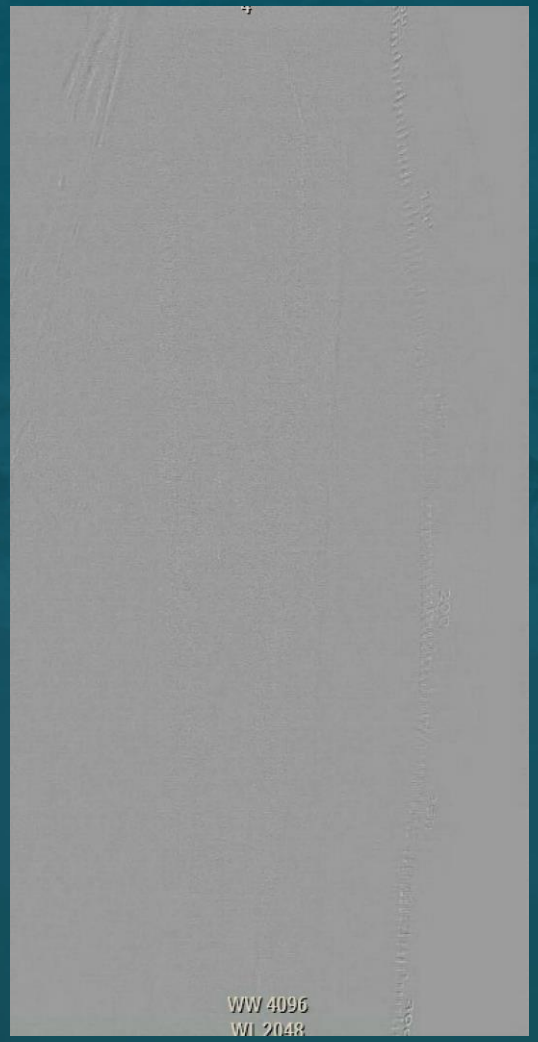
(ITT population, CEC adjudicated, by baseline Rutherford)



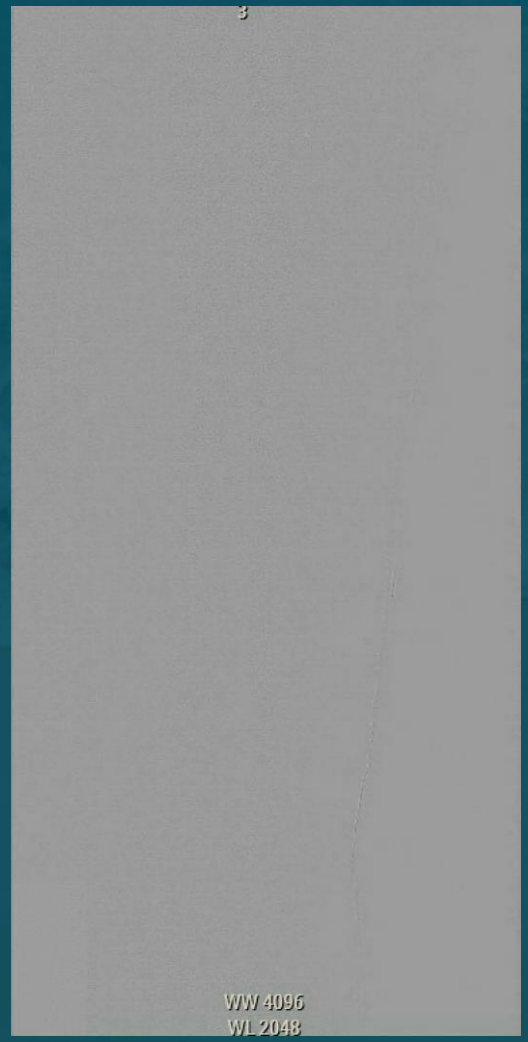
	0	30	180	210	360	390	720	750	1080	1110
RC 3	**100%**	**100%**	**94.4%**	**94.4%**	**88.5%**	**88.5%**	**85.4%**	**85.4%**	**85.4%**	**85.4%**
event	0	0	2	2	4	4	5	5	5	5
at risk	38	37	34	32	29	28	27	25	11	4
RC 4/5	**100%**	**100%**	**91.9%**	**88.8%**	**82.3%**	**81.6%**	**71.8%**	**71.8%**	**65.8%**	**65.8%**
event	0	0	14	19	29	30	42	42	48	48
at risk	194	188	150	139	117	107	84	78	43	12
All ITT	**100%**	**100%**	**92.3%**	**89.8%**	**83.4%**	**82.8%**	**74.4%**	**74.4%**	**69.6%**	**69.6%**
event	0	0	16	21	33	34	47	47	53	53
at risk	232	225	184	171	146	135	111	103	54	16

69.6%
(All pts)

Case – BTK



Antegrade AT



Retro Access AT

Hallux wound nonhealing ulcer
R5 disease

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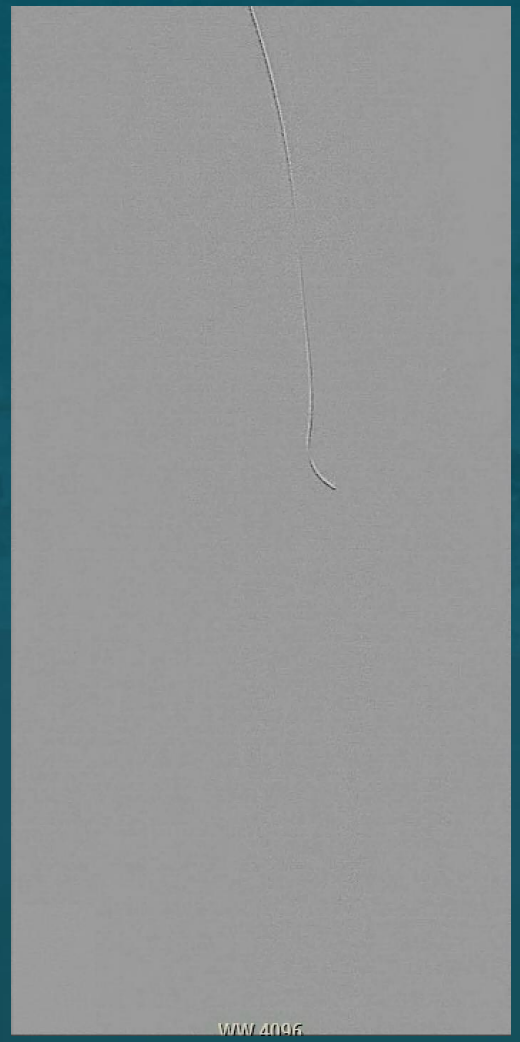
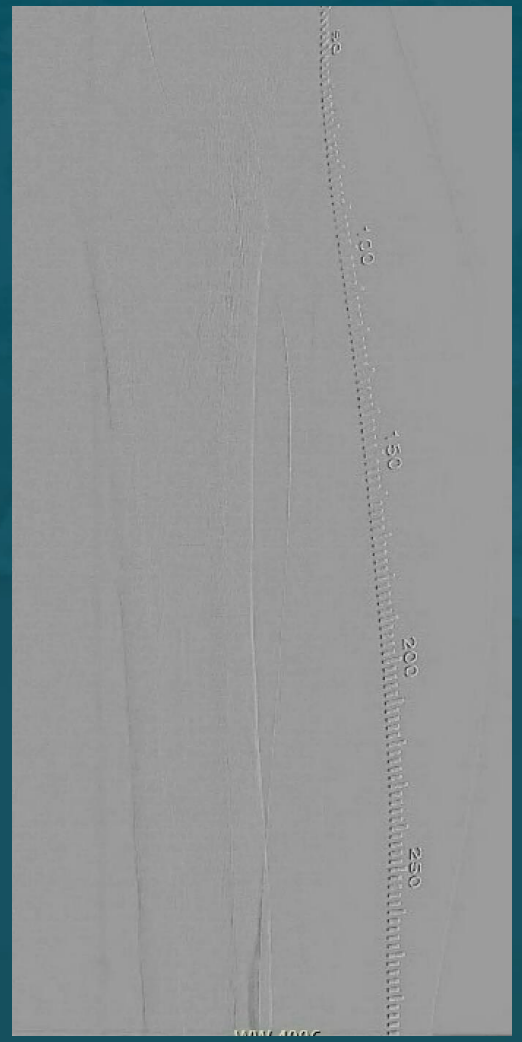
CASE- BTK



Extensive Dissection



Recoil Ostium

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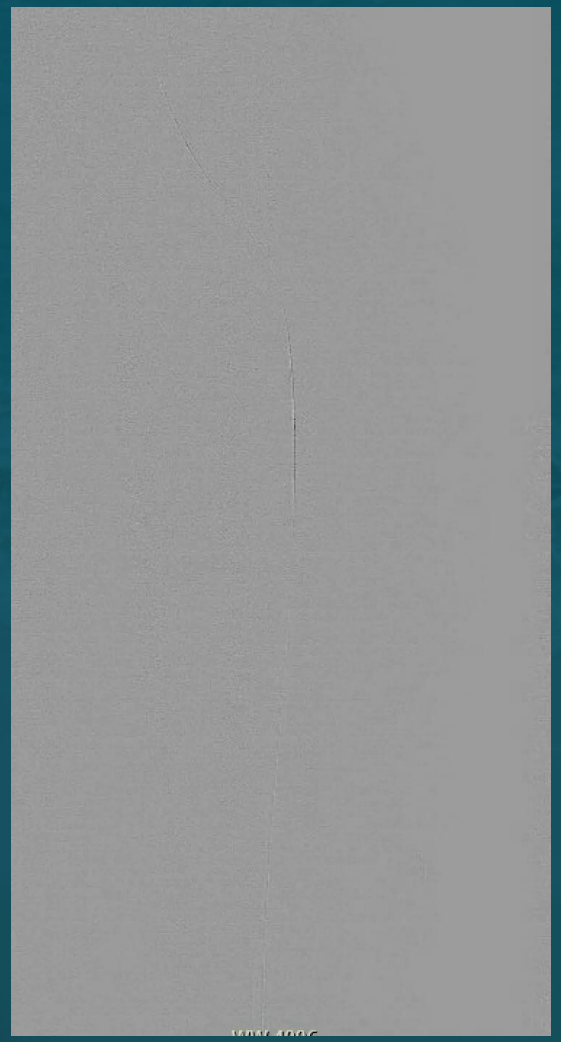
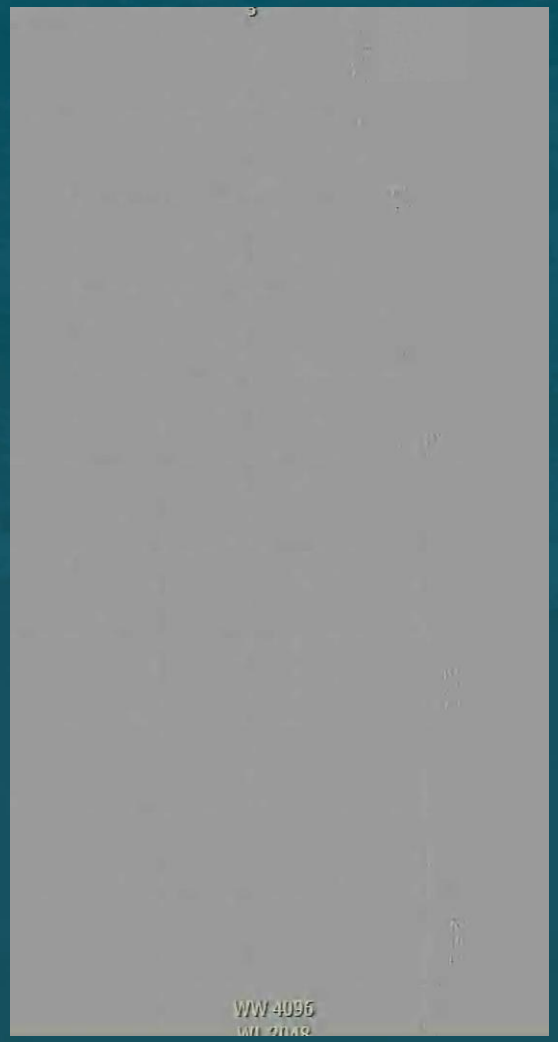
CASE- BTK



Ostial Recoil PTA



DES to Ostium

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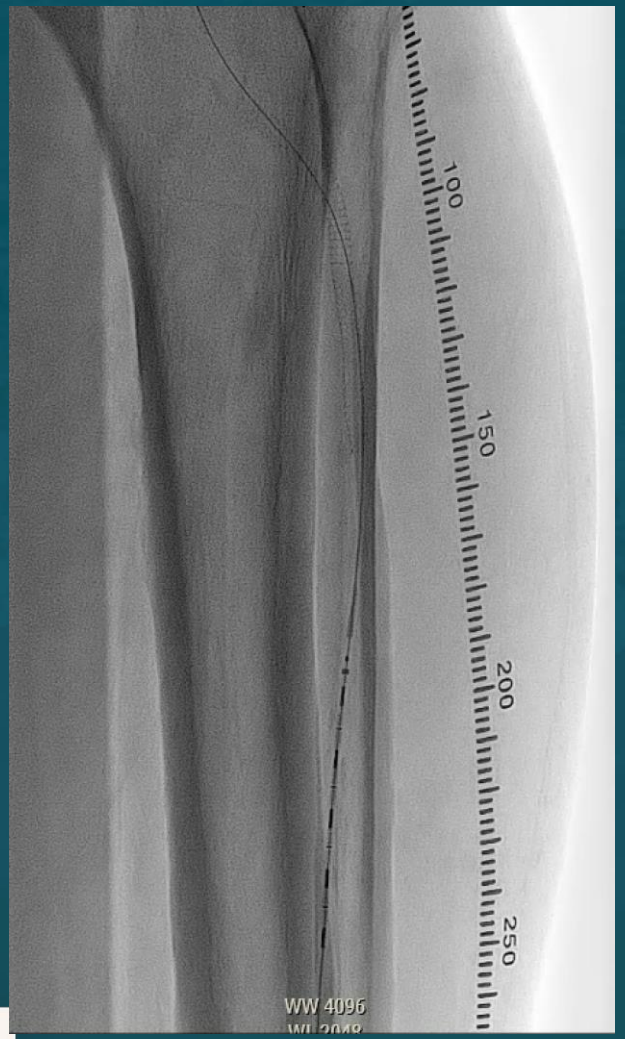
CASE- BTK



Tack to Mid AT

Retro deployment of 4 Tacks

Post-dil with Coyote

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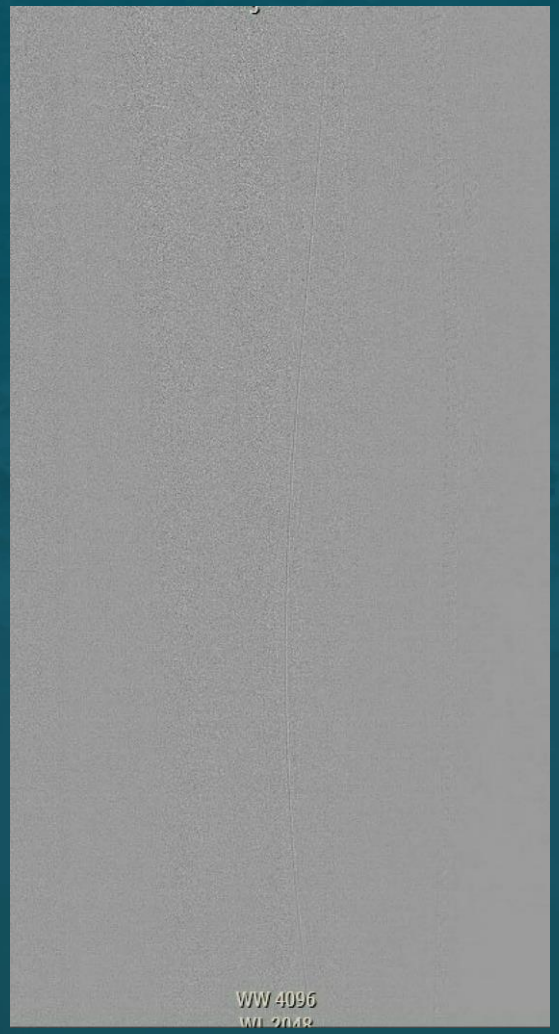
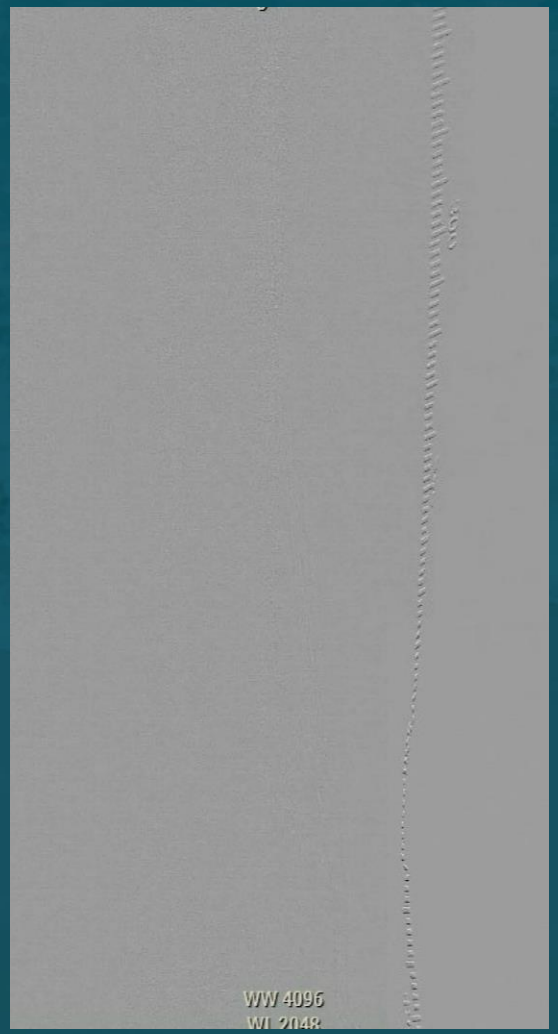
CASE- BTK



Final



Final

Hallux wound healed

Duplex at 12 months patent AT

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Thank you

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