Long Term Results and a Glimpse into the Future with Bioresorbable Scaffolds for BTK?

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Disclosure

Speaker name:

.....Ramon L. Varcoe.....

I have the following potential conflicts of interest to report:

- Consulting: Abbott Vascular, Medtronic, Boston Scientific, Intact Medical, Surmodics, Intervene

ALL CURRENT TREATMENT OPTIONS FOR BTK HAVE INHERENT LIMITATIONS

Current Treatment Options for the Tibial Circulation

- Elastic recoil
- Residual plaque
- Restenosis
- Dissection
- Primary patency 20-50% (TASC II)

- Device variability
- Lack of data
- Embolization

- Elastic recoil
- Residual plaque
- Dissection
- Failed RCTs
- No approved DCB (US)

- No on-label DES (US)
- Permanent implant
- Short lengths
- Surgical reintervention

- Restenosis
- No on-label DES (US)
- Permanent implant
- Short lengths
- Surgical reintervention

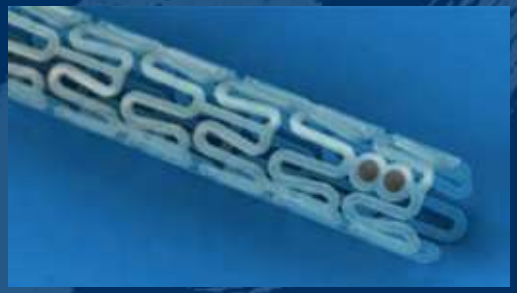
NIH: Neointimal hyperplasia

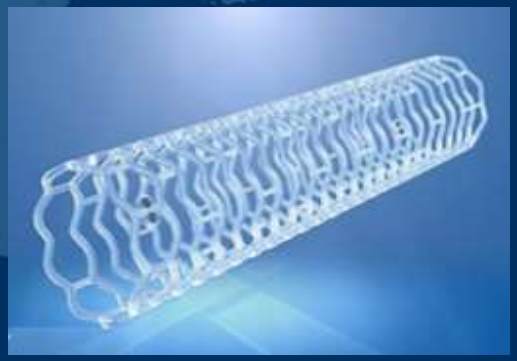
To effectively treat BTK disease:			
	Drug (inhibit NIH)	Scaffold (resist recoil)	Leave nothing behind
Angioplasty	✗	✗	✓
Atherectomy	✗	✗	✓
DCB	✓	✗	✓
BMS	✗	✓	✗
DES	✓	✓	✗

A BVS MAY BE THE BEST OF BOTH WORLDS?

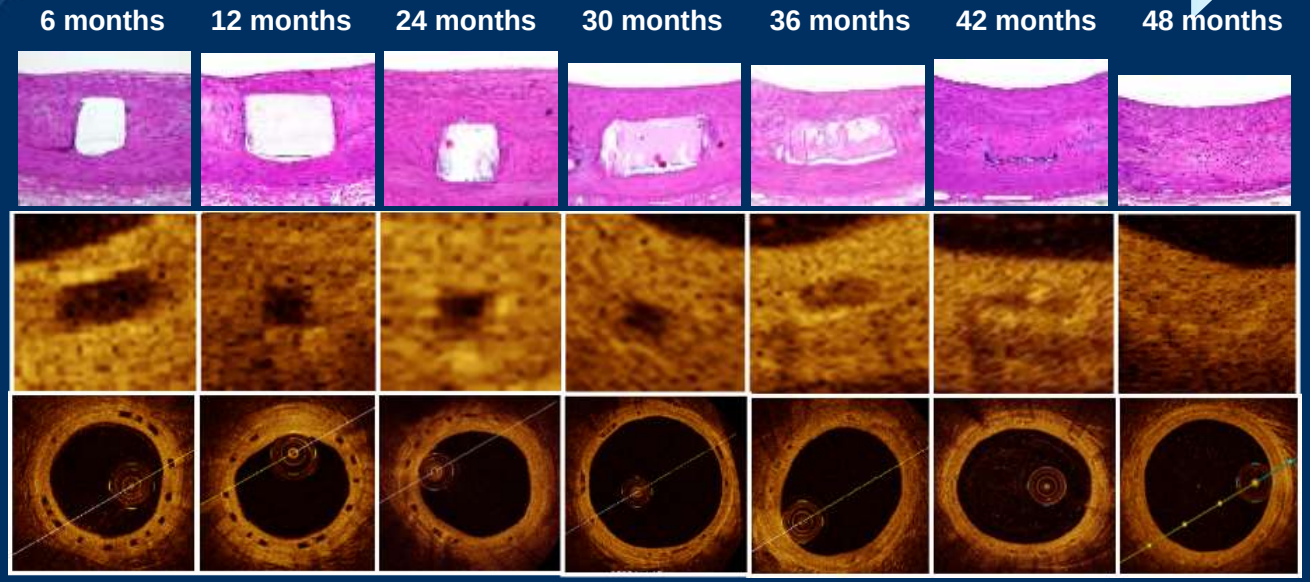
- Mechanical Scaffolding
- Drug Delivery
- Potential Return of Normal Vessel Wall Function
- Then Disappears!

Bioresorbable DES for BTK: Long-Term Results & Future Implications





Degrading polymer is replaced by an increasingly cellular provisional matrix.



ABSORB is currently a non-commercial product and is not available for sale.

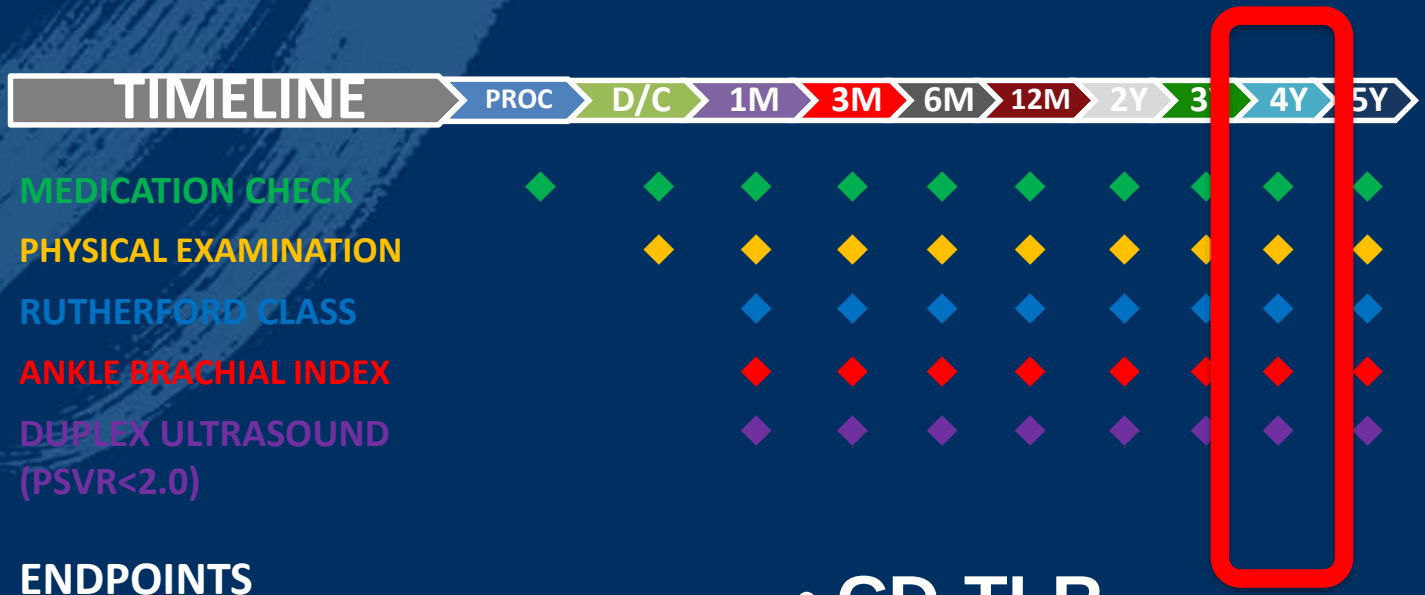
STUDY DESIGN

- Prospective, Non-Randomised, Single-Center Study

Inclusion Criteria

- Chronic lower limb ischemia: RC 3-6
- Life expectancy >1yr
- Single or Multiple De novo lesions; >60%
- Infrapopliteal arteries (distal P3)
- Total Lesion Length ≤5cm (Max 2xBVS)
- Diameters 2.5-4.0mm

ENDPOINTS



ENDPOINTS

- Binary Restenosis
- Primary Patency

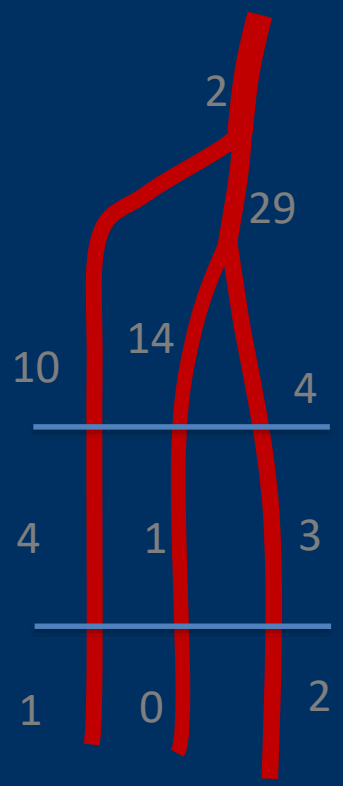
- **CD-TLR**
- **CD-TVR**

PATIENTS

- **48 Patients**
  - Male:Female 56:44%
  - Mean Age 82yrs (range 65-97yrs)
- **55 Limbs**
  - Left:Right 45:55%
  - CLI:IC 73:27%

RESULTS

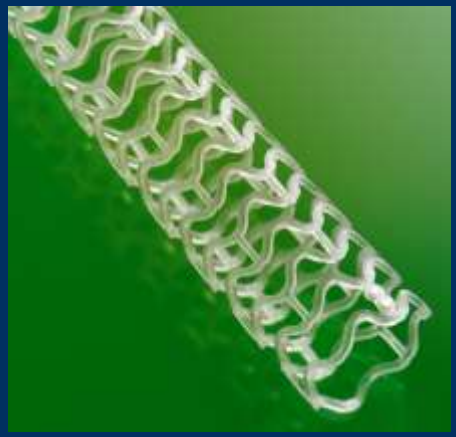
- **71 Scaffolds Implanted**
  - Target vessels treated
    - ATA 15
    - PTA 9
    - PA 15
    - TPT 29
    - P3 2



- Mean lesion length **20.1 ±10.8mm** (5-50mm)

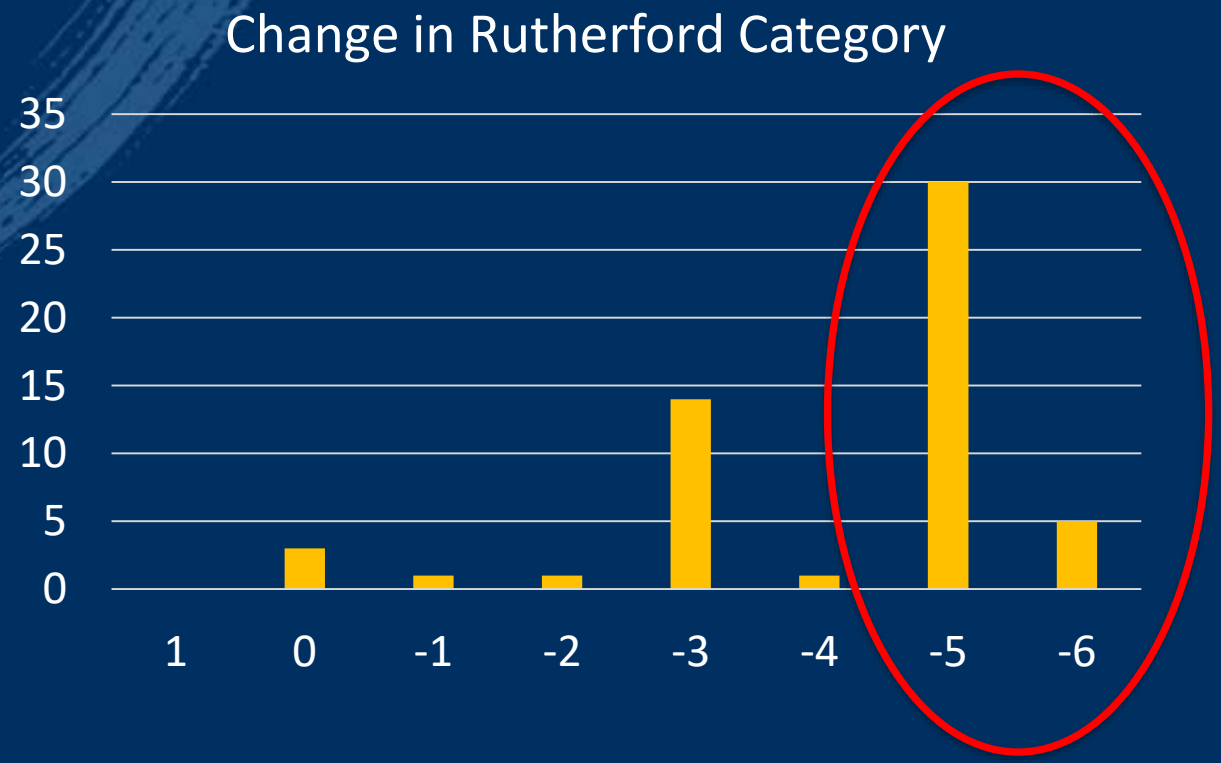
RESULTS

- **100% Procedural & Technical success**
- **18 deaths (38% of cohort) (All Outside 30d)**



Mean Follow-Up	**28 months**
Sustained Clinical Improvement	**95%**
Assisted primary/secondary patency	100%
Limb salvage	100%

Sustained Clinical Improvement in 95%



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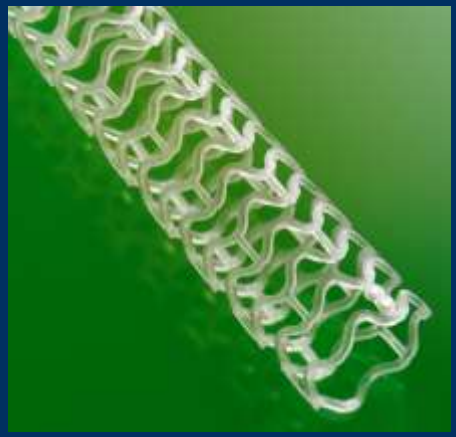

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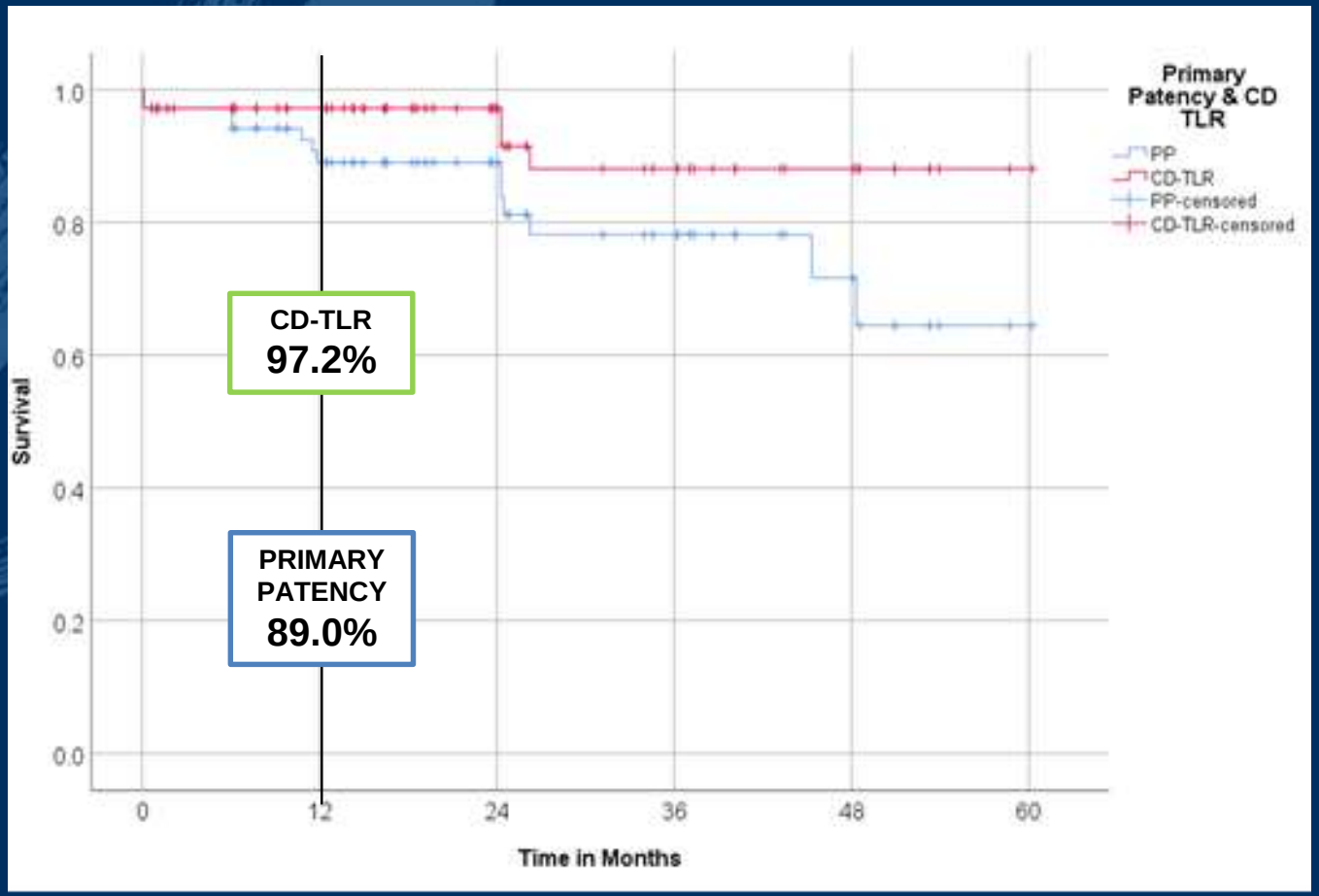
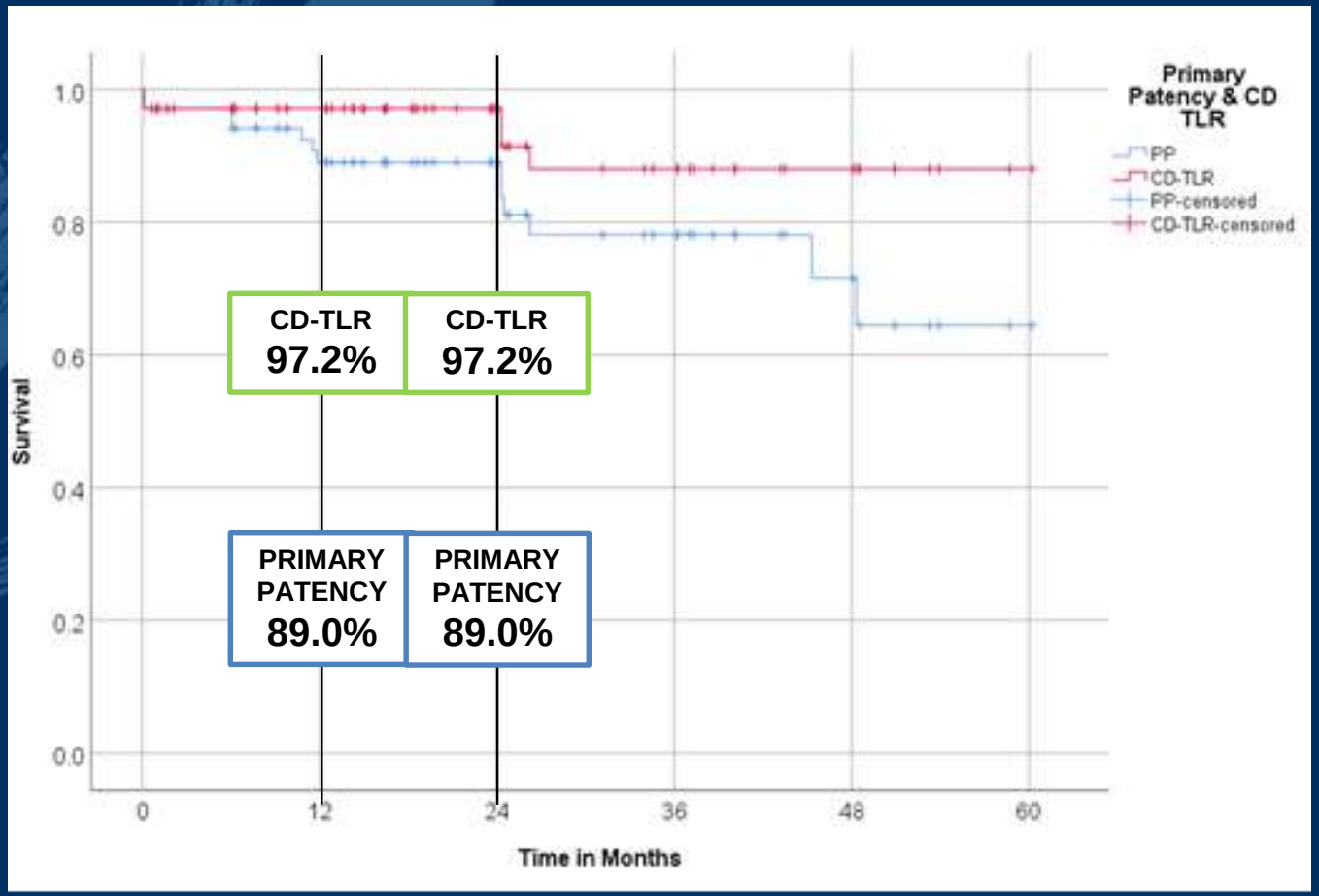


Patency	N at risk	53	36	24	12	3
	SE (%)	3.9	3.9	6.2	8.4	10.2
Freedom from TLR	N at risk	56	36	24	13	3
	SE (%)	2.0	2.0	5.3	5.3	5.3



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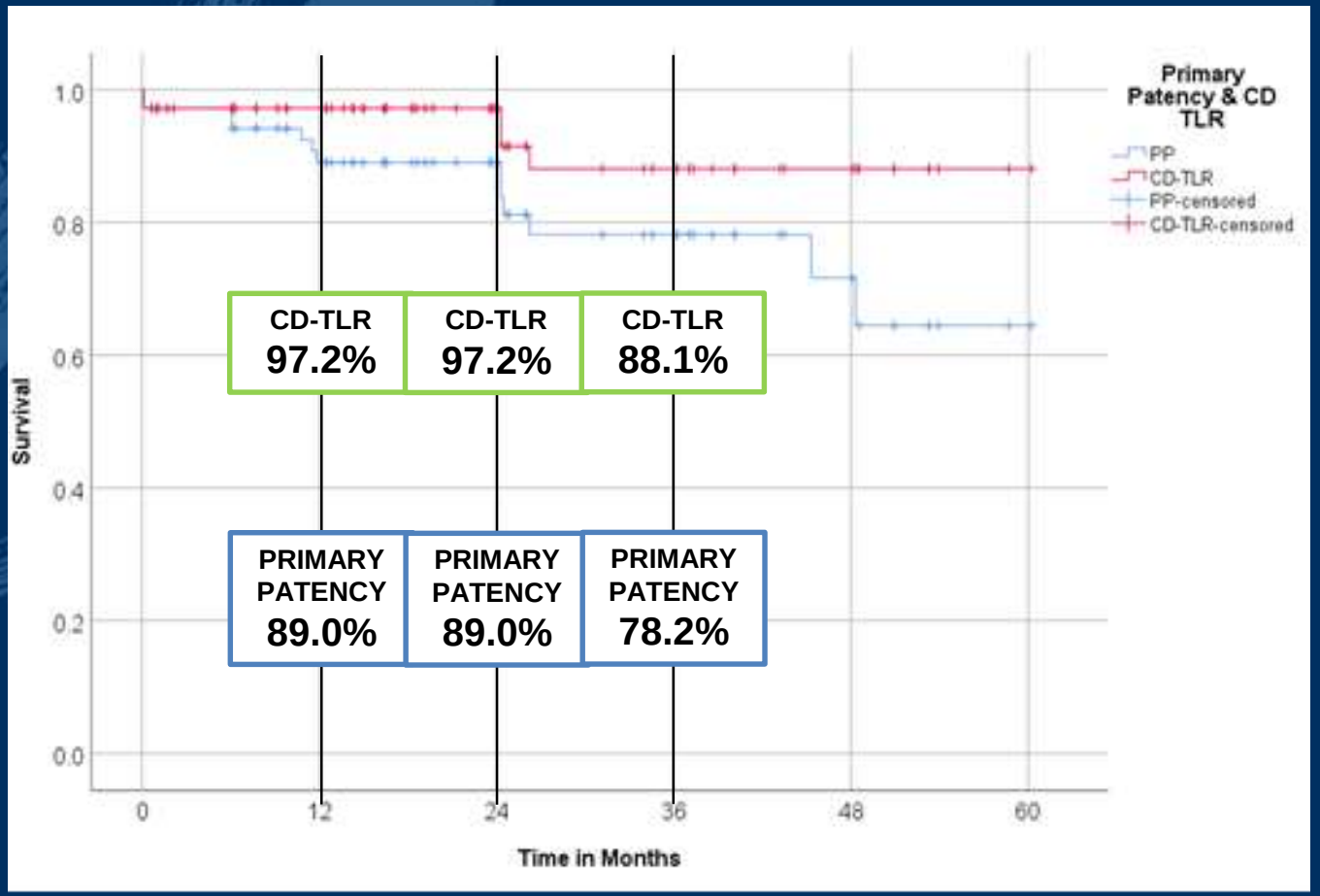

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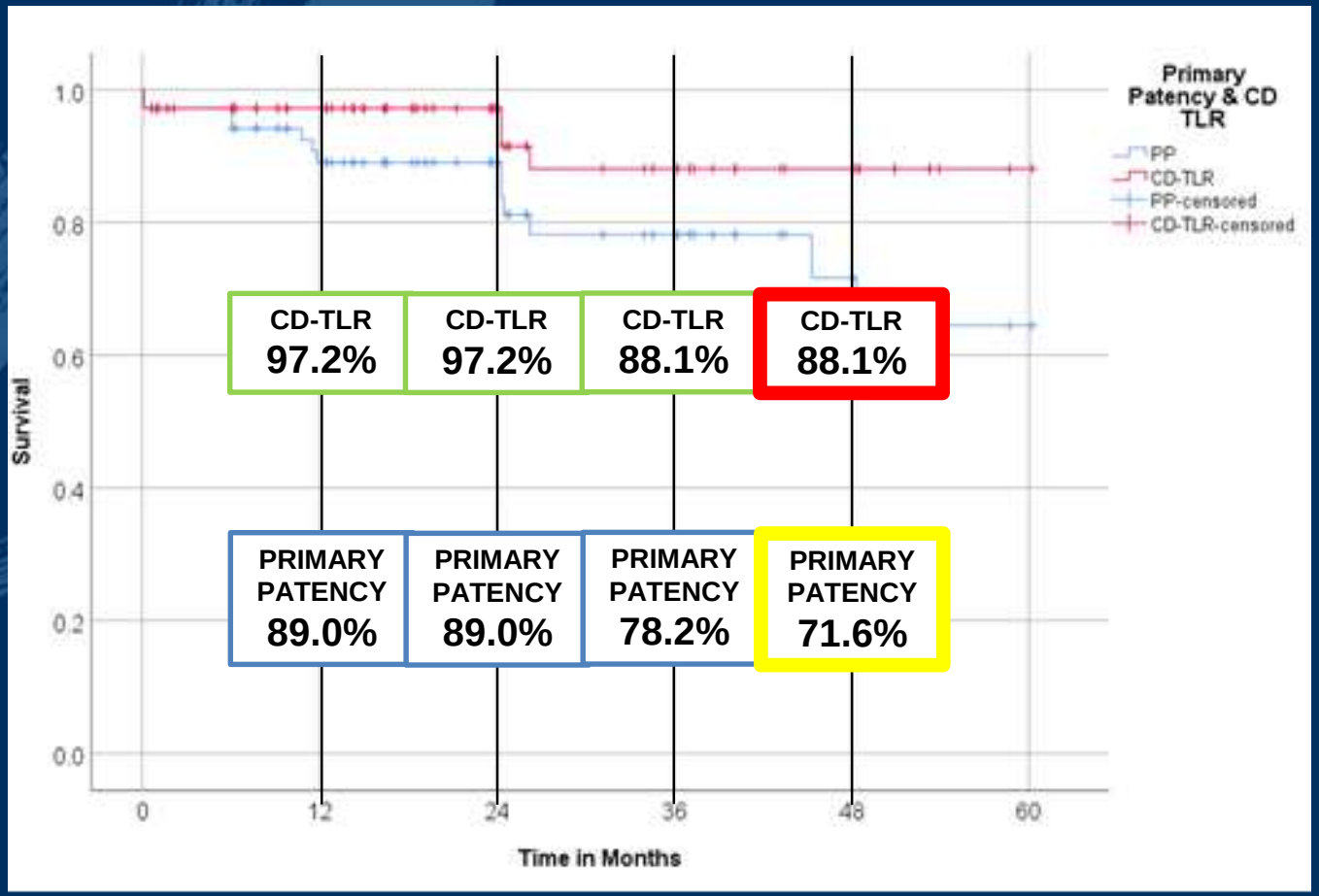

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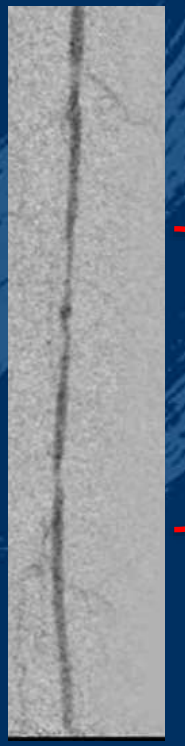
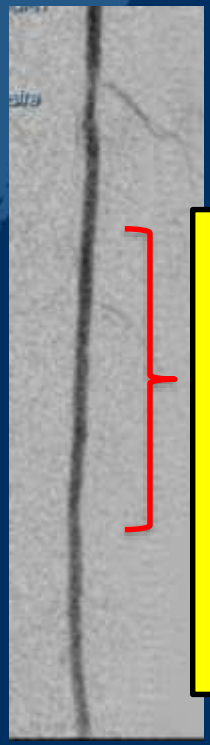


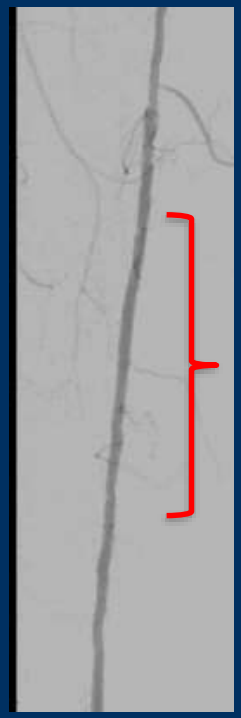
Aug 2012
pre
implantation



Aug 2012
post
implantation

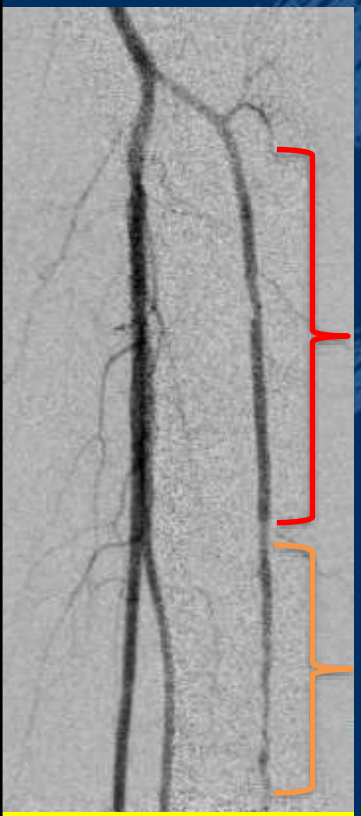
BVS
3 x 28
3 x 28
3 x 18

Total Stented
Length =
70mm



Oct 2016
Control
Angiogram

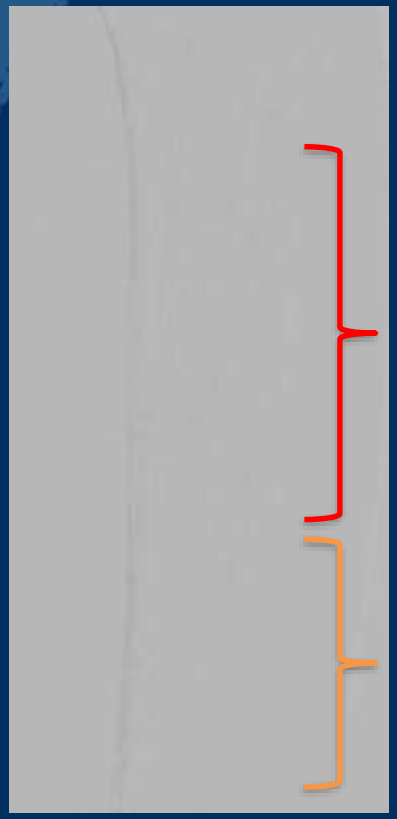
Progression of disease in non stented vessel



Upper ATA was normal

Disease segment

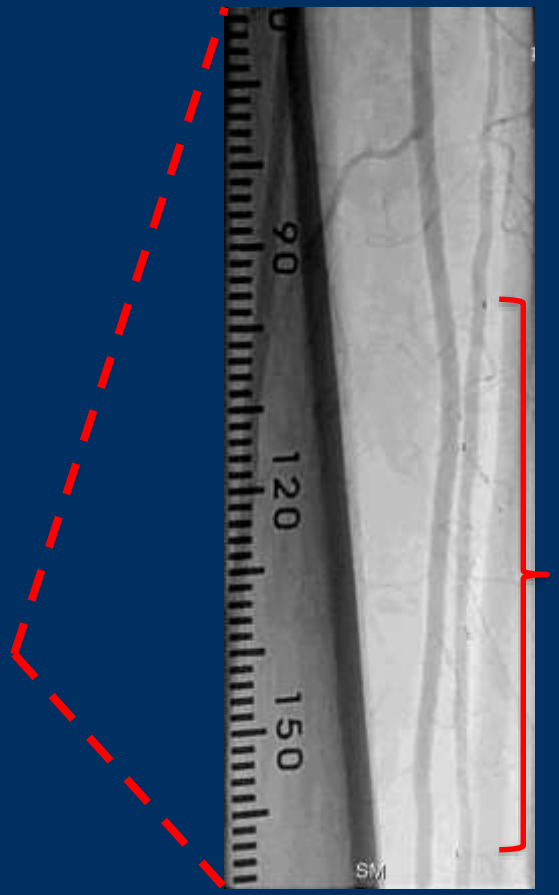
Index Angio 2012 (before BVS)



2016

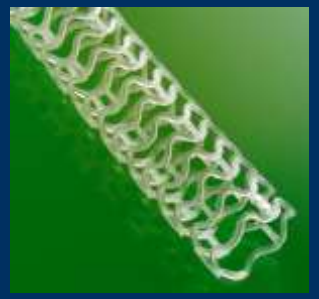
Progression of disease in the segment of ATA

BVS segment is disease free



LINC

CONCLUSIONS



- The First-Gen ABSORB BVS has achieved excellent long-term patency and freedom from TLR rates in the tibial arteries

- This proof-of-concept facilitates the next generation of BVS devices

3 Centre Combined BVS – Preliminary Results

- Consecutive patients treated with the Absorb BVS in hospitals in Singapore, US and Australia
- August 2012 to May 2017
- Inclusion :
  - Rutherford 3-6 CLTI
  - de novo BTK lesions distal popliteal or tibial arteries
  - diameter between 2.5 and 4 mm.

Patient/Lesion/Scaffolds

Demographics (%)	N= 125
Male	51.2
Rutherford Score	
3	15.7
4	8.7
5	55.9
6	19.7
TASC	
A	21.3
B	15.7
C	14.2
D	8.7
NA	43.3
Diabetes	55

Lesion Location (%)	N = 156
P3	5.51
ATA	35.43
TPT	36.22
PTA	33.07
PA	25.20
Lesion Length (mm)	
Mean	25.49
Min	4.00
Max	88.00
Scaffold (mm)	**N = 189**
No. of scaffolds deployed	189
Mean Diameter	3.20
Mean Length	25.5

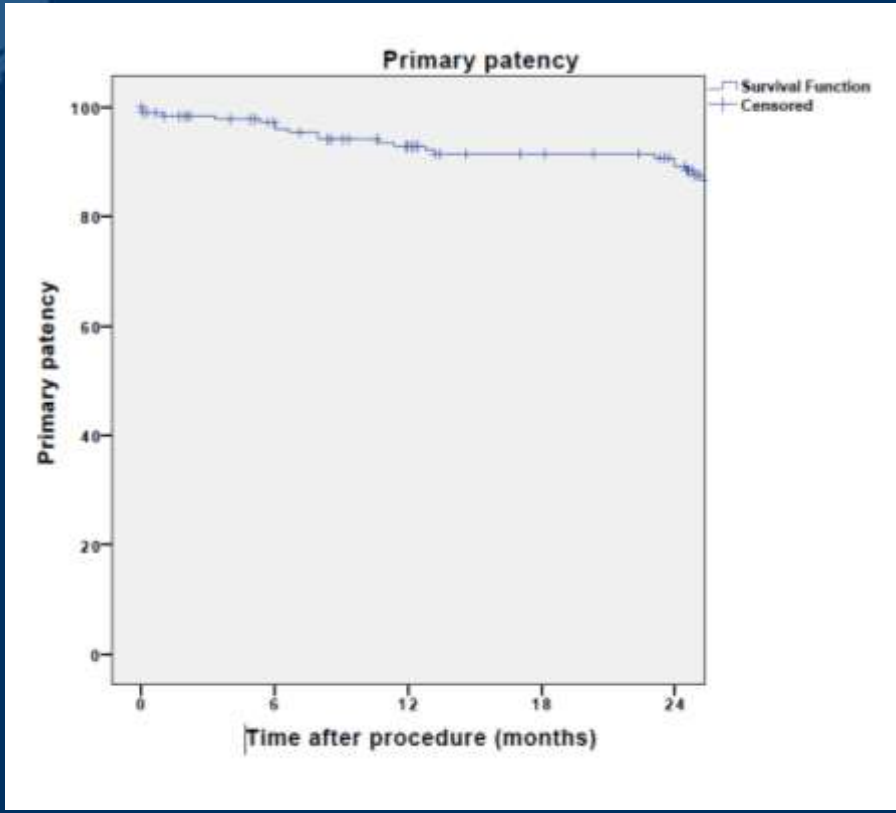
Primary Patency & TLR

Primary Patency

12 months	91.1%
24 months	88.6%

TLR

12 months	96.6%
24 months	94.5%



Future Implications: ESPRIT-BTK Peripheral Vascular Scaffold

ESPRIT-BTK

PLLA SCAFFOLD

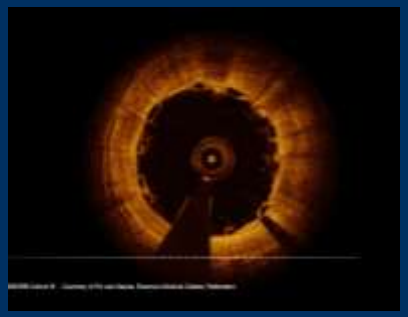
- Fully resorbable*
- Platinum markers for angiographic visualization
- 99 µm strut thickness†
- Supports treated artery
- Allows for uniform delivery of everolimus
- Resorbs in a benign, controlled manner (~36 mo).

PDLLA COATING

- Fully resorbable
- Conformal coating
- 1:1 PDLLA: everolimus blend
- Provides sustained everolimus release to maximize long term patency without downstream particulates

EVEROLIMUS

- Cytostatic
- Patented for restenosis reduction
- Broad therapeutic range
- 100 µg/cm^2 dose density
- Elution rate matched to restenosis cascade



* Platinum markers as proximal and distal ends remain for angiographic visualization
† ≤ 3.0 mm size; 3.5 – 3.75 mm sizes have 120 µm strut thickness

ESPRIT is currently under investigation and not available for sale.

LIFE-BTK

- pivotal Investigation of safety and Efficacy of BRS treatment—Below The Knee

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

6-MONTH PRIMARY ENDPOINTS

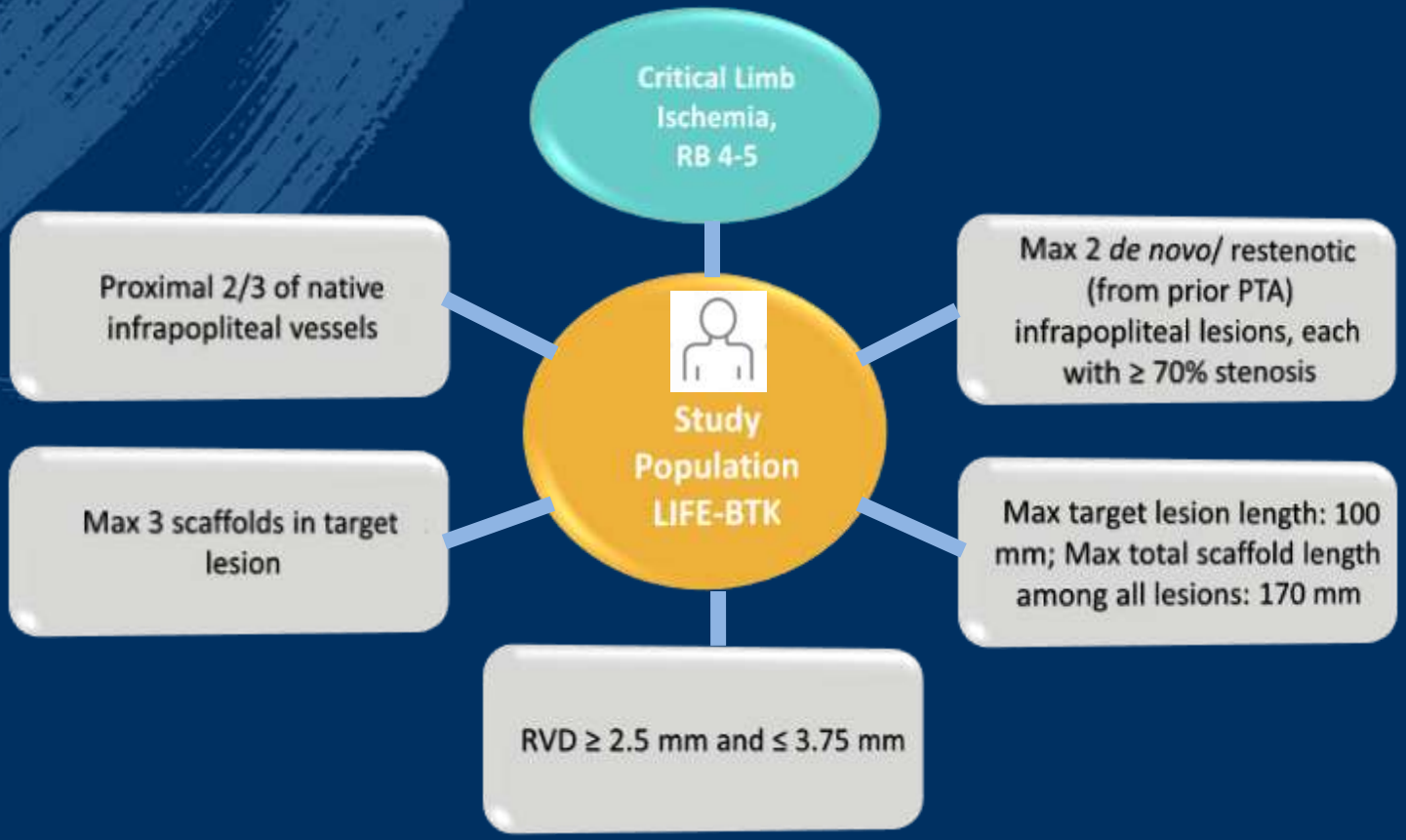
Safety Endpoint:
MALE+POD

Efficacy Endpoint:
Primary Patency+Limb Salvage

5-YEAR FOLLOW-UP

Trial Leadership:
Ramon Varcoe MBBS, MS, FRACS, PhD; Sahil Parikh MD, FACC, FSCAI; Brian DeRubertis MD, FACS,

LIFE-BTK Intended Study Population



ESPRIT-BTK Implantation Technique

Vessel Sizing (Quantitative imaging preferred)

Sizing accuracy is imperative for good clinical outcomes

Ideal POBA results Residual <30%

Complete PTA

1:1 balloon sizing (Estimate RVD)

Vessel Sizing (Quantitative imaging preferred)

Sizing accuracy allows correct scaffold size to be implanted

Implant the correct size ESPRIT

Scaffold Implant

High pressure

Postdilate

ESPRIT-BTK: finishing device

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