MERLION trial

iVascular
therapies for living

MERLION trial

Objective:

Prospective, single-arm multi-center trial investigating the safety and efficacy of the treatment with the Luminor and Angiolite BTK as bailout-stenting in TASC C and D tibial occlusive disease in patients with critical limb ischemia

Principle investigator:

Dr Tjun Tang (Singapore)

Patients:

50

Endpoints

Freedom from device- or procedure-related mortality, fTLR, PP, Freedom from major target lower limb amputation, Technical success and Clinical success

Presented at LINC 2021 by Dr Tang

iVascular
therapies for living

MERLION trial_ Patient demographics

High complex patients were included in the MERLION tial:

	Number (n=50)	Percentage (%)
Mean Age, years (sd)	66.42 ± 8.93	
Mean BMI (sd)	24.00 ± 4.13	
Gender		
Male	32	64.0
Female	18	36.0
Ethnic Group		
Chinese	25	50.0
Malay	12	24.0
Indian	12	24.0
Others	1	2.0
Smoking status		
Non-smoker	40	80.00
Smoker	9	18.00
Ex-smoker	1	2.0
Co-Morbidities (%)		
Diabetes	47	94.00
Hypercholesterolemia	46	92.00
Hypertension	44	88.00
Cerebrovascular accident	7	14.00
Ischemic Cardiomyopathy	25	50.00
End Stage Renal Failure (ESRF)	25	50.00

94% Diabetics
50% ESRF

Presented at LINC 2021 by Dr Tang

iVascular
therapies for living

MERLION trial_ Procedural information

The lesions were highly calcified and the main Rutherford Class was 5.

3 bailout stenting were performed, using Angiolite BTK.

Lesion details	Total lesions treated with DCB (n= 66)	Percentage (%)
Location of Treated Vessel		
Anterior Tibial Artery (ATA)	23	34.85
Posterior Tibial Artery (PTA)	16	24.24
Tibioperoneal trunk	14	21.21
Peroneal artery	9	13.64
Popliteal artery	1	1.52
Superficial femoral artery (SFA)	3	4.55
De novo	47	71.21
Re-stenotic	19	28.79
TASC Classification		
C (*multiple stenosis, > 10cm lesion length*)	40	60.61
D (*multiple occlusion, > 10cm lesion length*)	26	39.39
Total Occlusions	28	42.42
Diffused Disease	38	57.58
Calcification Classification		
1 (None)	0	0.0
2 (focal)	13	19.70
3 (mild)	19	28.79
4 (moderate)	26	39.39
5 (severe)	8	12.12
Lesion length (mm)	137.8 ± 95.0	
Diameter Stenosis (%)	85.8 ± 12.8	

Reason for intervention	Number (n=50)	Percentage (%)
Rutherford Classification		
4 (*Rest pain*)	6	12.00
5 (*Minor tissue loss – nonhealing ulcer, focal gangrene with diffuse pedal ischemia*)	41	82.00
6 (*Major tissue loss – Severe ischemic ulcers or gangrene*)	3	6.00
Duration of symptoms		
Less than 1 week	2	4.00
Less than 3 months	25	50.00
More than 3 months	23	46.00

3 bailout stenting performed for residual dissection and persistent recoil

>50% with moderate to severely calcified lesions!

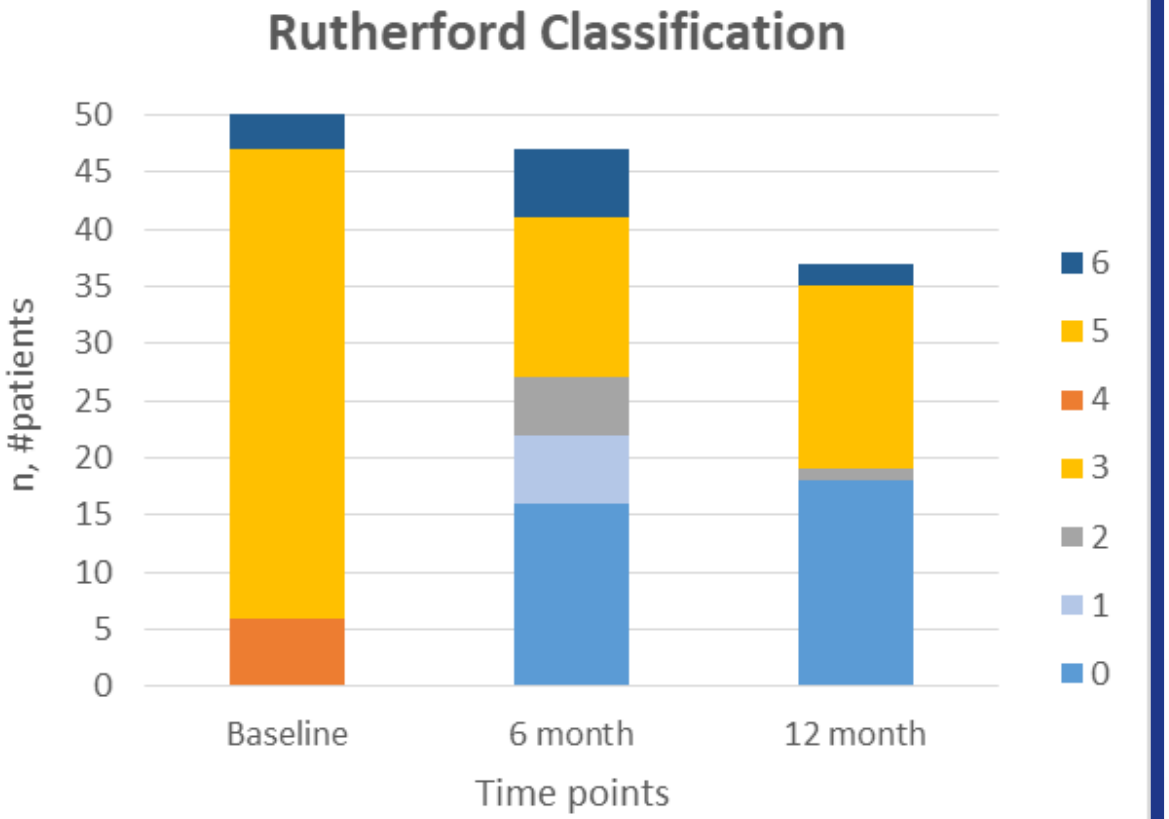
Presented at LINC 2021 by Dr Tang

iVascular
therapies for living

MERLION trial_ Rutherford Classification 1-year

After 1 year, 60% of the subjects improved minimum 1 Rutherford Class.

The ones still at 5 or 6, are because new wounds have appeared.



	Baseline, n (%) n=50	6 month, n (%) n=47	12 months, n (%) n=37
Rutherford Class			
0	0	16 (34.0)	18 (48.7)
1	0	6 (12.8)	
2	0	5 (10.6)	1 (2.70)
3	0	2 (4.3)	3 (8.11)
4	6 (12.0)	0	
5	41 (82.0)	12 (25.5)	14 (35.1)
6	3 (6.0)	6 (12.8)	2 (5.41)
Mean	4.94 ± 0.42	2.51 ± 2.39	2.38 ± 2.47
Changes from Baseline			
Improved by ≥ 1 category	-	29 (61.7)	22 (59.5)
No Change	-	12 (25.5)	13 (32.4)
Worsened by ≥ 1 category	-	6 (12.8)	3 (8.11)
Mean Change (range)	-	2.47 ± 2.50 (-2 – 6)	2.59 ± 2.63 (-2 – 6)

Presented at LINC 2021 by Dr Tang

MERLION trial_ Outcomes 1-year

	6 month, n (%) n=57 lesions	12 months, n (%) n=49 lesions
Target Lesion Primary Patency	45 (78.9)	34 (69.4)
Freedom from Target Lesion Revascularization (TLR)	52 (91.2)	40 (81.6)
Amputation Free Survival (n=50 pts)	43 (86.0)	37 (74.0)
Death	3 (6.0)	11 (22.0)
Major Amputation	4 (8.0)	5 (10.0)
Mean time to revascularization (days) (± SD)	142.6 ± 89.9	
Mean time to major amputation (days) (± SD)	111 ± 89.3	
Mean time to death (days) (± SD)	226.6 ± 82.6	
Clinical Symptomology	(n=47)	(n=37)
Improved	33 (70.2)	24 (64.9)
Worsened	6 (12.8)	3 (8.1)
No Change	8 (17.0)	10 (27.0)
Wounds healed* **(Exclude 2 with no wounds)**	27 (60.0)	23 (65.7)

At 1 year,

TLPP: 69.4%

Freedom from TLR: 81.6%

AFS: 74.0%

Clinical improvement in **64.9%** subjects.

65.7% subjects have index wounds healed at end of 1 year

Presented at LINC 2021 by Dr Tang

iVascular
therapies for living

MERLION trial_ Outcomes 1-year

There are few BTK trials with 1-year follow-up. Analysing them, the outcomes of Luminor in the MERLION trial are promising, considering the complexity of the lesions and of the patients.

PRODUCT	TRIAL	Type of trial	fTLR (1 year)
Luminor	**MERLION**	**Single-arm**	**81.6%**
In.Pact (Medtronic)	DEBATE BTK	RCT vs POBA	82.0%
Lutonix (BD)	LUTONIX BTK	RCT vs POBA	80.3% (no significant vs POBA)
Passeo-18 Lux (Biotronik)	BIOLUX P-II	RCT vs POBA	68.7% (no significant vs POBA)

Sources:
DEBATE BTK https://www.ahajournals.org/doi/full/10.1161/circulationaha.113.001811; LUTONIX BTK https://linc2020.cncptdlx.com/media/0805_Patrick_Geraghty_29_01_2020_Room_1_-_Main_Arena_1.pdf ; BIOLUX P-II https://www.sciencedirect.com/science/article/pii/S1936879815011395

iVascular
therapies for living

MERLION trial_ Conclusions

- Treatment of **long tibial occlusive lesions** (TASC C and D) in **CLTI** patients
- **50 patients (94% diabetes; 50% ESRF; 88%** Rutherford Score 5&6)
- **66 atherosclerotic lesions**; mean lesion length **13.7 ± 9.5cm**
- **100% technical success**; **low** bail out stenting (4.5%)
- **Safety profile excellent** (no deaths within 30 days); 6-month AFS = 86%, **12-month AFS = 74%**
- **Efficacious** - 6-month TLPP = 79%, **12-month = 69%;**
- **Freedom from TLR** = 91%, 12-month = **82%**
- **Wound closure** achieved in **66%** of subjects and **60%** improvement by at least 1 Rutherford category at 12 months. While index wounds have healed, new wounds have occurred on same limb.

Presented at LINC 2021 by Dr Tang

iVascular
therapies for living

MERLION trial_ Key messages at 1-year

High complex patients and BTK lesions

100%
Freedom from device related mortality

74%
Amputation free survival

81.6%
fTLR

iVascular
therapies for living

Luminor clinical trials

iVasTriam
The iVascular **Clinical Trial Program**

LUMINOR registry
Real world registry, 1-year follow-up BTK subgroup. N= 215
PP: 85.9%; fTLR:89.6%

EffPac
Randomized controlled trial (Luminor vs PTA). N=171
3.5-year follow-up. fTLR=90.1%, PP=69.6%

TINTIN
Prospective trial in complex SFA lesions. N=100
2-year follow-up. fTLR= 89.4%

MERLION
Prospective BTK trial. N= 50
1-year follow-up. fTLR= 81.6%

BIBLIOS
Prospective BTK trial, N=150

LUMBRA
Real world registry in Brazil. N=200

LUMIFOLLOW
France Registry. N=500

iVascular
therapies for living

Luminor messages

luminor

The best DCB ever

1

No risk of death

The safest DCB for the patients at long-term follow-up

2

To treat all type of lesions

Best efficacy evidence in different indications

3

Not all DCBs are the same

TransferTech nanotechnology makes the difference

iVascular

therapies for living

Thank you

iVascular
therapies for living