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LINC

# How Low Can You Go?

## SELUCTION SLR™ Tibial Artery Sirolimus-Coated Balloon Angioplasty in the Setting of CLTI

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LINC 2020



# Disclosures

Speaker name:

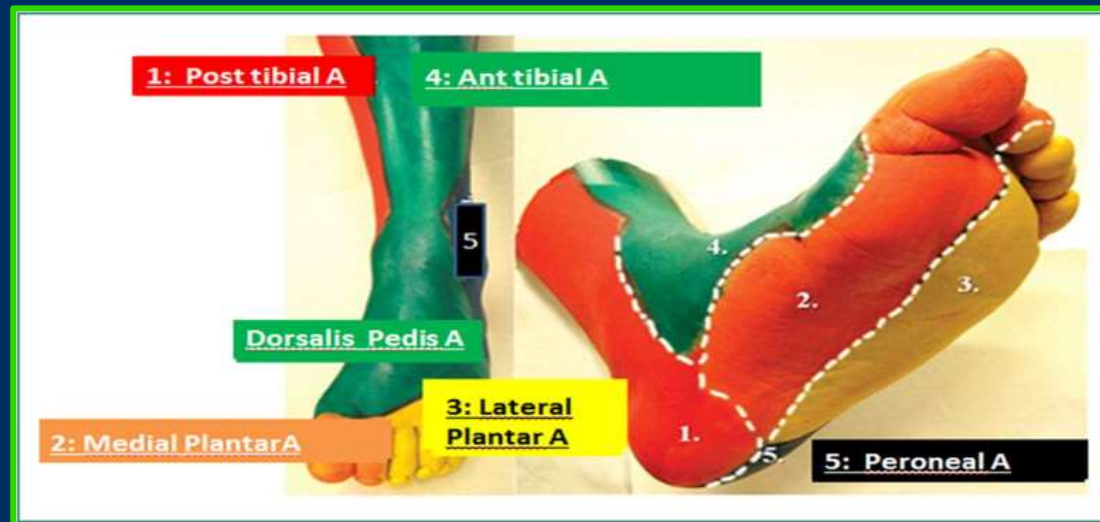
**TJUN TANG MD FRCS(Gen)**

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) – Investigator-initiated grant from Medalliance**
  
- I do not have any potential conflict of interest

# Goals of BTK Interventions in CLTI

- Restore straight-line pulsatile blood flow to the foot for wound healing
- Direct/Angiosome-directed endovascular revascularization if possible
  - Significantly improves wound healing and major amputation rates
- Access and traverse

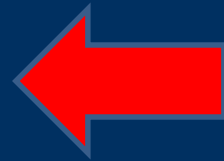


# Tibial Artery Angioplasty in CLTI: CHALLENGES

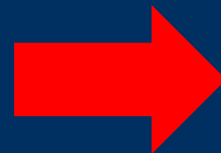
- Endovascular therapy for infra-popliteal arterial occlusion preferred option:
  - Minimally invasive and repeatable procedure
  - Setting of CLTI – patient with multiple co-morbidities
  - Lack of surgical venous conduits (Diabetics)
- Problem is prolonged wound healing (3-6 months!)
- POBA/BMS plagued by vessel restenosis
- Efficacy of paclitaxel –coated balloons in reducing restenosis and target lesion revascularization?



**Wound  
Healed!!**



**Wound**



# The DM Foot Challenge in Singapore



# SGH Lower Limb Angioplasty Experience



- 1200 lower limb angioplasties for CLTI over last 18 months
- 95% CLTI vs 5% claudicants!
- Patients present late!
- > 90% diabetics
- Approx. 50% with renal impairment
- Multi-level disease

# PRESTIGE Trial

**P**hysician initiated, prospective, non-**R**andomized single-center trial, investigating the safety and **E**fficacy of the Treatment with the **S**elution Sirolimus Coated Balloon in TASC C and D **T**ibial occlusive disease **I**n patients with critical limb **I**schemia from Sin**G**apor**E**

NCT04071782

# Primary Objective

- To evaluate the **6-month** safety and performance outcome of the Selution™ Sirolimus DCB
- Treatment of **long tibial occlusive lesions (TASC C and D) in patients with CLTI**



# PRESTIGE Endpoints

- Freedom from **device- or procedure-related mortality** through 30 days
- Freedom from **Target Lesion Revascularization (TLR)** at 6 months and 12 months post-study procedure
  - Defined as any re-intervention performed for  $\geq 50\%$  diameter stenosis Of target lesion
- **Freedom from major target limb amputation**
- **Primary Patency rate** at 6 and 12 months post-study procedure
- **Technical success** (i.e. able to cross and dilate lesion to achieve  $< 30\%$  residual stenosis)
- **Clinical success** (i.e. improvement of Rutherford classification at follow-up)
- **Wound healing** (i.e. complete closure of wound /  $> 70\%$  healed)

# Study Site and Recruitment Targets

- SGH, Department of Vascular Surgery
- 2 senior experienced endovascular surgeons
- Trial fully enrolled
  - Originally 20 patients planned but extended to 25
- 3 month enrollment (October - December 2019)
- As of 18 Jan 2020:
  - **71 patients screened**
  - **27 eligible (2 did not meet angiographic inclusion)**
  - **25 patients enrolled**

# Inclusion Criteria

1. De novo and post-PTA restenotic lesions located in **tibial arteries**
2. Target lesion is **>100mm, TASC C or D lesion**
3. Target lesion has angiographic evidence of **stenosis >50% or occlusion**
4. Lesion traversed with standard guidewire and **predilated to <30% residual stenosis**
5. Target vessel diameter visually estimated to be **> 1.5 mm and <4.5mm below knee**
6. Any tibial vessel intervened on must have **distal reconstitution above ankle**
7. Inflow iliac, SFA and popliteal lesions treated first prior to treating BTK lesions.  
**(<30% residual stenosis and no evidence of embolization)**
8. Angiographic evidence of at least **one vessel runoff through ankle and into foot**

Eligible patients identified & consented for study **prior to procedure**

Pre-op investigations performed **7 days before op**

- Walking Impairment Questionnaire
- EQ5D
- Ankle Brachial Pressure Index (ABPI)
- Duplex Ultrasound

**Day of Op**

To assess angiographic inclusion criteria intra-operatively

If **meet angiographic inclusion criteria**, patient will be enrolled into study – For treatment with SCB

ABI and ultrasound post-procedure and before discharge

If **do not meet angiographic inclusion criteria**, to either proceed any products, at individual discretion

#### Inclusion

1. Age > 21, able to give consent
2. Diagnosed with CLI
3. Rutherford 4 to 6

#### Exclusion

1. Wheelchair bound
2. Previous stenting done at lower limb
3. Intervention is performed to prepare for planned major amputation
4. Neurotropic ulcer / heel pressure ulcer / ulcer involving calcaneus
5. Uncorrected bleeding disorders

# Post-op Follow Up

## 1 month POST-SURGERY

- Clinical follow-up (telephone or office visit)
- Data collected:  
Walking impairment questionnaire  
EQ-5D



## 3 months POST-SURGERY

- Clinical follow-up (telephone or office visit)



## 6 months POST-SURGERY

- Clinical follow-up (office visit)
- Data collected:  
Walking impairment questionnaire  
EQ-5D  
Ankle Brachial Index Test  
Duplex Ultrasound



## 12 months POST-SURGERY

- Clinical follow-up (office visit)
- Data collected:  
Walking impairment questionnaire  
EQ-5D  
Ankle Brachial Index Test  
Duplex Ultrasound

# Patient Demographics

	Number (n=25)	Percentage (%)
Mean Age, years (sd)		63.72 ± 9.73
Mean BMI (sd)		24.40 ± 4.88
Gender		
Male	17	68.0
Female	8	32.0
Ethnic Group		
Chinese	18	72.0
Malay	4	16.0
Indian	3	12.0
Smoking status		
Smoker	5	20.0
Non-smoker	16	64.0
Ex-smoker	4	16.0

Co-Morbidities (%)		
Diabetes	22	88.0
Hypercholesterolemia	19	76.0
Hypertension	22	88.0
Family history of CAD	1	4.0
CVA in the past 12 months	1	4.0
Myocardial Infarction	3	12.0
Angina	2	8.0
Congestive Heart Failure	4	16.0
End Stage Renal Failure (ESRF)	11	44.0

**Diabetes – 88%**

**ESRF – 44%**

# Procedural Information

Reason for intervention	Number (n=25)	Percentage (%)
Rutherford Classification		
5 ( <i>Minor tissue loss – nonhealing ulcer, focal gangrene with diffuse pedal ischemia</i> )	25	100
<b>Lesion details</b>	<b>Total lesions treated with DCB (n= 33)</b>	<b>Percentage (%)</b>
Location of Treated Vessel		
Anterior Tibial Artery (ATA)	17	51.5
Posterior Tibial Artery (PTA)	10	30.3
Common Plantar Artery	3	9.1
Dorsalis Pedis Artery (DPA)	3	9.1
De novo	21	63.6
Re-stenotic	12	36.4
TASC Classification		
C ( <i>multiple stenosis, &gt; 10cm lesion length</i> )	18	54.5
D ( <i>multiple occlusion, &gt; 10cm lesion length</i> )	15	45.5
Calcification Classification		
2 (focal)	6	18.2
3 (mild)	6	18.2
4 (moderate)	11	33.3
5 (severe)	10	30.3
<b>DCB details</b>	<b>Number of balloons (n=54)</b>	<b>Percentage (%)</b>
Balloon Diameter (mm)		
2.0	3	5.6
2.5	16	29.7
3.0	17	31.5
3.5	18	33.3

**Below Ankle (18.2%)**

**TASC C (54.5%)**

**TASC D (45.5%)**

**Calcification**

**2 (focal) – 18.2%**

**3 (mild) – 18.2%**

**4 (moderate) – 33.3%**

**5 (severe) – 30.3%**

# PRESTIGE Trial Case Examples



1 month post-op



2 months post-op





# CASE STUDY: SGH03

**Procedure date:** 31 Oct 2019

**Clinical Indication:** 3<sup>rd</sup> and 4<sup>th</sup> toes gangrene

**Proposed procedure:** Left LL Angioplasty, 3<sup>rd</sup> and 4<sup>th</sup> toe ray amputation

**Target Vessel:** ATA

**Vessel details:** TASC D, CTO, 300mm in length

## **Procedural details**

(1) Antegrade crossing subintimal 0.018" wire; Cook CXI catheter support

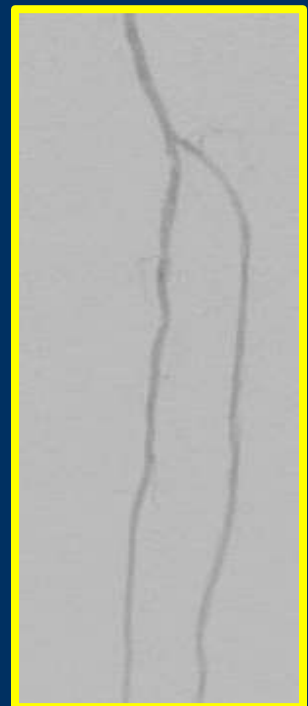
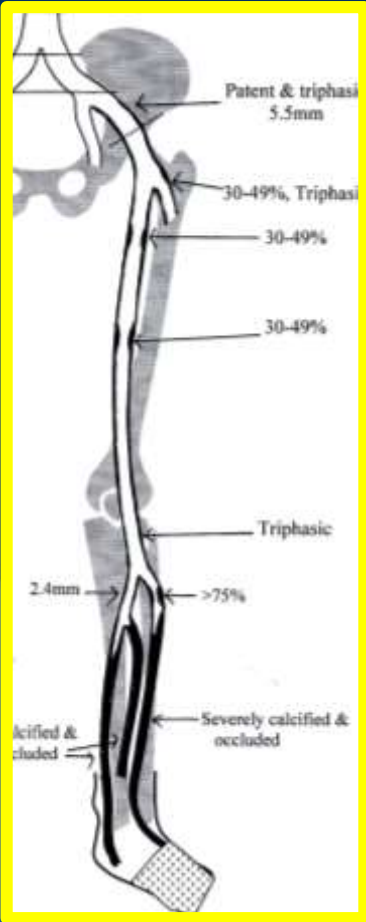
- Predilation: JADE (POBA) 2x180mm (dorsalis pedis distal ATA)
- Treated: Soluton SLR 2.5x150mm

(2)

- Predilation: Jade (POBA) 3x150mm (distal to prox ATA)
- Treated: Soluton SLR 3x150mm

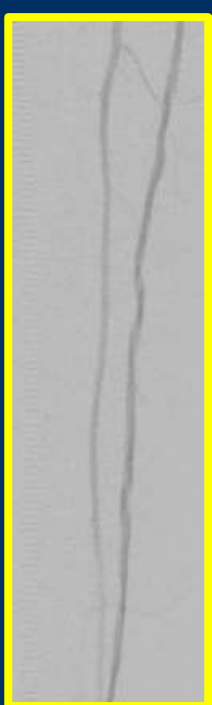
**Final Outcome:** < 30% Residual Stenosis

**Post-Angioplasty Angiogram findings:** 2 vessel run off via ATA and peroneal. DP2+



LEFT PRESSURES & TBI

Brachial		
Great Toe	54	
Toe 2		
Toe 3		
Toe 4		
Toe 5		



# SGH03 – Wound Healing Progression



Post-Amputation (Oct 2019)



1 week post-op



1 month post-op



2 months post-op

# CASE STUDY: SGH19

63-year-old Chinese male RIGHT lateral foot non healing wound for 4 weeks

**PMHx:** diabetes, hypertension, hypercholesterolemia, ESRF (DM nephropathy)

**Op date:** 26 Dec 2019

## **Target Vessel 1- ATA**

**Vessel details-** TASC D, long CTO and multifocal stenosis up to 95% (320mm)

### **Procedural details-**

Predilation: Armada 18 (POBA) 3x150mm

Treated: 2x Selution 3.5x150mm

**Final Outcome-** < 30% Residual Stenosis

## **Target Vessel 2- DPA**

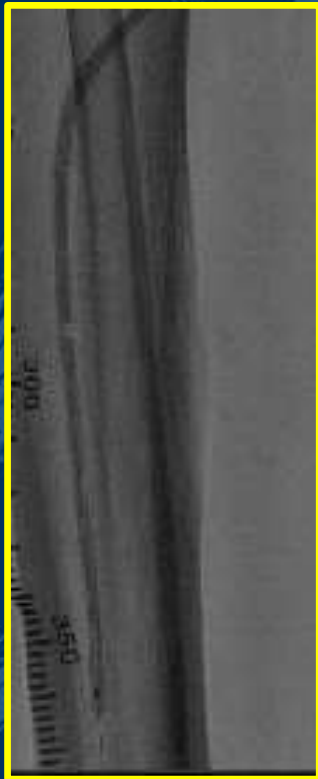
**Vessel details-** TASC C, Multifocal stenosis up to 90% , 60mm in length

### **Procedural details-**

Predilation: Coyote (POBA) 2x100mm

Treated: Selution 2.5x150mm

**Final Outcome-** < 30% Residual Stenosis



# CASE STUDY: SGH22

54 year old Chinese male; Diabetes, Hypercholesterolaemia, hypertension

Failed right lower limb angioplasty at another local hospital

**Op date:** 30 Dec 2019

**Clinical Indication:** RIGHT foot dorsal gangrene and 4<sup>th</sup> toe wet gangrene

## **Target Vessel 1- PTA**

**Vessel details-** TASC D, Proximal to mid PTA CTO, 150mm

**Procedural details-**

Predilation: JADE (POBA) 3x240mm

Treated: 2x Solution 3 x150mm

**Final Outcome-** < 30% Residual Stenosis

## **Target Vessel 2- Common Plantar and Lateral Plantar**

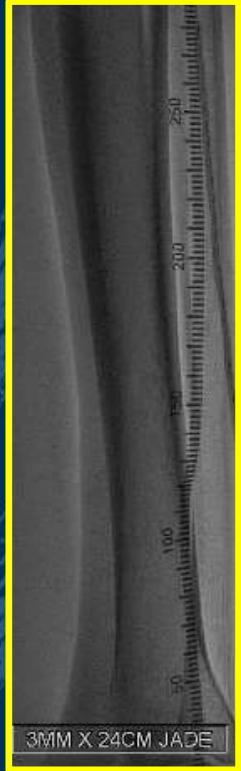
**Vessel details-** TASC C, Multifocal stenosis up to 99% , 150mm

**Procedural details-**

Predilation: JADE (POBA) 2x180mm

Treated: Solution 2.5x150mm

**Final Outcome-** > 30% Residual Stenosis mid CPA



# SGH22 – Wound Healing Progression





# Selution™ Balloon SGH Experience

- Positive Initial SCB Experience
- 2mm, 2.5mm, 3.0mm, 3.5mm and 4.0mm x150mm used
- Generally followed a 1:1 POBA-DCB sizing although using a DCB 0.5mm bigger no issue
- Good trackability over an 0.018" platform
- Short Deflation time
- Good visible markers to place the balloon accurately
- Minimal slow flow phenomenon even after treating infra-malleolar lesions
- No serious adverse events using the balloon catheter
- Six months data awaited – available July 2020

# Jade –Selution – PTx Combo



# Is Selution™ the Solution?



I was lucky to be in the right place at the right time. But many others were also in the same place. The difference was that I took action.

— *Bill Gates* —

AZ QUOTES

**Right Place, Right Time, Prime Time?**



**Thank You!**

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