Long-term Evidence of Directional Atherectomy and DCB: 3 Years Clinical Experience from Australia

Dr Vikram Puttaswamy FRACS
Head of Unit
Department of Vascular Surgery
Royal North Shore Hospital
Sydney

Disclosure

Speaker name: Vikram Puttaswamy

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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

An evolving practice for infra-inguinal occlusive disease in Australia

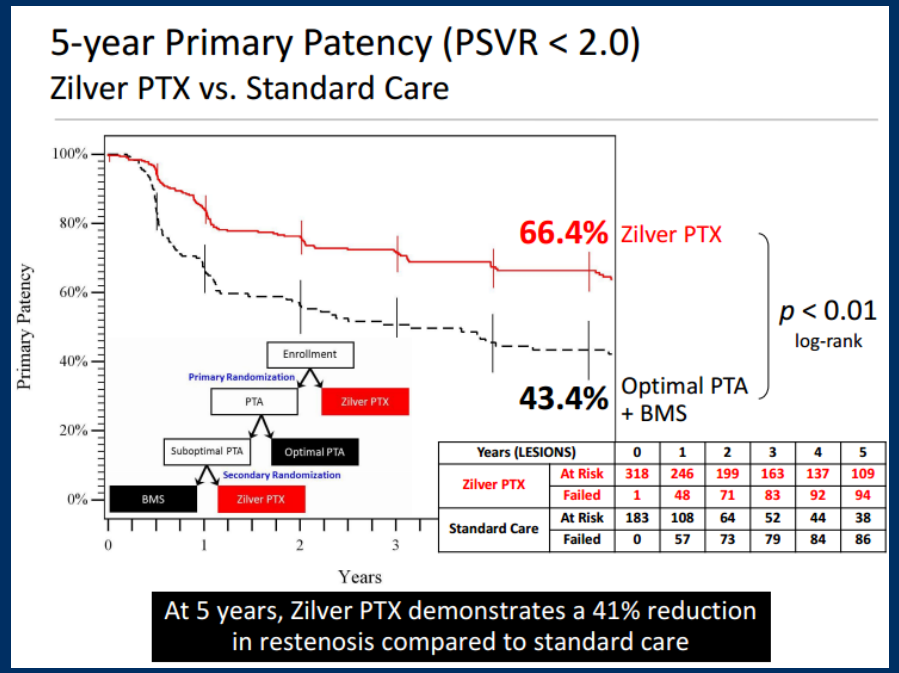
- ❖I have been performing open vascular surgical and endovascular procedures for over 19 years in a quaternary teaching hospital setting

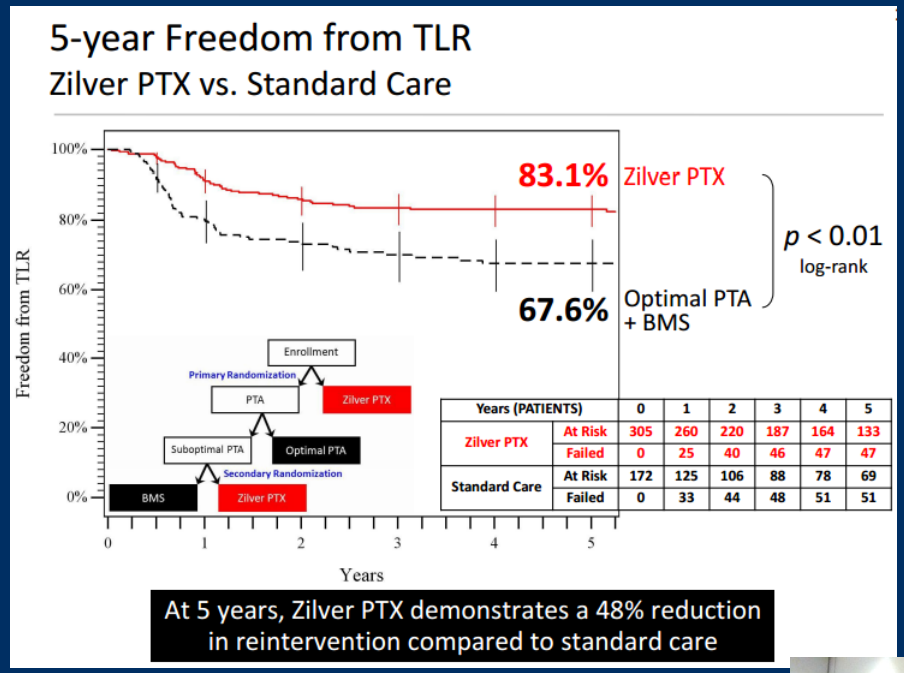
- ❖I have used many infra-inguinal endovascular revascularisation techniques

- In around 2016 it was clear from the available data sets that paclitaxel based treatments were providing the better results than their plain balloon angioplasty or bare metal stent counterparts

Zilver PTX RCT evidence

- 5 year evidence available from a large RCT (Zilver PTX n=236 vs. PTA n=238)

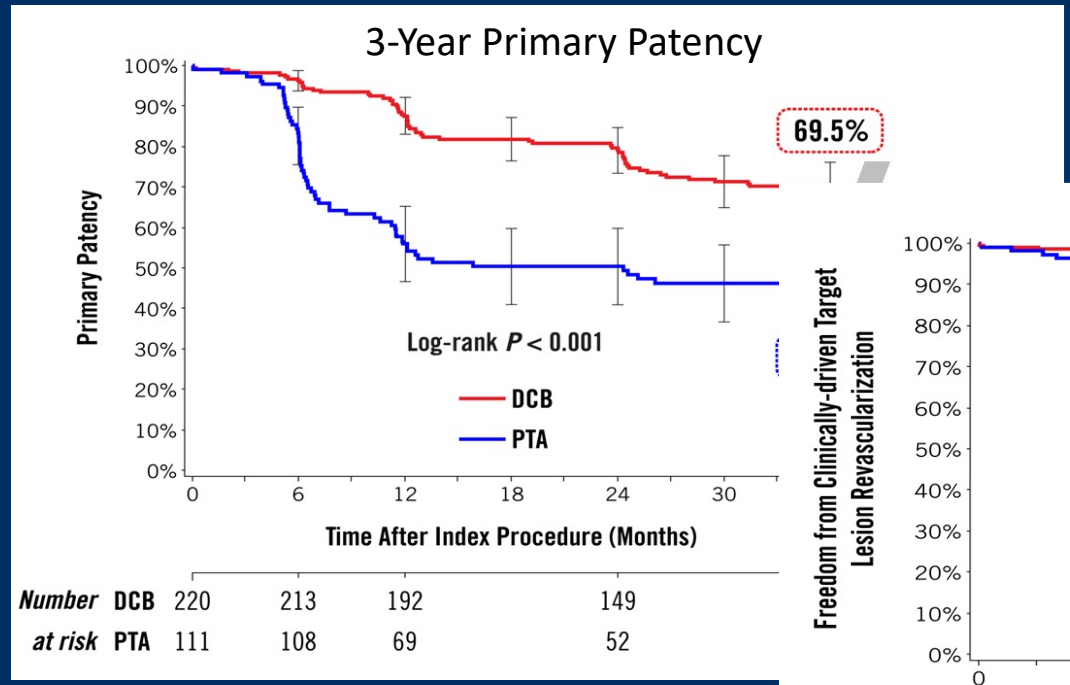


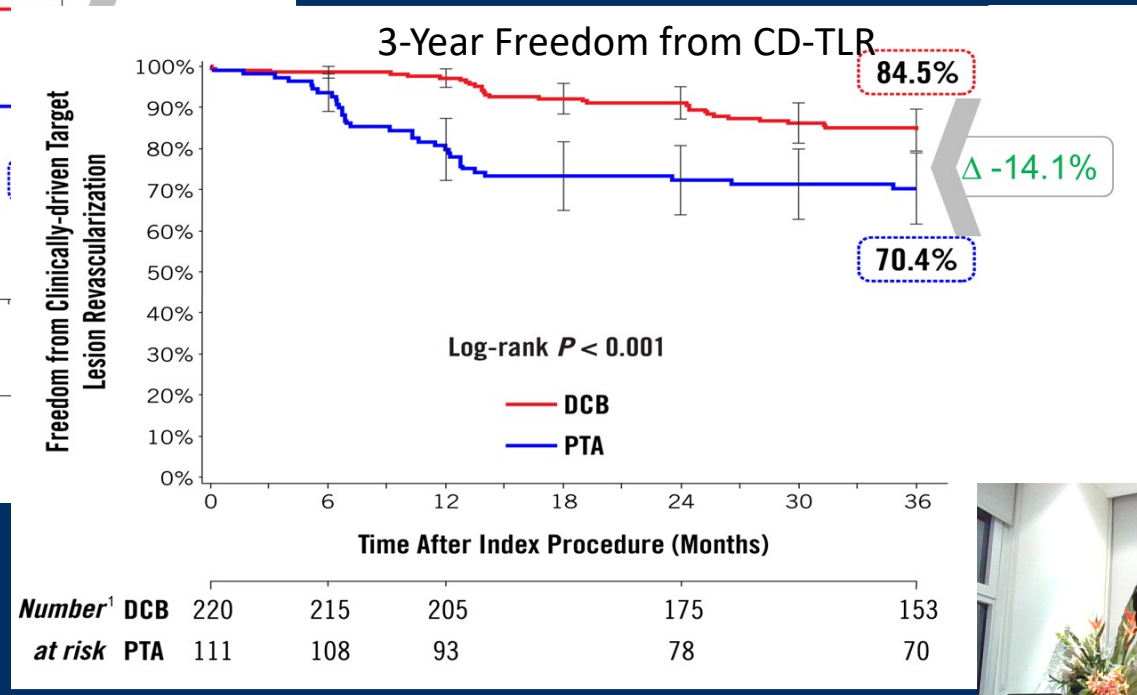


M. Dake. The Zilver PTX® Randomized Controlled Trial of Paclitaxel-Eluting Stents for Femoropopliteal Disease: 5-Year Results. Presented at LINC 2015.

IN.PACT Admiral DCB RCT

- **3 year Primary Patency** and **CD-TLR** available from the **IN.PACT SFA** - a large EU+US RCT (n=220 IN.PACT Admiral vs. n=111 PTA)





P. Krishnan. Drug-coated balloons show superior three-year outcom
angioplasty: results from IN.PACT SFA randomized trial. Presented a

Is there something better than these options?

- However despite using these treatments it was clear that many of my patients were requiring significant re intervention and the CLI patients were still requiring major amputations on a regular basis.

- Atherectomy systems were only just being introduced around that time in Australia

- There were so many to choose from, which one to use?

DEFINITIVE LE Trial Overview

DESIGN

- Prospective, multinational, single-arm study
- Clinical events committee (CEC) adjudicated adverse events
- Largest Core Lab* adjudicated atherectomy trial

OBJECTIVE

To evaluate the effectiveness of standalone SilverHawk™/TurboHawk™ Peripheral Plaque Excision Systems for endovascular treatment of peripheral arterial disease in the femoropopliteal and tibioperoneal arteries

PATIENTS

800 PATIENTS

- Pre-specified comparison of patients with / without diabetes

SITES

47 TOTAL SITES

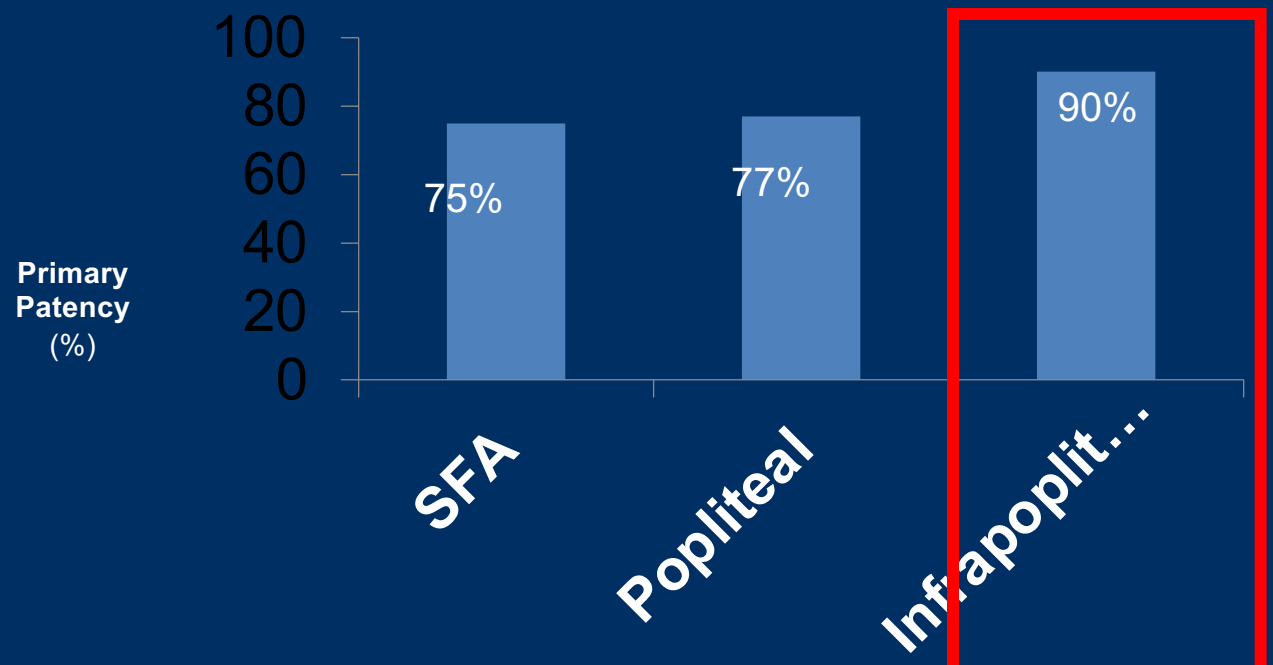
- US and EU

DEFINITIVE LE Patency - Overall

	Lesion Number	Lesion Length (cm)	Primary Patency at 12 months
All Claudicants	743	7.5	78%
All CLI patients	279	7.2	71%

Primary patency by duplex ultrasound at 12 months (PSVR ≤2.4 with no clinically-driven reintervention)

DEFINITIVE LE Patency - Claudicants



Mean Length:	8.1 cm	6.0 cm	5.5 cm
Number of Lesions:	536	114	93

Primary patency by duplex ultrasound at 12 months (PSVR ≤2.4 with no clinically-driven reintervention); Patency value determined by Kaplan-Meier analysis

McKinsey, J. F., et al. (2014). JACC Cardiovasc Interv 7(8): 923-933.

DEFINITIVE LE TRIAL COMPLICATION RESULTS

Distal Embolization 3.8%	Perforation 5.3%	Dissection 2.3%
Endovascular Intervention - 1.5% (12)	Endovascular Intervention - 4.0% (32)	Endovascular Intervention - 1.5% (12)
Surgical Intervention - 0.1% (1)	Surgical Intervention - 0.1% (1)	Surgical Intervention - 0.0% (0)
None - 2.1% (17)	None - 1.1% (9)	None - 0.8% (6)

DEFINITIVE AR[1]

Pilot study to detect trends in treatment differences between groups and designed to assess the effect of treating lesions with DA followed by DCB (DAART)

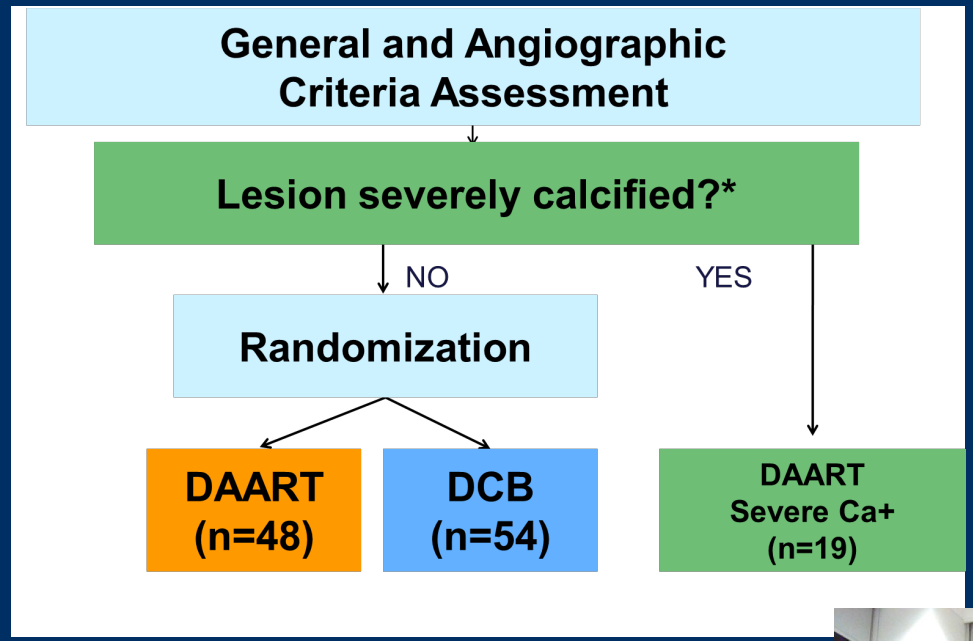
DAART: Directional Atherectomy + Anti-Restenotic Therapy

Inclusion Criteria

- RCC 2-4
- ≥ 70% stenosis of SFA and/or popliteal artery
- Lesion Length 7-15cm
- Reference Vessel ≥ 4mm and ≤ 7mm

Exclusion Criteria

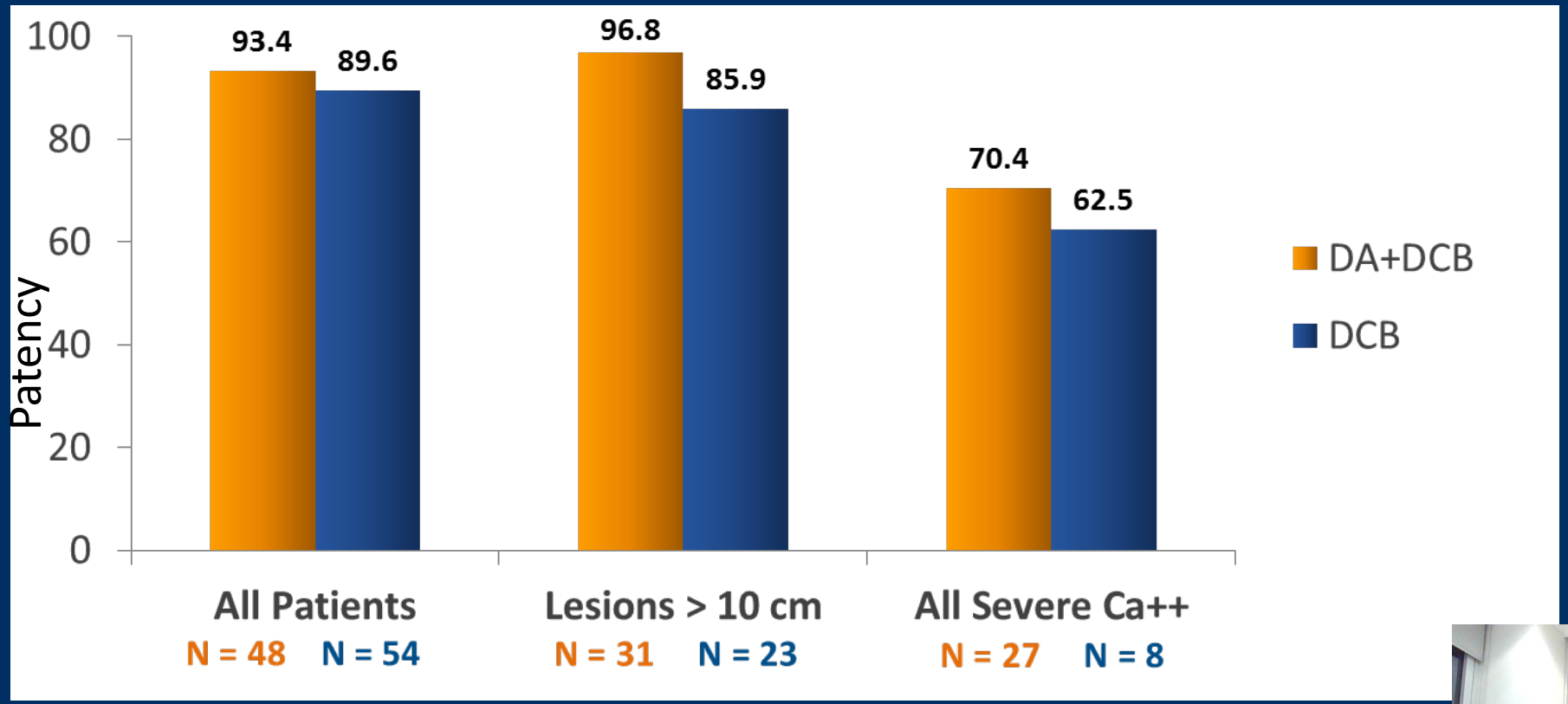
- In-stent restenosis
- Aneurysmal target vessel
- Multiple lesions in target limb that require treatment



1. "DEFINITIVE AR: A Pilot Study of Antirestenosis Treatment. 12-month Results: Direc
   Paclitaxel-Coated Balloon to Inhibit Restenosis and Maintain Vessel Patency" presente

DEFINITIVE AR: 12-mo Patency via DUS[1]

Potential Advantage Emerging in Long and Severely Calcified Lesions



Per Core Lab Assessment. "All Severe Ca++ " group includes all patients treated with DA+DCB therapy including randomized and non-randomized patients with severe calcium.

1. "DEFINITIVE AR: A Pilot Study of Antirestenosis Treatment. 12-month Results: Directional Atherectomy Followed by a Paclitaxel-Coated Balloon to Inhibit Restenosis and Maintain Vessel Patency" presented by Zeller T, VIVA Las Vegas 2014.

Directional atherectomy combined with DCB

- It made more sense to remove plaque with atherectomy and then once prepared, perform paclitaxel coated angioplasty to the diseased arterial tree

- The best evidence available at the time suggested that directional atherectomy with the Hawk system followed by DCB (InPact), was likely to be best treatment choice

North Shore Registry for Hawk Directional Atherectomy

(Oct 2016 – Feb 2022 ongoing)

- Established a single arm, prospective registry of patients with infrainguinal arterial disease requiring intervention with the TurboHawk or HawkOne atherectomy devices

- SFA / popliteal artery disease
- Common femoral artery disease
- Tibial artery disease
- In-stent SFA / popliteal stenoses

- Following treatment with Hawk DA all lesions, wherever possible, were then treate drug coated balloon angioplasty

North Shore Registry for Hawk Directional Atherectomy

(Oct 2016 – Feb 2022 ongoing)

- Patients have been followed up postoperatively at 1, 3, 6 months and then further regular intervals with clinical review and duplex ultrasound

- For reinterventions, angiograms were also assessed

- Independent assessors performed the assessment of clinical records , imaging and statistical analysis

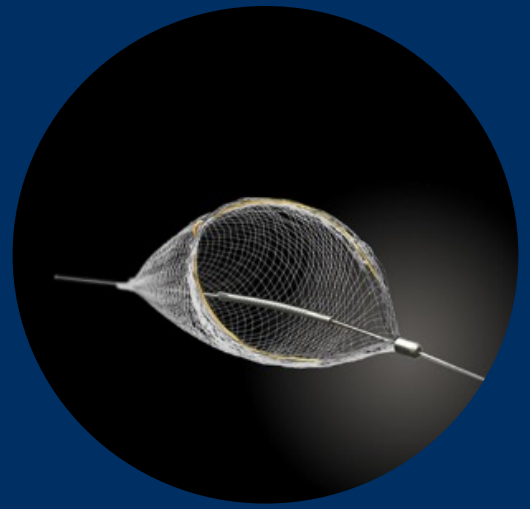
- Endpoints
  - primary patency (duplex defined with PSVR > 2.4)
  - freedom form cdTLR
  - MAE
  - and very importantly, major amputation rates

DA + DCB at North Shore Campus: Methods

- Usually via a retrograde puncture in the contralateral limb / less commonly antegrade

- Medtronic HawkOne Directional Atherectomy system

  - 7Fr Hawk LS or LX — for 3.5 to 7mm diameter arteries
  - 6 Fr Hawk M — for 3 to 7 mm diameter arteries
  - 6 Fr Hawk S — for 2 to 4mm diameter arteries



- Medtronic SpiderFX embolic protection device used in all cases

- DCB angioplasty of atherectomised segment used in combination
  - InPact for 7- 4mm arteries
  - Multiple tibial DCB's – Lutonix / Passeo Lux / Ranger

DA + DCB at North Shore Campus

- Total of 289 patients treated with directional atherectomy from October 2016 to June 2021
- 747 procedures
- 877 separate lesions in native arteries
- 102 instent SFA and popliteal arteries
- Technical success with intention to treat = 98.58%

Median age at first procedure	82
Sex	
Female	51.4%
Male	48.6%
Smoking status	
Current	10.6%
Ex	39.7%
Non	39.7%
Unknown	10.1%
Diabetes	20.7%
HTN	
Hyperlipidaemia	

DA + DCB in the SFA and popliteal arteries

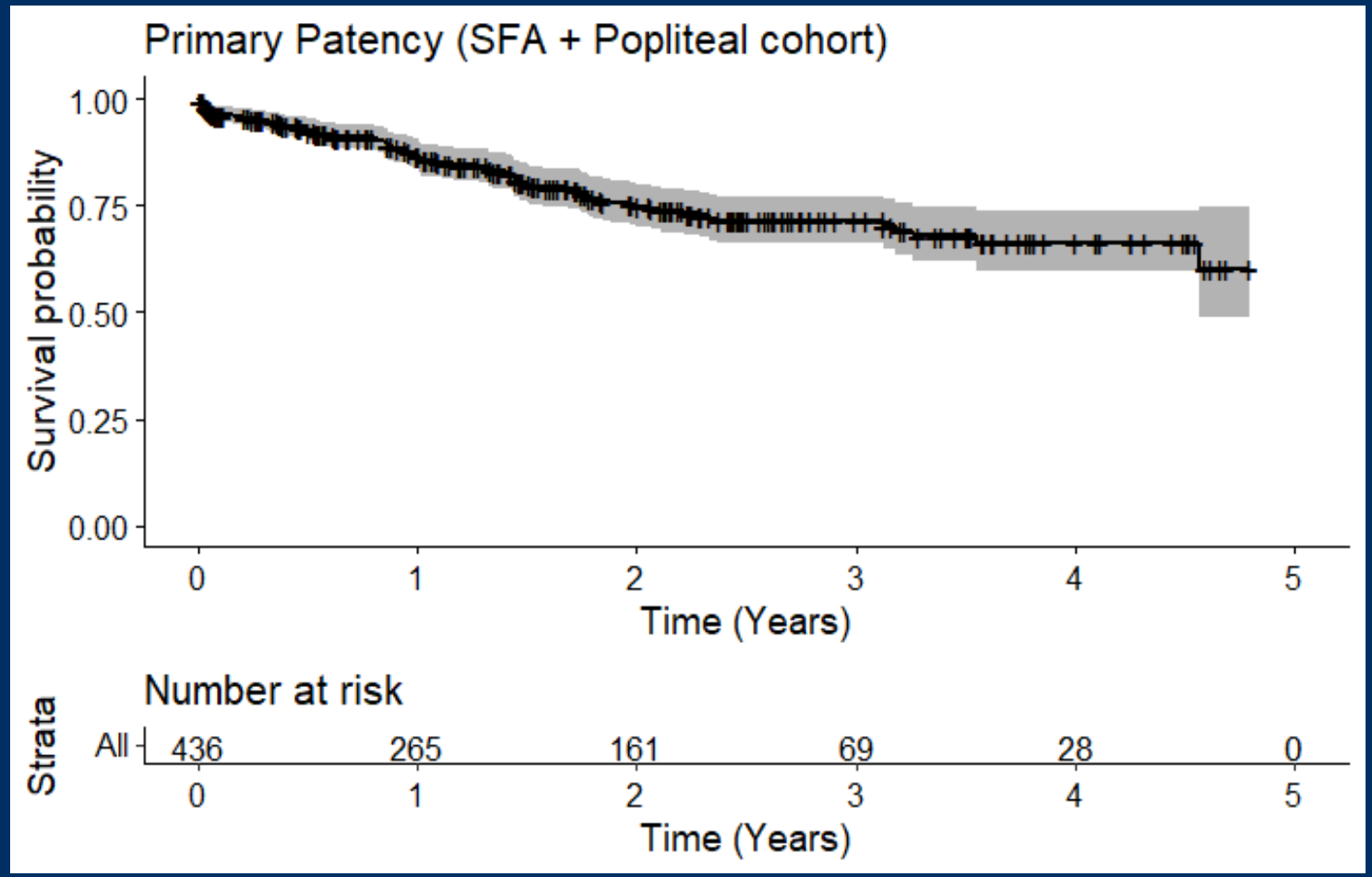
- 179 patients had atherectomy in the native femoropopliteal segment (not including in-stent)

- 436 native separate lesions treated in the SFA / popliteal atherectomy procedures
  - 56.5% claudicants
  - 43.5% CLI (rest pain or tissue loss/ulceration)

  - Lesion length ranged from 2 to 40 cm

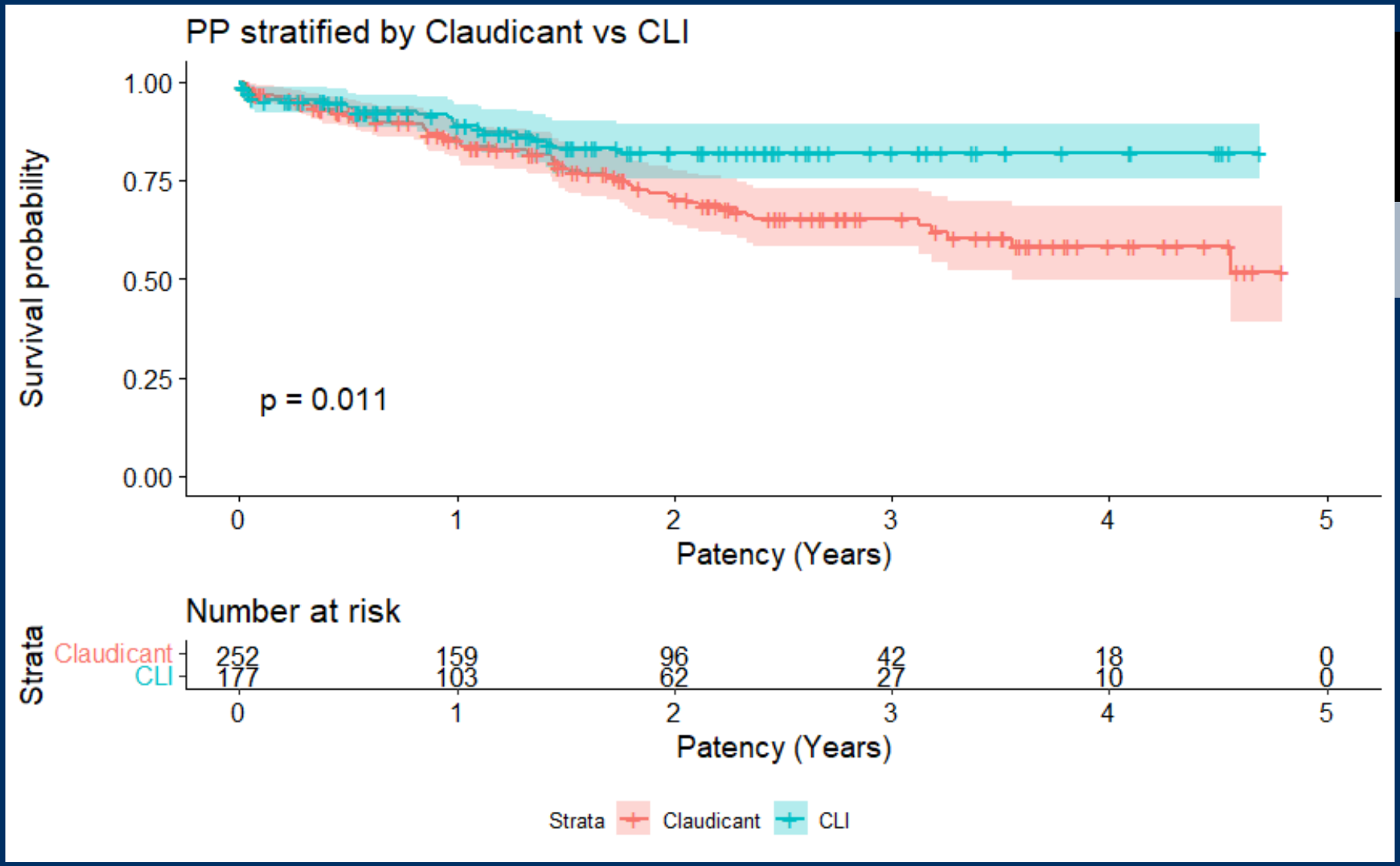
  - All comers were treated with DA and DCB first paradigm

Primary patency of SFA / popliteal lesions treated with DA and DCB



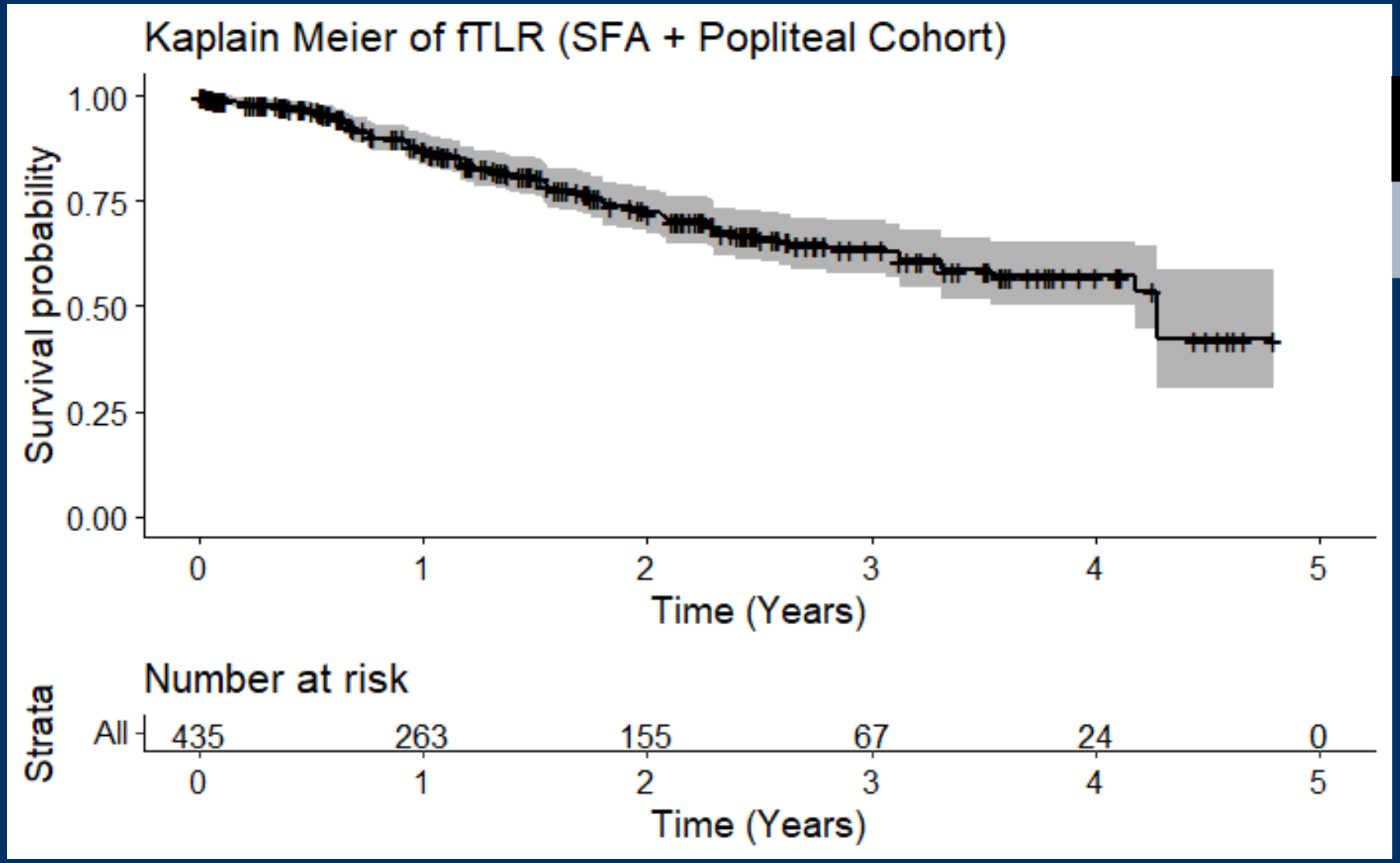
6 Month	1 Year	2 Year	3 Year
92.5%	86.8%	74.7%	71.4%

Primary patency of SFA / popliteal lesions Claudicants vs CLI



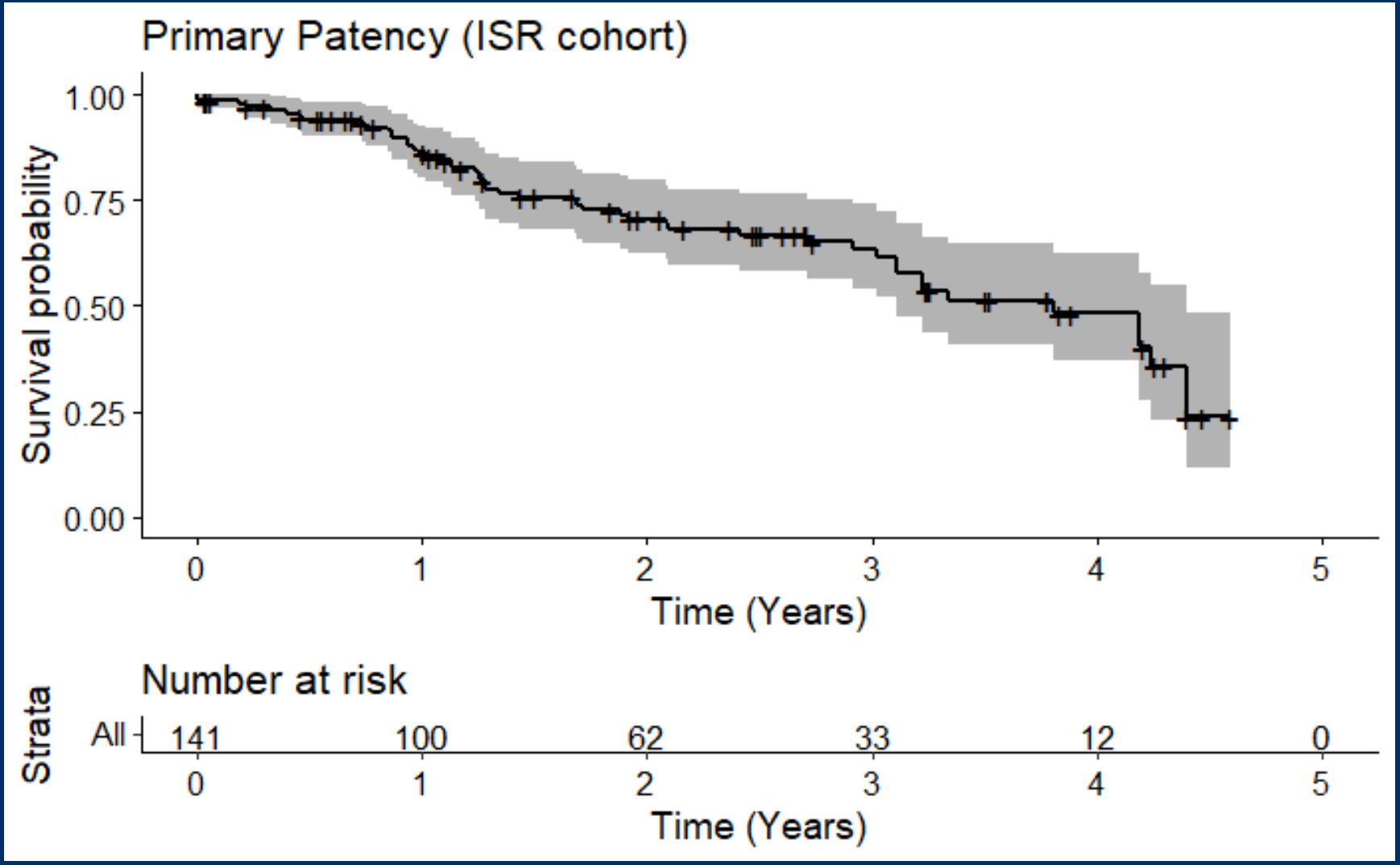
1 Year	2 Year	3 Year
86.8%	74.7%	71.4%

Freedom from cdTLR of SFA and Popliteal lesions



1 Year	2 Year	3 Year
87.2%	72.1%	63.8%

Primary patency of SFA / popliteal instent lesions treated with DA and DCB



- 102 SFA and popliteal instent procedures
- 141 lesions

1 Year	2 Year	3 Year
86.2%	70.5%	63.2%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Right


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Post-PTA
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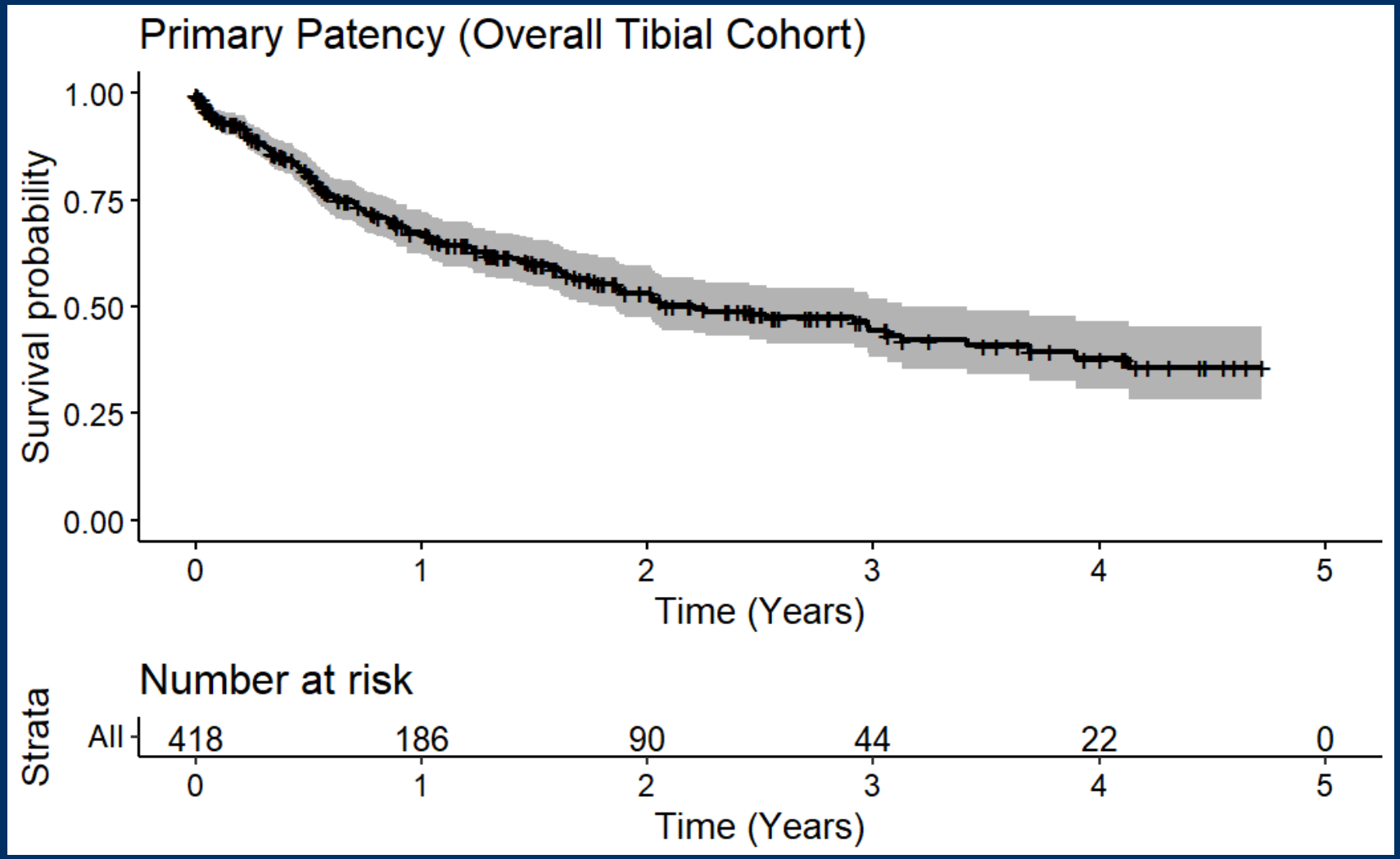
3

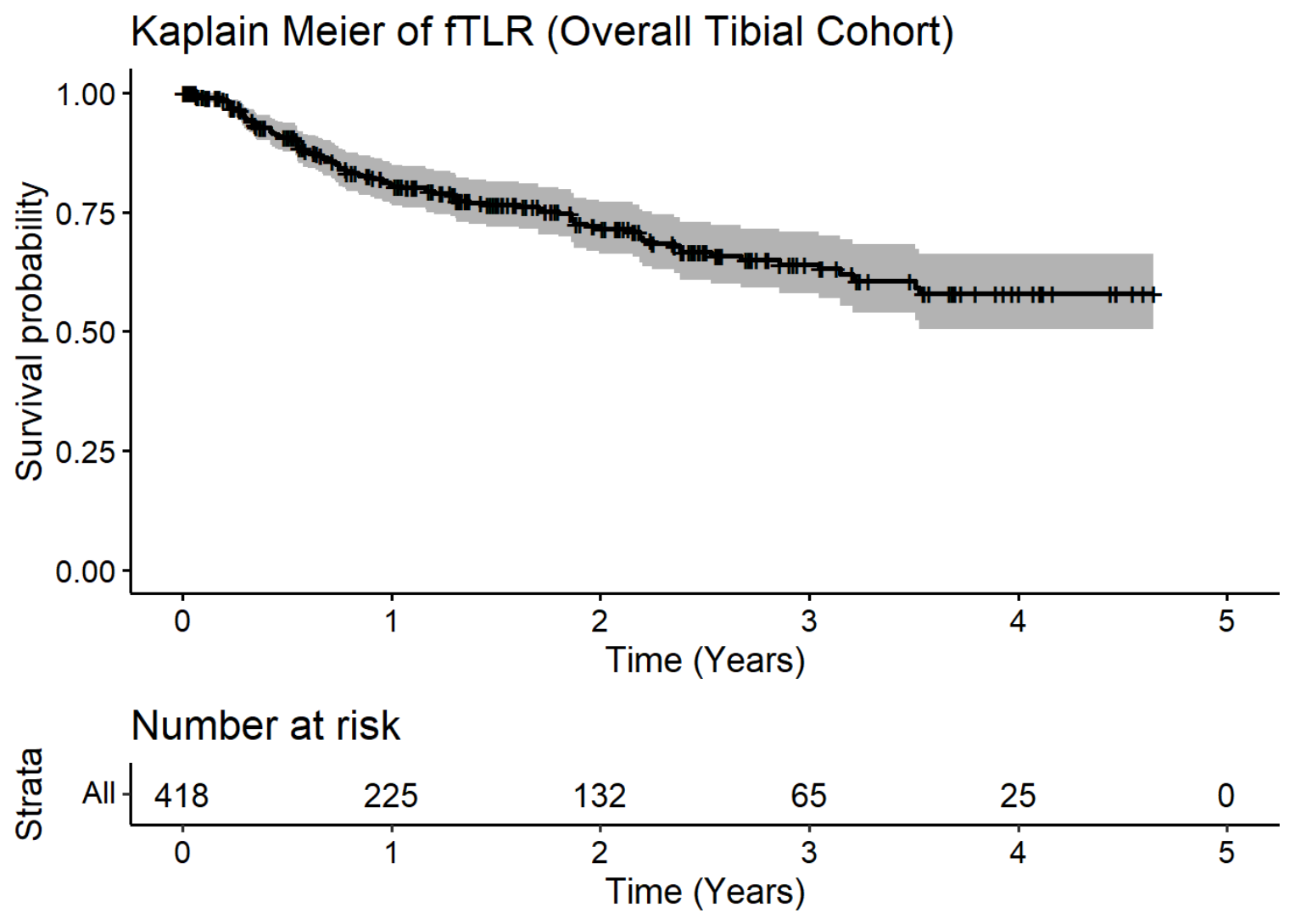
Primary patency of entire tibial cohort treated with DA and DCB



- 267 legs
- 418 discrete lesions

1 Year	2 Year	3 Year
67%	53.2%	44.4%

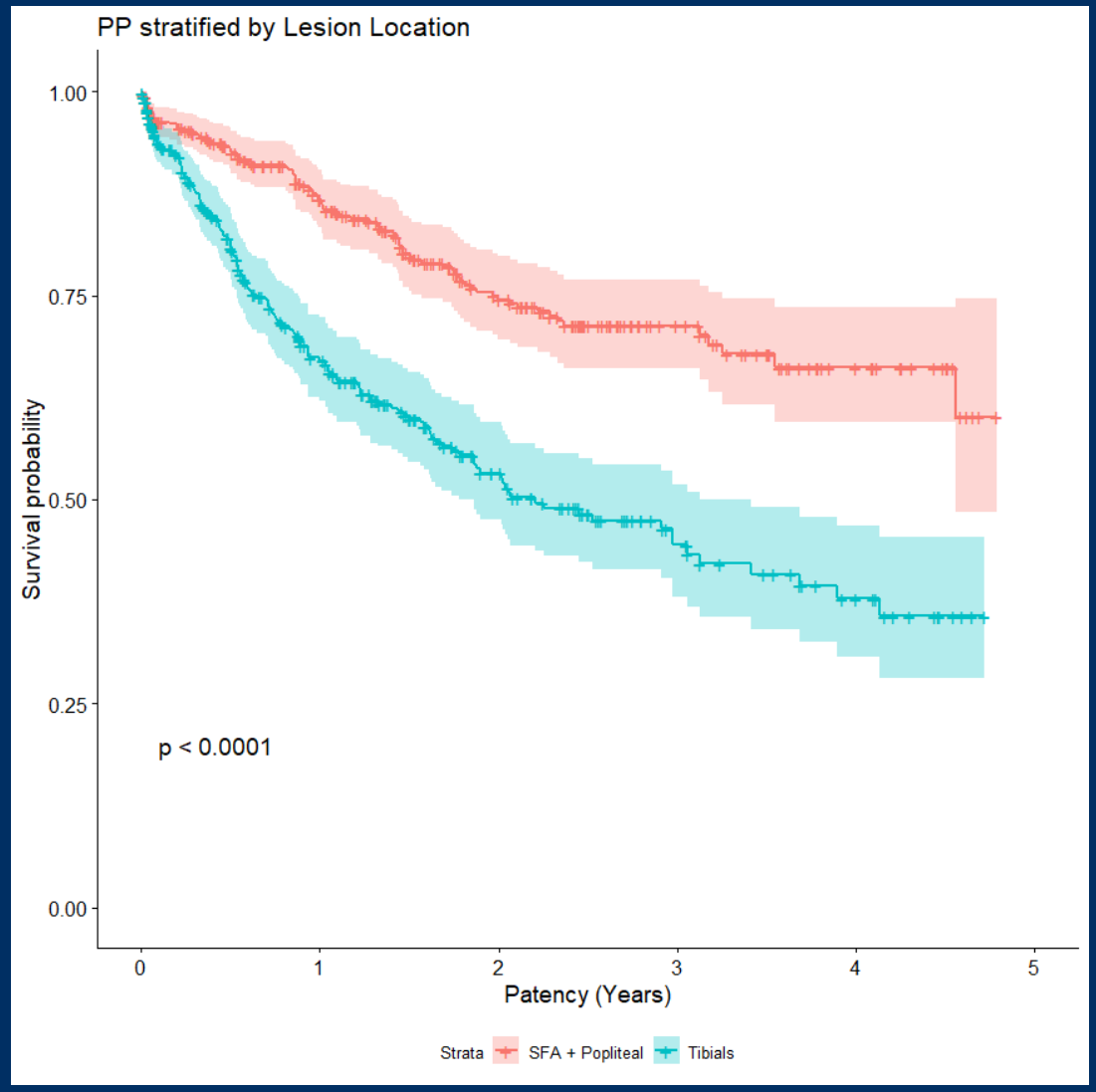
Freedom from cdTLR of entire tibial cohort treated with DA and DCB

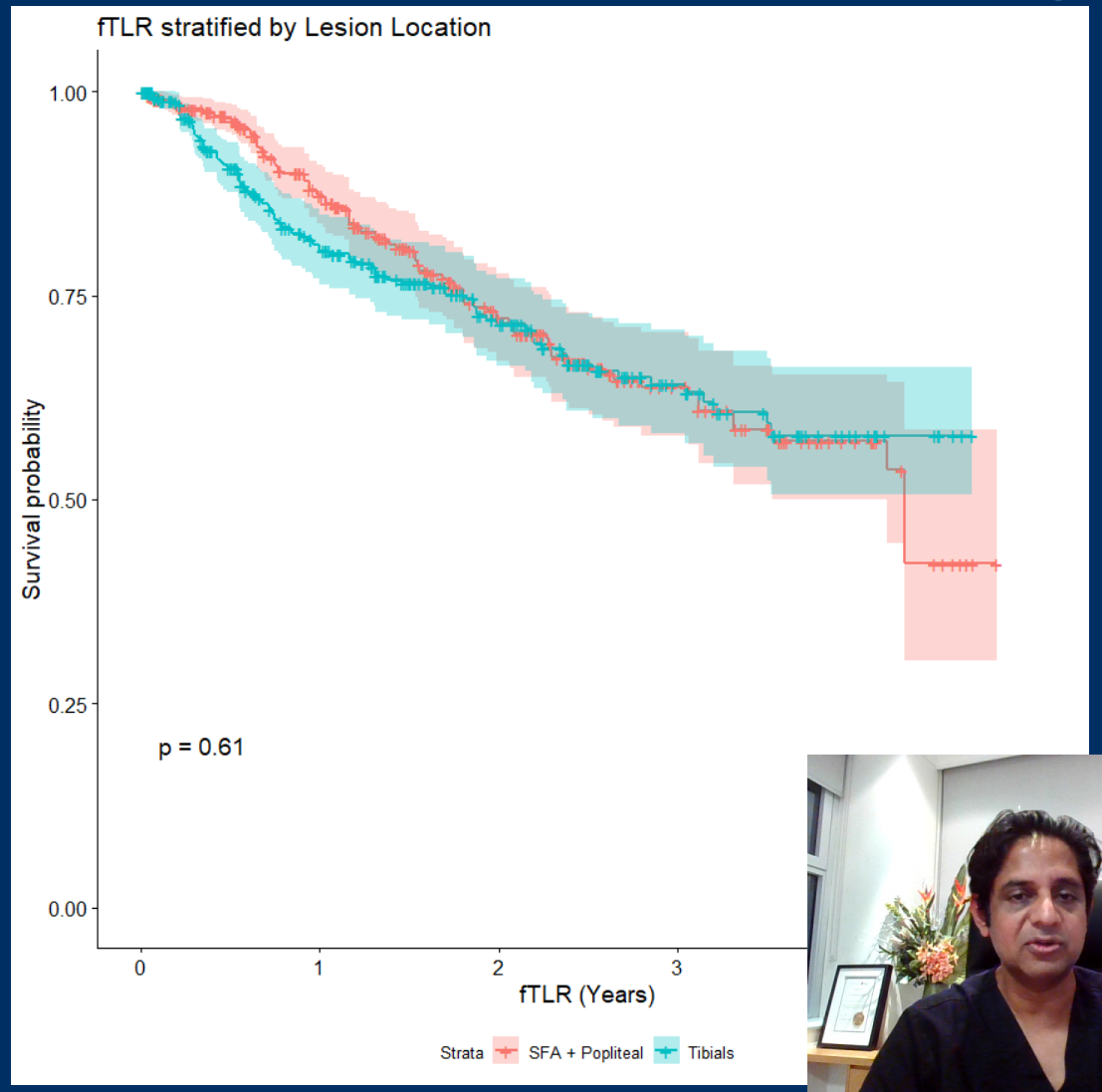


- 267 legs
- 418 discrete lesions

1 Year	2 Year	3 Year
80.5%	71.5%	64.1%

Femoropopliteal vs Infrapopliteal DA and DCB results





MAE results of DA + DCB: Entire Cohort

- Target vessel complications in 2.39%
- Bail out stenting in only 0.57%
- 1.87% distal embolisation/thrombosis
  - All treated with endovascular means
  - No surgical conversions
- All cause 3 year mortality 10.6%
  - No procedure related mortality
  - 0 deaths within 30 days
  - 7 deaths within 6 months
- 0 Major Amputations in the entire cohort

Access vessel	**2.4%**
Pseudoaneurysm	1.2%
Distal vessel	**2.28%**
Thrombosis / emboli	1.87%
Perforation	0.4%
Target vessel	**2.39%**
Thrombosis	0.23%
Dissection	0.57%
Perforation	
AV Fistula	
Filter complication	

HawkOne Directional Atherectomy combined with paclitaxel DCB

- Combination treatment of paclitaxel based DCB with HawkOne Directional atherectomy has a definite role in treating all supramalleolar infra-inguinal arteries; not only the SFA and popliteal arteries but also in tibial disease and ISR

- Our study, in a very elderly population, shows similar results in the SFA / Pop region to the REALITY trial, that continues in an encouraging way, over a 3 year period

- The risk of MAE is low and DA can decrease the chance of dissection when applied as a preparation tool for angioplasty and rarely causes target vessel complications nor needs bail out stenting

- If performed effectively and in conjunction with a robust surveillance program can lead to very low major amputation rates in CLI patients

- As the session states, this is just a Teaser. There is a lot mora data and analysis that we would like to discuss in the near future

Acknowledgements

- To the many dedicated staff involved in this ongoing project

- Registrars — Chris Selvaraj, David Herlihy, Naomi Anning, Raleene Gatmaitan, Kira Patel and Erin Saricilar

- Clinical Trials Nurse — Linda Pallot

- Data manager and statisticians — Peter Moritz and Eric Jiang

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