First time release of 1 year results of MagicTouch PTA XTOSI trial for SFA and BTK disease

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Disclosure

Speaker name:

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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) Research Grant from Concept Medical

- ☐ I do not have any potential conflict of interest

XTOSI First in man clinical trial:

Clinical use and safety of the Magic Touch – Sirolimus coated PTA balloon catheter in the treatment of infrainguinal peripheral arterial disease

Design: Prospective, premarket, non-randomized, all comers single-arm trial

Clinicaltrials.gov NCT04368091

XTOSI

Sirolimus Coated Balloon

N=50

EFFICACY ENDPOINT

Primary patency at 6 months

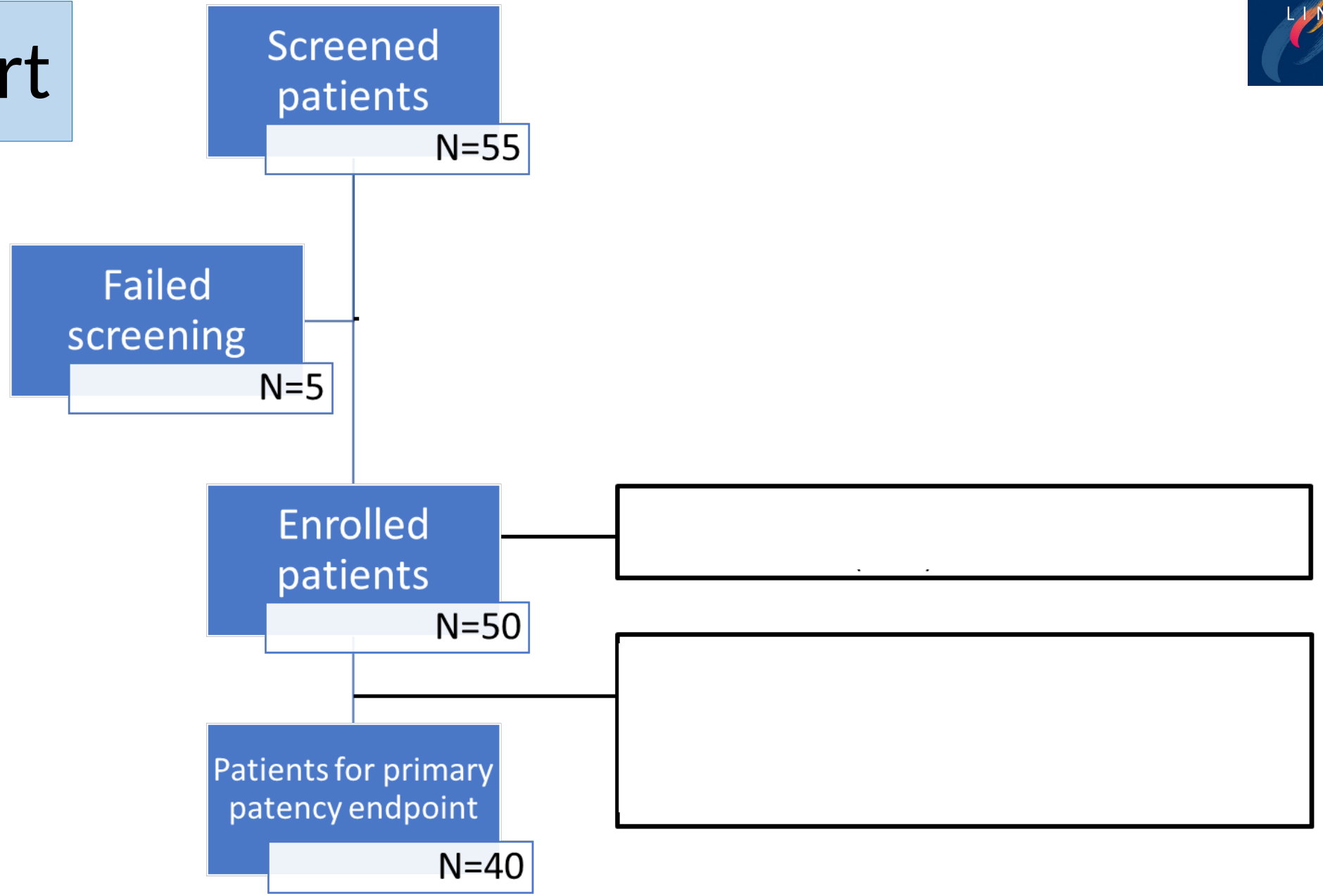
Duplex PSVR ≤ 2.4

SAFETY ENDPOINT

Composite of freedom from

1) **30-day mortality and amputation**
2) **6 month TLR**

Flow chart


Screened patients
N=55
Failed screening
N=5
Enrolled patients
N=50
Patients for primary patency endpoint
N=40

Demographics (High risk with critical limb ischemia)

	N=50
Age	67 (41-89)
Male	31 (62%)
Diabetes	45 (90%)
Hypertension	41 (82%)
High cholesterol	43 (86%)
Dialysis	10 (20%)
Coronary artery disease	18 (36%)
Previous stroke	6 (12%)
Smoker (current or prior)	23 (46%)

	N=50
ASA Score	
2	10 (20%)
3	39 (78%)
4	1 (2%)
Rutherford scores	
3	2 (4%)
4	1 (2%)
5	39 (78%)
6	8 (16%)
WIFI scores	N=47 (%)
1 to 3	23 (49%)
4 to 8	24 (51%)

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Lesion characteristics (Long hostile lesions)

	N=50	Femoropopliteal N=20	Below the knee N=30
Lesion characteristics			
Total length of lesions	227mm ± 81	277 ± 108	193 ± 22
Stenosis	31 (62%)	10 (50%)	21 (70%)
Occlusion	18 (36%)	9 (45%)	9 (30%)
In stent restenosis	1 (2%)	1 (5%)	0
Procedural details			
Stent use after SCB	4 (8%)	4 (20%)	0
Retrograde access to cross target lesion	13 (26%)	9 (45%)	4 (13%)
Fluoroscopic time (minutes)	28.2 ± 17	33.3 ± 17	24.4 ± 17
Contrast volume (mls)	86.9 ± 49	106.4 ± 33	74.4 ± 54

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Primary Endpoints

	All N=50	Femoropopliteal N=20 (% or range)	Below the knee N=30 (% or range)
6 Month Primary patency	80.0%	88.2%	74.0%
For comparison		RANGER RCT 87.0% LEVANT 2 LUTONIX 90.0%	SINGAPACLI 42.0%
6 month Freedom from MAE	86.3%	89.5%	84%

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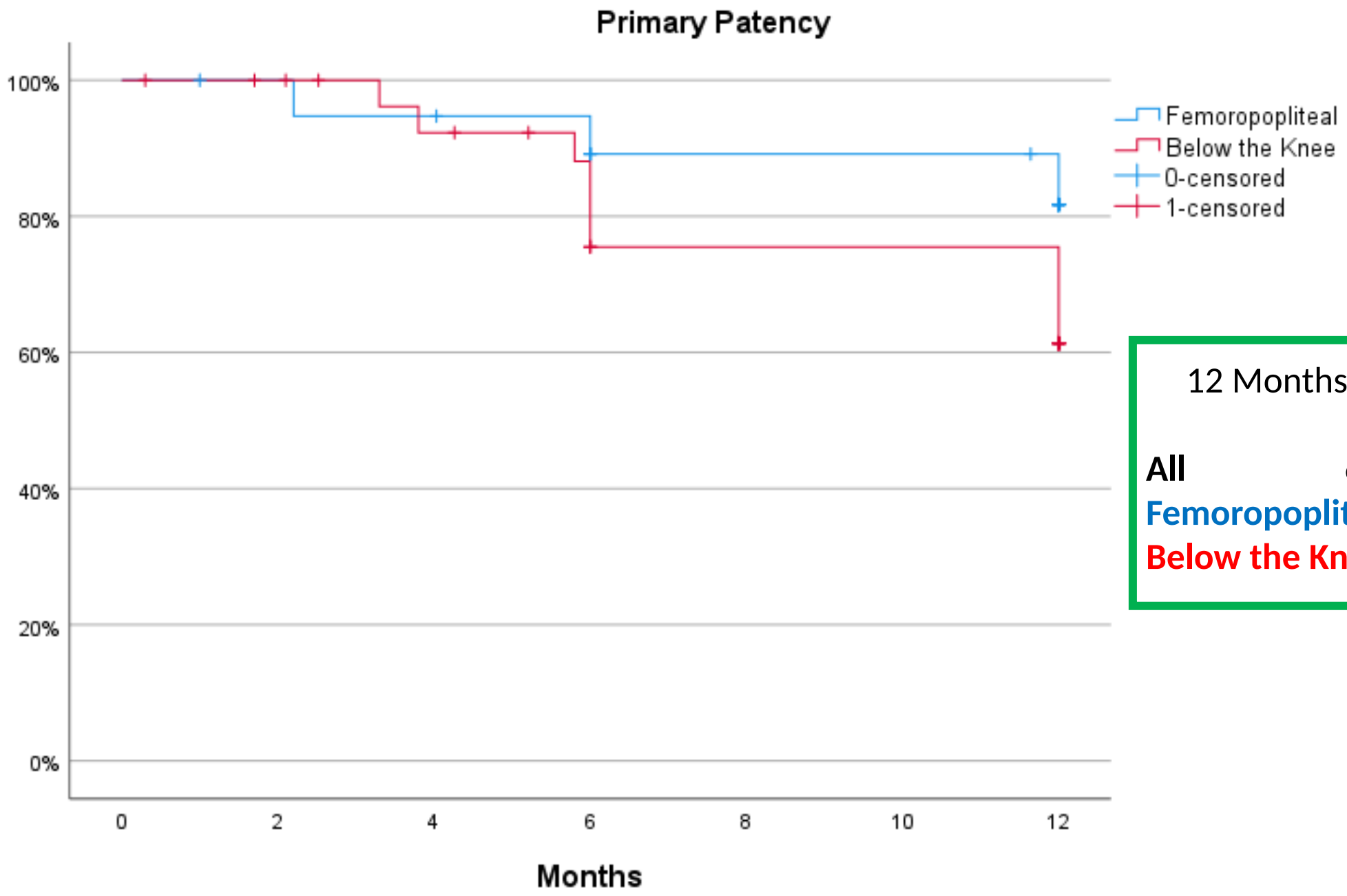
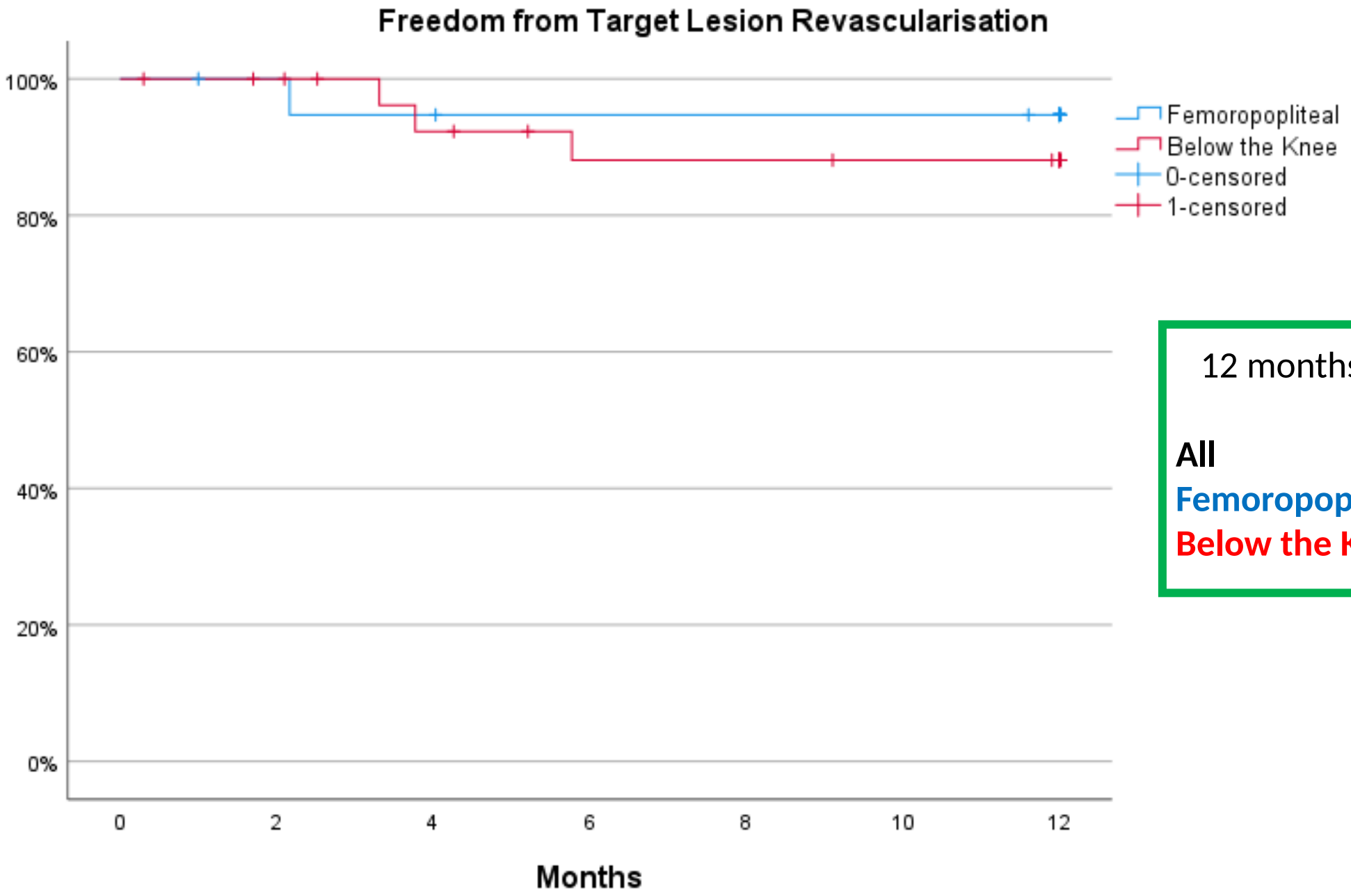
12 month results



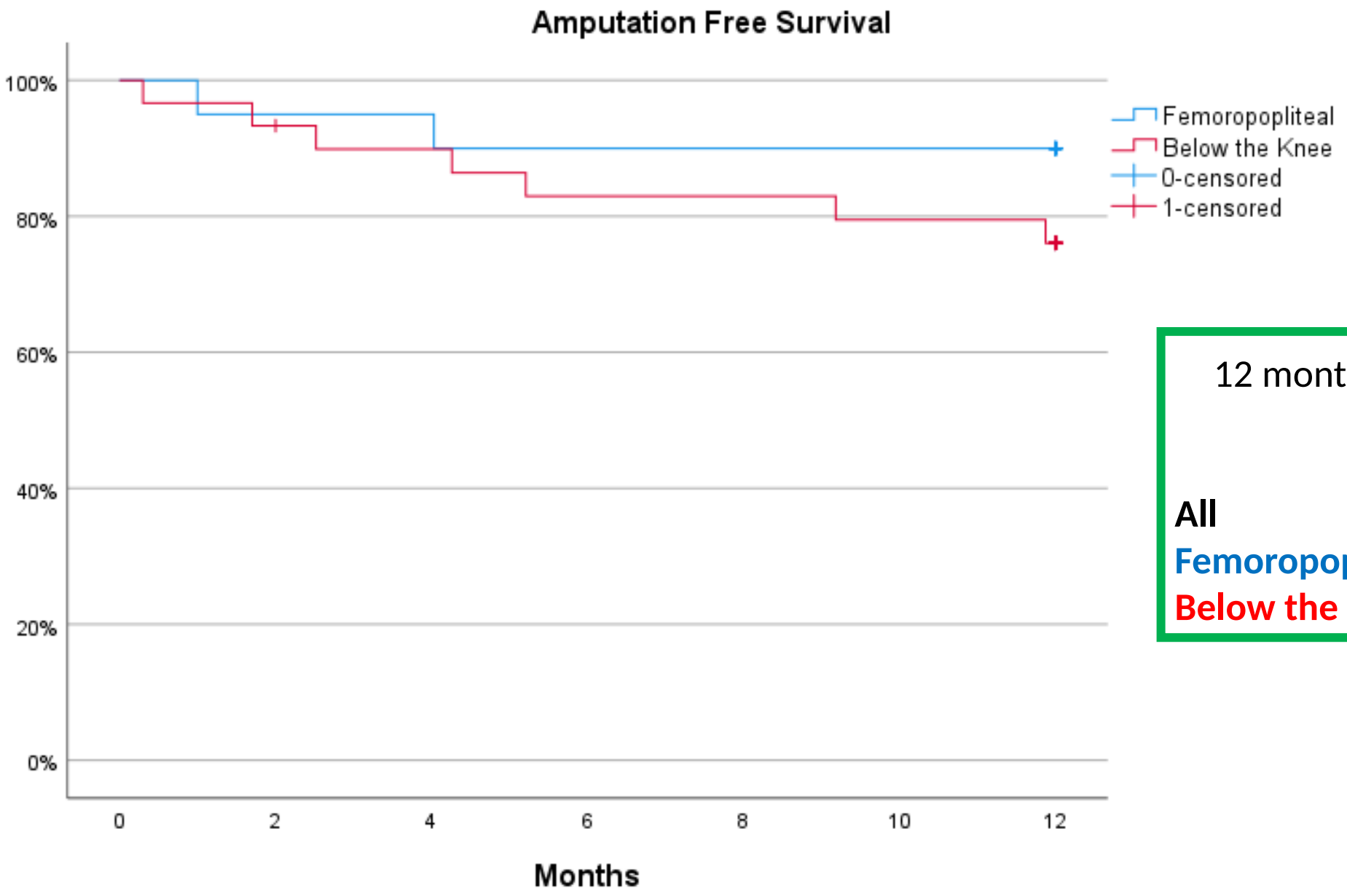
12 Months Primary Patency

All	66.7%
Femoropopliteal	78.6%
Below the Knee	59.0%



12 months Freedom from TLR

All	89.7%
Femoropopliteal	94.1%
Below the Knee	86.3%



12 months Amputation Free Survival	
All	81.6%
Femoropopliteal	90.0%
Below the Knee	75.9%

Death and Amputations at 1 year

	N=50
Death at 1 year	7(14%)
Ischemic Heart Disease	3 (6%)
Pneumonia	1 (2%)
Stroke	1 (2%)
Unknown (Died elsewhere)	2 (4%)
Amputation at 1 year	3 (6%)

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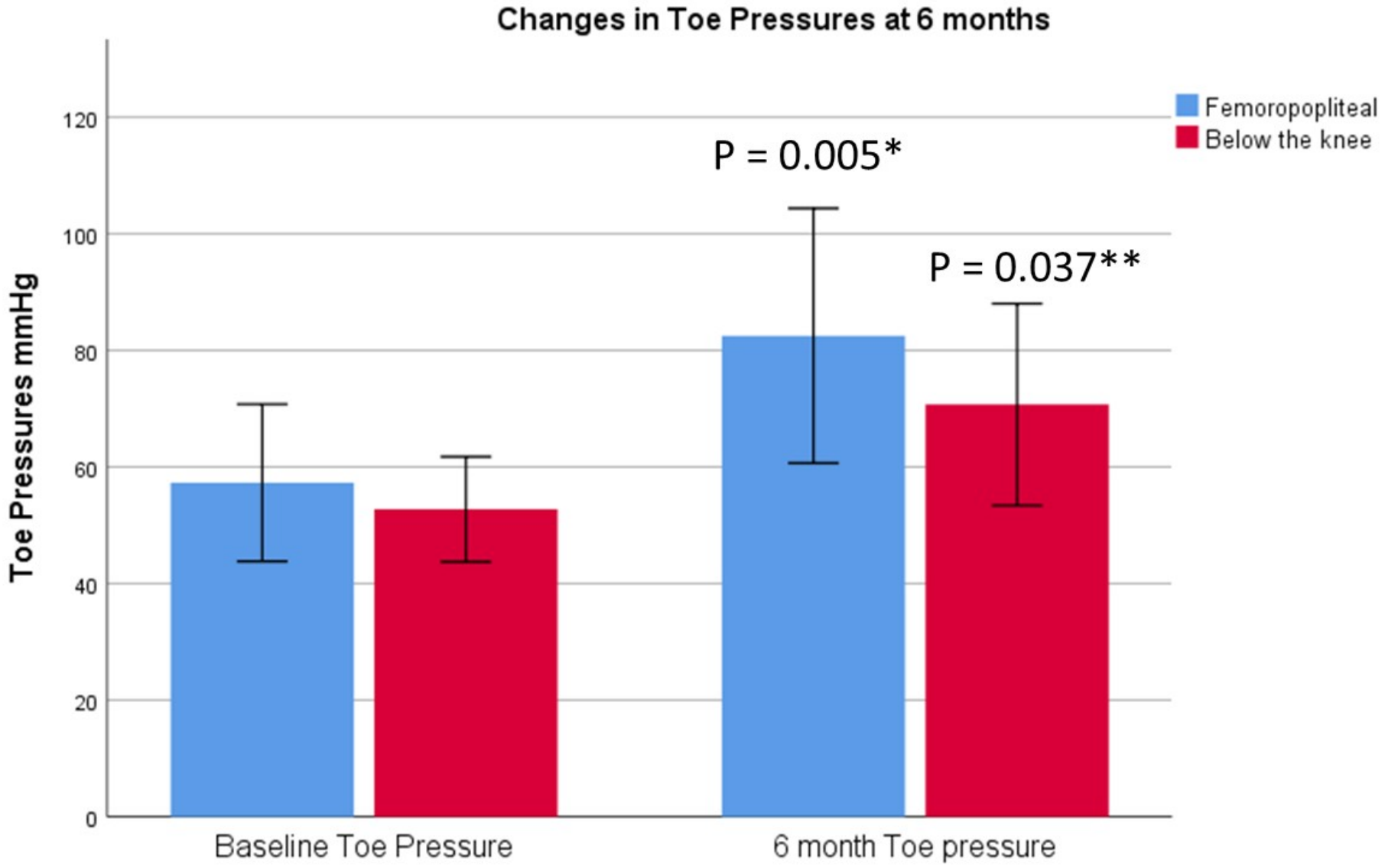
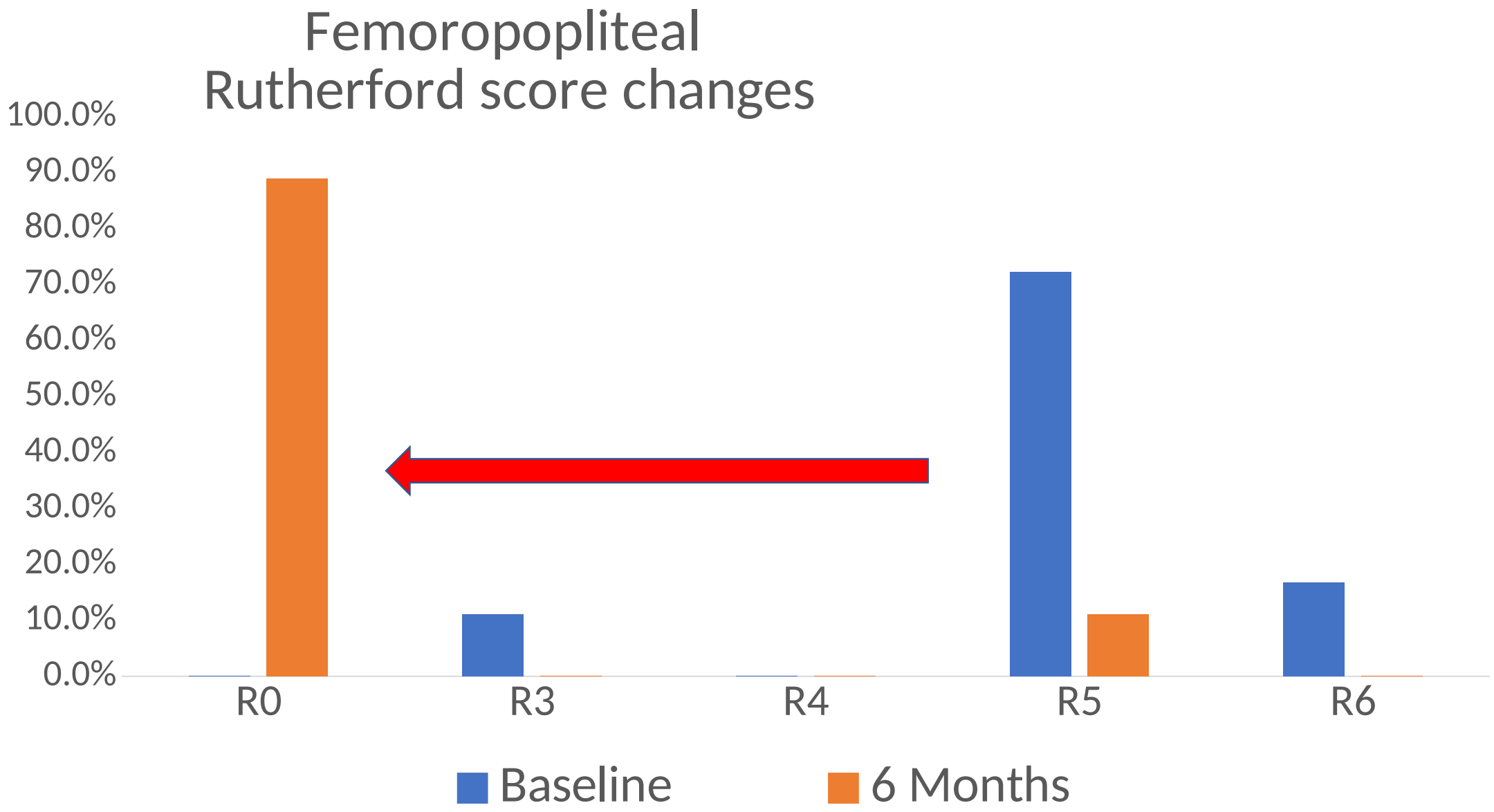
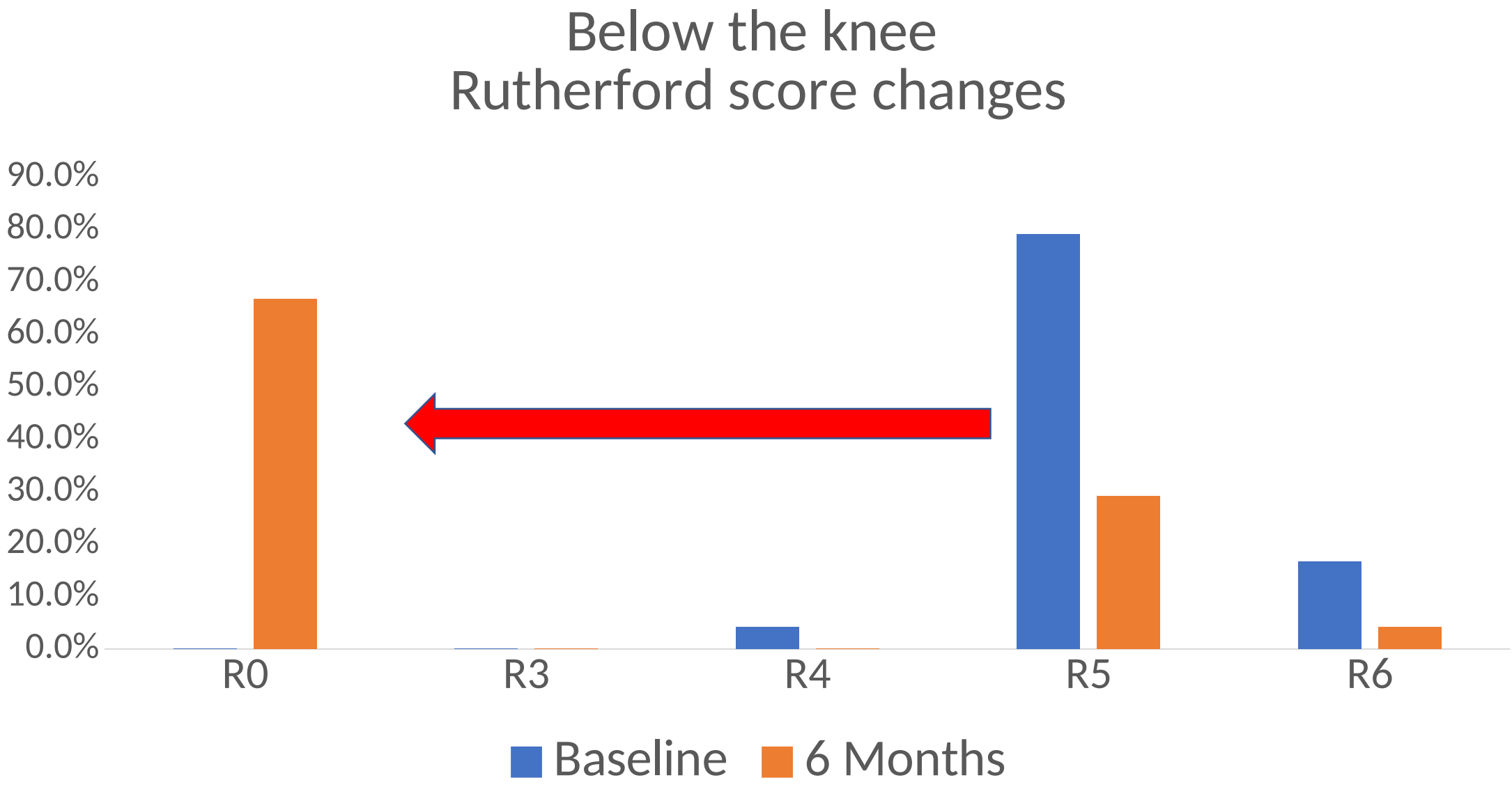
Sustained improvement in toe pressures at 6 months




Femoropopliteal
Rutherford score changes
100.0%
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
R0
R3
R4
R5
R6
Baseline
6 Months


Below the knee
Rutherford score changes
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
R0
R3
R4
R5
R6
Baseline
6 Months

Summary

- MagicTouch PTA
  - Promising 6 and 12 month efficacy and safety
    - high risk patient group
    - CLI cohort
    - hostile lesions