



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

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Singapore

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



EFFICACY ENDPOINT

Primary patency at 6 months

Duplex PSVR \leq 2.4



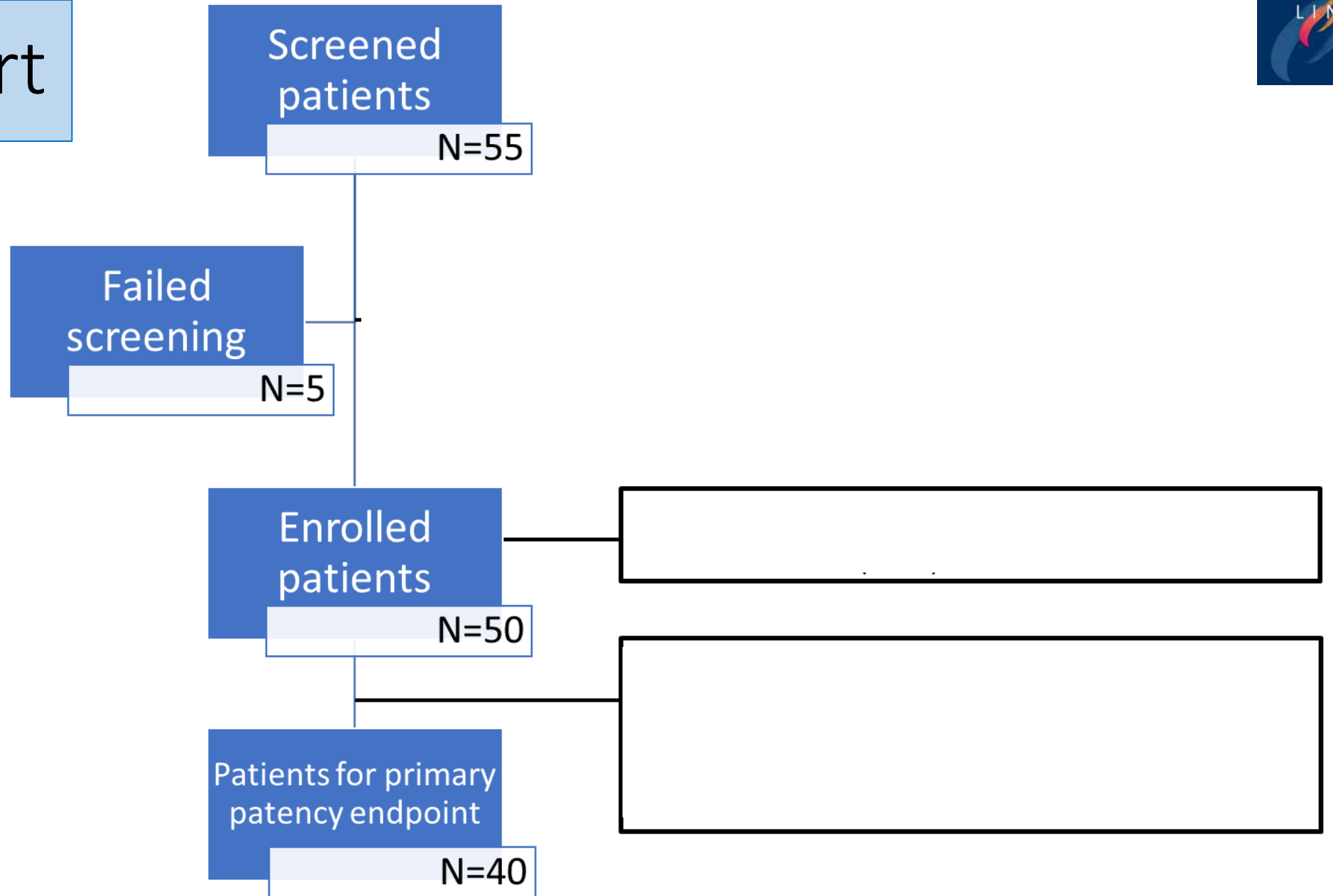
SAFETY ENDPOINT

Composite of freedom from

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

N=50

Flow chart



Demographics (High risk with critical limb ischemia)



| N=50 | | N=50 | |
|---------------------------|------------|-------------------|----------|
| Age | 67 (41-89) | ASA Score | |
| Male | 31 (62%) | 2 | 10 (20%) |
| Diabetes | 45 (90%) | 3 | 39 (78%) |
| Hypertension | 41 (82%) | 4 | 1 (2%) |
| High cholesterol | 43 (86%) | Rutherford scores | |
| Dialysis | 10 (20%) | 3 | 2 (4%) |
| Coronary artery disease | 18 (36%) | 4 | 1 (2%) |
| Previous stroke | 6 (12%) | 5 | 39 (78%) |
| Smoker (current or prior) | 23 (46%) | 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% |
| | | RANGER RCT 87.0% | SINGAPACLI |
| | For comparison | LEVANT 2 LUTONIX 90.0% | 42.0% |
| 6 month Freedom from MAE | 86.3% | 89.5% | 84% |

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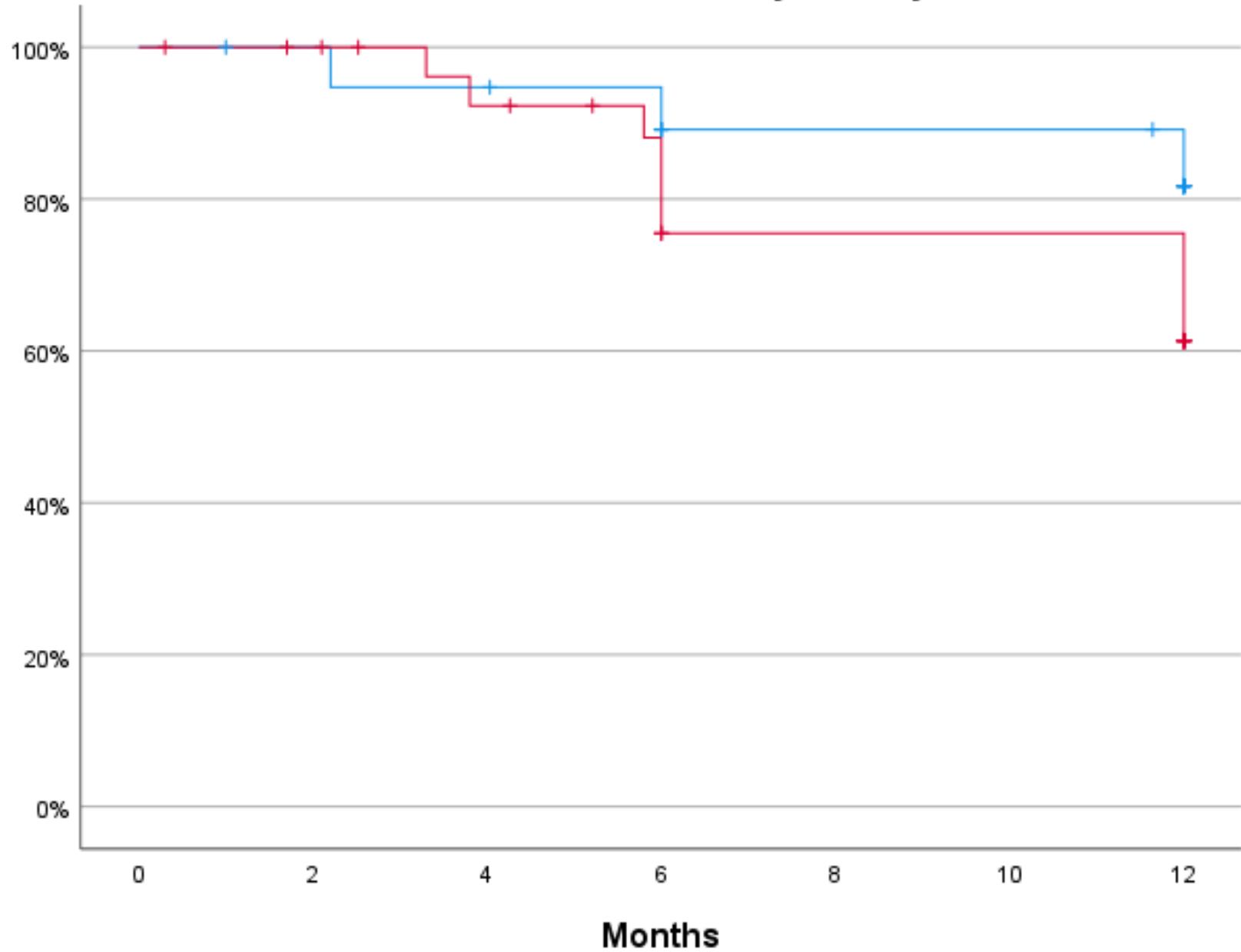


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12 month results

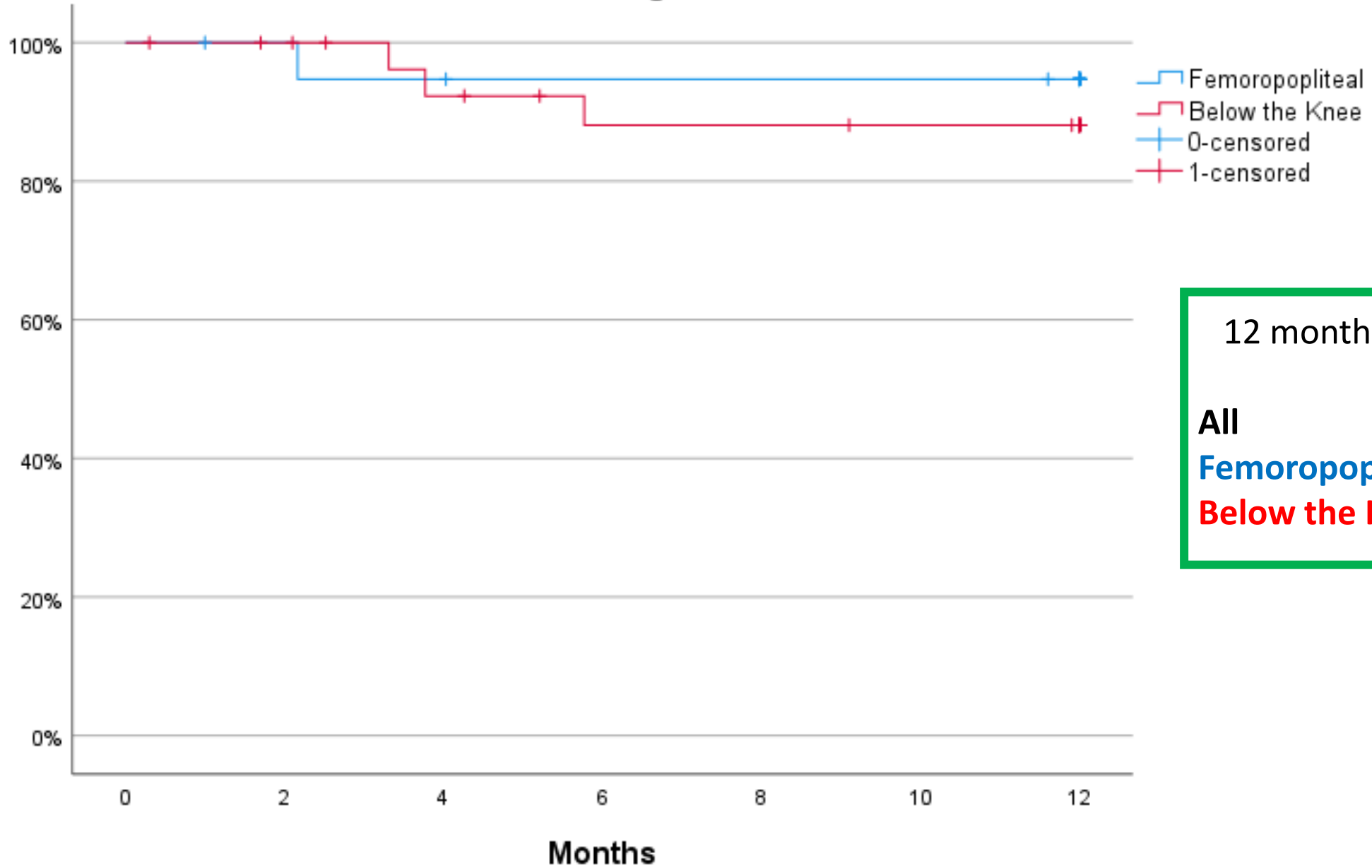
Primary Patency



Femoropopliteal
Below the Knee
0-censored
1-censored

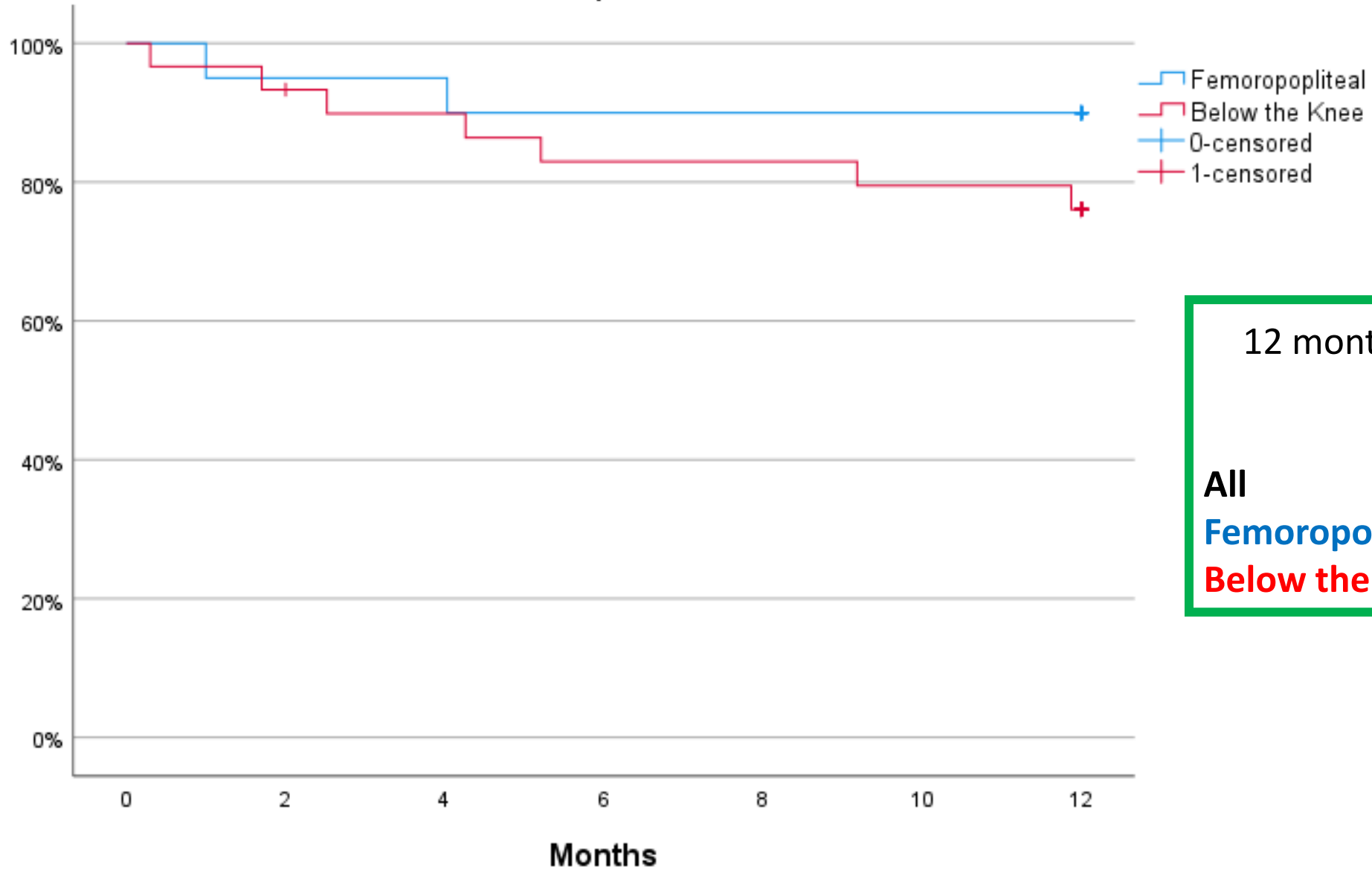
| 12 Months Primary Patency | |
|---------------------------|--------------|
| All | 66.7% |
| Femoropopliteal | 78.6% |
| Below the Knee | 59.0% |

Freedom from Target Lesion Revascularisation



| 12 months Freedom from TLR | |
|----------------------------|-------|
| All | 89.7% |
| Femoropopliteal | 94.1% |
| Below the Knee | 86.3% |

Amputation Free Survival



| 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%) |
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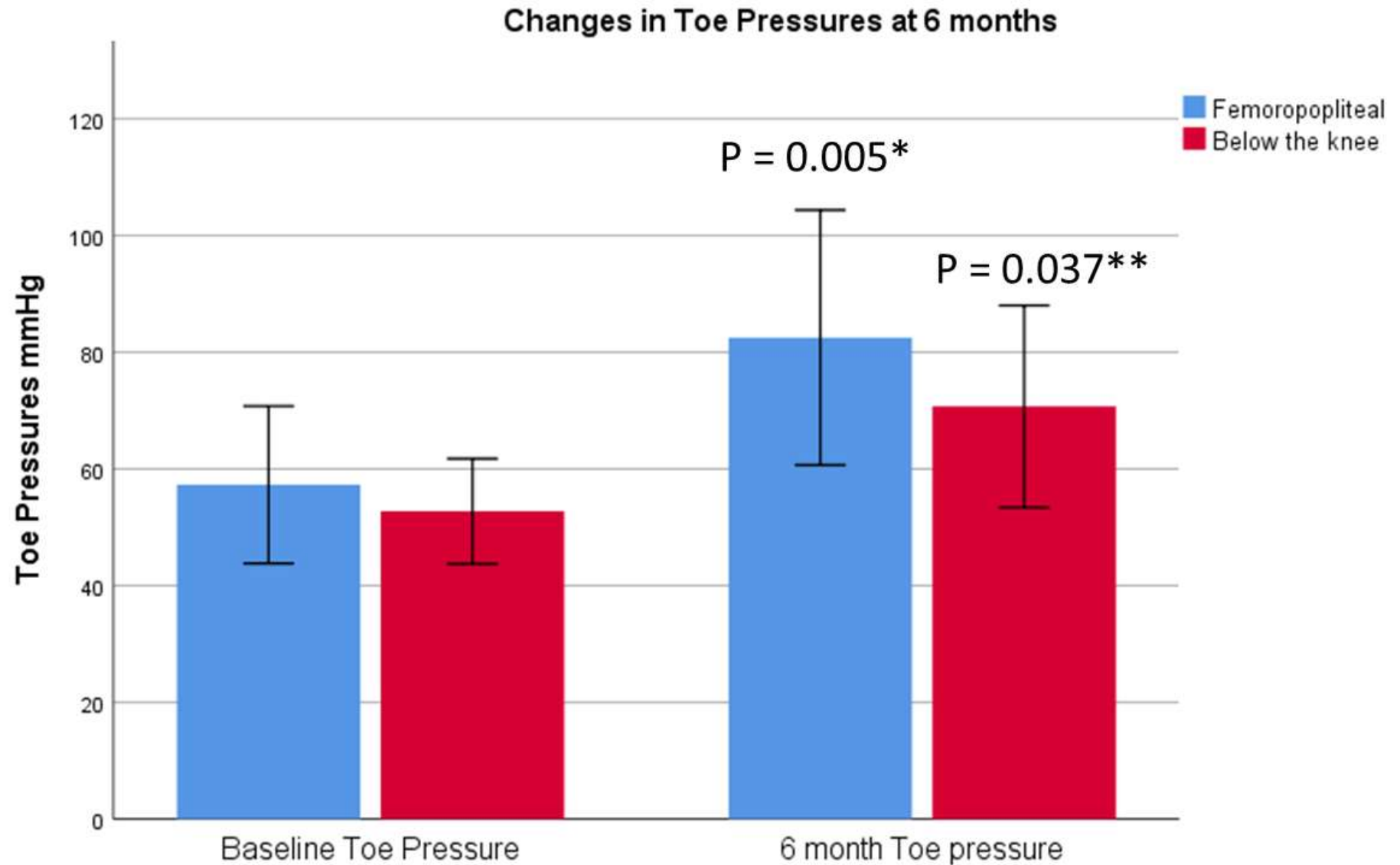
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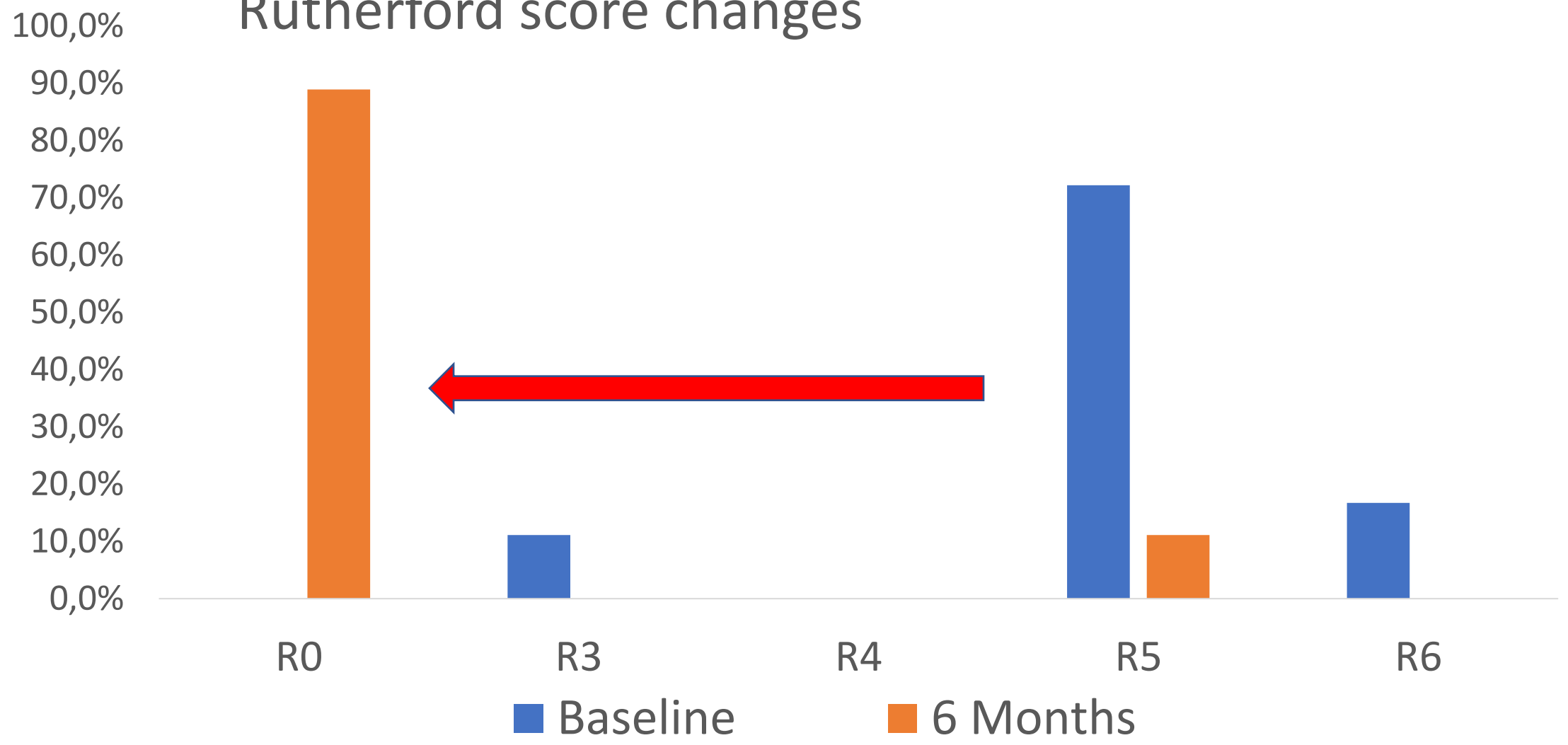
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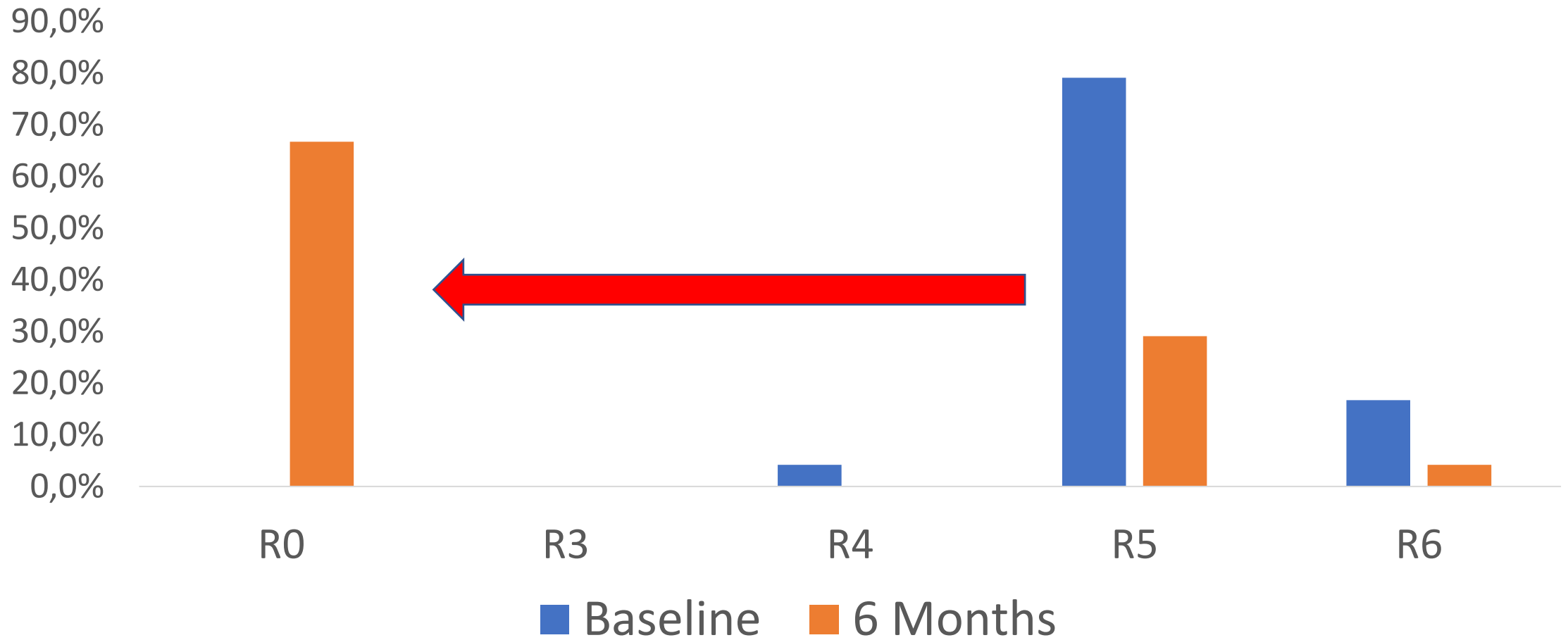
Sustained improvement in toe pressures at 6 months



Femoropopliteal Rutherford score changes



Below the knee Rutherford score changes



Summary



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