BAD KROZINGEN

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Longterm durable outcomes with SUPERA and the economical implications

Faculty Disclosure

Thomas Zeller, MD

For the 12 months preceding this presentation, I disclose the following types of financial relationships:

- **Honoraria received from:** Abbott Vascular, Angioslide, Bard Peripheral Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Cordis Corp., Covidien, Gore & Associates, Medtronic, Spectranetics, Straub Medical, TriReme, VIVA Physicians
- **Consulted for:** Abbott Vascular, Bard Peripheral Vascular, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Spectranetics, ReCor
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SUPERB
Study Overview

Design

- Supera implant compared to VIVA OPG[1]
- 264 subjects (ITT) - 34 sites; 36 month follow up
- HCRI data coordinating center, CEC & DSMB, Vascore duplex ultrasound and X-Ray core laboratory, and BIDMC angio core laboratory

Primary Safety Endpoint

- Composite of all death, TLR, or any amputation of index limb to 30 days

Primary Efficacy Endpoint

- Vessel patency at 12 months
- Defined: freedom from restenosis [diameter stenosis > 50% with peak systolic velocity (PSV) ratio ≥ 2.0 measured by duplex ultrasound] and TLR

Key Inclusion Criteria:

- Lifestyle limiting claudication or rest pain (Rutherford-Becker scale 2-4)
- Resting ABI ≤ 0.9
- Single SFA/popliteal lesion (>60% stenosis or total occlusion) 40 mm – 140 mm
- Reference vessel diameter 4.0 mm - 6.0 mm; Lesion > 3 cm above knee joint
- At least single vessel runoff (< 50% stenosis) to ankle or foot

Clinical data on file at Abbott Vascular , [1]Rocha-Singh K., Performance Goals and Endpoint Assessments, Catheterization and Cardiovascular Interventions 69:910–919 (2007)

SUPERB
Patient Characteristics

	ITT Population (N=264 Patients)
Age	68.7±10.0
Male gender	63.6%
Hypertension	93.9%
Dyslipidemia	86.7%
Diabetes mellitus	43.5%
Current cigarette smoking	31.8%
Renal insufficiency	9.1%
Rutherford-Becker scale	
(2) Moderate claudication	37.5%
(3) Severe claudication	57.2%
(4) Ischemic rest pain	5.3%

Clinical data on file at Abbott Vascular .

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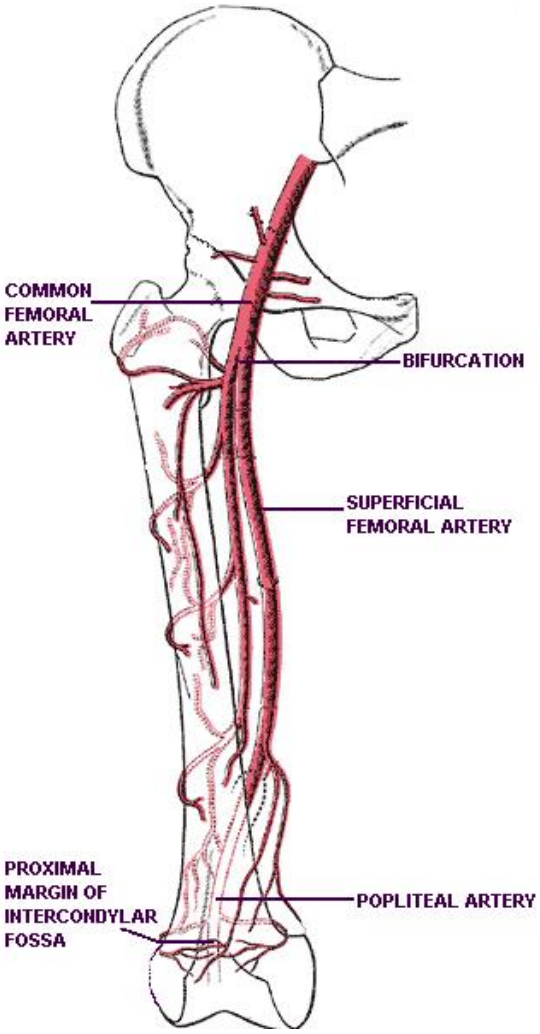
Target Lesion Characteristics



Lesion location	Patients=264 Segments=265
Proximal SFA	12.1%
Mid SFA	54.3%
Distal SFA	31.7%
Distal SFA extending into popliteal	10.9%
Popliteal, above knee	1.9%

Clinical data on file at Abbott Vascular.

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SUPERB
Target Lesion Characteristics

	Patients=264 Segments=265
Lesion length (mm) (operator reported)	82.8±33.0
Lesion length (mm) (core lab)	78.1±42.8
Pre-procedure RVD (mm)	4.96±0.92
Pre-procedure diameter stenosis (%)	78.0±16.8
Total occlusion	24.6%
Severe calcification	44.7%
Lesion ulceration	15.5%
TASC II type A	55.5%
TASC II type B	38.9%
TASC II type C	5.7%

Clinical data on file at Abbott Vascular.

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SUPERB
Primary Safety Endpoint

Freedom from death, TLR or any amputation of the index limb at 30 (± 7) days

30-day event free rate **99.2%**

- Freedom from death 99.6%
- Freedom from TLR 99.6%
- Freedom from amputation 100%

Superior to VIVA safety OPG of 88%, p<0.001

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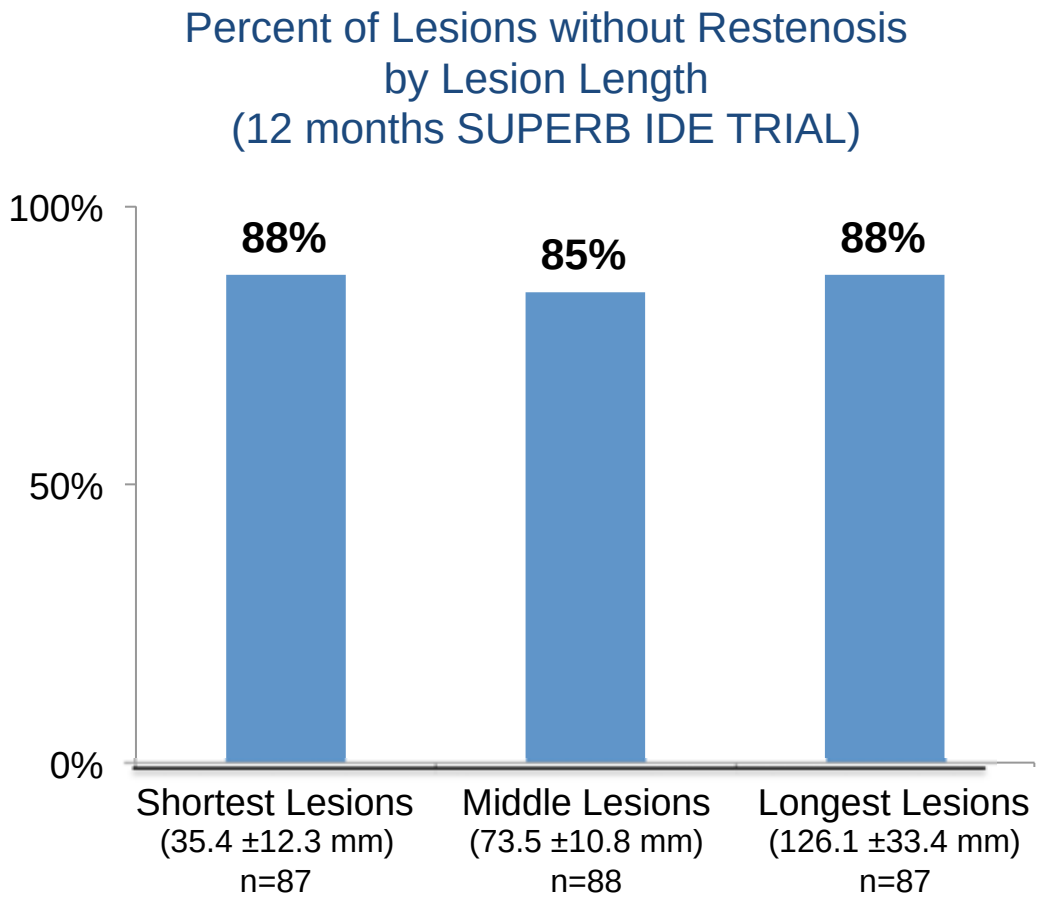
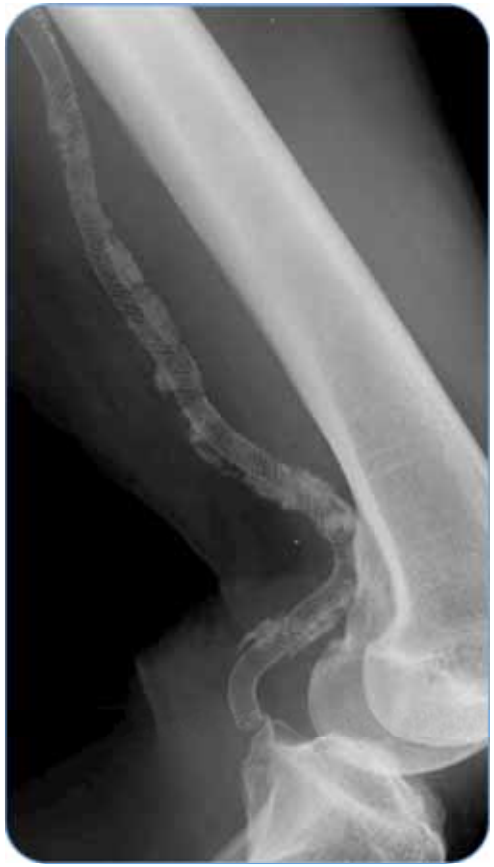
SUPERB
1-Year Results Across Lesion Lengths





Source: Image from SUPERB trial. Data on file at Abbott Vascular.

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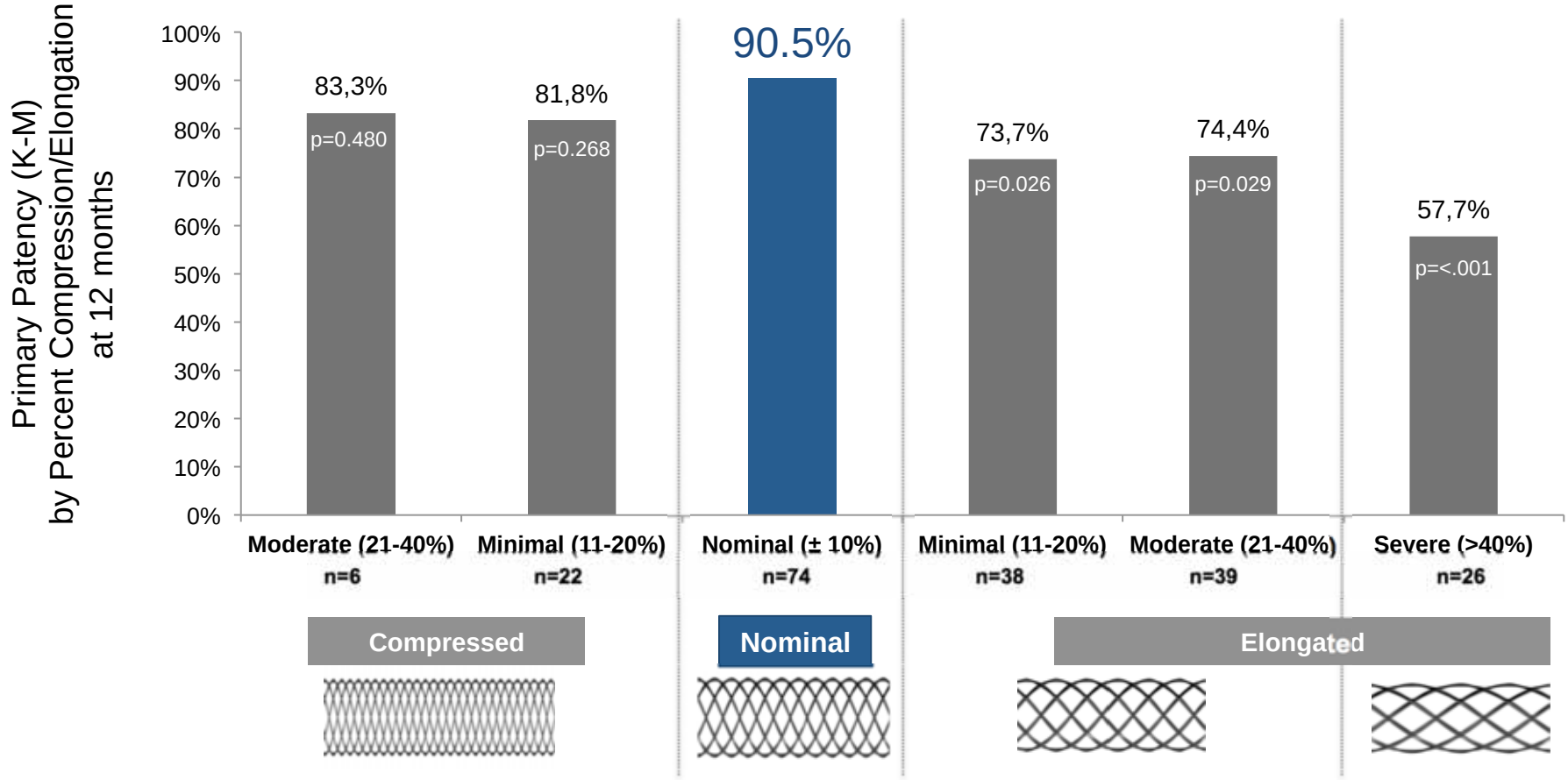
1-Year Outcomes Stratified to Deployment Technique

High patency rates are demonstrated in cases where appropriate implant selection, vessel preparation, and deployment technique are used.



Source: Data on file at Abbott Vascular.

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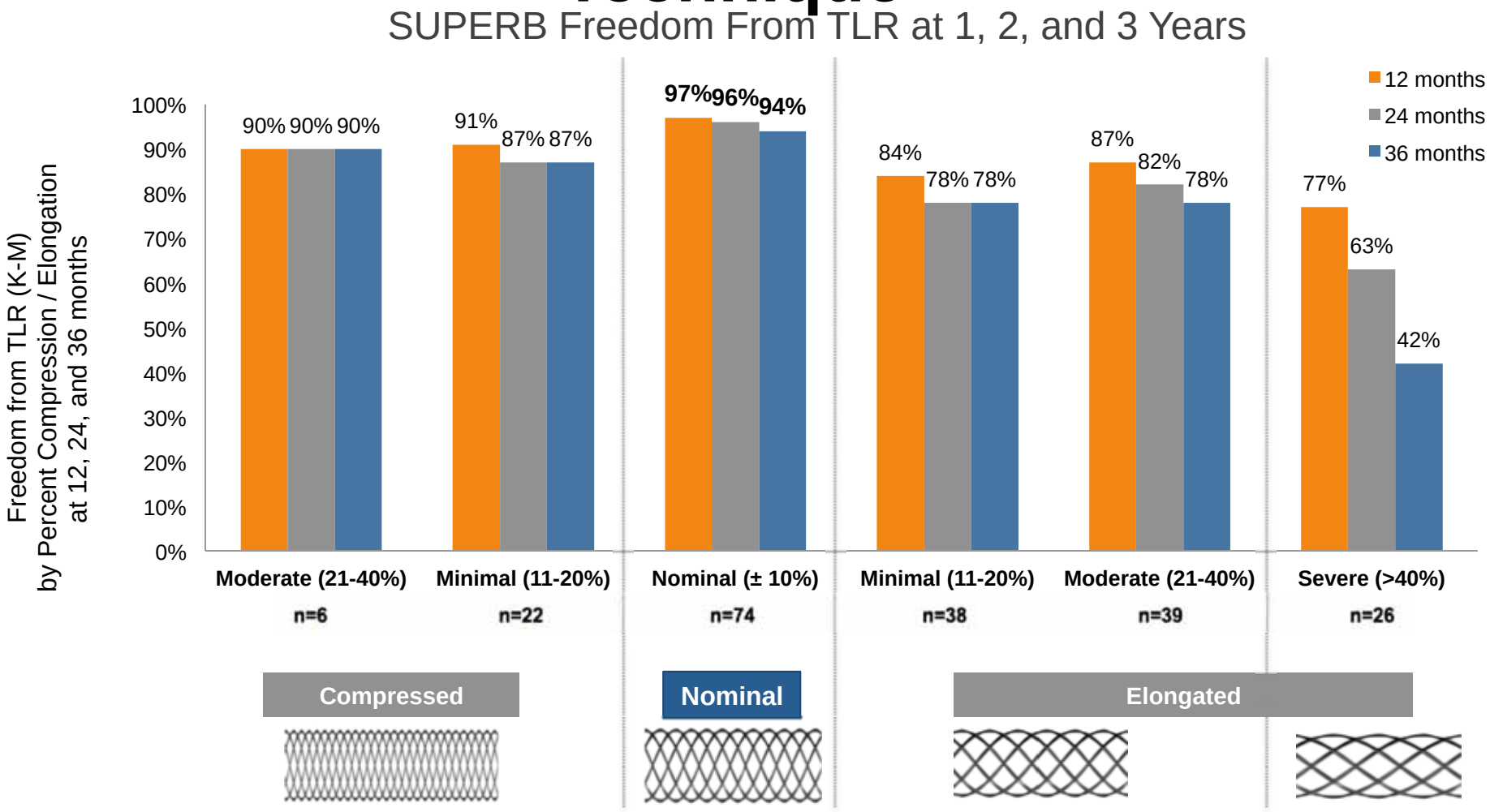
SUPERB
3-Year Outcomes Stratified to Deployment Technique



Clinical data on file at Abbott Vascular.

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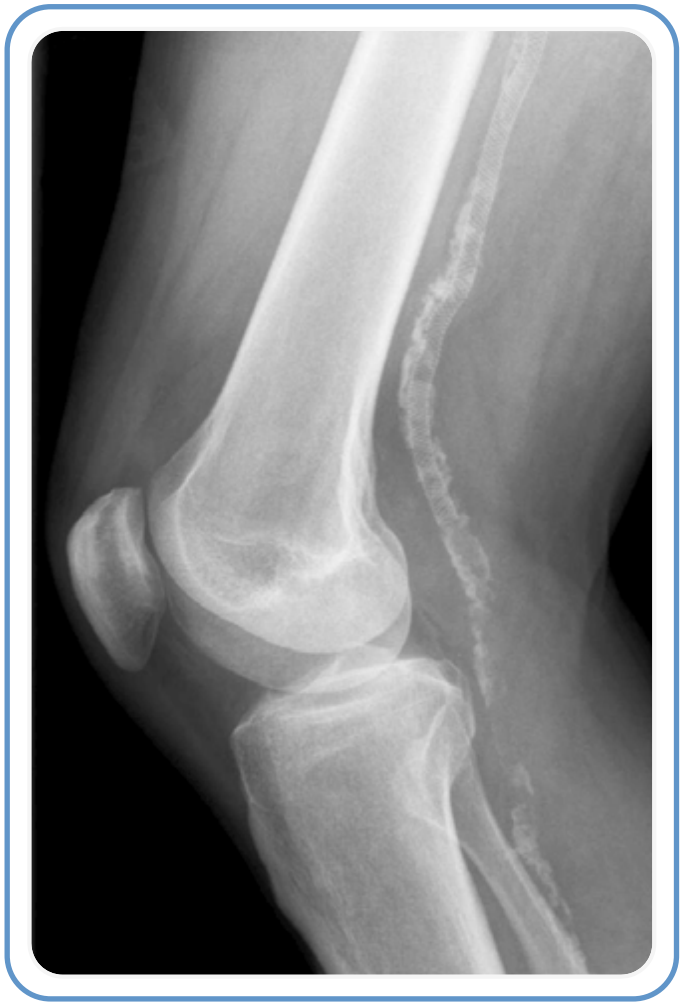
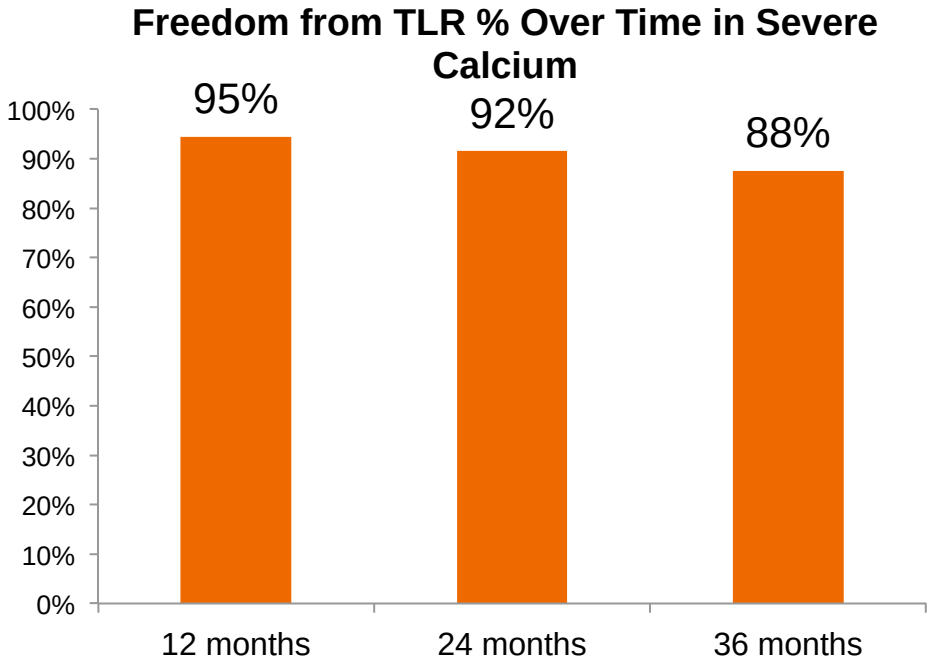
SUPERB Freedom from TLR Outcomes in Calcification at 3 Years





SUPERB Data - Severe Calcification

% of Lesions with Severe Calcification (SUPERB Trial)	45% (n=118)
Patency (VIVA 12 months)	89%

Clinical data on file at Abbott Vascular.

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SUPERB
Stent Fractures at 12 and 24 Months

Assessed by core lab review of AP and lateral X-ray views

Stent fracture	12 Months (N=243)	24 Months (N=200)
Type I - Single time fracture	0.0% (0/243)	0.0% (0/200)
Type II - Multiple time fractures	0.0% (0/243)	0.0% (0/200)
Type III – Stent fracture(s) with preserved alignment of the components	0.0% (0/243)	0.5% (1/200)*
Type IV – Stent fracture(s) with mal-alignment of the components	0.0% (0/243)	0.0% (0/200)
Type V – Stent fracture(s) in a trans-axial spiral	0.0% (0/243)	0.0% (0/200)

Evaluated by X-ray [anterior-posterior (AP) and lateral views in both straight and flexed knee positions] per an independent core lab.
*One subject experienced a Type III fracture at 24 months after three directional atherectomy procedures to treat in-stent restenosis

Clinical data on file at Abbott Vascular.

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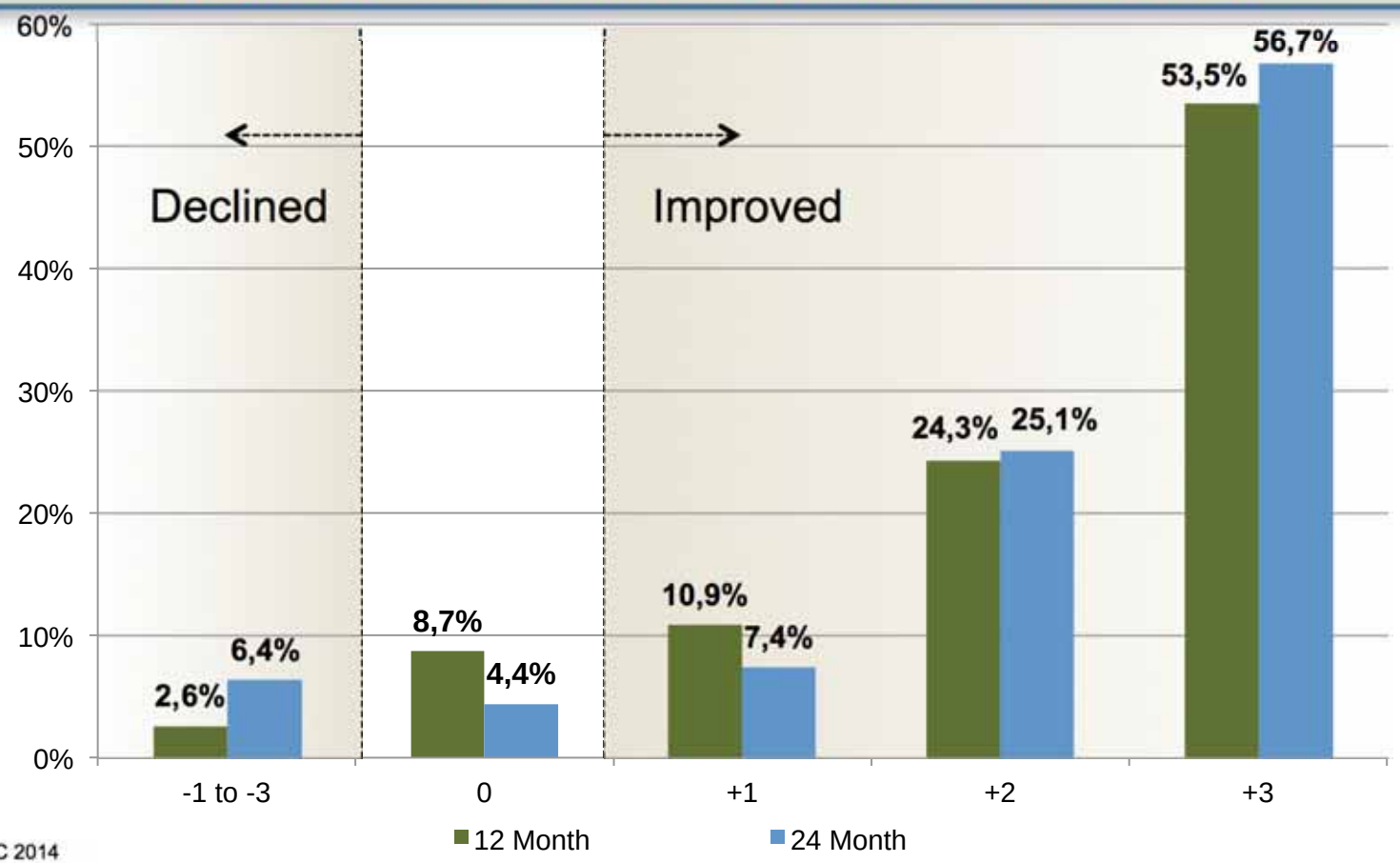
SUPERB
Change in Rutherford-Becker Scores at 1 and 2 Years

88.7% and **89.2%** of subjects improved by one or more categories at **12** and **24** months respectively



Source: Garcia LINC 2014

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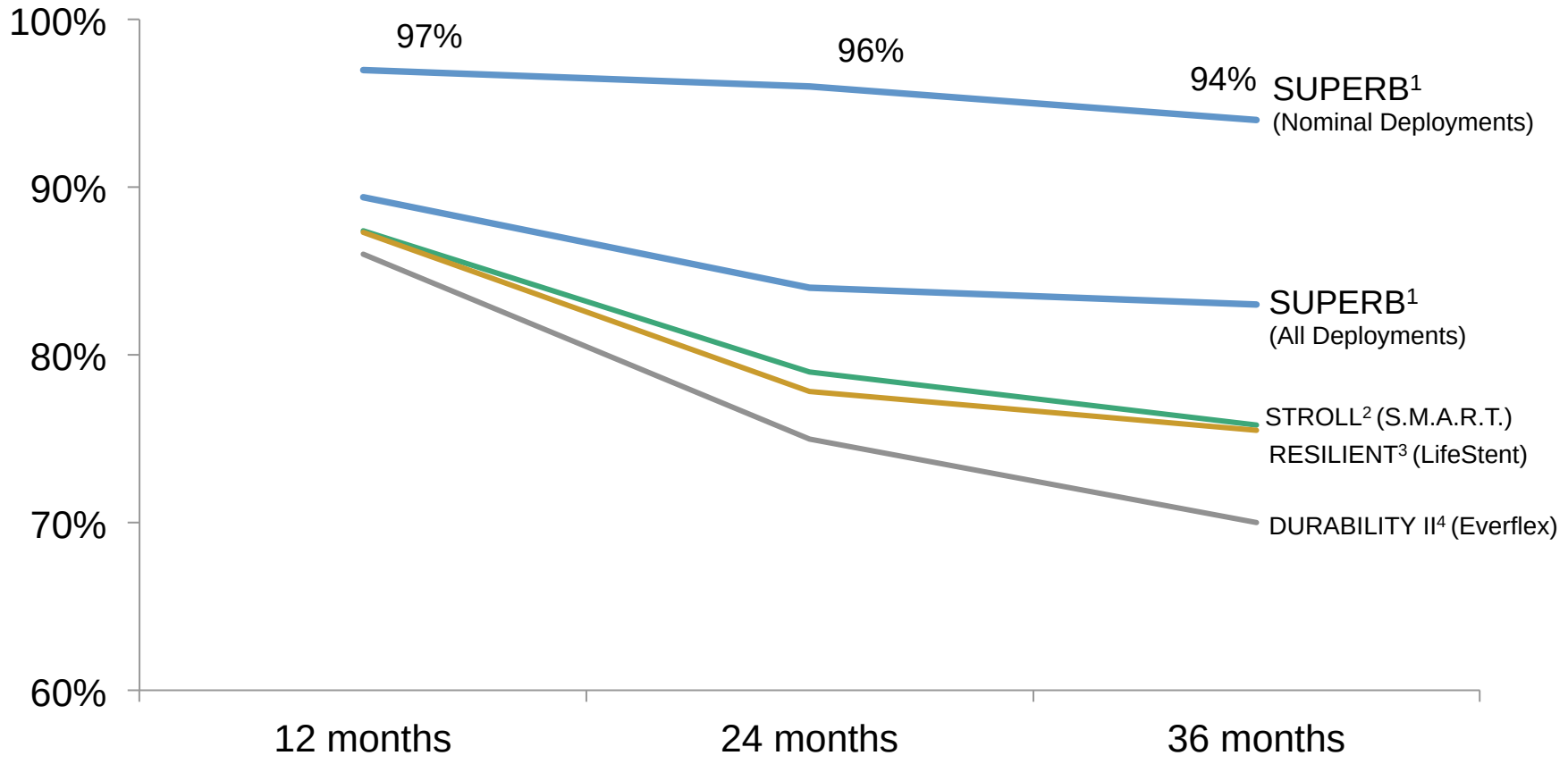
Freedom From Clinically Driven TLR Through 3 Years
Comparison SUPERA & Slotted Tube Stents



1. Clinical data on file at Abbott Vascular.
2. STROLL 1-year, G. Ansel, LINC 2013; 2-year, W. Gray ISET 2013. 3-year, M Jaff ISET 2014
3. Laird, J. Journal of Endovascular Therapy 2012;19:1–9
4. DURABILITY II, K Rocha-Singh, VIVA 13; M Razavi ISET 2014.

Data differences depicted between these trials may not be statistically significant or clinically meaningful and different clinical trials may include differences in the demographics of the patient populations.

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Supera 500 registry – objectives

- To assess the efficacy of the Supera interwoven nitinol stent in a real world setting
- Retrospective analysis of
  → **495** patients undergoing treatment with
  → **750** Supera stents in
  → **528** legs between 2008 and 2011
- Standard hospital FU protocol including duplex ultrasound and clinical follow-up

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SUPERA 500
Lesion characteristics

Occlusions	278 (52.7%)
Instent lesion	29 (5.5%)
Mean degree of stenosis	94.9% (± 6.03)
Localisation	
Proximal SFA	17 (3.2%)
Mid SFA	50 (9.5%)
Distal SFA	241 (45.6%)
Popliteal Artery	220 (41.6%)

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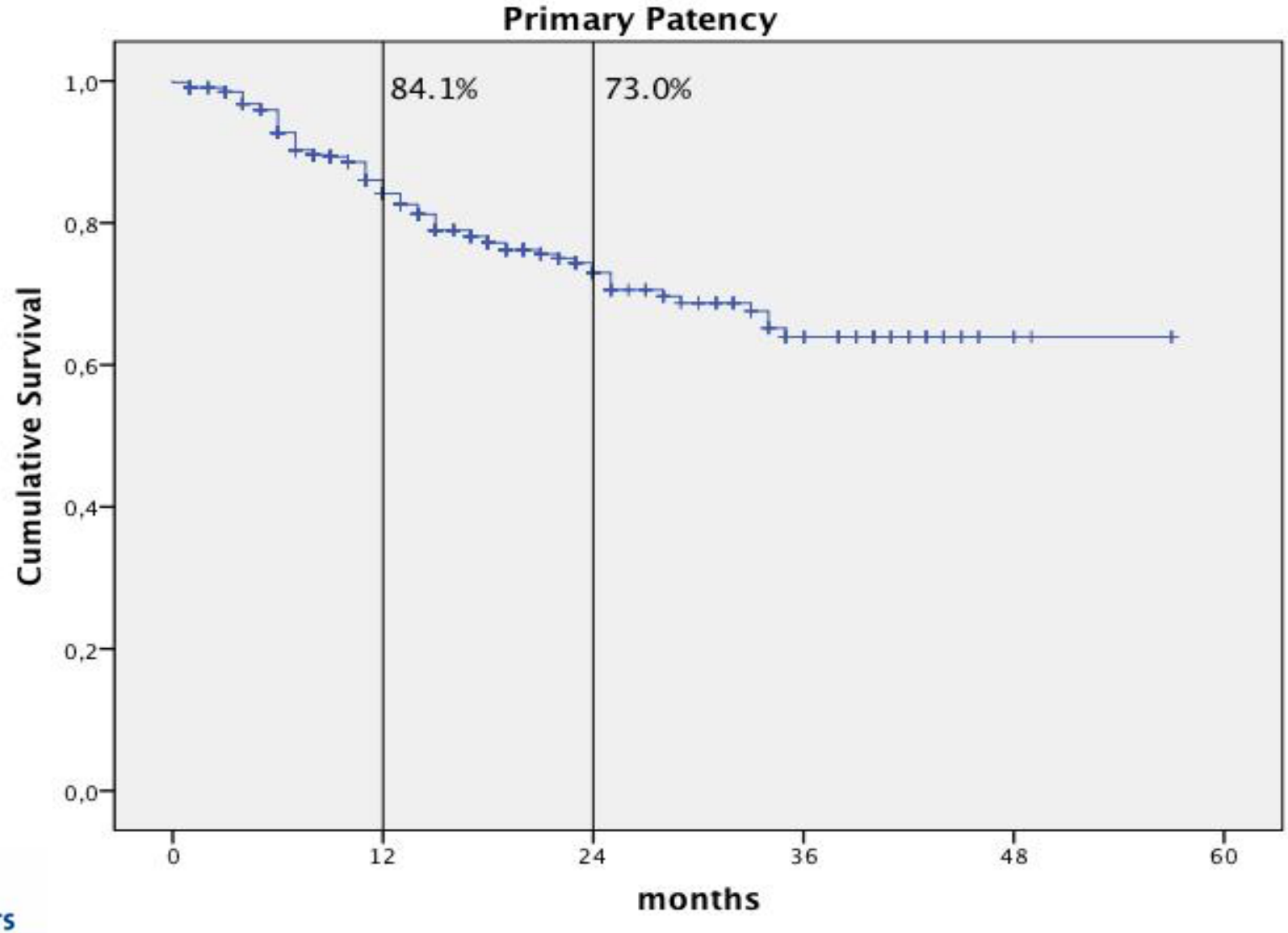
Supera 500 Registry



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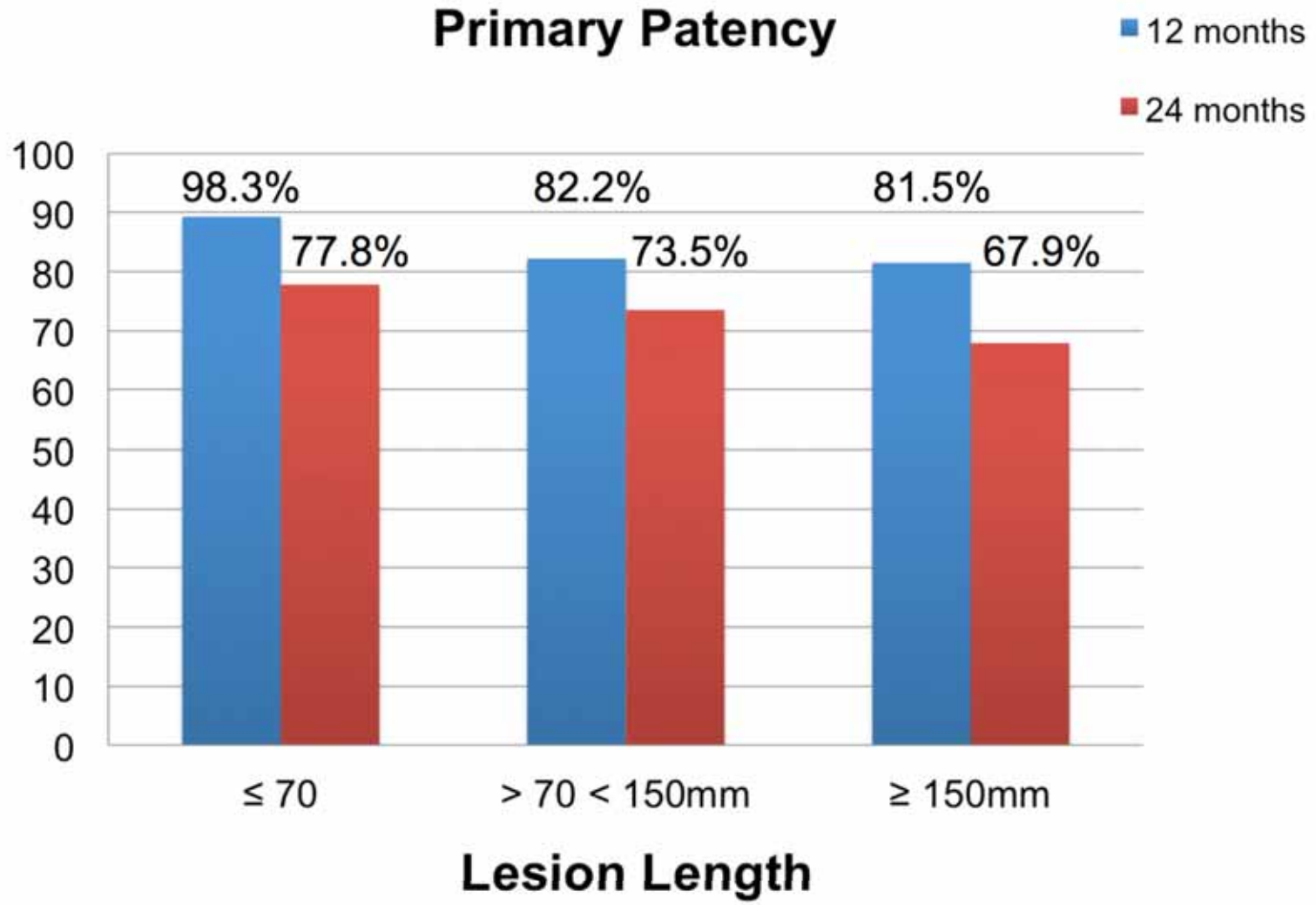
Supera 500 Registry



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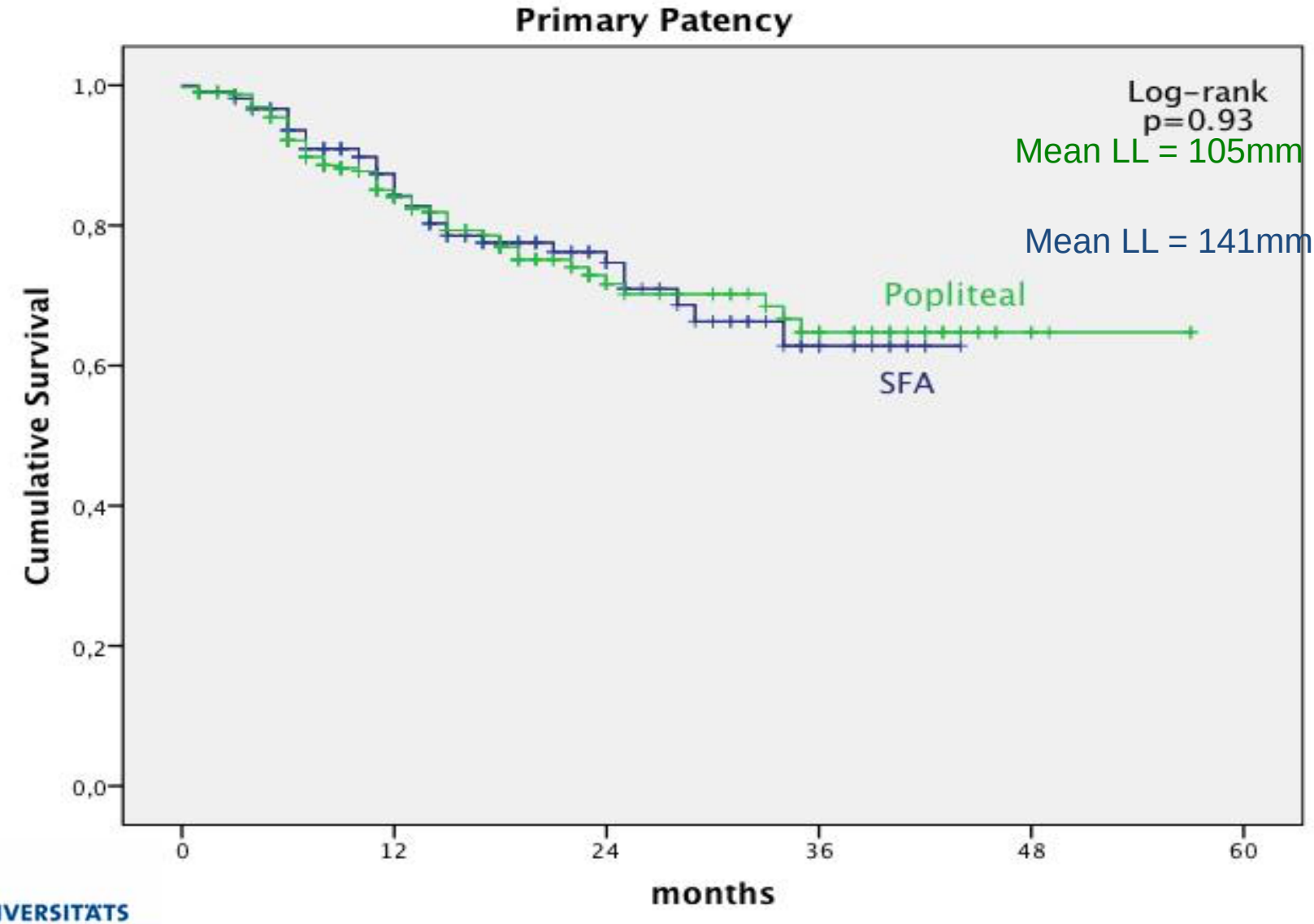
Supera 500 Registry



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Long Term, Real World Experience from Leipzig

- Based on an analysis of real-world patients undergoing femoropopliteal treatment with DCB, BMS or Supera at a single institution.
- Key assessment: Primary patency up to 40 months using duplex ultrasound and/or angiography.
- To reduce selection bias:
  - Propensity scores for clinical and lesion characteristics were calculated
  - Matched data sets who shared a similar propensity score value were formed for each comparison to achieve a similar distribution of baseline covariates between the compared groups

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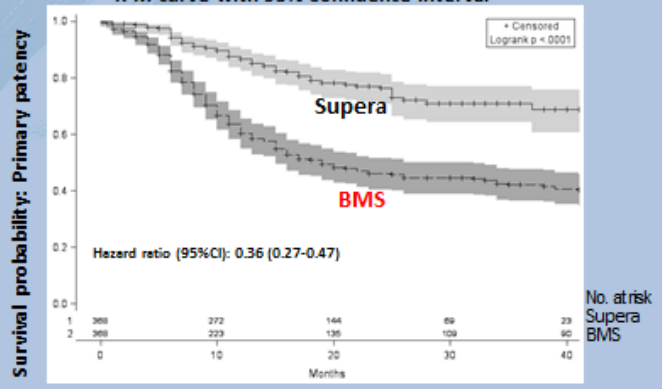
Supera Real World* Long Term Data

Supera - BMS

Matched Cohort:	Supera	BMS	P-Value
Lesion length, mm	130 ± 83	139 ± 100	0.2
Instent restenosis, %	16	16	0.9

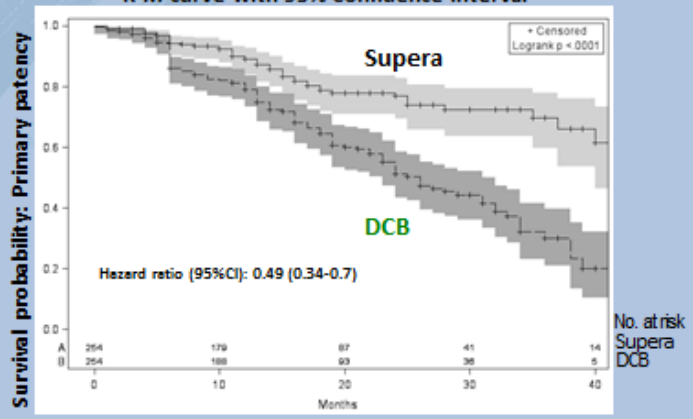
K-M curve with 95% Confidence Interval



Supera -DCB

Matched Cohort:	Supera	DCB	P-Value
Lesion length, mm	143 ± 92	157 ± 102	0.09
Instent restenosis, %	16	17	0.6

K-M curve with 95% Confidence Interval



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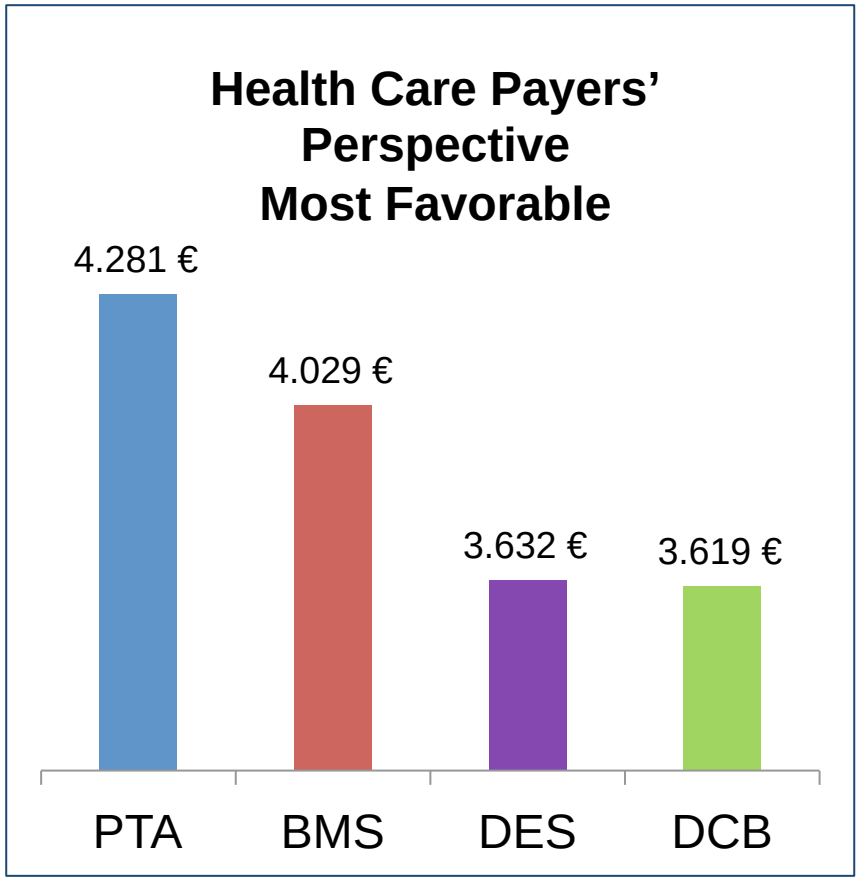
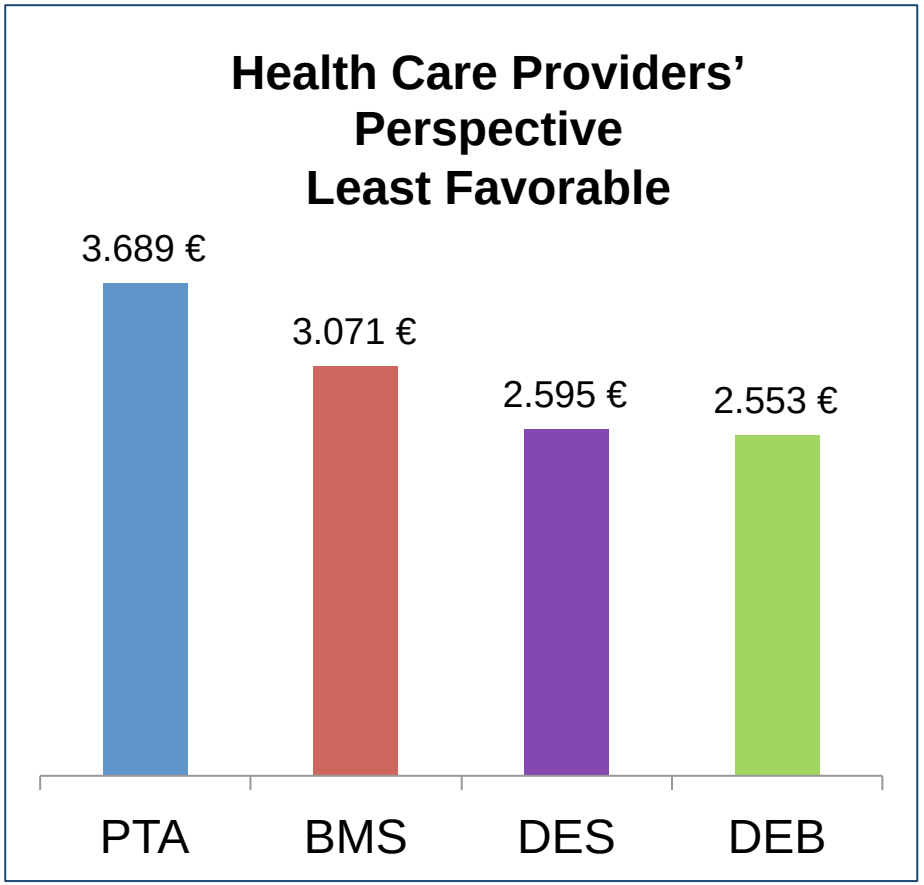
*Propensity Matched
Steiner, LINC 2015

German Payer and Provider Budget Impact Results



Payer Perspective



Provider Perspective

Source: : Pietzxch J., Geisler B., Garner A, Zeller T., and Jaff M. Economic Analysis of Endovascular Interventions for Femoropopliteal Arterial Disease: A Systemic Review and Budget Impact Model for the United States and Germany. Catheter Cardiovasc Interv. 213 April 30 (epub ahead of print)

SC1654092014A

SUPERA Longterm Outcomes Summary

- Supera offers excellent longterm technical and clinical outcomes up to 3 years comparable to Zilver PTX drug eluting stents
- Stent fractures don‘t occur in properly released stents up to 2 years
- Supera specific costeffectiveness analyses do not yet exist

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