CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
CONTROVERSIES & UPDATES IN VASCULAR SURGERY
JANUARY 19-21 2017
MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE

Do the latest Bare stent justify their use in the SFA/popliteal arteries

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Disclosure

Speaker name:

.....maxime sibé.....

☒ I have the following potential conflicts of interest to report:

☒ Consulting

☐ Employment in industry

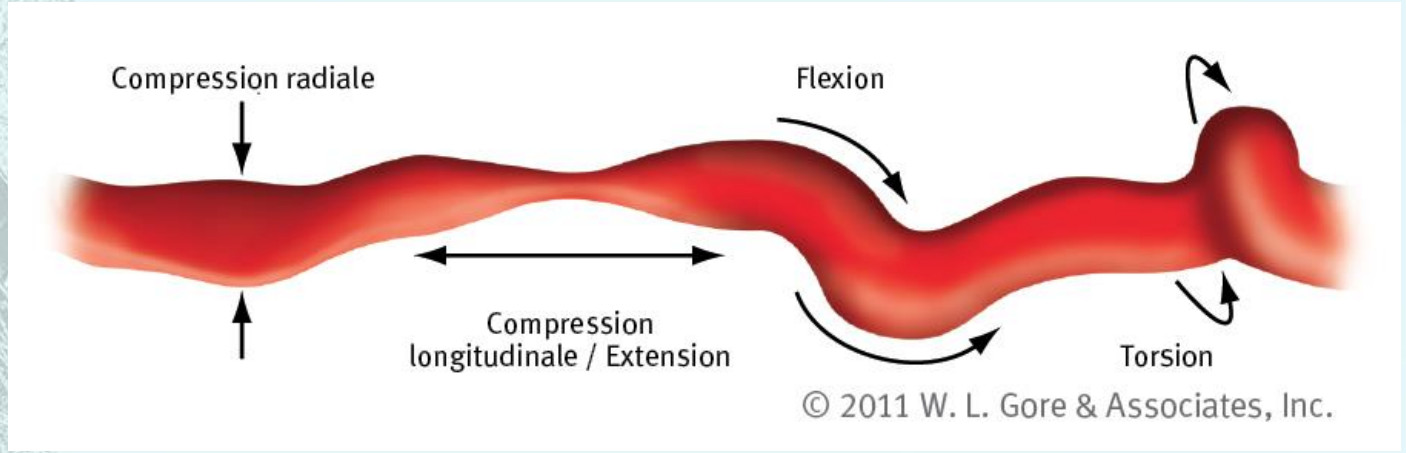
☐ Shareholder in a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☐ I do not have any potential conflict of interest

Unmet Need in Short Focal Lesions of the SFA



Design goal

- Incorporate flexibility and proven fracture resistance to allow for vessel movement and decrease fracture rate

PTA Randomized Data

- Most studied interventional technique
- 9 cm lesion average ~40% primary patency at 1 yr
- Patency appears to be dependent on lesion length

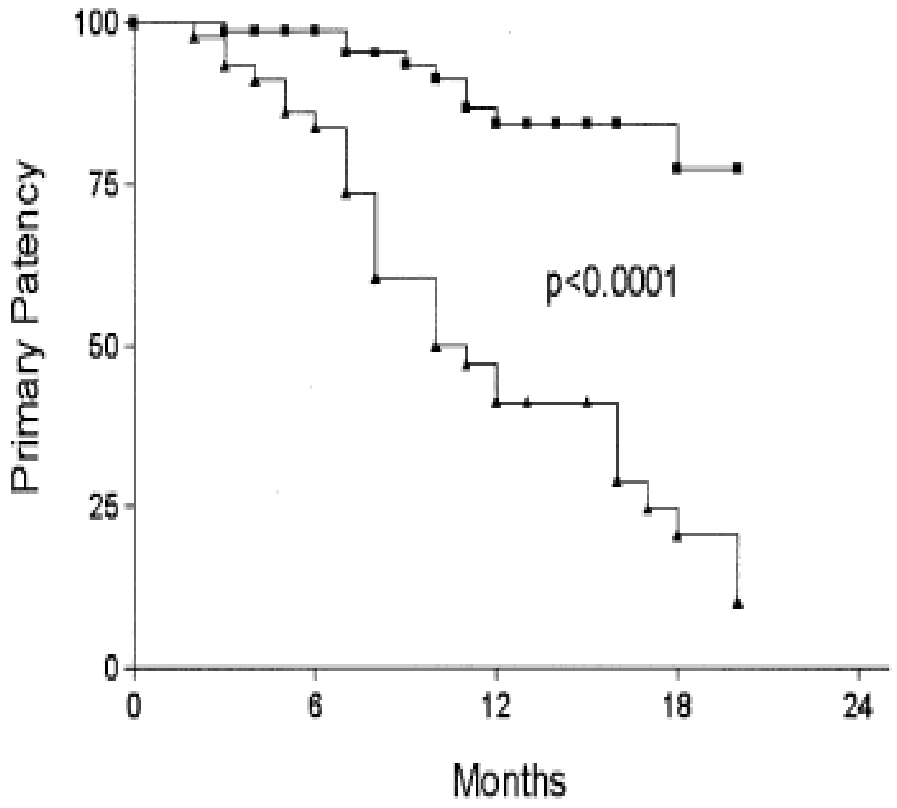
Study/Author	Year	No. of Limbs	Lesion Length (cm)	% Occlusions	Primary Patency (years / %) 1	2
FAST	2007	121	4.4	25	61	
RESILIENT	2010	72	6.4	18.5	37	
VIENNA	2006	52	9.3	31	37	31
ASTRON	2009	39	7.1	39	29	
Kougias	2009	57	19.0	100	28	
Saxon	2008	100	7.0	29	40	
VIENNA-3	2005	46	10.3	28	47	39
Total		***487***	***9***	***39***	***40***	***35***

Stent vs. PTA Randomised Trials

- First generation stents' superiority over PTA has been demonstrated in prospective, randomised, controlled trials:

Trial	Stent	Patency (BMS vs. PTA)	Lesion Length	% Occlusions
FAST	Luminexx	68% vs. 61%	4.5 cm	31%
RESILIENT	LifeStent	81% vs. 34%	7.1 cm	21%
VIENNA	Absolute	63% vs. 37%.	11 cm	41%
ASTRON	Astron Pulsar	66% vs. 39%	8 cm	39%

Stent fractures significantly influenced the patency of the stented segment



No-fractured stents

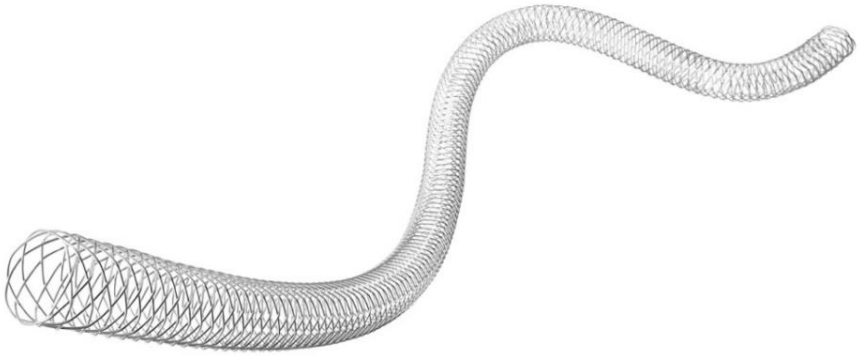
Fractured stents

Scheinert D et al. Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol. 2005 Jan 18; 45 (2): 312-5.

Supera Device Details

Vascular Mimetic Implant

- Self-expanding nitinol implant
- 6 closed-end interwoven nitinol wires
- 4.0, 5.0, 6.0, 7.0, 8.0 mm diameter; 20–200 mm lengths



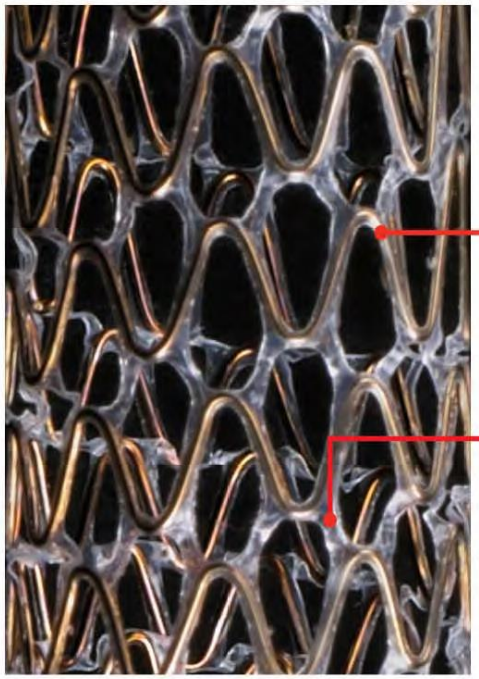
Delivery System

- Unique deployment catheter system using stent driver
- 0.014" and 0.018" guide wire compatible
- 6F sheath compatible
- 80, 120 cm working length
- Two-year shelf life

Source: Data on file at Abbott Vascular.

MENU

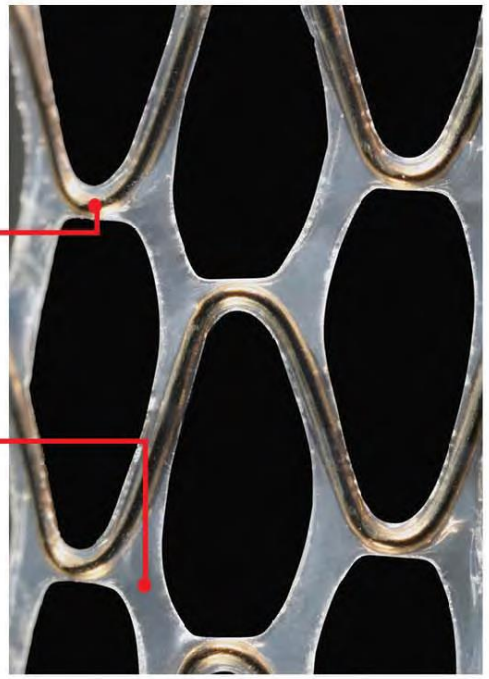
Dual-Component Stent Design



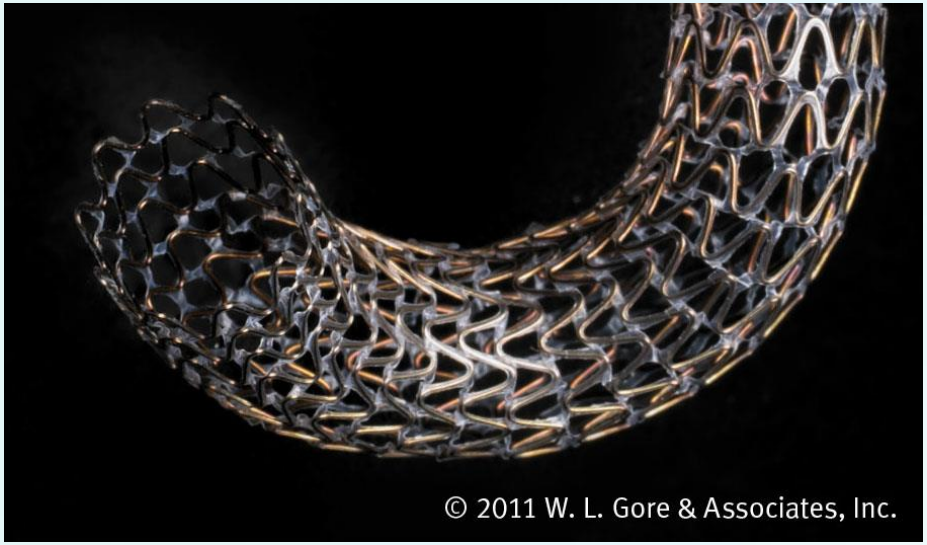
Clinically Established
Stent Frame
Nitinol Wire

Fluoropolymer
Interconnecting Structure

All surfaces incorporate CBAS®
Heparin Surface



Flexible design

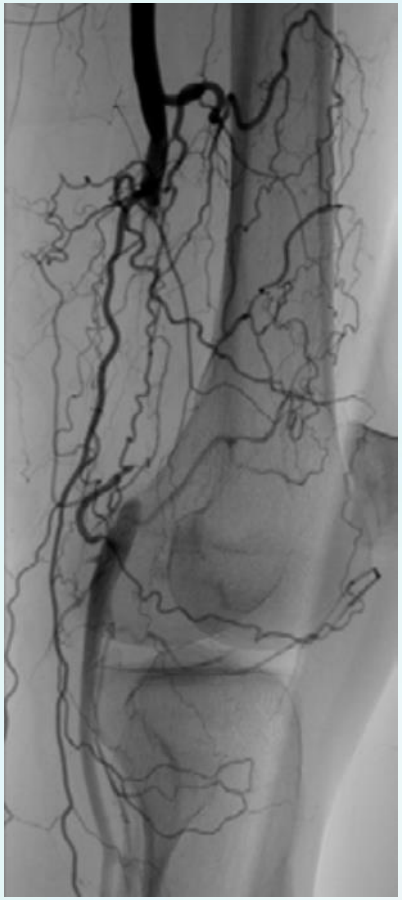


Designed to:

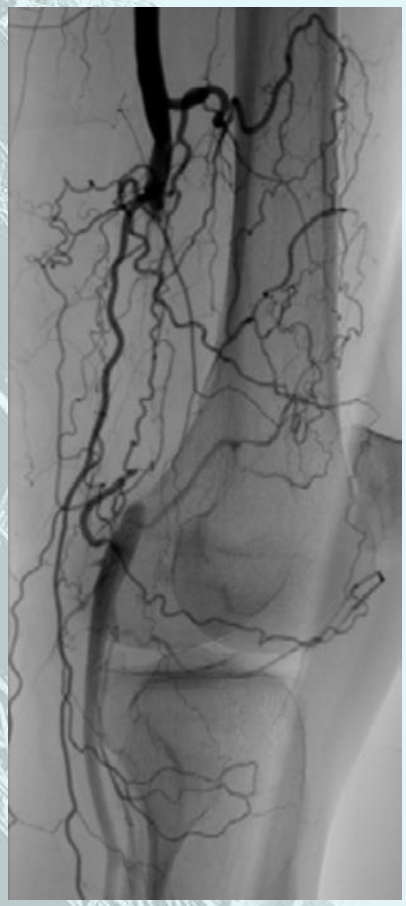
- Maximize flexibility while minimizing risk of stent fracture
- Allow axial compression while resisting stent elongation
- Naturally conforms and allows vessel movement

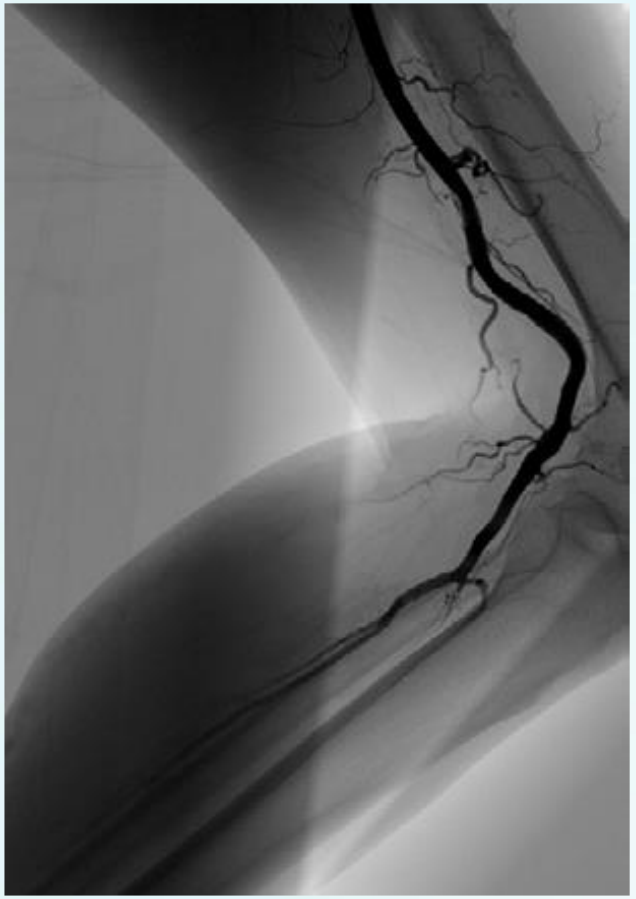
Case example 1

- 73 year old male with > 8 cm left leg distal (SFA) and proximal popliteal artery occlusion
- • Relevant history:
  - Moderate claudication, walking distance of 150 meters
  - Ankle Brachial Index (ABI) left: 0.75
- Angio:
  - Popliteal artery above knee occlusion.
  - Patent distal popliteal
  - artery with three crural vessel runoff
  - Suboptimal result after PTA



Case example 1





Proven Clinically in Both SFA and Popliteal Arteries, Claudicants and CLI Patients

Supera Trials and Registries with 12-Month % Primary Patency (K-M)

- **SFA/Proximal Popliteal Artery**
  - SUPERB IDE Trial[1] 86%
    - -7.8 cm avg lesion length
  - Leipzig SFA Registry[10] 85%
    - -9 cm avg lesion length
- **Popliteal Artery**
  - Leipzig Popliteal Registry[11] 88%
    - -5.8 cm avg lesion length
  - Germany Goltz[8] 68%*
    - -Elevated Operative Risk
  - Tucson[9] 79%*
    - -12 mean stented length
- **ZERO Stent Fractures at 1 year**
  - Over 1,300 patients studied[1–15]

- **SFA and Popliteal Artery**
  - SUPERA 500[2] 83%
    - >15 cm[2] 81%
    - 12.6 cm avg stented length
  - AURORAA[3] 81%*
    - 14.3 cm avg lesion length
  - SAKE[4] 85.8%
    - 14.3 cm avg lesion length
  - RESTORE[5] 88%
    - 18.5 cm avg lesion length
  - QM HK[6] 79%*
    - 12.6 cm mean stented length
  - CWZ[7] 75%*
    - 21.8 cm avg stented length
  - Turkey[12] 86%
    - 10.5 cm avg lesion length
  - St. Louis University[13] 86%*
    - 24.0 cm avg lesion length
  - Australia[14] 74 %* **
    - 18.9 cm avg lesion length
  - NYU[15] <8 :86%,8-150:93%, >15:80.5%
    - 13.4 cm avg lesion length

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 $\geq$ 2.0 measured by duplex ultrasound] and TLR

Key Inclusion Criteria:

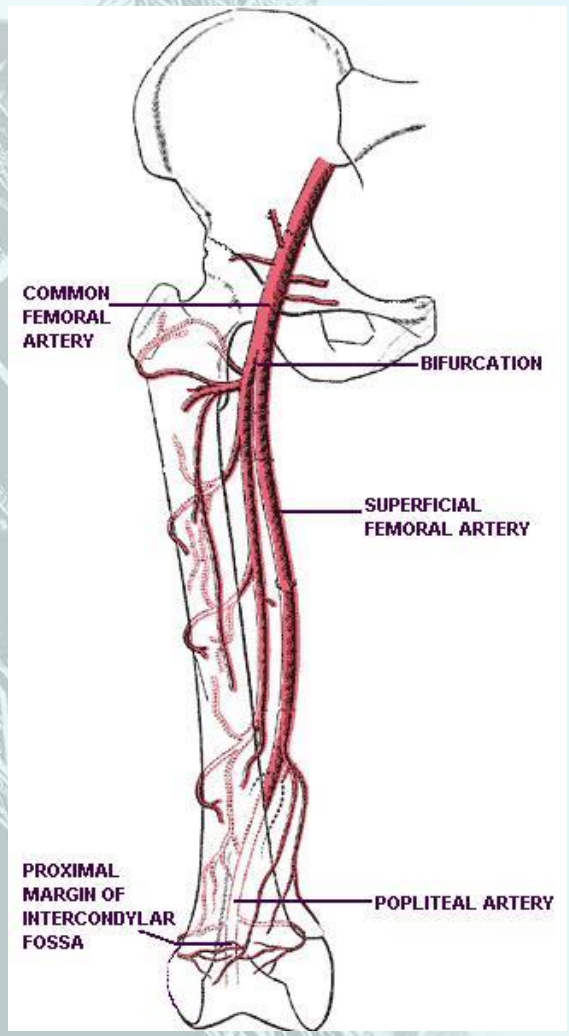
- Lifestyle limiting claudication or rest pain (Rutherford-Becker scale 2-4)
- Resting ABI $\leq$ 0.9
- Single SFA/popliteal lesion (>60% stenosis or total occlusion) 40 mm – 140 mm
- Reference vessel diameter 4.0 mm - 6.0 mm; Lesion > 3 cm above knee joint
- At least single vessel runoff (< 50% stenosis)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

US Supera Peripheral Stent System Instructions for Use. [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%

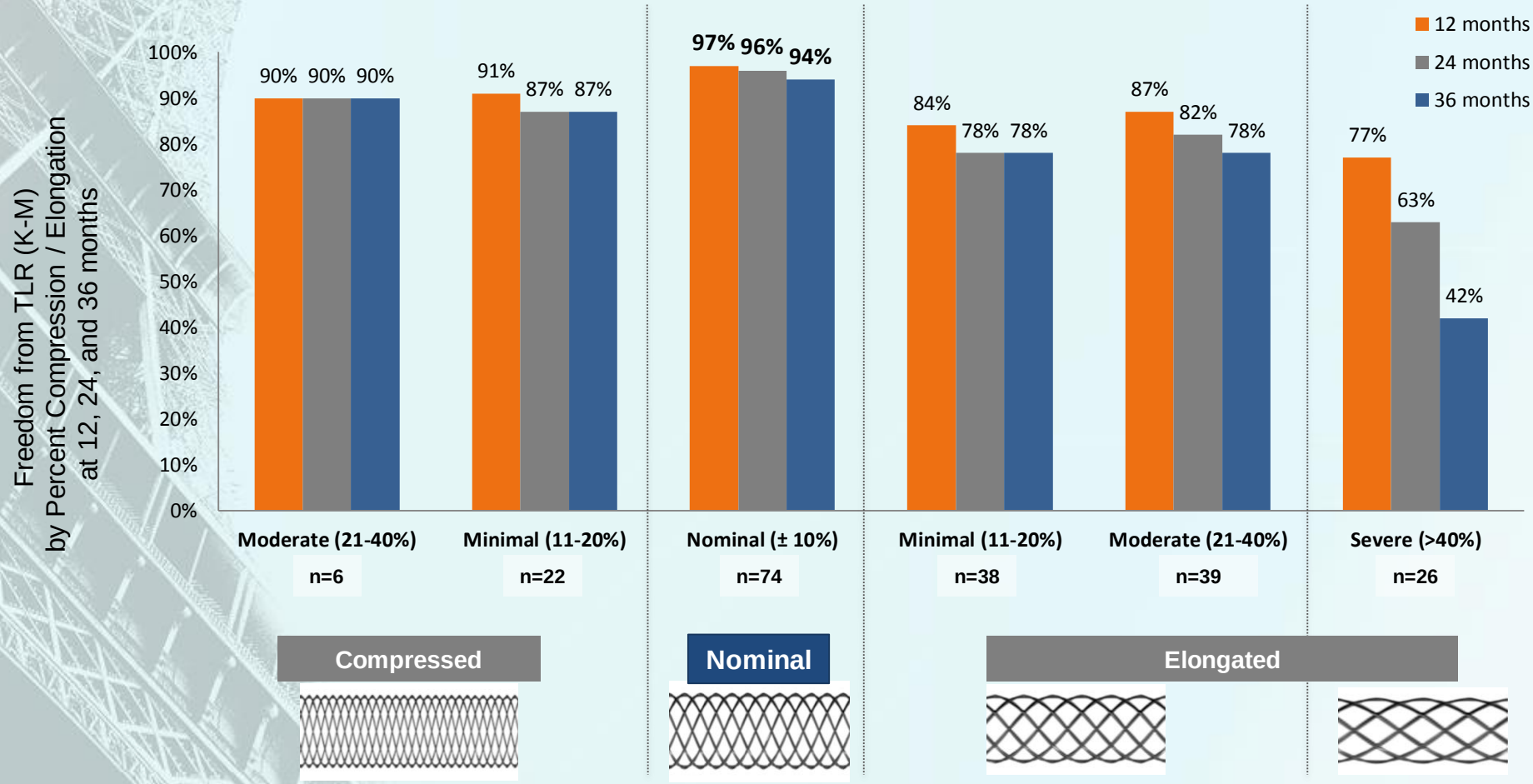
SUPERB Target Lesion Characteristics



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%

Optimal Deployment Leads To Low Re-intervention Rate Out to 3 Years

SUPERB Freedom From TLR at 1, 2, and 3 Years



Garcia, L., The SUPERB Trial 3-year Results, VIVA 2014

Our clinical experience

French multicenter experience with GORE® TIGRIS® Vascular Stent in superficial femoral and popliteal arteries (JVS, 2016 , accepted)

Single-arm, multicenter cohort study

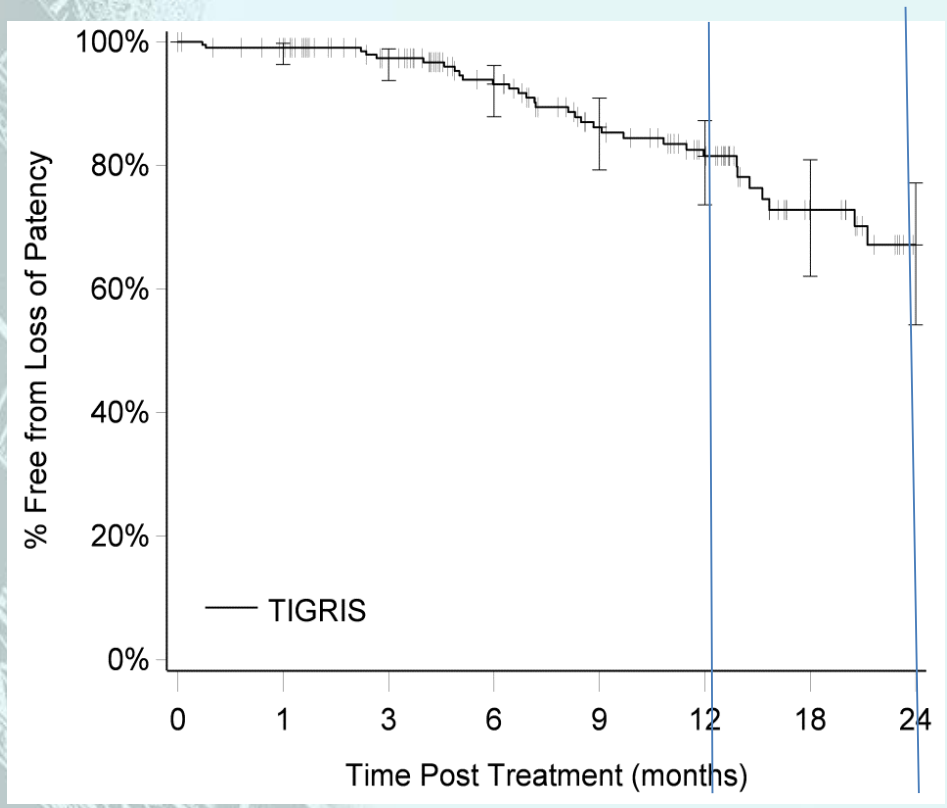
included 215 patients

239 lesions

Baseline characteristics

Patient characteristics	N=215
Mean age (yrs)	74.1 ± 11.7 (range 49 – 102)
Men	145 (67.8%)
Rutherford	
III	114 (48.9%)
IV	48 (20.6%)
V	67 (28.8%)
VI	4 (1.7%)
Lesion characteristics	**N=239**
Lesion location	
SFA	141 (59%)
Popliteal	98 (41%)
Lesion type	
Stenotic	196 (88.8%)
Thrombotic	25 (12.7%)
Lesion length (mm)	
SFA	82.4 ± 35.0 (range 30 – 200)
Popliteal	93.0 ± 55.3 (range 30 – 360)

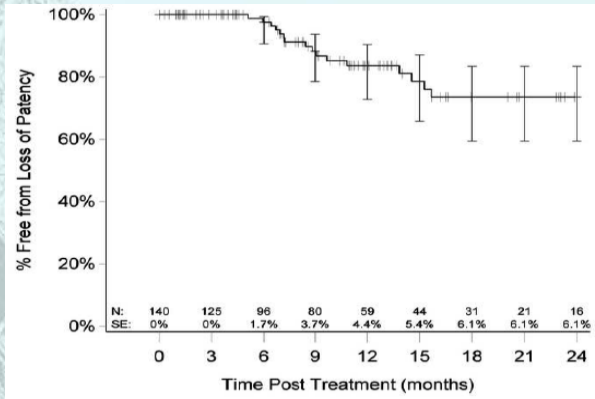
Outcomes – Patency all lesion



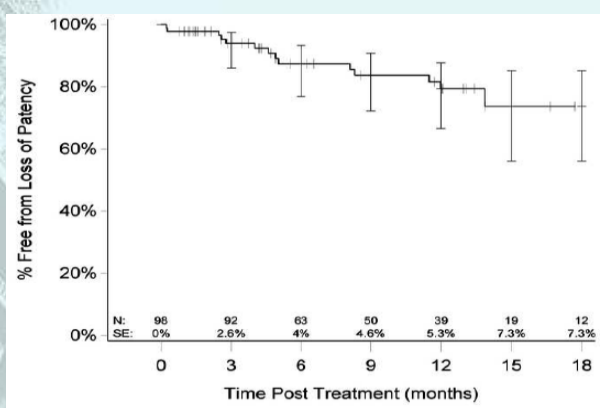
1Y primary patency: 82%

2Y primary patency: 67%

Outcomes – Patency SFA VS Pop



SFA 12M primary patency: 84%



Popliteal 12M primary patency: 79%

Similar outcomes for SFA and Popliteal

Conclusion

- Accurate placement, conformability and fracture resistance are key features

- Our experience demonstrates a good performance in both the SFA and the popliteal arteries.

- Currently the longest lenght available is 100mm which may require to use overlapping stents for treating longer lesions resulting in a compromise of flexibility in that region.

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