Novel Stent Technology Can Shed Light: SUPERA or BVS

RICHARD R. HEUSER, MD, FACC, FACP, FESC, FSCAI
Chief of Cardiology, St. Luke's Medical Center, Phoenix, Arizona
Professor of Medicine Univ. of Arizona, College of Medicine, Phoenix, Arizona

Presenter Disclosure Information

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

- ***QuantumCor, Major Stock Holder/Medical Director;***
- ***Radius Medical, Avinger and Claret Medical, Major Stock Holder;***
- ***PQ ByPass, Founder and Major Stock Holder;***
- ***CSI, Stockholder;***
- ***Spectranetics, Abbott, Medtronic, Bard, Abiomed, Honorarium;***
- ***Medtronic, Abbott, AngioScore, Speaker;***
- ***Acist Medical Systems Grant; and***
- ***Verve Medical, Inc., Major Stockholder***
- ***Founder, Arizona Medical Systems***
- ***Owner/Inventor, ORACLE Thrombus Removal System***

Patents *-- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure, Vascular Access Patents*

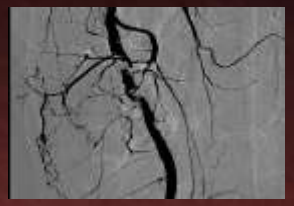
Background

- Approximately *8 million Americans* over the age of 40 have PAD.
- PAD causes morbidity in the form of claudication (a painful cramp in the muscles of the leg with exercise)
- At its worst, PAD results in failing to heal wounds and ultimately amputation.
- Diabetes increases the risk of developing PAD.

Am J of Prev Med. 2007;32:328-334.

J Vasc Interv Radiol. 2002;13:7-11.

The SFA and Popliteal Arteries Are Complex!

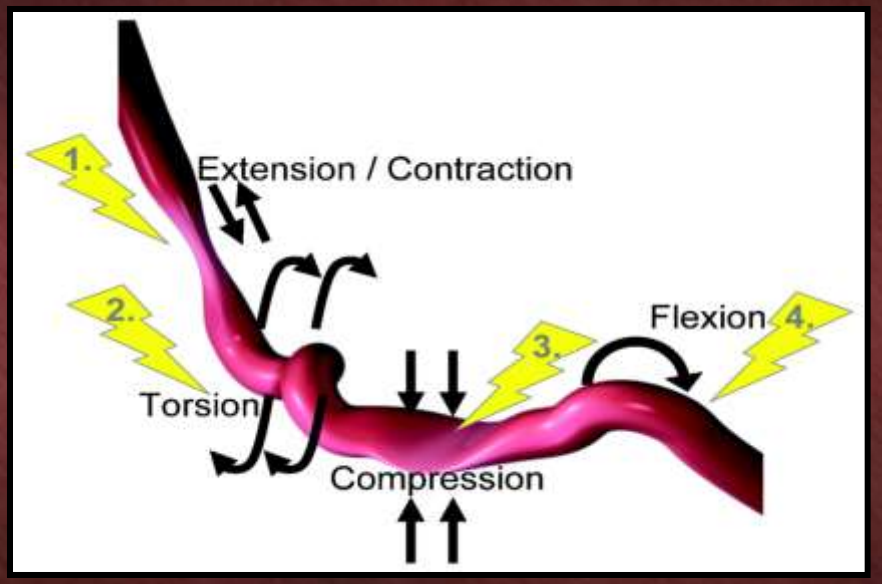


1. Extension / Contraction
2. Torsion
3. Compression
4. Flexion

R. Heuser

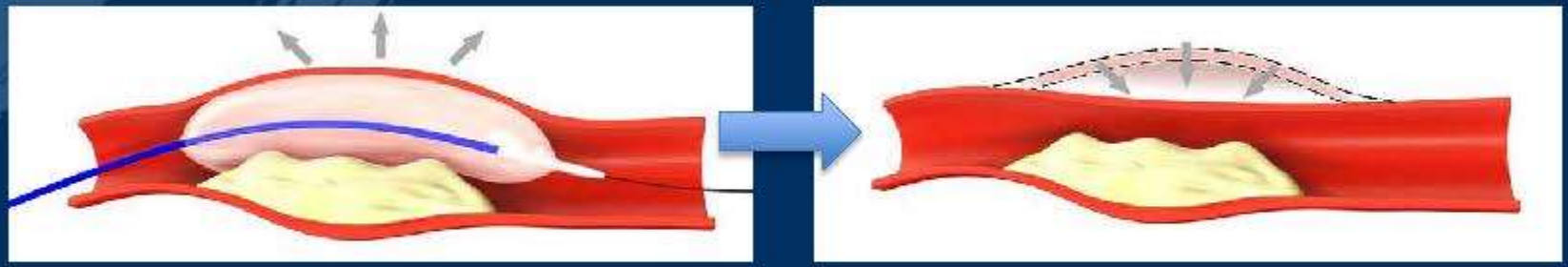
SFA/Popliteal Intervention – Nature of the Problem

- Occlusion predominates over stenosis
- Diffuse disease common
- Low flow/high resistance
- Coexistant disease of distal run-off vessels
- Triplanar intermittent mechanical stresses



Therapy for SFA/POP Comparison Studies

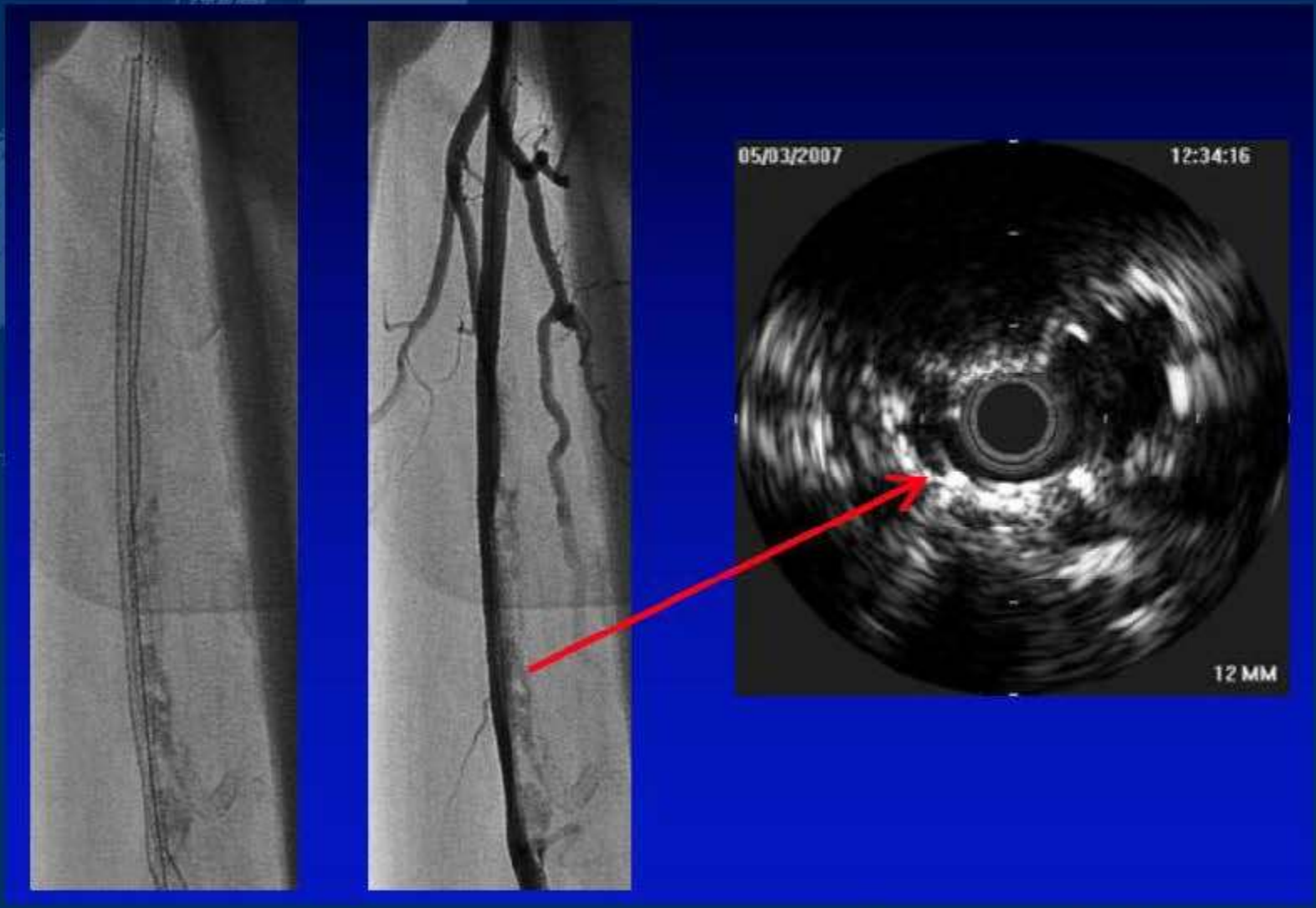
Calcium as a Barrier



Fully inflated balloon

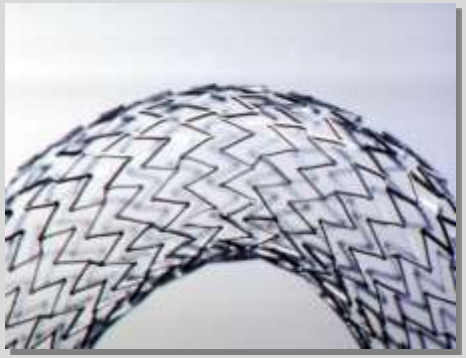
Elastic recoiled
Residual high-grade stenosis

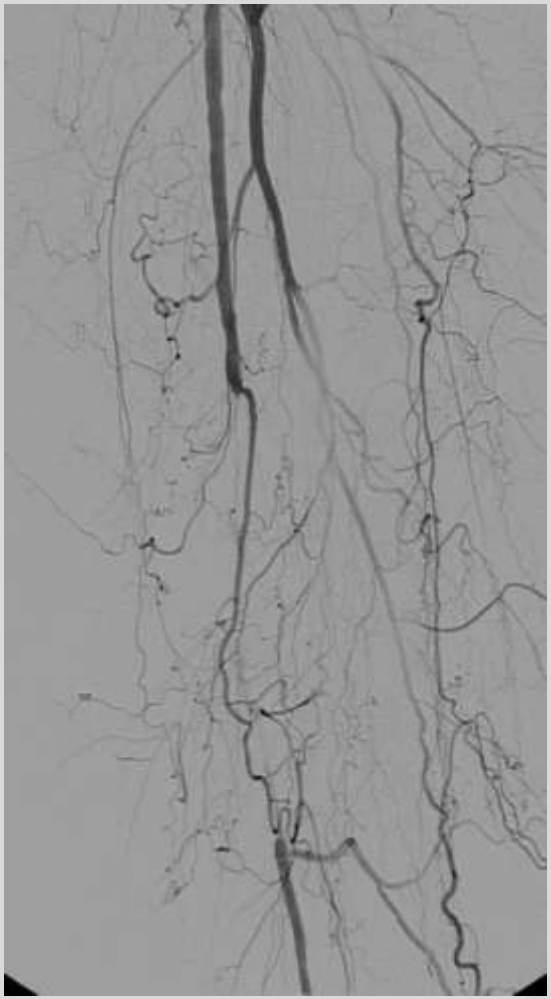
Insufficiency of radial strength

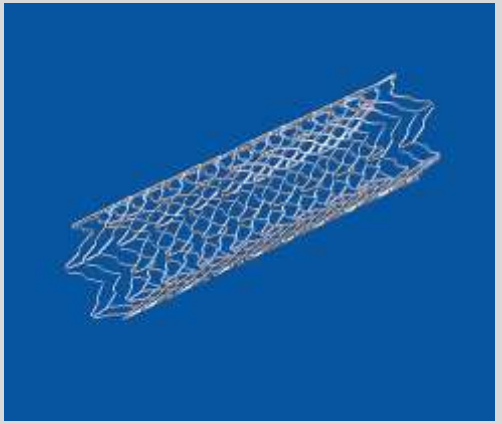


Lawrence A. Garcia, MD

Nitinol Stents for the SFA







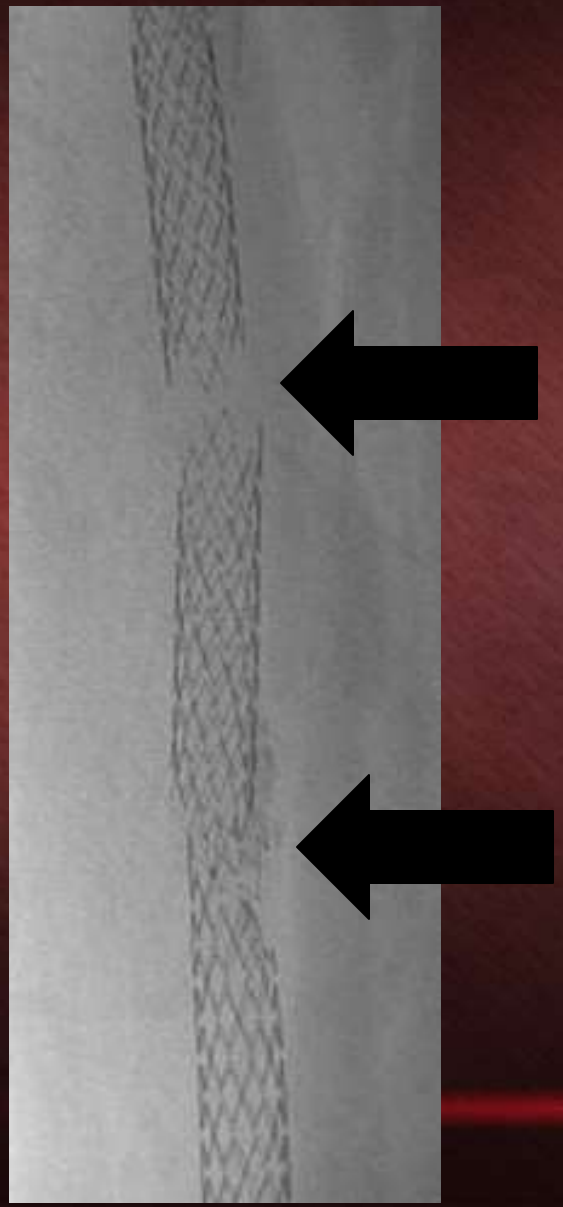
Advantages of Stenting in the SFA

- High technical success rates with excellent acute results
- Beautiful angios- *"stent- like results"*
- Short procedural times
- Low complication & distal embolization rates
- Provides scaffolding stability to vessel
- Well studied with ~ favorable data
- Widely applicable to most operators

Problems with Nitinol Slotted -Tube Stents

- Limited stent flexibility in a dynamic artery
- Suboptimal radial strength
- Limited conformability
- POOR results in popliteal, CFA, adductor canal
- Poor performance in heavy calcium, long dz.
- These issues are magnified in long SFA disease

Stent Fracture



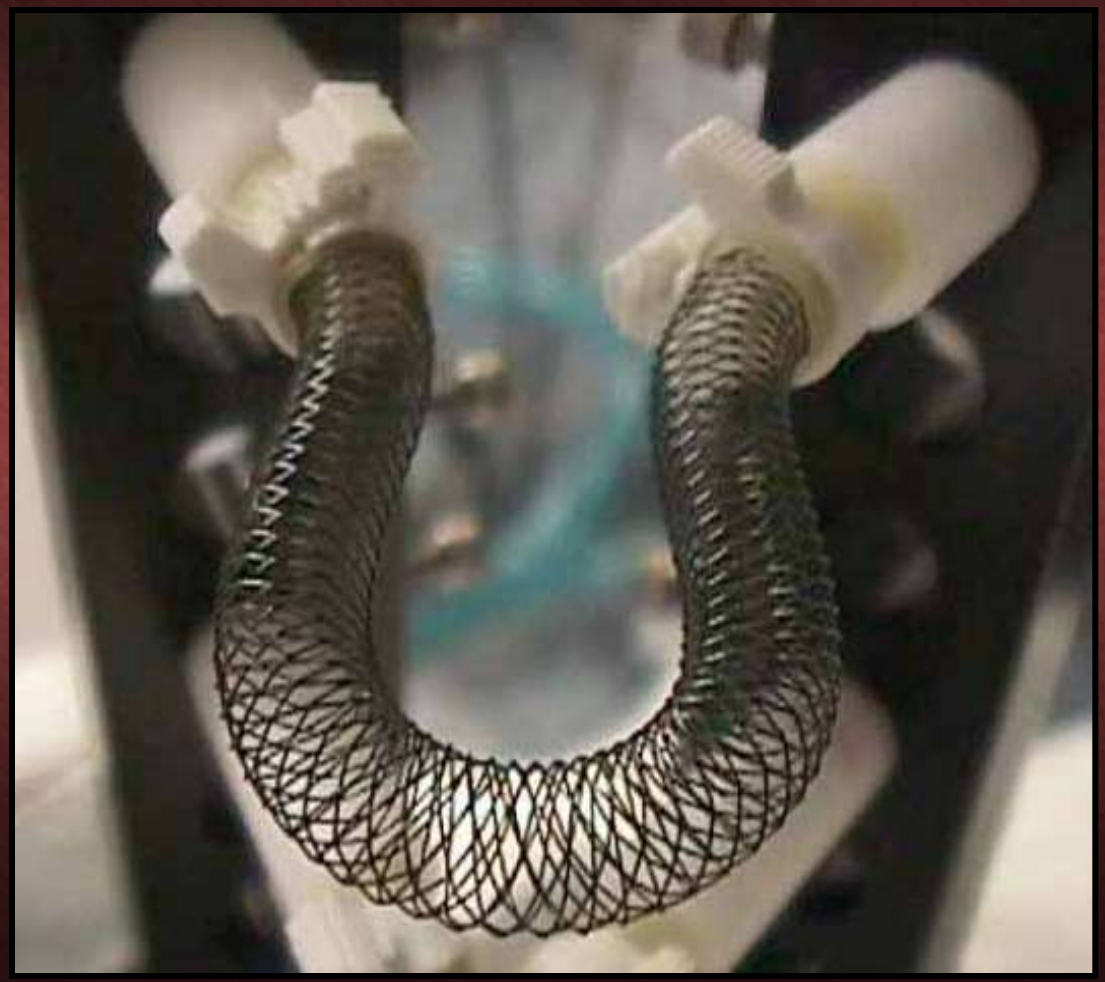
R. Heuser

So Some Advocate "Leave Nothing Behind"

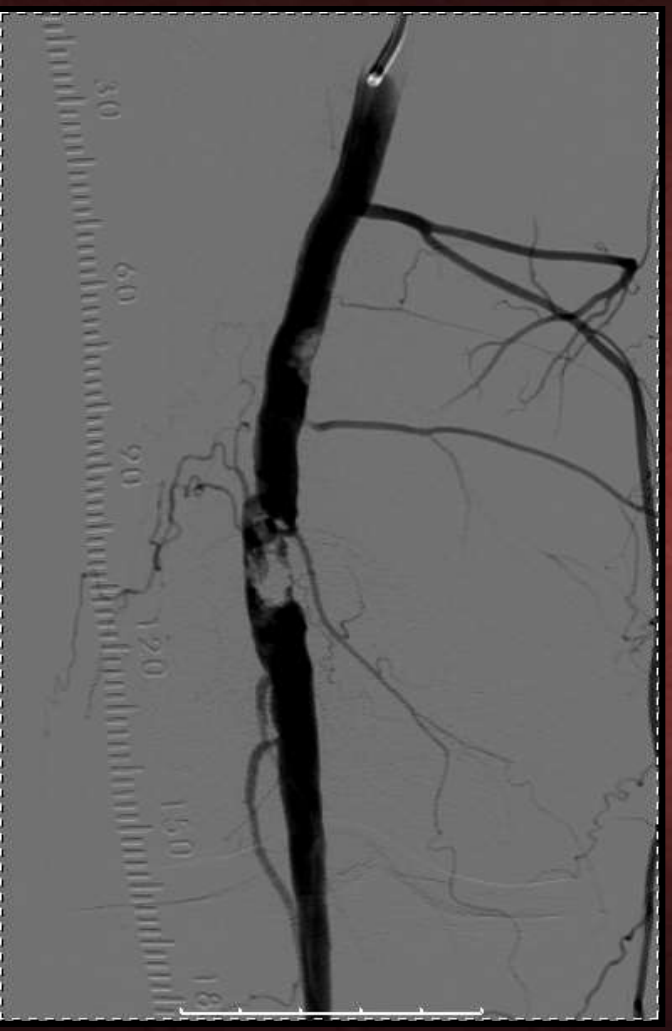
What's Bad About Stents?

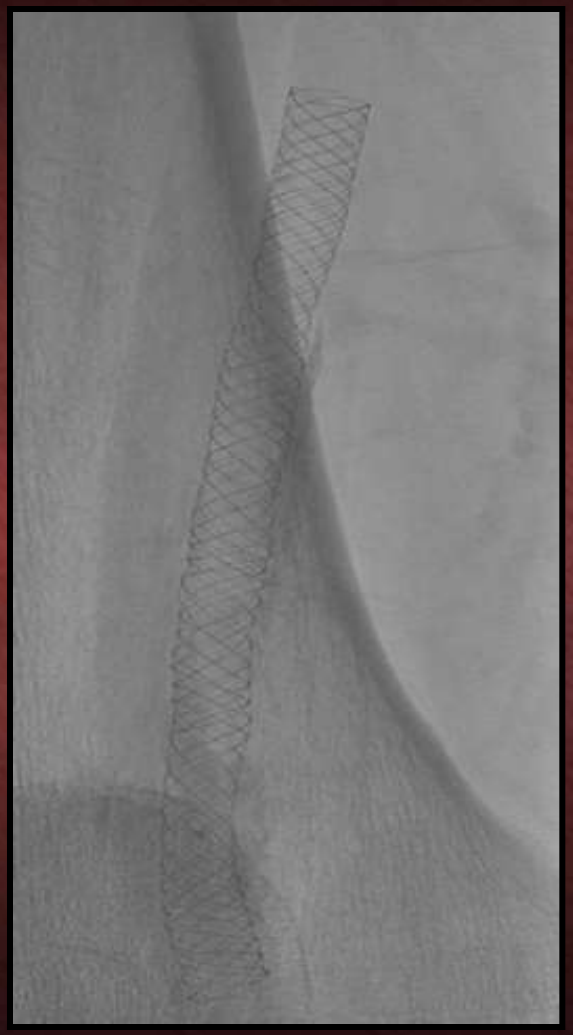
- They bend, kink, or fracture
- There are poor options for treating ISR
- They don't do well in long lesions or CA++
- They have poor long term patency/durability
- They have incomplete expansion/recoil
- Eliminates other "treatment bridges"

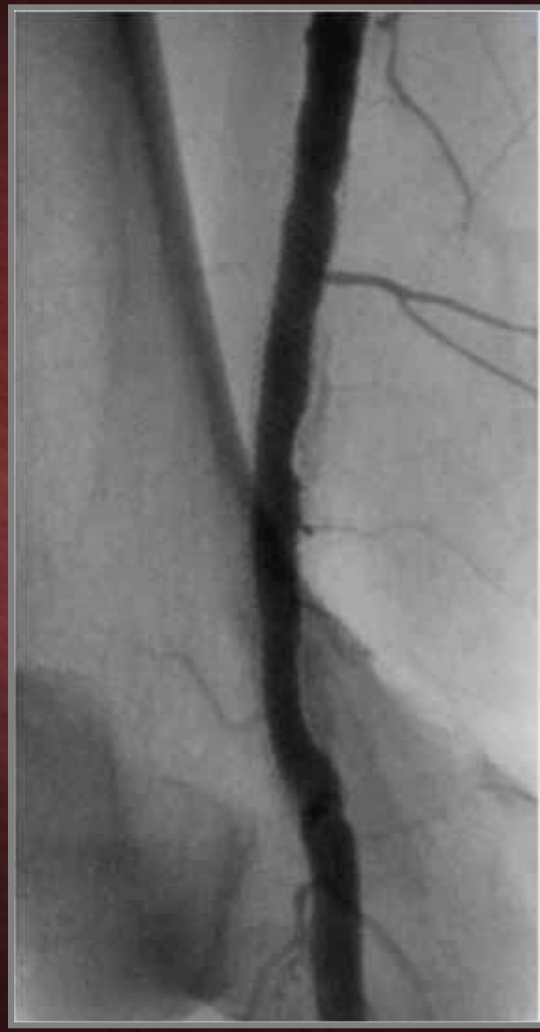
Supera Stent
Interwoven Nitinol Design



Supera Stent

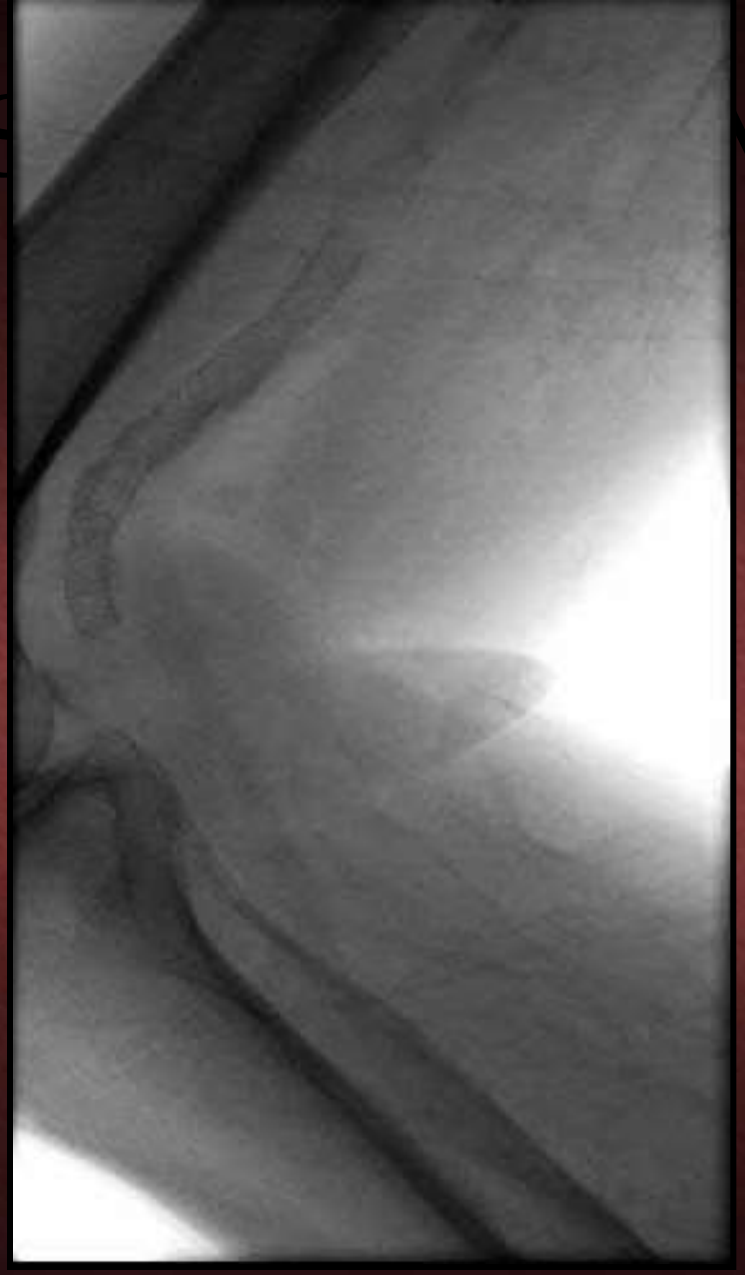


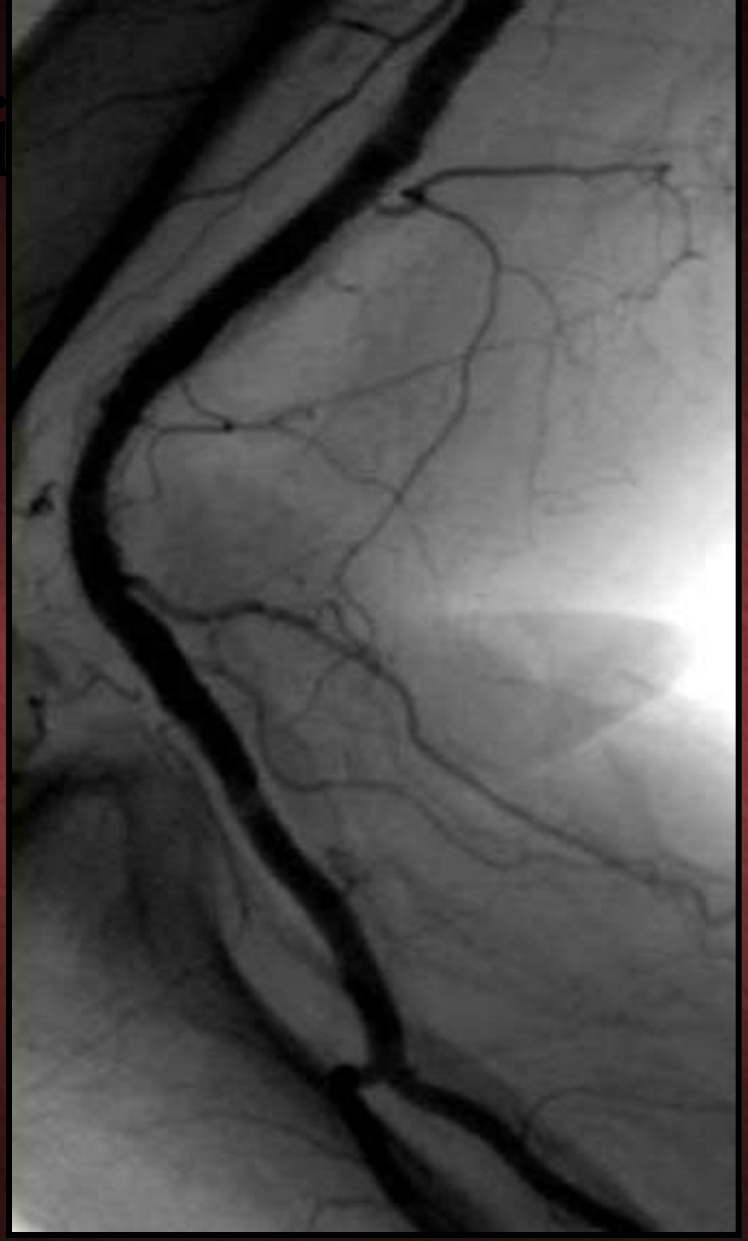




R. Heuser

S Mi





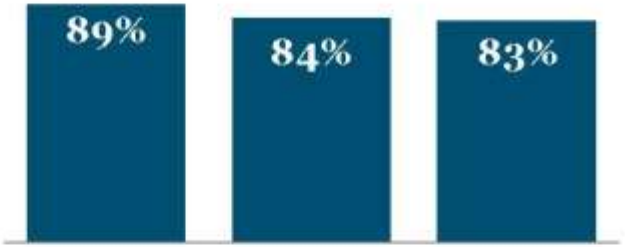
Supera®

SUPERB TRIAL RESULTS

Primary Patency (VIVA)[1]

Primary Patency (K-M)[1]

Freedom from TLR (K-M)[2]



Patient Baseline	264
Ave. Lesion Length (cm)	7.8
Fracture Rate* (%)	0
% Distal SFA/PPA	34
Occlusions (%)	25
Severe Calcium (%)	45
Rutherford 1 - 3 (%)	95
Rutherford 4 (%)	5
PSVR	2.0

1. Supera® Peripheral Stent System Instructions for Use.
2. Garcia, L., The SUPERB Trial 3-year Results, VIVA 2014.
*0% fracture rate is at 1 year.

Important Safety Information referenced within

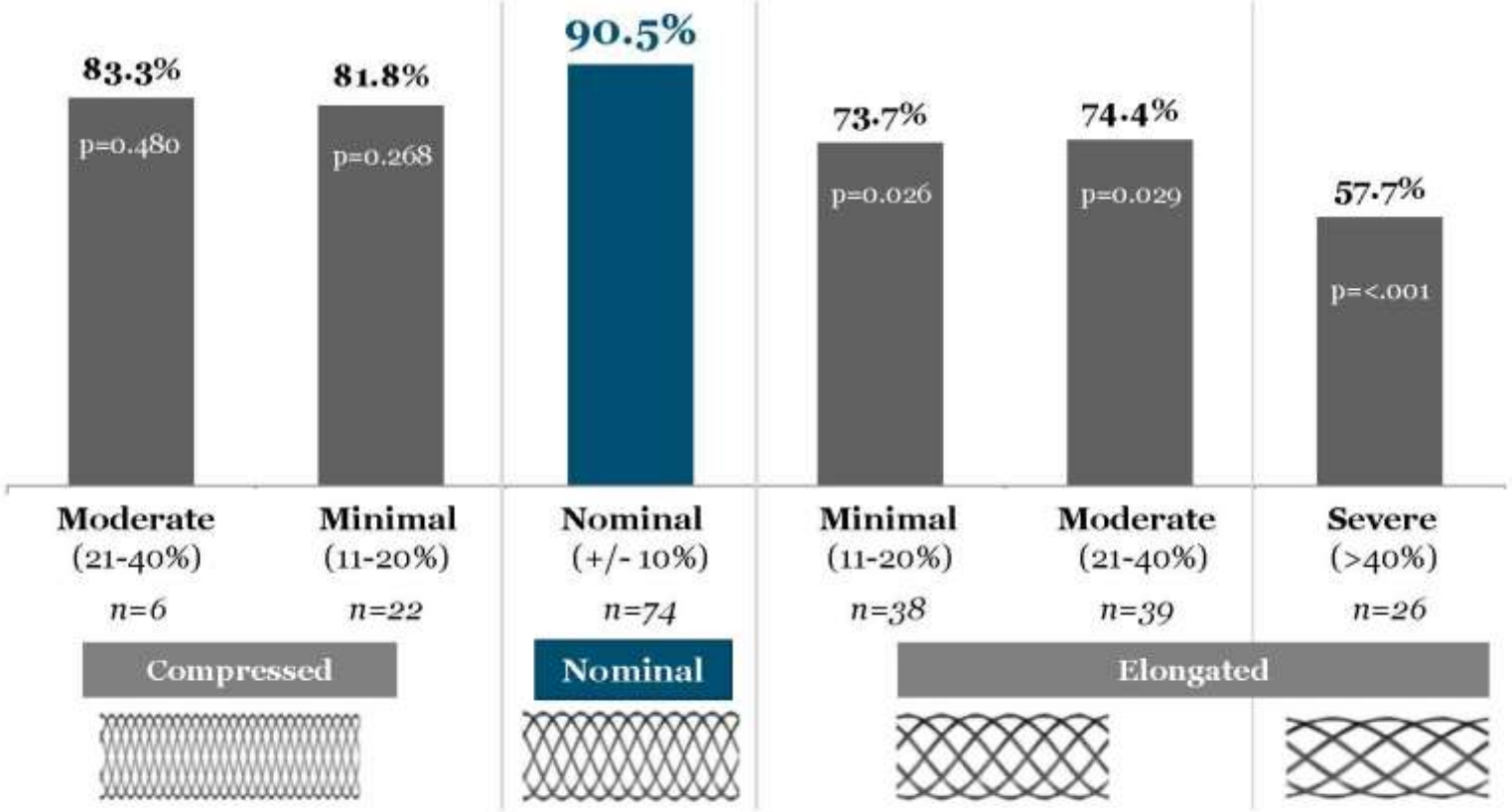
MENU

 |

PROPER SIZING, PREPARATION, AND DEPLOYMENT TECHNIQUE RESULT IN EXCELLENT PATENCY RATES

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

Primary Patency (K-M) by Percent Compression/Elongation at 12 months



Source: Supera® Peripheral Stent System Instructions for Use.
This data is from a post-hoc analysis

Important Safety Information referenced within

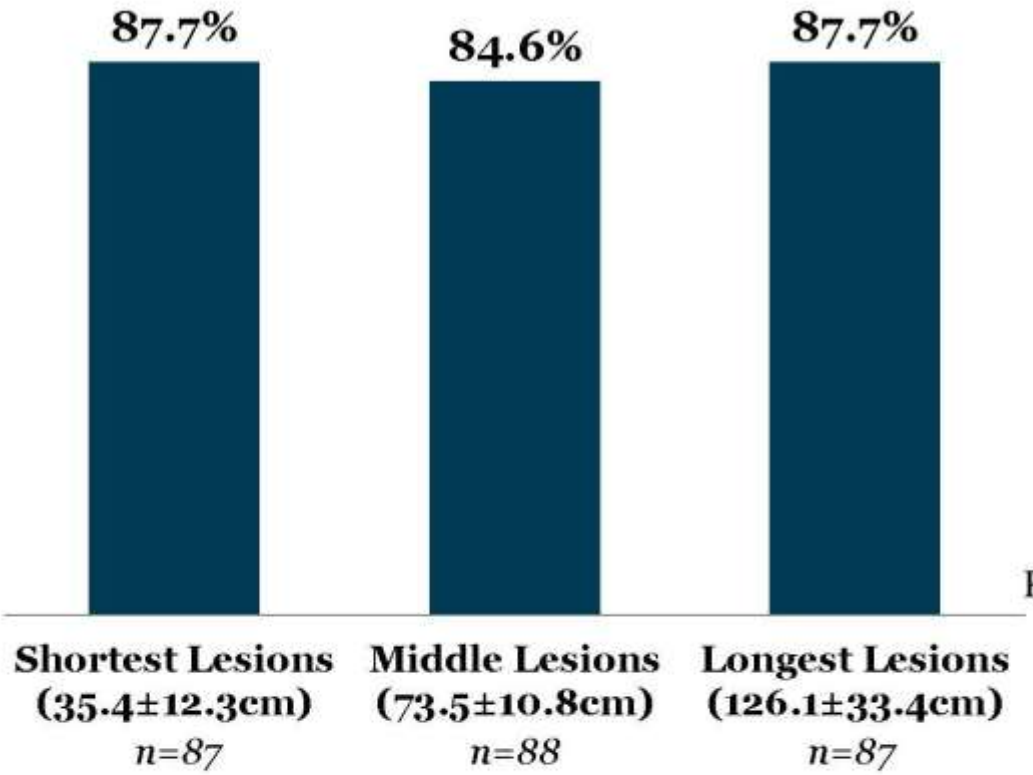
MENU

 |

SUPERB TRIAL RESULTS IN LONG LESIONS

Consistent results across lesion lengths

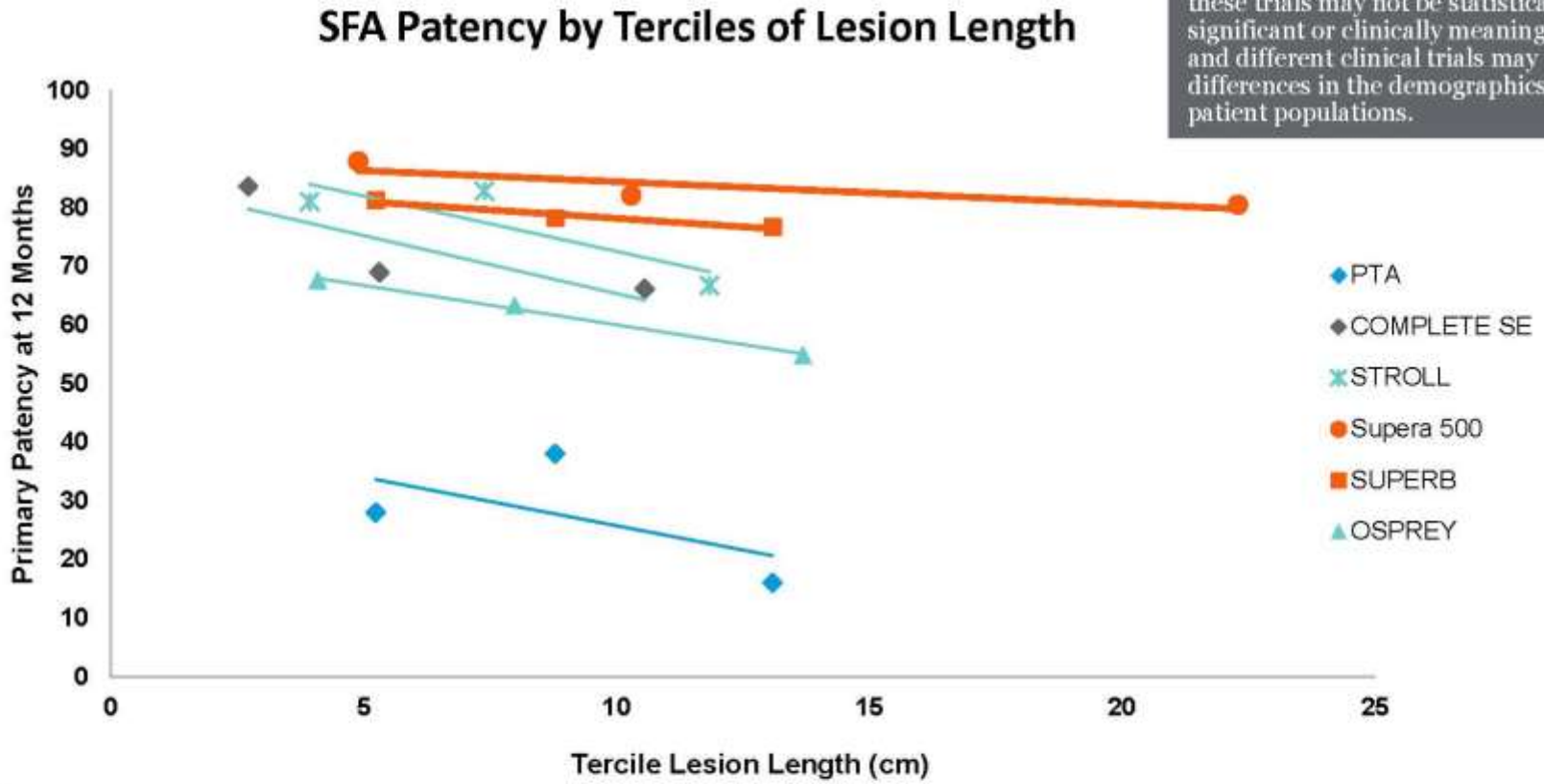
Non-Restenosis Rate by Lesion Length (12 months SUPERB IDE Trial)



Source: Supera® Peripheral Stent System Instructions for Use. Image from SUPERB trial. Photos taken by and on file at Abbott Vascular.

SFA PATENCY AT 12 MONTHS BY LESION LENGTH (TERCILES)

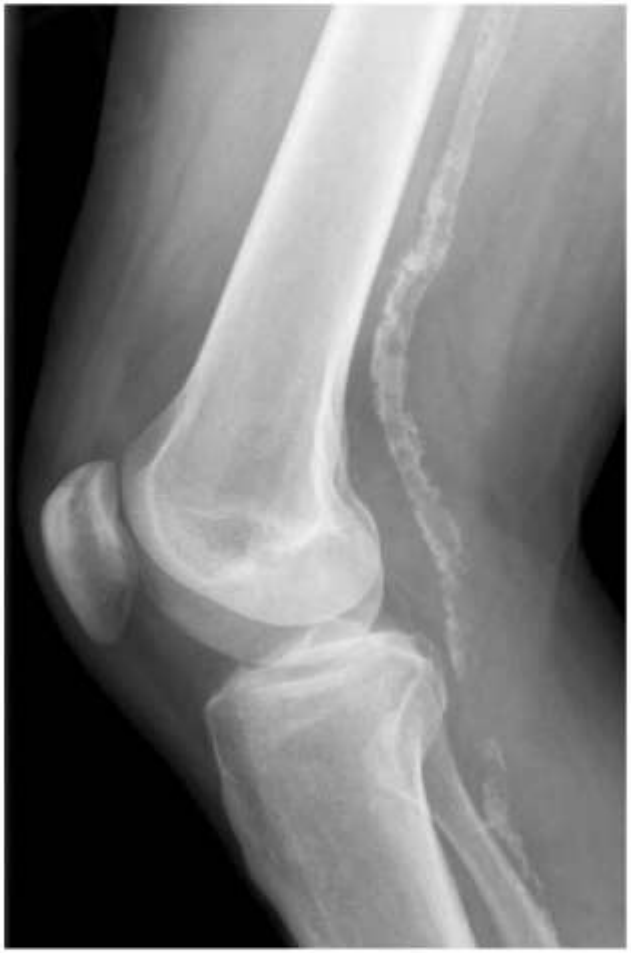
Data differences depicted between these trials may not be statistically significant or clinically meaningful and different clinical trials may include differences in the demographics of the patient populations.



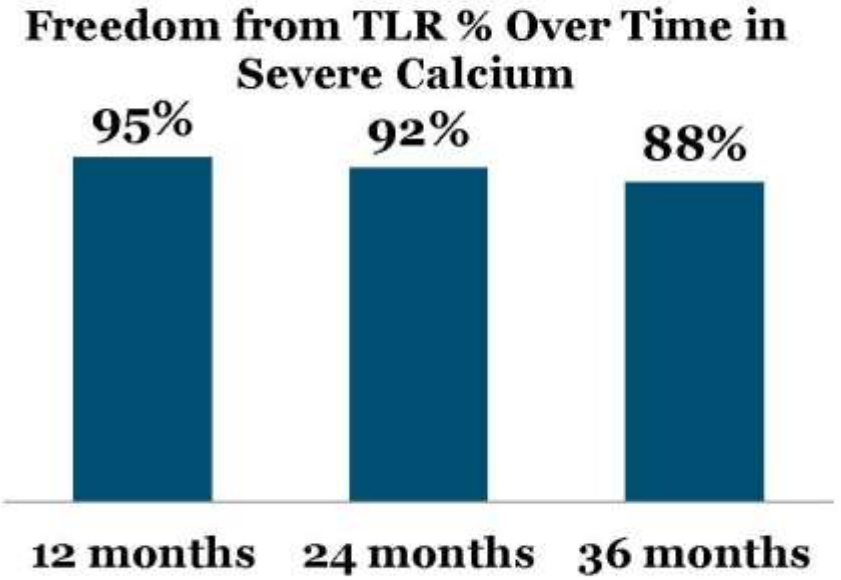
Sources:

- [PTA] Singh, K.R. Performance Goals and Endpoint Assessments for Clinical Trials of Femoropopliteal Bare Nitinol Stents in Patients With Symptomatic Peripheral Arterial Disease. Catheterization and Cardiovascular Interventions 69:910–919. 2007.
- [SNS] Data points represent patency by tercile of lesion length for Complete® SE and S.M.A.R.T. ® Control®. Patency by lesion length tercile as listed in US Instructions for Use, Complete® SE and US Instructions for Use, S.M.A.R.T.®Control® Stent.
- (SNS) US Instructions for Use, Misago® Stent.
- SUPERA 500 – LINC 2013, D. Scheinert.
- US Supera®Peripheral Stent System Instructions for Use.

SUPERA® HAS STRONG CLINICAL OUTCOMES IN SEVERE CALCIUM AT 3 YEARS

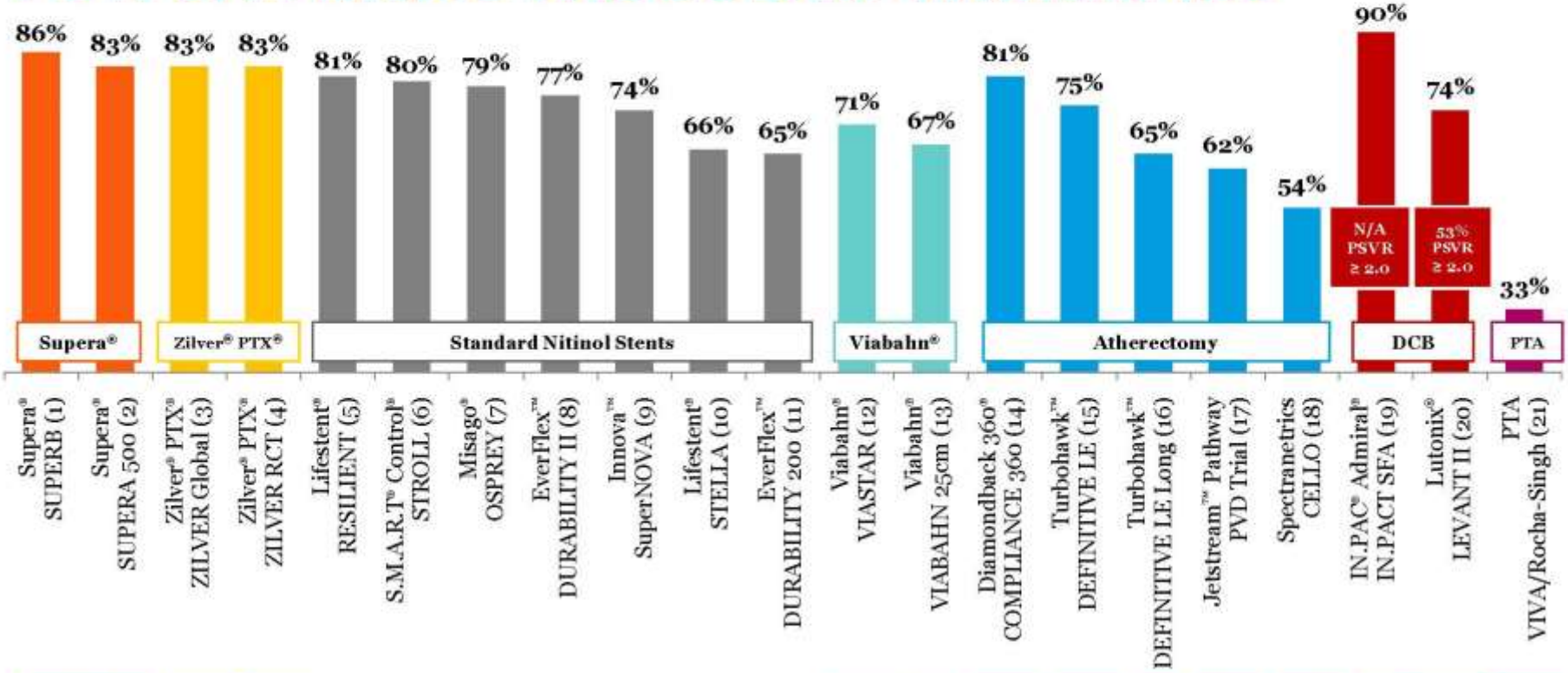


SUPERB Data - Severe Calcification	
% of Lesions with Severe Calcification (SUPERB Trial)	45% (n=118)
Patency (VIVA 12 months)	89%



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

12-MONTH PRIMARY PATENCY (K-M) FOR SFA ENDOVASCULAR THERAPIES



n	264	470	787	241	134	250	261	287	299	58	100	72	71	25	671	232	172	65	220	316	307
cm	7.8	12.6	10	5.5	7.1	7.7	8.4	8.9	9.3	22	24	19	27	5.6	8.1	14.6	2.7	5.6	8.9	6.3	8.7
PSVR	2	2.4	2	2	2.5	2	2	2	2.4	2.4	2.4	2.5	N/A	2.5	2.4	2.4	2.4	N/A	2.4	2.5	N/A

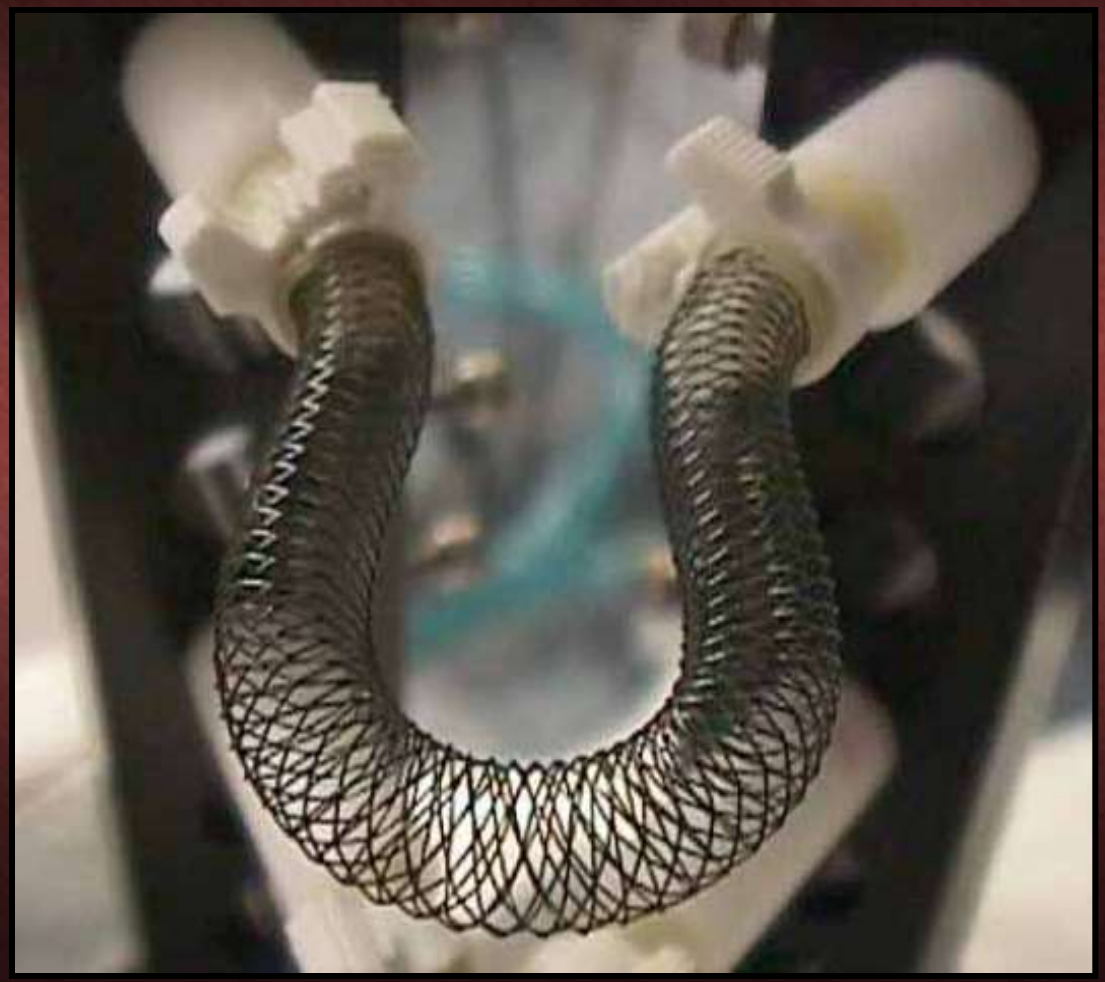
See appendix for sources.
Data differences depicted between these trials may not be statistically significant or clinically meaningful and different clinical trials may include differences in the demographics of the patient populations.

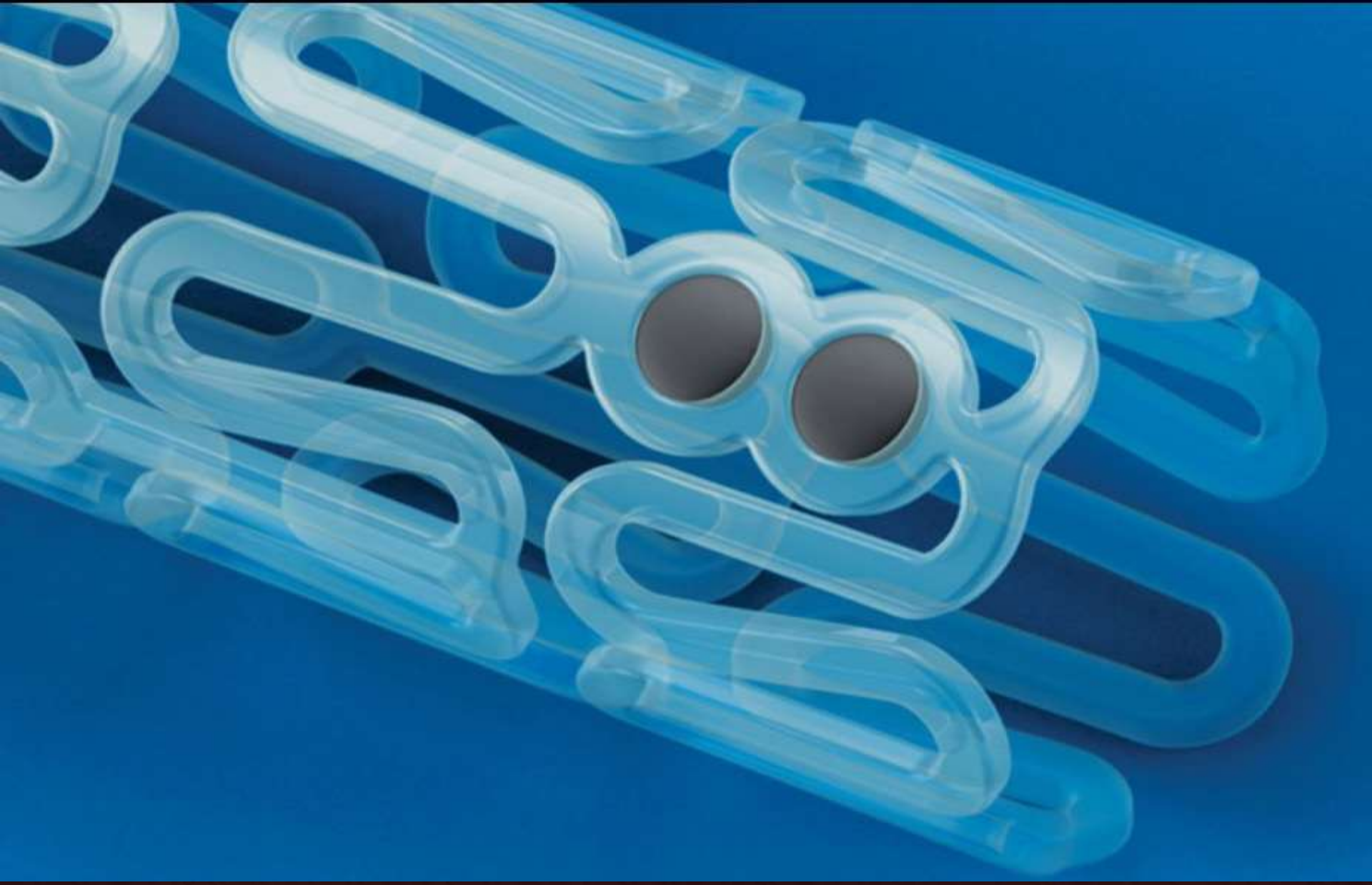
Important Safety Information referenced within

Fem-Pop Treatment

- Long lesions can be treated endovascularly with good results using DES, DCB and interwoven nitinol showing similar 1 year results
- Interwoven nitinol stents show less impact of lesion length on patency
- With correct vessel preparation and technique, interwoven nitinol stents can provide a unique fracture free, calcium resistant, non drug dependent device for long term patency in long lesions

Supera Stent
Interwoven Nitinol Design





Novel Stent Technology Can Shed Light: SUPERA or BVS

BVS

- Significant clinical need remains for a therapy that
  - Achieves durable patency and reduces restenosis
  - Reduces rates of repeat interventions
  - Does not require a permanent implant
  - Preserves future treatment options

Bioresorbable Scaffolds

- Disadvantages
  -- Inflammation
  -- Embolization of material
  -- Unknown time of support need

ESPRIT 1 – TRIAL DESIGN

- A single *de novo* lesion in the superficial femoral (SFA) or iliac arteries in patients with symptomatic claudication (Rutherford Becker Category 1-3)

  -- Prospective, Single Arms Multi-Center OUS trial evaluating the Esprit BVS (N=35)

  -- One target lesion treated with a single 6.0 x 58mm Esprit BVS

  -- Vessel diameter from ≥ 5.5 - ≤ 6.5mm, segment length ≤ 50mm

ESPRIT 1 – TRIAL DESIGN

Trial Objective:	Evaluate safety and performance of the Esprit BVS in subjects with symptomatic atherosclerotic disease of the SFA or iliac arteries
Endpoints:	Procedural, clinical, functional, hemodynamic, angiographic, IVUD, non-invasive imaging in-hospital and at F/U time points indicated (1, 6, 12 months, 2, 3 years)

ESPRIT 1 LESION CHARACTERISTICS

	Esprit BVS (N= 35)
External Iliac (%) SFA (%)	11.4 88.6
Proximal	14.3
Mid	31.4
Distal	54.3
Target lesion length (mm)	35.7
Total occlusions (%)	22.9*
Occlusion length (mm)	**30.6***

*Site value. All other data reported are from angiographic core laboratory

ESPRIT 1 Key Study Endpoints

	Esprit BVS (N=34*) 1-Month	Esprit BVS (N=34*) 6-Month	Esprit BVS (N=34*) 12-Month
Deaths (%)	0.0	0.0	0.0
Any amputation of treated limb (%)	0.0	0.0	0.0
Bypass surgery of treated limb (%)	0.0	0.0	0.0
Target lesion revascularization (TLR) (%)	0.0	0.0	8.8% (3/34)
Scaffold thrombosis (%)	0.0	0.0	2.9% (1/34)

One subject withdrew consent for follow-up

Patient selection and oversized vessels increased risk in two patients having TLR

- TLR #2/scaffold thrombosis – oversized vessel resulting in malapposition, prior thrombolectomy with Dacron patch graft proximal to target lesion, diseased profunda and inflow lesion left untreated increased the risk for TLR
- TLR #3 – oversized vessel resulting in malapposition increased the risk for TLR

ESPRIT 1 Rutherford Becker Class and Ankle Brachial Index

	Esprit BVS baseline (N=35)	Esprit BVS Month (N=33)	Esprit BVS 6-Month (N=34)	Esprit BVS 12-Month (N=34)
Rutherford 0 (%) (no claudication)	0.0	84.9	76. 6	73.5
Rutherford 0 (%) (mild claudication)	8.6	12.1	23.5	11.8
Rutherford 0 (%) (moderate claudication)	34.3	3.0	8.8	8.8
Rutherford 0 (%) (severe claudication)	57.1	0.0	0.0	5.9
ABI	0.75	1.00	0.99	0.98

ESPRIT 1 Duplex Ultrasound Results

	Post-Procedure (N=24)	6 Month (N=30)	12 Month (N=29)
PSVR	**1.27**	**1.35**	**1.6 6**
Binary restenosis	**NA**	**0%**	**12.9% (4/31)***

ESPRIT 1 Angiographic Results

	Pre-Procedure (N=35)	Post-Procedure (N=35)	1 Year (N=27)
In-segment RVD 9mm)	4.9	4.9	5.0
In-segment MLD (mm)	1.0	4.2	3.1
In-segment diameter Stenosis (%)	80.0	14.0	35.3

ESPRIT 1 Angiographic Results
Impact of vessel size on outcomes

	All 1-year F/U Patients (N=27)	Patients with D_{max}* ≤ median N=14	Patients with D_{max}* > median N=13
In-scaffold %DS post-procedure	**8.7%**	**8.9%** ↓ +11.2%	**8.5%** ↓ +11.2%
In-scaffold %DS 1 year	**31.8%**	**20.1%**	**44.4%**

*D_{max} = largest diameter within the scaffolded segment by core lab assessment median 5.57mm)

Outcomes are better in small vessels appropriately Sized to the scaffold

R. Heuser

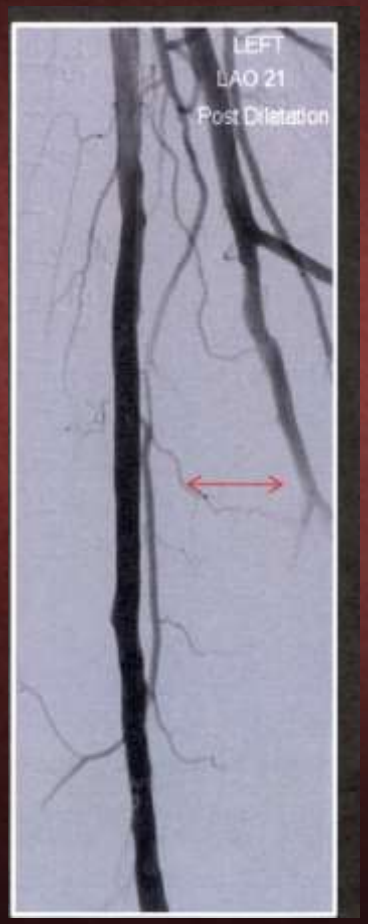
ESPRIT 1 One year Conclusions

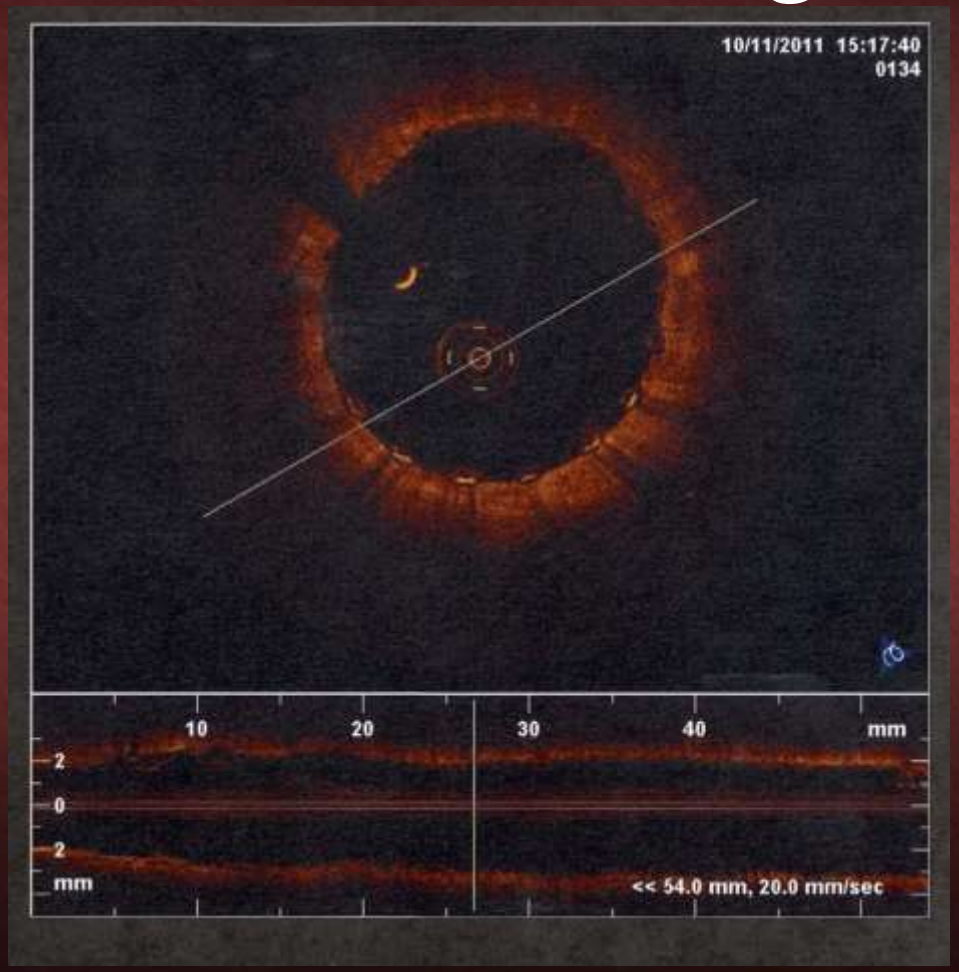
- Safety demonstrated with no deaths or amputations
- Low occurrence of revascularizations (8.8% at 1y)
- Sustained improvement in Rutherford category (RB 0-1 97% at 1mo, 85% at 1y)
- Angiographic restenosis at 1 year is lower in smaller vessels where scaffold is matched appropriately to vessel diameter…match the scaffold to the vessel size

Stanza™ Scaffold Characteristics

- Composite structure of PLGA fibers +
- Flexible, self-expanding design
- Radial resistive force similar to nitinol stents
- Resorbs in 12-15 months

Optical Coherence Tomography: Post Procedure Image





R. Heuser

Novel Stent Technology Can Shed Light: SUPERA or BVS

BVS

-- Provides minimal resistance to arterial movement

-- Allows vessel to relax to its native state

-- Permits radial strength, flexibility, resistance to recoil;

-- Enables single or combination drug loading

-- Does not preclude or complicate re-intervention options

Novel Stent Technology Can Shed Light: SUPERA or BVS

BVS

- Current materials – sub-optimal flexibility, radial force, conformability to underlying anatomy, accommodation to arterial motion – compression, torque, etc.
- Ideal award-winning SFA stent recipe may be unobtainable with currently available ingredients BECAUSE:
  - -- Limited opportunity to manipulate radial force
  - -- Unresolved questions of acute fracture resistance/safety

Conclusion

- We are better at obtaining excellent initial outcomes than providing sustained and durable results
- Device-drug combination therapy will ultimately be instrumental in improving results for certain vessels prone to restenosis

Continued

Continued

Conclusion

- Bioabsorbables may play an important role
- We look forward to new generation biomimetic stents
- As with any PAD lesion, the exact ideal treatment will depend on the patient's lesion characteristics