What is needed in the future for SFA treatment?

Jochen Bauer
Manager R&D Innovation and Technology, Abbott Vascular, Switzerland

Turning Science into Caring

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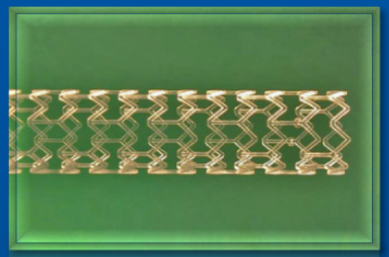
Current Treatment Lessons Learned: Factors for Maintaining Long-Term Patency

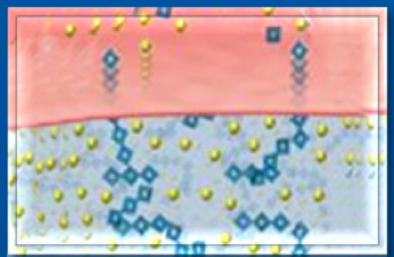
- Lesion preparation is important
- Stent sizing is important – do not grossly oversize
- Not all self-expanding stents are the same
  - Low chronic outward force is important
  - Strut/cell movement during longitudinal compression is important
- DES can effectively mask the effects above, as long as it is being eluted and present in tissue.
  - Without the active agent, in the presence of constant irritation, patency inevitably decreases.

Drug Eluting BVS



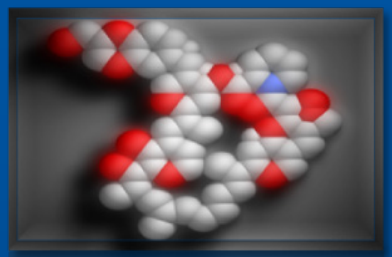
Bioresorbable Scaffold

- Poly(L-lactide) (PLLA)
- Naturally resorbed, fully metabolized
- Designed for SFA and Iliac Arteries



Bioresorbable Coating

- Poly(D,L-lactide) (PDLLA) coating
- Naturally resorbed, fully metabolized



Everolimus

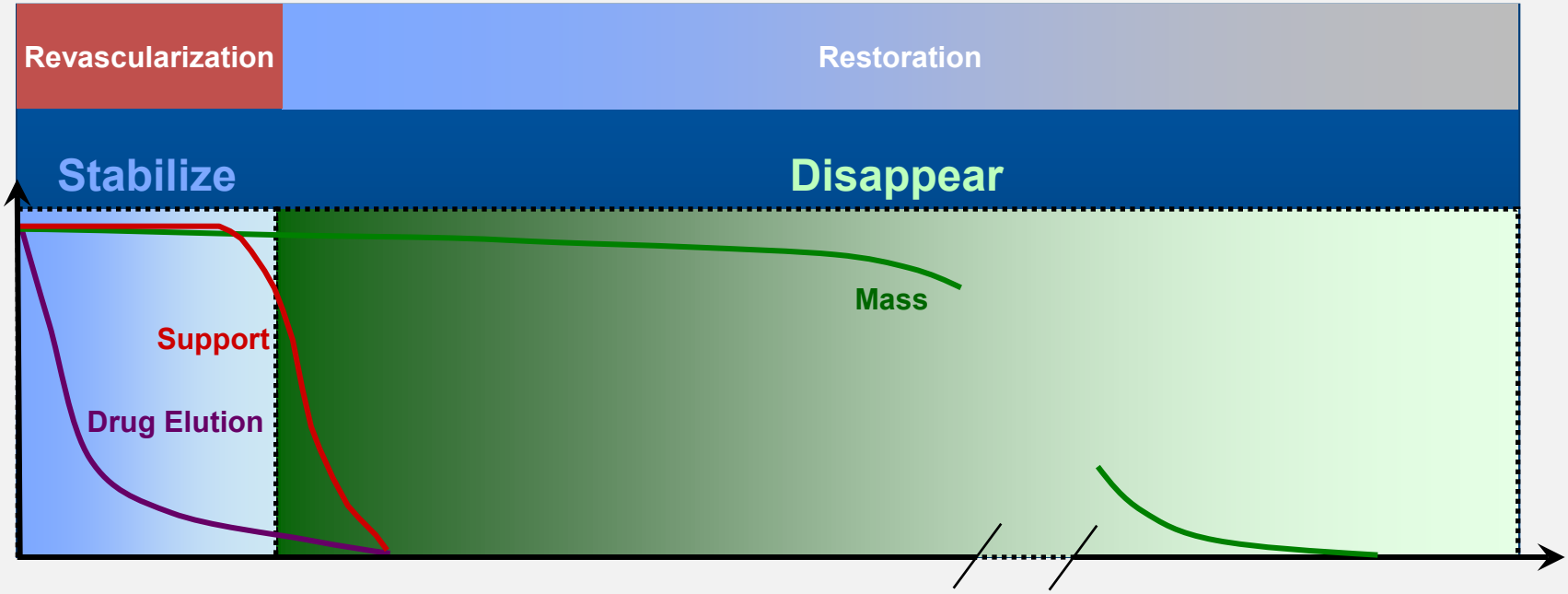
- 100 µg/cm2

Esprit Delivery System

- Balloon-expandable delivery system
- 035” OTW platform

BVS for the peripheral arteries in an investigational device outside the U.S. Not available for sale.
All illustrations are artists’ renditions. Illustrations created by Abbott.

Drug Eluting BVS Phases of Functionality



- Lumen stabilization and scaffold disappearance are the key ingredients for a durable SFA therapy
- Combining endovascular legacy with deep coronary BVS experience creates a specialized platform to address long term SFA needs

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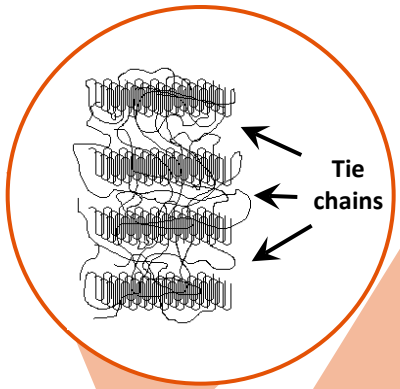
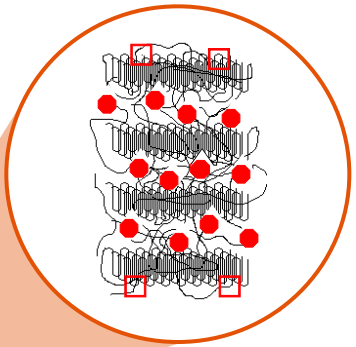
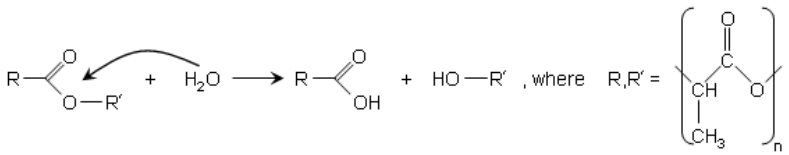
Intentionally Employing Natural Polylactide Degradation

Hydrolysis occurs via random chain scission of the ester bond

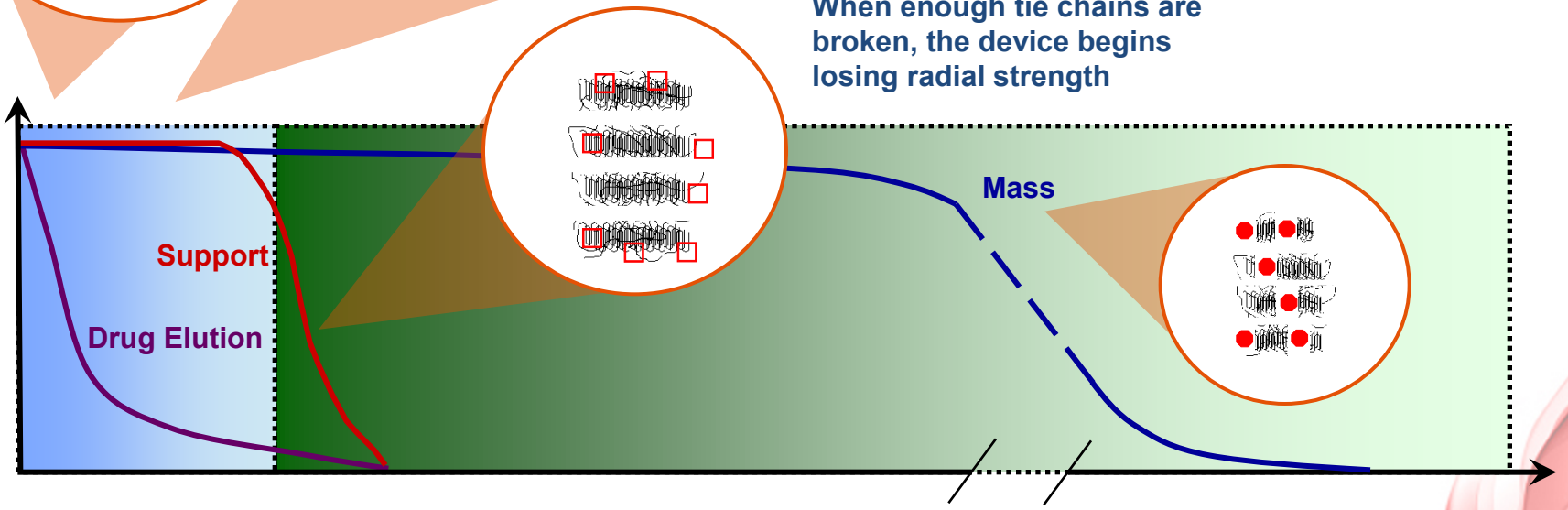




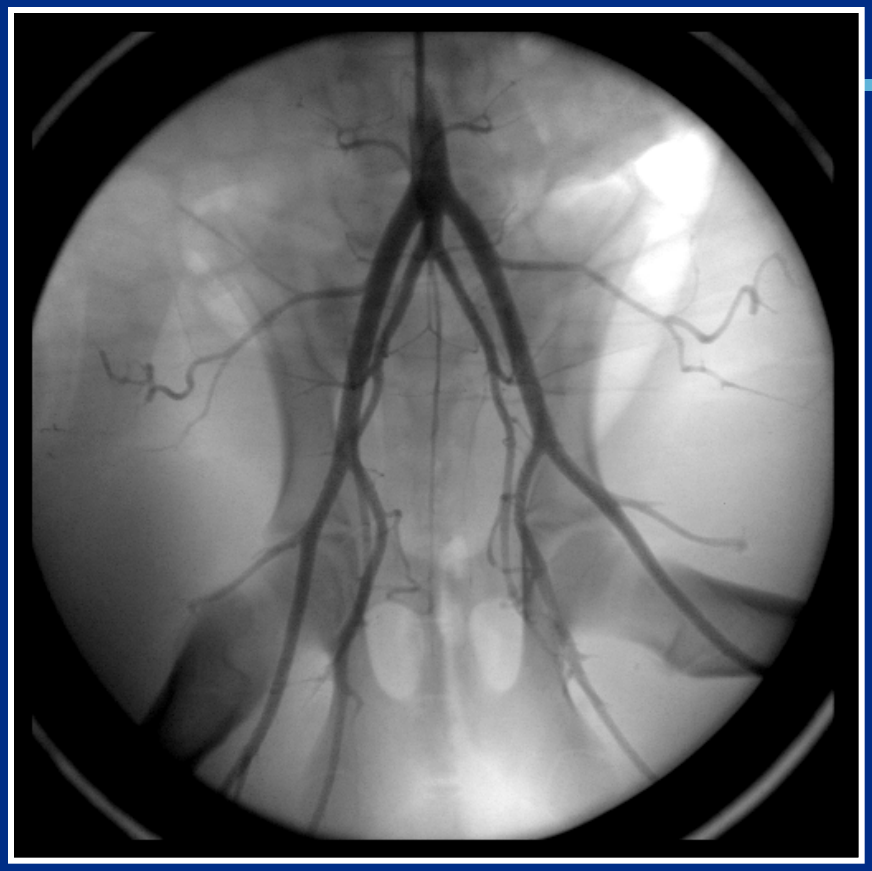


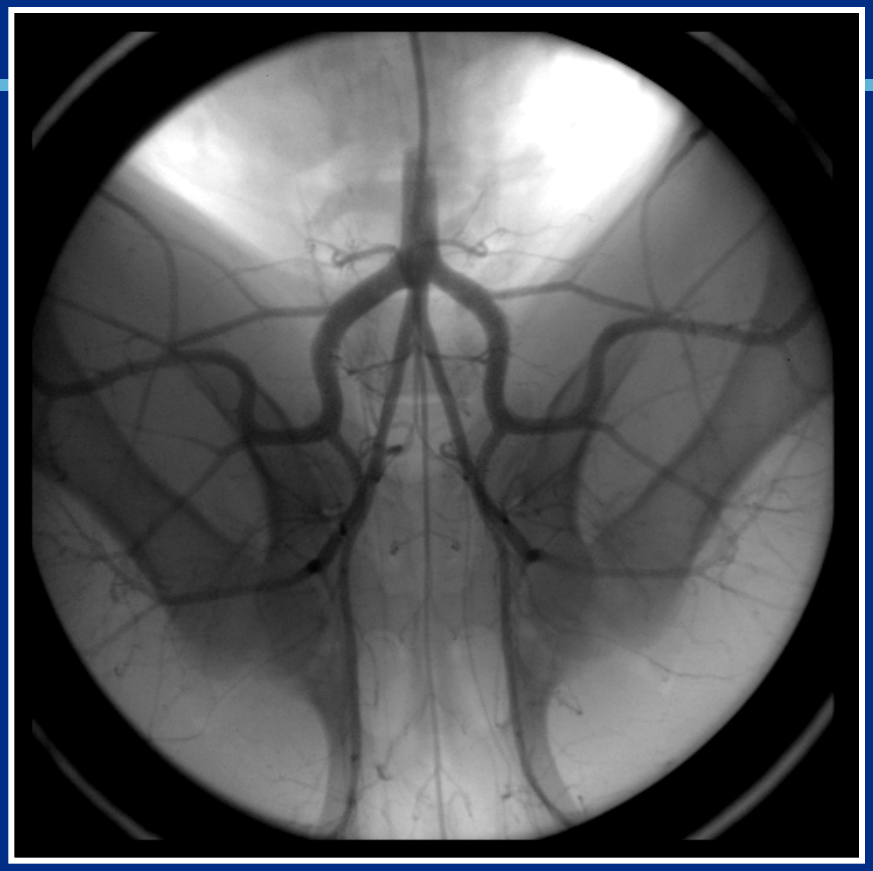
Hydrolysis randomly cleaves amorphous tie chains, leading to a decrease in molecular weight without altering radial strength

When enough tie chains are broken, the device begins losing radial strength



Porcine iliac model of PVI



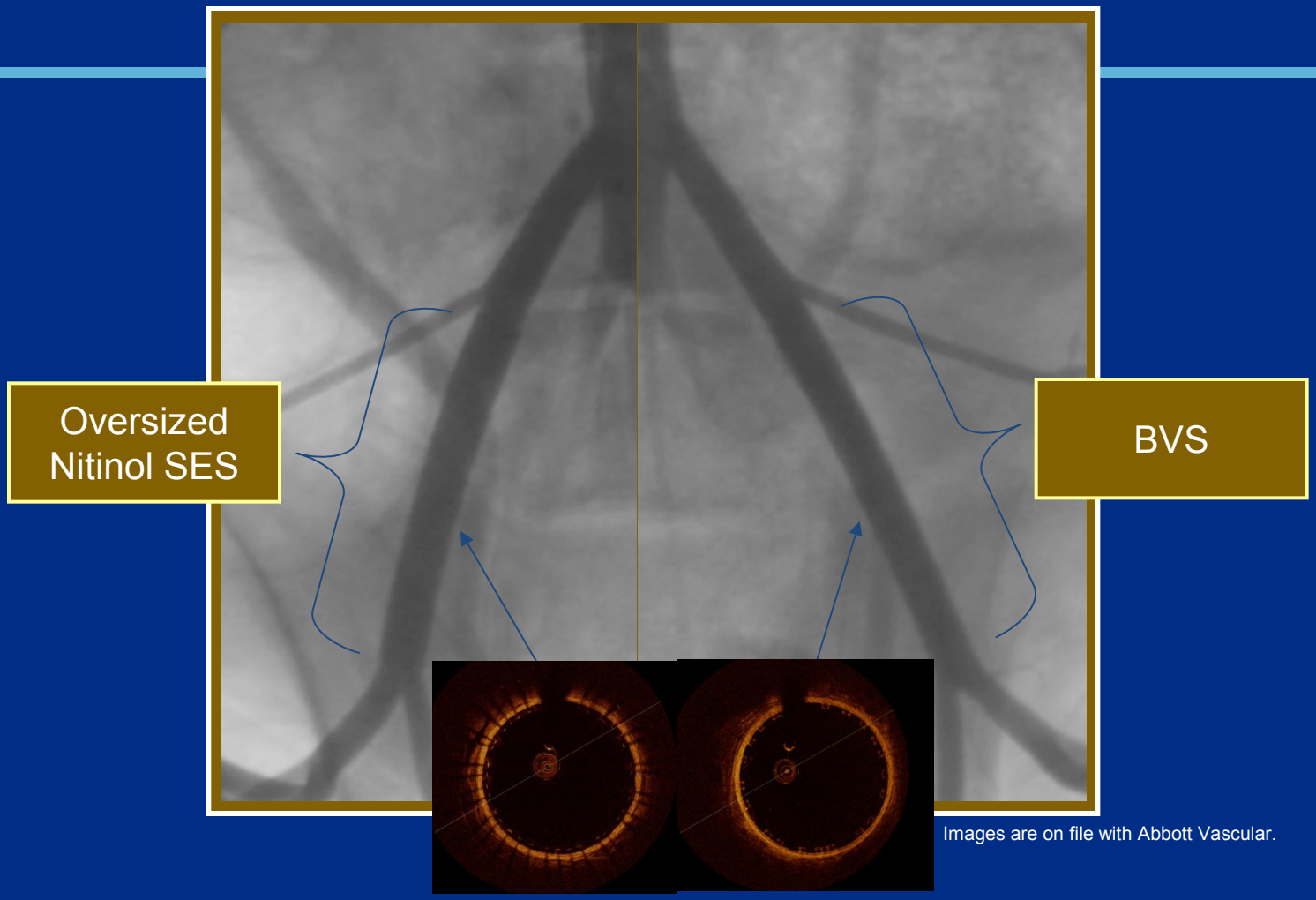


Hip Extension **vs.** **Flexion**

ABSORB BTK is currently in development at Abbott Vascular. Neither approved nor available for sale.

Peripheral Bioresorbable Vascular Scaffold (BVS)

Acute implantation in a porcine iliac artery



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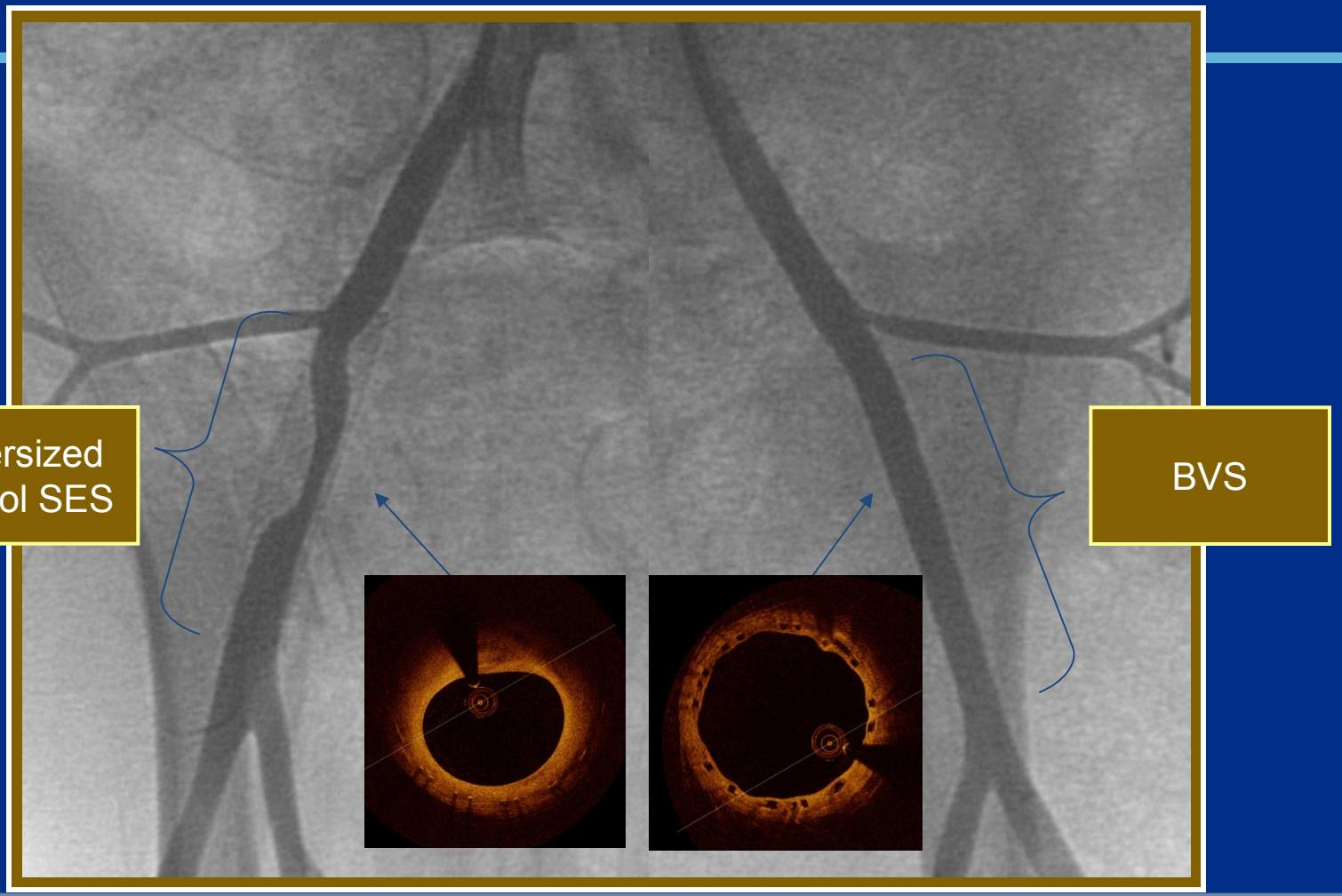
Peripheral Bioresorbable Vascular Scaffold (BVS)

6 mos. after implantation in a porcine iliac artery



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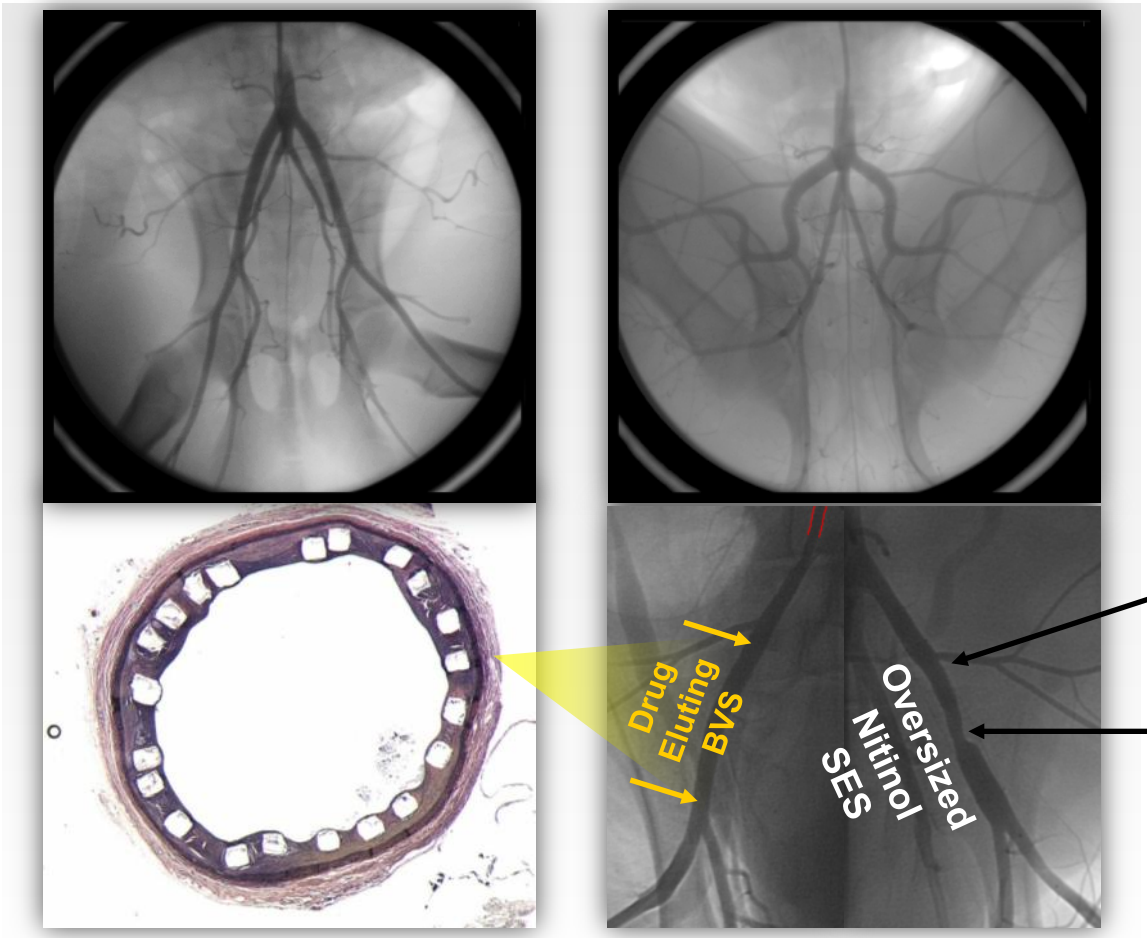
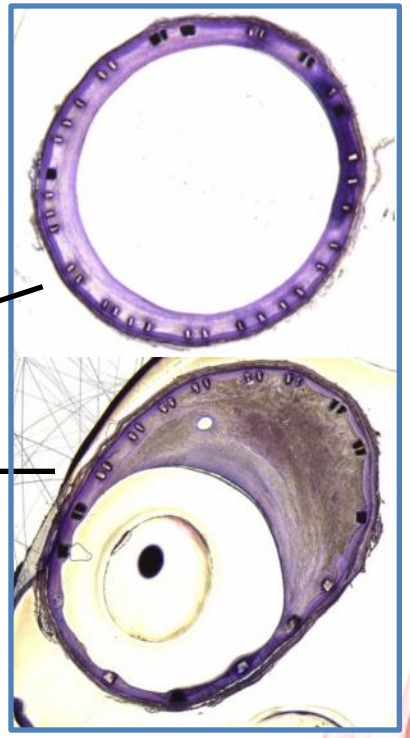
Chronic Deformation Effects on Neointima



Leg flexion causes stent deformation and neointimal formation



BVS for the peripheral arteries in an investigational device outside the U.S. Not available for sale.
Photos taken by and on file at Abbott Vascular. Tests performed by and data on file at Abbott Vascular. Representative preclinical data from porcine coronary arteries, 2x objective.

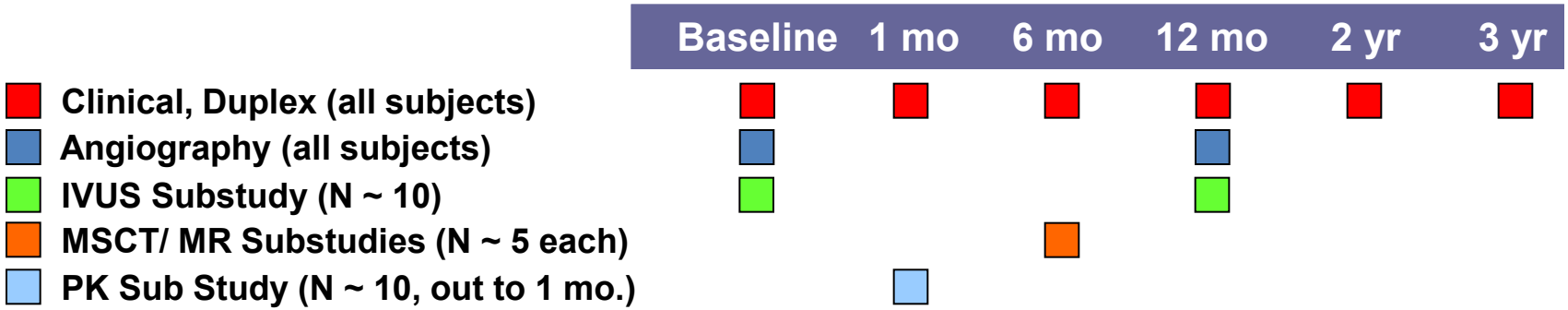
Crush Recovery Comparison:
Balloon Expandable Stent vs. Bioresorbable Scaffold

* This video demonstrates the physical properties and capabilities of PLLA-based bioresorbable scaffolds.

ESPRIT I 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 Arm, Multi-Center OUS trial evaluating the Esprit BVS (N=35)
- One target lesion treated with a single 6.0 x 58 mm Esprit BVS
- Vessel diameter from ≥ 5.5 – ≤ 6.5 mm, segment length ≤ 50 mm



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, IVUS, non-invasive imaging in-hospital and at F/U time points indicated

www.clinicaltrials.gov
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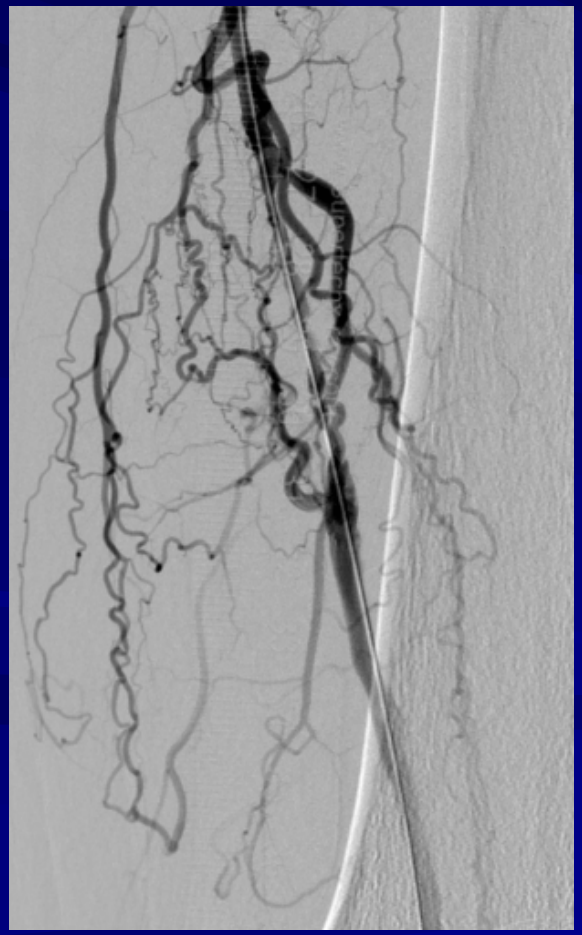
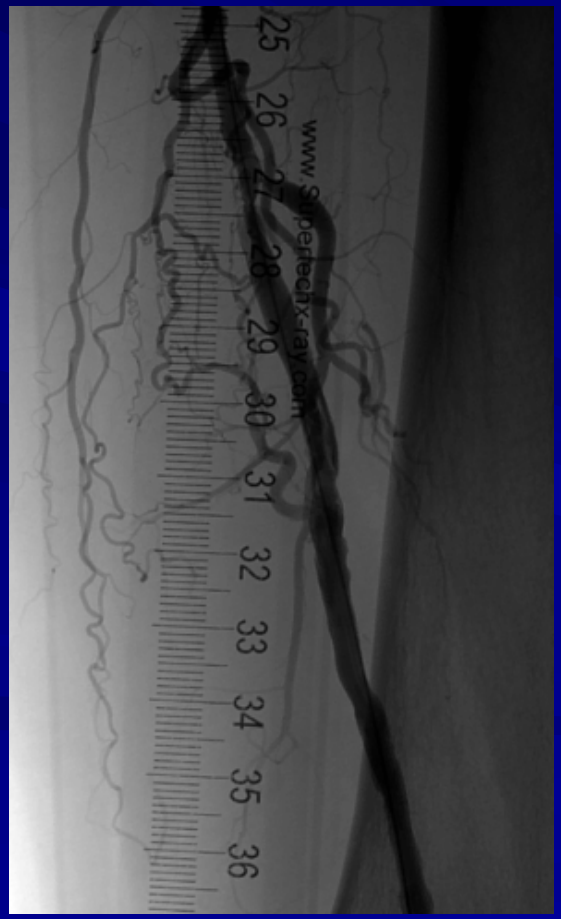
ESPRIT I FEMORAL

Pre- and post-procedure subtracted angiograms

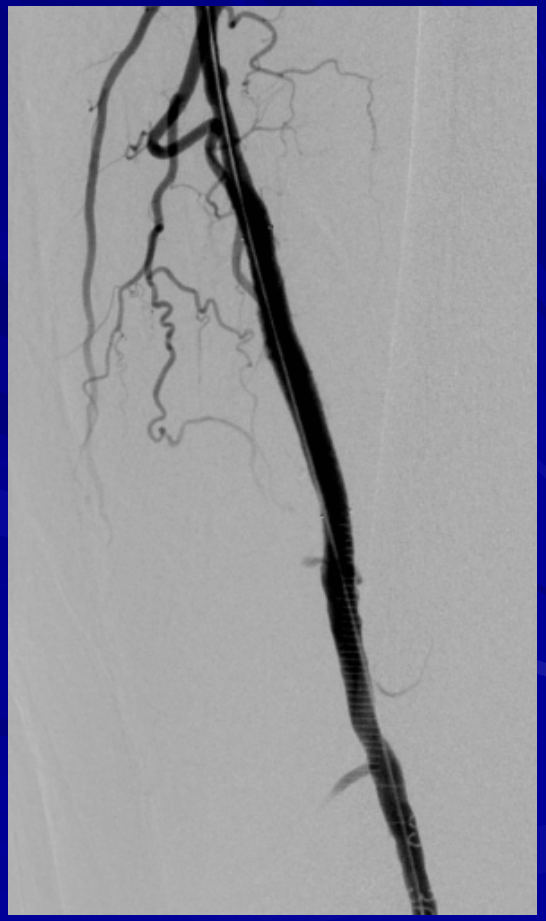
Pre-procedure



Post-PTA



Post-scaffold



ESPRIT I Acute Success

	Esprit (N=35)
Device Success Achievement of successful delivery and deployment of the study device(s) at the intended target lesion and successful withdrawal of the delivery catheter.	**100.0%**
Technical Success Attainment of a final residual stenosis of < 30% at the intended target lesion(s).	**100.0%**
Clinical Success Attainment of a final residual stenosis of < 30% using the study device(s) and/or any adjunctive device at all intended target lesion(s) without complications within 2 days after the index procedure or at hospital discharge, whichever is sooner	**100.0%**

Source: ESPRIT I Clinical Investigation Plan, Version 2.0, 22 October 2012. Data on file at Abbott Vascular

ESPRIT I Functional and Hemodynamic Results

	ESPRIT baseline (N=35)	ESPRIT 1-month (N=34)	ESPRIT 6-month (N=34)
Rutherford 0 (no claudication)	**0 %**	**84.9 %**	**67.6%**
Rutherford 1 (mild claudication)	**8.6 %**	**12.1 %**	**23.5%**
Rutherford 2 (moderate claudication)	**34.3 %**	**3.0 %**	**8.8%**
Rutherford 3 (severe claudication)	**57.1 %**	**0**	**0**
Ankle-Brachial Index*	**0.75**	**1.00**	**0.99**

Source: ESPRIT I Clinical Investigation Plan, Version 2.0, 22 October 2012. Data on file at Abbott Vascular

ESPRIT I Key Study Endpoints

	Esprit BVS (N=34*) 6 months
Deaths (%)	**0.0**
Any amputation of treated limb (%)	**0.0**
Bypass surgery of treated limb (%)	**0.0**
Scaffold thrombosis (%)	**0.0**
Target lesion revascularization (TLR) (%)	**0.0**
Target vessel revascularization (TVR) (%)	**0.0**
Target extremity revascularization (TER) (%)	**0.0**

* One subject withdrew consent for further follow-up

Source: ESPRIT I Clinical Investigation Plan, Version 2.0, 22 October 2012. Data on file at Abbott Vascular

Conclusions

- Self expanding metallic stents can impart chronic injury through oversizing / chronic outward

- Fully resorbable scaffolds have the potential to
  - Sustain lumen dimensions while vessel wall heals
  - Disappear mechanically and not cause chronic injury
  - Fully resorb to restore mechanical integrity to the vessel wall

Scheinert D. ESPRIT I Clinical Study 30-day results: LINC Course 2013.
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