



Accurate Vessel Sizing Drives Clinical Results IVUS In the Periphery

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- Conclusion

Why Size Matters

IVUS GUIDED STENT STUDIES

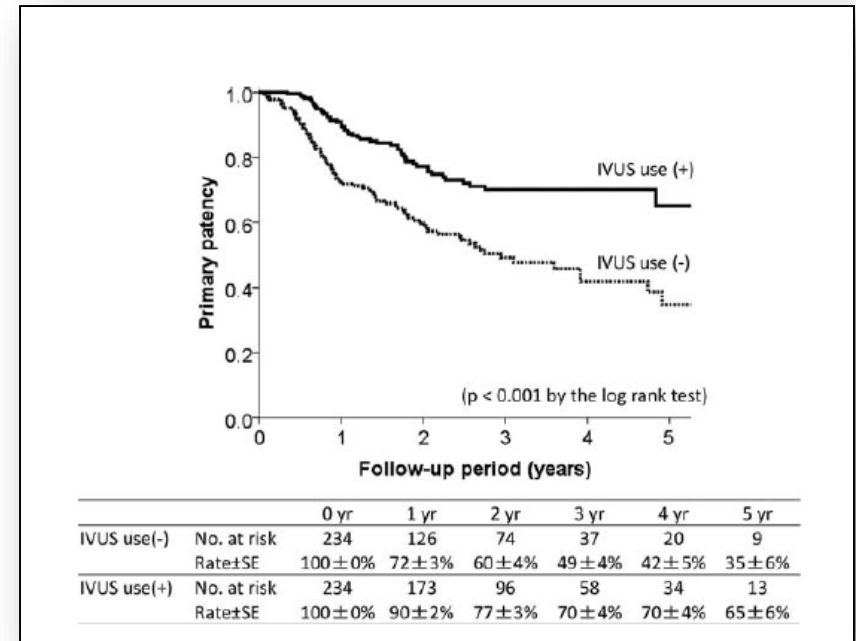
Efficacy of Intravascular Ultrasound in Femoropopliteal Stenting for Peripheral Artery Disease With TASC II Class A to C Lesions

Compared primary patency rates of IVUS vs. non-IVUS guided procedures in 234 propensity score matched pairs.

- 35.5% of procedures were TASC II Class C Patients.
- Higher 5-year primary patency with IVUS than without (65%±6% vs. 35%±6%, $p < 0.001$).

Significantly better

- Assisted primary patency ($p < 0.001$)
- Freedom from any adverse limb event ($p < 0.001$),
- Event-free survival ($p < 0.001$).



IVUS use was associated with a significantly higher primary patency rate than no IVUS use in TASC II class A-C femoropopliteal lesions ($p < 0.001$ by log-rank test).

Iida O, et. al. Efficacy of Intravascular Ultrasound in Femoropopliteal Stenting for Peripheral Artery Disease With TASC II Class A to C Lesions. *J Endovasc Ther.* 2014 Aug;21(4):485-92.

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PHILIPS

Efficacy of Intravascular Ultrasound in Femoropopliteal Stenting for Peripheral Artery Disease With TASC II Class A to C Lesions

90±2% Primary Patency at 1 year in IVUS Guided group

		0 yr	1yr
IVUS Use (-)	No. at risk	234	126
	Rate ± SE	100±0%	72±3%
IVUS Use (+)	No. at risk	234	173
	Rate ± SE	100±0%	90±2%

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Iida O, et. al. Efficacy of Intravascular Ultrasound in Femoropopliteal Stenting for Peripheral Artery Disease With TASC II Class A to C Lesions. *J Endovasc Ther.* 2014 Aug;21(4):485-92.

Iida O, et. al.-Takeaways

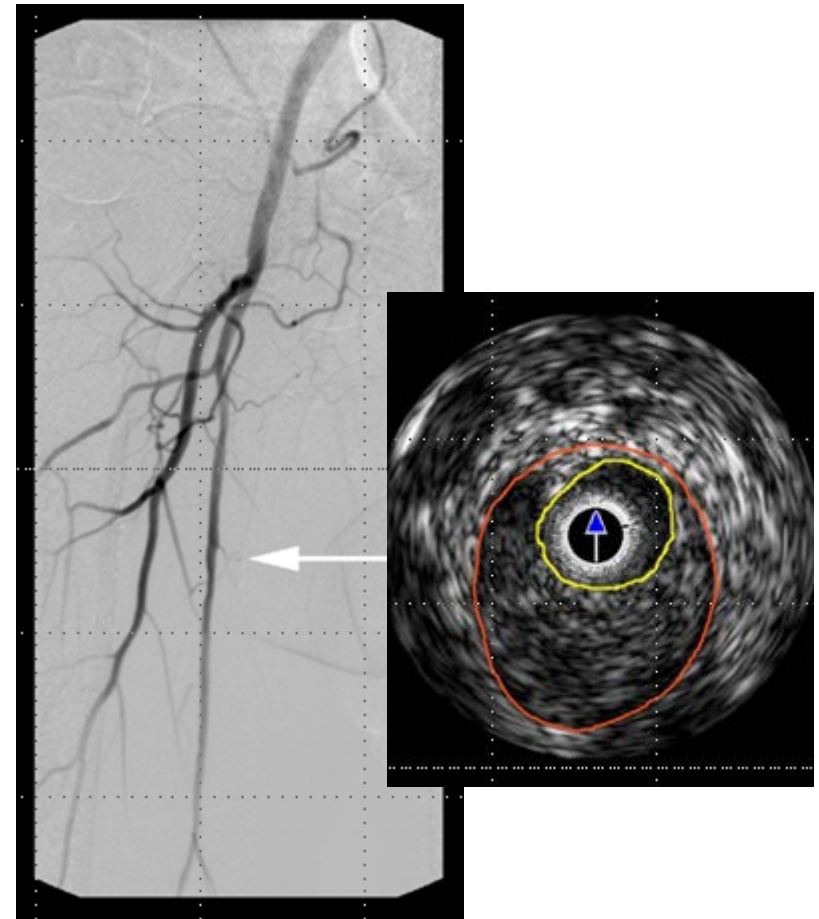
The group with IVUS use had a significantly higher rate of primary patency compared to the group without IVUS use.

These findings suggest a favorable impact of IVUS use on patency regarding femoropopliteal stenting.

IVUS use in femoropopliteal stenting might enable more accurate evaluation of vessel diameter and more appropriate stent selection according to vessel diameter prior to stenting.

IVUS Utilization Beneficial During Lower-Limb Peripheral Interventions

- Researchers analyzed data from the Healthcare Cost and Utilization Project Nationwide Inpatient Sample on peripheral endovascular interventions performed from 2006 to 2011 (n = 92,714; 55% men; mean age, 60 years).
- The primary outcomes were in-hospital mortality and amputation; the secondary outcome was complications after the procedure.
- In total, IVUS was utilized in 1.4% of cases analyzed.
- Conclusion of Study:
 - IVUS use during lower limb endovascular interventions is predictive of lower postprocedural complication and amputation rates with a nonsignificant increase in hospitalization costs.



Panaich S.S., et al Key Takeaways

IVUS utilization during lower extremity peripheral vascular procedures was independently predictive of lower **Amputation rates** (OR = 0.59; 95% CI, 0.45-0.77; $P < .001$).

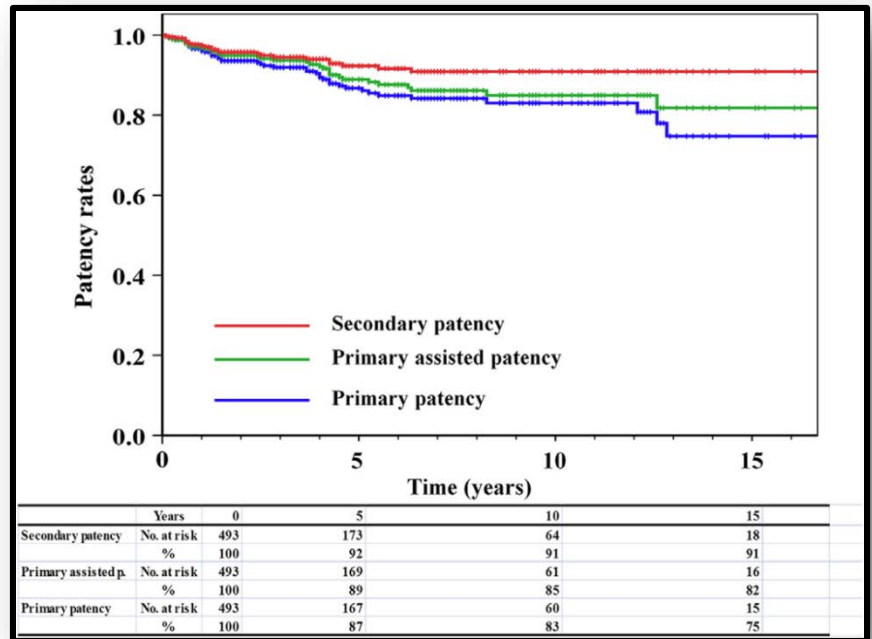
The overall rate of amputation was 9.7%, with a lower rate in the IVUS group (5.3%) compared to the group without IVUS (9.8%, $p < 0.001$).

IVUS utilization was also predictive of a **Non-Significant** rise in hospitalization **Costs** (\$1,333 [95% CI, -167 to \$2,833; $P = .082$).

Panaich et, al, Intravascular Ultrasound in Lower Extremity Peripheral Vascular Interventions: Variation in Utilization and Impact on In-Hospital Outcomes From the Nationwide Inpatient Sample (2006–2011). J. Endovascular Therapy 2015.

Fifteen-Year Patency and Life Expectancy After Primary Stenting Guided by Intravascular Ultrasound for Iliac Artery Lesions in Peripheral Arterial Disease

- The purpose of this study was to evaluate 15-year patency and life expectancy after endovascular treatment (EVT) with primary stenting guided by intravascular ultrasound (IVUS) for iliac artery lesions.
- EVT was performed for 507 lesions in 455 patients.
- Primary Patency Rate of IVUS Guided Iliac Stenting.
 - 87% at 5 years
 - 83% at 10 years
 - 75% at 15 years



Kumakura H, et al. J Am Coll Cardiol Intv. 2015;Epub ahead of print.

Kumakura H, et al. Key Takeaways

IVUS-guided stenting for the iliac artery had favorable 15-year patency in all TASC categories.

5-year patency of IVUS-guided stenting in iliac artery lesions was 87%.

Lesion length, pre- and post-procedural angiographic stenosis rates, pre and post-procedural MLA, calcified lesions, in-stent thrombosis, and discontinuation of antiplatelet therapy were found to be significant factors associated with restenosis.

Why Size Matters

VIPER TRIAL

VIPER Trial:

“GORE VIABAHN Endoprosthesis With Heparin Bioactive Surface in the Treatment of SFA Obstructive Disease”

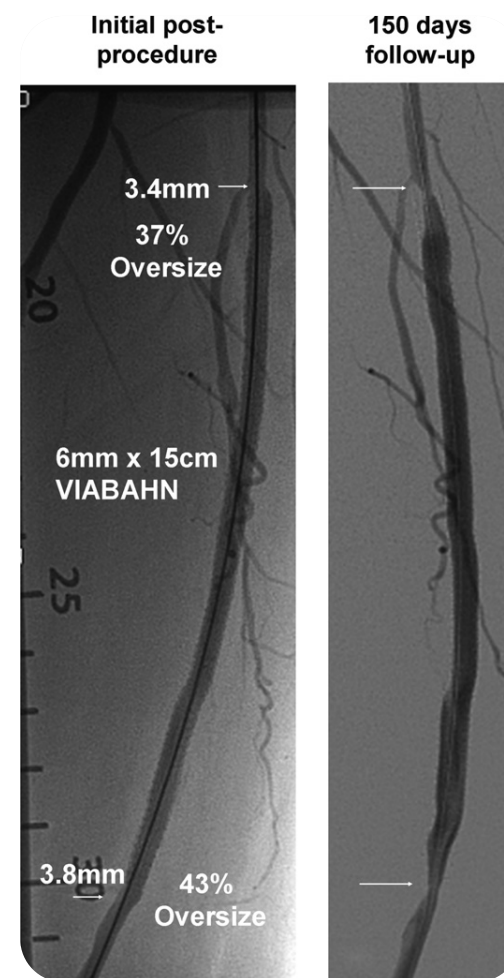
Objective	Evaluate the performance of VIABAHN Endoprosthesis with Heparin Bioactive Surface (W.L. Gore, Inc.) in treating long-segment SFA disease (> 5 cm in length)
Design	Single-arm, Prospective, 12 U. S. sites, 120 patients
Primary Endpoints	Primary patency at 12 months <ul style="list-style-type: none">• No evidence of restenosis or occlusion within the originally treated lesion based on CDUS; PSVR <2.5;• No angiographic evidence of stenosis >50% when the CDUS was uninterpretable or unavailable or TVR performed Proportion of subjects experiencing major procedure related adverse events within 30 days of procedure
Secondary Endpoints	Primary assisted patency Secondary patency Device related major adverse events at 12 months

Saxon R., MD et. al. Heparin-bonded, Expanded Polytetrafluoroethylene- lined Stent Graft in the Treatment of Femoropopliteal Artery Disease: 1-Year Results of the VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) Trial. J Vasc Interv Radiol 2013; 24:165–173 .

VIPER Trial-Results

The overall 1-year primary patency rate for complex lesions with a mean length of 19 cm was 73%.

The **1-year primary patency rate** for devices that were **not over sized ($\leq 20\%$)** relative to the proximal landing zone was **88%**, significantly better than the **70%** 1-year primary patency rate for devices that were **oversized $> 20\%$** ($P = .047$).



Saxon R., MD et. al. Heparin-bonded, Expanded Polytetrafluoroethylene-lined Stent Graft in the Treatment of Femoropopliteal Artery Disease: 1-Year Results of the VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) Trial. J Vasc Interv Radiol 2013; 24:165–173 .

VIPER Trial-Takeaways

Primary patency rate was 88% in the VIPER trial if the stent was sized $\leq 20\%$ relative to the proximal landing zone to the vessel.

In the VIPER Trial if the stent was oversized by more than 20% then the primary patency rate dropped to 70% ($P < 0.05$)

Per the investigators, “Most of the excessive over sizing in this trial resulted from operators’ overestimation of the diameter of the arterial lumen. To avoid this, clinicians may employ quantitative techniques to optimize stent graft treatment.”

Saxon R., MD et. al. Heparin-bonded, Expanded Polytetrafluoroethylene- lined Stent Graft in the Treatment of Femoropopliteal Artery Disease: 1-Year Results of the VIPER (Viabahn Endoprosthesis with Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease) Trial. J Vasc Interv Radiol 2013; 24:165–173 .

Why Size Matters

SUPERB TRIAL

SUPERB Trial:

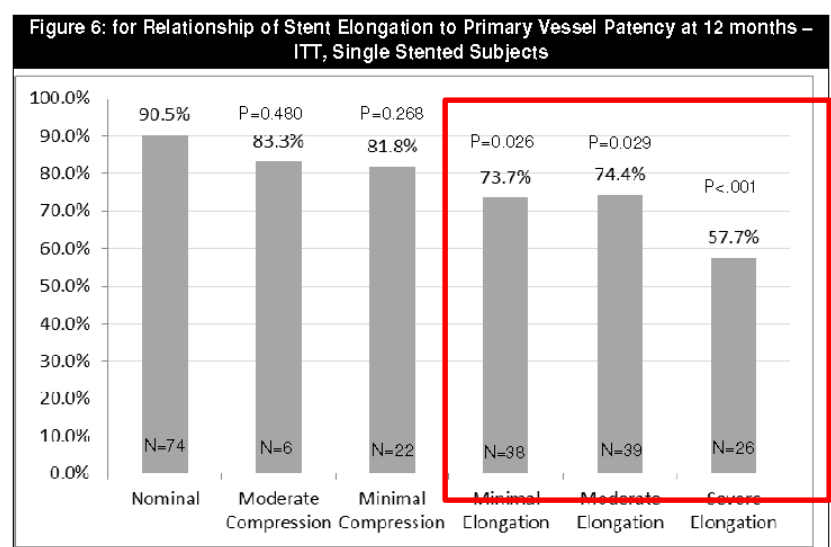
“Comparison of the Supera® PERipheral System to a Performance Goal Derived From Balloon Angioplasty Clinical Trials in the Superficial Femoral Artery”

Objective	Comparing percutaneous transluminal angioplasty (PTA) and primary stenting with the Supera® Peripheral Stent Systems to performance goals of PTA alone in the treatment of atherosclerotic lesions of the native superficial femoral artery (SFA) or the superficial femoral and proximal popliteal arteries.
Design	Prospective, multicenter, non- randomized, un-blinded single arm clinical study
Primary Endpoints	<ul style="list-style-type: none">• The primary safety endpoint for the SUPERB SFA/PPA study was a composite of Major Adverse Events (MAEs) defined as all death, TLR or any amputation of the index limb to 30 days (± 7 days).• The primary effectiveness endpoint for the SUPERB SFA/PPA study was primary stent patency rate at 12 months. Primary patency was defined as Peak Systolic Velocity (PSV) ratio < 2.0 at the stented target lesion assessed by duplex ultrasound (DUS) with no clinically-driven reintervention within the stented segment.

PMA P120020: FDA Summary of Safety and Effectiveness Data

SUPERB Trial-Results

12 month primary patency rate was 78.9%



- Due to the mechanical behavior of the woven Supera stent, the stent should not be oversized by more than 1 mm relative to the RVD.
- This ensures optimum deployment of the Supera stent, maximizing radial strength and assisting in accurate stent length deployment.

PMA P120020: FDA Summary of Safety and Effectiveness Data

SUPERB Trial-Takeaways

Primary patency rate was 90.5% in the SUPERB trial if the stent was sized appropriately to the vessel.

If the stent was not sized appropriately in a 1:1 ratio then there was an increased rate of stent elongation and a drop in primary patency – from 74.4% to 57.7% ($P = 0.026$ to $p < 0.001$) depending on the amount of elongation.

PMA P120020: FDA Summary of Safety and Effectiveness Data

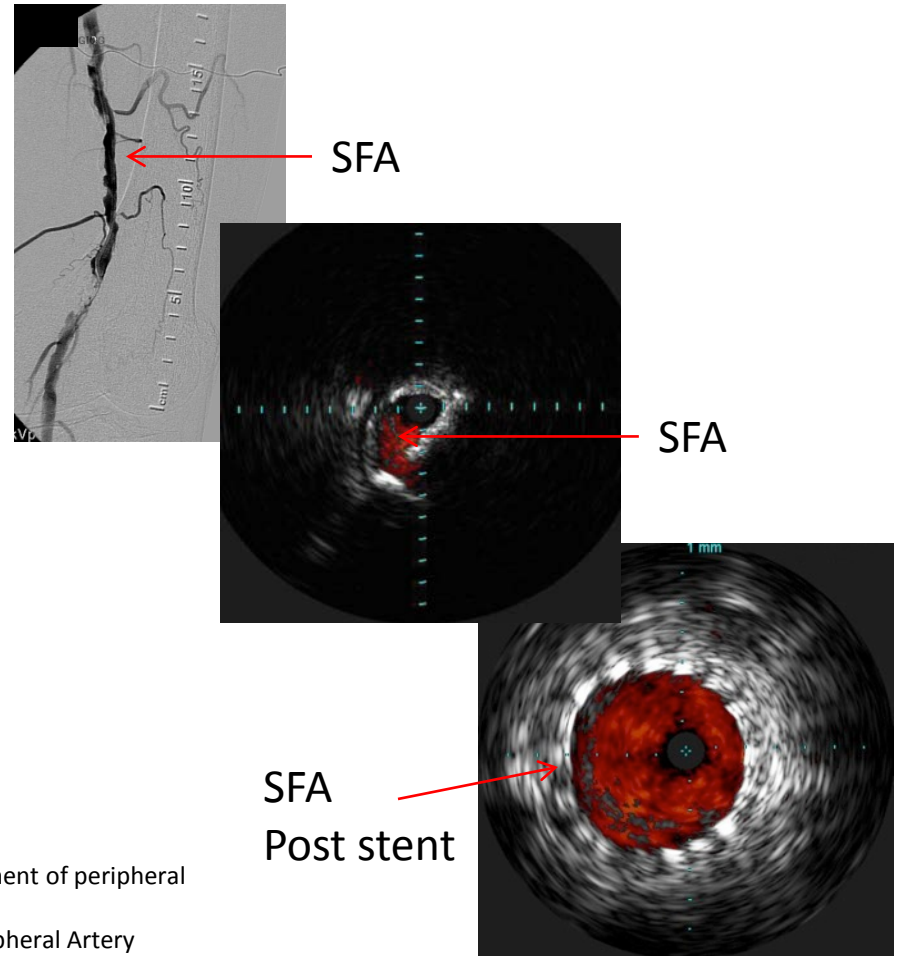
Conclusion

Pre-Treatment Strategy

Confirm Diameter
of Treatment
Area^{1,2}

Assess Plaque
Morphology³

Assess Length of
Stenosis^{1,2}



Images Courtesy of Volcano Corporation

SFA
Post stent

1. Lee JT, Fang TD, and White R. A. Applications of intravascular ultrasound in the treatment of peripheral occlusive disease. *Seminars in Vascular Surgery*. 2006. 19(3), 139–44.
2. Iida O, et. al. Efficacy of Intravascular Ultrasound in Femoropopliteal Stenting for Peripheral Artery Disease With TASC II Class A to C Lesions. *J Endovasc Ther*. 2014 Aug;21(4):485-92.
3. Niwamae et al. Intravascular Ultrasound Analysis of Correlation between Plaque-Morphology and Risk Factors in Peripheral Arterial Disease. *Annals of Vascular Diseases* Vol. 2, No. 1 (2009).

Conclusion

Post Treatment Imaging

Assess
Completeness
of Treatment

Is the stent fully
apposed?

Did I cover the area of
interest?

Did I achieve the
necessary luminal
gain?

Did I cut into the
adventitia?



Image Courtesy of Volcano Corporation