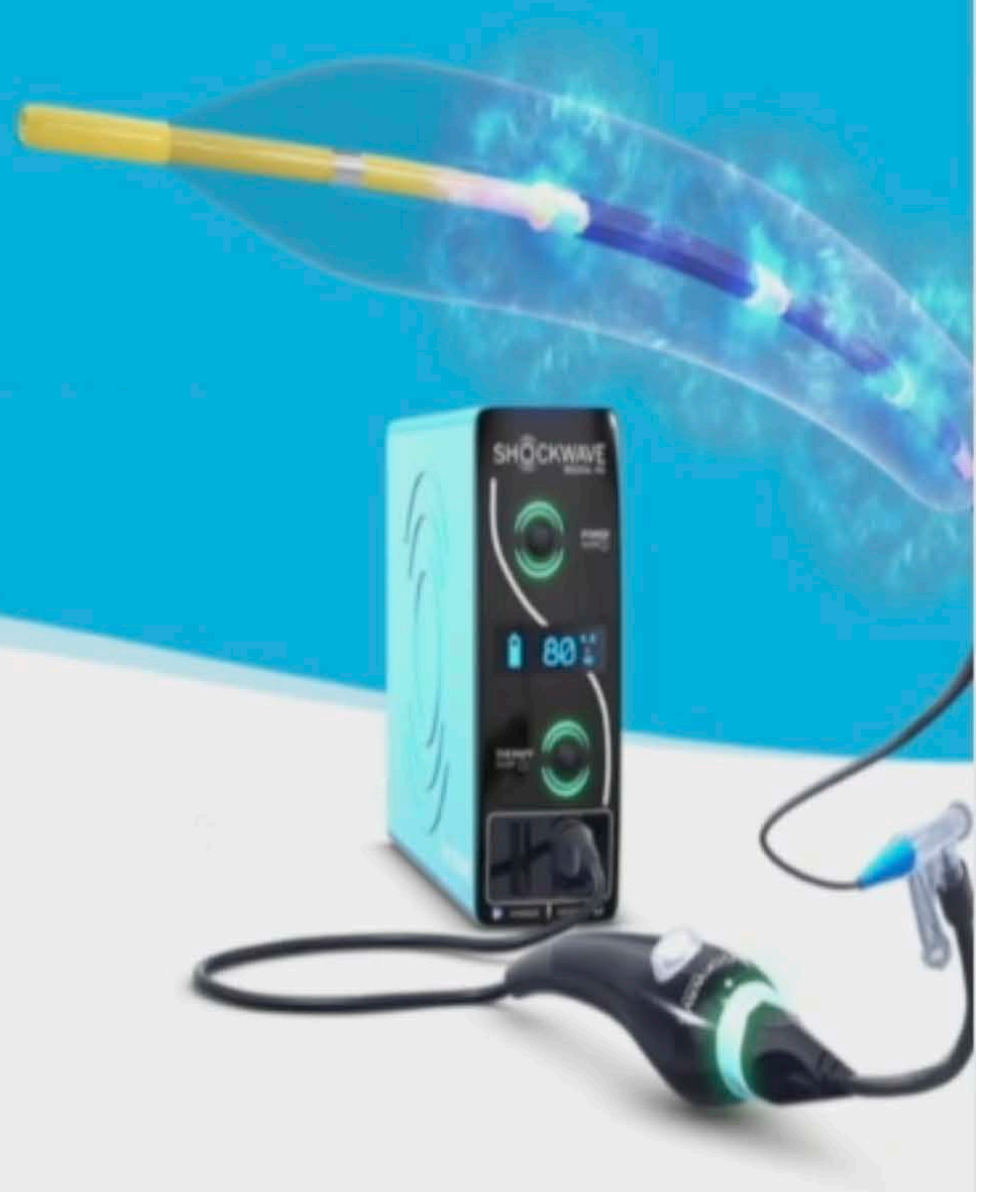
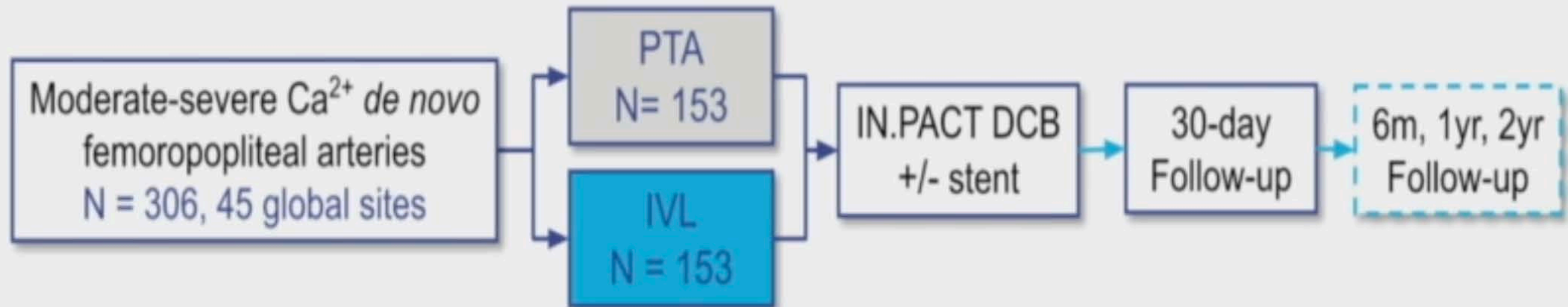


# SHOCKWAVE | IVL

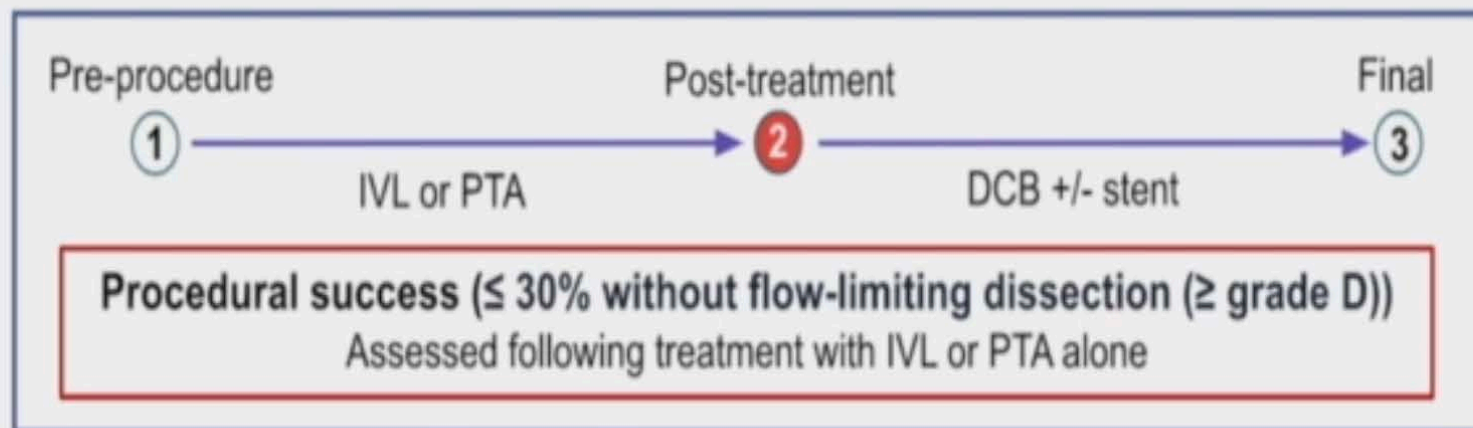
DISRUPT PAD III RANDOMIZED TRIAL  
ACUTE (30 DAY) PRIMARY ENDPOINT



# PAD III is the Largest-Ever RCT of Calcified Lesions



## Primary Endpoint: Procedural success



Secondary Endpoints at 30 days: Major Adverse Events, CD-TLR, ABI, RC, WIQ  
 Powered Secondary Endpoint at 12 months: Primary patency\*

## PAD III Enrolled Complex Calcified SFA/Pop Lesions

PAD III Exclusively Enrolled Complex Lesions Excluded from Contemporary Trials

**306**

SFA/Popliteal lesions  
randomized to IVL or PTA

**83%**

Severe calcification by PARC by  
an independent core-lab\*

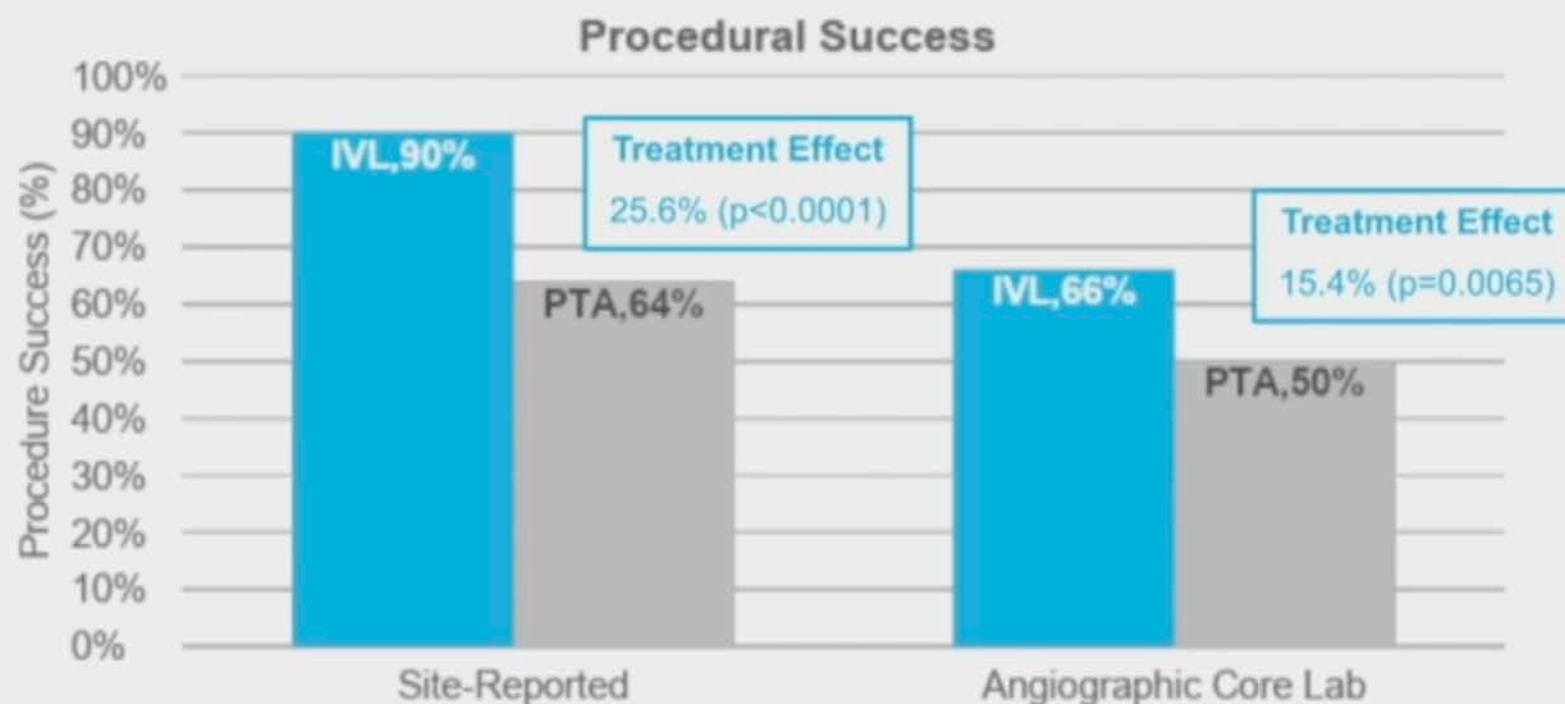
**129**mm

Average calcified length by  
independent core-lab\*

\* Data refer to IVL arm of randomized study

## IVL Demonstrated Superiority over PTA

IVL achieved superiority over PTA in both site-reported and rigorous core-lab adjudication



## IVL Achieved Superior Vessel Preparation

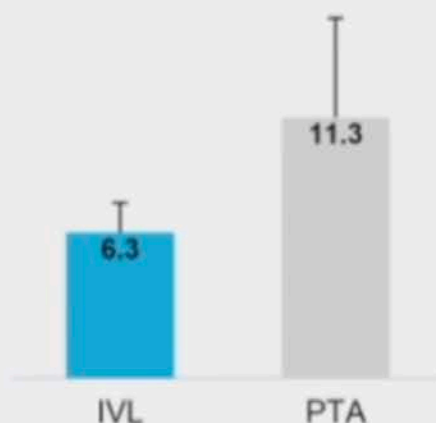
IVL used lower pressure, fewer stents, less post-dilatation and had fewer dissections vs. PTA

**↓ 44%**

Lower pressure to achieve better results with IVL

### Max Inflation Pressure

P<0.0001



**↓ 75%**

Reduction in provisional stent placement risk with IVL

### Stent Placement

p = 0.0002



**↓ 69%**

Reduction in need for post-dilatation with IVL

### Post-Dilatation

p = 0.001

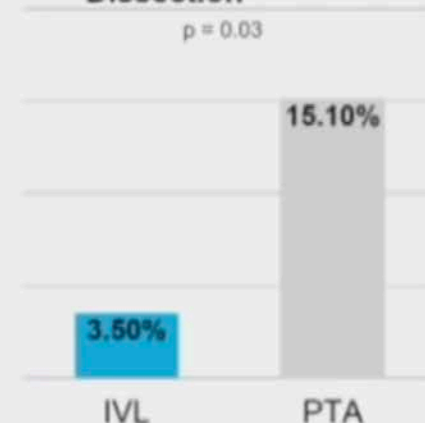


**↓ 77%**

Reduction in Type ≥C Dissection with IVL

### Grade C or Higher Dissection

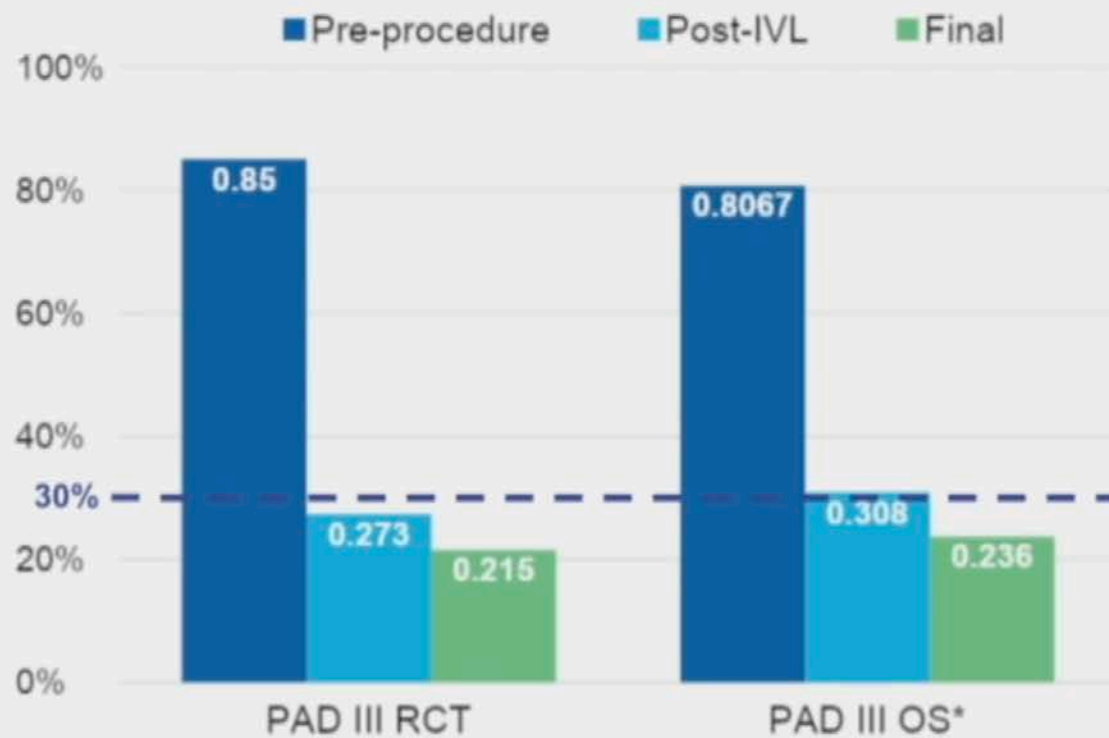
p = 0.03



# Randomized IVL Results are Consistent with Real-World



## Diameter Stenosis (Core-Lab)



## Final Angiographic Complications (Core-Lab)

	PAD III RCT	PAD III Observational*
N	153	200
Vessels	SFA/Pop	Iliac, CFA, SFA/Pop, BTK
Dissection (Type D-F)	0%	1.1%
Perforation	0%	0.5% <sup>†</sup>
Embolization	0%	0%
Thrombus	0%	0%
No reflow	0%	0%
Abrupt closure	0%	0%

<sup>†</sup>Following DCB inflation; unrelated to IVL

## Calcium Studies\*

	Intravascular Lithotripsy	Directional Atherectomy	Multiple Atherectomy Devices	Orbital Atherectomy	
	PAD III	REALITY Single-Arm	LIBERTY 360; RC 4-5 Single-Arm	COMPLIANCE 360 RCT	CONFIRM Registries
# of Patients	153	102	571	25	3135
Mod-Severe Calcium <sup>2</sup>	99%	86.2%	71.3%	52%	81%
Angiographic Core Lab	Yes	Yes	Yes	No	No
Dissections $\geq$ Grade C	2.7%	14.3%	3.0%	--	--
Dissection (Type D-F)	0.0%	--	--	--	1.8%
Stents Placed	4.6%	8.8%	14.5%	5.3%	5.7%
Embolic Protection Used	1.3%	99%	--	--	--
Distal embolization	0.0%	12.8%	5.5%	4.0%	2.2%
Perforation	0.0%	3.1%	2.5%	0.0%	0.7%
Abrupt Closure	0.0%	--	2.3%	--	1.5%
Slow Flow	0.0%	--	--	--	4.4%
1yr Primary Patency	TBD	76.7%	--	--	--
1yr CD-TLR	TBD	92.6%	--	81.2%	--

\*Clinical trial data among different studies are not directly comparable and presented for educational/observational purposes only.

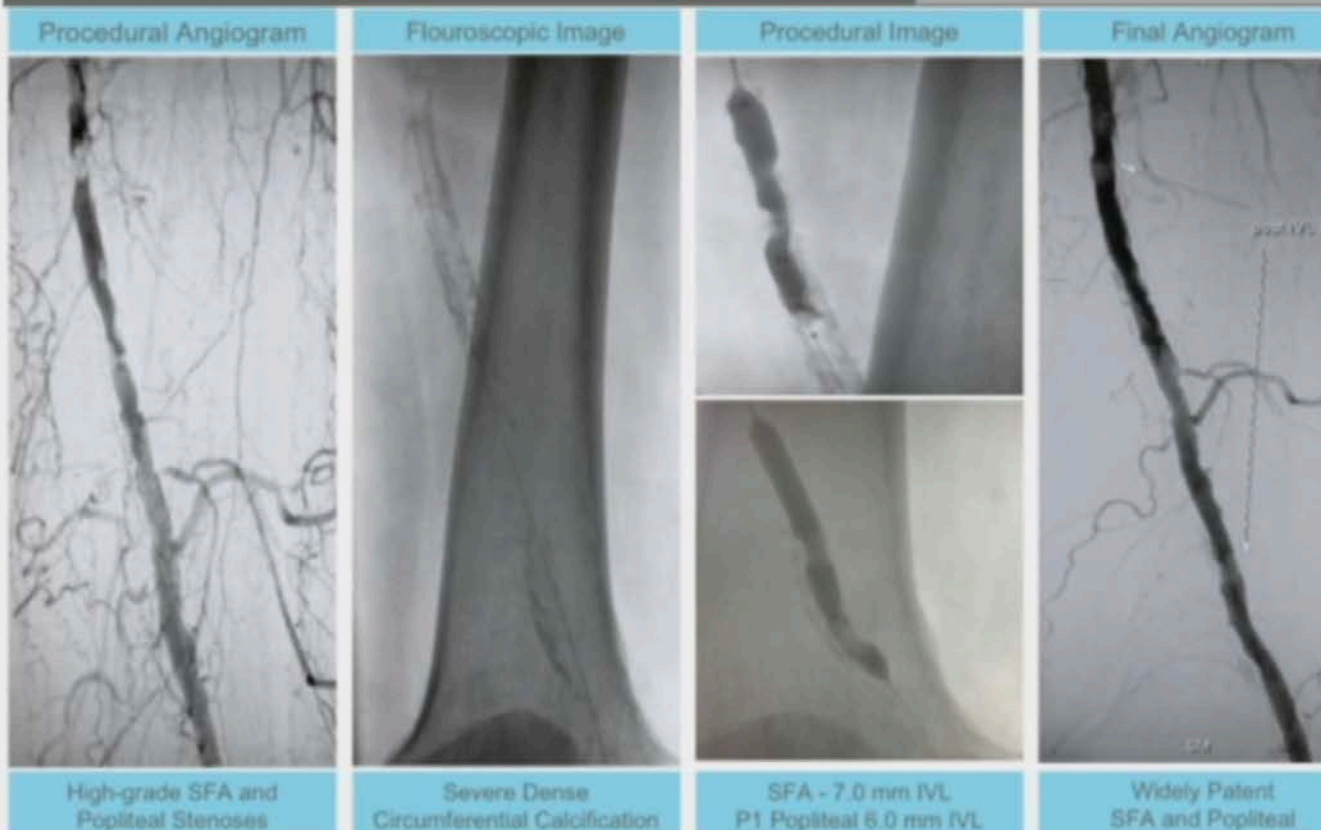
<sup>2</sup>Definition of Moderate-Severe Calcium varies between studies. REALITY used PACCS. PAD III and LIBERTY 360 used PARC. COMPLIANCE used moderate  $<180^\circ$  &  $\geq 50\%$  lesion length, severe  $\geq 180^\circ$  and  $\geq 50\%$  total length. CONFIRM used moderate  $>50\%$  calcium, severe  $>75\%$  calcium.

(--) = Not Reported

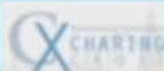
# IVL Livecase at CharingX

## Shockwave Medical Case Review

**Severely Calcified  
Multi-level  
IVL Treatment**



Case Performed By Dr. Arne Schwandt and Dr. Theo Bisdas  
St. Franziskus Hospital Münster Germany 25 April 2018



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## PAD III Key Take-Aways

1. In the largest-ever randomized clinical trial of severely calcified peripheral lesions, IVL demonstrates superiority over PTA
2. IVL demonstrates a significant reduction in dissections and provisional stenting versus PTA
3. IVL achieves superior vessel preparation with lower pressure, fewer stents, less need for post-dilatation and fewer dissections than PTA
4. Disrupt PAD randomized data confirm the consistent safety and effectiveness of IVL from previous studies in multiple vessel beds