# Introduction, IVL Mechanism of Action & Historical Perspective

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# Disclosure

Speaker name: Thomas Zeller

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I have the following potential conflicts of interest to report:

- ☒ Consulting
- ☐ Employment in industry
- ☒ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

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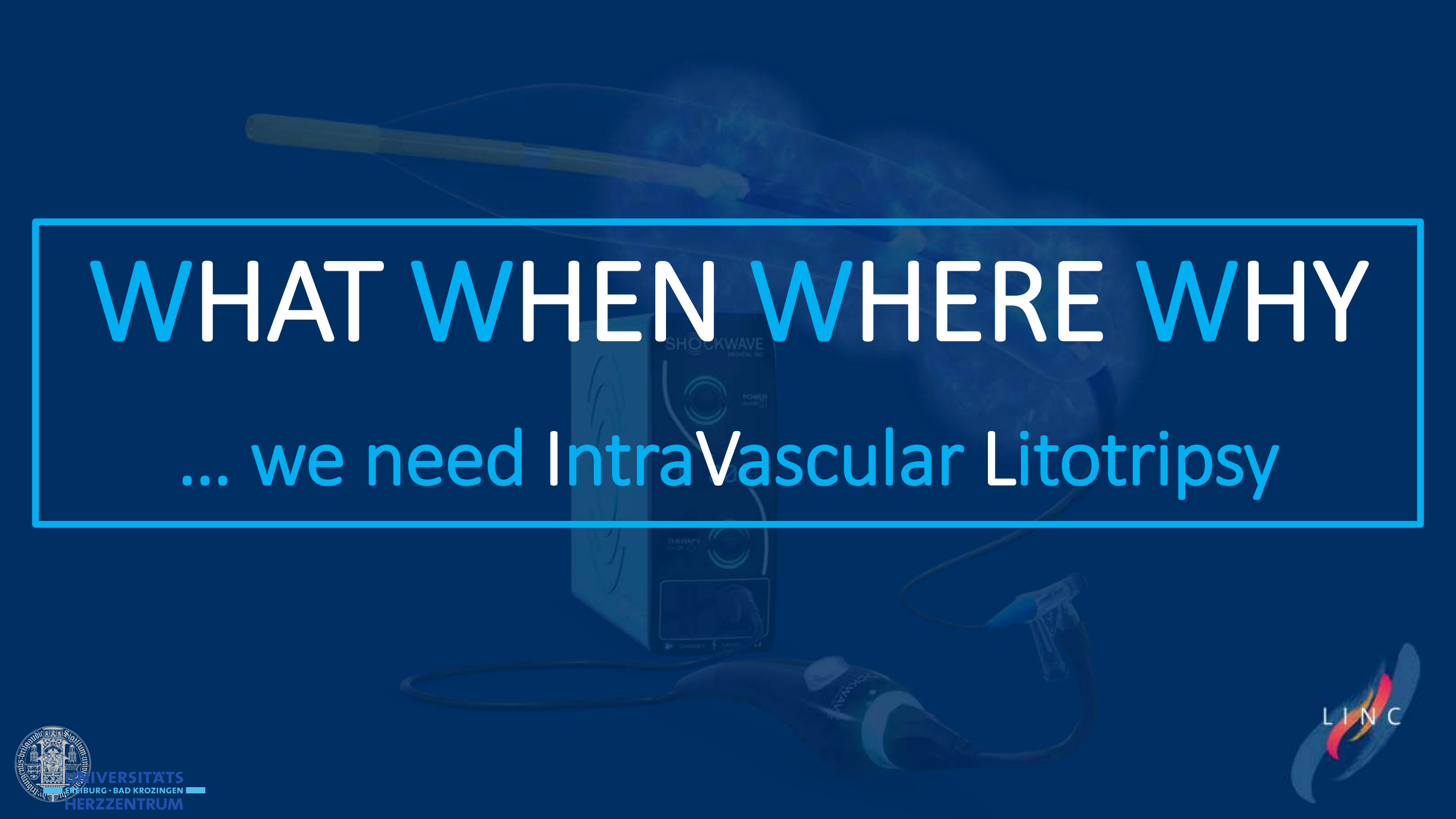
# WHAT WHEN WHERE WHY

## … we need IntraVascular Litotripsy

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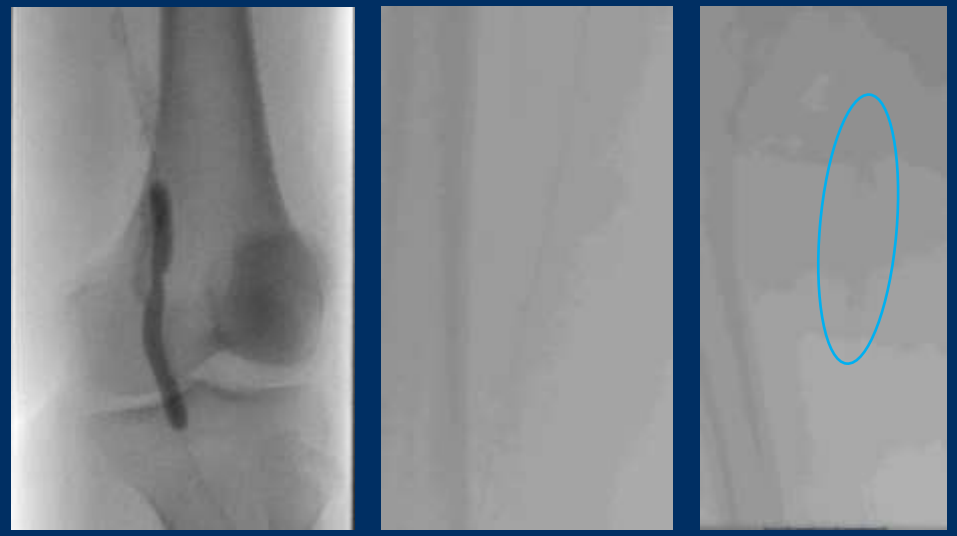
# Endovascular Treatment for Calcified PAD

## CALCIUM RESTRICTS ARTERIAL COMPLIANCE

- Results in poor balloon expansion, dissections and perforation
- May impair effectiveness of DCBs by limiting drug uptake
- Stents to address PTA failure may complicate future revascularization



Distal embolization, dissection and perforation remain a concern with atherectomy treatment

Patients with moderate-severe calcification are often excluded from endovascular treatment trials resulting in little available evidence to provide treatment guidance in this challenging patient population

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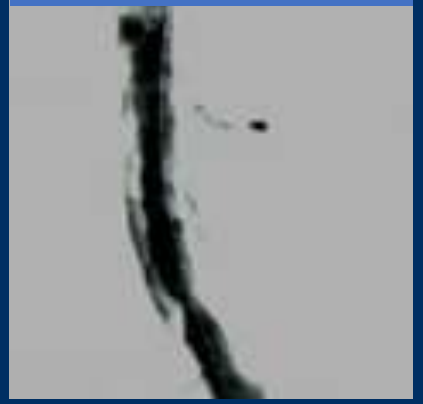
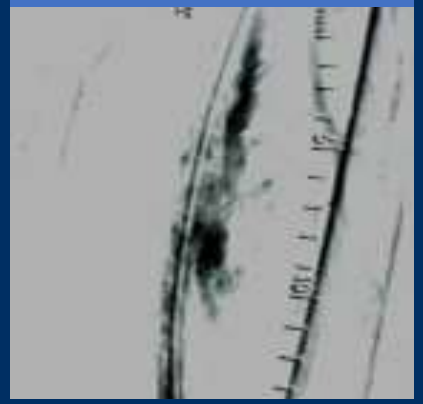
*Rocha-Singh et al., *Catheter Cardiovas Interv* 2014; Tosaka et al, *JACC* 2012; Walker et al., *J. Vasc Surg* 2015

# Challenges Associated with Problematic Calcium

**Dissections**

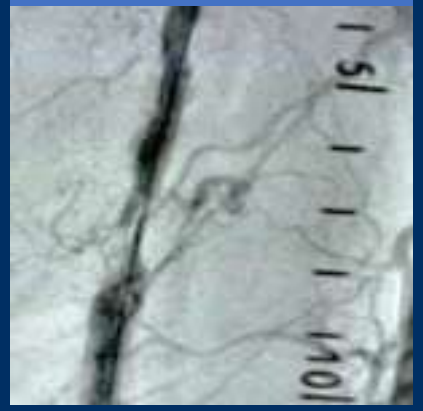


**Perforations**

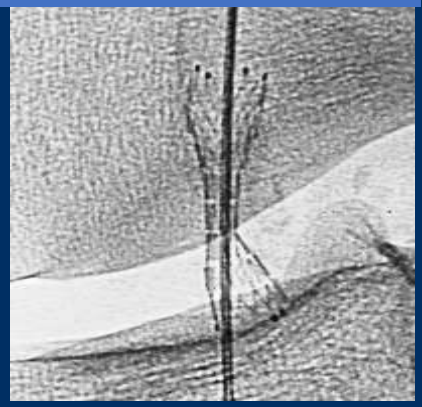


**Embolization**

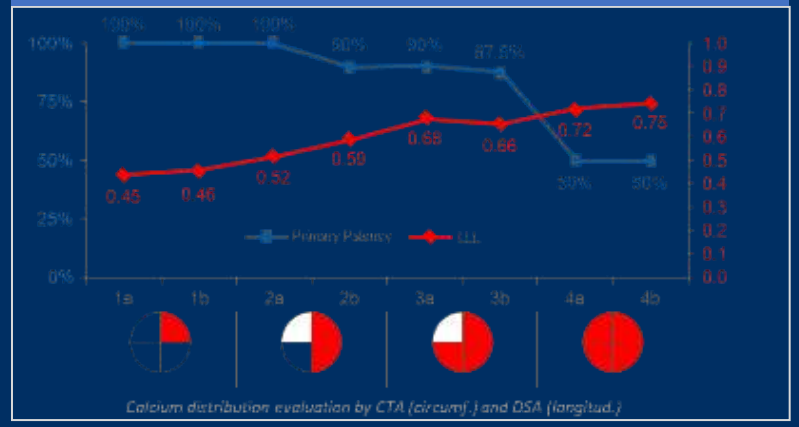
**Vessel Recoil**



**Stent Crush / compression**

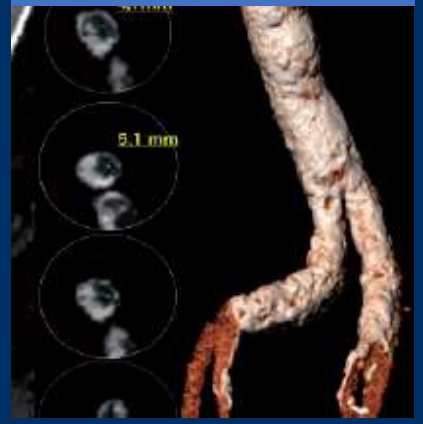


**Limited Drug Uptake**



Calcium distribution evaluation by CTA (circumf.) and DSA (longitud.)

**Iliac Access for Devices**

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Images Courtesy of: 1) Dr Hector Dourron, Wellstar Cobb Hospital, 2) Case Presented at LINC 2016

# Intravascular Lithotripsy (IVL): Localized Lithotripsy to Treat Cardiovascular Calcium

Inspired by urological applications, but designed for cardiovascular system

## Lithotripsy

30 years of safety data
in kidney stone treatment

***Sonic Pressure Waves*** preferentially impact hard tissue, disrupt calcium, leave soft tissue undisturbed

## Cardiovascular Lithotripsy

Miniaturized and arrayed Lithotripsy Emitters for localized lithotripsy at the site of the vascular calcium

**Optimized for the Treatment of Cardiovascular Calcium**

**Peripheral IVL Catheters**

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# Intravascular Lithotripsy

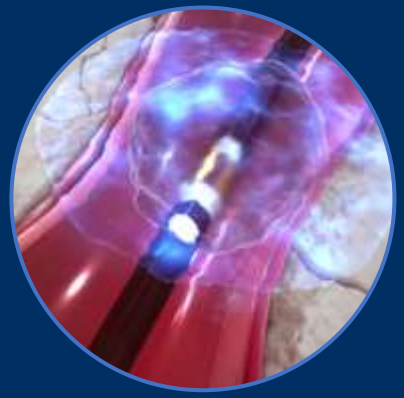
**IVL**

1 pulse/sec (effective pressure of ~50 atm)

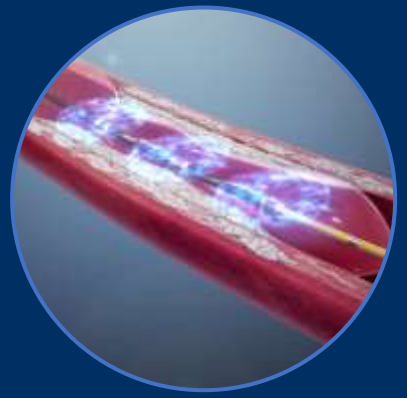
LOW balloon inflation pressure

Fractures both superficial and deep calcium

**Deliver catheter and inflate to low pressure**

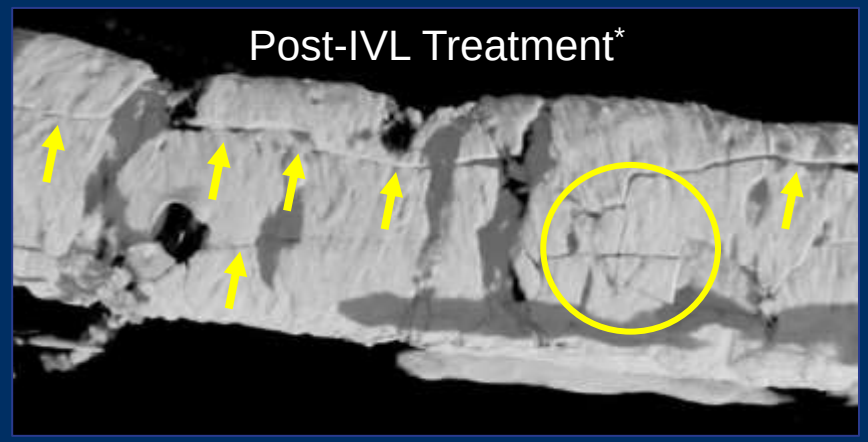


**Generate sonic pressure waves using lithotripsy**



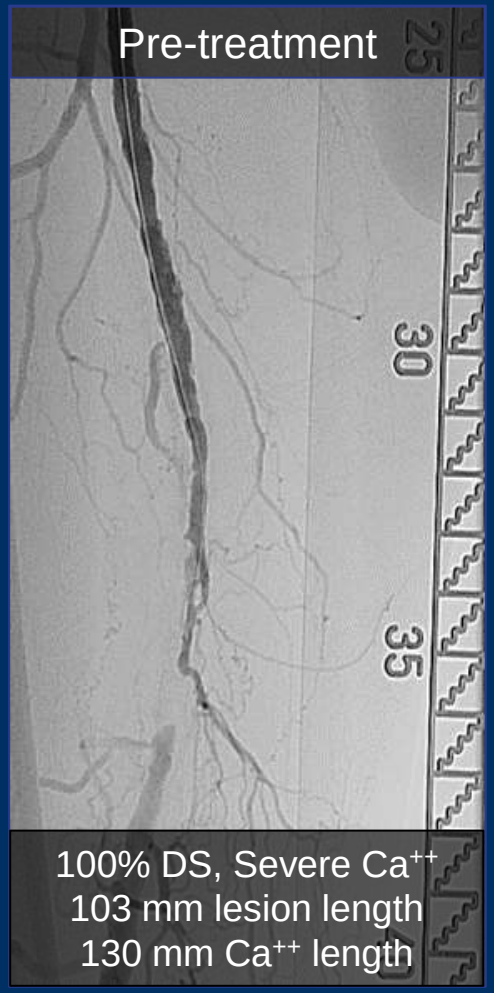
**Crack calcium**

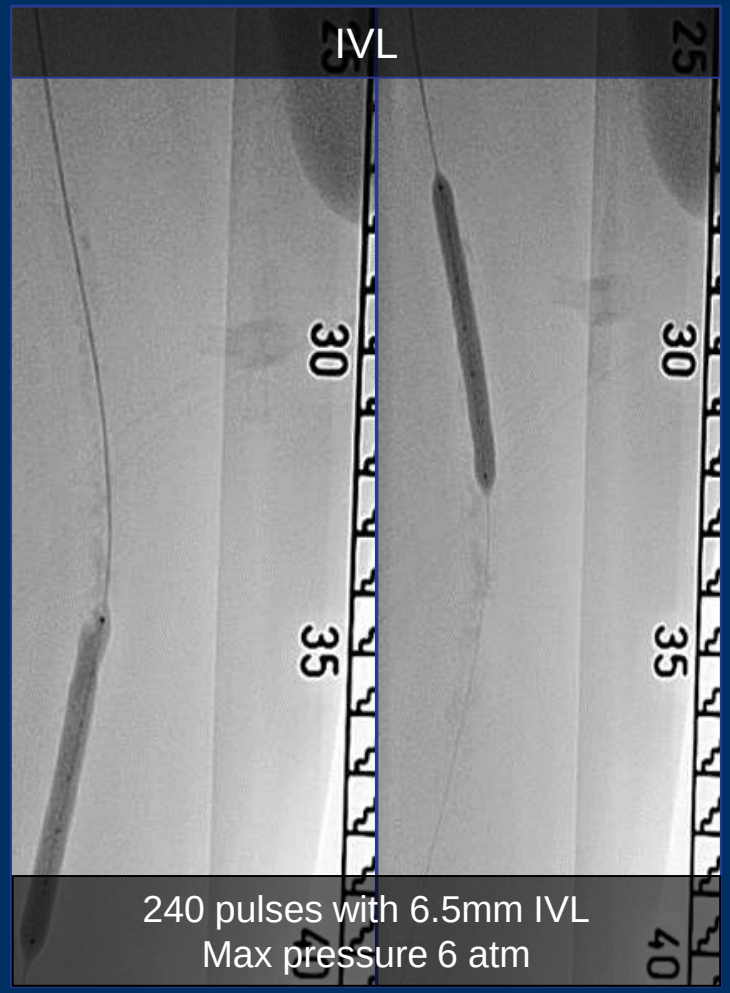
**Safely expand the vessel**

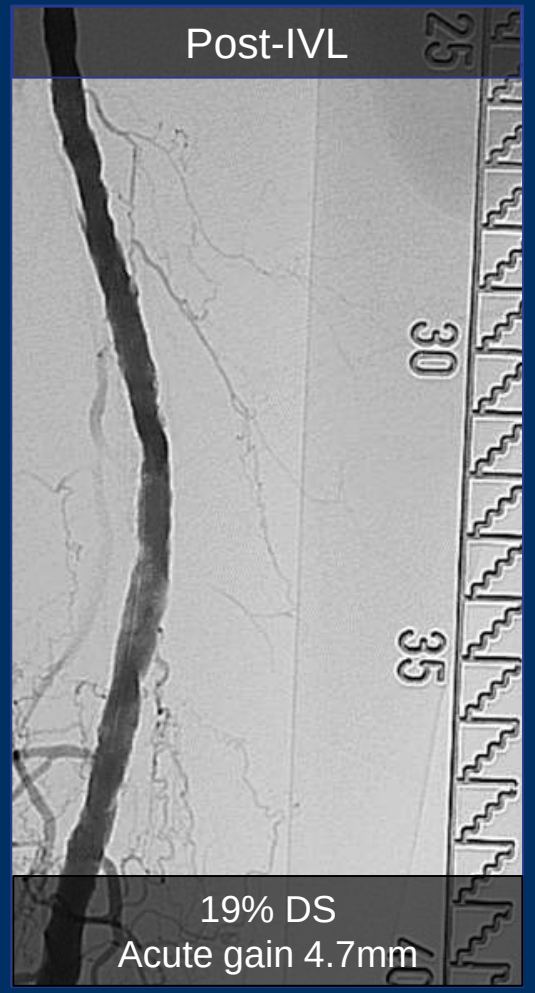



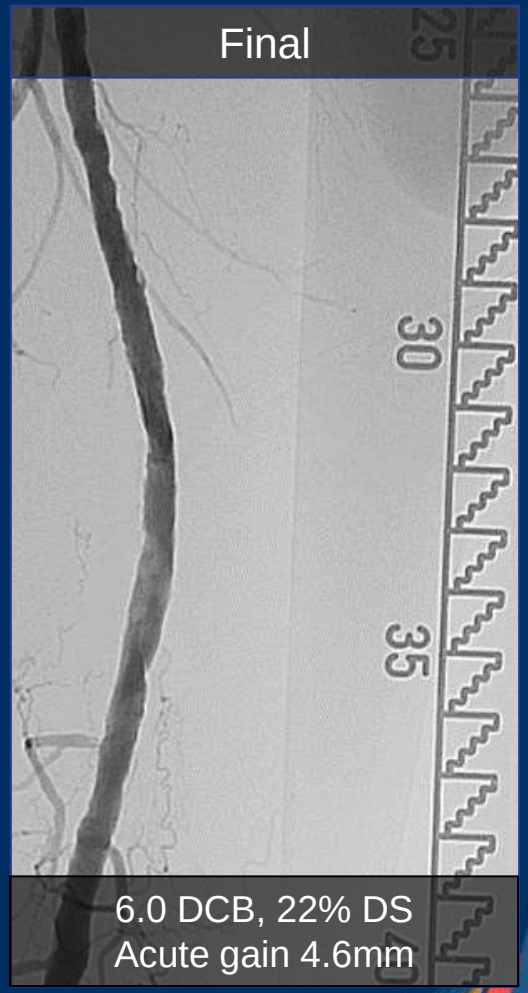

*Micro-CT scan analysis: R. Virmani, CV Path Institute

# IVL Treatment: Mid-SFA




IVL treatment at low balloon pressure resulted in marked improvement in diameter stenosis with no stent implantation

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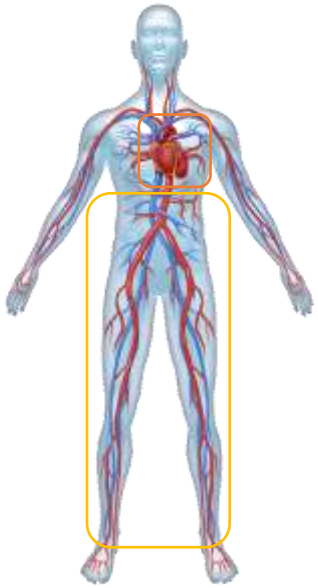
# Broad Range of IVL Applications

| Types of Calcium | Treatment Strategy | Vessels | | Disease States |
|---|---|---|---|---|
|  |  |     | | DISRUPT PAD III |
| **Eccentric**<br>**Concentric** | **Stand-alone**<br>**Vessel prep**<br>**Alternative to Surgery**<br>**Enable TF access** | **Fem-Pop**<br>**Infra-Pop** | **Iliac**<br>**CFA** | **PAD Claudicant**<br>**PAD CLI** |

**The Shockwave Medical Coronary IVL Catheter is for Investigational Use only in the United States*

# Peripheral IVL Clinical Programs

| | Disrupt PAD I | Disrupt PAD II | Disrupt BTK | Disrupt PAD III RCT | Disrupt PAD III OS |
|---|---|---|---|---|---|
| Status | Enrollment completed | Enrollment completed | Enrollment completed | Enrollment completed | Enrolling |
| Study design | Single arm, safety & performance | Single arm, safety & effectiveness | Single arm, pilot | RCT, safety & effectiveness | Single arm, observational study |
| Study conduct* | CEC, ACL | CEC, ACL | ACL | CEC, ACL | ACL |
| # of patients | 35 | 60 | 20 | 306 | Up to 1,500 |
| # of sites | 3 | 8 | 3 | 45 | 32 |
| Regions | NZ, EU | NZ, EU | NZ, EU | U.S., NZ, EU | U.S., NZ, EU |

*CEC: Independent clinical events committee; ACL: Angiographic core lab