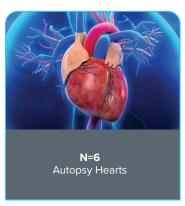


# IMPACT OF SHOCKWAVE IVL, WOLVERINE™ AND OPN NC® IN SEVERELY CALCIFIED CORONARY LESIONS

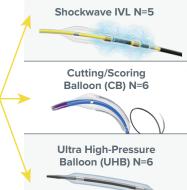
## **Cadaveric Specimens Used to Compare Strategies**

Sekimoto, T et al. Comparison of Vascular Injury From Intravascular Lithotripsy, Cutting, or Ultra-High-Pressure Balloons During Coronary Calcium Modification.

J Am Coll Cardiol Intv. 2025 Sep., 18 (17) 2093–2104. Cadaveric study. May not be indicative of actual clinical use.





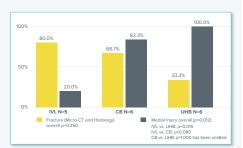


Shockwave C2+ IVL Catheter IFU: 120 pulses @ 4 ATM; balloon sized 1:1 to RVD

Wolverine™ Cutting Balloon™ COPS¹: Avg. inflation pressure of 18 atm; balloon sized according to IFU

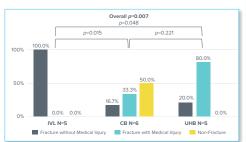
OPN NC® ISAR CALC<sup>2</sup>: Avg. inflation pressure of 34 atm; balloon downsized 0.5mm to RVD

## Comparison of Calcium Fracture and Injury by Lesion<sup>3</sup>



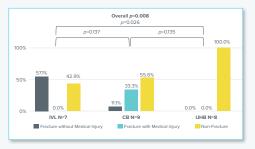
- Calcium fractures were most frequently observed with IVL
- Medial injury was significantly less frequent with IVL compared to CB and UHB
- Medial injury occurred in 100% of lesions treated with UHB

# Calcium Fracture and Injury Within Calcium Arcs ≥180° by Histological Section<sup>3</sup>



- IVL produced calcium fracture in 100% of histologic sections without medial injury
- CB produced calcium fracture in 50% of histologic sections and were mostly associated with medial injury
- Majority of calcium fractures produced by UHB were associated with medial injury

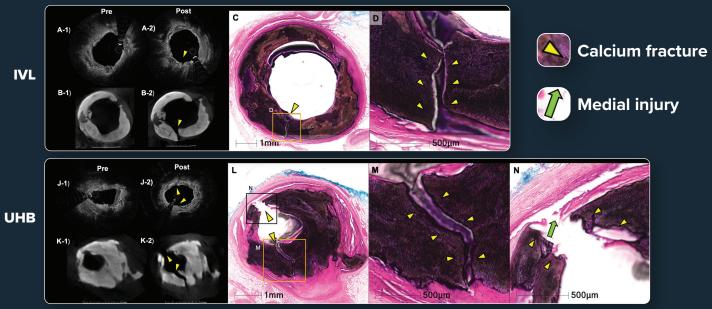
## Calcium Fracture and Injury Within Calcium Arcs <180° by Histological Section<sup>3</sup>



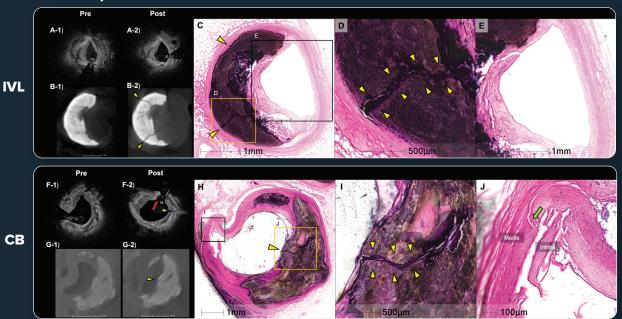
- IVL produced calcium fracture in >50% of histologic sections without medial injury
- CB produced fractures in <50% of histological sections and were mostly associated with medial injury
- No calcium fracture identified under micro-CT and histology for UHB

## DeepOCT™, Micro- CT, and Histology Examples of Fracture and Medial Injury Analysis³

### **Device Impact on Circumferential Calcium**



### **Device Impact on Calcium Arcs <180°**



This study mirrors clinical trial findings demonstrating the safety and efficacy of Shockwave IVL across calcium arcs<sup>4</sup>. Additional clinical research appropriately powered for safety is warranted to reaffirm benefits of IVL in this ex-vivo study.

Sekimoto, T et al. Comparison of Vascular Injury From Intravascular Lithotripsy, Cutting, or Ultra-High-Pressure Balloons During Coronary Calcium Modification. J Am Coll Cardiol Intv. 2025 Sep. 18 (17) 2093–2104. Cadaveric study. May not be indicative of actual clinical use.

- Mangieri A, Nerla R, Castriota F et al. Cutting balloon to optimize predilation for stent implantation: The COPS randomized trial. Catheter Cardiovasc Interv 2023;101:798-805
   Rheude T, Rai H, Richardt G et al. Super high-pressure balloon versus scoring balloon to prepare severely calcified coronary lesions: the ISAR-CALC randomised trial EuroIntervention 2021;17:481-488.
- 3. Sekinoto, T et al. Comparison of Vascular Injury From Intravascular Lithotripsy, Cutting, or Ultra-High-Pressure Balloons During Coronary Calcium Modification. J Am Coll
- 4. Ali, Ziad A., et al. Impact of Calcium Eccentricity on the Safety and Effectiveness of Coronary Intravascular Lithotripsy: Pooled Analysis from the Disrupt CAD Studies. Cardiovasc Interv 2023

In the US: Rx Only. Prior to use, please reference Instructions For Use for information on indications, contraindications, warnings, precautions, and adverse events. www.shockwavemedical.com/IFU

Please contact your local Shockwave representative for specific country availability.

© 2025 Shockwave Medical, Inc. All rights reserved. SPL-76233 Rev. A

