CORONARY INTRAVASCULAR LITHOTRIPSY (IVL)

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I THE BIOPHYSICAL MECHANISM (SONIC ACOUSTIC WAVEFRONT)

- **Technology:** Adapted from urological extracorporeal shockwave lithotripsy; the **Shockwave C2+ Coronary IVL catheter** is a rapid-exchange semi-compliant angioplasty balloon (2.5 to 4.0 mm diameters, 12 mm length) containing two radiopaque **electrohydraulic lithotripsy emitters** connected to an external pulse generator.
- **Mechanism of Action:** The IVL balloon is inflated gently to **4 atmospheres** (solely to achieve fluid-coupled apposition with the arterial wall without barotrauma), and electrical discharge across the emitters vaporizes the 50:50 saline-contrast mixture inside the balloon, creating a rapidly expanding and collapsing **cavitation vapor bubble**. This generates **unfocused, circumferential sonic acoustic pressure waves (1 pulse per second; 10 pulses per cycle; up to 80 to 120 pulses per catheter)** with a peak positive pressure equivalent to **~50 atmospheres**.
- **Selective Calcium Fracture:** Acoustic waves pass harmlessly through soft elastic vascular tissue (which has the same acoustic impedance as water) while imparting compressive and shear stress on high-acoustic-impedance **superficial intimal and deep medial calcium**, creating **multi-plane longitudinal and circumferential micro- and macro-fractures** that restore vessel compliance and enable full stent expansion at low pressures.

II CLINICAL INDICATIONS FOR CORONARY IVL

- **Severely Calcified De Novo Lesions:** Indicated when **OCT or IVUS** identifies a high calcium burden—specifically an **OCT Calcium Score of 4** (**calcium arc greater than 180 degrees, thickness greater than 0.5 mm, and length greater than 5.0 mm**) or a superficial **IVUS calcium arc greater than 270 to 360 degrees**.
- **Deep Medial and Eccentric/Nodular Calcification:** Uniquely effective for **deep medial calcium** (separated from the lumen by fibrous tissue) that superficial rotational/orbital atherectomy burrs cannot reach, as well as concentric (360-degree) and eccentric/nodular calcium.
- **Large-Vessel and Bifurcation Calcification (e.g., Distal Left Main):** Ideal for large-caliber vessels (**3.5 to 4.0+ mm**) where a 1.5–1.75 mm rotational burr has an inadequate burr-to-artery ratio, and for **calcified bifurcations** because a **side-branch protection wire can remain safely in place** during lithotripsy.
- **Refractory Stent Under-Expansion / Calcified In-Stent Restenosis (Off-Label High-Value Niche):** Safely fractures thick circumferential calcium **behind the struts of a previously deployed, under-expanded metallic stent** where high-speed atherectomy burrs carry high risks of burr entrapment and strut avulsion.

III ADVANTAGES OF IVL OVER ROTATIONAL ATHERECTOMY (ROTABLATION)

Technical / Clinical Feature	Coronary Intravascular Lithotripsy (IVL)	Rotational Atherectomy (Rotablator)
Mechanism of Action	**Disruptive:** Sonic acoustic pressure waves (~50 atm) fracture calcium *in situ*	**Ablative:** High-speed (140–160k RPM) diamond burr sands superficial calcium into microparticles
Depth of Calcium Modification	**Both superficial intimal AND deep medial calcium**	**Superficial (luminal) calcium only**
Slow-Flow / No-Reflow Risk	**Extremely Low (<0.5%)** — fractured calcium stays inside the vessel wall	**Higher (2% to 5%)** — embolic microparticle debris & platelet activation
Guidewire & Side-Branch Wire	Uses any standard **0.014-inch workhorse wire**; **safe to keep a jailed side-branch wire**	Requires dedicated **0.009-inch RotaWire**; **side-branch wire must be removed** (burr severs wire)
Perforation & Dissection Rate	**Very Low (<0.5%)** — low 4-atm balloon inflation	Higher risk in angulated/eccentric vessels (~1–2%)
Uncrossable Pinhole Lesions	**Cannot cross** until a channel is created (crossing profile ~0.044–0.047 inch)	**Gold Standard** for balloon-uncrossable pinhole stenoses

IV LIMITATIONS AND PROCEDURAL CONSIDERATIONS

- **Crossability Limitation:** Because the IVL catheter is a relatively bulky balloon platform (crossing profile 0.044 to 0.047 inches, requiring a 6F guide catheter), **it cannot cross severe "balloon-uncrossable" pinhole calcified stenoses** without prior predilation with a small low-profile balloon or initial rotational/orbital atherectomy (**"RotaTripsy"**).
- **"Shocktopics" (Ventricular Ectopy / Pacing Capture):** Acoustic pulses can mechanically depolarize the myocardium (mechano-electrical coupling), producing benign ventricular ectopy or transient pacing capture in ~40 percent of cases (with **zero** sustained VT/VF reported in DISRUPT CAD when heart rate is >60 bpm).
- **Balloon Rupture and Cost:** Sharp calcium spicules can occasionally pinhole-rupture the IVL balloon, and single-use IVL catheters carry a substantially higher device cost than standard balloons or rotational burrs.

V LANDMARK EVIDENCE AND CURRENT STATUS

- **DISRUPT CAD I, II, III, and IV Trials (Pooled Analysis, Kereiakes et al., *JACC Cardiovasc Interv* 2021):** Across 628 patients with severely calcified lesions in 4 prospective studies, IVL achieved **92.4 percent primary procedural success**, **99.5 percent freedom from 30-day perforation, abrupt closure, or no-reflow**, and an OCT-confirmed **minimum stent area of 6.5 mm2 (>100% stent expansion)** with multi-plane calcium fractures.
- **The "RotaTripsy" Hybrid Standard:** In severe **balloon-uncrossable AND deep thick circumferential** calcified lesions, contemporary practice combines **front-end Rotational Atherectomy** (using a small 1.25 or 1.5 mm burr to create a lumen channel) followed immediately by **IVL (sized 1:1 to the reference vessel)** to fracture the deep medial calcium ring.

KEY REFERENCES

- **Hill JM, Kereiakes DJ, Shlofmitz RA, et al. (DISRUPT CAD III Investigators):** Intravascular lithotripsy for treatment of severely calcified coronary artery disease, *Journal of the American College of Cardiology*, 2020.
- **Kereiakes DJ, Di Mario C, Riley RF, et al.:** Intravascular Lithotripsy for Treatment of Calcified Coronary Lesions: Patient-Level Pooled Analysis of the Disrupt CAD Studies, *JACC: Cardiovascular Interventions*, 2021.
- **Riley RF, Patel MP, Abbott JD, et al.:** SCAI Expert Consensus Statement on the Management of Calcified Coronary Lesions, *JSCAI*, 2024.