EuroIntervention
2026;22:255-264
DOI: 10.4244/EIJ-D-25-00618

ORIGINAL RESEARCH

Hertz contact intravascular lithotripsy for calcified coronary artery disease: the PINNACLE-I trial

Stefan Verheye[1]*, MD, PhD; Bert Ferdinande[2], MD, PhD; Valeria Paradies[3], MD; Pim A.L. Tonino[4], MD, PhD; Yoann Bataille[5], MD, PhD; Daan Cottens[2], MD; Fabrizio Spano[6], MD; Zlatko Mehmedbegovic[7], MD; Pieter C. Smits[7], MD, PhD; Marie-Claude Morice[7,8], MD; Johan Bennett[9], MD, PhD

**Corresponding author: Cardiovascular Center, ZAS Middelheim, Lindendreef 1, 2020, Antwerp, Belgium. E-mail: stefan.verheye@gmail.com*

This paper also includes supplementary data published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-25-00618

ABSTRACT

BACKGROUND: Calcified coronary lesions impede stent expansion and are associated with poor outcomes after percutaneous coronary interventions. Intravascular lithotripsy (IVL) has emerged as a safe and effective pretreatment to optimise stent implantation.

AIMS: This study assesses the LithiX lithotripsy device, which uses the Hertz contact (HC) mechanism to fragment calcium while minimising injury to surrounding soft tissue, without requiring an external energy source.

METHODS: The multicentre, prospective PINNACLE-I clinical trial enrolled patients with up to two moderately to severely calcified *de novo* lesions. The primary endpoints were <50% residual stenosis without in-hospital major adverse cardiovascular events (MACE) and the 30-day MACE rate. Clinical events were assessed up to 6 months.

RESULTS: Sixty patients with 63 lesions were treated with successful delivery and use of the HC-IVL catheter and a median procedure time of 59.5 min (interquartile range: 40.5-76.0). The primary endpoint was achieved in 98.3%. All patients had residual stenosis <30% after stent placement. The 30-day MACE rate was 1.7%, due to 1 periprocedural target vessel non-Q-wave myocardial infarction. There were no cardiovascular deaths, no definite or probable stent thromboses, nor any device-related events up to 6 months of follow-up. The optical coherence tomography substudy in 32 subjects identified a wide range of calcium morphologies, including calcium arcs of 96-360° and calcified nodules. Following HC-IVL, calcium fractures were achieved in 90.6% of lesions, and the mean fracture depth was 0.81±0.33 mm. Stent expansion at the minimum stent area site was 96.7±25.5%.

CONCLUSIONS: PINNACLE-I demonstrated the feasibility, safety, and efficacy of the novel HC-IVL to fracture calcified lesions and achieve optimal stent expansion in a broad range of calcium morphologies.

KEYWORDS: calcified coronary lesions; coronary artery disease; intravascular imaging; lithotripsy; optical coherence tomography; vascular calcification

SUBMITTED ON 10/06/2025 - REVISION RECEIVED ON 1st 24/10/2025 / 2nd 24/11/2025 - ACCEPTED ON 08/12/2025

Calcified coronary lesions remain a key challenge in percutaneous coronary interventions (PCI). Vessel calcification impedes stent expansion, increases the risk for malapposition, and is associated with increased complication rates and poor outcomes[1-3]. At present, nearly one-third of PCI involve lesions with moderate to severe calcification[2,4].

Previous calcium treatment modalities, including off-label use of high-pressure balloons, cutting or scoring balloons, and atheroablative technologies (i.e., laser, rotational, and orbital atherectomy), have inherent limitations[2,4]. These include safety and effectiveness concerns (bulky device profiles hindering crossability, risk of vascular injury, and guidewire bias leading to eccentric ablation) and usability challenges (steep learning curves, high capital equipment costs, long procedure and fluoroscopy times, and minimum procedure volume requirements to maintain proficiency)[2,4]. In contrast, lithotripsy offers effective calcium fragmentation while minimising injury to adjacent non-calcified tissue through mechanical (manual) and energy-based modalities[5,6]. Energy-based intravascular lithotripsy (IVL) was developed after mechanical devices at the time failed to achieve effective calcium fragmentation without significantly injuring non-calcified adjacent vessel tissue or the vessel itself[2,4,6]. However, current energy-based IVL technologies require an external energy source and capital equipment for amplified stress generation[7,8].

The LithiX Hertz Contact IVL (HC-IVL) System (Elixir Medical) is the first mechanical IVL platform without the need for an external energy source or capital equipment, offering an efficient procedure workflow and a potentially faster learning curve. It is based on the Hertz contact theory, which explains how discrete stress develops when a spherical surface deforms a planar object[9]. The parameters that influence the mechanism of amplified stress are contact force, the modulus of elasticity of the two contact surfaces, and the small, discrete area of contact. The novel application of Hertz contact theory to a balloon-based form factor led to the development of HC-IVL.

The PINNACLE-I clinical trial evaluated the feasibility, safety, and efficacy of HC-IVL for treating moderately to severely calcified coronary artery lesions.

Impact on daily practice

The novel LithiX Hertz Contact Intravascular Lithotripsy catheter uses the Hertz contact mechanism to fragment coronary calcium without an external energy source. The outcomes presented herein demonstrate a reassuring safety and performance profile, with high procedural success, calcium fractures in more than 90% of lesions, and optimal stent expansion in a broad range of calcium morphologies. The platform's workflow and ease of use may improve productivity in the catheterisation laboratory and enable broader patient access.

Methods

STUDY DESIGN

PINNACLE-I is a multicentre, prospective, single-arm study conducted at 7 sites in Belgium and the Netherlands, which enrolled 60 patients. Thirty-two patients were scheduled for additional optical coherence tomography (OCT) assessment preprocedure, post-LithiX treatment, and post-stent implantation. Clinical follow-up was scheduled at 30 days and 6 months.

An independent core laboratory (Cardiovascular European Research Center) performed angiographic and OCT analyses, and an independent clinical events committee (RARAS Contract Research Organization) adjudicated all endpoint-related events. The study was conducted according to the Declaration of Helsinki, ISO14155, and local and national regulations, and was approved by the independent ethics committee of each participating centre and the respective regulatory authorities. All patients provided their written informed consent prior to any study procedure. The trial is registered at ClinicalTrials.gov: NCT05828173.

PARTICIPANTS

Patients requiring PCI in up to 2 *de novo* coronary artery lesions with moderate to severe calcification, reference vessel diameters between 2.25 mm and 3.5 mm, and a lesion length ≤34 mm were included. The full list of eligibility criteria is provided in **Supplementary Table 1**.

INTERVENTIONS

The LithiX HC-IVL catheter is a mechanical lithotripsy device that consists of multiple low-profile metallic hemispheres, uniformly distributed and integrated across the surface of a semicompliant balloon. The hemispheres break the calcium directly or indirectly through application of physical forces targeting hard coronary calcification under low balloon pressure without removing the calcium. The Hertz contact mechanism provides exponential amplification of the discrete stress required for calcium fragmentation, eliminating the need for an external energy source **(Central illustration, Figure 1, Moving image 1)**.

The delivery system is compatible with standard 0.014" (0.36 mm) guidewires, and the device crossing profile is compatible with a 5 Fr guiding catheter with an internal

Abbreviations

HC	Hertz contact
IVL	intravascular lithotripsy
MACE	major adverse cardiovascular events
MC	maximum calcium
MI	myocardial infarction
MLA	minimum lumen area
MSA	minimum stent area
OCT	optical coherence tomography
PCI	percutaneous coronary intervention
TLR	target lesion revascularisation

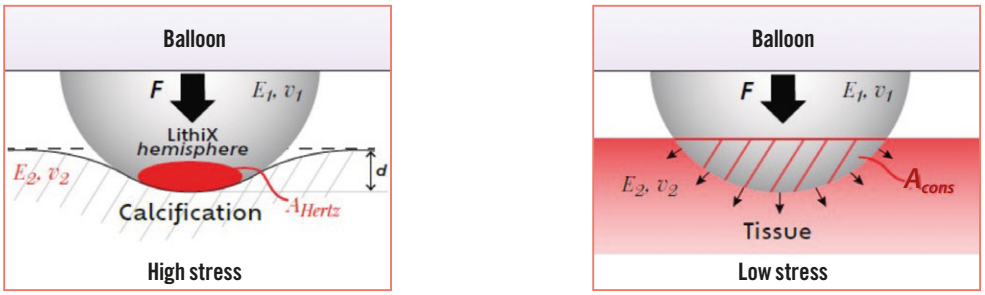
EuroIntervention — Central Illustration

PINNACLE-I: treating calcified lesions with the Hertz contact mechanism.

A — PINNACLE-I TRIAL

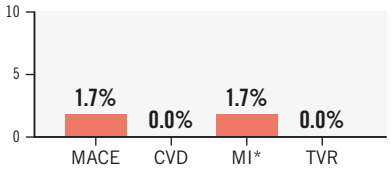
PURPOSE	DESIGN
Assess the safety and efficacy of the LithiX Hertz Contact Intravascular Lithotripsy system	Prospective, multicentre, international, single-arm trial, including 60 patients with moderately to severely calcified coronary lesions

B — HERTZ CONTACT INTRAVASCULAR LITHOTRIPSY



C — KEY STUDY OUTCOMES
N=60 patients, N=63 lesions

CLINICAL SUCCESS*	98.3% (95% CI: 91.1-100.0)* **Primary efficacy and safety endpoint met**
PRIMARY SAFETY ENDPOINT	**MACE up to 30-day follow-up**



Procedural imaging endpoints (final, post-stent)

Angiographic success	63 (100%)
In-lesion diameter stenosis <30%	63 (100%)
Stent expansion by OCT (n=32)	
at minimum lumen area site	100.9±24.3%#
at maximum calcium site	103.4±25.6%†
at minimum stent area site	96.7±25.5†

Stefan Verheye *et al.* • *EuroIntervention* 2026;22:255-264 • DOI: 10.4244/EIJ-D-25-00618

*A) PINNACLE-I trial design. B) The Hertz contact theory describes the development of localised stress when a spherical surface deforms a planar object. Parameters that influence the mechanism of amplified stress are contact force (F), the effective modulus of elasticity of the two contact surfaces (E, v), and the area of contact at the interface (A_{Hertz}: discrete, small contact area with hard calcium; A_{cons}: sustained, large contact area with soft tissue). C) Key study outcomes. MACE was a composite of CVD, MI, and TVR. *The primary efficacy and safety endpoint (clinical success) was achieved in all but one patient who experienced a periprocedural target vessel non-Q-wave MI. No angiographic complications were observed post-stenting, and all lesions had a final residual stenosis <30%. Optimal stent expansion was demonstrated by optical coherence tomography imaging (n=32). #n=29 lesions; †n=30 lesions. CI: confidence interval; CVD: cardiovascular death; HC-IVL: Hertz contact intravascular lithotripsy; MACE: major adverse cardiovascular events; MI: myocardial infarction; OCT: optical coherence tomography; TVR: target vessel revascularisation*

lumen diameter of at least 1.67 mm (0.066"). Size 6 Fr guiding catheters are recommended to facilitate the use of adjunct devices. The distal portion, including the balloon and hemispheres, is coated with a hydrophilic coating to enhance deliverability to the target location.

Available balloon nominal diameters range from 1.5 mm to 3.5 mm, with a nominal length of 14 mm. The nominal inflation pressure is 5 atm, and the rated burst pressure is 12 atm. The number of hemispheres per balloon ranges from 27 to 45 depending on the balloon diameter.

At the start of the study, predilatation was performed with a 1.5 mm LithiX device, thereafter upsizing to the reference vessel diameter. Over the course of the trial, the procedure was revised to a standard PCI workflow, and predilatation using a non-compliant balloon was required to assess resistance to lesion expansion due to calcification prior to the use

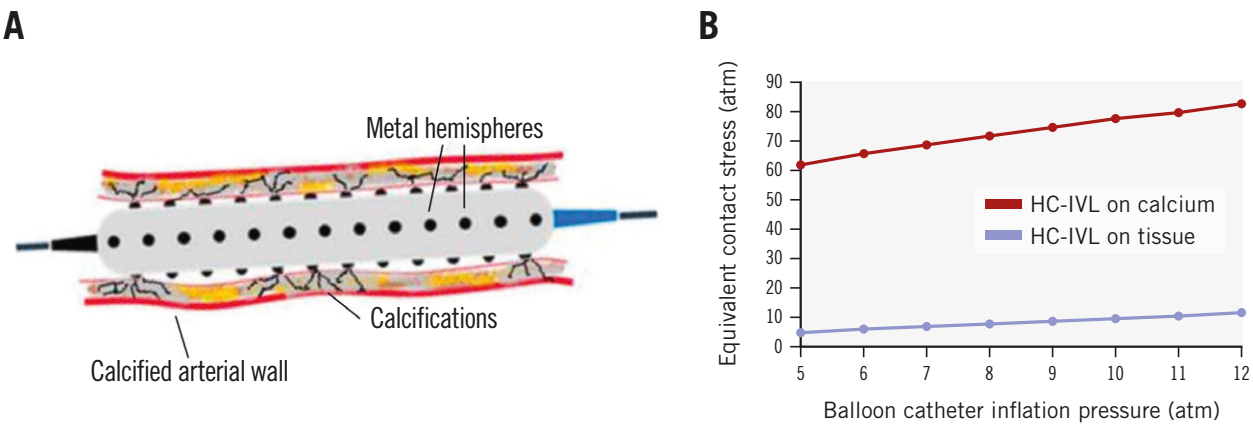


Figure 1. *HC-IVL and its effects on tissue and calcium. A) The HC-IVL device consists of multiple low-profile metal hemispheres integrated along the surface of a semicompliant balloon. These hemispheres fragment calcium through exponential amplification of discrete stresses on calcified plaque while minimising stress on adjacent non-calcified tissue. B) Contact stress on calcium versus tissue. HC-IVL: Hertz contact intravascular lithotripsy*

of HC-IVL. The nominal size of the HC-IVL device was recommended to be approximately 0.25 mm smaller and not larger than a 1:1 ratio to the reference vessel diameter. The device was recommended to be expanded to at least nominal pressure, but no higher than the rated burst pressure. The workflow allowed multiple inflations within the same lesion to create new points of contact and cracks that propagate under sustained pressure during each inflation phase. Post-dilatation with a non-compliant balloon sized at a 1:1 ratio to the reference vessel diameter was recommended to optimise lesion preparation. The selection of stent size was left to the discretion of the investigators, and stent implantation was performed per standard practice.

ENDPOINTS AND DEFINITIONS

The primary effectiveness and safety endpoint was clinical success, defined as residual stenosis <50% after final treatment (with or without stenting) with no evidence of in-hospital major adverse cardiovascular events (MACE; a composite of cardiovascular death, myocardial infarction [MI], and target vessel revascularisation). An additional primary safety endpoint was the rate of MACE up to 30 days post-procedure.

Secondary endpoints included in-lesion angiographic success post-stenting, defined as success in facilitating stent delivery with <50% residual stenosis and without serious angiographic complications of the main branch (severe dissection impairing flow [type D-F], perforation, abrupt closure, persistent slow-flow, or no-reflow); stent delivery success; target lesion failure (TLF; composite of cardiovascular death, target vessel MI, and clinically indicated target lesion revascularisation [TLR]); MI (periprocedural MI defined according to the Academic Research Consortium 2 definitions[10] and spontaneous MI according to the third universal definition[11]); target vessel revascularisation (any repeat PCI or surgical bypass of any segment of the target vessel); TLR; definite or probable stent thrombosis[10]; and mortality. Angiographic endpoints included acute gain and residual diameter stenosis (<50% and <30%), and OCT endpoints included the presence of calcium fractures, stent area, acute area gain, and stent expansion (stent area / average reference lumen area x 100).

Moderate to severe calcification is characterised by radiopacities visible before contrast dye injection during the cardiac cycle or without cardiac motion. The maximum continuous calcium arc corresponds to the arc of an individual calcium deposit from the cross-sectional image by OCT[12]. Eccentric calcium is defined as a calcium arc of ≤270°, whereas concentric calcification is defined as a calcium arc of >270°[13]. The procedure time is defined as the time elapsed from the insertion of the first guide catheter until the removal of the last guide catheter.

STATISTICAL ANALYSIS

The primary safety and performance endpoint was compared against an objective performance goal of 80%. The objective performance goal was based on a review of the approved calcium modification devices reported in the literature[14,15].

The primary analysis is based on data available for the intention-to-treat population. The number of subjects, percentages, and Clopper-Pearson exact 95% confidence intervals (CI) were constructed for the primary endpoints. Continuous data are presented as mean and standard deviation or median and interquartile range (IQR) as appropriate, and categorical data as frequency counts and percentages. Missing data were not imputed. The statistical analysis of clinical data was performed using SAS, version 9.4 or later (SAS Institute).

Results

BASELINE CHARACTERISTICS

From 27 April 2023 to 1 March 2024, 60 patients were enrolled. Patients were 72.1±6.8 years old, 81.7% presented with chronic coronary syndrome and 18.3% with acute coronary syndrome. Complex type B2/C lesions were present in 79.4%. Reference vessel diameter, minimum lumen diameter, and target lesion length were 2.79±0.47 mm, 1.09±0.34 mm, and 14.4±6.8 mm, respectively **(Table 1)**.

The OCT substudy included 32 subjects. The average maximum continuous calcium arc by OCT was 263.4±77.1°

Table 1. Baseline characteristics.

Baseline characteristics	N=60 patients
Age, years	72.1±6.8
Sex	
Male	39 (65.0)
Female	21 (35.0)
Current smoker	13 (21.7)
Hypertension	46 (76.7)
Dyslipidaemia	45 (75.0)
Diabetes mellitus	18 (30.0)
Renal insufficiency	9 (15.0)
Prior myocardial infarction	12 (20.0)
Prior PCI	17 (28.3)
Prior CABG	4 (6.7)
Prior stroke	5 (8.3)
Clinical presentation	
Acute coronary syndrome	11 (18.3)
Chronic coronary syndrome	49 (81.7)
Lesion characteristics	**N=63 lesions**
Target lesion classification	
A/B1	13 (20.6)
B2/C	50 (79.4)
Target vessel	
LAD	33 (52.4)
LCx	5 (7.9)
RCA	23 (36.5)
Protected left main	1 (1.6)
Ramus	1 (1.6)
Reference vessel diameter, mm	2.79±0.47
Minimum lumen diameter, mm	1.09±0.34
Diameter stenosis, %	60.7±10.9
Target lesion length, mm	14.4±6.8
Calcified length, mm	25.1±11.9
Calcification classification[a]	
Severe	38 (60.3)
Moderate	25 (39.7)
Bifurcation with side branch involvement	9 (14.3)

Data are displayed as mean±standard deviation or N (%). [a]Site assessed. CABG: coronary artery bypass graft; LAD: left anterior descending artery; LCx: left circumflex; PCI: percutaneous coronary intervention; RCA: right coronary artery

Table 2. Optical coherence tomography characteristics following Hertz contact intravascular lithotripsy (core laboratory).

	Preprocedure N=32 lesions[a]	Following HC-IVL N=32 lesions[a]
Minimum lumen area[b], mm²	2.25±0.96	-
Area stenosis[b], %	72.6±10.0	-
Calcium length, mm	23.9±6.6	-
Maximum continuous calcium arc, °	263.4±77.1	-
Range	96°-360°	-
≤270°	13 (40.6)	-
>270°	19 (59.4)	-
Presence of a calcified nodule[c]	9 (31.0)	-
Calcium fracture	-	29 (90.6)
1 fracture	-	5 (15.6)
2 fractures	-	12 (37.5)
≥3 fractures	-	12 (37.5)
Fracture depth, mm	-	0.81±0.33
Fracture width, mm	-	0.66±0.29

Data are displayed as mean±standard deviation or N (%). [a]One subject had two target lesions but had OCT analysis on one target lesion only; [b]N=30 lesions; [c]N=29 lesions. HC-IVL: Hertz contact intravascular lithotripsy; OCT: optical coherence tomography

with a minimum of 96° and a maximum of 360°. Calcium length was 23.9±6.6 mm. A total of 13 subjects had eccentric calcified lesions, 19 had concentric calcifications, and nearly one-third of all lesions presented with calcified nodules (n=9), per the core lab assessment **(Table 2, Table 3)**.

PROCEDURAL CHARACTERISTICS

Procedural details are provided in **Table 4**. The median procedure time was 59.5 min (IQR: 40.5-76.0), and the median fluoroscopy time was 13.1 min (IQR: 9.9-20.4). Predilatation prior to HC-IVL use was performed in 81% (51/63) of lesions, all lesions were treated with a stent, and post-stent dilatation was subsequently performed in 90.5% (57/63) of lesions.

PRIMARY OUTCOMES

The primary safety and effectiveness endpoint was met, with in-hospital clinical success achieved in 59 subjects out of 60 (98.3% [95% CI: 91.1-100.0]); all patients achieved angiographic success with residual diameter stenosis below 30%, and one patient had a periprocedural non-Q-wave MI caused by distal embolisation post-stenting.

This periprocedural MI was the only incidence of MACE up to 30 days of follow-up (1.7% [95% CI: 0.0-9.1]). Six months of follow-up was available for all patients, except for one patient who died of a non-cardiovascular cause (acute myeloid leukaemia). There were no cardiovascular deaths, no definite or probable stent thromboses, no unanticipated events reported, nor any additional TLF events up to 6 months **(Table 5)**.

IMAGING OUTCOMES

The stent delivery success rate was 100%. Angiographic success post-procedure was 100% with no severe dissections, perforations, nor other angiographic complications involving the main branches. One subject had a side branch occlusion with no further complications. The angiographic acute lumen gain following HC-IVL was 0.79±0.40 mm and 1.60±0.48 mm post-stenting **(Figure 2)**.

Calcium fractures post-HC-IVL were identified by OCT in 90.6% of lesions (2 or more calcium fractures in 75.0% of lesions) with a mean fracture depth of 0.81±0.33 mm. The final area stenosis was 11.2±14.2% at the minimum lumen area (MLA) site, 3.5±5.7% at the maximum calcium (MC) site, and 14.2±12.7% at the minimum stent area (MSA)

Table 3. Optical coherence tomography characteristics at the sites of minimum lumen area, maximum calcium, and minimum stent area (core laboratory).

At the site of minimum lumen area	Preprocedure N=30 lesions	Final, post-stent N=29 lesions
Calcium angle, °	170.5±85.7	-
Maximum calcium thickness, mm	0.77±0.30	-
Lumen area and stent area, mm²	2.25±0.96	7.52±2.37
Acute area gain[a], mm²	-	4.70±1.83
Area stenosis, %	72.6±10.0	11.2±14.2
Stent expansion*, %	-	100.9±24.3
At the site of maximum calcium	**N=30 lesions**	**N=30 lesions**
Calcium angle, °	210.1±96.1	-
Maximum calcium thickness, mm	1.04±0.34	-
Lumen area and stent area[b], mm²	4.86±2.46	8.34±2.29
Acute area gain[c], mm²	-	3.87±2.47
Area stenosis, %	38.2±27.1	3.5±5.7
Stent expansion*, %	-	103.4±25.6
At the site of minimum stent area	**N=28 lesions**	**N=30 lesions**
Calcium angle, °	125.8±91.9	-
Maximum calcium thickness, mm	0.72±0.43	
Lumen area and stent area, mm²	3.82±1.77	6.57±2.14
Acute area gain[a], mm²	-	3.38±1.90
Area stenosis, %	51.7±22.3	14.2±12.7
Stent expansion*, %	-	96.7±25.5

Data are displayed as mean±standard deviation or N (%). *Stent area / average reference lumen area x 100. Data were not available for all 32 lesions in each group. [a]N=28 lesions; [b]N=29 lesions; [c]N=27 lesions

Table 4. Procedural characteristics.

	N=60 patients N=63 lesions
Access	
Radial	52 (86.7)
Femoral	8 (13.3)
Procedure time, min	59.5 (40.5-76.0)
Contrast volume, mL	180 (149-250)
Fluoroscopy time, min	13.1 (9.9-20.4)
Number of LithiX devices used*[a]	2 (1-2)
LithiX crossing success*	62 (98.4)
Balloon rupture	0 (0)
Device diameters[a] (N=104)	
1.5 mm	19 (18.3)
2.0 mm	6 (5.8)
2.25 mm	5 (4.8)
2.5 mm	19 (18.3)
2.75 mm	9 (8.7)
3.0 mm	26 (25.0)
3.5 mm	20 (19.2)
Predilatation*	51 (81.0)
Number of stents implanted*	1.2±0.5, 1 (1-1)
Post-dilatation*	57 (90.5)

Data are displayed as mean±standard deviation, median (interquartile range), or N (%). Values are patient level unless otherwise indicated. *Lesion-level analysis. [a]Twelve 1.5 mm LithiX devices were used for predilatation.

site. Stent expansion at the MLA, MC, and MSA sites was 100.9±24.3%, 103.4±25.6%, and 96.7±25.5%, respectively **(Table 2, Table 3)**.

In a *post hoc* analysis of the OCT subgroup, lesions were assessed by calcium morphology. The fracture depth was 0.76±0.28 mm in eccentric calcified lesions (N=13) and 0.85±0.36 mm in concentric calcified lesions (N=19). Stent expansion at the MLA site, the MC site, and the MSA site was 101.0±19.6%, 97.9±19.3%, and 101.4±23.7% for eccentric lesions and 100.8±26.9%, 106.6±28.7%, and 94.0±26.7% for concentric lesions, respectively **(Supplementary Table 2, Supplementary Table 3)**. In lesions with calcified nodules (N=9), the average preprocedural calcium angle was 202.6±96.4°, and a stent expansion of 102.8±16.0% was achieved at the site of maximum calcium. Representative OCT images for eccentric and concentric calcified lesions and calcified nodules are provided in **Figure 3**.

Discussion

PINNACLE-I assessed the safety and effectiveness of the HC-IVL device to fragment calcium for the treatment of moderately to severely calcified coronary lesions. The main observations from PINNACLE-I showed (i) effective calcium modification, with calcium fractures identified in more than 90% of lesions, with an average fracture depth of 0.81 mm across a wide range of calcium morphologies (eccentric lesions, concentric lesions, and calcified nodules); (ii) optimised % stent expansion and MSA regardless of calcium morphology or distribution; (iii) extremely low incidences of MACE and other adverse angiographic or clinical outcomes; and (iv)

Table 5. Clinical events during the procedure and follow-up period.

	N=60 patients N=63 lesions
Final, post-stent	
Serious angiographic complication[a]	0/63 (0)
Severe dissection (type D-F)	0/63 (0)
Perforation	0/63 (0)
Abrupt closure	0/63 (0)
Slow-flow or no-reflow	0/63 (0)
Thrombus	0/63 (0)
Spasm	0/63 (0)
Distal embolism	0/63 (0)
30 days	
Major adverse cardiovascular events	1/59 (1.7)
Cardiovascular death	0/59 (0)
Myocardial infarction[b]	1/59 (1.7)
Target vessel revascularisation	0/59 (0)
Target lesion failure[b]	1/59 (1.7)
Non-cardiovascular death[c]	1/60 (1.7)
Definite or probable stent thrombosis	0/59 (0)
6 months	
Target lesion failure[b]	1/59 (1.7)
Cardiovascular death	0/59 (0)
Myocardial infarction[b]	1/59 (1.7)
Clinically indicated target lesion revascularisation	0/59 (0)
Target vessel revascularisation[d]	1/59 (1.7)
Non-cardiovascular death[c]	1/60 (1.7)
Definite or probable stent thrombosis	0/59 (0)

Data are displayed as n/N (%). [a]In the main branch, one side branch occlusion without further complication was reported. [b]Target vessel myocardial infarction (periprocedural, non-Q-wave). [c]Autopsy report concluded acute myeloid leukaemia with haemophagocytic lymphohistiocytosis. [d]One subject had target vessel revascularisation (not target lesion), non-target vessel revascularisation, and non-target vessel myocardial infarction (spontaneous, non-Q-wave)

short procedure times, attributed to the efficient workflow and ease of use of HC-IVL.

The HC-IVL system was designed to achieve effective calcium fragmentation and to allow optimal stent expansion by applying discrete physical forces that selectively interact with calcium while being atraumatic to adjacent soft tissue, minimising vessel injury. The Hertz contact mechanism provides effective amplification of low balloon pressures and application of discrete stress directly or indirectly on hard calcified surfaces that are consistent with the fracturing stress developed by energy-based lithotripsy systems[16] without requiring an external energy source. The multiplicity of uniformly positioned small hemispheres along the balloon surface allows operators to secure multiple contact points along the calcified lesion to achieve effective fragmentation and lesion preparation.

In the OCT imaging substudy, 90.6% of lesions demonstrated calcium fractures with an average fracture depth of 0.81±0.33 mm and a fracture width of 0.66±0.29 mm. The extension of calcium fractures into the medial layer provides evidence of HC-IVL's effective mechanism of action. Calcium fractures resulted in optimal stent expansion of 103.4±25.6%, 100.9±24.3%, and 96.7±25.5% at the site of maximum calcium, minimum lumen area, and minimum stent area, respectively. Importantly, these results were consistent regardless of the extent of calcification (concentric or eccentric) or the presence of calcium nodules, which remain a challenge with existing calcium modification options[17]. Interestingly, no balloon ruptures were observed in PINNACLE-I, potentially owing to the uniform coverage by metal hemispheres which limit direct contact between the balloon and the calcium, thereby reducing the risk of balloon damage.

The degree of stent expansion in PINNACLE-I is particularly notable, given that achieving at least 80% expansion at the site of minimum stent area has been recommended by expert consensus[3]. The results appear at least comparable to those observed in the Disrupt CAD I-IV pooled analysis[12].

The HC-IVL procedure appears to be safe, without major angiographic complications, with the exceptions of an isolated

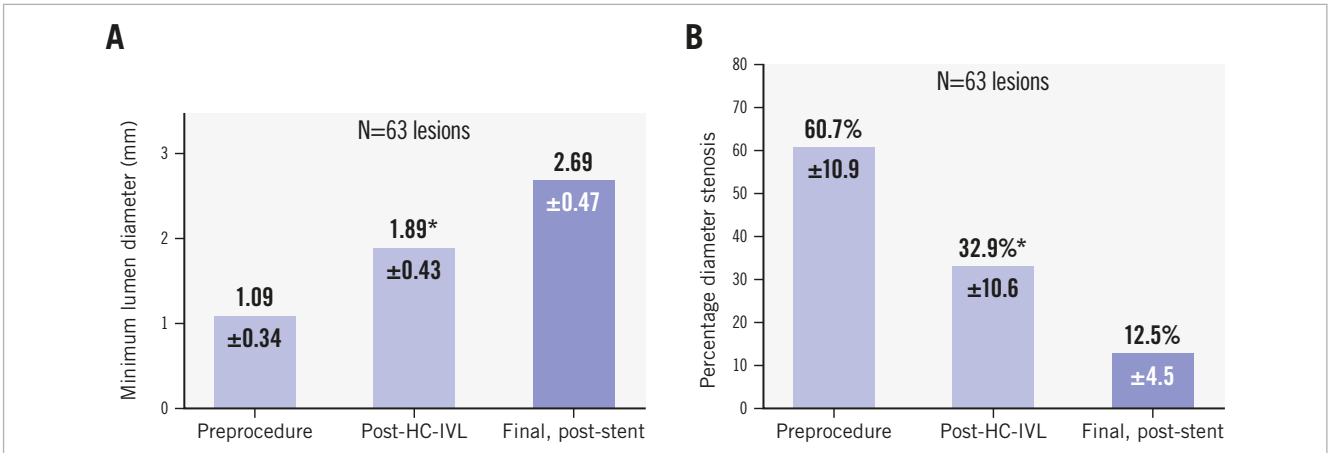


Figure 2. *Angiographic outcomes after HC-IVL and stent implantation. A) Lumen gain: acute lumen gain post-HC-IVL was 0.79±0.40 mm and final, post-stent was 1.60±0.48 mm. B) %DS reduction post-HC-IVL and post-stent implantation confirms effective calcium fragmentation and vessel expansion. *N=55 lesions. %DS: percentage diameter stenosis; HC-IVL: Hertz contact intravascular lithotripsy*

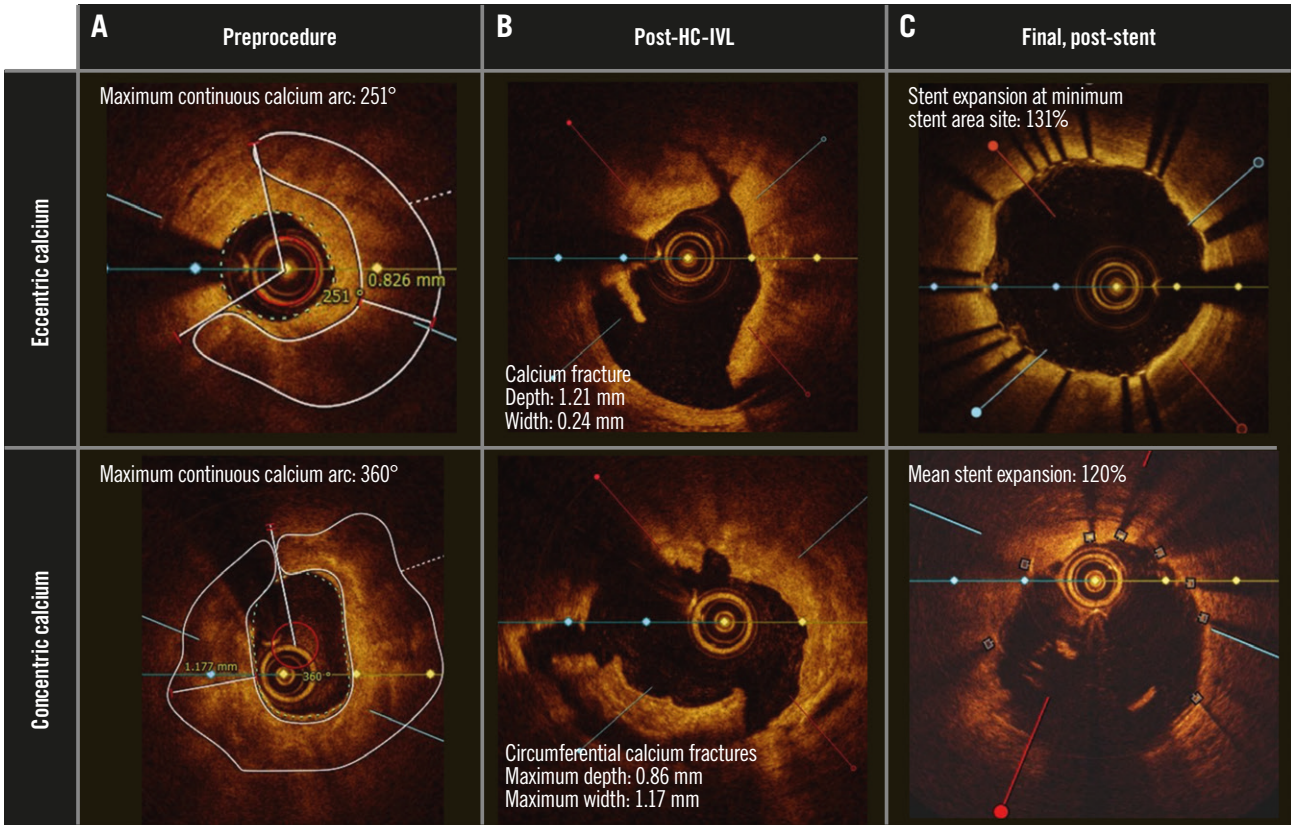


Figure 3. *Optical coherence tomography of HC-IVL in eccentric and concentric calcified coronary plaques. A) Cross-sectional OCT images of representative eccentric calcified and concentric calcified coronary lesions prior to HC-IVL. The white line marks the calcium. B) Following HC-IVL, OCT images demonstrate calcium fractures. C) Following stent implantation, optimal stent expansion was achieved. HC-IVL: Hertz contact intravascular lithotripsy; OCT: optical coherence tomography*

small side branch occlusion occurring without clinical sequelae, and one MACE event in the first 30 days (a periprocedural MI, 1.7%). Although the present cohort size is limited, this event rate compares favourably with other recent trials and a meta-analysis of multiple trials using calcium-modifying technologies during coronary intervention[7,16,18,19]. Furthermore, a potentially attractive aspect of HC-IVL is the lack of electromechanical transduction or myocardial electrical capture, which are common during electrohydraulic IVL procedures. The absence of myocardial capture mitigates the occurrence of associated hypotension observed with this phenomenon[20-22].

In addition, the rate of TLF at 6 months remained at 1.7%, with no additional TLF events observed between 30 days and 6 months. These salutary clinical outcomes demonstrate that the HC-IVL technology has a reassuring safety profile, attributed to its novel design that enables exponential force amplification through discrete contact points which selectively target the calcium while minimising injury to adjacent non-calcified vessel tissue, as well as a low-profile, trackable system.

Notably, despite all operators being first-time users, lesion crossing and clinical success rates were 98.4% and 98.3%, respectively, and procedure duration and fluoroscopy times were relatively short (mean total procedure time: 58 minutes; fluoroscopy time: 13 minutes), comparing favourably with previously published data on other calcium-modifying technologies[7,8,14,16,17,19,22-24]. These findings suggest little or no "learning curve" associated with HC-IVL technology. Further, the high procedural efficiency of HC-IVL can be attributed to the small device profile, improved trackability, and the workflow not requiring capital equipment or an electrical source. Therefore, the efficient workflow and ease of use of the HC-IVL may improve productivity in the cardiac catheterisation laboratory, expanding patient access – especially in emergent and urgent settings – and enabling calcium fragmentation capabilities in smaller clinics and PCI centres, including those in rural areas.

Limitations

The main limitation of the present study is the lack of a randomised comparison to other devices. Furthermore, the outcomes are restricted to the patient population presented herein. Calcification severity was site assessed, and 39.7% of patients had moderate calcification. Importantly, intravascular imaging indicated substantial complexity even within these moderate cases, such as eccentricity and calcified nodules, and optimal stent expansion (>90%) was consistently achieved across MLA, MC, and MSA sites. Angiographic parameters after predilatation were not assessed. While the study was not designed to assess performance in specific risk groups, the

results (100% angiographic lesion success) were encouraging and support device effectiveness.

Conclusions

In conclusion, PINNACLE-I demonstrates the safety and effectiveness of the novel HC-IVL device to facilitate and optimise coronary stent implantation through an efficient IVL workflow. Optimised stent parameters (% expansion, MSA) were obtained following HC-IVL, regardless of calcium severity, distribution, or the presence of calcified nodules. Further studies, including larger and more diverse patient populations with longer-term follow-up, appear warranted.

Authors' affiliations

1. Interventional Cardiology, ZAS Cardiovascular Center Middelheim, Antwerp, Belgium; 2. Department of Cardiology, Ziekenhuis Oost-Limburg, Campus Sint Jan, Genk, Belgium; 3. Department of Cardiology, Maasstad Ziekenhuis, Rotterdam, the Netherlands; 4. Heart Center, Catharina Ziekenhuis, Eindhoven, the Netherlands; 5. Hasselt Heart Center, Jessa Ziekenhuis, Hasselt, Belgium; 6. Department of Cardiology, Meander Medical Center, Amersfoort, the Netherlands; 7. CERC (Cardiovascular European Research Center), Massy, France; 8. Department of Cardiology, ICPS Ramsay, Massy, France; 9. Department of Cardiovascular Medicine, Universitaire Ziekenhuizen Leuven, Leuven, Belgium

Acknowledgements

We thank Beatrix Doerr, medical writer, for her help in preparing the manuscript, which was funded by Elixir Medical.

Funding

The study was funded by Elixir Medical.

Conflict of interest statement

S. Verheye reports consulting fees and payment/honoraria from Elixir Medical and Shockwave Medical. V. Paradies reports grants from Abbott paid to her institution; honoraria from Elixir Medical, Abbott, Boston Scientific, Novo Nordisk, and SMT; support for attending meetings/travels from Novartis; is an EAPCI Congress Committee Chair; and is an ESC CPC member. P.A.L. Tonino reports research grants from Opsens and Biosensors; lecture fees from Medtronic; a patent issued for SAVI index; participates in the DSMB of the Urgent 2.0, Elite and Elite Venous stent studies; and is the Chair of the Dutch Working Group Transcatheter Heart Valve Interventions. D. Cottens reports consulting fees from Elixir Medical; and honoraria from Boston Scientific and Abbott. Z. Mehmedbegovic is an independent core laboratory specialist at CERC. P.C. Smits reports institutional research grants from Abbott, SMT, MicroPort, and Daiichi Sankyo; consulting fees from Abbott, AstraZeneca, Terumo, and MicroPort; payments/honoraria from Abiomed, Terumo, and MicroPort; and participates in the DSMB of the Protector, Legacy, and ASET Japan trials, in the global advisory board of Abbott, and the European advisory board of Terumo (the latter paid to the institution); and is a minor shareholder of CERC. M.-C. Morice is a shareholder of Electroducer; and a shareholder and CEO of CERC. J. Bennett reports consulting fees from Elixir Medical, Biotronik, and Boston Scientific; honoraria/speaker fees from Elixir Medical, Biotronik, and Medtronic; an institutional research grant from Shockwave Medical; and participates on the advisory board of Elixir Medical. The other authors have no conflicts of interest to declare.

References

1. Généreux P, Madhavan MV, Mintz GS, Maehara A, Palmerini T, Lasalle L, Xu K, McAndrew T, Kirtane A, Lansky AJ, Brener SJ, Mehran R, Stone GW. Ischemic outcomes after coronary intervention of calcified vessels in acute coronary syndromes. Pooled analysis from the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) and ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) TRIALS. *J Am Coll Cardiol.* 2014;63:1845-54.

2. Cialdella P, Sergi SC, Zimbardo G, Donahue M, Talarico GP, Lombardi d'Aquino UM, Di Fusco P, Calò L. Calcified coronary lesions. *Eur Heart J Suppl.* 2023;25:C68-73.

3. Räber L, Mintz GS, Koskinas KC, Johnson TW, Holm NR, Onuma Y, Radu MD, Joner M, Yu B, Jia H, Meneveau N, de la Torre Hernandez JM, Escaned J, Hill J, Prati F, Colombo A, di Mario C, Regar E, Capodanno D, Wijns W, Byrne RA, Guagliumi G; ESC Scientific Document Group. Clinical use of intracoronary imaging. Part 1: guidance and optimization of coronary interventions. An expert consensus document of the European Association of Percutaneous Cardiovascular Interventions. *Eur Heart J.* 2018;39:3281-300.

4. Barbato E, Gallinoro E, Abdel-Wahab M, Andreini D, Carrié D, Di Mario C, Dudek D, Escaned J, Fajadet J, Guagliumi G, Hill J, McEntegart M, Mashayekhi K, Mezilis N, Onuma Y, Reczuch K, Shlofmitz R, Stefanini G, Tarantini G, Toth GG, Vaquerizo B, Wijns W, Ribichini FL. Management strategies for heavily calcified coronary stenoses: an EAPCI clinical consensus statement in collaboration with the EURO4C-PCR group. *Eur Heart J.* 2023;44:4340-56.

5. Troncone E, Mossa M, De Vico P, Monteleone G, Del Vecchio Blanco G. Difficult Biliary Stones: A Comprehensive Review of New and Old Lithotripsy Techniques. *Medicina (Kaunas).* 2022;58:120.

6. Blachutzik F, Honton B, Escaned J, Hill JM, Werner N, Banning AP, Lansky AJ, Schlattner S, De Bruyne B, Di Mario C, Dörr O, Hamm C, Nef HM. Safety and effectiveness of coronary intravascular lithotripsy in eccentric calcified coronary lesions: a patient-level pooled analysis from the Disrupt CAD I and CAD II Studies. *Clin Res Cardiol.* 2021;110:228-36.

7. Wang Q, Ma W, Zhang D, Zhang W, An J, Dou K, Li P, Jiang J, He Y, Tong Q, Zhang X, Pang W, Qiu C, Yang Q, Hu X, Zhong L, Cheng X, Peng X, Kan J, Zhang J, Zhang B, Li Y. Effectiveness and Safety of a Novel Intravascular Lithotripsy System for Severe Coronary Calcification: The CALCI-CRACK Trial. *Can J Cardiol.* 2024;40:1657-67.

8. Brinton TJ, Ali ZA, Hill JM, Meredith IT, Maehara A, Illindala U, Lansky A, Götberg M, Van Mieghem NM, Whitbourn R, Fajadet J, Di Mario C. Feasibility of Shockwave Coronary Intravascular Lithotripsy for the Treatment of Calcified Coronary Stenoses. *Circulation.* 2019;139:834-6.

9. Johnson KL. One hundred years of Hertz contact. *Proceedings of the Institution of Mechanical Engineers.* 1982;196:363-78.

10. Garcia-Garcia HM, McFadden EP, Farb A, Mehran R, Stone GW, Spertus J, Onuma Y, Morel MA, van Es GA, Zuckerman B, Fearon WF, Taggart D, Kappetein AP, Krucoff MW, Vranckx P, Windecker S, Cutlip D, Serruys PW; Academic Research Consortium. Standardized End Point Definitions for Coronary Intervention Trials: The Academic Research Consortium-2 Consensus Document. *Eur Heart J.* 2018;39:2192-207.

11. Thygesen K, Alpert JS, Jaffe AS, Simoons ML, Chaitman BR, White HD; Joint ESC/ACCF/AHA/WHF Task Force for Universal Definition of Myocardial Infarction; Authors/Task Force Members Chairpersons; Thygesen K, Alpert JS, White HD; Biomarker Subcommittee; Jaffe AS, Katus HA, Apple FS, Lindahl B, Morrow DA; ECG Subcommittee; Chaitman BR, Clemmensen PM, Johanson P, Hod H; Imaging Subcommittee; Underwood R, Bax JJ, Bonow JJ, Pinto F, Gibbons RJ; Classification Subcommittee; Fox KA, Atar D, Newby LK, Galvani M, Hamm CW; Intervention Subcommittee; Uretsky BF, Steg PG, Wijns W,

Bassand JP, Menasche P, Ravkilde J; Trials & Registries Subcommittee; Ohman EM, Antman EM, Wallentin LC, Armstrong PW, Simoons ML; Trials & Registries Subcommittee; Januzzi JL, Nieminen MS, Gheorghiade M, Filippatos G; Trials & Registries Subcommittee; Luepker RV, Fortmann SP, Rosamond WD, Levy D, Wood D; Trials & Registries Subcommittee; Smith SC, Hu D, Lopez-Sendon JL, Robertson RM, Weaver D, Tendera M, Bove AA, Parkhomenko AN, Vasilieva EJ, Mendis S; ESC Committee for Practice Guidelines (CPG); Bax JJ, Baumgartner H, Ceconi C, Dean V, Deaton C, Fagard R, Funck-Brentano C, Hasdai D, Hoes A, Kirchhof P, Knuuti J, Kolh P, McDonagh T, Moulin C, Popescu BA, Reiner Z, Sechtem U, Sirnes PA, Tendera M, Torbicki A, Vahanian A, Windecker S; Document Reviewers; Morais J, Aguiar C, Almahmeed W, Arnar DO, Barili F, Bloch KD, Bolger AF, Botker HE, Bozkurt B, Bugiardini R, Cannon C, de Lemos J, Eberli FR, Escobar E, Hlatky M, James S, Kern KB, Moliterno DJ, Mueller C, Neskovic AN, Pieske BM, Schulman SP, Storey RF, Taubert KA, Vranckx P, Wagner DR. Third universal definition of myocardial infarction. *J Am Coll Cardiol.* 2012;60:1581-98.

12. Ali ZA, Kereiakes DJ, Hill JM, Saito S, Di Mario C, Honton B, Gonzalo N, Riley RF, Maehara A, Matsumura M, Shin D, Stone GW, Shlofmitz RA. Impact of Calcium Eccentricity on the Safety and Effectiveness of Coronary Intravascular Lithotripsy: Pooled Analysis From the Disrupt CAD Studies. *Circ Cardiovasc Interv.* 2023;16:e012898.

13. Suzuki Y, Uehara M, Ando H, Suzuki A, Murata A, Matsuda H, Tokuda T, Amano T. Clinical outcomes of percutaneous coronary intervention for severely calcified lesions: comparison between the morphologies of severely calcified coronary lesions. *Heart Vessels*. 2025;40:275-84.

14. Mhanna M, Beran A, Nazir S, Sajdeya O, Srour O, Elzanaty A, Eltahawy EA. Efficacy and Safety of Intravascular Lithotripsy in Calcified Coronary Lesions: A Systematic Review and Meta-Analysis. *Cardiovasc Revasc Med*. 2022;36:73-82.

15. Redfors B, Sharma SK, Saito S, Kini AS, Lee AC, Moses JW, Ali ZA, Feldman RL, Bhatheja R, Stone GW. Novel Micro Crown Orbital Atherectomy for Severe Lesion Calcification: Coronary Orbital Atherectomy System Study (COAST). *Circ Cardiovasc Interv.* 2020;13:e008993.

16. Kereiakes DJ, Di Mario C, Riley RF, Fajadet J, Shlofmitz RA, Saito S, Ali ZA, Klein AJ, Price MJ, Hill JM, Stone GW. Intravascular Lithotripsy for Treatment of Calcified Coronary Lesions: Patient-Level Pooled Analysis of the Disrupt CAD Studies. *JACC Cardiovasc Interv.* 2021;14:1337-48.

17. Blachutzik F, Meier S, Blachutzik M, Schlattner S, Gori T, Ullrich-Daub H, Gaede L, Achenbach S, Möllmann H, Chitic B, Aksoy A, Nickenig G, Weferling M, Dörr O, Boeder N, Bayer M, Hamm C, Nef H; ROTA.shock Investigators. Comparison of interventional treatment options for coronary calcified nodules: A subanalysis of the ROTA.shock trial. *Cardiovasc Revasc Med*. 2024;68:37-42.

18. Rodriguez-Leor O, Cid-Alvarez AB, Lopez-Benito M, Gonzalo N, Vilalta V, Diarte de Miguel JA, López LF, Jurado-Roman A, Diego A, Oteo JF, Cuellas C, Trillo R, Travieso A, Alfonso F, Carrillo X, Vegas-Valle JM, Cortes-Villar C, Pascual I, Muñoz Camacho JF, Flores X, Vera-Vera S, Moreu J, Barreira de Sousa G, Martí D, Jimenez-Mazuecos J, Fuertes M, Ocaranza R, de la Torre Hernandez JM, Lozano F, Solana Martinez SG, Gómez-Lara J, Perez de Prado A; REPLICA-EPIC18 Investigators. A Prospective, Multicenter, Real-World Registry of Coronary Lithotripsy in Calcified Coronary Arteries: The REPLICA-EPIC18 Study. *JACC Cardiovasc Interv.* 2024;17:756-67.

19. Sagris M, Ktenopoulos N, Dimitriadis K, Papanikolaou A, Tzoumas A, Terentes-Printzios D, Synetos A, Soulaidopoulos S, Lichtenberg M, Korosoglou G, Honton B, Tousoulis D, Tsioufis C, Toutouzas K. Efficacy of intravascular lithotripsy (IVL) in coronary stenosis with severe calcification: A multicenter systematic review and meta-analysis. *Catheter Cardiovasc Interv.* 2024;103:710-21.

20. Wilson SJ, Spratt JC, Hill J, Spence MS, Cosgrove C, Jones J, Strange JW, Halperin H, Walsh SJ, Hanratty CG. Incidence of "shocktopics" and asynchronous cardiac pacing in patients undergoing coronary intravascular lithotripsy. *EuroIntervention.* 2020;15:1429-35.

21. McGarvey M, Kumar S, Violaris A, Elghamaz A, Salukhe TV, Yeh JS. Ventricular fibrillation induced by a lithotripsy-pulse on T during coronary intravascular shockwave lithotripsy. *Eur Heart J Case Rep*. 2020;4:1-3.

22. Jakobsen L, Christiansen EH, Thim T. A case report of ventricular fibrillation following Shockwave intravascular lithotripsy during percutaneous coronary intervention. *BMC Cardiovasc Disord*. 2024;24:219.

23. Blachutzik F, Meier S, Weissner M, Schlattner S, Gori T, Ullrich H, Gaede L, Achenbach S, Möllmann H, Chitic B, Aksoy A, Nickenig G, Weferling M, Pons-Kühnemann J, Dörr O, Boeder N, Bayer M, Elsässer A, Hamm CW, Nef H; ROTA.shock Investigators. Coronary intravascular lithotripsy and rotational atherectomy for severely calcified stenosis: Results from the ROTA.shock trial. *Catheter Cardiovasc Interv.* 2023;102:823-33.

24. McInerney A, Travieso A, Jerónimo Baza A, Alfonso F, Del Val D, Cerrato E, Garcia de Lara J, Pinar E, Perez de Prado A, Jimenez Quevedo P, Tirado-Conte G, Nombela-Franco L, Brugaletta S, Cepas-Guillén P, Sabaté M, Cubero Gallego H, Vaquerizo B, Jurado A, Varbella F, Jimenez M, Garcia Escobar A, de la Torre JM, Amat Santos I, Jimenez Diaz VA, Escaned J, Gonzalo N. Impact of coronary calcium morphology on intravascular lithotripsy. *EuroIntervention.* 2024;20:e656-68.

Supplementary data

Supplementary Table 1. Inclusion and exclusion criteria.

Supplementary Table 2. Optical coherence tomography characteristics following Hertz contact intravascular lithotripsy (core laboratory).

Supplementary Table 3. Optical coherence tomography characteristics at the sites of minimum lumen area, maximum calcium, and minimum stent area (core laboratory).

Moving image 1. LithiX device – mechanism of action.

The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-25-00618

Supplementary data

Supplementary Table 1. Inclusion and exclusion criteria.

Inclusion criteria	• Subject is ≥ 18 years of age. • Subject or a legally authorized representative must provide written informed consent prior to any study related procedures. • Subject must agree not to participate in any other clinical study during the course of the study that would interfere with the endpoints of this study. • Subjects must have a single or double vessel coronary artery disease (CAD) and clinical evidence of ischemic heart disease, such as CAD, silent ischemia, stable / unstable angina, and non-ST elevation myocardial infarction if biomarkers are stable or falling at time of inclusion. • Subject must have de novo lesion(s) in native coronary arteries suitable for percutaneous coronary intervention. • Up to 2 de novo coronary artery lesions in separate epicardial vessels, which are moderately to severely calcified, meeting all of the following criteria visually assessed by angiography: o ≥70% diameter stenosis by visual estimation o reference vessel diameters of 2.25 mm - 3.5 mm o lesion length of ≤ 34 mm o TIMI flow ≥ 1 at baseline • Any non-target lesion must be located in different coronary artery from a target lesion. Treatment of non-target lesion, if any, must be completed prior to treatment of target lesion and must be deemed a clinical angiographic success as visually assessed by the physician.
Exclusion criteria	• Subject with a known hypersensitivity or contraindication to aspirin, heparin, bivalirudin, anti-platelet medications, or sensitivity to contrast media which cannot be adequately pre-medicated. • Subject with known diagnosis of ST-elevation myocardial infarction at index presentation or within 7 days of study screening. • Patient refusing or not a candidate for emergency coronary artery bypass grafting surgery. • Subject with known pregnancy or is nursing. Women of child-bearing potential should have a documented negative pregnancy test within 7 days before index procedure. • Planned use of atherectomy, laser, lithoplasty, thrombectomy, scoring or cutting balloon, or any investigational device other than LithiX in the target lesion during the index procedure. • Patients on renal dialysis or with known eGFR < 30 ml/min. • New York Heart Association class III or IV heart failure. • Patient has active systemic infection.

	• Cerebrovascular accident or transient ischemic attack within the past 6 months. • Active peptic ulcer or active gastrointestinal bleeding within the past 6 months. • Subject has a known left ventricular ejection fraction (LVEF) <30% (LVEF may be obtained at the time of the index procedure if the value is unknown, if necessary). • Subject is a member of a vulnerable population as defined Good Clinical Practice E6, including individuals with mental disability, persons in nursing homes, children, impoverished persons, persons in emergency situations, homeless persons, nomads, refugees, and those incapable of giving informed consent. Vulnerable populations also may include members of a group with a hierarchical structure such as university students, subordinate hospital and laboratory personnel, employees of the Sponsor, members of the armed forces, and persons kept in detention. • More than two target lesions or more than 1 target and 1 non-target lesion requiring treatment. • Extreme angulation (90º or greater) proximal to or within the target lesion. • Previous percutaneous intervention of lesions in a target vessel (including side branches) conducted within 6 months before the study procedure, or any prior lesion treated within 10 mm (proximal or distal) from the current target lesion. • Previous percutaneous intervention of lesions in a non-target vessel (including side branches) conducted within 30 days before the study procedure. • Angiographic evidence of a target lesion dissection prior to LithiX Hertz Contact Lithotripsy. • Visible thrombus (by angiography) at target lesion site. • Unprotected left main coronary artery disease (Greater than 50% diameter stenosis). • Target lesion is located in a native vessel distal to anastomosis with a saphenous vein graft or LIMA/RIMA bypass. • Evidence of aneurysm in target vessel. • Coronary artery spasm of the target vessel in the absence of a significant stenosis. • Target lesion involves a bifurcation requiring treatment with more than one stent or pre-dilatation of a side branch >2.0 mm in diameter

Supplementary Table 2. Optical coherence tomography characteristics after Hertz contact intravascular lithotripsy (core laboratory).

	Eccentric Calcium L=13	**Concentric Calcium L=19**
Pre-procedure		
Minimum lumen area, mm ²	2.45 ± 1.00[a]	2.12 ± 0.94[a]
Area stenosis, %	67. 8 ± 11.7[a]	75.8 ± 7.4[a]
Calcium length, mm	23.15 ± 6.93	24.45 ± 6.56
Maximum continuous calcium arc, °	184.4 ± 56.4	317.5 ± 22.5
Maximum calcium thickness, mm	1.32 ± 0.36	1.24 ± 0.21
Presence of calcified nodule	4 (33.3%)[a]	5 (29.4%)[b]
Post LithiX HC-IVL		
Calcium fracture, any	11 (84.6%)	18 (94.7%)
1 fracture	3 (23.1%)	2 (10.5%)
2 fractures	4 (30.8%)	8 (42.1%)
3 fractures	4 (30.8%)	8 (42.1%)
Fracture depth, mm	0.76 ± 0.28	0.85 ± 0.36
Fracture width, mm	0.51 ± 0.23	0.75 ± 0.29

Data are displayed as mean ± SD or n (%). Eccentric calcification was defined as maximum continuous calcium arc ≤ 270°, and concentric calcification as maximum continuous calcium arc < 270°. Data were not available for all lesions, [a]Data not available for one lesion, [b]Data not available for two lesions. L=lesions

Supplementary Table 3. Optical coherence tomography characteristics at the sites of minimum lumen area, maximum calcium, and minimum stent area (core laboratory).

	At minimum lumen area site		**At maximum calcium site**		**At minimum stent area site**	
	Eccentric Calcium L=13	**Concentric Calcium L=19**	**Eccentric Calcium L=13**	**Concentric Calcium L=19**	**Eccentric Calcium L=13**	**Concentric Calcium L=19**
Pre-procedure	L=12	L=18	L=12	L=18	L=10	L=18
Calcium angle, °	122.8 ± 50.0	202.4 ± 90.7	133.4 ± 63.1	261.3 ± 79.0	60.3 ± 45.7	162.2 ± 91.5
Maximum calcium thickness, mm	0.85 ± 0.36	0.72 ± 0.24	1.16 ± 0.45	0.97 ± 0.23	0.74 ± 0.60	0.71 ± 0.32
Area stenosis, %	67.8 ± 11.7	75.8 ± 7.4	34.3 ± 26.2	40.8 ± 28.2	49.9 ± 16.5	52.6 ± 25.4
Lumen area, mm²	2.45 ± 1.00	2.12 ± 0.94	5.02 ± 2.79	4.76 ± 2.32	3.60 ± 1.31	3.94 ± 2.01
Final post-stent	L=10	L=19	L=11	L=19	L=11	L=19
Area stenosis, %	12.2 ± 17.3	10.8 ± 12.9	1.5 ± 4.2	4.7 ± 6.2	15.4 ± 15.5	13.5 ± 11.1
Stent area, mm²	7.14 ± 2.16	7.72 ± 2.51	8.6 ± 1.7	8.17 ± 2.58	6.30 ± 2.07	6.73 ± 2.22
Acute area gain, mm²	3.98 ± 1.74	5.09 ± 1.81	3.57 ± 2.05	4.03 ± 2.70	3.14 ± 1.68	3.51 ± 2.04
Stent expansion, %	101.0 ± 19.6	100.8 ± 26.9	97.9 ± 19.3	106.6 ± 28.7	101.38 ± 23.70	94.0 ± 26.7

Data are displayed as mean ± SD or n (%). Eccentric calcification was defined as maximum continuous calcium arc ≤ 270°, and concentric calcification as maximum continuous calcium arc < 270°. Data were not available for all lesions. L=lesions