

RESEARCH LETTER



Laser- and Optics-Based Intravascular Lithotripsy for the Treatment of Calcified Coronary Stenoses: The RESTORE First-In-Human Study

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Coronary intravascular lithotripsy (IVL) has emerged as a safe and effective alternative to restore vessel compliance within calcified stenoses, thereby facilitating stent delivery and expansion.¹ A novel coronary IVL system (SEISMIQ 4CE, Boston Scientific, Marlborough, MA) uses optical fibers to deliver laser energy (light) to tungsten emitters, thereby generating a plasma discharge within a semicompliant balloon. The plasma discharge creates acoustic pressure waves that radiate circumferentially and transmurally as well as a rapidly expanding plasma-induced cavitation bubble. Two stations of 4 emitters/station are positioned 6 mm apart on the inner balloon shaft; emitters are oriented 90° apart, delivering up to 160 pulses/station/catheter. We evaluated the safety and efficacy of this novel system for the treatment of severely calcified coronary lesions in a prospective, single-arm first-in-human feasibility study. Patients presenting with stable, unstable, or silent ischemia undergoing percutaneous coronary intervention were eligible for enrollment. Key angiographic inclusion criteria included a $\geq 70\%$ stenosis, functional evidence of ischemia, or a minimal lumen area $\leq 4.0\text{ mm}^2$ by intravascular imaging; a target reference vessel diameter ≥ 2.5 mm and ≤ 4.0 mm; lesion length ≤ 60 mm; and evidence of severe calcification by angiography or by the presence of ≥ 270 degrees of calcium on intravascular imaging. Atherectomy or the use of cutting/scoring balloons was not permitted. The primary safety end point was freedom from major adverse cardiovascular event (composite of cardiac death, myocardial infarction [MI], or target vessel

revascularization) at 30 days. MI was defined as CK-MB $>3\times$ the upper limit of normal at discharge and according to the fourth Universal Definition of MI beyond discharge. The primary efficacy end point was procedural success, defined as stent delivery with residual stenosis $<50\%$ and without an in-hospital major adverse cardiovascular event. An independent clinical event committee adjudicated all events. The protocol was approved by the Ethical Committee at each participating center. All patients signed written informed consent. The data that support the findings of this study may be available from the corresponding author on reasonable request.

A total of 41 patients were enrolled. Clinical, angiographic, procedural characteristics and outcomes are shown in the Table. Mean baseline reference vessel diameter was 2.9 ± 0.3 mm, mean lesion length was 17.1 ± 8.5 mm, and median calcified length was 26.3 mm (interquartile range, 18.4–36.7 mm). Device success was 97.4%, as the target lesion could not be crossed by the IVL catheter in 1 patient. A median of 120 pulses (interquartile range, 120–220) was applied. There were no perforations, abrupt closures, or no-reflow after IVL therapy. Five dissections were noted after IVL therapy and before stent implantation: type B in 3 (7.3%) and type C in 2 (4.9%). The primary safety end point was 90.2%, driven entirely by periprocedural MI.

Quantitative coronary angiography was evaluable in 38 patients. Final in-segment diameter stenosis was $13.2\pm 4\%$, and final in-stent diameter stenosis was $10.6\pm 4.5\%$. All cases had final in-segment and in-stent

Key Words: atherectomy ■ coronary angiography ■ ischemia ■ stent

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Table. Characteristics and Outcomes

Characteristics	
Clinical	N=41
Age, y	71.7±7.7
Male sex	27 (65.9%)
Current smoker	6 (14.6%)
Diabetes	12 (29.3%)
Hypertension	36 (87.8%)
Hypercholesterolemia	39 (95.1%)
Prior stroke	2 (4.9%)
Prior myocardial infarction	6 (14.6%)
Prior CABG	2 (4.9%)
Prior PCI	12 (29.3%)
Renal insufficiency or failure	1 (2.4%)
Angina classification	
Class 0	2 (4.9%)
Class 1	3 (7.3%)
Class 2	13 (31.7%)
Class 3	20 (48.8%)
Not assessed	3 (7.3%)
Lesion	
Target vessel*	
Left anterior descending	28 (68.3%)
Left circumflex	3 (7.3%)
Right coronary	10 (24.4%)
Reference vessel diameter, mm	2.9±0.3†
Minimum lumen diameter, mm	0.9±0.3†
Diameter stenosis, mm	64.9±11.1†
Lesion length, mm	17.1±8.5†
Calcified length, mm	26.3 (IQR, 18.4–36.7)‡
Procedural details	N=41
Procedure time, mins	70 (59–87)
Fluoroscopy time, mins§	12 (9–19)
Contrast volume, mL	120 (100–170)
IVL catheters used/procedure	
1	21/41 (51.2%)
2	17/41 (41.5%)
3	3/41 (7.3%)
Number of pulses delivered§	120 (120–220)
Predilatation	15/40 (37.5%)
Postdilatation after IVL treatment	6/41 (14.6%)
IVL-induced capture	6/41 (14.6%)
Outcomes	
Performance	N=38
Device crossing success¶	37 (97.4%)
Angiographic success	38 (100.0%)
Procedural success (primary efficacy end point)¶¶	34 (89.5%)
Angiographic (QCA)	N=38
	Preprocedure Postprocedure
Minimum lumen diameter, mm	0.9±0.3 2.6±0.4

(Continued)

Table. Continued

Acute gain, mm		1.6±0.5
Diameter stenosis, %	64.9±11.1	
In-segment		13.2±4.1
In-stent		10.6±4.5
In-segment diameter stenosis <30%		100.0%
In stent diameter stenosis <30%		100.0%
IVUS characteristics and outcomes	N=26	
Lesion length, mm	18.4 (IQR, 9.5–26.6)	
Minimal lesion area, mm ²	2.6±0.7	
% Area stenosis	67.6±9.6	
Calcium angle (degrees)	282.3±61.3	
Final assessment		
Minimal stent area, mm ²	8.0±1.7	
Stent expansion	1.0±0.2	
Acute lumen area gain, mm ²	5.4±1.4	
% Acute lumen area gain	215.2 (IQR, 159.6–286.4)	
Clinical and angiographic outcomes		
Dissections (post-IVL/prestent), type*		
None	36/41 (87.8%)	
B	3/41 (7.3%)	
C	2/41 (4.9%)	
Perforations	0/38 (0.0%)	
Abrupt closure	0/38 (0.0%)	
No reflow	0/38 (0.0%)	
MACE in-hospital	4/41 (9.8%)	
MACE within 30 d	4/41 (9.8%)	
Cardiac death	0/41 (0.0%)	
Stroke	0/41 (0.0%)	
MI	4/41 (9.8%)	
Spontaneous	0/41 (0.0%)	
Peri-procedural	4/41 (9.8%)	
Target vessel revascularization	0/41 (0.0%)	

Data are presented as mean±SD, median (IQR, Q1–Q3), or n (n/N%). Angiographic success is defined as stent delivery with <50% residual stenosis and without serious angiographic complications. CABG indicates coronary artery bypass grafting; IQR, interquartile range; IVL, intravascular lithotripsy; IVUS, intravascular ultrasound; MACE, major adverse cardiovascular events; MI, myocardial infarction; PCI, percutaneous coronary intervention; and QCA, quantitative coronary angiography.

*Site reported; other characteristics assessed by the core laboratory.

†n=38.

‡n=34.

§n=40.

¶Delivery of the IVL catheter across the target lesion and delivery of lithotripsy without serious angiographic complications immediately after IVL.

¶¶Stent delivery with a residual stenosis <50% and without in-hospital MACE.

diameter stenosis of <30%. Procedural success (the primary effectiveness end point) was 89.5% (4 patients with periprocedural MI). Baseline and poststent intravascular ultrasound imaging were available in 26 patients. The maximal calcium angle was 282.3±61.3°. Acute lumen area gain was 5.4±1.4mm² and mean stent expansion was 100±20%. Final mean MSA was 8.0±1.7mm² and

was $>5.0\text{mm}^2$ in 25 (96%) and $>5.5\text{mm}^2$ in 24 patients (92%).

In this first-in-human study, we explored the safety and efficacy of a novel coronary IVL system using similar criteria as currently available IVL technology.^{1–3} We demonstrate that the use of this catheter in severely calcified coronary stenoses is feasible and results in substantial improvement in luminal area, excellent stent expansion, and high rates of procedural success. The characteristics of the target lesions in the current study are similar to those in the Disrupt CAD I feasibility study.² Final residual stenosis was $<30\%$ in 100% of cases compared with 92% in Disrupt CAD I, and freedom from 30-day MACE was 91% compared with 95%.² Our results are also similar to the intravascular ultrasound substudy of the Disrupt CAD III trial.⁴ We observed a baseline maximal calcium angle of $282.3\pm 61.3^\circ$ and a final MSA of $8.0\pm 1.7\text{ mm}^2$, while in that study, the target lesions had a maximal calcium angle of $267\pm 78.3^\circ$ and a final MSA of $6.99\pm 2.14\text{mm}^2$.⁴

This feasibility study was not powered for specific end points. Quantitative coronary angiography and intravascular imaging data were collected and analyzed at baseline and after stent implantation, and therefore the isolated effects of IVL before stenting could not be evaluated.

Laser and fiber-optic-based IVL may have several advantages over electrical, copper-wire-based arc discharge systems. For example, plasma discharge systems are not reliant on electrical spark gaps that erode pulse-by-pulse, which can introduce pulse-to-pulse variability. We observed low rates of myocardial capture, possibly because copper wires, unlike optical fibers, generate electromagnetic noise during arc discharge that may affect the cardiac conduction system. The 8-emitter configuration of the novel IVL catheter produces a uniform energy profile which may increase the likelihood of fracturing both concentric and eccentric calcification. The safety and effectiveness of this technology will be robustly evaluated in the FRACTURE trial (Modification of Coronary Calcium With Laser Based Intravascular Lithotripsy for Coronary Artery Disease; URL: <https://www.clinicaltrials.gov>; Unique identifier: NCT06181240), a

prospective, international multicenter Food and Drug Administration approval trial of this IVL system for the treatment of severely calcified lesions in patients indicated for percutaneous coronary intervention.

ARTICLE INFORMATION

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