Pulse Intravascular Lithotripsy to Open vessels with calcific Walls and Enhance vascular compliance and Remodeling

First-in-human report from the POWER-PAD I study

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Disclosure of Relevant Financial Relationships

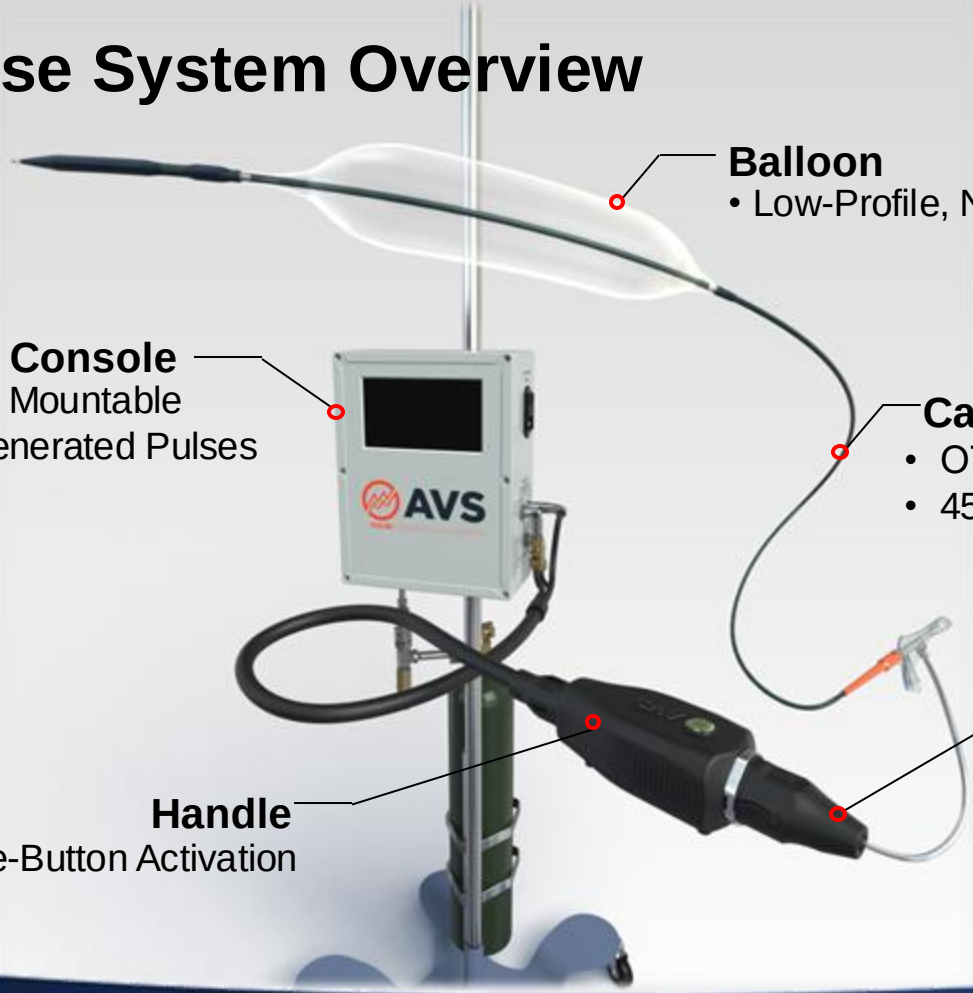
Jon C George, MD

Independent Medical Consultant

Amplitude Vascular Systems, Inc.

Faculty /Author disclosure information can be found on the app

AVS Pulse System Overview



Balloon
- Low-Profile, Non-Compliant, Resilient

Console
- IV-Pole Mountable
- CO_2-Generated Pulses

Catheter
- OTW, 0.014” Guidewire Compatible
- 45 seconds/lesion, 7 lesions/balloon

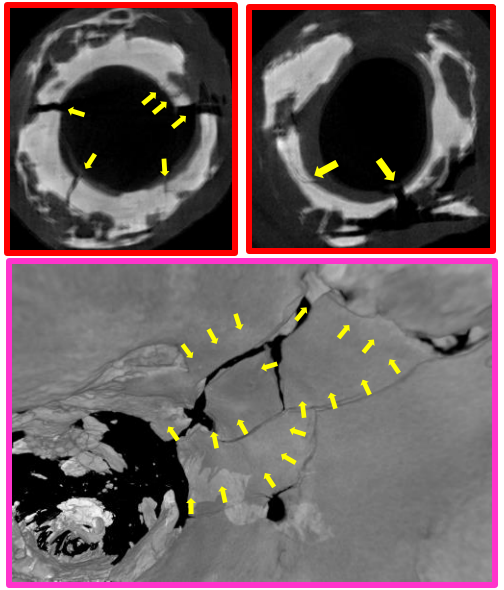
Amplifier
- Quick latch connection
- Intelligent energy transfer
- Smart sensing

Handle
- Single-Button Activation

Pulsatile IVL (PIVL) Fundamentals

Procedure Demo

PIVL results in calcium fracture



[Virmani R, Finn A, et.al., 2023]

Virmani R, Finn A V., Kutyna M, et al. Pulsatile Intravascular Lithotripsy: A Novel Mechanism for Peripheral Artery Calcium Fragmentation and Luminal Expansion. Cardiovasc Revascularization Med. 2023;50:43-53. doi:10.1016/j.carrev.2023.01.003

POWER-PAD I – First-in-Human Summary of PIVL

Study Design: Prospective, single-arm, multicenter, feasibility study. 12-month F/U
Objective: Safety and performance evaluation of AVS Pulse IVL system in *moderate and severely calcified* superficial femoral and popliteal arteries.

Study Endpoints

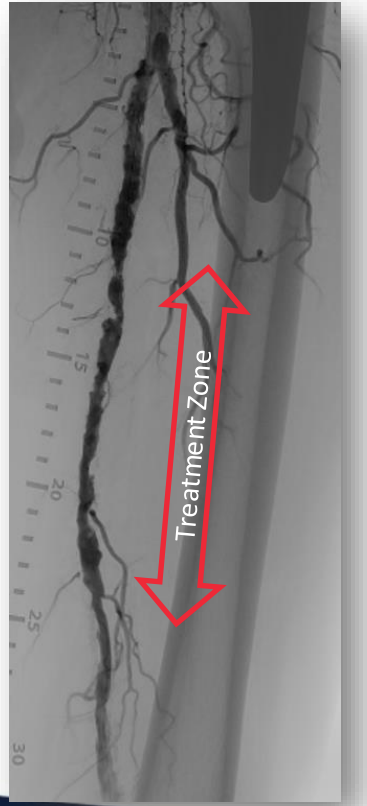
Primary	Performance	Device Success, Technical Success, Procedural Success
	Safety	Major Adverse Events (MAE), consisting of Major Adverse Limb Events (MALE) at **30 days** (unplanned major amputation or major reintervention of target limb.)
Secondary	Performance	• Freedom from clinically driven TLR at 30 days, 6 month and 12 months • <30% residual stenosis (QA) • Improvement in Rutherford Class Score, ABI, EQ-5D, Walking Impairment
	Safety	• Major Adverse Events at 30 days (Major Adverse Limb Events and Procedure-related death at 30 days • Major unplanned amputation of the target limb at 6 and 12 months

POWER-PAD I – Study Sites

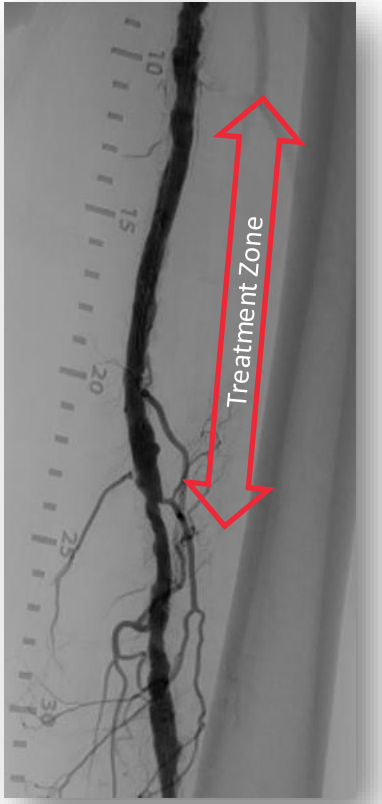
Principal Investigators	 **Jon George** Study PI	 **Nelson Encarnación** Centro Medico Moderno	 **Patrice Mwipatayi** Royal Perth Hospital	 **Fernando Picazo Pineda** Royal Perth Hospital
Location	 Centro Medico Moderno Dominican Republic		 Royal Perth Hospital Australia	
# Enrolled	2		7	

In-Depth Case Review #1

Pre-Treatment



Post-Treatment

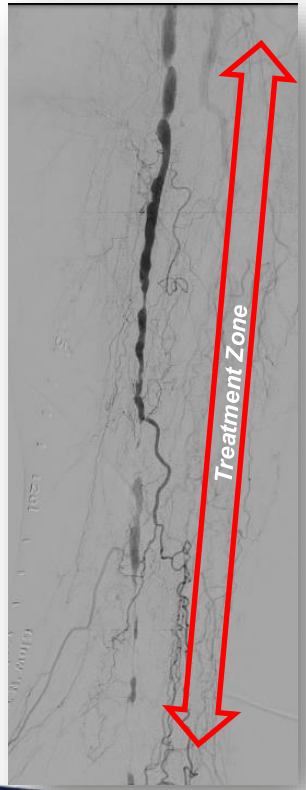


Case Details

- 84 years old, male
- 402 mm Calcium Length
- 78% Pre-Tx Diameter Stenosis → 25% Post-Tx Diameter Stenosis
- ~30 sec/lesion
- 100mm DCB used
- No stents used

In-Depth Case Review #2

Pre-Treatment



Post-Treatment

Case Details

- 94 years old, female
- 312mm Calcium Length
- 100% Pre-Tx Diameter Stenosis → 23% Post-Tx Diameter Stenosis
- ~45 sec/lesion
- 2x150mm DCBs used
- No debris in Distal Embolic Protection
- No stents used

Results: Primary Endpoints & Functional Outcomes

Primary Performance:	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9
Device Success: • Successful delivery • Balloon inflation, deflation and retrieval	✓	✓	✓	✓	✓	✓	✓	✓	✓
Technical Success: • Successful vascular access • Completion with or without adjunctive therapy • Achievement of ≤50% residual stenosis	✓	✓	✓	✓	✓	✓	✓	✓	✓
Procedural Success: • Absence of procedural complications	✓	✓	✓	✓	✓	✓	✓	✓	✓

Primary Safety Endpoint:									
Major Adverse Events @ 30 days: • Major amputation • Major reintervention	No MAE	No MAE	No MAE	No MAE	No MAE	No MAE	No MAE	No MAE	No MAE

A Real-World, First-in-Human Study By the Numbers

9
Patients with calcified femoral-popliteal lesions

20
Lesions treated with 89% defined as heavily calcified by PARC

253mm
Average calcified lesion length

22% ± 6%
Average post-procedural stenosis vs. 82% ± 11% at baseline

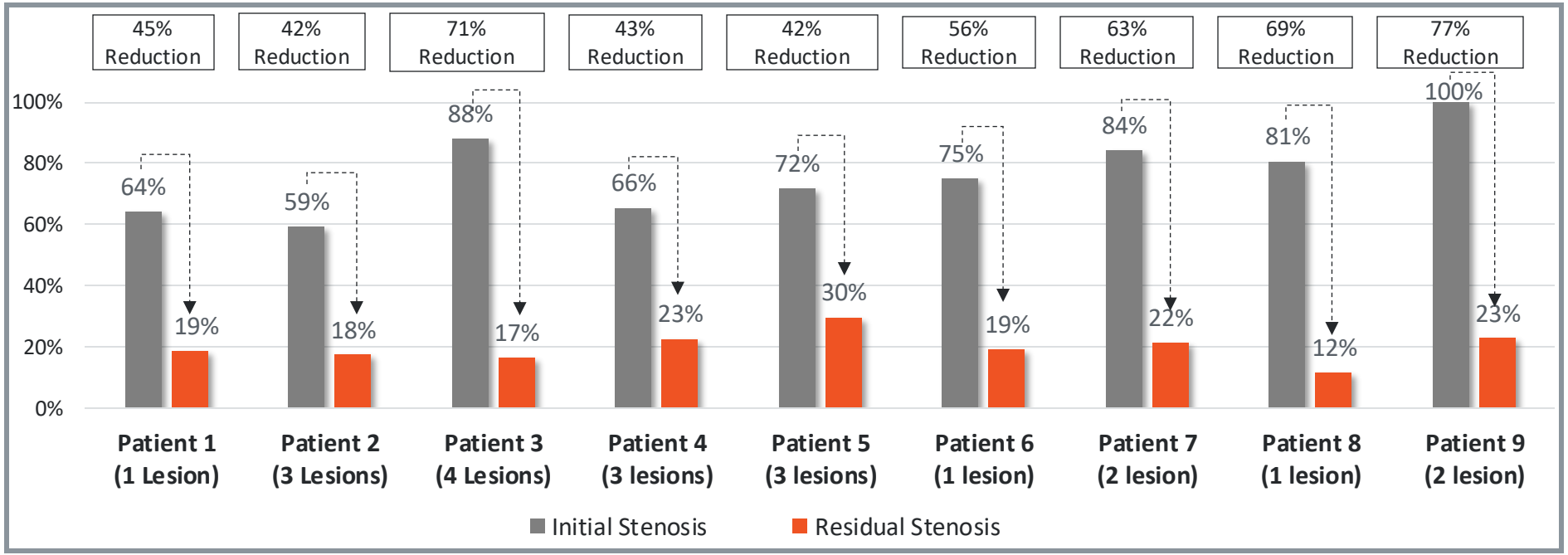
0
≥ Grade D dissections

3.0mm ± 0.8mm
Acute luminal gain

1.0 ± 0.2
Mean ABI at 30 days vs. 0.6 ± 0.1 at baseline

0.55 ± 1.3
Mean Rutherford Score at 30 days vs. 3.2 ± 0.6 at baseline

Snapshot of Per Patient Stenosis Pre- vs. Post-Procedure



*Results adjudicated by Yale Angiographic Core Lab

POWER-PAD I Study Conclusion

The conclusions of the first-in-human study are:

1) The AVS Pulse IVL System met its primary and secondary performance and safety endpoints;

2) The technology was successful in treating heavily calcified femoropopliteal disease;

3) Acute results from normally challenging cases were impressive;

4) Pivotal trial is warranted for powered outcomes.