Vessel preparation
Does IVL eliminate the need for other devices

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• Abbott, Medtronic
• Consulting (non-compensated)	• Medtronic, Boston Scientific, Abbott, Phillips
• Major Stock Shareholder/Equity	• Primacea, TissueGen, Orchestra, R3 Vascular, Transit Medical, Syntervention, Cagent
• Royalty Income	• None
• Ownership/Founder	• Innovation Vascular Partners, LLC
• Intellectual Property Rights	• None
• Other Financial Benefit	• None

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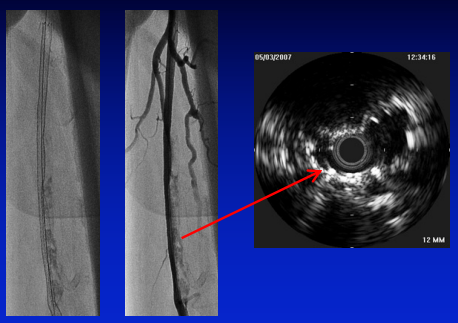
Why discuss this?



Insufficient radial strength in calcified lesions

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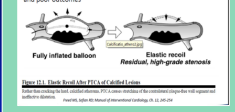
Clinical Limitations & Unmet Needs

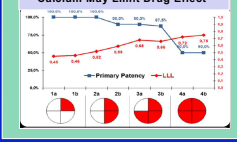
Calcium as a Barrier

Calcium Limits Vessel Expansion[1]

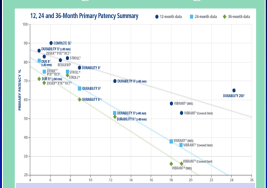
Significant difference in vessel compliance leads to overstretch in non-diseased tissue causing dissections, recoil, excessive injury, and poor outcomes



Calcium May Limit Drug Effect[2]



Longer Lesion Length



Increased lesion length is an independent predictor of decreased patency[5].

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REALITY
Lesion & Procedure Metrics

Lesion Metrics:	
Lesion Length (mm)	**179.36 ± 81.40**
Lesion Length ≥ 150 mm	**55.6%**
MLD (mm) at Baseline	**0.57 ± 0.61**
Chronic total occlusions at Baseline	**39.0%**
Chronic total occlusion length (mm)	**226.0 ± 86.0**
Procedure Metrics:	
Diameter Stenosis (%) at Baseline	**88.8 ± 11.7**
Diameter Stenosis (%) Post-DA Treatment	**40.4 ± 14.9**
Diameter Stenosis (%) Post DA+DCB Treatment	**28.1 ± 12.0**
Procedural Success*	**57.6%**

**Procedural Success defined as ≤30% post DA+DCB as assessed by the angiographic core lab*

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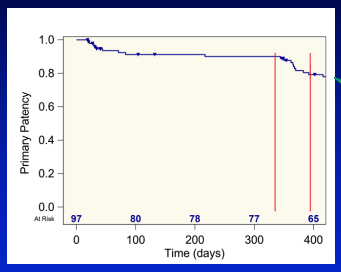
REALITY
Primary Effectiveness Endpoint: 12-Month Primary Patency†



† PSVR ≤2.4 by duplex ultrasound in the absence of CD-TLR assessed by the DUS core lab

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REALITY

Procedure Related Complications

Provisional stents implanted	9/102 (8.8%)
Perforations	3/98 (3.1%)
Perforations requiring stenting	3/3 (100%)
Dissections ≥ Grade C	14/98 (14.3%)
Dissections requiring stenting	5/14 (35.7%)
Distal embolization	11/86 (12.8%)
Distal embolization requiring aspiration only	5/11 (45.5%)
Distal embolization requiring stenting	1/11 (9.1%)

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JET registry

	Overall (N=258 lesions)	Non-Stent[a] (N=165 lesions)	Stent[a] (N=93 lesions)
Lesion location			
Superficial Femoral	75.6%	72.1%	81.7%
Common Femoral	10.9%	15.2%	3.2%
Popliteal	13.6%	12.7%	15.1%
Lesion length, mean ± SD	16.4 ± 13.6 cm	14.1 ± 12.6 cm	20.5 ± 14.4 cm
Calcium Grade[b]			
0	10.0%	10.2%	9.5%
1	16.2%	14.6%	19.0%
2	24.1%	17.8%	35.7%
3	28.2%	31.8%	21.4%
4	19.5%	21.0%	16.7%
Lesion RVD, mean ± SD	5.7 ± 0.9 mm	5.5 ± 0.9 mm	5.9 ± 0.9 mm
Occlusion (100% stenosis)	36.1%	28.7%	50.0%
Pre-treatment stenosis estimate, mean ± SD	91.1% ± 9.8%	90.2% ± 10.0%	92.7% ± 9.4%

[a]Post hoc analysis of patients who received and did not receive adjunctive stents.
[b]Calcium grading: 0= no visible calcification; 1= one individual segment of vessel calcification representing <25% of the length of the entire segment; 2= aggregate calcification representing <50% of the segment length; 3= aggregate calcification representing >50% of the segment length; 4= dense circumferential calcification along the segment length.

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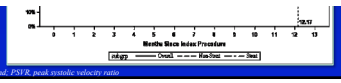
JET registry

- 22.8% overall restenosis rate at 12 months

Post-treatment stenosis estimate, mean ± SD	Overall (N=258 lesions)	Non-Stent (N=165 lesions)	Stent (N=93 lesions)
Post-Jetstream	44.4% ± 20.0%	38.5% ± 16.2%	54.8% ± 22.0%
Post Adjunctive Treatment	9.8% ± 11.4%	11.6% ± 11.7%	6.6% ± 10.2%

Three patients (1.4%) had a device-related distal embolization requiring a separate intervention (Table 3). One of these events occurred in a patient who had protection, thus the distal embolic event rate among patients without embolic protection was 1.1% (2/187). All three distal embolizations requiring a separate intervention occurred during the index procedure, involved athero-fibrinomatous debris, and were resolved with additional aspiration.



DUS, duplex ultrasound; PSVR, peak systolic velocity ratio

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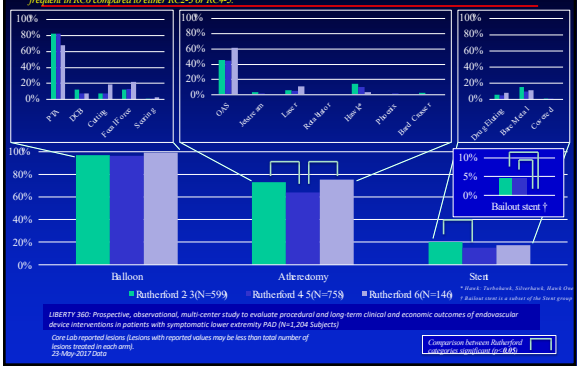
LIBERTY Device Usage by Lesion

Balloon and/or atherectomy were preferred devices with orbital atherectomy (OAS) the most frequently used atherectomy device. RC6 subjects saw significantly higher use of focal, force/cutting balloons, OAS, and laser atherectomy. Bailout stenting was significantly less frequent in RC6 compared to either RC2-3 or RC4-5.



LIBERTY 360: Prospective, observational, multi-center study to evaluate procedural and long-term clinical and economic outcomes of endovascular device interventions in patients with symptomatic lower extremity PAD (N=1,204 Subjects)

Core Lab reported lesions (Lesions with reported values may be less than total number of lesions treated in each arm).
25-May-2017 Data

Comparison between Rutherford categories significant (p<0.05).

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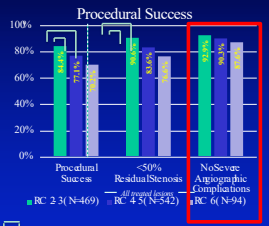
Procedural Success Endpoint

In RC6 group, <50% residual stenosis in 76.6% of the subjects, and no angiographic complications in 87.6% of subjects.



Comparison between Rutherford categories significant (p<0.05)

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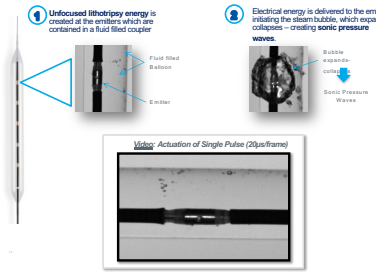
How Shockwave Creates Localized Lithotripsy

High Speed Sonic Pressure Wave Created Safely Inside Integrated Balloon



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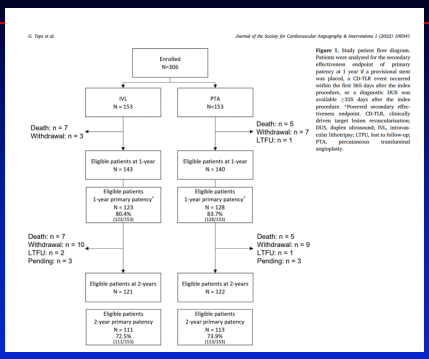
PAD III RCT



Tepe G, et al JSCAI 2022

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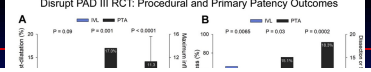
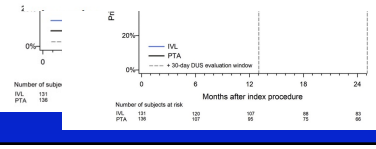
Disrupt PAD III RCT: Procedural and Primary Patency Outcomes



Secondary outcomes

The MAE rate at 1 year was similar in both groups (IVL: 0.0% vs PTA: 1.4%, $P = .15$). The 2 clinical events committee-adjudicated MAEs occurred in the PTA group during the index procedure (distal embolization and perforation) with no further events through 1 year. While both groups demonstrated marked clinical improvement in ankle-brachial index, WIQ, EQ-5D, and Rutherford category, there were no differences in the change from baseline to 1 year between the 2 groups (Table 3).



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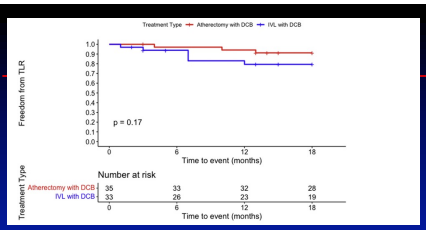

Secondary outcomes	*n* (%)	*n* (%)	Odds ratio (95% CI)
Residual angiographic stenosis <30%	35 (100)	33 (100)	—
Procedural complications	2 (5.7)	1 (3.0)	0.52 (0.01-10.45)
Perforation	0 (0)	0 (0)	
Flow-limiting dissection requiring stent	0 (0)	1 (3.0)	
Bailout stenting	2 (5.7)	0 (0)	
Retained embolic device	0 (0)	0 (0)	

Baig, M et al JSCAI May 2022

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Pt CO

- 67 year old female with history CAD, HTN, HLP and recent onset LLE rest pain
- US confirms CFA and SFA disease
- Heavy calcification noted diffusely
- Shockwave and atherectomy outcomes

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Who wins?

- Long calcified lesions remain difficult for endovascular treatments
  - Vessel compliance through atherectomy or lithoplasty have shown efficacy and safety
  - *Each device has pros and cons*
- Lithoplasty has demonstrated improved vessel compliance in a simple to use PTA format
  - Issues with eccentric non-concentric Ca remains a real question for IVL
  - If not in contact with the artery its benefit may be limited
- Atherectomy device need for DEP are muted with IVL
  - *0-1% compared with up to 8% despite DEP with atherectomy devices*
- Both atherectomy and IVL remain complimentary

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