BOLT MEDICAL

A New More Complex (?) Device for Treating Calcified Arterial Lesions with Lithotripsy (From Bolt Medical): How Does It Work and Advantages

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Disclosures

- PI of FIH ATK Study

Bolt Medical IVL Background

Arterial calcification portends higher rates of procedural challenges and is associated with poor long-term outcomes

Intravascular lithotripsy (IVL) is a safe and effective treatment for moderate to severe calcified peripheral lesions

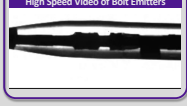
Currently approved IVL technology uses electrical energy, the Bolt IVL System uses laser light through fiber optics within a balloon to create acoustic pressure waves

Bolt IVL^{TM} Lithotripsy Catheter

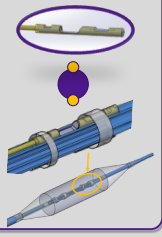
Bolt Mechanism of Action

- Laser energy converted to acoustic pressure waves within the balloon
- 2 Emitters/station – 5 stations for ATK, 4 stations for BTK
- Initial pressure waves fracture calcium and secondary cavitation bubbles expand the fracture

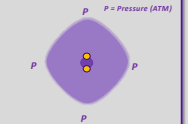
High Speed Video of Bolt Emitters



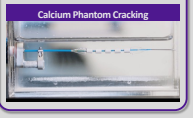
Peripheral Emitter Station



Acoustic Profile

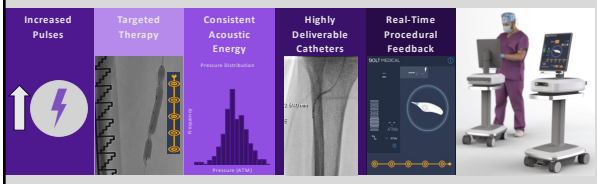


Calcium Phantom Cracking



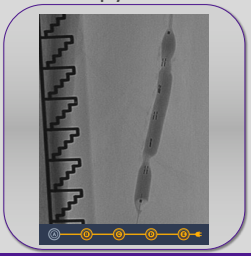
Bolt Medical IVL Design Goals

Advanced laser platform with inherent advantages over electrical based intravascular lithotripsy (IVL)



Increased Pulses & Targeted Therapy

- Increased number of pulses allowing for treatment of longer lesions
- Highly radiopaque emitters provide ability to align emitters with calcium for directional pulses
- On/Off emitter station selectivity allowing for targeted treatment and the ability to save pulses at each emitter station to extend treatment capability of the catheter



RESTORE ATK & BTK Trial Designs

The RESTORE ATK & BTK are prospective, non-randomized, investigational multi-center studies (Austria, Germany, Lithuania, Croatia)

RESTORE ATK

PI: Prof. Marianne Brodmann
95 subjects were enrolled with follow up to 6m

Major Eligibility Criteria:
- Rutherford Classification 2-4
- Target lesion is de novo SFA or popliteal artery ≥70% stenosed by angiography
- Reference vessel diameter 3.5 – 8.0 mm
- Target lesion ≤150 mm in length
- Moderate to severe calcification by angiography

Study Device:
- Diameters: 3.5 – 8.0 mm
- Length: 60 mm

RESTORE BTK

PI: Dr. Michael Lichtenberg
20 subjects were enrolled with follow up to 30-d

Major Eligibility Criteria:
- Rutherford Classification 3-5
- Target lesion is de novo tibial arteries ≥70% stenosed by angiography
- Reference vessel diameter 2.5 – 4.0 mm
- Target lesion ≤150 mm in length
- Moderate to severe calcification by angiography

Study Device:
- Diameters: 2.5 – 4.0 mm
- Length: 40 mm

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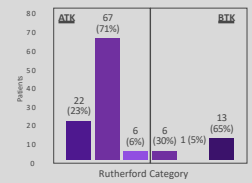
Baseline Clinical Characteristics

Clinical Characteristics	ATK N=95[‡]	BTK N=20[‡]
Age (years)	70 ± 8	73 ± 10
Biological Sex (Female)	31 (33%)	6 (30%)
BMI	27 ± 4	27 ± 4
Coronary Artery Disease	35 (37%)	11 (55%)
Diabetes	41 (43%)	15 (75%)
Hypertension	83 (87%)	20 (100%)
Myocardial Infarction	16 (17%)	3 (15%)
Smoking Status (Past/Current)	69 (73%)	10 (50%)
Renal Insufficiency	9 (10%)	7 (35%)
Stroke	4 (4%)	6 (30%)

[‡]n (%), Mean ± SD

Rutherford Category



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Initial Lesion Characteristics

Lesion Characteristics	ATK N=95	BTK N=20
Treated Vessel	SFA (78.9%) Popliteal (21.1%)	Anterior Tibial (50.0%) Tibioperoneal Trunk (30.0%) Posterior Tibial (10.0%) Peroneal (10.0%)
Reference vessel diameter (mm)	5.5 ± 0.7	2.9 ± 0.4
Mean luminal diameter (mm)[‡]	0.8 ± 0.8	0.8 ± 0.7
Diameter stenosis (%)	93.7 ± 7.2	91.4 ± 8.8
CTO[‡]	32 (33.7%)	6 (30.0%)
Lesion Length (mm)	96.0 ± 37.5	69.2 ± 41.3
Calcified length of lesion (%)	85.5 ± 14.0	76.4 ± 14.1
Severe calcification (Core Lab)	89 (93.7%)	-
Severe calcification (PARC)	87 (91.6%)	16 (80.0%)

[‡]Calculated by Angiographic Core Lab

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Procedure and Final Lesion Characteristics

Procedural Details	ATK N=95	BTK N=18*
Pre-dilatation	25 (26.3%)	4 (22.2%)
Successful IVL Delivery	95 (100.0%)	18 (100.0%)
Post-dilatation	17 (17.9%)	3 (16.7%)
Stent	3 (3.2%)	0 (0%)
Final Lesion Characteristics (Core Lab)		
Mean luminal diameter (mm)	4.0 ± 0.7	2.2 ± 0.5
Diameter stenosis (%)	21.2 ± 8.4	22.8 ± 11.5
Acute gain (mm)	3.2 ± 0.9	1.3 ± 0.6
Dissections - None	76 (80.0%)	18 (100.0%)
A	3 (3.2%)	0 (0%)
B	12 (12.6%)	0 (0%)
C	3 (3.2%)	0 (0%)
D	1 (1.0%)	0 (0%)

*2 subjects did not receive IVL: inability to cross lesion (1) and no therapy attempted (1)

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RESTORE ATK/BTK Safety Outcomes

Primary Safety Endpoint Met

Major Adverse Events	ATK 30 Days N=93	ATK 6 Months N=92	BTK 30 Days N=18
Death	0 (0.0%)	0 (0.0%)	0 (0.0%)
Clinically Driven Target Limb Revascularization	0 (0.0%)	2 (2.2%)	0 (0.0%)
Target Limb Major Amputation	0 (0.0%)	0 (0.0%)	0 (0.0%)

No cases of perforation, distal embolization, abrupt closure, no reflow, or dissections meeting SAE criteria, n=95 (ATK) and n=18 (BTK)

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RESTORE ATK/BTK Efficacy Outcomes

Primary Effectiveness Endpoints Met

ATK Performance	N=95*
Residual Diameter Stenosis <50% Post Treatment	100.0%
Target Lesion Patency (freedom from > 50% restenosis) at 30 Days	98.9%
Target Lesion Patency (freedom from > 50% restenosis) at 6 Months	70.5%

*30 Day Patency 92/93 (98.9%) and 6 Month Patency 62/88 (70.45%)

BTK Performance	N=18
Acute Reduction in % Diameter Stenosis	47.5 ± 29.7%
Residual Diameter Stenosis ≤50% Post Treatment	100.0%

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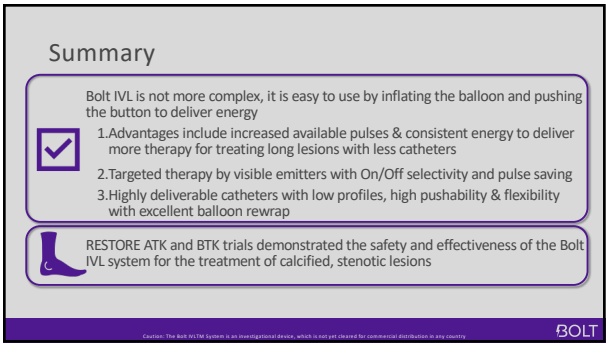
Summary
Bolt IVL is not more complex, it is easy to use by inflating the balloon and pushing the button to deliver energy
1.Advantages include increased available pulses & consistent energy to deliver more therapy for treating long lesions with less catheters
2.Targeted therapy by visible emitters with On/Off selectivity and pulse saving
3.Highly deliverable catheters with low profiles, high pushability & flexibility with excellent balloon rewrap
RESTORE ATK and BTK trials demonstrated the safety and effectiveness of the Bolt IVL system for the treatment of calcified, stenotic lesions
Caution: The Bolt IVLTM System is an investigational device, which is not yet cleared for commercial distribution in any country
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