A Pilot Study to Evaluate Effect of Turbo-Power Laser Settings in Specific Lesion Morphologies – Interim Data

George Adams, MD, MHS, MBA

UNC REX HEALTHCARE

Raleigh, NC – United States

Disclosure

Speaker name: George Adams, MD, MHS, MBA

I have the following potential conflicts of interest to report:

- ☒ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

Laser Atherectomy

What We Know . . .

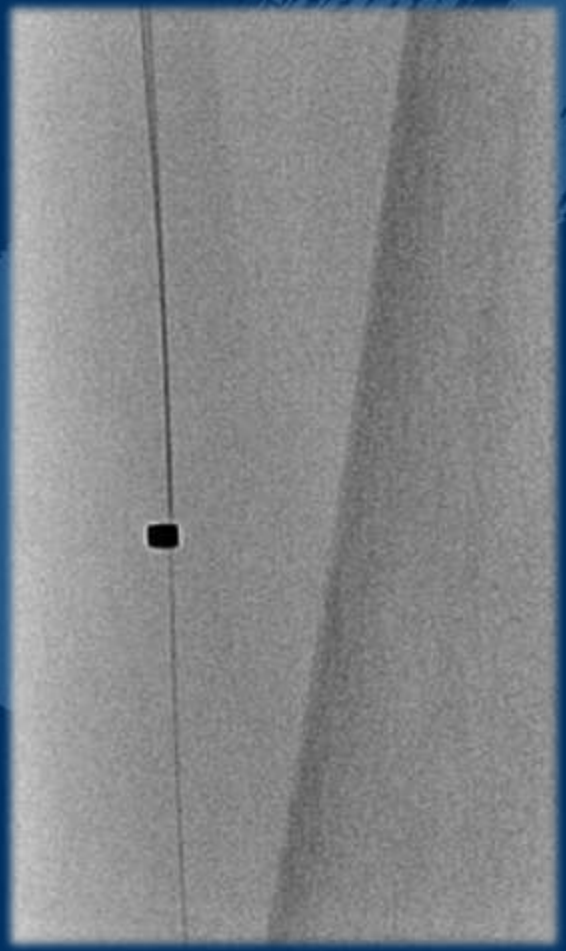
- Laser in SFA lesions
  - Luminal gain device
    - >40% acute reduction in %DS[1]
- Laser in SFA ISR
  - Outcomes can be morphology specific
    - 73.5% freedom from TLR @ 6 months[2]
- Laser + DCB in SFA ISR
  - Vessel preparation tool
    - 87.1% freedom from TLR @ 12 months in Tosaka III ISR[3]

What We Don't . . .

- Optimal Device Settings
  - Fluence/Herz (Power/Rate)
- Optimal Treatment
  - When is enough, enough?
    - % residual stenosis?
    - Acute luminal gain?
- Personalized Algorithm
  - Lesion morphology?
  - Patient co-morbidities?

1 Dave RM, Patlola R, Kollmeyer K, et al. Excimer laser recanalization of femoropopliteal lesions and 1-year patency: results of the CELLO registry. *J Endovasc Ther.* 2009;16(6):665-675.
2 Dippel EJ, et al., EXCITE ISR Investigators. Randomized controlled study of excimer laser atherectomy for treatment of femoropopliteal in-stent restenosis: initial results from the EXCITE ISR trial (EXCImer Laser Randomized Controlled Study for Treatment of FemoropopliTEal In-Stent Restenosis). JACC Cardiovasc Interv. 2015
3 Kokkinidis et al., Laser Atherectomy Combined With Drug-Coated Balloon Angioplasty Is Associated With Improved 1-Year Outcomes for Treatment of Femoropopliteal In-Stent Restenosis. J Endovasc Ther. 2018

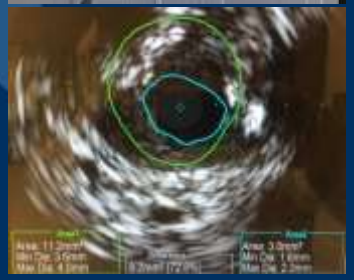
Next-Generation Laser Atherectomy: Turbo Power

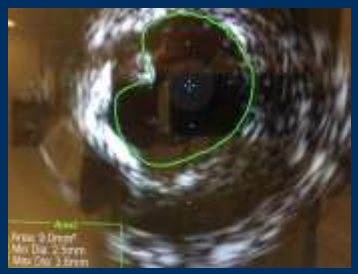


- Modify lesion from the tip with no moving parts
- Laser now directional/rotational
- Rotation reduces “dead space” and may increase ablation capabilities
- More deliverable in calcific lesions

Observation –

Acute Results Change w/ Laser Settings





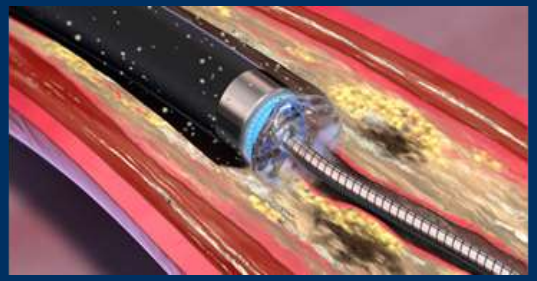
Baseline

Laser
Rate 60
Power 40

Laser
Rate 60
Power 60

Why?

Light absorbed



Acoustic Pressure Wave

Increased Hydraulic Vapor Bubble

Study Rationale and Design

Investigator-initiated trial

Pilot study
(n=40/60)

Including all RCC
Lesion classification

Rationale:
To study the effectiveness of different laser settings in different lesion morphologies in order to personalize treatment

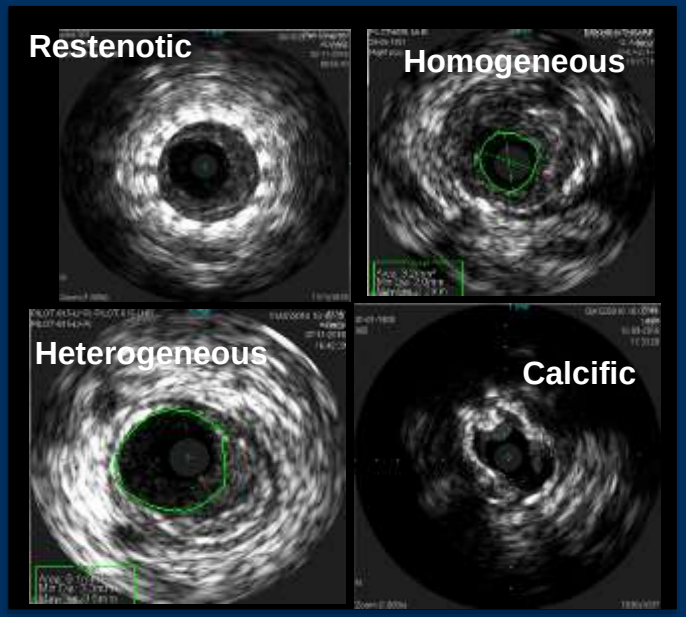
- **Homogeneous (n=7/15)**
- **Heterogenous (n=13/15)**
- **Calcific (n=10/15)**
- **Restenotic (n=10/15)**

3 Laser Passes
40 Fluence/60 Hz
60 Fluence/40 Hz
60 Fluence/60 Hz

IVUS assessment after each laser pass

12 mo follow-up - TLR

Interim analysis of core lab adjudicated data for n=40



Patient Characteristics

(n=40)

	N (%)
Male gender	20 (50%)
Age	70.5 ± 9.2
Race	
African American or Black	9 (22.5%)
White	31 (77.5%)
Hypertension	39 (97.5%)
Hyperlipidemia	38 (95.0%)
Diabetes Mellitus	21 (52.5%)
Hx of CAD	30 (75.0%)
Hx of CVA	11 (27.5%)
Smoking	
Never	6 (15%)
Current	11 (27.5%)
Stopped	23 (57.5%)

	N (%)
RCC	3.4±0.7
1	0 (0.0%)
2	1 (1.9%)
3	25 (48.1%)
4	11 (21.2%)
5	3 (5.8%)
6	0 (0.0%)

Lesion and Procedural Characteristics

(n=40)

	N (%)
Lesion length* (mm)	102.3±93.2
Calcification*	
None	13 (32.5%)
Mild	9 (22.5%)
Moderate	10 (25%)
Severe	8 (20.0%)

*Site reported

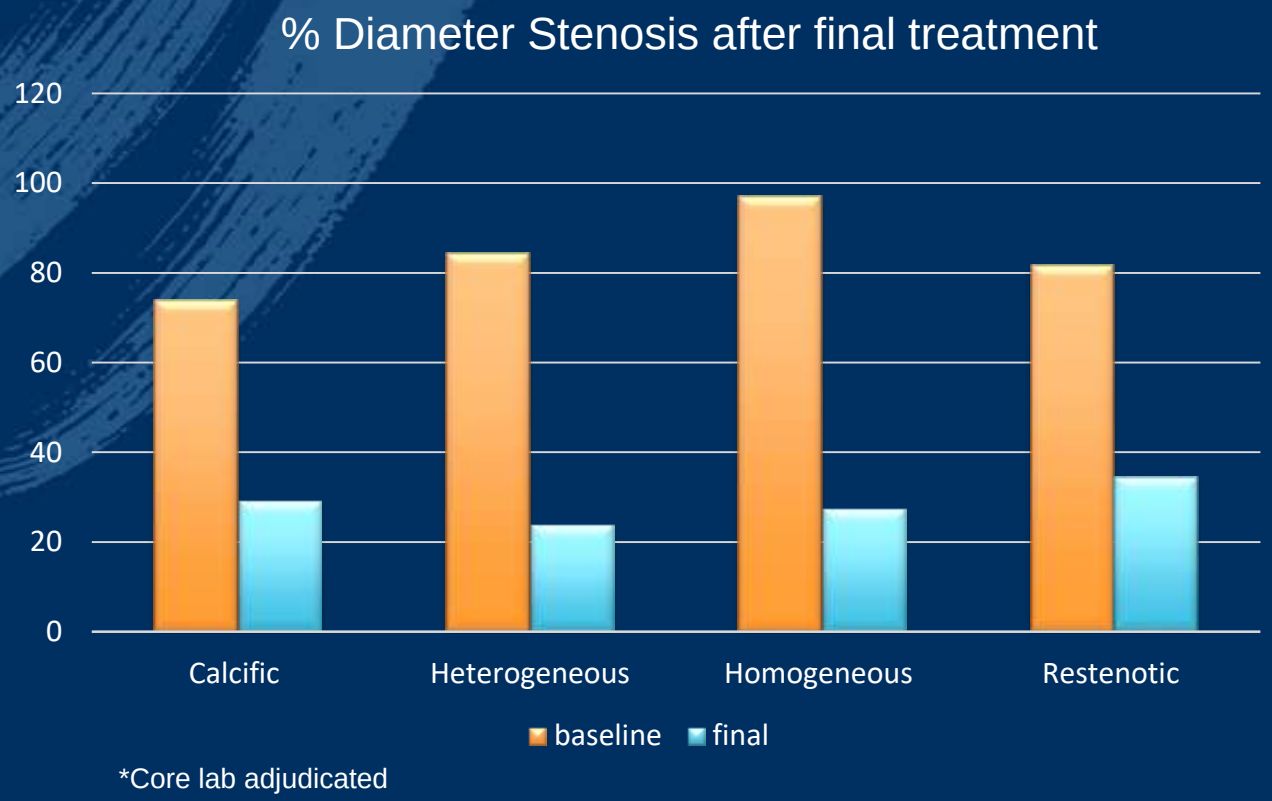
	N (%), mean±SD
RVD (mm)	4.46±0.97
%DS	83.27±17.22

*Core lab adjudicated

Adjunctive Therapy	**N (%)**
DCB alone	26 (65%)
DCB+Stent placed	9 (22.5%)

Acute Angiographic Outcomes

Procedural success (>50% reduction in DS) achieved across all lesion morphologies



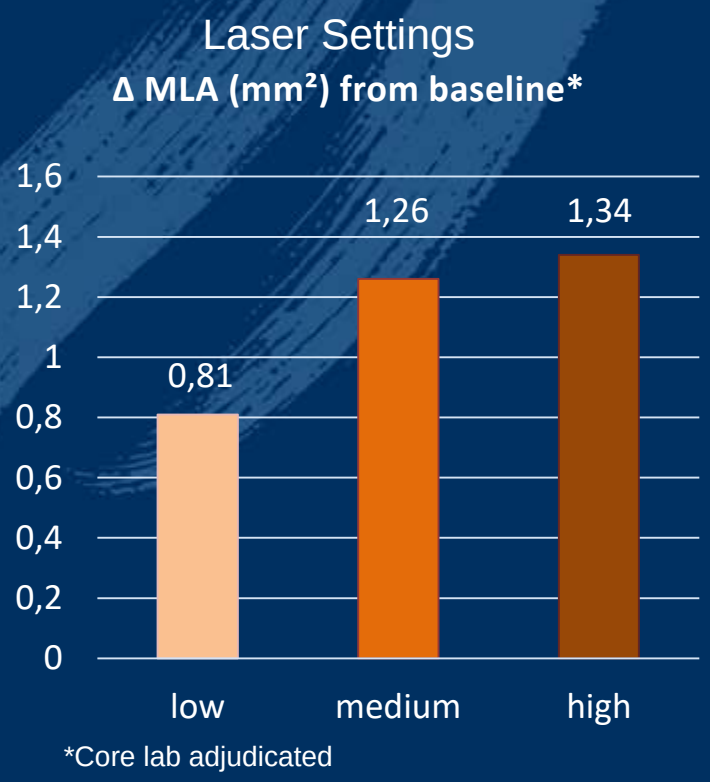
*Core lab adjudicated

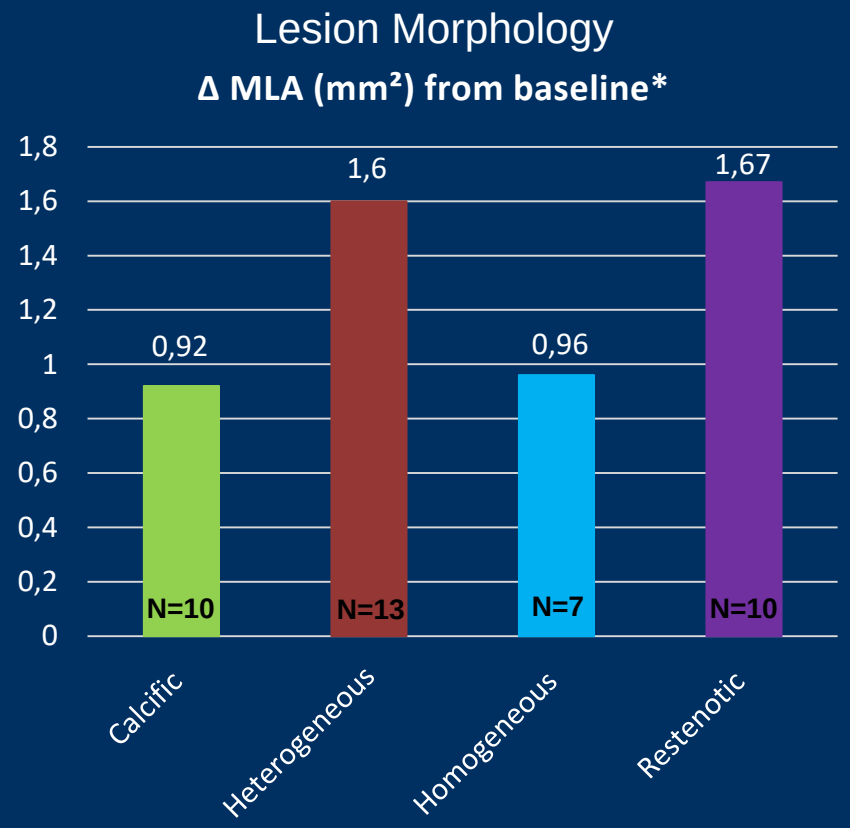
In all lesions (n=40)

- **Average % RSD = 28.5%**
- **Average reduction in % DS = 52.5%**

Acute IVUS Outcomes

Increase in MLA observed across laser settings and morphologies





- A primary goal of vessel preparation for DCB is plaque reduction / increased lumen in order to optimize drug delivery. **But how much gain is enough?**
- Our 12 month TLR data, correlated with this acute luminal gain, will give indication of potential vessel prep threshold and inform future studies.

Representative Cases

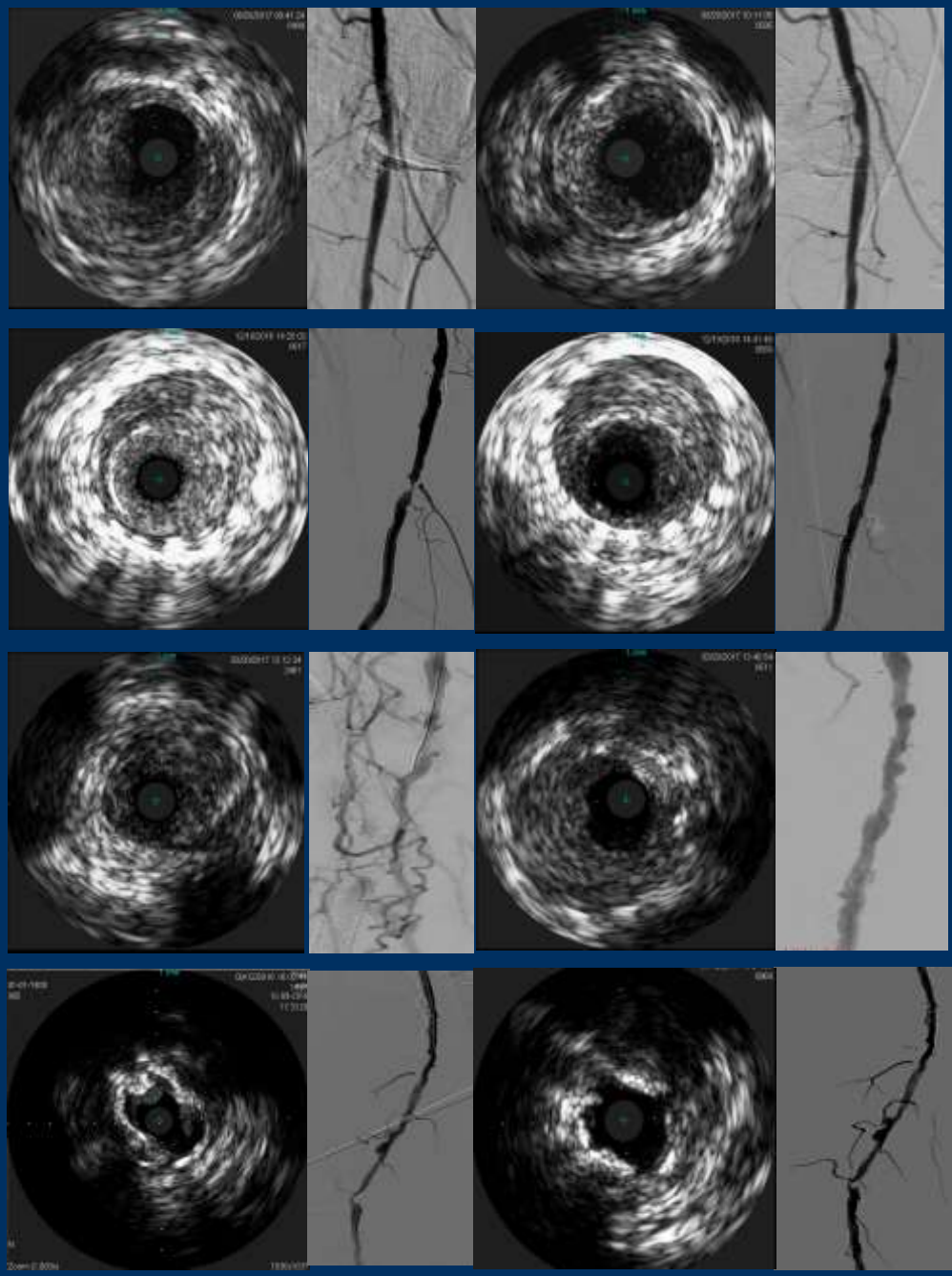
Plaque Morphology

Heterogenous

Restenotic

Homogenous

Calcific



Conclusion

This interim analysis gives a first idea of how the laser performs in different lesion morphologies

Further analysis will help to clarify how laser settings play into outcomes in different lesions

Finally, this might be a first step to develop a personalized algorithm to optimize treatment for each patient