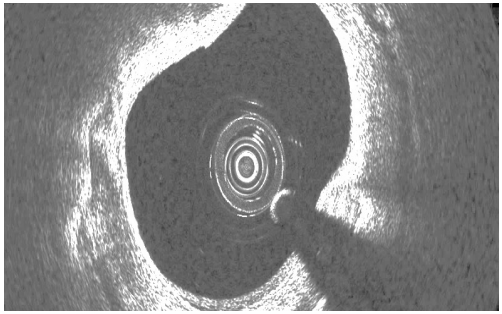


Laser Intravascular Lithotripsy

A new approach for calcified coronary stenoses

Thomas Milner / Marc D. Feldman

Clayton Biotechnologies

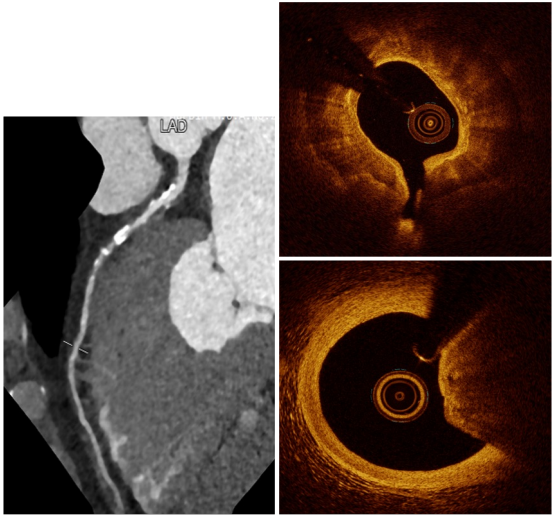
Calcified Coronary Stenoses

Calcium problematic in PCI procedures

- Calcium in coronary arteries:
  - reduces vessel compliance
  - prevents full stent deployment
  - increases mortality, stent thrombosis, TVR and MACE

Develop a better tool to remove severe calcium build-up:

- easy to prepare and use
- trackable across challenging calcified segments
- low profile to be used in small-hard lumen
- delivers reliable results



Introduction to Laser-IVL

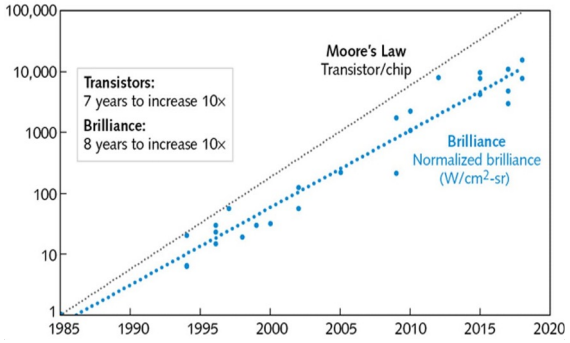
Lithotripsy	Laser IVL
➢ Demonstrated to be safe and effective in cracking calcium ➢ Long history of use in kidney stones ➢ Recently developed for intravascular applications	➢ Precise ➢ Cost effective ➢ Allows access to small tight spaces ➢ Can be combined with imaging ➢ No ventricular pacing

Advantages of Laser over Electric Intravascular Lithotripsy

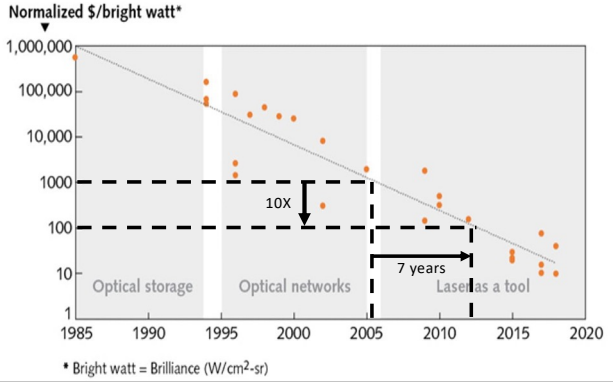
	Electric Lithotripsy	Laser Lithotripsy
Ventricular pacing	!	✗
Profile	1200 µm	150µm-400µm (fiber optic)
Max. number of attempts	80 shots	> 150 shots
Pressure for calcium cracking	50 ATM	60-100 ATM
Pulse power control	✗	✓
Image guidance	✗	✓ IVOCT or IVUS if desired

Benefit of Using Lasers

Laser Brilliance and Moore's Law

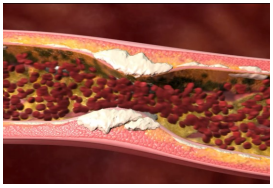
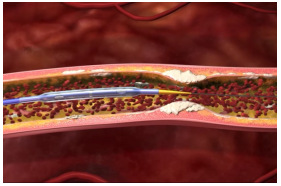
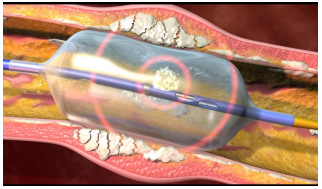
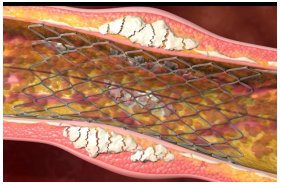


Exponential Cost Reduction ($/Bright Watt)



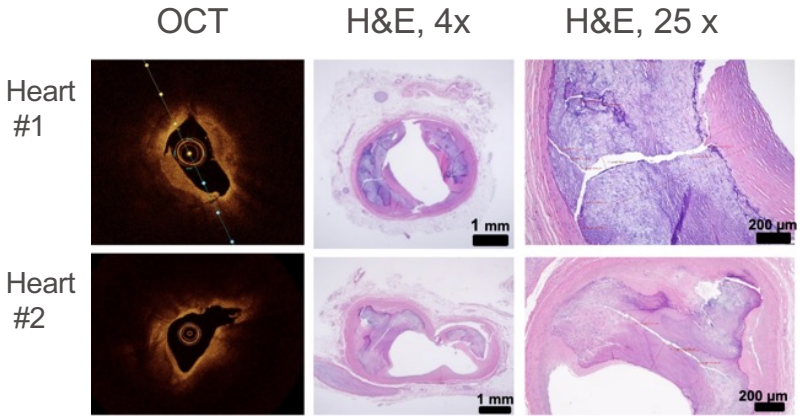
* Manoj Kanskar, Scott Keeney, and Robert Martinsen
Laser Focus World

LIVL : Laser Intravascular Lithotripsy

- LIVL easy to prepare and use
- Low profile and can be used in small-hard lumen
- Trackable across challenging calcified segments
- Powerful and allows for multiple sites shockwave delivery (in image: 6 sites)
- Reliably allows for stenting without resorting to other procedures

Calcium Fracturing – Ex-Vivo Human Coronary Arteries

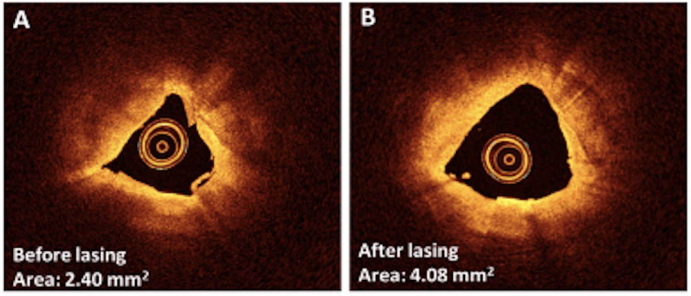


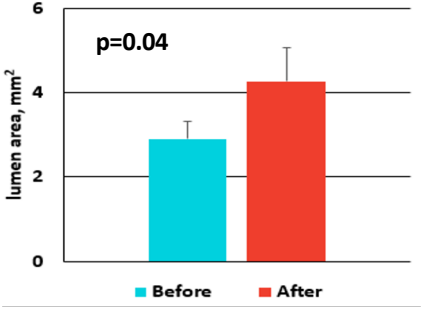
7 human hearts, 16 arteries (RCA, LAD, LCX)

Laser lithotripsy effective in fracturing the calcium plates

Changes in Lumen Area – Ex-Vivo Human Coronary Arteries

Laser Lithotripsy treating calcified coronary arteries **increases lumen area** and can prevent atherectomy





7 human hearts, 15 arteries (RCA, LAD, LCX)

Growth Drivers for Laser IVL

Opportunities

Rapidly expanding IVL market for arterial lithotripsy with anticipated sales approaching *$0.5 billion* in 2022

Electrical Discharge Lithotripsy limitations of ventricular *pacing* and microfiber of Laser IVL provide opportunity for improvements

Second to market of superior laser device can *capitalize* on established IVL market

Laser IVL can *resolve* some limitations associated with Electrical Discharge Lithotripsy

Low-Cost Laser System makes COGs comparable to electric approach

Time for Lasers in Interventional Medicine

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Medical Research for Mankind
Since 1933

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