Excimer Laser angioplasty for femoro-popliteal disease

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Speaker's name: Naoto Inoue

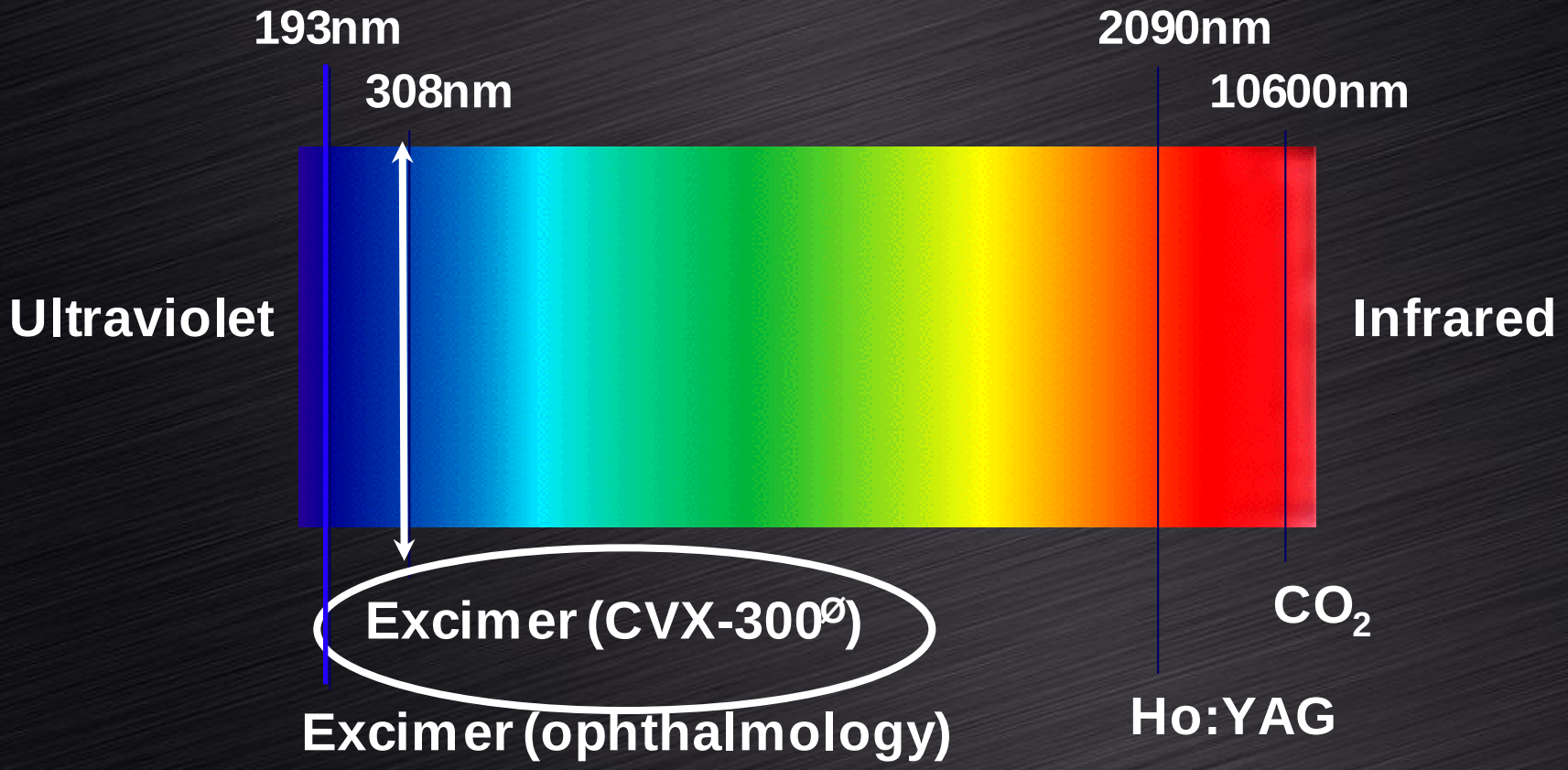
■ **I have the following** potential conflicts of interest to report:

- ☐ Research contracts
- ■ Consulting- Kaneka, Tokai-Medical
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

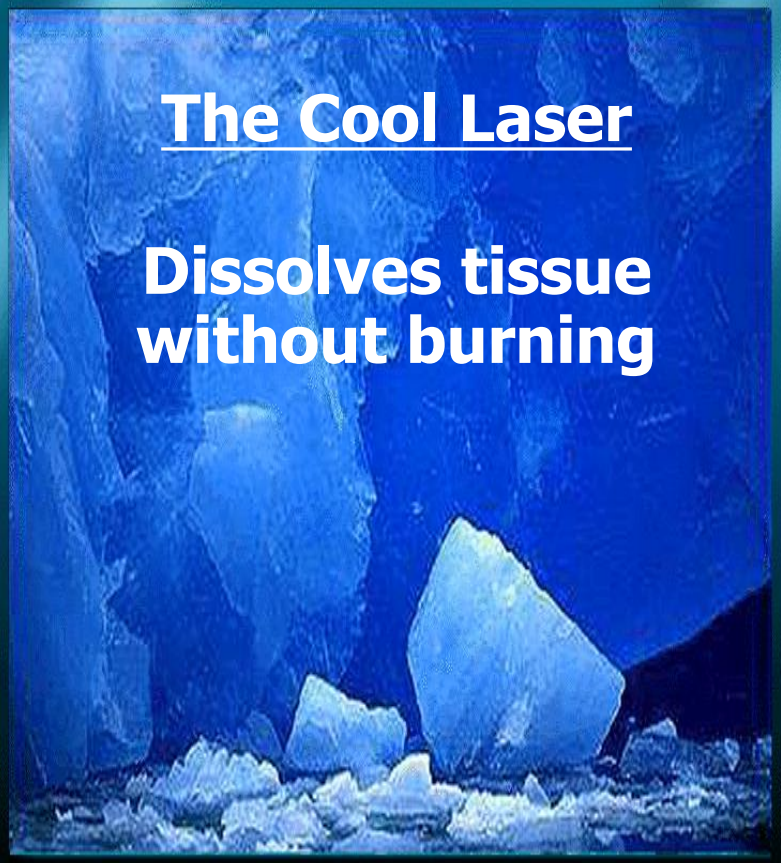
☐ **I do not have any potential conflict of interest**

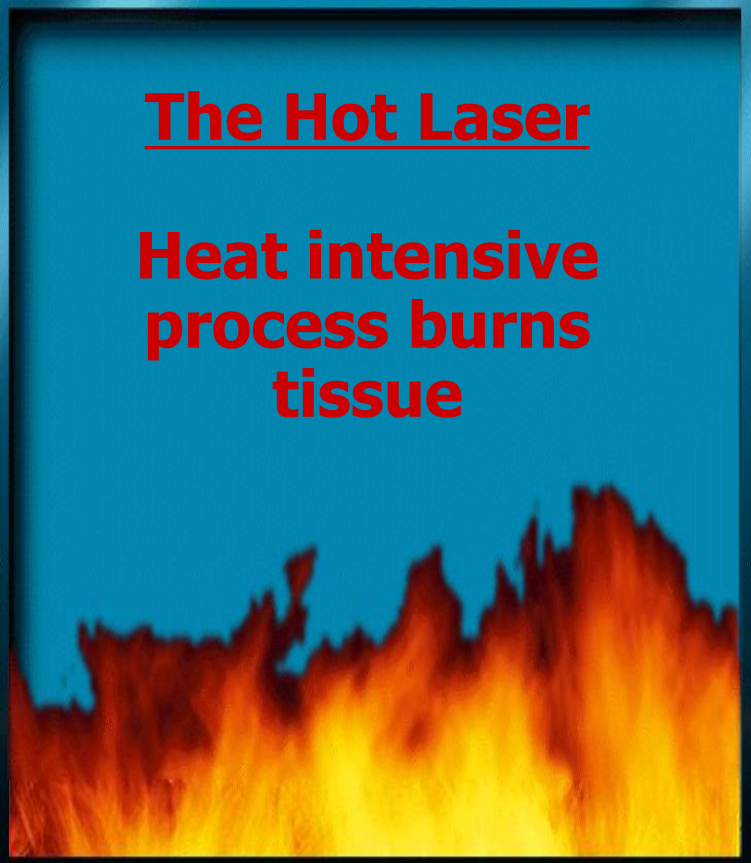
The Wavelength Story

Ultraviolet vs. Infrared

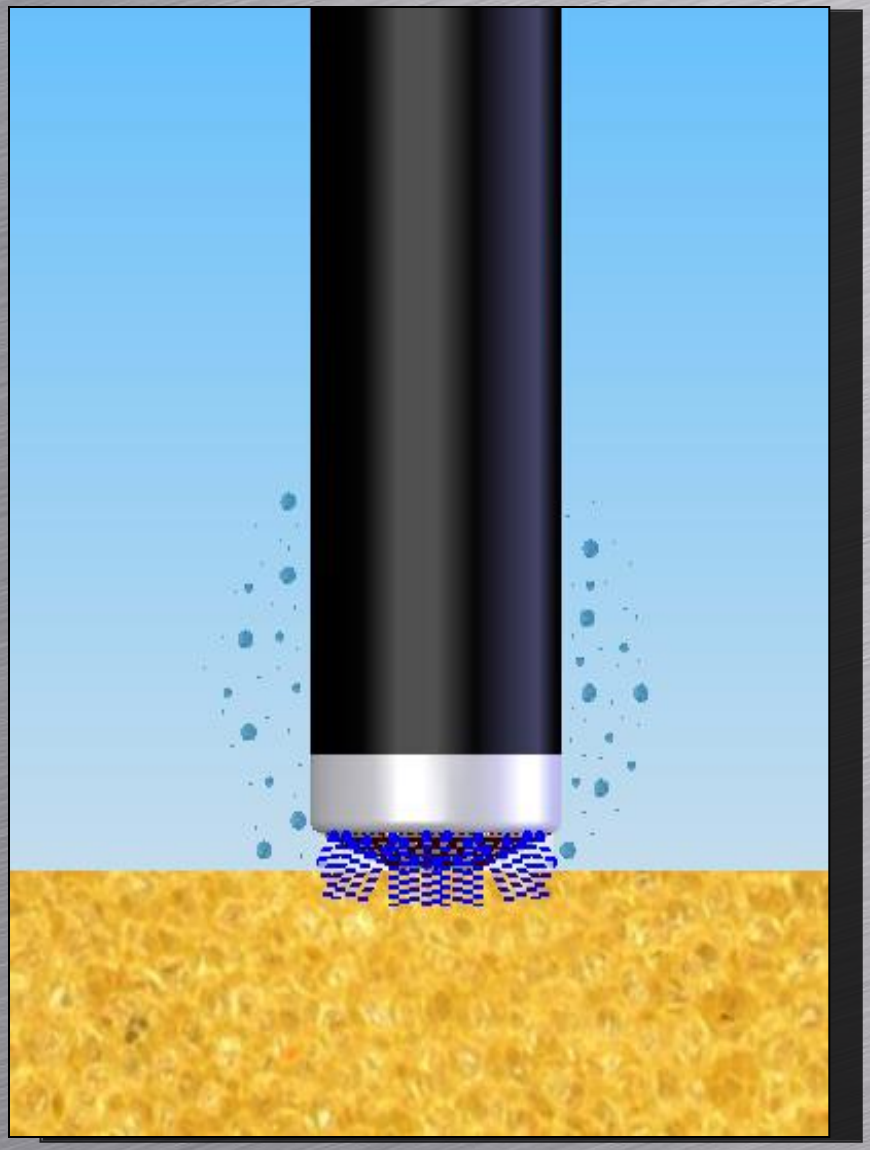


The XeCl Excimer Laser
(The Cool Laser)





Photochemical



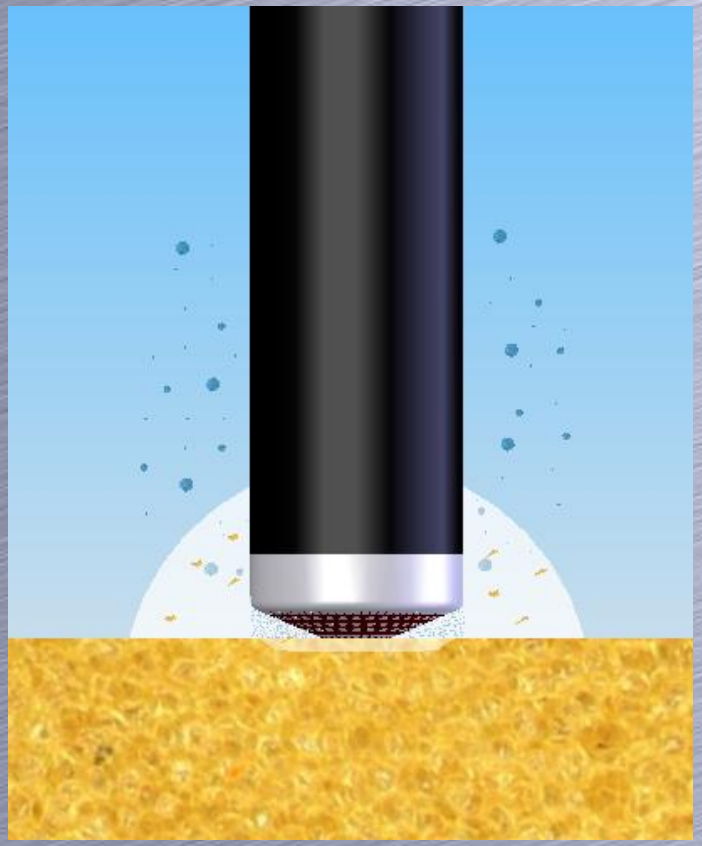
-UV light pulse hits tissue

-125 nanosecond duration

-100 microns penetration

-billions of tissue bonds fracture per pulse

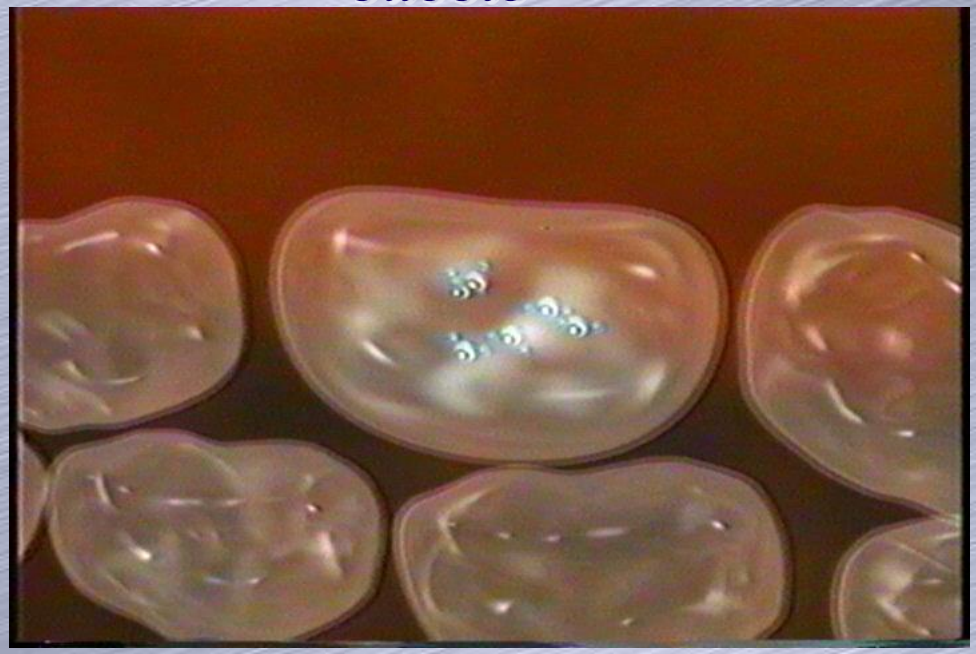
Photothermal



-absorption creates molecular ***vibration*** in tissue

-vibration of molecules ***heats*** intracellular water

-***steam*** forms expanding ***vapor bubble***



Photomechanical

-expansion and collapse of vapor bubble breaks down tissue and sweeps debris away from tip

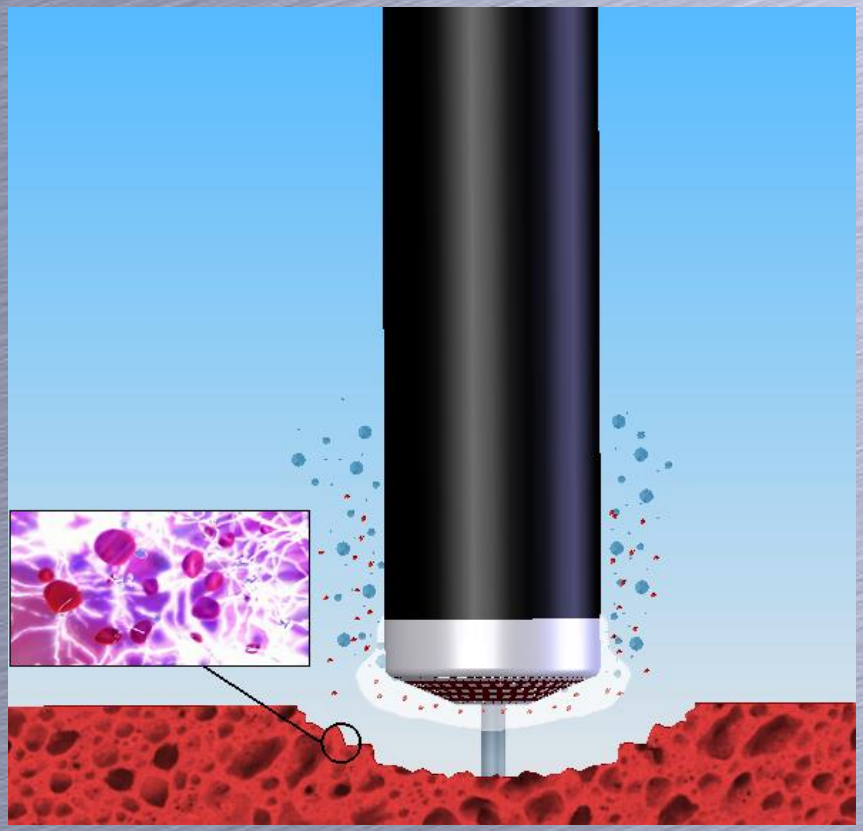
-debris is water,gas, small particles (90% < 10 microns)

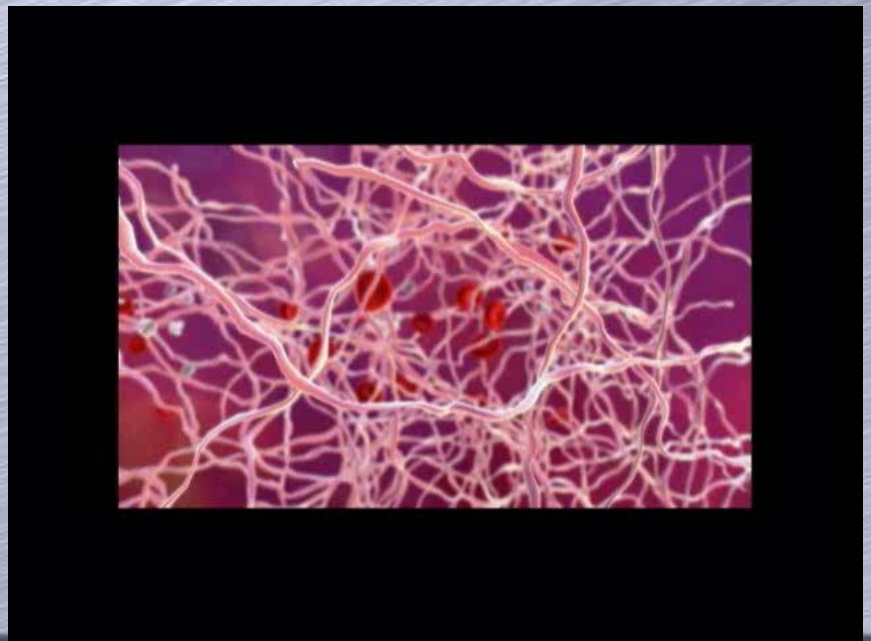
-ablation depth >> 10 microns per pulse

-entire process time per pulse is 500 millionths of a second

120-500 us

Thrombus





Laser angioplasty in PAD

Laser+balloon angioplasty for de novo lesion?

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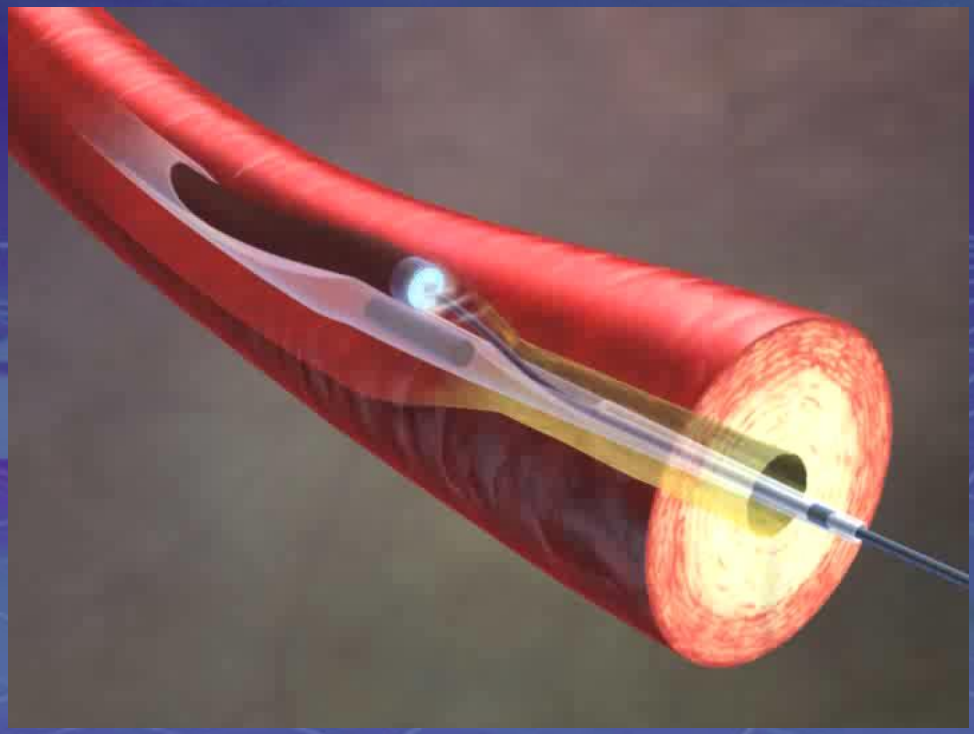
Laser angioplasty in PAD

Turbo-Tandem™

Laser Guide Catheter with Laser Atherectomy Catheter



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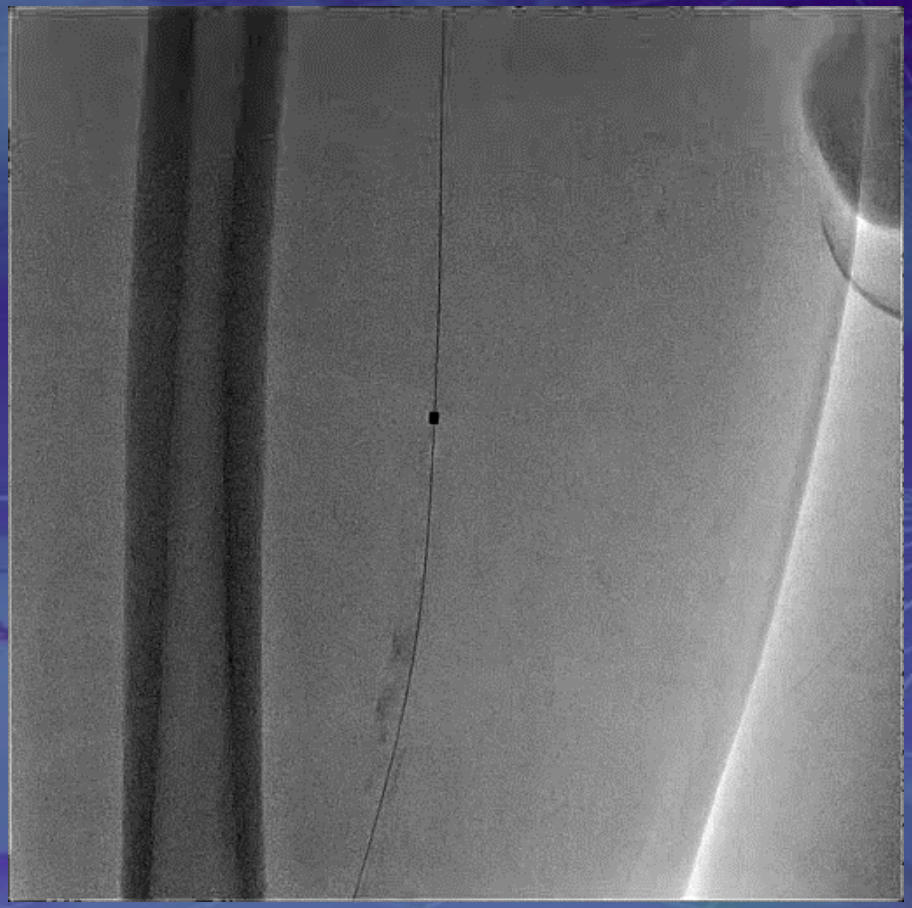
Laser+balloon angioplasty for de novo lesion



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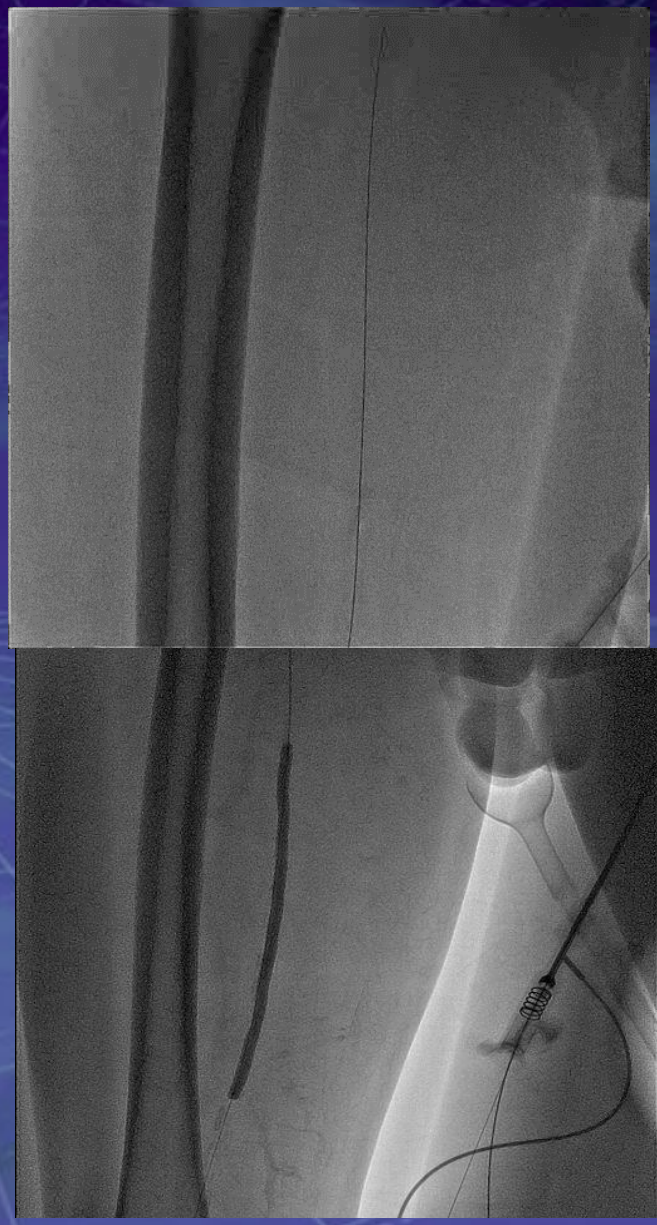
Laser+balloon angioplasty for de novo lesion



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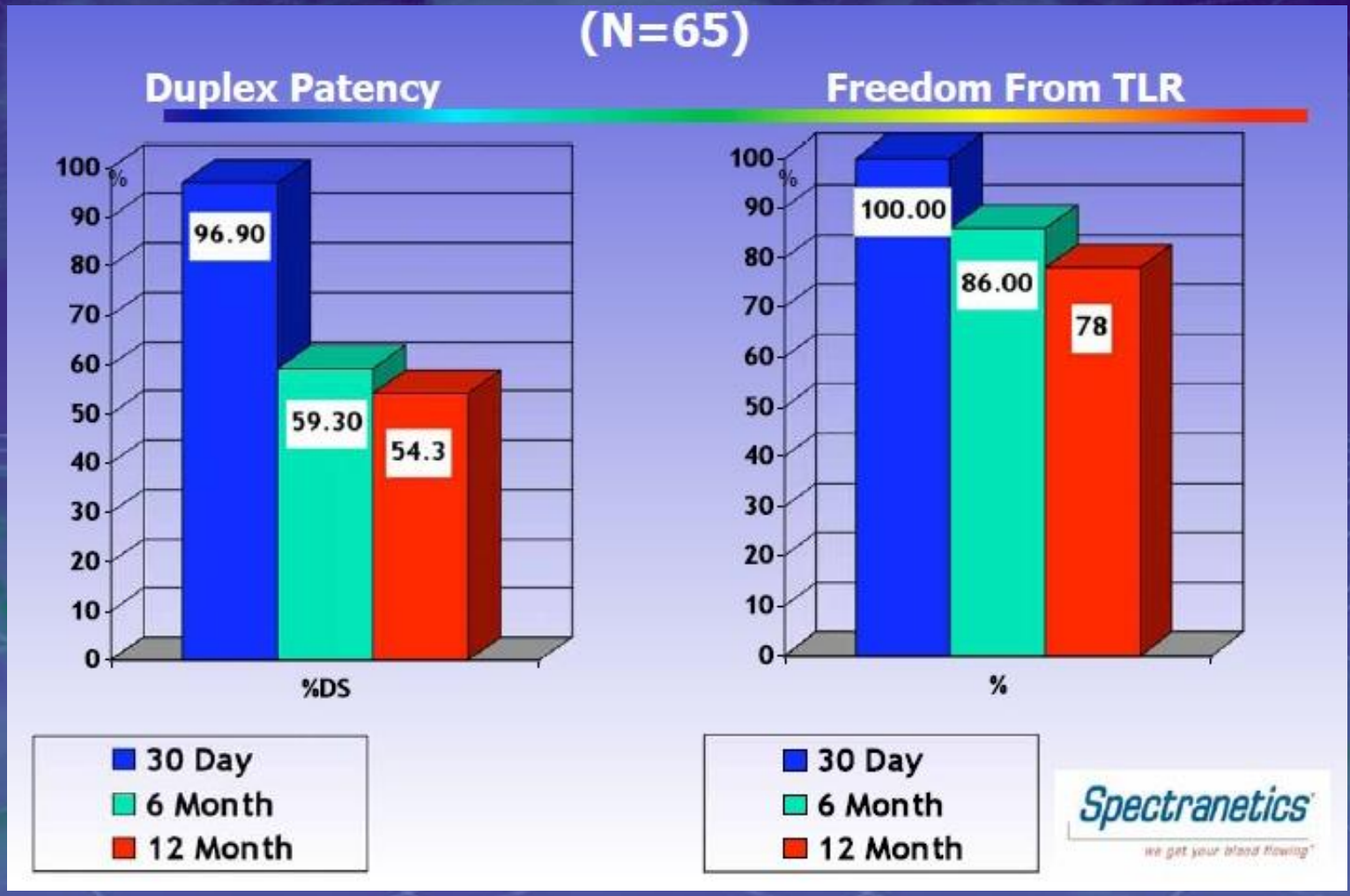
CELLO trial



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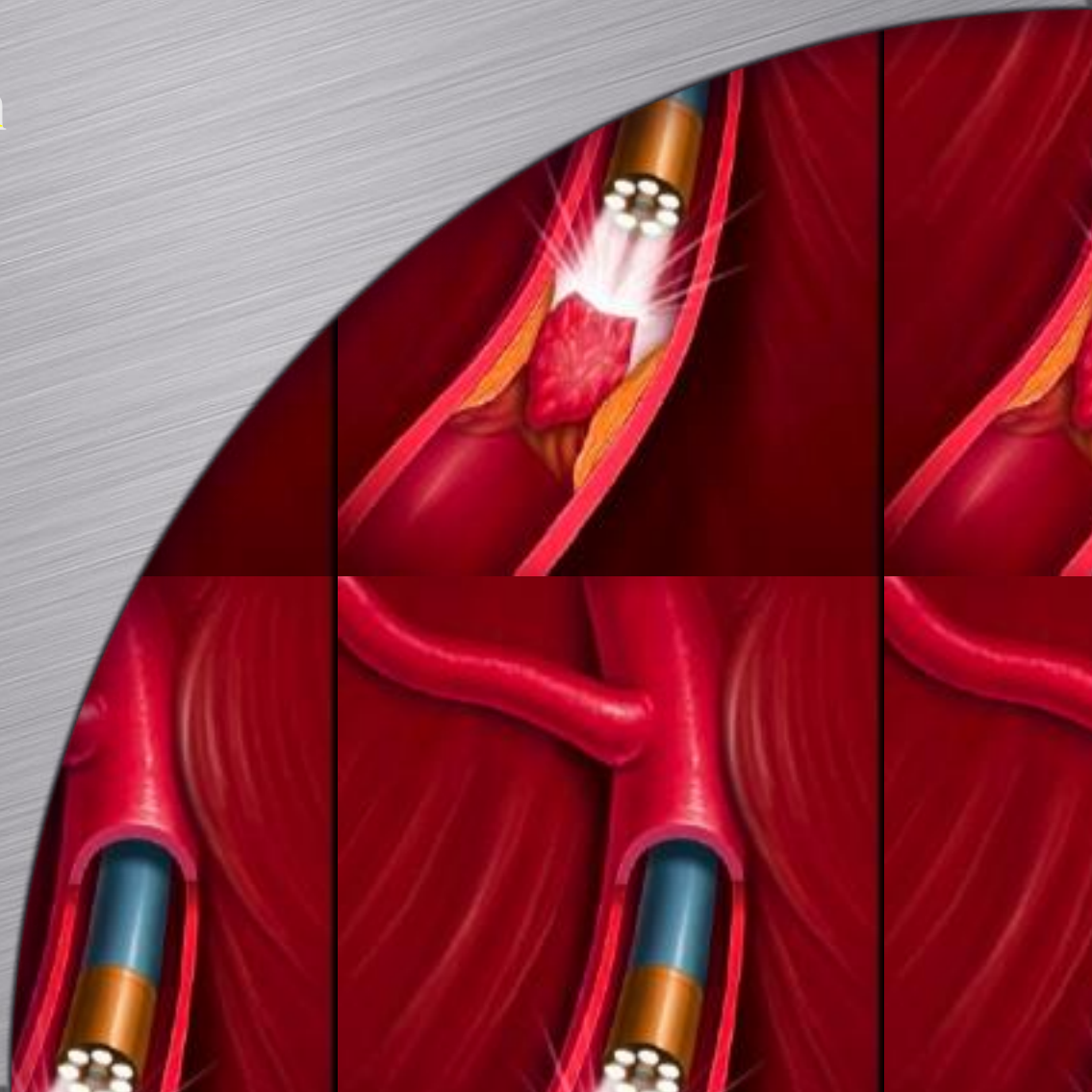
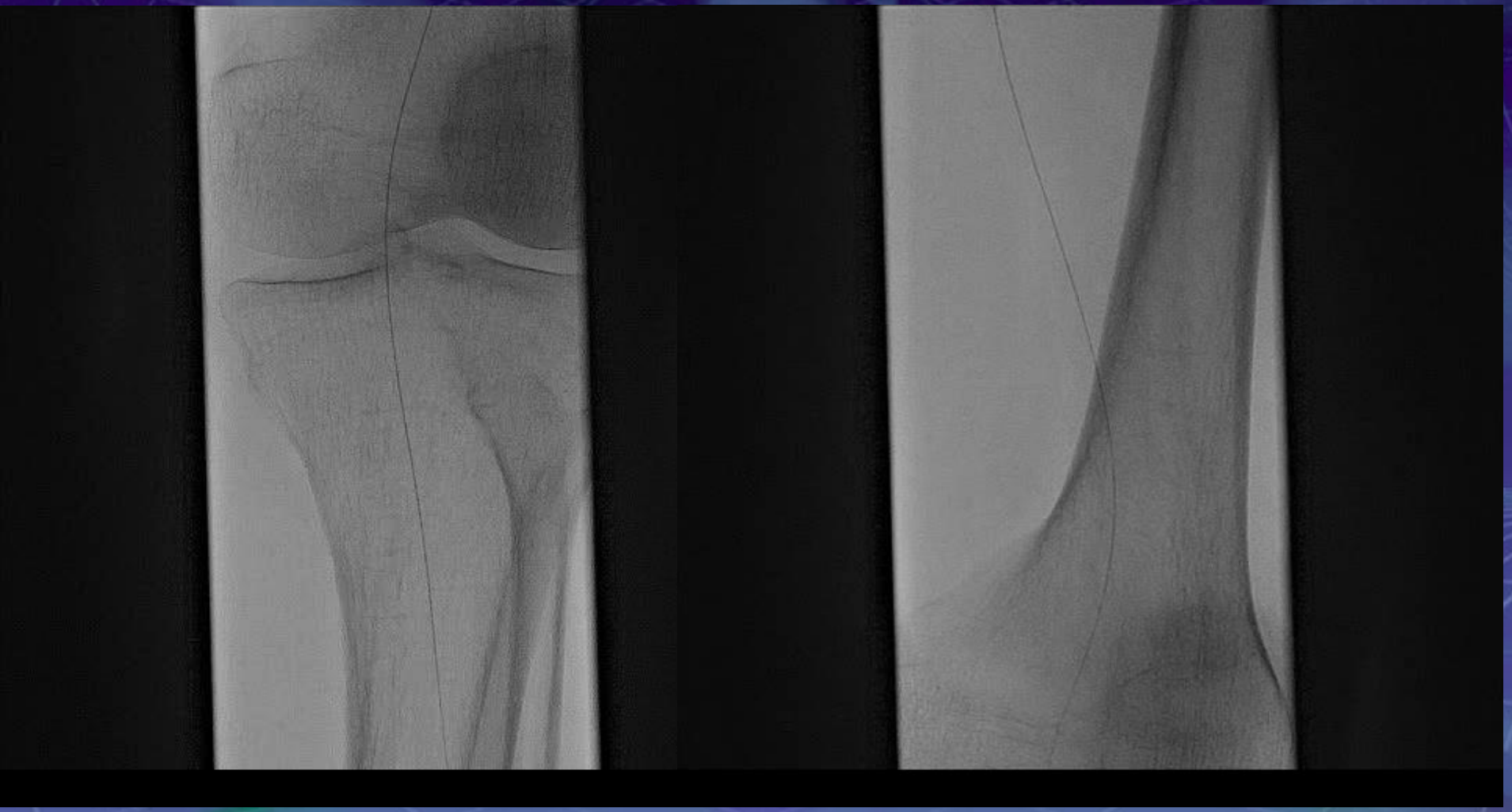
Efficacy of laser in PAD

- **Thrombotic lesion**
- **Calcified lesion**
- **ISR**
- **Below the knee**



Thrombotic occlusion due to AF

Thrombotic occlusion due to AF



7F 1.7 Turbo booster

Post adjunctive ballooning

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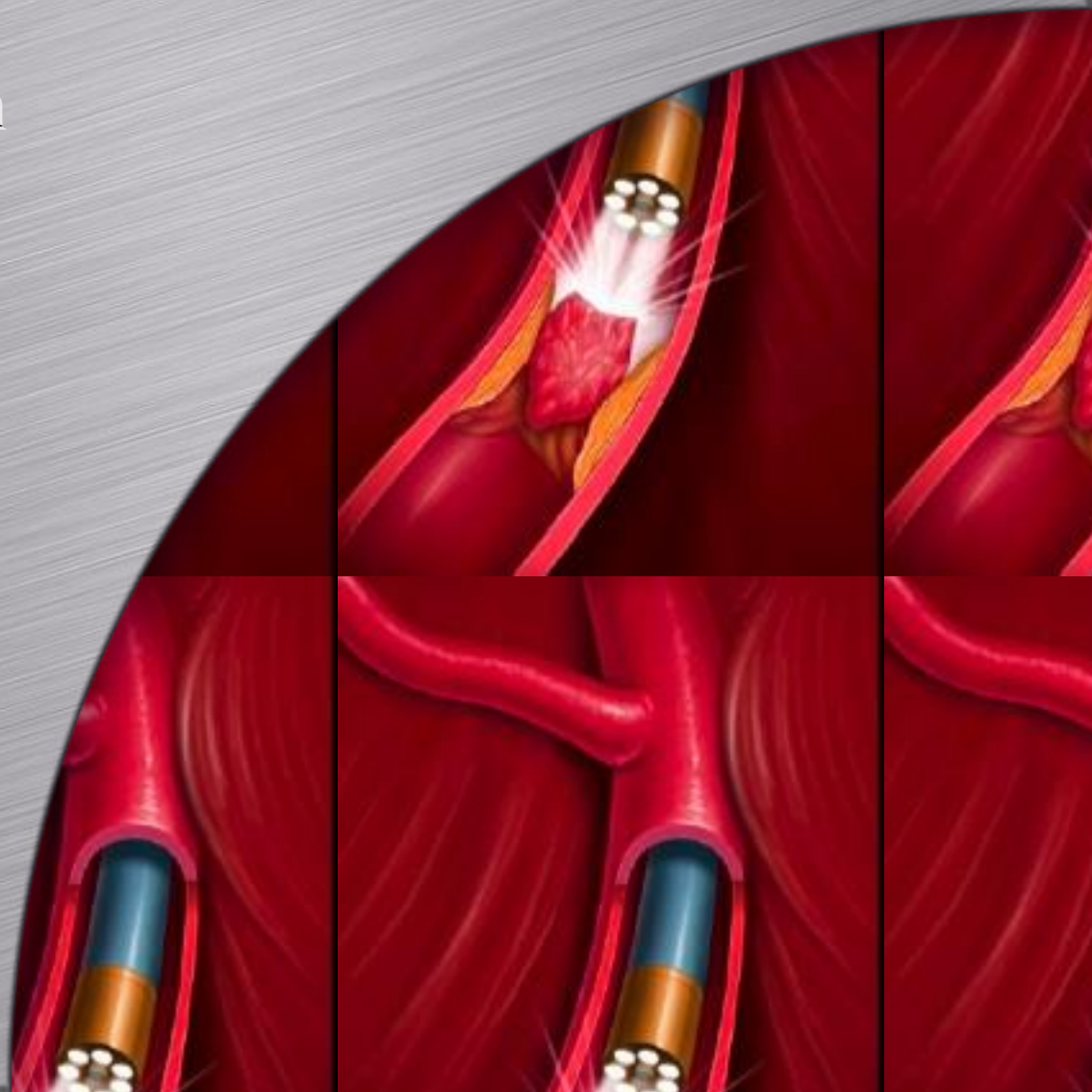
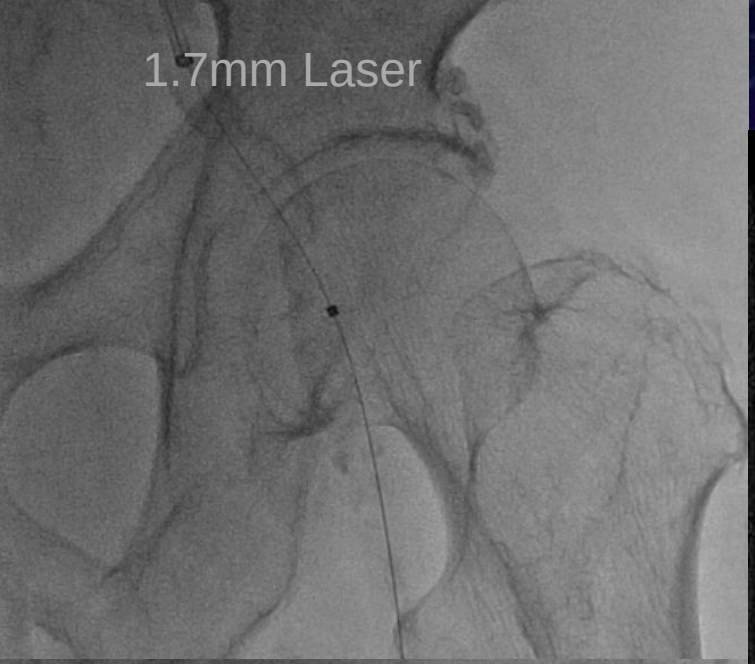
Efficacy of laser in PAD

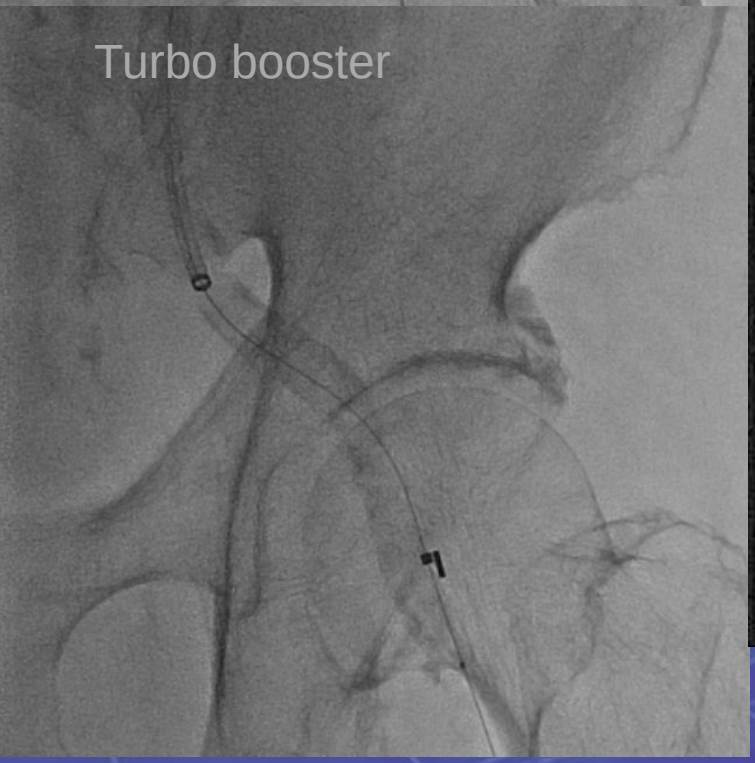
- Thrombotic lesion
- Calcified lesion
- ISR
- Below the knee



Calcified CFA

Calcified CFA





Calcified CFA

Adjunctive ballooning

Efficacy of laser in PAD

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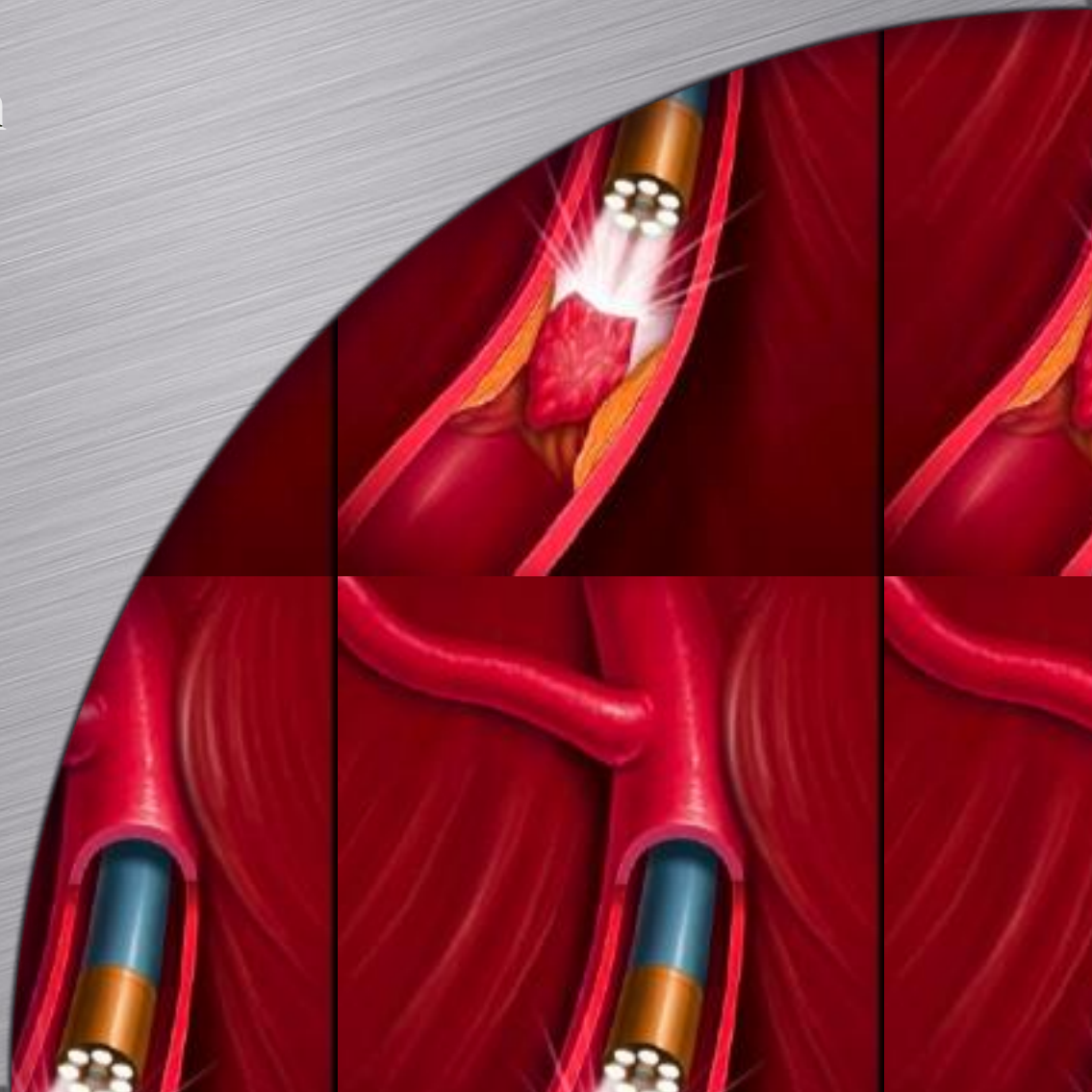
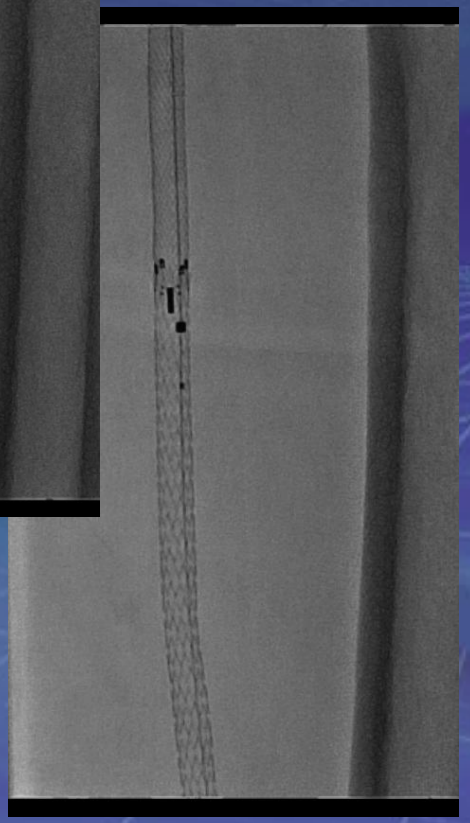


Turbo Booster for long stent occlusion



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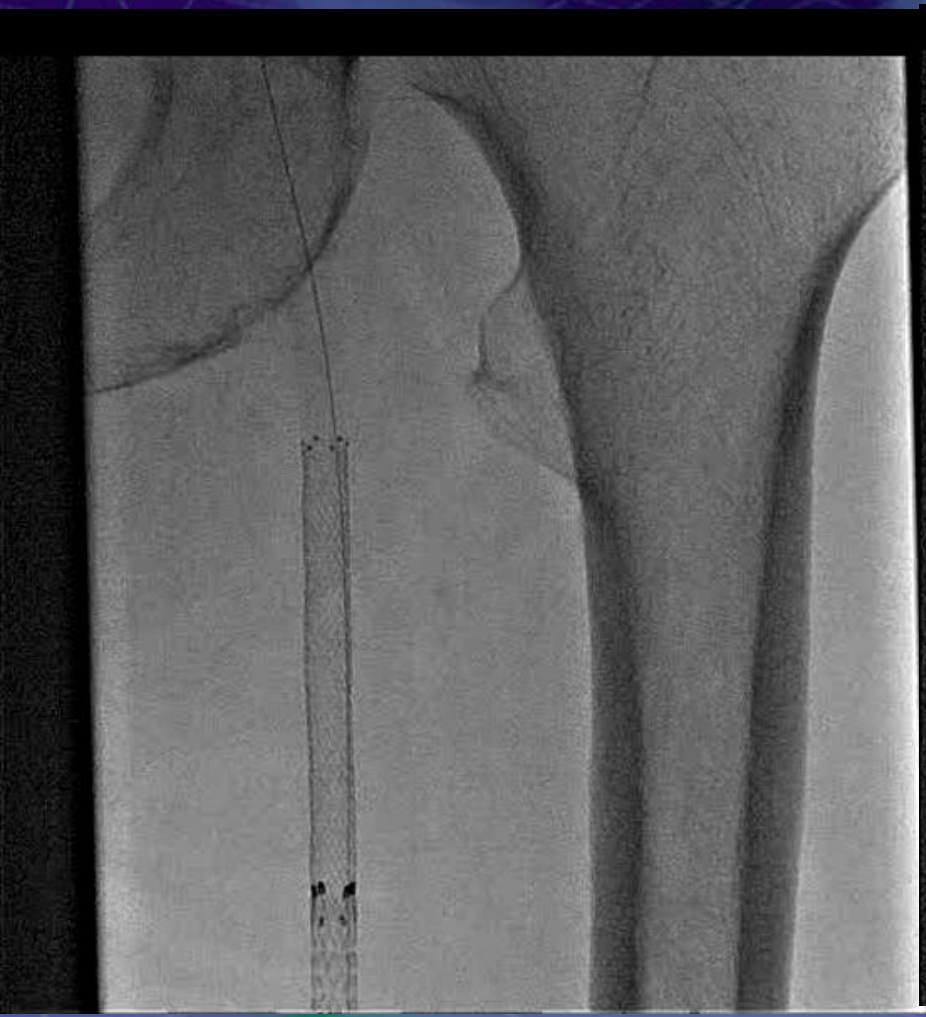
Turbo Booster for long stent occlusion



Post laser catheter

Post adjunctive ballooning

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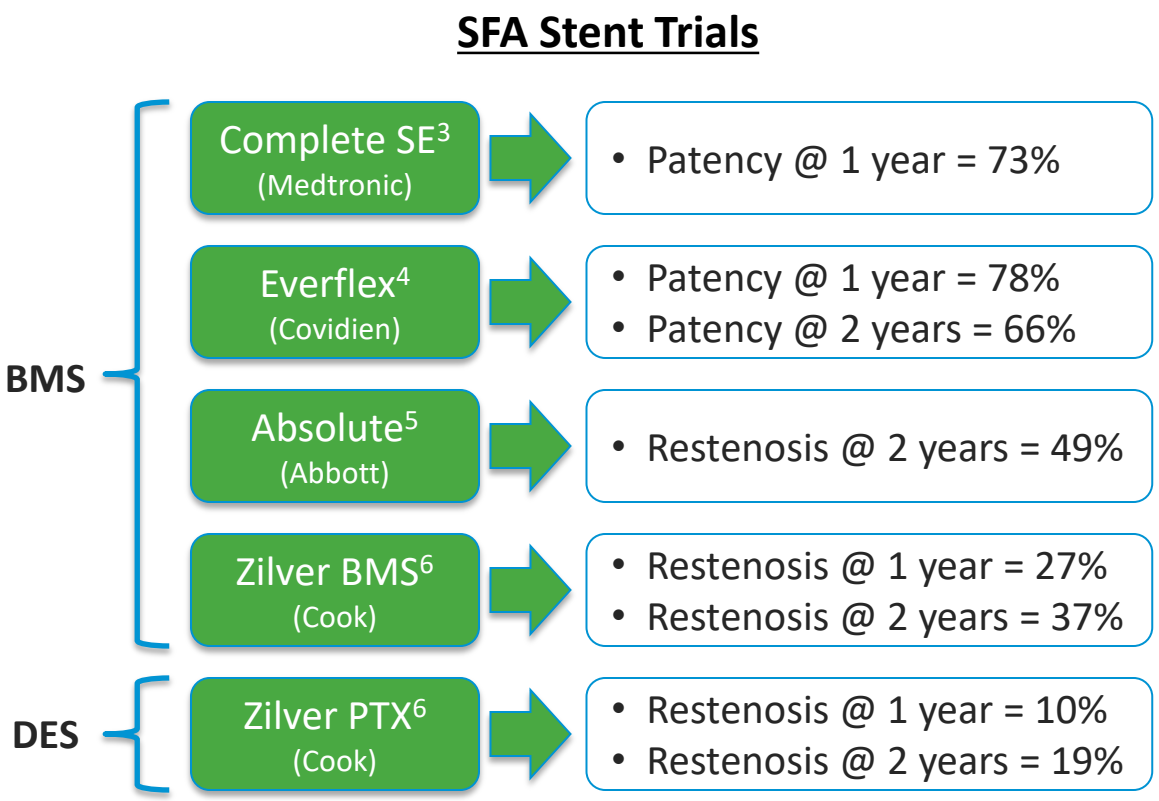
SFA Trials Show Restenosis / Loss of Patency is an Issue for All Stents



Results May Be Understated

1. Are these "real-world" patient sets with inclusion of
   - Long lesions
   - Multiple stents
   - Repeat ISR
   - Severity of underlying disease

2. Has disease stabilized at 2 years or will restenosis continue?

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Development of Restenosis Has 3 Components[7]

Stage	Timing	Effect
1. Vessel Recoil	Early (within 24 hours)	Immediate shrinkage of vessels due to arterial wall elasticity
2. Negative Remodeling	Mid-stage (within days to weeks)	Injury response causing contraction of vessel wall
3. Neointimal Hyperplasia	Late (within weeks to months to years)	Injury response causing new tissue growth within artery

Stents inhibit

Primary Component of ISR

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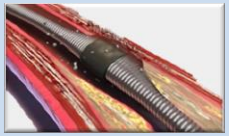
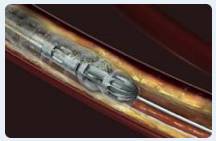
Atherectomy Treatment Options[19-21]

	ISR Indication	Low Risk of Stent Interaction	Low Risk of Embolization
Turbo-Power™ Laser Atherectomy Catheter	✔	✔	✔
SilverHawk	Contraindicated	X 	X Ablation vs. Displacement/Dislodgement
Diamondback	Contraindicated	X 	X Ablation vs. Displacement/Dislodgement
Jetstream	Not indicated	X 	X Ablation vs. Displacement/Dislodgement

According to FDA Guidance, contraindicated device *should not* be used, as the risk of use clearly outweighs any benefit

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Advantage of Laser for ISR

- **Difficult to Cross** the entire segment with a wire
  - The wire frequently exists through the stent struts
- ***Too much tissue*** to be displaced by balloon dilatation
- Need to treat ***w/o disturbing*** the underlying stent
- Need to ***avoid distal embolization***

EXCITE Study Overview[22]

Purpose

Evaluated the safety and effectiveness of Excimer Laser Atherectomy (ELA) with adjunctive PTA vs. PTA alone in the treatment of FemPop ISR

Method

Prospective, randomized (2:1), multi-center study

Primary Safety = 37 day MAE

Primary Efficacy = freedom from 6 month clinically driven TLR

Third-party assessment for all clinical events & angiographic/ultrasound readings

Patients

Real-world population

Enrollment:

169 ELA + PTA vs.

81 PTA alone

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Designed for Real-World ISR
CHALLENGING CONDITIONS

- Long stents
- Multiple stents
- Common stent fractures (Grades 1-3)

- Key Inclusion Criteria
  - ISR lesion ≥ 4 cm
  - Rutherford classification 1-4
  - RVD ≥ 5.0 mm and ≤ 7.0 mm
  - ≥ 1 patent tibial artery
- Key Exclusion Criteria
  - Target lesion extends > 3 cm beyond stent margin
  - Untreated inflow lesion
  - Grade 4 or 5 stent fracture
- Follow-up
  - Discharge, 30 days, 6 months and 1 year post-procedure

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Designed for Real-World ISR
SICK PATIENTS

- Elderly patients
- High rates of diabetes, hypertension, & CAD
- 1/3 had **recurrent** ISR

Patient Demographics

	ELA + PTA (N=169)	PTA Alone (N=81)	P-value
Age (mean)	68.5	67.8	0.60
Male	62.7%	61.7%	0.89
Hypertension	95.8%	93.8%	0.53
Hyperlipidemia	96.4%	95.0%	0.73
Diabetes Mellitus	47.0%	47.5%	1.00
CAD	64.3%	68.8%	0.57
Previous ISR	32.57%	30.0%	0.77
Smoking	85.0%	91.3%	0.23
CLI	16.0%	12.3%	0.57
Claudicants	84.0%	87.7%	

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Designed for Real-World ISR
CHALLENGING LESIONS

- Among longest lesions studied in any SFA trial
- 20% of lesions > 30 cm
- 1/3 total occlusions
- Laser treated significantly more calcified lesions/arteries
  - ✧Difference due to statistical chance, not design

Third-Party Angiographic Core Lab Assessment

Baseline Lesion Characteristics

	ELA + PTA (N=169)	PTA Alone (N=81)	P-value
Mean Lesion Length (cm)	19.6	19.3	0.85
Diameter Stenosis (%)	81.7%	83.5%	0.42
Popliteal Lesion	21.3%	23.4%	0.923
Total Occlusion	30.5%	36.8%	0.37
Calcium (Mod/Sev)*	27.1%	9.1%	0.002
Stent Fracture			0.08
None	85.8%	95.8%	
Type 1 or 2	11.4%	4.2%	
Type 3, 4 or 5	2.8%	0.0%	

* Calcium Grade: **0** - No calcification; **1** - Superficially localized non-confluencing wall calcifications, < 5 mm on fluoroscopy; **2** - Confluencing calcifications > 5 mm, including multiple deposits, not involving the whole vessel diameter in angiographic working projection; **3** - Confluencing calcifications filling up the whole vessel diameter.

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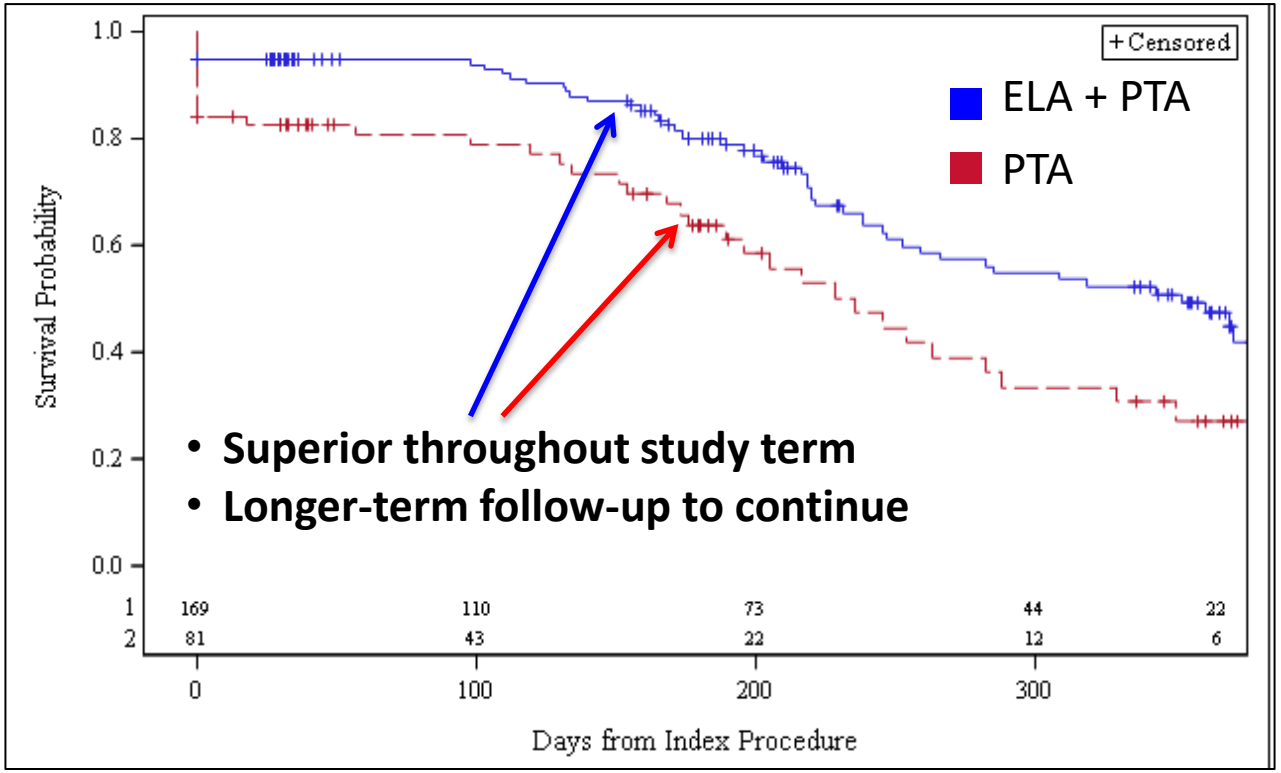
Superiority in Freedom from TLR Consistent Throughout Follow-up Period

Freedom From Target Lesion Revascularization



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Efficacy of laser in PAD

- Thrombotic lesion
- Calcified lesion
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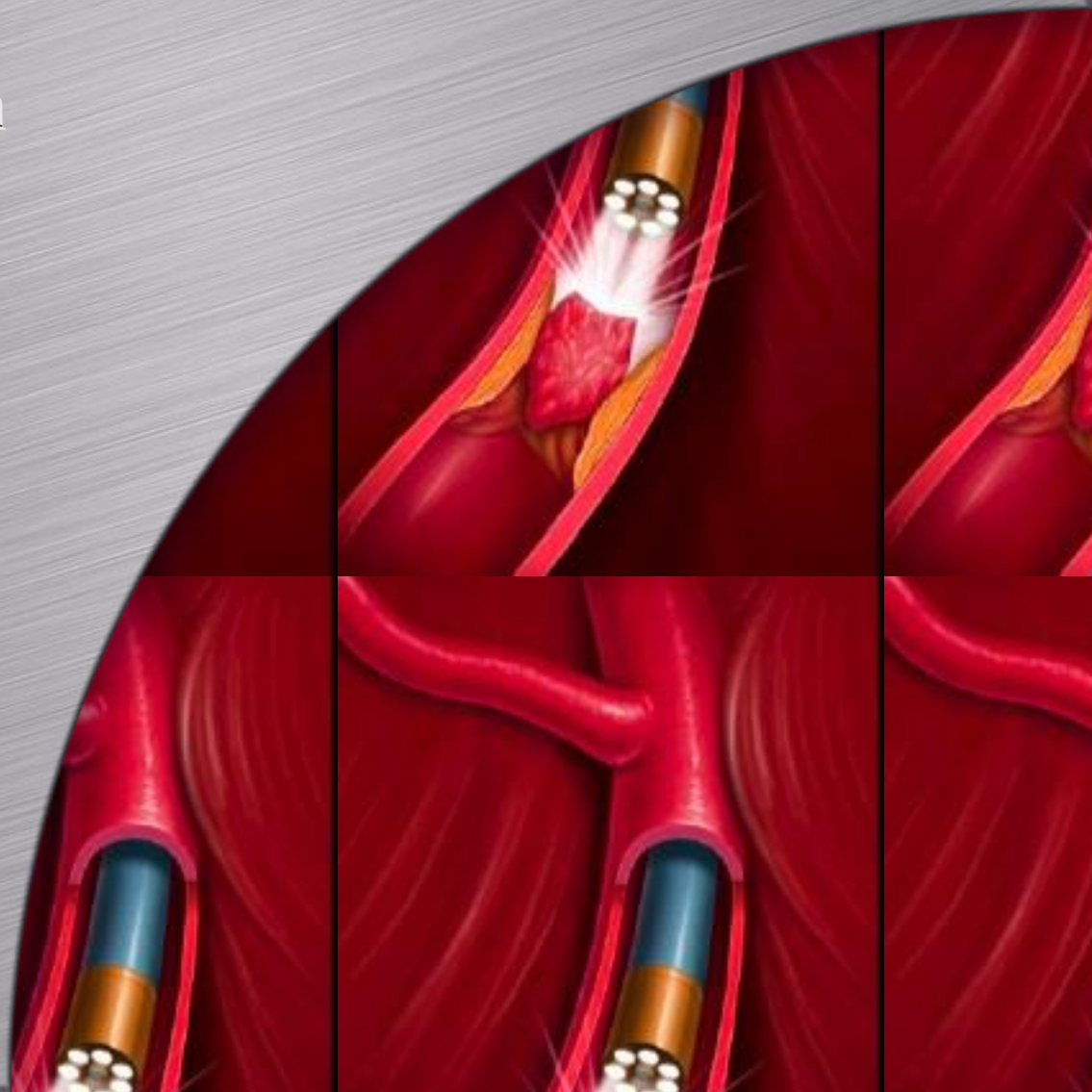

BK lesion

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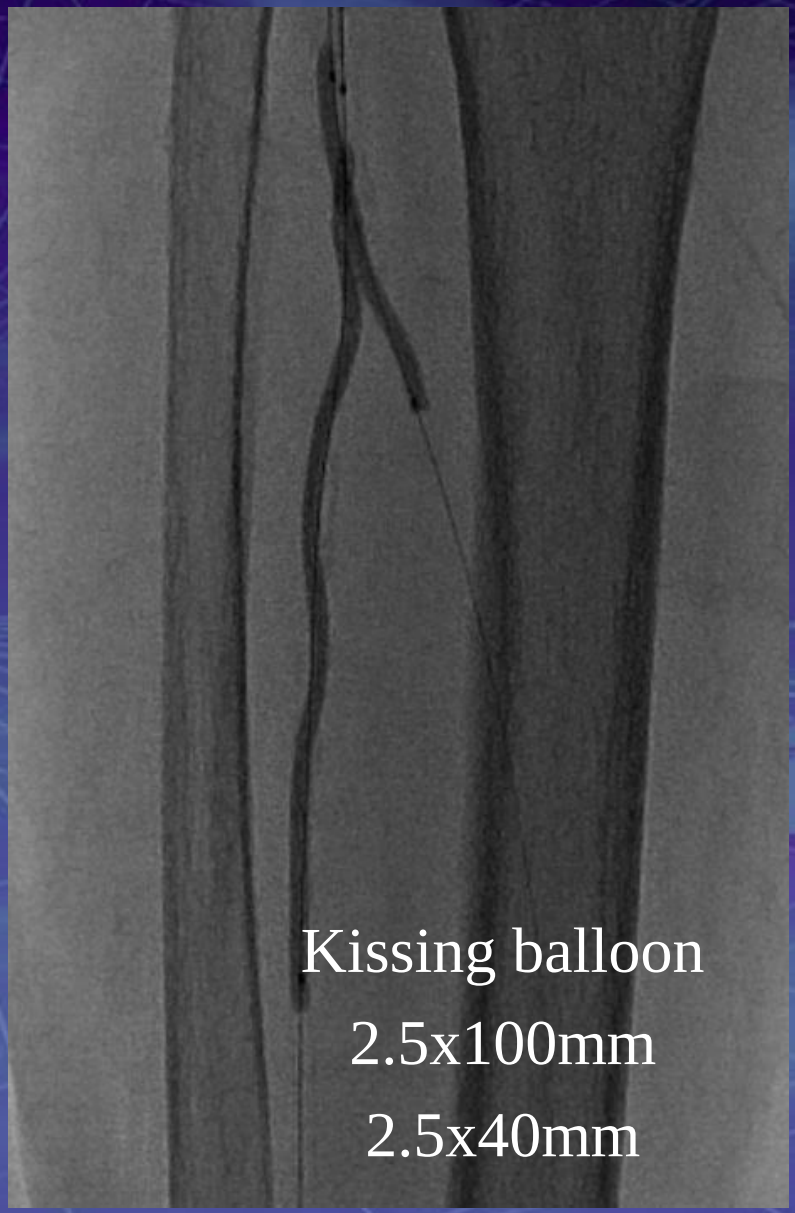
BK lesion



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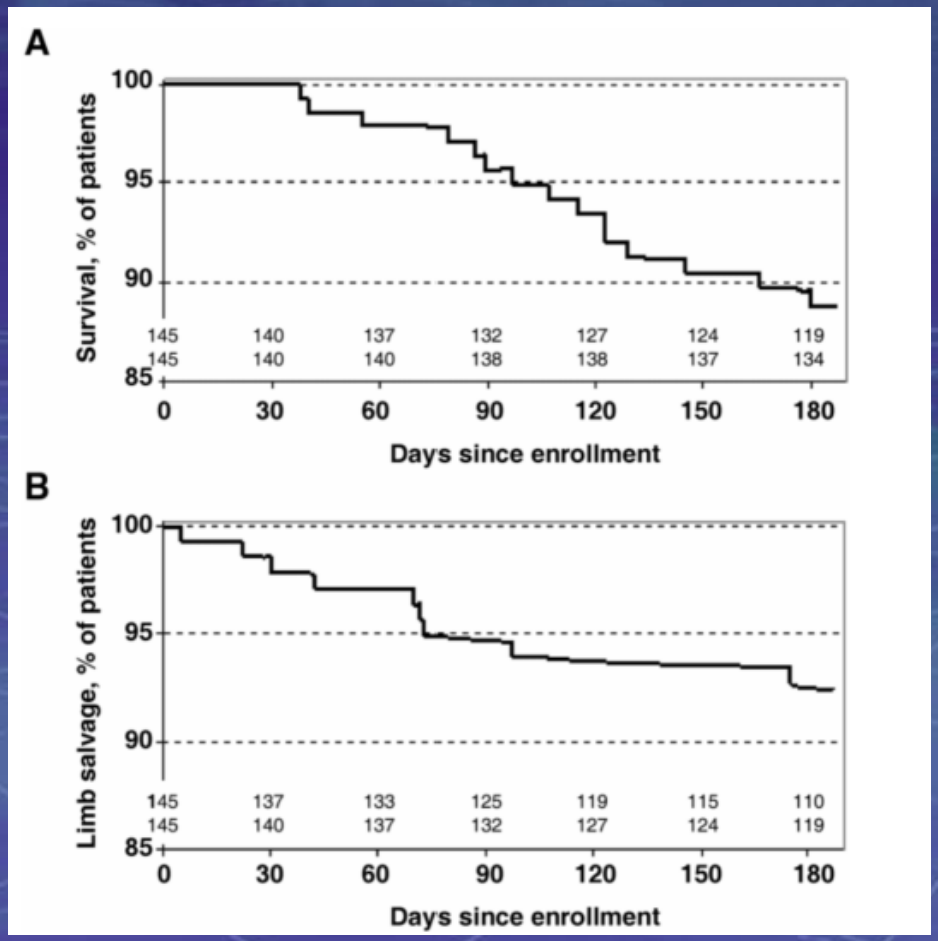
Limb Salvage Following Laser-Assisted Angioplasty for Critical Limb Ischemia: Results of the LACI Multicenter Trial

John R. Laird, MD[1]; Thomas Zeller, MD[2]; Bruce H. Gray, DO[3]; Dierk Scheinert, MD[4]; Mitar Vranic, DO[5]; Christopher Reiser, PhD[6]; and Giancarlo Biamino, MD[4] for the LACI Investigators

J ENDOVASC THER
2006;13:1–11

Limb salvage 93%



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0.9 TURBO ELITE

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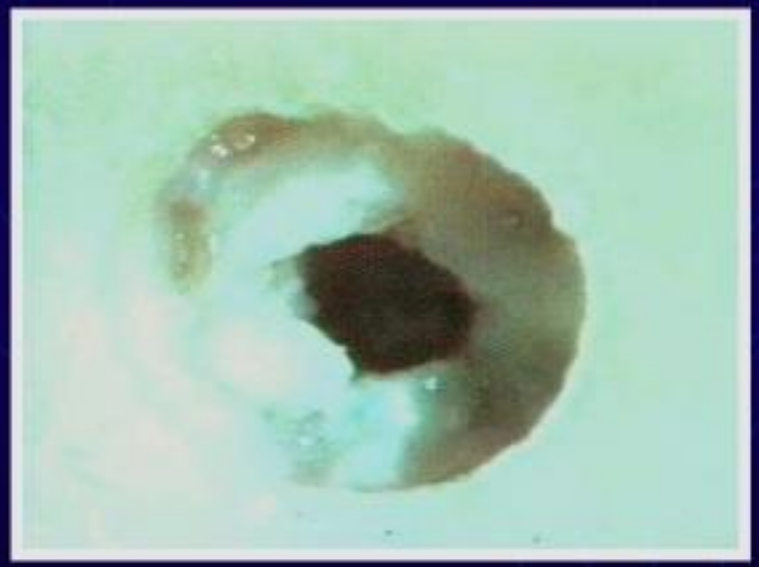
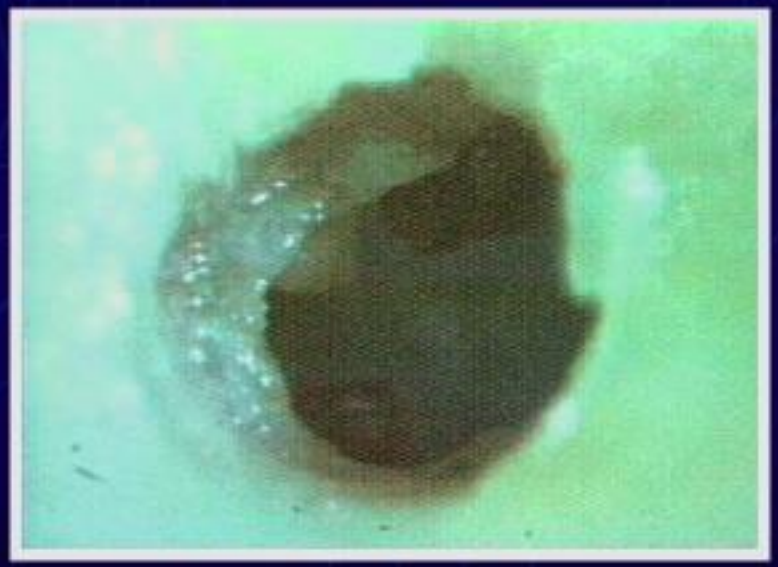
Penetration of calcium

Human cadaver calcified plaque, 1 mm thick



1.4 mm catheter,
60/40, 65 seconds



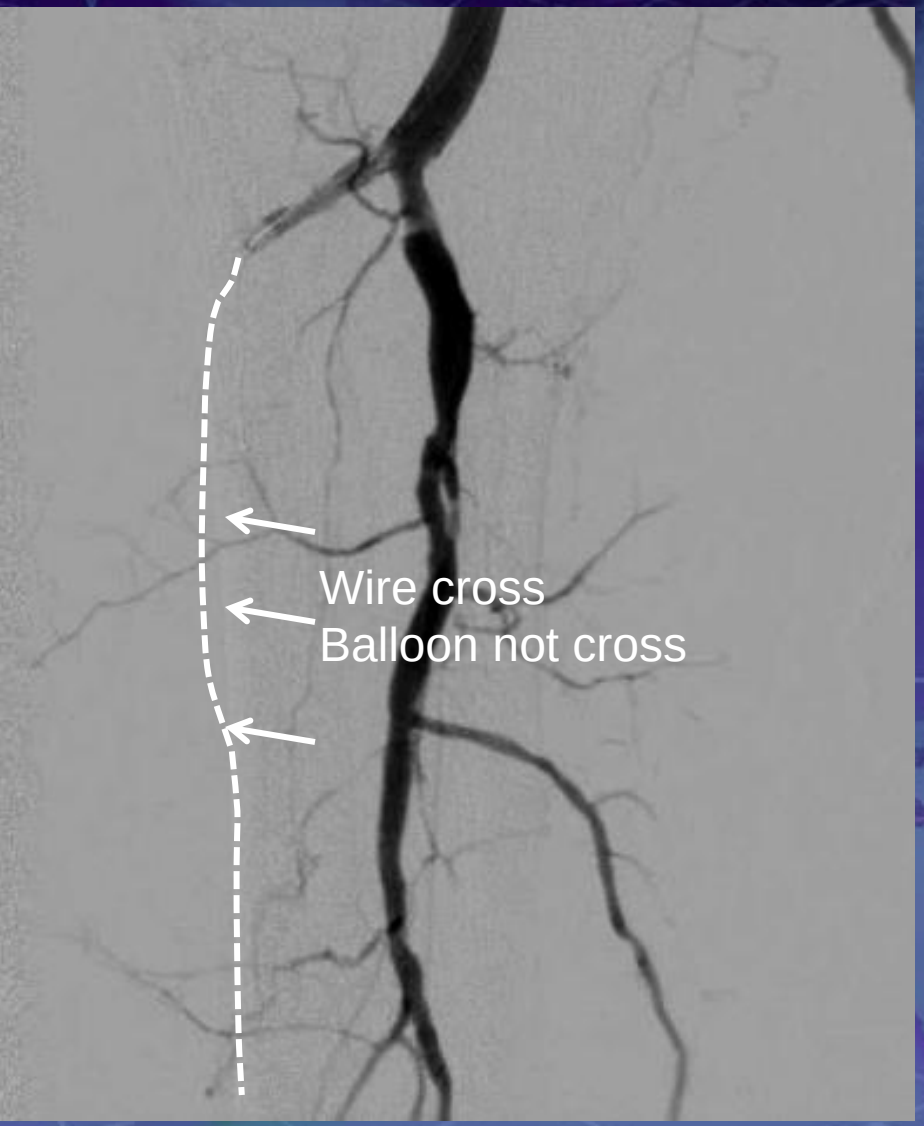
0.9 mm catheter,
80/80, 33 seconds

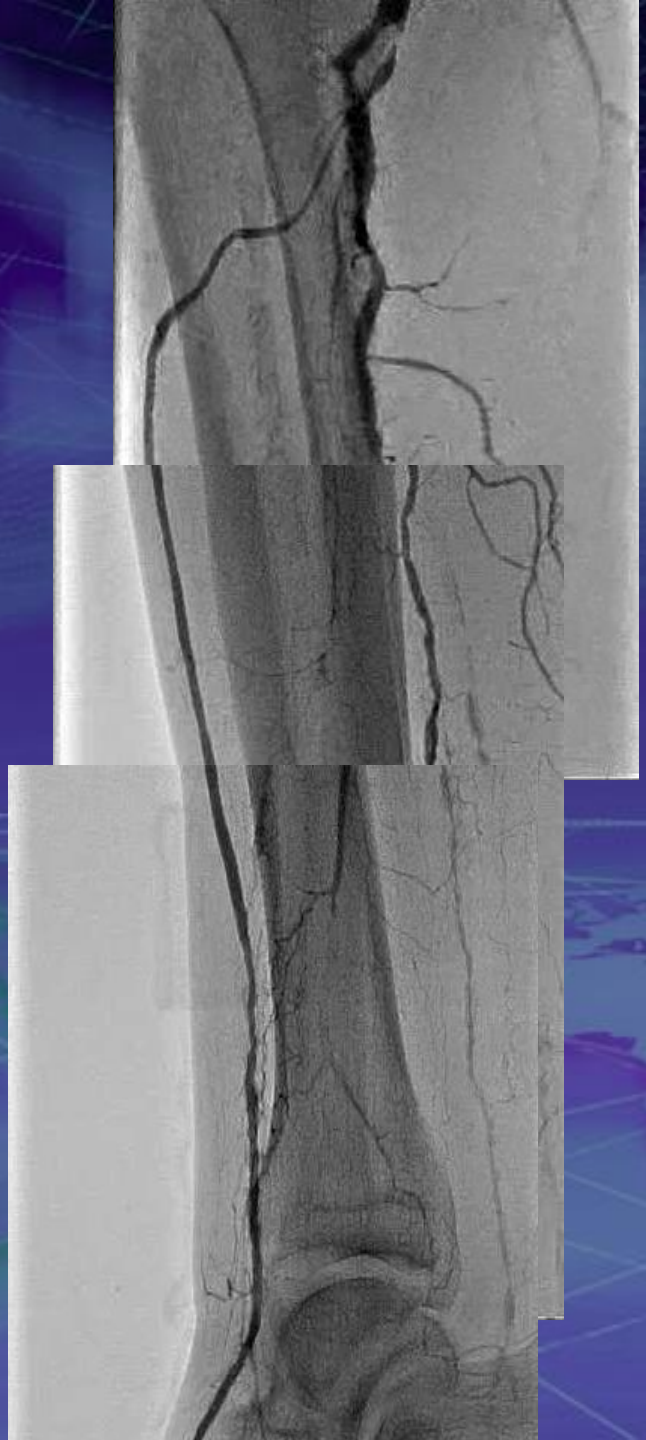
0.9 (80/80) Laser is not almighty

Severe calcified lesion-Balloon uncrossable lesion

↓

0.9 Laser unable to cross

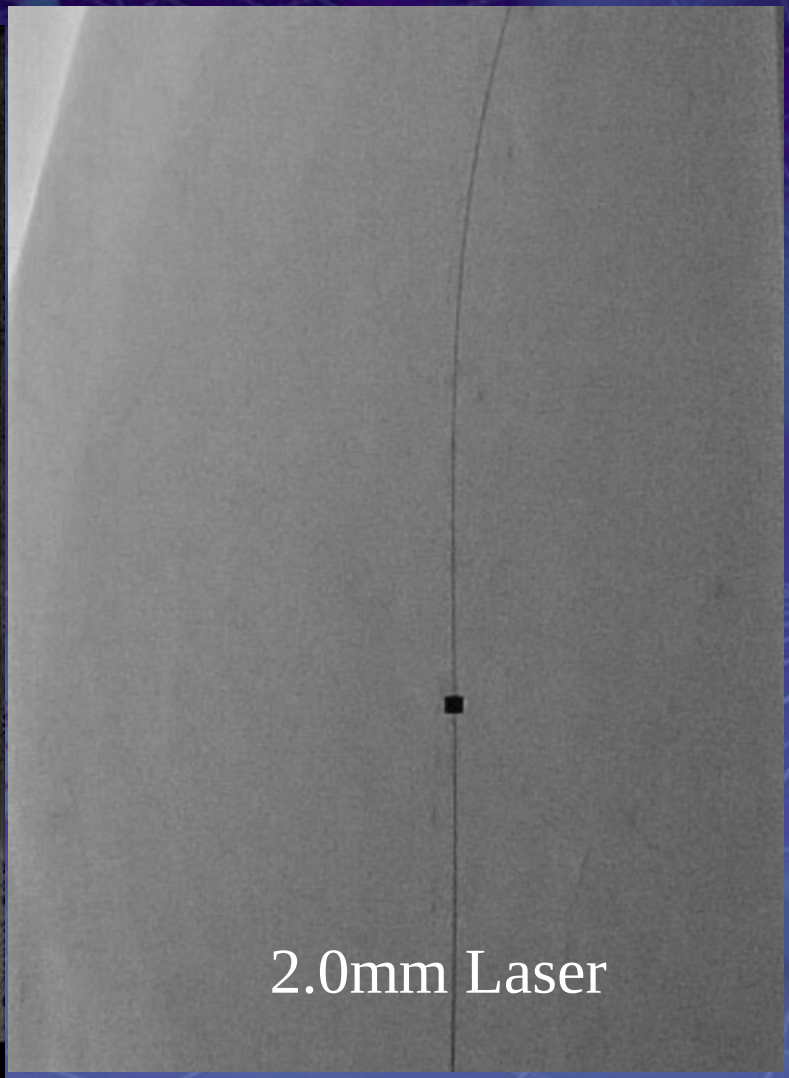

Wire cross
Balloon not cross



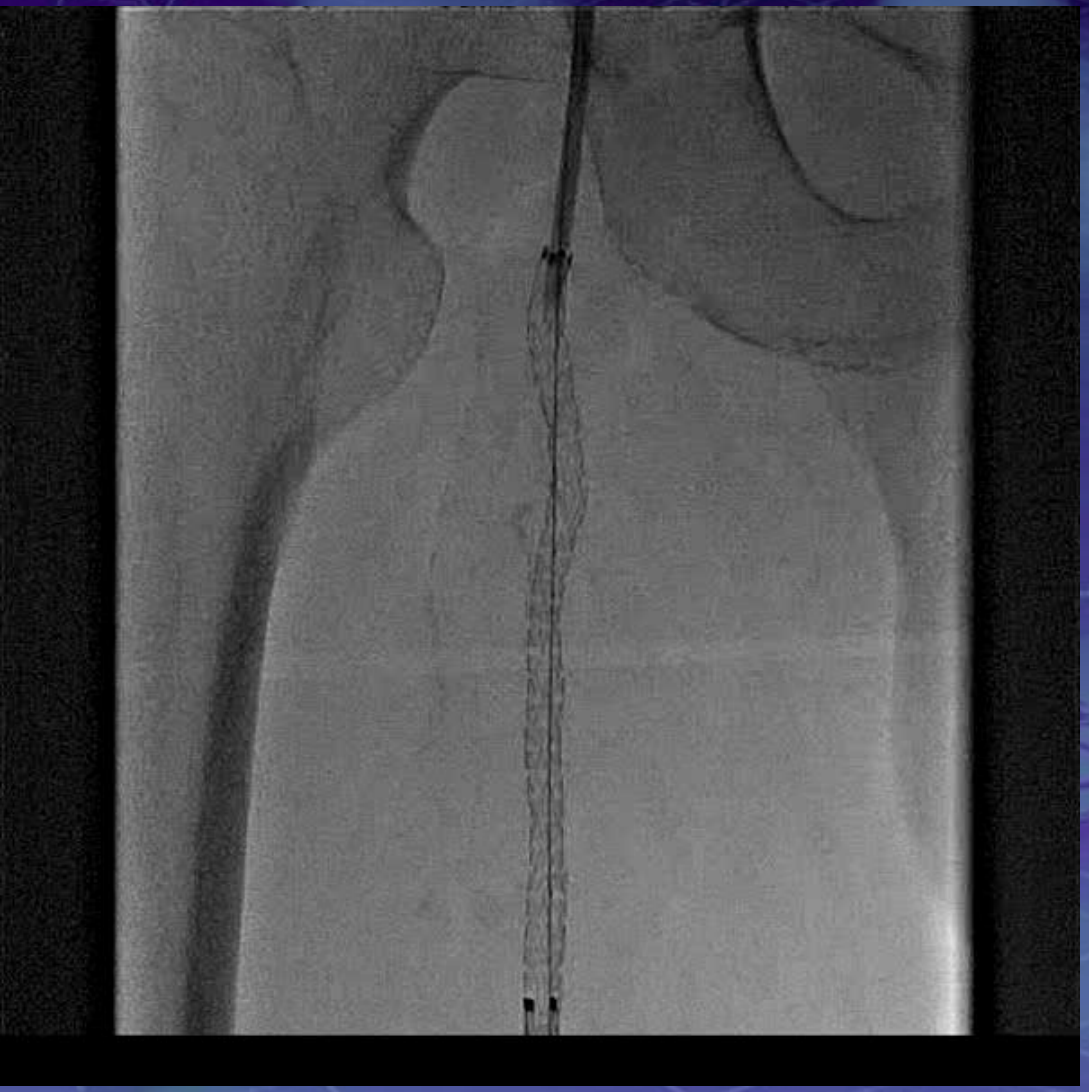
Distal bypass

Perforation due to deep ablation

Laser perforation



Laser perforation



Conclusions

- Laser is the assisted device to facilitate balloon response
- ISR is the ideal indication of laser compared to other debulking devices
- Laser can ablate moderate calcification but dose not work in the severe calcified lesion
- Careful selection of laser size and power are needed to prevent perforation

Thank you!