Plaque Modification During Infrainguinal Intervention: Rationale, Devices and Results

D. Scheinert, MD

Heart Center/Park Hospital

University of Leipzig, Germany

Angioplasty Summit TCT Asia Pacific 2008

Wednesday, April 23 ~ Friday, April 25, 2008

The Convention Center of Sheraton Walkerhill Hotel, Seoul, Korea

CARDIOVASCULAR RESEARCH FOUNDATION

Presenter Disclosure Information

Name: Dierk Scheinert MD

Within the last 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organizations listed below.

Company	Relationship
Abbott	*Advisory Board*
Cordis	*Advisory Board*
Cook Medical	*Advisory Board*
Square one	*Advisory Board*
Novostent	*Advisory Board*
Angioslide	*Advisory Board*
Invatec	*Consultant*
Ev3	*Consultant*
Pathway Medical	*Consultant*
IDEV Techn.	*Stockholder*
CSI	*Stockholder*

Atherectomy Concepts

Rotational

- **Orbital Atherectomy**
- **Pathway Atherectomy**

- **Directional**
  - **Fox Hollow**
  - **Turbo Booster Laser**

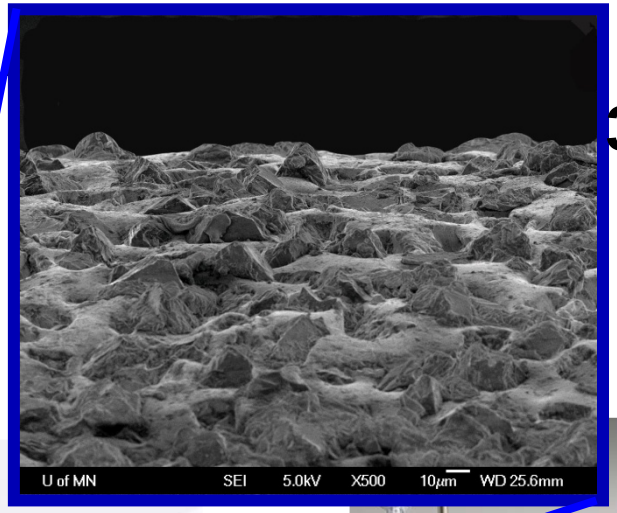
CSI Orbital Atherectomy System

Rotational atherectomy system using an excentric diamond crown

Cr

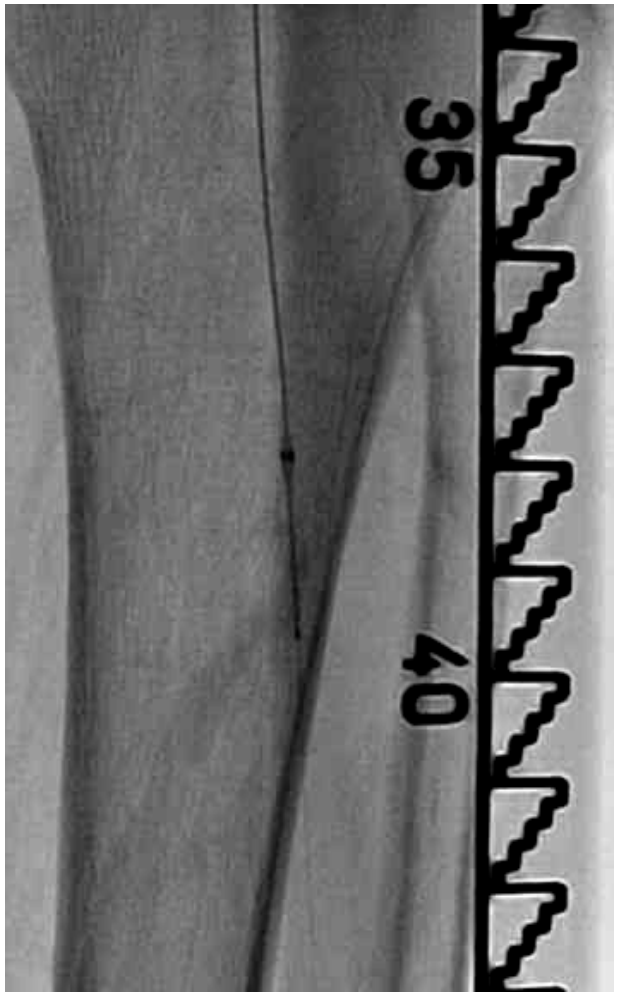
- **1.2 mm**
- **1.7 mm**
- **1.9 mm**

3 different speeds:
80.000 rpm
140.000 rpm
200.000 rpm



OAS Atherectomy System - Case 1

Subtotal stenosis left TPT

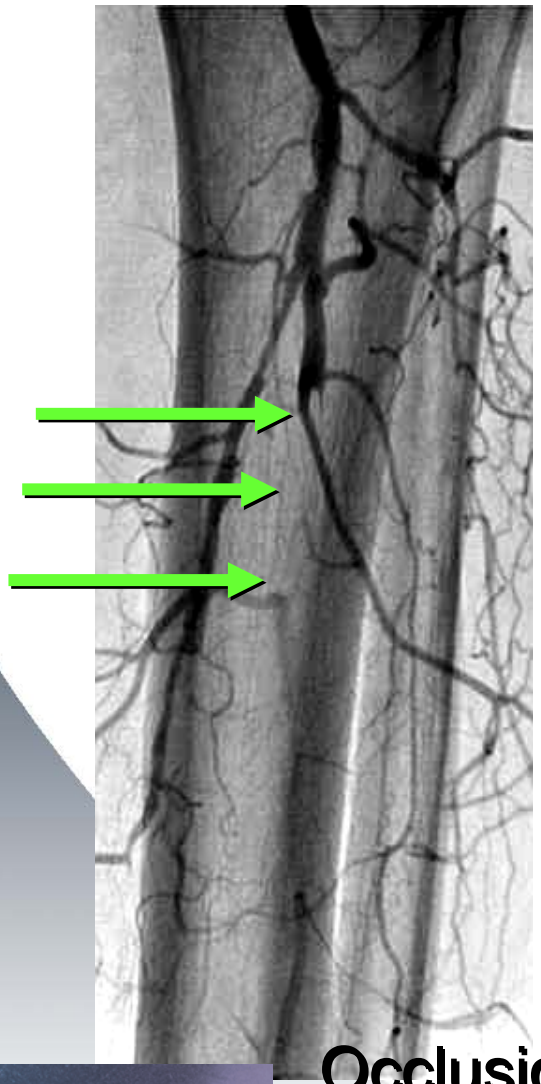


OAS 1.7 mm

OAS Atherectomy System - Case 1

Stand-alone result

OAS Atherectomy System - Case 2



Occlusion left TPT

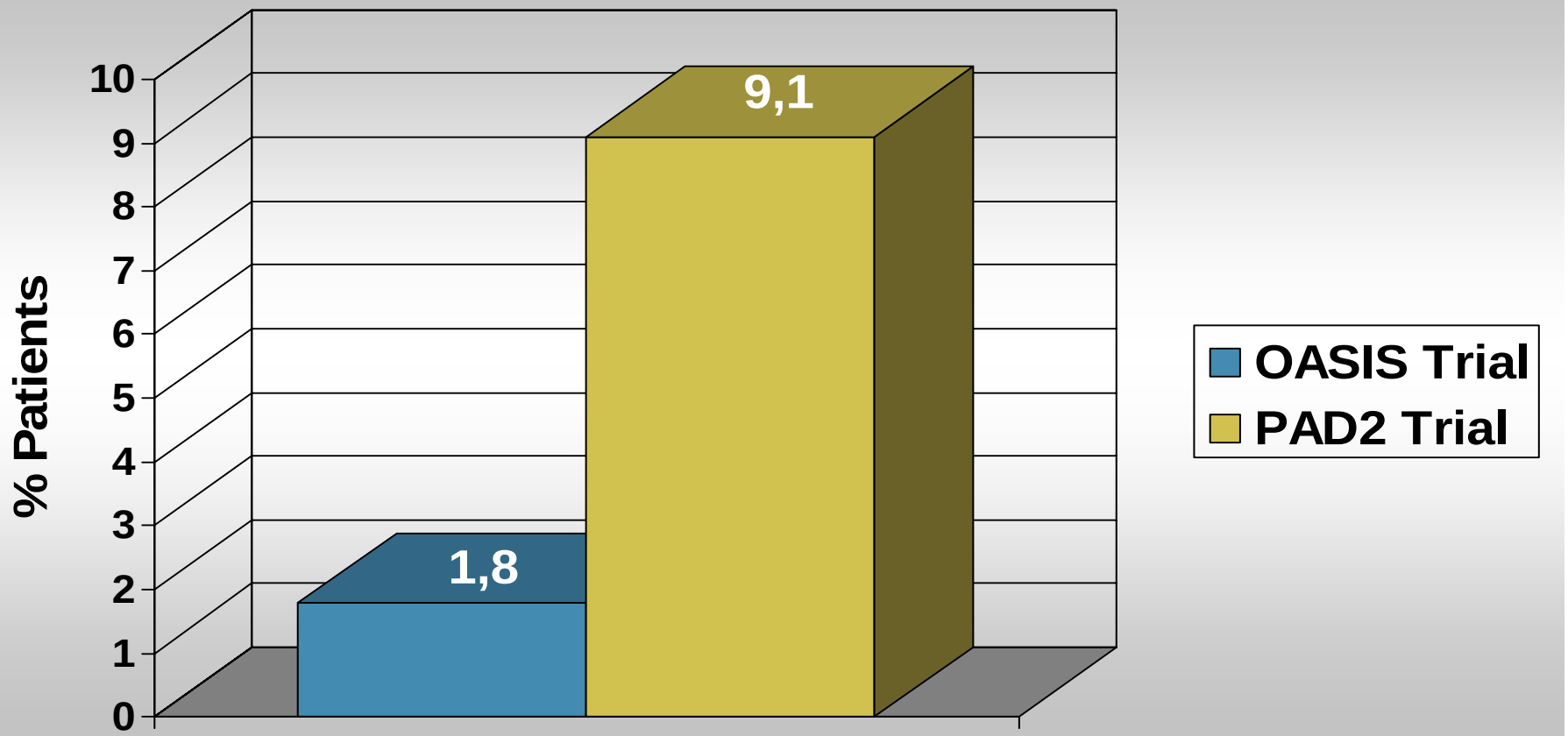
Stand-alone result OAS 1.7mm

Results

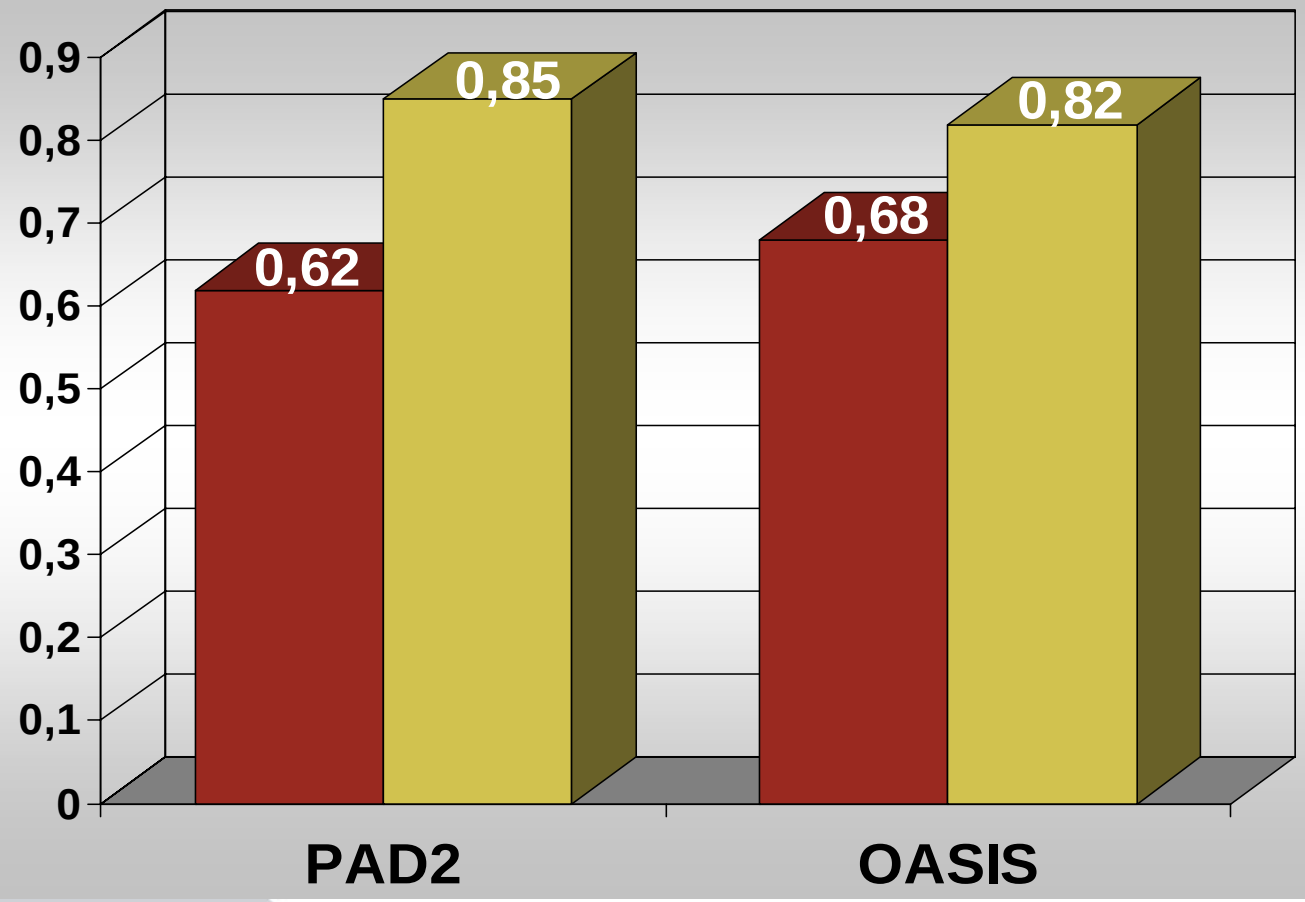
Endpoint	PAD2 (EU)	OASIS (US)
Primary efficacy endpoint Acute debulking measured angiographically	55% reduction	62% reduction
Device Success: ≤ 30% residual stenosis with orbital atherectomy alone (before adjunctive therapy)	42%	78%
Adjunctive Therapy	60%	42%

MSOffice2 , 2007-07-16

Target Lesion Revascularization @ 6 months



Average ABI Score

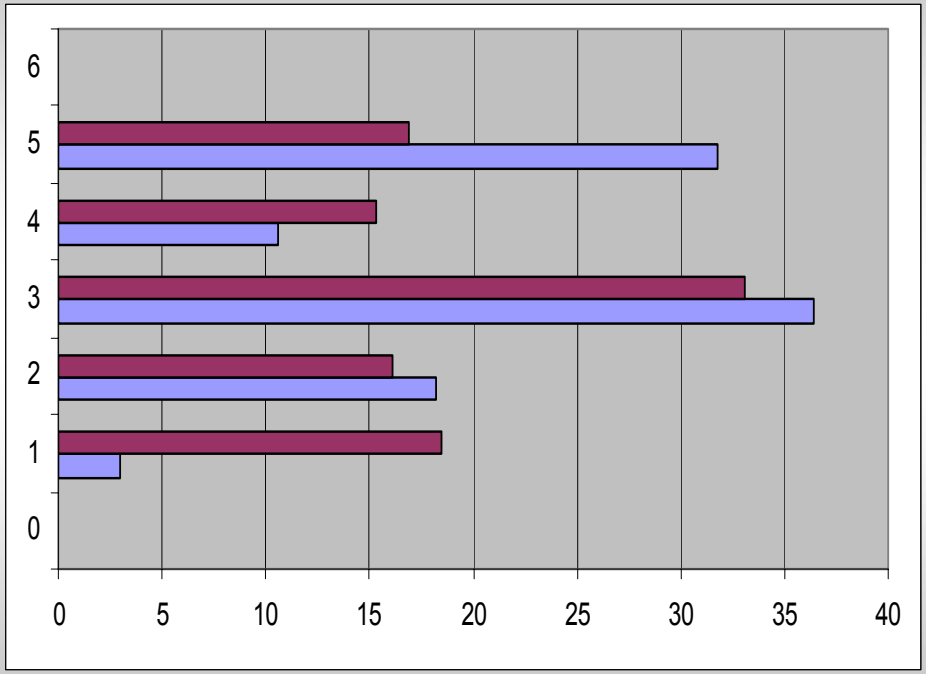


p < 0.0001

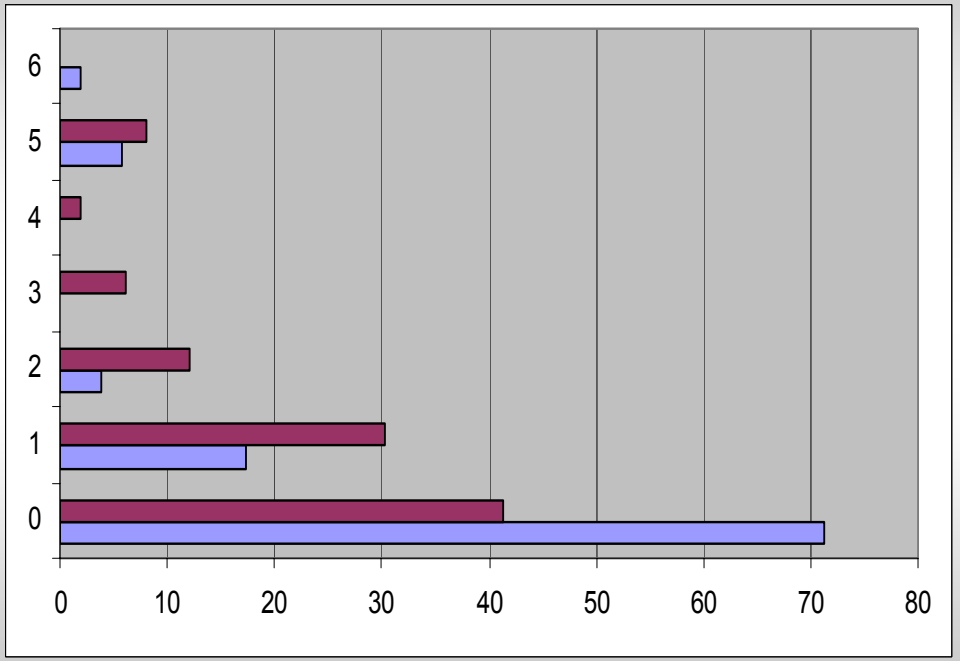
p < 0.0009

Rutherford Classification Comparison

Baseline



180 Days



PAD2

OASIS

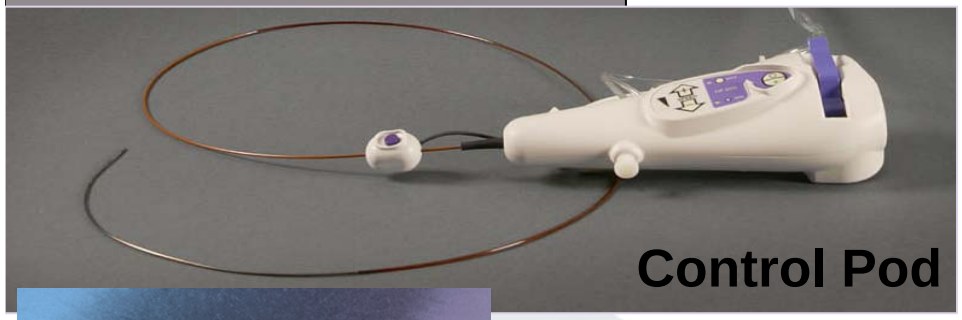
Standard and Solid Crowns

Standard Crown
1.7 x orbit
0.014-inch platform

Solid Crown
Up to 2.5x orbit
For larger vessels

Pathway PV Atherectomy System

Console



Control Pod

OTW 133cm Rotating System

- 55 krpm
- .014 guide wire
- 8F sheath

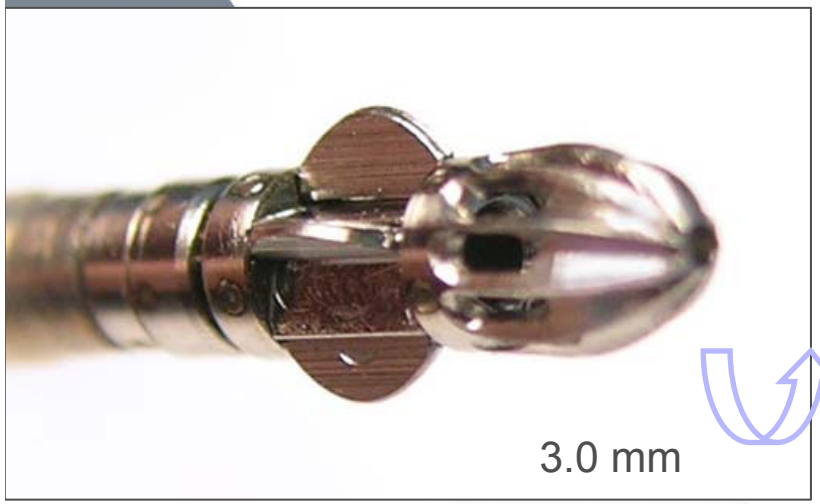
Simple data display and set up outside sterile field

Integrated system control within sterile field

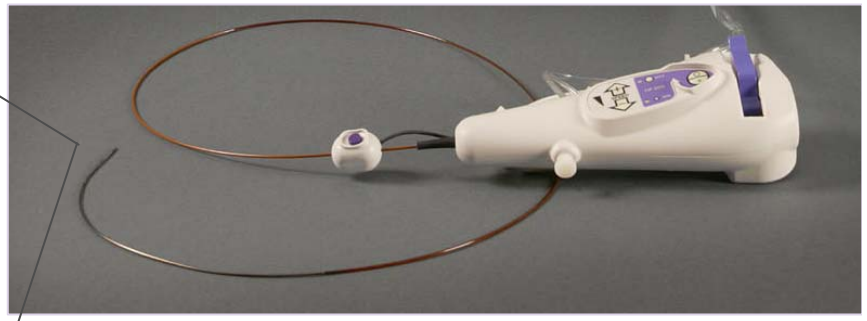
- speed
- size / expansion

Pathway PV Atherectomy System

2.1 mm



3.0 mm



- **Differential scraping flutes remove all plaque types**
- **Aspiration ports collect plaque and thrombus**
- **One step expansion**

CARDIOVASCULAR RESEARCH FOUNDATION

Pathway PVD Study

- *Prospective, multi-center registry*
  - 172 patients (210 lesions), 9 study sites in Europe
- *Angiographic core lab and independent CEC adjudication*
- *Inclusion criteria:*
  - Rutherford Class 1-5
  - Reference vessel size: 3mm-5mm
  - Lesion length: up to 10cm
  - Diameter stenosis ≥ 70% and can be crossed by a guidewire

Leipzig – 43 patients Enrolled in PVD Study (March 06 – Dec 06)

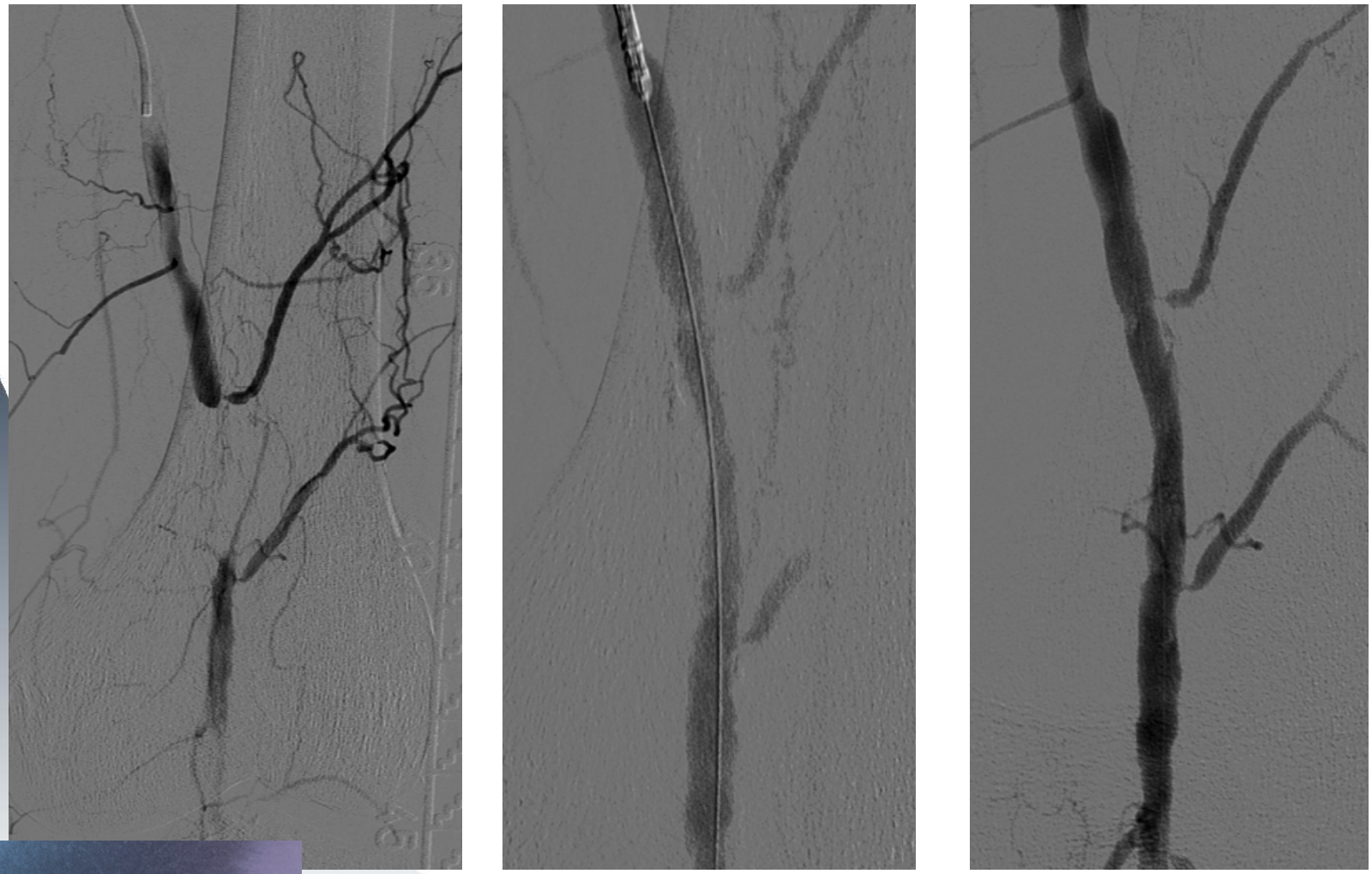
- *Average reference vessel* *3.9mm*
- *Average lesion length* *4.6cm*
- *Moderate to high calcium* *45%*
- *Occlusion* *33%*
- *Lesion Location:*
  - SFA 64%
  - Popliteal 32%
  - Tibial/ Peroneal 4%

Procedural Outcomes

- **Device success rate*** — **99%**
- **PVS activation time** — **4:19 minutes**
- **<u>Adjunctive treatment</u>**
  - **None** — **38%**
  - **Balloon angioplasty** — **58%**
  - **Stent** — **4%**
- **<u>Angiographic results (% stenosis)</u>****
  - **Baseline** — **88.6%**
  - **Post PVS** — **34.0%**
  - **Post adjunctive** — **25.0%**

**** Defined as crossing and debulking lesion***
***** Core lab analysis for lesions meeting inclusion criteria of ≥70% diameter stenosis***

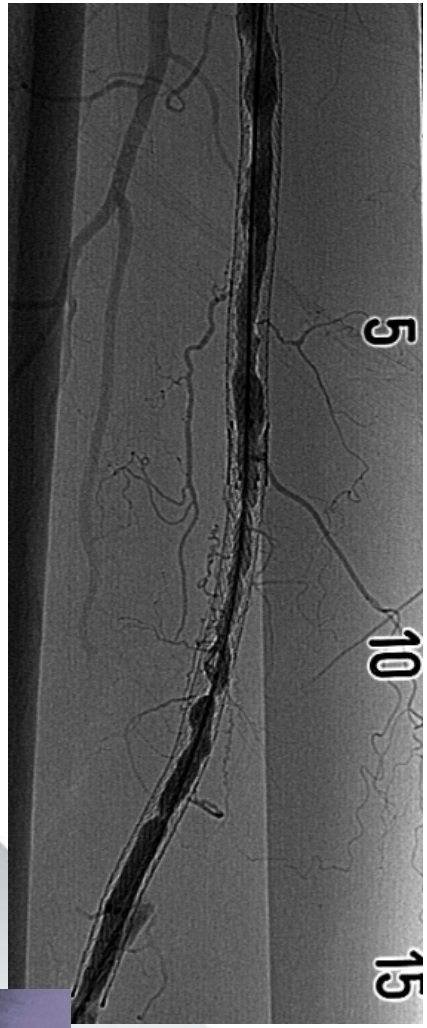
Left popliteal artery occlusion



Leipzig - 6 Month Patency

N = 37	Number of patients (%)
Target Lesion Revascularization	3 (7.7%)

...still ahead, Pathway for ISR!



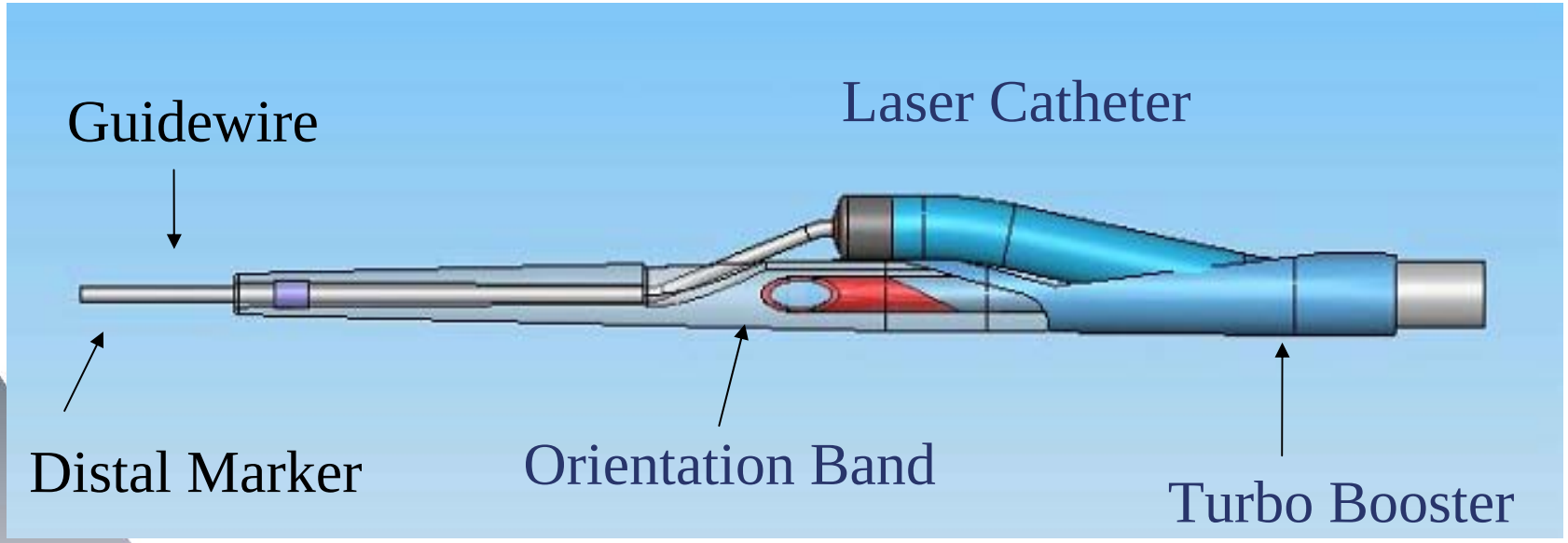
Atherectomy Concepts

Rotational

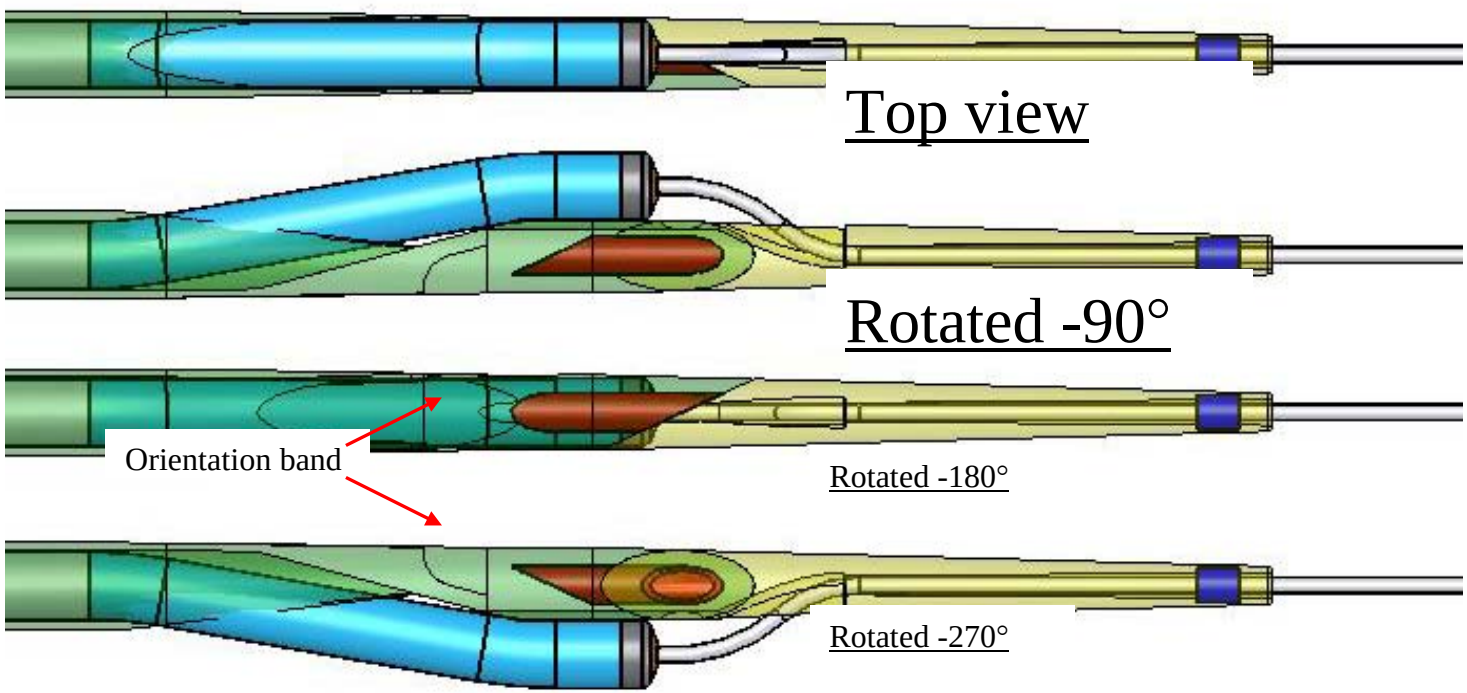
- **Orbital Atherectomy**
- **Pathway Atherectomy**

- **Directional**
  - **Fox Hollow**
  - **Turbo Booster Laser**

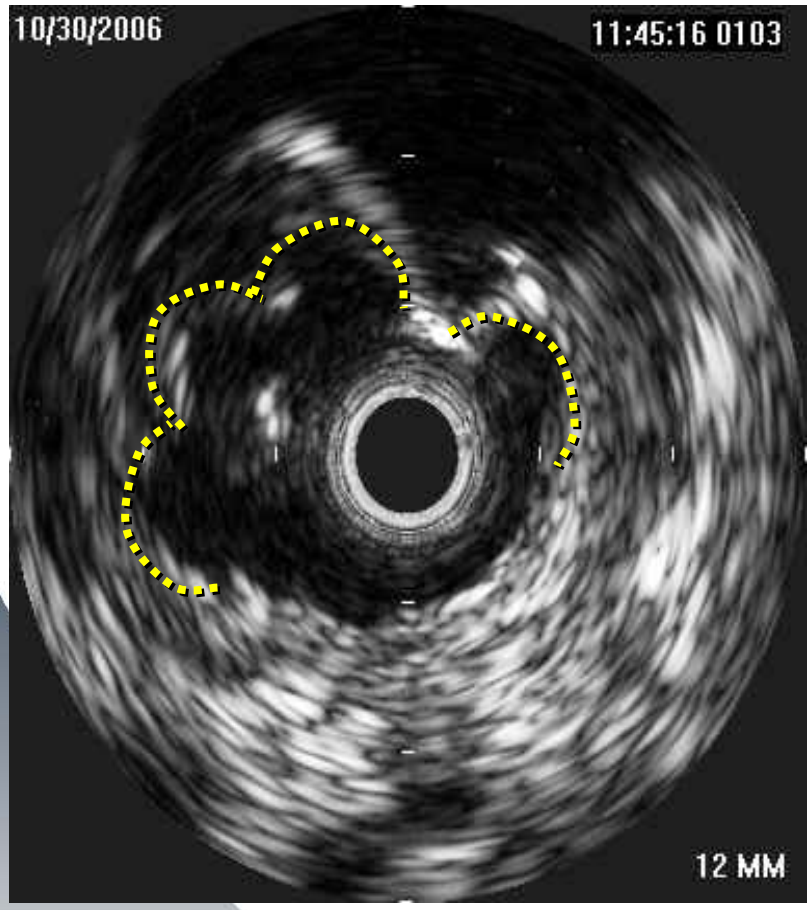
The Booster Catheter
The Next Generation Laser-Catheter

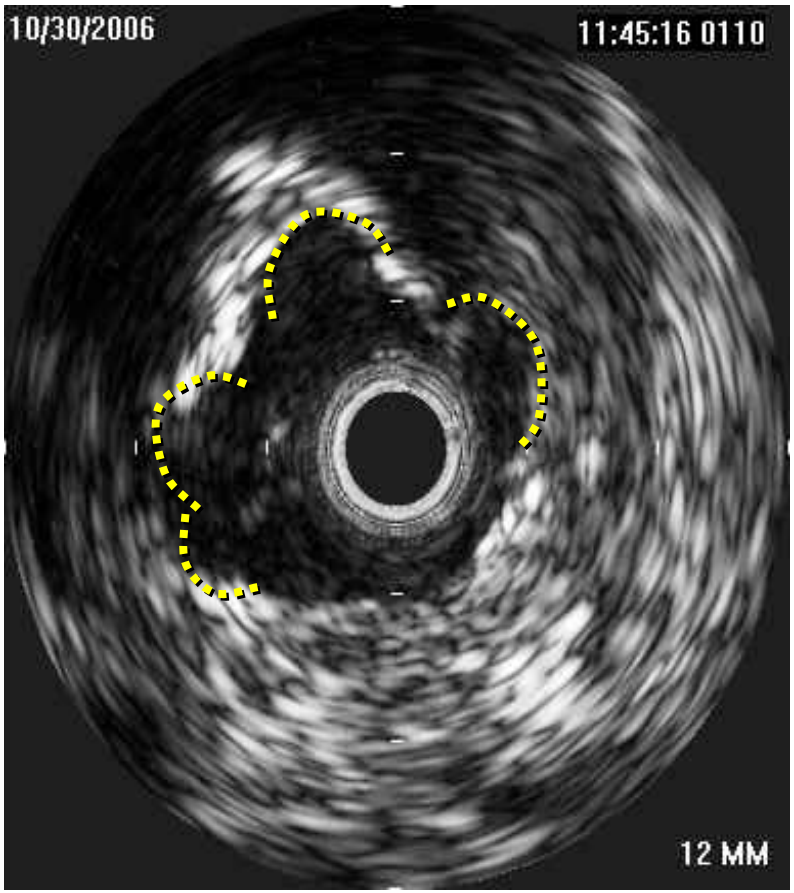


The Booster-Laser Catheter



8F Booster-Laser for native SFA





IVUS after 8 French Turbo-Booster-Laser

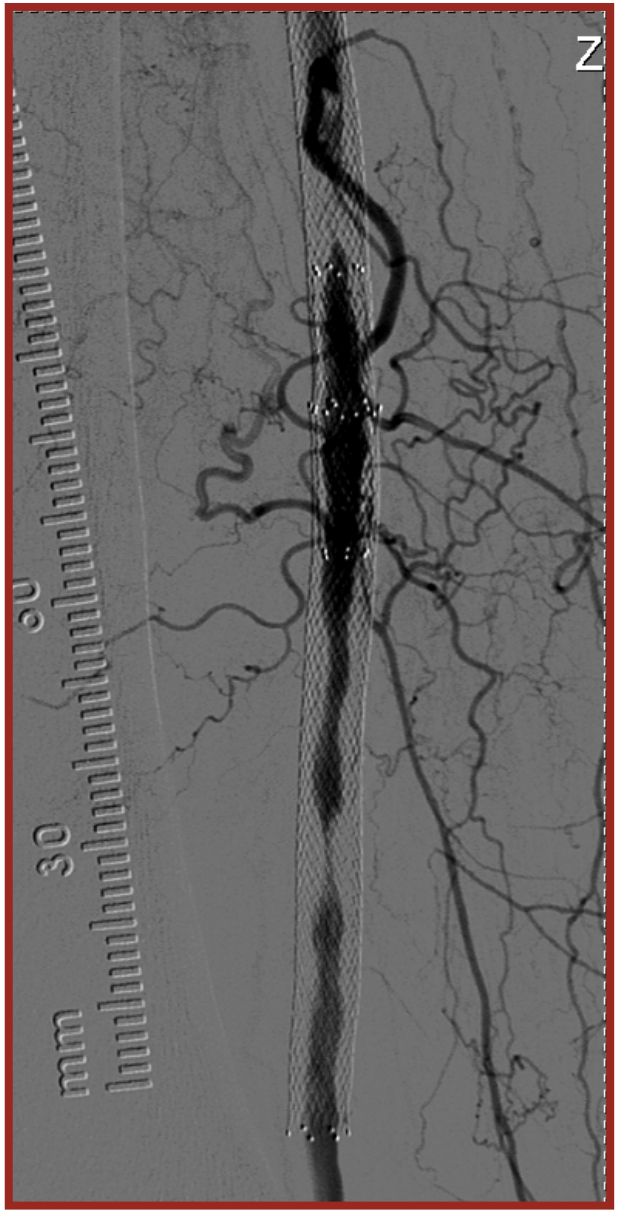
Turbo-Booster Laser-Catheter for Treatment of SFA-In-Stent Restenosis

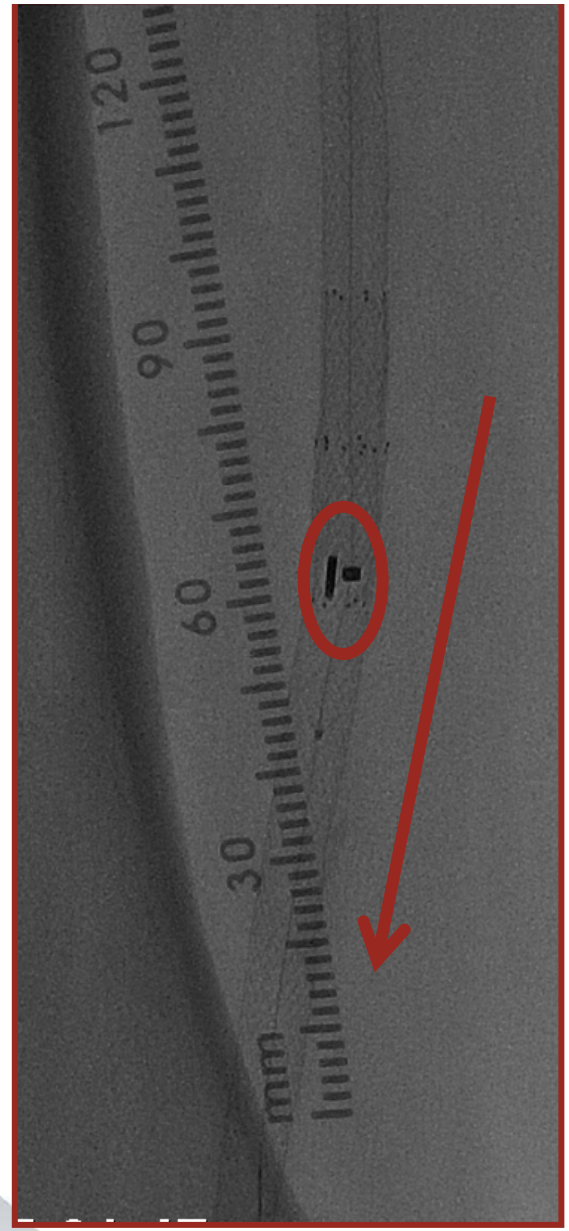
The Patent Trial

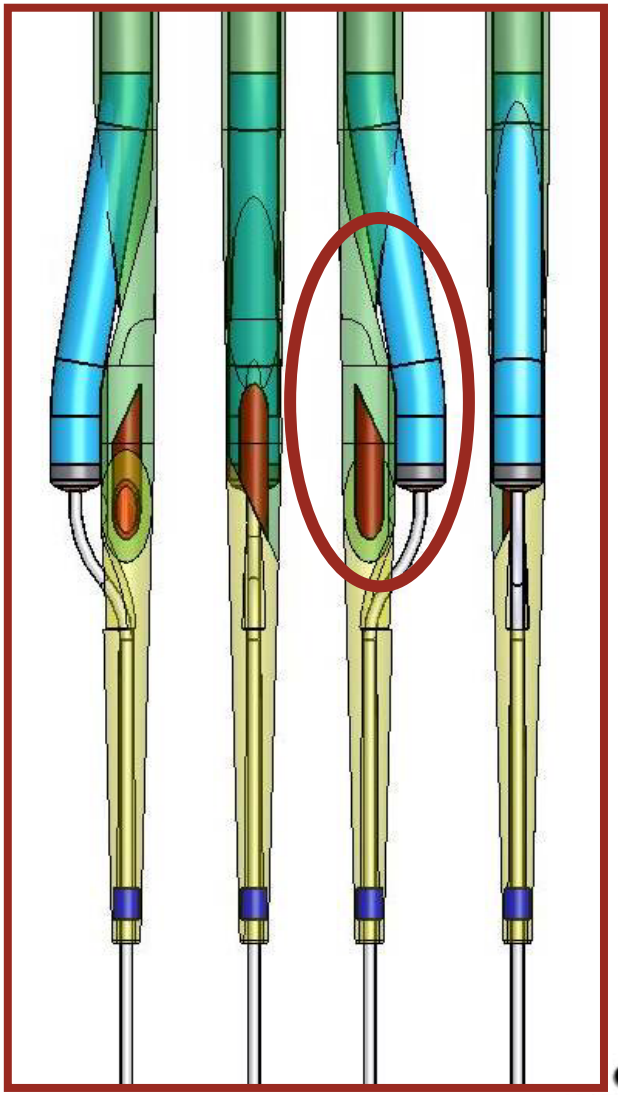
Photo-Ablation using the Turbo-booster and Excimer laser for iN-stent restenosis Treatment

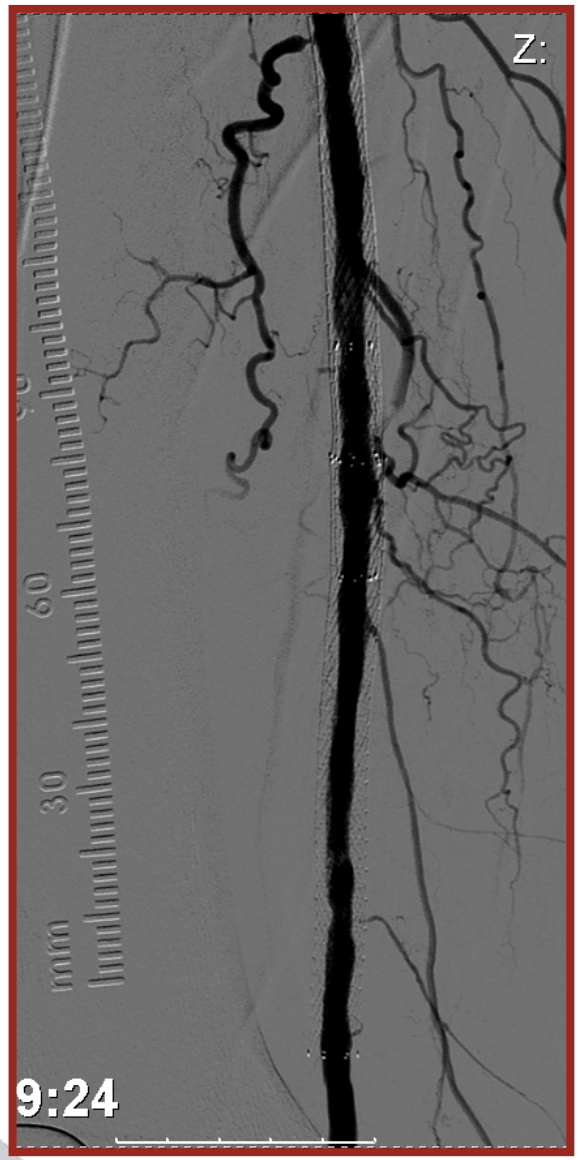
- Non-randomized, prospective trial at 4 german centers
- Up to 80 patients with in-stent restenosis of the SFA
- Endpoints:
  - Safety of the treatment
  - 6 and 12 months patency-rate

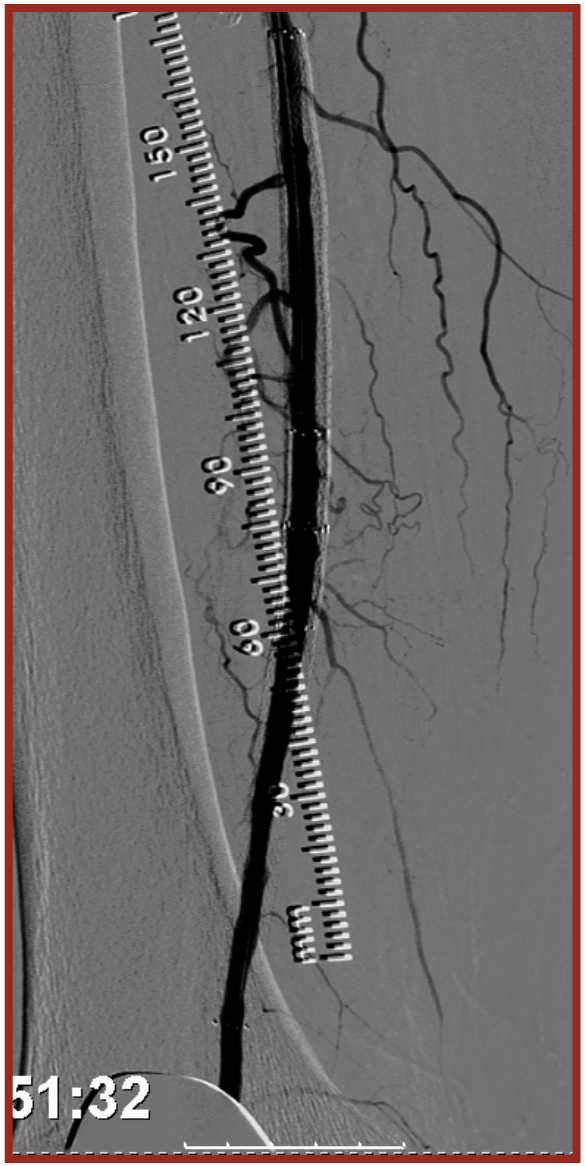

:55:42


Z


120
90
60
30
mm



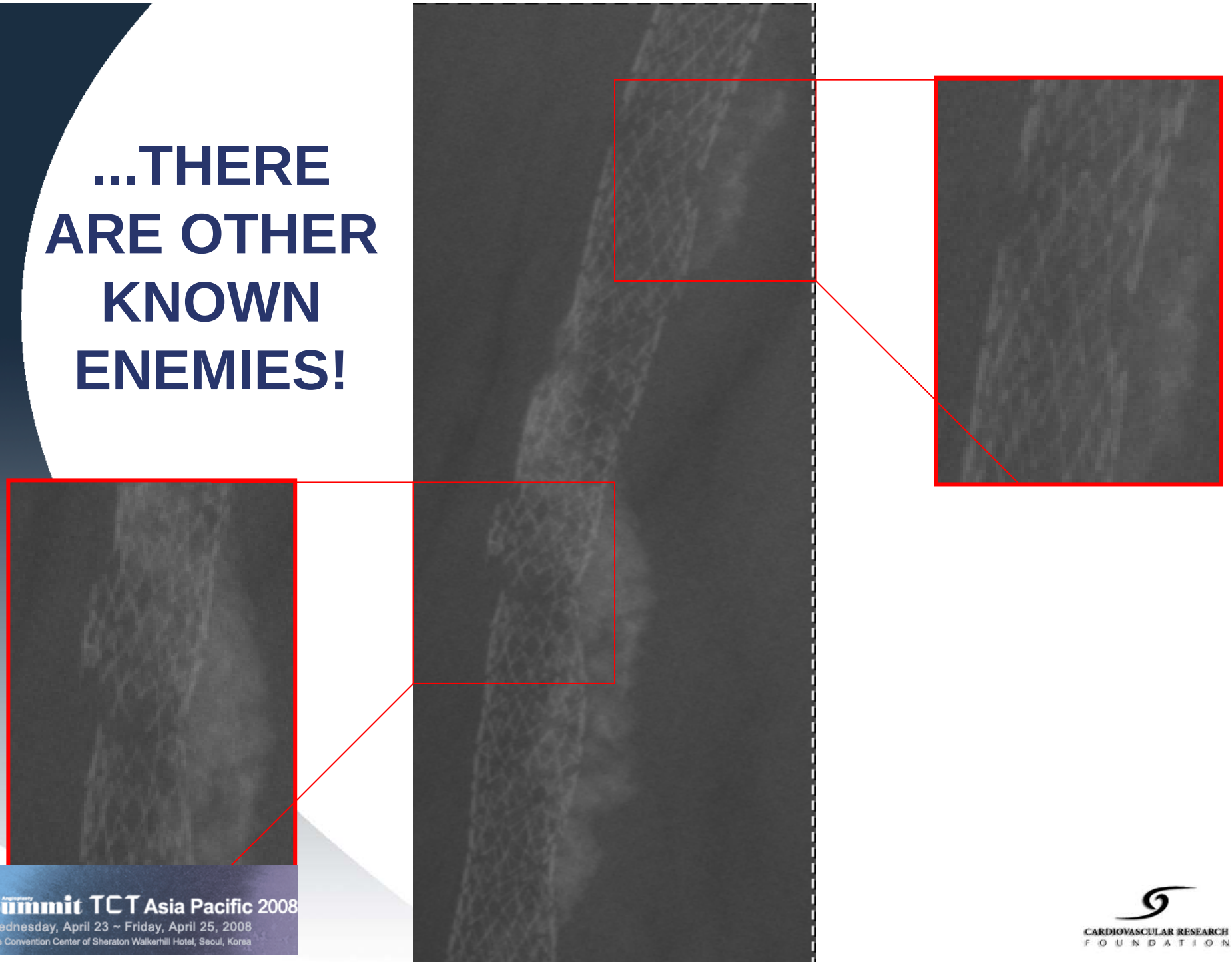




Summit TCT Asia Pacific 2008
Wednesday, April 23 ~ Friday, April 25, 2008
The Convention Center of Sheraton Walkerhill Hotel, Seoul, Korea

CARDIOVASCULAR RESEARCH
FOUNDATION

...THERE ARE OTHER KNOWN ENEMIES!



SFA-Stent Deployment Evaluation
n=20

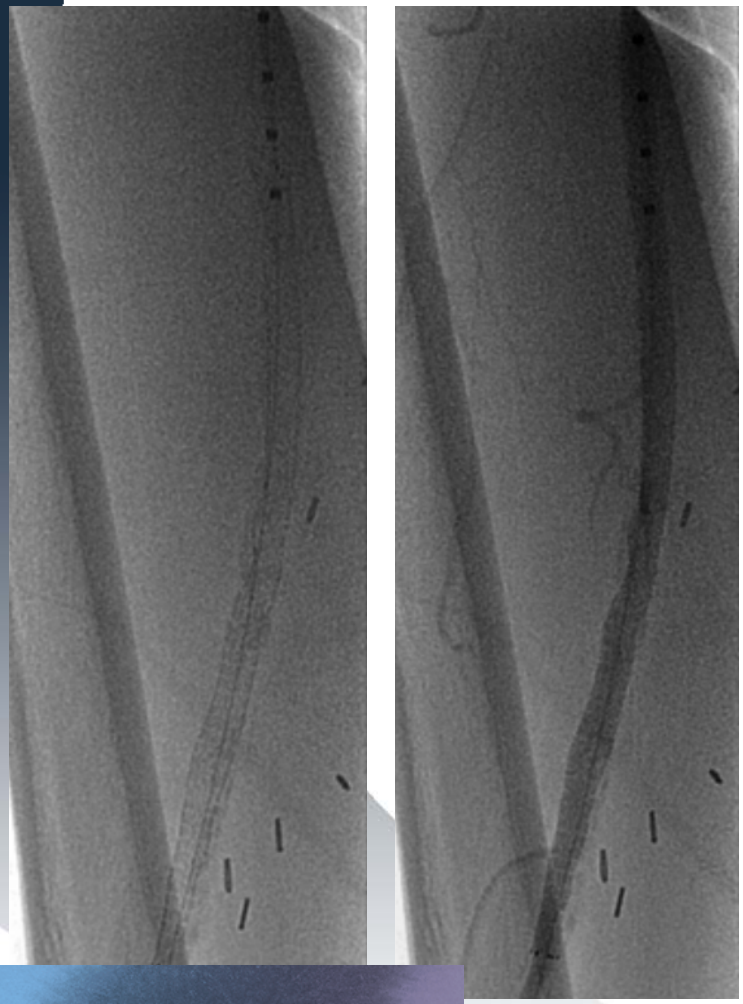
Lesions Characteristics

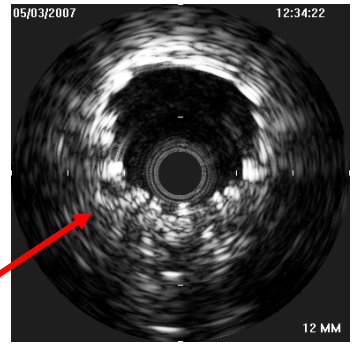
Length	69±30mm (30-150mm)
% Stenosis	90±8%
Total occlusions	n=5 (25%)

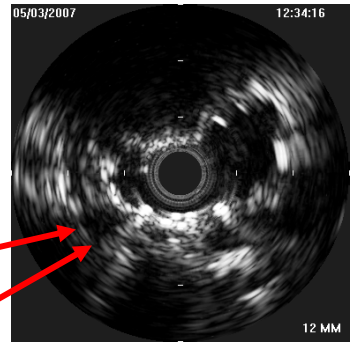
Degree of Calcification (0-3)	1.6±0.8
0 – no calcifications	1
1 – mild calcifications	9
2 – moderate calcifications	7
3 – severe calcifications	3

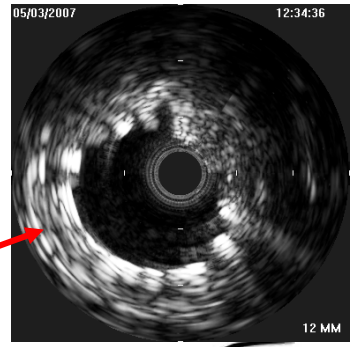
Angio AP projection

Angio LAO projection









Calcified vs. Non-calcified Lesions

	Calcified lesions **(grade 2-3)** **n=10**	Non-calcified lesions **(grade 0-1)** **n=10**	P value
MLD_{angio} **(mm)**	**4.1±0.7**	**4.8±0.4**	0.02
$\%DS_{angio}$	**30±8**	**16±4**	0.0007
MLD_{IVUS} **(mm)**	**3.8±0.7**	**4.6±0.3**	0.01
$\%DS_{IVUS}$	**30±11**	**17±4**	0.01
Procedural Success			
$\%DS_{AP,RAO,LAO\ angio}$ >30	**8 (80%)**	**0**	0.001
$\%DS_{IVUS}$ >30	**6 (60%)**	**0**	0.01

DS – diameter stenosis, MLD – minimal luminal diameter

…solutions?

Aggressive Atherectomy prior to stent implantation?

- **OR/AND**

Improve stent designs (with higher radial force)?

…both concepts currently under investigation at our institution