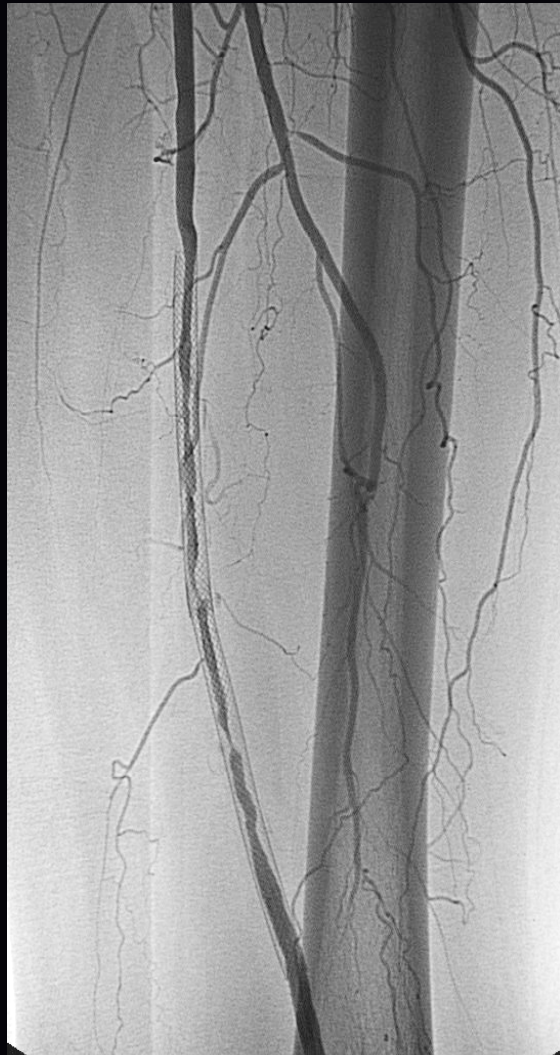


Current Treatment of Femoropopliteal Instent Restenosis

John R. Laird, MD
Professor of Medicine
Medical Director of the Vascular Center
UC Davis Medical Center

SFA In-stent Restenosis



- Common: 18%- 40% at 12 months in recent trials
- More common in the setting of long SFA occlusions, small diameter SFA, diffuse disease
- May be associated with stent fracture or stent overlap

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Potential Treatment Options for ISR

- POBA
- Cutting/scoring balloon
- Cryoplasty
- Drug-eluting balloon
- Brachytherapy
- Debulking
- Restent (BMS or DES)
- Stent graft

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POBA vs Cutting Balloon for ISR

- 40 patients randomized to cutting balloon (CB) or POBA for ISR – lesions up to 20 cm in length
- Primary endpoint: Primary patency at 6 months by duplex ultrasound (PSVR > 2.4)
- Clinical success assessed by change in ABI and treadmill walking distance

POBA vs Cutting Balloon for ISR

Mean lesion length = 8 cm

Primary patency at 6 months poor for both groups:

- | | | |
|-------------------|-----|----------|
| – Cutting balloon | 27% | $p = ns$ |
| – POBA | 35% | |

No difference in walking difference:

- | | | |
|-------------------|-------|----------|
| – Cutting balloon | 103 m | $p = ns$ |
| – POBA | 117 m | |

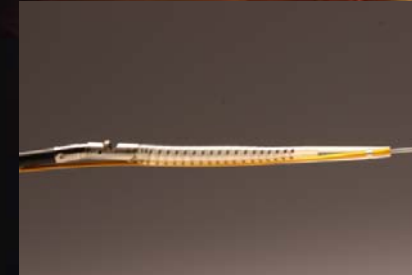
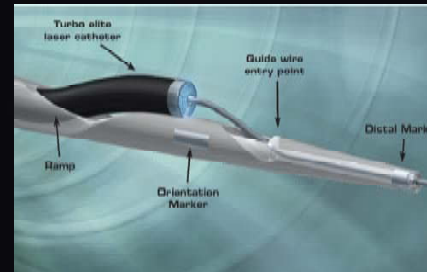
No difference in ABI

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Debulking for ISR

Potential advantages:

- Better angiographic and hemodynamic result
- Remove thrombus within stent to reduce distal embolization (Laser, Pathway)

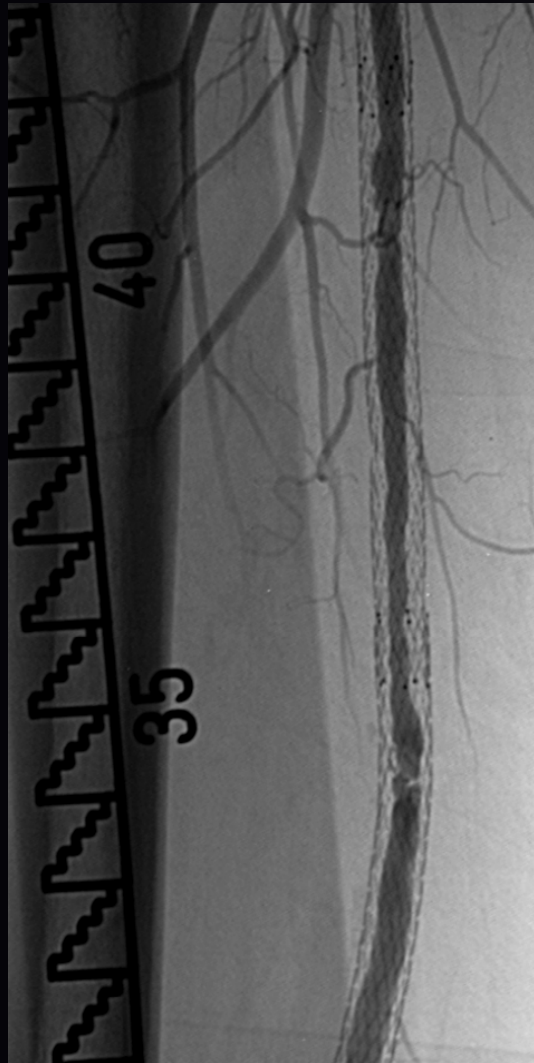


Not FDA approved for treatment of in-stent restenosis.

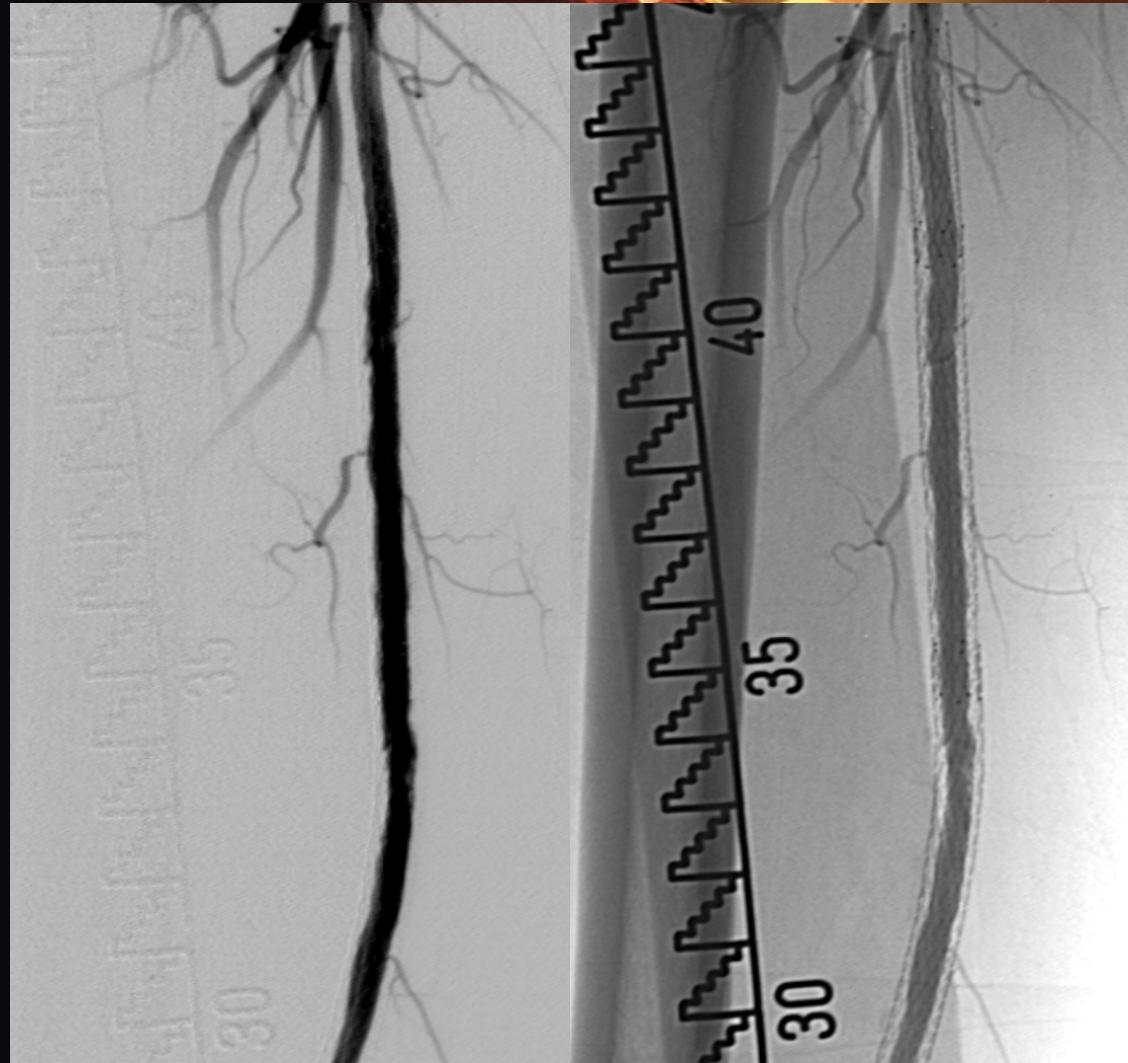
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Result after 2.0mm Turbo Booster-Laser



before



after treatment



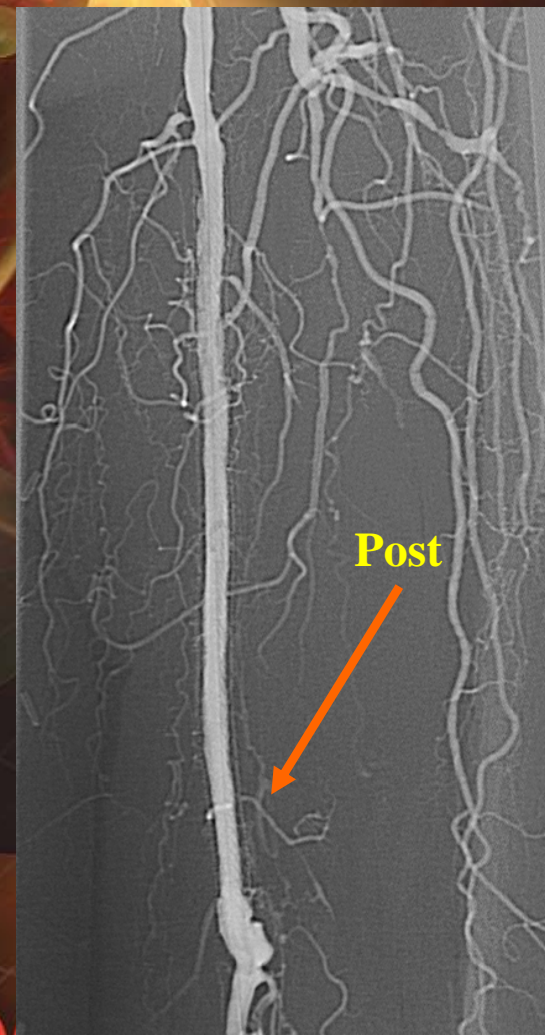
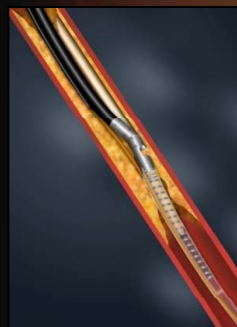
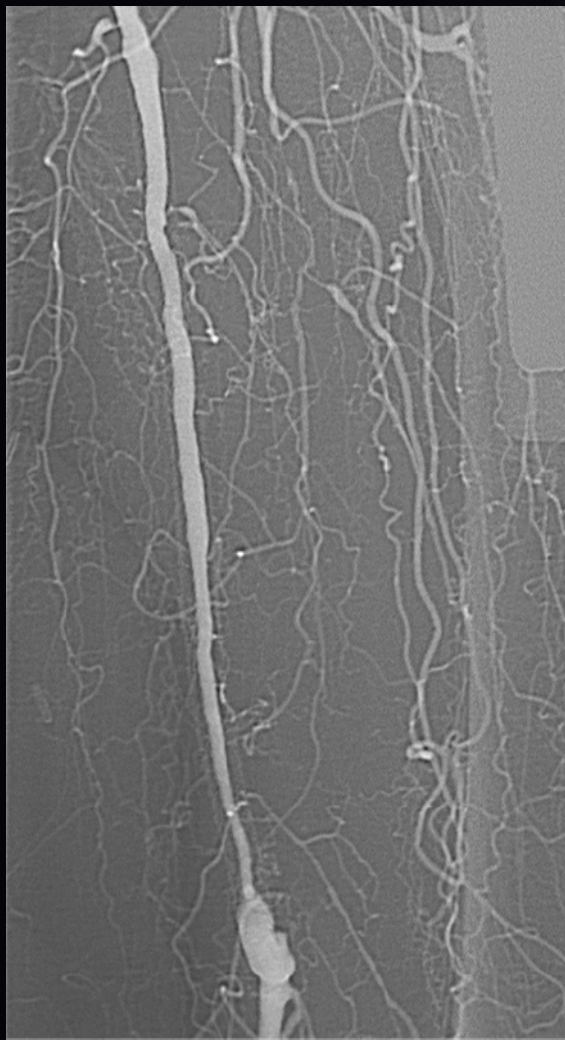
PATENT

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

EXCITE ISR

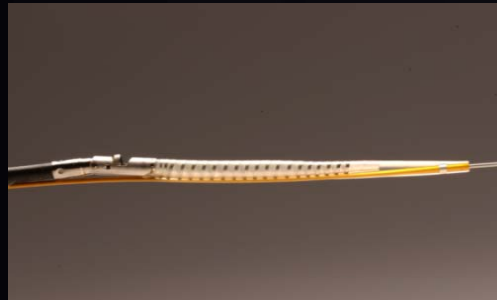
***TEXCimer Laser Randomized Controlled Study for
Treatment of Femoropopliteal In-Stent Restenosis)***

Excisional Atherectomy for ISR



Excisional Atherectomy for ISR

- 43 limbs with femoropopliteal ISR
- Mean lesion length 131 ± 111 mm
- Additional low pressure balloon inflation in 59%
- Primary patency at 12 months: 54%
- Primary patency at 18 months: 49%



J Am Coll Cardiol.2006;48:1573-8.

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Treatment of ISR: *UC Davis Experience*

- 21 limbs in 20 patients treated over a 2-year period
- Multiple modalities used:
 - Laser and PTA 52.4%
 - Excisional atherectomy and PTA 9.5%
 - Cryoplasty 9.5%
 - Stenting (or stent graft) 19.0%
 - POBA 9.5%

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Treatment of ISR: *UC Davis Experience*

- Pattern of in-stent restenosis
 - Type 1 (focal) 23.8%
 - Type 2 (diffuse) 19.0%
 - Type 3 (proliferative) 14.3%
 - Type 4 (total occlusion) 42.9%
- Mean lesion length: **13.6 ± 11.4 cm**

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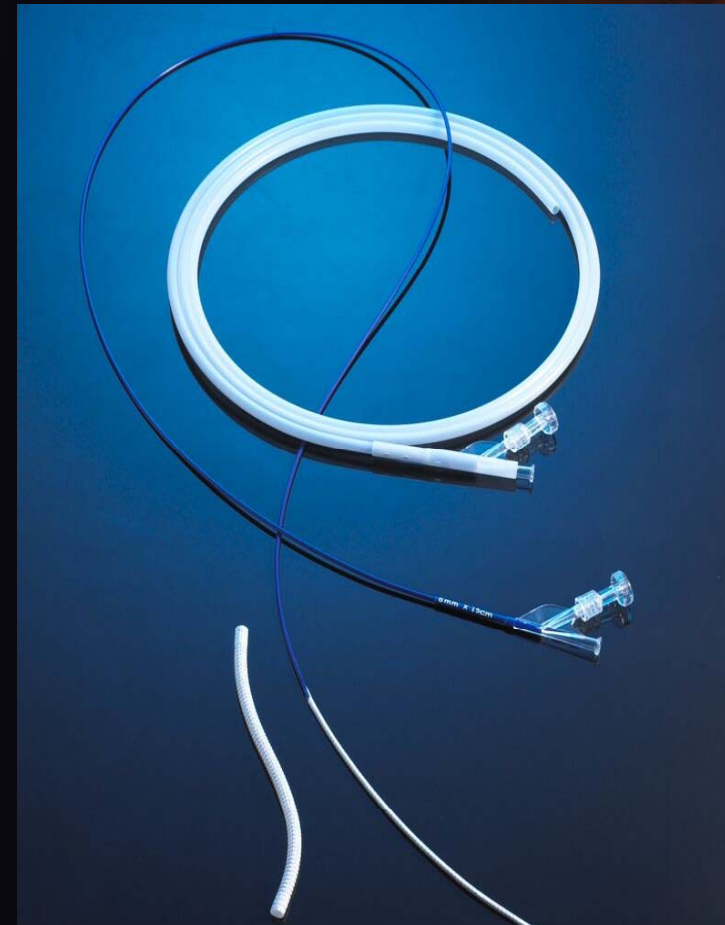
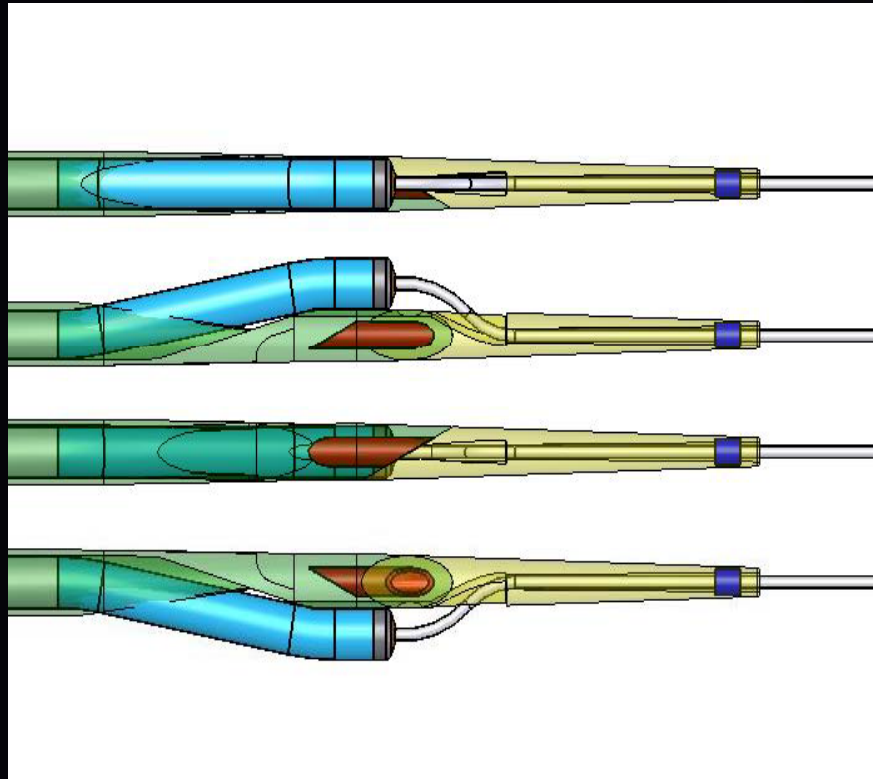
Treatment of ISR: *UC Davis Experience*

- Procedural success in 20/21 limbs (95.2%)
- 12-month duplex obtained in all patients
- Primary patency defined as absence of reintervention or duplex restenosis (defined as PSVR > 2.0)
 - Primary patency: 47.6%
 - Secondary patency: 57.1%
- (Reintervention deferred for patients with moderate restenosis and no symptoms)

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Is Debulking Enough?

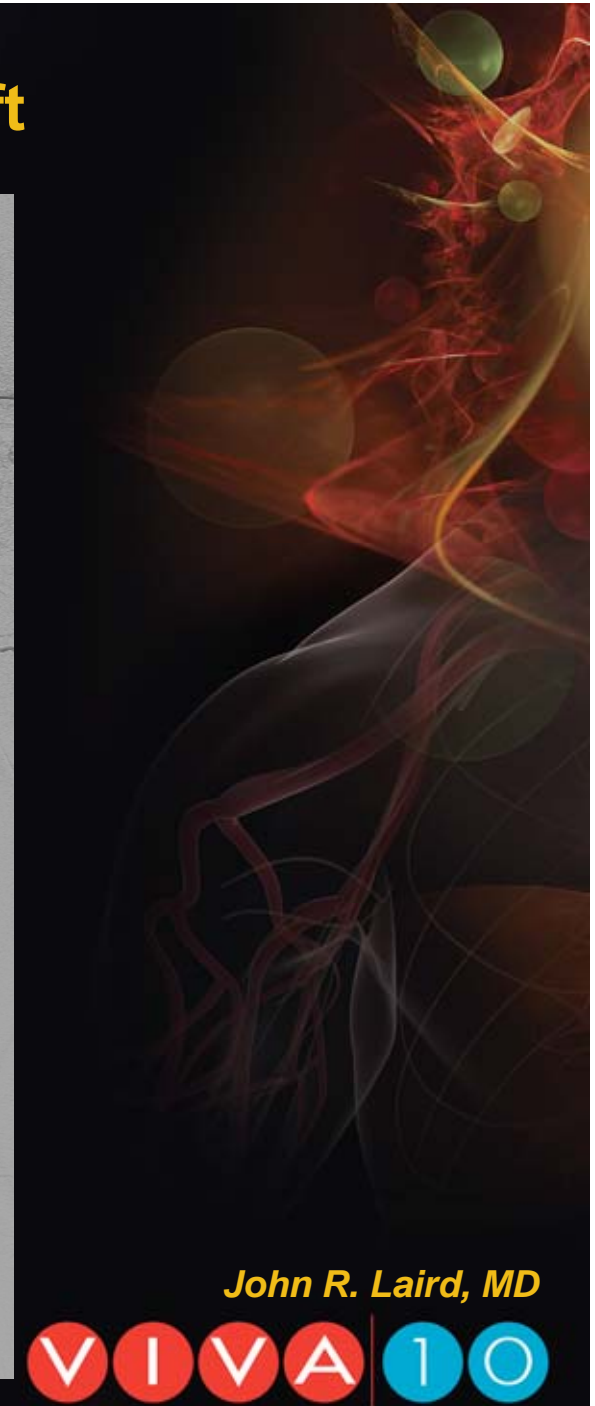


Viabahn With Heparin Bioactive Surface

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In-stent Restenosis Following Stent Graft



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Laser/PTA + Viabahn for SFA ISR Single Center Registry Data

- *39 patients undergoing Eximer laser/PTA + Viabahn for in-stent restenosis (62% male; ave. age 58 yrs.)*
- *Average RC=3 (range 1-6)*
- *Average stented length **27 cm** (range 5-44 cm)*
- *Average balloon diameter 6 mm (range 3-7 mm)*

Laser/PTA + Viabahn

6-month follow-up

- N= 33 (85%)
- 4 lost to follow-up
- 1 death (non-procedure related)
- 1 refused follow-up
- **No deaths, amputations, bypasses thru 6 mos.**

Primary Patency (DUS)	73%
Primary Assisted Patency	76%
Occluded	24%





**ProSpective Multi-Center TriAL to
EValuate the Safety and Performance of
the Spectranetics Laser with Adjunct PTA
and GorE Viabahn Endoprosthesis for
the Treatment of SFA In-stent Restenosis**

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Baseline Angiographic Characteristics

Angiographic Characteristics	Enrolled Subjects (n=27)
Pre-procedure target lesion % stenosis by visual estimate (mean \pm SD)	93.2 \pm 8.5
Target lesion calcification	
None	14 (51.8)
Mild	9 (33.3)
Moderate	3 (11.1)
Severe	1 (3.7)
Target lesion length (visual estimate), cm (mean \pm SD)	20.7 \pm 10.3
Viabahn length, cm (mean \pm SD)	23.8 \pm 9.6
Viabahn diameter, cm (mean \pm SD)	5.9 \pm 0.4
Viabahn per subject (mean \pm SD)	1.9 \pm 0.8
Post-procedure target lesion % stenosis by visual estimate (mean \pm SD)	3.7 \pm 5.6

Numbers are presented as n (%), unless otherwise indicated.

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Primary Endpoint

Core Lab Reported 12-Month Duplex U/S Patency

Defined as a ratio of ≤ 2.0 , measured as the upstream peak systolic velocity (PSV), compared with PSV in the area of greatest stenosis.

Target Lesion Status at 12 Months	# of Subjects (n= 25*)
Restenotic	12
Patent	11
Unknown**	1
Non-Diagnostic Study†	1

*1 subject lost to follow-up prior to 12 month follow-up; 1 subject expired between 6 and 12 month follow-up.

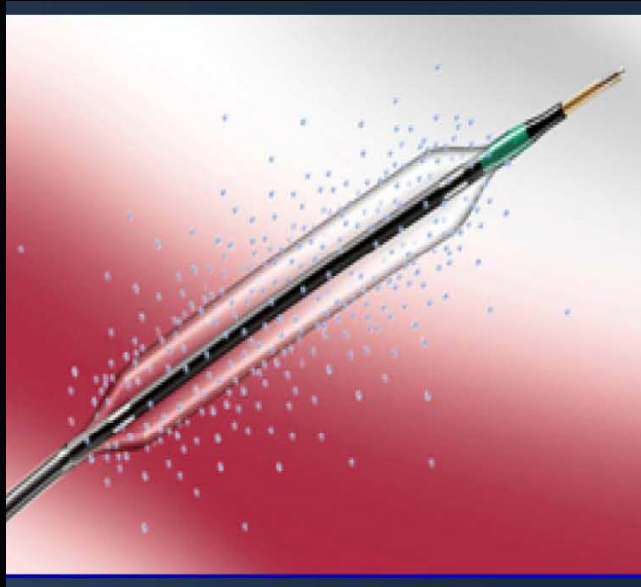
**Distal SFA stenosis but unable to determine if within target lesion area as stent not clearly visualized.

†Media corrupted, unable to read.

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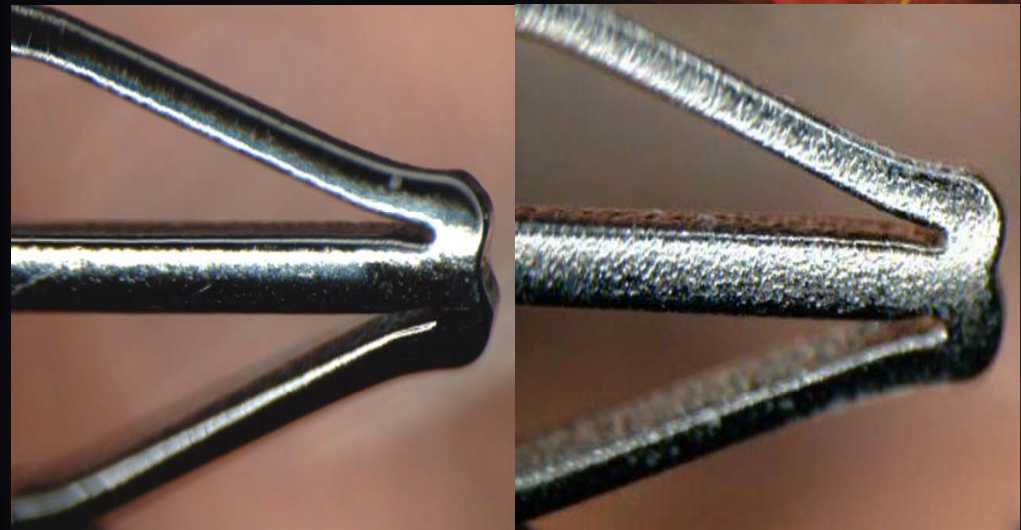
DEB or DES for ISR



Paccocath ISR 1 & 2*

PEPPER*

FAIR Trial



Zilver PTX Registry

*coronary

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Zilver PTX Registry

Lesion Characteristics

Patients	718
Lesions	818
TASC Class*: A	26%
B	29%
C	26%
D	14%
Lesion > 7 cm	47%
Lesion > 15 cm	22%
Total occlusion	38%
Restenosis (all)	24%
In-stent restenosis (ISR)	15%

*TASC 2000

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Freedom From TLR

Subgroup	12 Months	24 Months
Overall	89% (n = 818)	82% (n = 427)
<i>De novo</i> (all)	91%	88%
≤ 7-cm lesions	94%	91%
> 7-cm to 15-cm lesions	92%	86%
> 15-cm lesions	84%	80%
TASC C and D*	87%	78%
Occlusions	86%	77%
Stenosis	90%	85%
Restenosis (all)	81%	70%
Restenosis (not ISR)	87%	73%
In-stent restenosis (ISR)	78%	69%

*TASC 2000

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Summary

- PTA alone ineffective for diffuse ISR
- Improved but not optimal results with debulking and adjunctive PTA
- Local drug delivery (DEB or DES) with or without debulking offers the most promise for improved long-term results

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