Treatment of SFA In Stent Occlusions: Techniques of Direct Stent Puncture: And Value Of the Excimer Laser To Cross And Treat The Occlusions: How Is It Done And Advantages

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Disclosures

- Consultant:
- Abbott
- Bard
- Boston Scientific
- Cordis
- Lake Regional Medical
- Medtronic
- Philips

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Background

- Nitinol stents are being used more commonly in the therapy of SFA, popliteal, and infrapopliteal disease as multiple reports have shown improved patency and better symptomatic relief as compared with balloon angioplasty. (Crucial with flow-limiting dissections)
- In-stent restenosis and stent fracture over time is common
- Interventional therapy of ISR has historically been associated with high restenosis rates and complications.

[1] Schillinger M. Sabeti S. Loewe C. et al. Balloon Angioplasty versus Implantation of Nitinol Stents in the Superficial Femoral Artery. N. Engl J Med. 2006: 354:1879-1888.
[2] Edwards' Resilient Trial Demonstrates Statistically Superior Results for Treating Peripheral Arterial Disease in the Leg. Medical News Today, www.medicalnewstoday.com. 24 Oct 2007 American College of Cardiology. 10/23/07.
[3] Ms. Sabina A Murphy. RESILIENT (RESILIENT – Presented at TCT 2007) Cardiosource. American College of Cardiology. 10/23/07.

Background

- Restenosis is usually secondary to intimal in-growth in a fully expanded stent and reocclusion usually has superimposed thrombus. (Several investigators have noted increased incidence when stent fractures are present.)
- Historically treatment of long diffuse disease and occlusions showed very poor patency (one study < 20%) at 3 months with high embolization rate during intervention.

Rationale of ISR Therapy

- Suboptimal results with balloon angioplasty are common
  - PTA dilatation of intimal hyperplasia compresses aqueous extra-cellular matrix; however, rehydration ensues.
  - Thrombotic material may embolize and is thrombogenic.
  - Elastic recoil (NO POSITIVE REMODELING)
- Suboptimal results with repeat bare metal stenting within ISR
  - Embolization
  - No barrier to intimal ingrowth/won't seal pseudo aneurysms
  - Lumen compromised by at least the stent strut thickness
- Mechanical stabilization of fractured stents with either covered stents or Nitinol stents is probably crucial.
- There are 3 FDA approved therapies that have been proven superior to balloon angioplasty for ISR that may be utilized alone or in conjunction (Laser/Gore Viabahn Device/DCB)

EXCITE ISR

(308 nm excimer laser atherectomy to treat ISR)

Principal Investigator
Eric Dippel, MD

Laser atherectomy is superior to PTA alone for treatment of femoropopliteal ISR

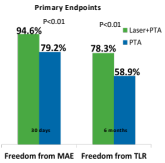
	Laser + PTA n=170	PTA n=82
Mean lesion length	19.6 cm	19.3 cm
Calcium (mod/sev)	27.6 %**	10.0 %
Stent Fracture		
Type 1 or 2	11.0 %**	2.5 %
Type 3, 4 or 5	3.0 %	0 %
Residual Stenosis >30%	4.2%*	13.4%
Procedural Success#	93.5%**	82.7%
Bailout stenting after treatment	4.1%	11.1%
Major dissection	2.4%	7.4%

20% of lesions > 30 cm

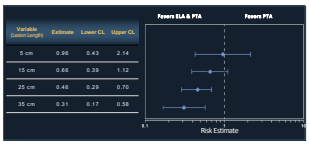
*<30% residual stenosis by visual assessment without bailout procedure

†P<0.05

‡P<0.01



Lesion Length and TLR

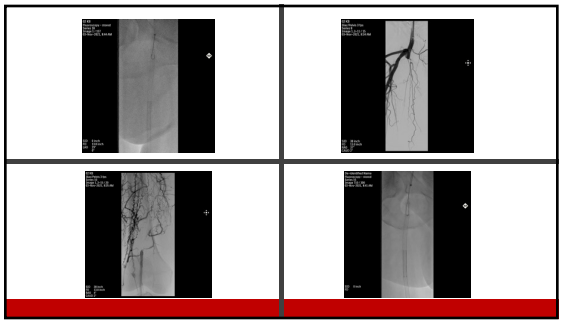


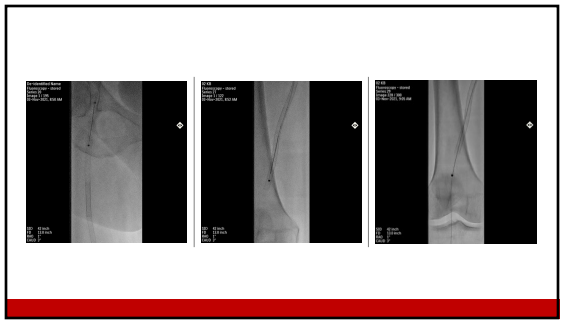
Dippel et al. JACC CI. 2015;8:92-101

EXCITE ISR Conclusions

- 308nm Laser + PTA is superior to PTA alone for the treatment of femoropopliteal ISR
- 1st FDA approved IDE randomized control study demonstrating the benefits of laser atherectomy in the lower extremities
- 308nm Laser + PTA is the only atherectomy treatment FDA indicated for femoropopliteal ISR

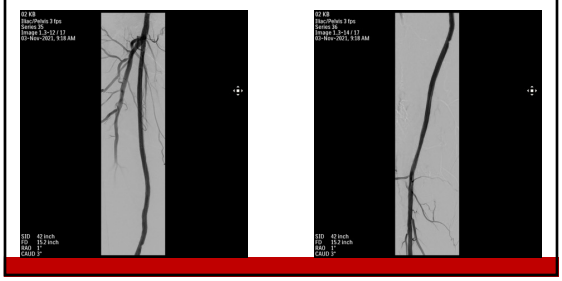
Laser can help cross ISR lesions, not crossable by wire





Post Laser

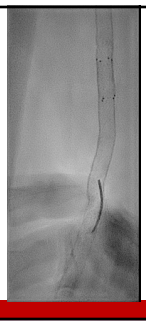
Post PTA



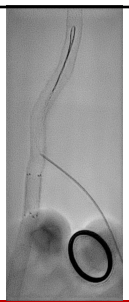
Direct Stent Puncture

- Useful when there is an occluded stent that cannot be crossed from above or below because wire goes around stent. (Once stent access is achieved, the stent is opened allowing wire access from above into the stent to then wire crossing of the distal occlusion to treat the entire occluded segment)
- Closure of Direct-Stent Access either balloon inflation for 5 minutes, or covered stent (which may be indicated for ISR)

Direct Stent Puncture of right SFA from LAO projection

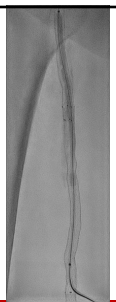


Once access has been obtained, go to RAO projection to ensure in stent lumen, the wire is able to pass retrograde into the SFA and the sheath is in place or wire is steered into sheath from above



Now that accessed has been obtained, therapies are able to be delivered.

Following balloon angioplasty, stent can now be entered easily in antegrade manner allowing operator to treat entire occlusion from above



Conclusions

- 308nm Laser has proven to be superior to PTA for treating ISR
- 308nm Laser can cross lesions uncrossable by guidewires
- Technique is critical, must advance no faster than 1mm per second with saline flush
- Useful in thrombotic lesions as well as atherosclerotic lesions
- Photoacoustic effect of laser may facilitate balloon expansion at lower pressures in calcified lesions