Options for Debulking of In-Stent Restenosis for Infra-inguinal Occlusive Disease: Atherectomy

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Endovascular Treatment of Infra-Infrainguinal Disease

- Stenting of the SFA and Popliteal Arteries
  - IFU indication/approval of Stents for SFA
  - Increased number of CTO & Re-entry devices
  - Widening breadth of techniques for complex disease

Cordis S.M.A.R.T. Stent

Drug-Coated Stent
(Cook Zilver – RCT of Zilver PTX v. Zilver BMS)

66mm 32.8%
12mo 83.1% 24mo 74.8%

While stenting offers better patency rates than PTA alone, there remains a 20-30% rate of restenosis at 1-2 years...

...and far worse results for infrapopliteal disease

Nitinol Stent Implantation for Infra-Infrainguinal Disease

How do we manage the problem of restenosis?
In-Stent Restenosis in Infra-Iguinal Occlusive Disease

Strategies for Managing In-Stent Restenosis

- Prevention
  - Stent Oversizing / Chronic Outward Radial Force
  - Pharmacotherapy

- Re-Intervention
  - Balloon Angioplasty
  - Cryoplasty

- Atherectomy / Debulking

SFA In-Stent Restenosis

Options for Debulking ISR

- Turbohawk Excisional Atherectomy
  - FDA clearance in PAD in 2003
  - Directional excisional atherectomy catheter
  - Single-use battery operated motor unit
  - Carbide cutter blade (8000 rpm)
  - Excised plaque directed into nose cone

Limitations of Debulking Devices for ISR

- Devices not designed for myointimal hyperplasia
- No device available with indication for ISR
- Some devices are contraindicated for ISR
- No effect on the biology of restenosis
**SFA In-Stent Restenosis**

*Turbohawk Excisional Atherectomy*

- Porous nose cone allows dense packing
- Hinged elbow for vessel wall apposition
- Advantages
  - No interruption of blood flow during excision
  - No balloon for wall apposition

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**SFA In-Stent Restenosis**

*Turbohawk Excisional Atherectomy*

- Monorail design
- 0.014-inch guidewire system
- 6Fr to 7Fr sheath compatibility
- Catheter working length 135cm
- Luminal gain 2mm to 5.5mm

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Heavily calcified and stented lesion with in-stent occlusion

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PRE  POST

PRE  POST

PRE  POST

Occlusions crossed
SFA In-Stent Restenosis

**Turbohawk Excisional Atherectomy**

- Long-term results after directional atherectomy of femoro-popliteal lesions.
  - Retrospective analysis of 131 lesions in 84 patients
  - 43 lesions were in-stent restenosis of fempop stents
  - Results (of the ISR lesions):
    - 83% technical success w/atherectomy alone
    - Primary patency (50% by duplex) at 12months: 54%
    - Secondary patency at 12months: 91%
    - Only independent predictor of restenosis: Rx of Restenotic lesions

- Safety and 1-year revascularization outcome of SilverHawk atherectomy in treating in-stent restenosis of femoropopliteal arteries: a retrospective review from a single center.
  - Shammas NW, Shammas GA, Helou TJ, Voelliger CM, Mrad L, Jerin M.
  - Retrospective analysis of SFA in-stent restenosis treated w/ atherectomy
  - 41 patients, mean follow-up of 12months
  - 100% technical success (w/ 98% adjunctive PTA at 11ATMs)
  - Adjunctive stenting in 24%
  - Adverse events: 7.3% embolization, 4.9% stent thrombosis
  - Results:
    - Mean ABI at 1 month: Increased from 0.66 to 0.91
    - Mean ABI at 12 months: 0.61 (NS compared to preop)

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**Medrad Jetstream Navitus Atherectomy**

- 7F sheath compatibility
- 0.014 wire platform
- Tip diameter 2.4/3.4 or 2.1/3.0 mm
- Expanding rotational blades for two different luminal diameters
- Self-contained disposable drive unit
- Combines atherectomy and active aspiration of generated debris

- Rotational and aspiration atherectomy for infrainguinal in-stent restenosis.
  - Multicenter prospective registry, non-randomized
  - 33 patients (40 lesions) with in-stent restenosis
  - All infrainguinal disease; 5% infrapop
  - Atherectomy alone in 40%, adjunctive angioplasty in 60%
  - Results:
    - No device related complications or embolizations
    - Primary patency at 12- and 24-months: 33% and 25%
    - Secondary patency at 12- and 24-months: 92% and 92%
SFA In-Stent Restenosis
Spectranetics Laser Atherectomy

- Catheter and laser generator
- Xenon laser: 308nm (ultraviolet) wavelength
- Tissue penetration 10µm, no adjacent temp increase
- Vaporizes thrombus, plaque, luminal debris
- 6Fr-7Fr Sheath compatibility
- Guide wire 0.014-inch or 0.018-inch
- Catheter diameters range 0.9-2.5mm

Disadvantages: Small resultant luminal diameter
- 7Fr Turbo-Booster: 0.9mm-1.7mm
- 8Fr Turbo-Booster: 1.7mm-2.0mm

Advantages: Indications
- In-stent restenosis Indication (CAD)
- Thrombolytics (off-label)
SFA In-Stent Restenosis

**Spectranetics Laser Atherectomy**

**Photo-Ablation using the Turbo-booster and Excimer Laser for In-stent Restenosis (PATENT) Study**

- Zeller T, Presented at Leipzig Interventional Course (LINC) 2013, Leipzig, Germany;
- 90 patients at five centers in Germany; Non-randomized registry
- Average lesion length 109 mm
- Turbo Elite laser and turbo booster system
- Mean pre- and post-laser stenosis: 87% and 32.4%
- Adjunctive angioplasty in most cases
- Technical success of 98.8%
- Two episodes of stent thrombosis
- Freedom from TLR at 6- and 12-months: 82% and 52%

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**THE EXCITE ISR TRIAL**

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

- U.S. FDA IDE trial
- Turbo Elite laser and turbo booster system
- 35 Centers with goal of 353 patients - stopped at 250 (early efficacy at prospectively-specified interim analysis)
- 2:1 Randomization between laser with PTA v. PTA alone
- Results:
  - Procedural success 93.5% v 82.7% (p=0.01)
  - Favorable at 6 months (freedom from TLR 73.5% v 51.8% (p<0.005)

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**Excimer Laser and Heparin Bonded Viabahn for Treatment of Femoropopliteal In-Stent Restenosis (12m SALVAGE Study Results)**

- Single arm non-randomized study
- 27 pts with fempop in-stent restenosis
- Claudicants and CLI patients
- Results:
  - 100% technical success
  - No MAE (TLR, mortality, amputation)
  - 12mo primary patency: 48%
  - 12mo TLR: 17.4%
Conclusions

**Debulking of In-stent Restenosis:**

- Can be performed safely with multiple available atherectomy devices.

- All of these debulking strategies have been plagued by high rates of restenosis, just as has been demonstrated in previous literature on balloon angioplasty, cryoplasty, and cutting balloon angioplasty.

- Improvements in long term outcome may be improved by understanding technical factors contributing to restenosis and by modulating the disease biology with drug-eluting technology & pharmacotherapy.