**What Is The Best Current Treatment In The US For ISR: How Can OCT Improve Outcomes?**

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- ~200,000 stents implanted in the U.S. each year\(^1\)
- ~30-40% restenosis within 12 months\(^2,3\)
- Few technologies reported on improved ISR patency rates as compared to PTA-treatment.\(^4,5\)

\(^1\) Cooke JP, Chen Z. A compendium on peripheral arterial disease. Circ Res. 2015;116:1505-1508.

**Disclosures**

- Member, Scientific Advisory Board for Avinger, Redwood City, CA

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**In-Stent Restenosis Overview**

- Stents may prevent elastic recoil, but intimal hyperplasia leads to ISR
- No consensus for endovascular treatment for ISR

**Pathophysiology of Restenosis**

**Classification and Clinical Impact of Restenosis After Femoropopliteal Stenting**

The RELINE study
- Multicenter RCT conducted
  - 7 sites in Belgium and Germany
- Viabahn endoprosthesis with PROPATEN Bioactive Surface

The 12-month primary patency rates were 74.8% for the Viabahn group and 28.0% for the angioplasty group \((p < 0.001)\).

Conclusion: The treatment of femoropopliteal in-stent restenosis with a Viabahn endoprosthesis showed significantly better results than treatment with a standard balloon at 1 year.

- DCB 70.5% vs. PTA 38.5% \((P = 0.004)\)
Standard balloon angioplasty
Repeat stenting
Covered stent-grafts
Drug eluting stents
Drug coated balloon angioplasty

Atherectomy
Excisional
Laser

Atherectomy

- In theory........

Atherectomy can effectively debulk neointimal tissues, as well as thrombus
Pantheris OCT Image Guided Atherectomy and DCB combined

Benefits of Optical Coherence Tomography (OCT) in ISR

- Appreciate disease proximal and distal to scaffold edges
- Overall disease burden throughout the stent
- Condition of the stent
  - Strut malapposition or Fracture
- Visualization provides cut depth guidance to avoid stent struts

In-Stent Restenosis Case

Evaluation of the Pantheris OCT-Imaging Atherectomy System for Treatment of In-Stent Restenosis Lesions in Lower Extremity Arteries (INSIGHT)

- Prospective, single arm, global trial, multi-center study
- Evaluate the safety and effectiveness of the Pantheris Luminvascular Atherectomy System for treating in-stent restenosis (ISR) in lower extremity arteries.
- 140 patients will be enrolled in the INSIGHT trial at up to 20 US and international centers
**OVERALL Conclusions for ISR**

- Very high rates of recurrence with POBA
- Data to support the use of atherectomy with adjunctive angioplasty
- Data to support relining with covered stents may be used to successfully treat diffuse in-stent restenosis
- Data to support use of DCBs
  - May have a significant role in for hyperplasia

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**OVERALL Conclusions for ISR**

- Future studies to assess the theoretical benefit of combining atherectomy with DCBs
- Current studies to assess the Benefits of Optical Coherence for ISR
- May provide the dual advantage of combining neointimal debulking with medication