Veith 2015
The Spectranetics Excimer Laser Plus Balloon Angioplasty is the Best Treatment for ISR: Based on the Excite-ISR Trial: Should the Balloon be a DEB

DISCLOSURES
Consultant/Medical/Scientific Boards
- Abbott
- Boston Scientific
- Cardiva
- Cook Medical
- CR Bard
- Lake Regional Medical
- Medtronic
- Spectranetics

PVD Training
- Abbott
- Bard
- Boston Scientific
- Spectranetics
- Triflame Medical

Stockholders
- CardioProlific
- Cardiva
- Medtronic
- Spectranetics

Speaker’s Bureau
- Abbott
- Bard
- Boehringer-Ingelheim
- Bristol-Myers-Squibb/Sanofi
- Cardiva
- Cook Medical
- Cordis
- DS/Philly
- Spectranetics

Treating ISR is a Significant Issue as Lower Limb Stenting Continues to Increase

Stent Cases in the U.S.¹

200,000
150,000
100,000
50,000
0

2010 2011 2012 2013 2014

Fem-Pop

Infrapopliteal

*Nevertheless, a 45% restenosis rate in stented patients at 2 years underlines the need for further improvement*

—Professor Martin Schillinger

Treating ISR is a Significant Issue as Lower Limb Stenting Continues to Increase

SFA Trials Show Restenosis / Loss of Patency is an Issue for All Stents

SFA Stent Trials

BMS
- Complete SD (inclusion)
- Everflex (Covidien)
- Absolute (Abbott)
- Zilver BMS (Cook)

- Restenosis @ 1 year = 27%
- Restenosis @ 2 years = 37%
- Restenosis @ 1 year = 10%
- Restenosis @ 2 years = 19%

RESULTS MAY BE UNDERSTATE

1. Are these “real-world” patient sets with inclusion of
   - Long lesions
   - Multiple stents
   - Repeat ISR
   - Severity of underlying disease

2. Has disease stabilized at 2 years or will restenosis continue?

Fem-Pop ISR Treatment (PTA)

Tosaka Classification

2-Year Restenosis Rate

Restenosis is usually secondary to intimal in-growth in a fully expanded stent.

Reocclusion usually has superimposed thrombus.

Several investigators have noted increased incidence when stent fractures are present.
60-80% of the ISR Lesion is Aqueous in Nature\textsuperscript{8-14}

\begin{itemize}
  \item Neointimal Hyperplasia (NIH)
  \begin{itemize}
    \item Dense rubbery cap of smooth muscle cells
    \item Hydrated collagen matrix
    \item “Watery sponge”
  \end{itemize}
  \item Intima
  \begin{itemize}
    \item Vessel Lumen
    \item Vessel Wall
    \item Media
    \item Adventitia
  \end{itemize}
\end{itemize}

\textsuperscript{2}

Original Plaque

\begin{itemize}
  \item Intima
  \item Vessel Wall
\end{itemize}

\textsuperscript{2}

Initial Lesion

\begin{itemize}
  \item “Removal of ECM and its components is critical in the regression of the lesion”\textsuperscript{25}
\end{itemize}

\begin{itemize}
  \item Laser atherectomy is superior to PTA alone for treatment of femoropopliteal ISR

    \begin{itemize}
      \item Longest lesions in any IDE peripheral study
      \item 20% of lesions > 30 cm
    \end{itemize}
\end{itemize}

\begin{itemize}
  \item Laser Ablates NIH While PTA Temporarily Displaces It

    \begin{itemize}
      \item Mechanism of Action in ISR
      \item Laser ablates NIH and thrombus to create a channel for subsequent PTA
    \end{itemize}
\end{itemize}

\begin{itemize}
  \item EXCITE ISR Trial Overview

    \begin{itemize}
      \item EXCITE ISR
        \begin{itemize}
          \item DESIGN: Prospective, randomized, multi-center clinical evaluation of excimer laser atherectomy (ELA) for ISR
          \item PRIMARY SAFETY ENDPOINT: Major Adverse Events (MAE) during hospitalization through 37-day follow-up to include all death, unplanned major amputation, or target lesion revascularization
          \item PRIMARY EFFECTIVENESS ENDPOINT: Freedom from clinically driven TLR through 6 month follow-up (212 days)
          \item Principal investigator: C. Walker/E. Dippel
        \end{itemize}
    \end{itemize}
\end{itemize}

\begin{itemize}
  \item Baseline Lesion Characteristics

    \begin{itemize}
      \item Angiographic Core Lab Assessment
        \begin{itemize}
          \item ELA + PTA
          \item PTA Alone
        \end{itemize}
    \end{itemize}
\end{itemize}

\begin{itemize}
  \item Laser + PTA vs PTA Alone

    \begin{itemize}
      \item Patients with 12 Month Visit
        \begin{itemize}
          \item 100 (59%)
          \item 42 (51%)
        \end{itemize}
      \item Average Lesion Length (cm)
        \begin{itemize}
          \item ELA + PTA: 19.2
          \item PTA Alone: 16.3
        \end{itemize}
      \item TASC C/D Lesion (%)
        \begin{itemize}
          \item ELA + PTA: 58.9
          \item PTA Alone: 20.5
        \end{itemize}
      \item Withdrawal/ LTF
        \begin{itemize}
          \item ELA + PTA: 24 (14%)
          \item PTA Alone: 12 (15%)
        \end{itemize}
      \item Survival (%)
        \begin{itemize}
          \item ELA + PTA: 98.3
          \item PTA Alone: 94.8
        \end{itemize}
      \item Freedom from TLR (%)
        \begin{itemize}
          \item ELA + PTA: 53.8
          \item PTA Alone: 47.7
        \end{itemize}
      \item Freedom from Amputation (%)
        \begin{itemize}
          \item ELA + PTA: 100
          \item PTA Alone: 95
        \end{itemize}
      \item ABI Average
        \begin{itemize}
          \item ELA + PTA: 0.8
          \item PTA Alone: 0.8
        \end{itemize}
      \item Rutherford Class Average
        \begin{itemize}
          \item ELA + PTA: 1.22
          \item PTA Alone: 0.93
        \end{itemize}
      \item New Stent Fracture (%)
        \begin{itemize}
          \item ELA + PTA: 2.9 (5/170)
          \item PTA Alone: 3.7 (3/82)
        \end{itemize}
    \end{itemize}
\end{itemize}
EXCITE ISR Conclusions

EXCITE

• Laser + PTA is **superior** to PTA alone for the treatment of femoropopliteal ISR.
• **No adverse interaction with the stents was noted.**
• 1st FDA approved IDE randomized control study demonstrating the benefits of laser atherectomy in the lower extremities
• Laser+ PTA is the only atherectomy treatment FDA indicated for femoropopliteal ISR

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**Laser/DCB vs. DCB Alone**

- RCT laser+DCB (n=24) vs. DCB n=24
- All diabetic CLI and total occlusions + CTO
- Treated stent length and lesion length >20cm
- 100% crossing success
- Complications:
  - Distal embolizations 3:
  - Laser+DCB: 1 (4%), DCB: 2 (8%)
  - Zero perforations
  - Zero dissections

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12 months result: Laser/ DCB had much better outcomes than DCB Alone

- Patency Freedom from TLR
- Freedom from amputation

- **P ≤ 0.03**
- **P = 0.01**
- **P = 0.03**
- **P = 0.03**

Gandini R et al, JEVT 2013;20:805-813
Conclusion

• I strongly suspect that laser atherectomy will become the standard of care in ISR.
  • To remove intimal hyperplasia and clot
    • As a prep for additional DES or DEB
    • As a prep for Covered stents to help create a larger initial lumen.