Versatility of Directional Atherectomy: Clinical Use Below the Knee

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Disclosure
Speaker name: Ravish Sachar

☒ ☐ I have the following potential conflicts of interest to report:

☒ ☐ Receipt of grants/research support
  Details: Abbot, Boston Scientific, Gore, Medtronic, Microvention, Surmodics

☒ ☐ Receipt of honoraria and travel support
  Details: Boston Scientific, Medtronic

☐  ☐ Employment in industry
  Details:

☐  ☐ Shareholder in a healthcare company
  Details: Contego Medical

☐  ☐ Owner of a healthcare company
  Details:

☐  ☐ I do not have any potential conflicts of interest to report
BTK Disease is not the same as ATK Disease

- Smaller Vessels
- More diffuse disease/CTOs
- Less Elastic Vessels/More Recoil
- Calcium tends to be more medially located as compared to luminal
- More Calcification – worse outcomes

Tibial artery calcification (TAC) score predicts the short-term risk of amputation

![Graph showing the relationship between TAC score and amputation risk](image)
Goal of Treatment of BTK Disease

- Treat CLI
- Improve Wound Healing
- Eliminate or lower the level of amputation
- More flow = Better results
DM, ESRD, Rutherford 5
Difficult to cross

Directional atherectomy may be a good option.
Benefits of Atherectomy for BTK

- Maximize lumen gain
  - Resistance in Series
  - Flow increases exponentially as radius of the vessel increases

- Remove Calcium
  - Improve vessel compliance
  - Lower risk of re-occlusion due to recoil
  - Lower risk of dissection/bailout stenting

- Maximize Drug Delivery
  - DCB?
  - DES?

Poiseuille's Law

\[ Q = \frac{\pi Pr^4}{8\eta l} \]
Directional Atherectomy Clinical Data Including BTK Lesions

- **Sarac**: N = 73 patients
- **Zeller**: N = 36 patients
- **TALON**: N = 601 patients

Overall Patency at 12 Months

* include calcified lesions
† multi-center study

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DEFINITIVE LE
STUDY DESIGN & PRIMARY ENDPOINTS

800 Patients | 47 Centers

Claudication
598 Patients*

Critical Limb Ischemia
201 Patients

Primary Patency by Duplex US at 12 months

Freedom From Major Unplanned Amputation at 12 months
145 subjects with 189 infrapopliteal lesions

48.3% CLI

Lesion length 58 ± 44 mm

20.2% were occluded

Definitive LE: Infrapopliteal subgroup

<table>
<thead>
<tr>
<th></th>
<th>1 Year Patency</th>
<th>Freedom from CD-TLR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>84%</td>
<td>91.2%</td>
</tr>
<tr>
<td>Claudicants</td>
<td>89.6%</td>
<td>95.4%</td>
</tr>
<tr>
<td>CLI</td>
<td>78%</td>
<td>86.6%</td>
</tr>
</tbody>
</table>

Definitive LE: IP subgroup
Low Complication Rate

- The adjunctive stent rate: 1.6%
- Perforation 5.5%
- Abrupt closure 2.1%
- Distal embolization 2.8%
- Flow-limiting dissections 2.8%
DEF LE CLI Cohort Primary Endpoint

Freedom from Major Amputation at 12 Months

95%
Wound Healing in CLI (RCC 5 & 6 at baseline)

- 52% @ 3 months
- 61% @ 6 months
- 72% @ 12 months
BTK Directional Atherectomy: Versatility

- Proximal Tibial Lesions
- Bifurcation Disease
- Multi-level Diffuse disease
- EPD use
- Works well for soft plaque/moderate Ca++
- May be challenging in severe diffuse intraluminal Ca++
Proximal Tibial Disease

- HawkOne™ S device
- Run through wire in PT
- No EPD
- One pass
Bifurcation Disease – Avoiding Plaque Shift
76yo female with gangrene- Initial RLE angio

Images Courtesy of Gregory Stanley, MD
HawkOne 6Fr™ S catheter

3mm Spider FX filter in distal peroneal
4 additional cuts with HawkOne™ S device

Images Courtesy of Gregory Stanley, MD
76yo female with gangrene- Final angiogram

Images Courtesy of Gregory Stanley, MD
Left anterior tibial artery

3mm SpiderFX™ Filter deployed in the dorsalis pedis

TurboHawk™ SXC device for proximal and mid disease

Images Courtesy of John Winscott MD
Before and after angiography's

Images Courtesy of John Winscott MD
Tips

• Less is More – 1-2 cuts, then angiography
• After initial cuts, direct cuts to the area of disease
• Use embolic protection where possible
• Low pressure PTA as needed
• Low risk of perforation – prolonged PTA if it does occur
Conclusions: BTK Directional Atherectomy

- Limited Prospective/Randomized Data
- Both PTA and Atherectomy increase lumen size, but atherectomy results in a larger lumen, and therefore exponentially more flow
- Directional atherectomy is feasible and versatile in BTK disease but may be challenging in severe diffuse intraluminal calcification
- Atherectomy may also increase drug delivery, therefore patency – no level 1 data so remains a hypothesis
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