Atherectomy Device in CLI

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Disclosure

Speaker name:
Chung-Ho Hsu

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest
Choice of Lower Limb Atherectomy Device in Taiwan

- 1991: Laser
- 1995: Rotablator
- 2015: Turbohawk LS-M
- 2016: Rotarex
- 2016: Turbohawk LS-C
- 2017: Jetstream
- 2018: HawkOne
- 2019: Phoenix
How to Choose Your Atherectomy Device

Lesion character
  Soft plaque vs heavily calcified lesion
  Concentric (rotational) vs eccentric (directional)

Length and procedure time

Size  how large hole you want to make?
Stent?

Crossover sheath
  6 Fr, 7Fr, 8Fr?

Cost

Protection device (EZ filter, spider, NAV-6..etc)

Courtesy of Dr. 柯博仁
Laser Atherectomy

Ultraviolet 308 nm excimer laser
Debulking thrombus, atheroma, emboli
Poor effect for heavy calcified vessel
The step by step technique can be used to cross SFA CTO, lead with laser not wire
Perforation 2%
Embolization 4%
Laser Atherectomy: Key Trial

**EXCITE ISR**

- **Study Design and Oversight**
  - Prospective, RCT, US study
  - 250 patients, 40 centers
  - Angio + Duplex Core lab

**Key Inclusion**
- RCC 1-4
- ISR lesion ≥ 4 cm, no lesion limit
- ≥ 1 patent tibial artery
- RVD ≥ 5.0mm to ≤ 7.0mm

**Key Exclusion**
- Target lesion extends > 3cm beyond stent margin
- Untreated inflow lesion
- Grade 4 or 5 stent fx
EXCITE ISR

Primary Efficacy Endpoint

*Freedom from TLR thru 6 months*

![Bar chart showing primary efficacy endpoint results for different patient populations and treatment groups. The chart compares the percentage of patients remaining free from target lesion revascularization (TLR) over 6 months for different patient populations and treatment groups. The results are presented for three categories: ITT, ITT w/o Bailout Stenting as TLR, and Per protocol. The chart indicates statistical significance for certain comparisons, with p-values noted for each group comparison.](chart)
Rationale for Combination Treatment
Atherectomy and DCB

Theoretical benefit for atherectomy

• DCB may inhibit the inflammatory response caused by mechanical trauma
• DCB may improve patency in longer lesions and occlusions
Rationale for Combination Treatment
Atherectomy and DCB

Theoretical benefit for DCB therapy

• Plaque removal could facilitate local drug delivery into vessel wall
• Atherectomy in SFA lesions improve clinical success by
  • Residual restenosis
  • Flow limiting dissections
  • Bailout stent rate


\textbf{LAART: Laser Atherectomy Antirestenotic Therapy}
Kaplan-Meier curve of 12-month primary patency

Laser + DEB

DEB alone

## Laser Debulking and DCB +/- Stent in de novo SFA/pop in CMUH, Taiwan, 2013~

<table>
<thead>
<tr>
<th></th>
<th>6 m</th>
<th>12 m</th>
<th>24 m</th>
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<tbody>
<tr>
<td><strong>Primary Patency</strong> (PSVR &lt; 2)</td>
<td>95%</td>
<td>95%</td>
<td>84%</td>
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<tr>
<td><strong>Assisted Patency</strong></td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td><strong>ABI</strong></td>
<td>0.56</td>
<td>0.85</td>
<td>0.80</td>
</tr>
<tr>
<td><strong>TLR</strong></td>
<td>5%</td>
<td>11%</td>
<td>16%</td>
</tr>
<tr>
<td><strong>Major amputation</strong></td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td>0</td>
<td>16%</td>
<td>16%</td>
</tr>
</tbody>
</table>
LAART

DAART
DEFINITIVE AR 1-yr Result (Angio Primary Patency)

- All Patients: 82.4% (DAART) vs. 71.8% (DCB)
- Lesions > 10 cm: 90.9% (DAART) vs. 68.8% (DCB)
- All Severe Ca++: 58.3% (DAART) vs. 42.9% (DCB)
Jetstream

Discover the Value of Versatility

Versatility means not having to guess the morphology! Peripheral arterial lesions can present with a range of morphologies from soft thrombus to plaque and difficult calcification – often in the same vessel. The Jetstream™ Atherectomy System is indicated for both thrombectomy and atherectomy and has demonstrated its ability to deliver luminal gain in soft, hard and calcified lesions.12

Ergonomic, Single or Dual-Operator Design

The lighter, more ergonomic XC and SC catheters are designed to enhance ease of use. Control buttons are integrated into the mouse, which can be used either in the pod or removed for remote activation. The improved Wire GARD simplifies wire management.

- Ergonomic design with 50% smaller* POD enhances user experience
- Intuitive user interface facilitates single or dual operator use

Rotarex
PHOENIX ATERECTOMY SYSTEM

**CUT**
Front-cutting design for direct access to lesions

**CAPTURE**
Unique blade design shaves material directly into the catheter

**CLEAR**
Continuous plaque removal helps reduce risk of distal emboli and allows single insertion use
Phoenix Product Family

Phoenix 2.4mm (7F deflecting)*
3.0 – 7.0 mm vessels

Phoenix 2.2mm (6F non-deflecting)
3.0 – 4.0 mm vessels

Phoenix 1.8mm (5F non-deflecting)
2.5 – 3.5 mm vessels

* 2.4mm Phoenix is not yet commercially available
<table>
<thead>
<tr>
<th></th>
<th>Laser</th>
<th>HwakOne</th>
<th>Jetstream</th>
<th>Rotarex</th>
<th>Phoenix</th>
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<tbody>
<tr>
<td>Sheath Fr</td>
<td>6-8</td>
<td>6-7</td>
<td>7</td>
<td>6 or 8</td>
<td>5-7</td>
</tr>
<tr>
<td>Created lumen (mm)</td>
<td>4.5</td>
<td>4-5, depends</td>
<td>4</td>
<td>depends</td>
<td>4-5, depends</td>
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<tr>
<td>Heavily Ca+</td>
<td>V</td>
<td>V</td>
<td>V</td>
<td>V</td>
<td>V</td>
</tr>
<tr>
<td>Thrombus</td>
<td>V</td>
<td>V</td>
<td>V</td>
<td>V</td>
<td>?</td>
</tr>
<tr>
<td>Long lesion</td>
<td>V</td>
<td>V</td>
<td>V</td>
<td>V</td>
<td>V</td>
</tr>
<tr>
<td>Stent +</td>
<td>V</td>
<td>V</td>
<td>V/?</td>
<td>V</td>
<td>V</td>
</tr>
<tr>
<td>Protection</td>
<td>V</td>
<td>V</td>
<td>NAV-6</td>
<td>X</td>
<td>X/NAV 6</td>
</tr>
<tr>
<td>Cost</td>
<td>$$$</td>
<td>$$</td>
<td>$$$</td>
<td>$</td>
<td>$</td>
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Case Series Discussion

How to choose your atherectomy weapon?
58 y/o M, IC 1 year, L-ABI 0.55

Soft plaque, length 15 cm

Laser

Rotarex

HawkOne

Jetstream

Phoenix
Laser angioplasty with 2.5 mm Turbo Elite
5.0/150 mm Pacific extreme balloon at 10 atm

5.0/120 mm Inpact DEB balloon at 8 atm x 5 min
After laser atherectomy with DCB
6 mo f/u Ultrasound (ABI 0.91)

LCFA: 124 cm/s  LSFA: 122 cm/s  LPOP: 200 cm/s

LPTA: 138 cm/s  L PDA: 105 cm/s
55 y/o M, uremia, HTN, CAD, DM, RC3, ABI 0.45

Short rock like vessel

Laser

Rotarex

HawkOne

Jetstream

Phoenix
Turbohawk LSM atherectomy
POBA with 6.0/40 mm, 7.0/80 mm balloon
POBA with 7.0/80 mm InPACT DCB
**R-ABI 1.11**

**POBA CTO RATA 2.5-3.0/210 mm, 4.0/120 mm balloon**
86 y/o F uremia CAD DM RC5 ABI 0.46

Short calcified
Laser
Rotarex
HawkOne V V
Jetstream V
Phoenix V
Atherectomy with HawkOne, 5 mm Spider
After Atherectomy with HawkOne
4.0/300 mm Pacific extreme balloon

Two 4.0/150 mm InPACT DCB at 5 min
76 y/o F Af CAD DM RC5

Long soft plaque/organized thrombus

Laser V

Rotarex V V

HawkOne

Jetstream V

Phoenix V

CT 6 mo ago
CDT with 30 cm Fountain, UK 240000 units
6Fr Rotarex
After Atherectomy with Rotarex
5.0/300 mm Pacific extreme, one 6.0/120 mm Zilver PTX over ostial RSFA, two 5.0/150 mm InPACT DCB

ABI 0.82

CTO RATA 2.0/150 mm Freeway DCB, 3 2.5/120 mm Lutonix DCB 10 atm 3 min
77 M CAD DM RC5 ABI 0.53

Soft plaque with little calcification, tandem lesion

Laser V
Rotarex V
HawkOne V
Jetstream V V
Phoenix V
Jetstream XC 2.4/3.4 mm blades down under NAV-6 protection/UK 240000 units via 20 cm Fountain catheter
Jetstream XC 2.4/3.4 mm, blades up
6.0/300 mm Pacific extreme 10 atm
Two Ranger DCB
6.0/100 mm

InPACT DCB
7.0/80 mm, 6.0/150 mm
No flow/slow flow phenomenon after DCB
No dissection on IVUS, ACT 280, NTG infusion
Flow recover after repeated NTG, ABI 1.01
57 M CAD DM HTN CKD
Acute on chronic PAD ABI 1.0

Soft plaque with thrombus

Laser  V  V
Rotarex
HawkOne
Jetstream  V
Phoenix  V  V
Phoenix 1.8 mm, 5Fr
Fracture of Spider Wire
Laser Turbo-Elite 2 mm
Freeway DCB x 3
Slow flow after DCB, improved by NTG, strong pulse, R-ABI 1.1
Take Home Message

Atherectomy device should be lesion specific

Before choosing your atherectomy weapon, consider
Character/calcification/concentric or eccentric
Size
Length/procedure time
Stent
Protection device
Procedure time
Cost
Thanks For Your Attention
Lesion Specific Solution of Atherectomy Devices

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