Endovascular tibial *in situ* bypass using the everlinQ system

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Disclosure

Speaker name: Jihad Mustapha, M.D.

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
# Critical Limb Ischemia

<table>
<thead>
<tr>
<th>Count:</th>
<th>65,000-80,000&lt;sup&gt;1-3&lt;/sup&gt; major amputations performed annually in the U.S. (&lt;~36% - 50%)&lt;sup&gt;1-5&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulation:</td>
<td>60%-80% can’t walk&lt;sup&gt;6&lt;/sup&gt;</td>
</tr>
<tr>
<td>Depression:</td>
<td>35%&lt;sup&gt;4,5&lt;/sup&gt;</td>
</tr>
<tr>
<td>Discharge Status:</td>
<td>Only 11%-24% go home routinely&lt;sup&gt;7,8&lt;/sup&gt;</td>
</tr>
<tr>
<td>Mortality @ 2 years:</td>
<td>30%-50% (frequently MI)&lt;sup&gt;9-11&lt;/sup&gt;</td>
</tr>
<tr>
<td>Increased Patient Costs:</td>
<td>Lost wages &amp; modifications for disabled living&lt;sup&gt;12&lt;/sup&gt;</td>
</tr>
</tbody>
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## Limitations of Current Limb Salvage Techniques

<table>
<thead>
<tr>
<th>Tibial Bypass Surgery</th>
<th>Endovascular Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long incision</td>
<td>BTK Atherectomy, PTA &amp; Stenting lack long-term durability</td>
</tr>
<tr>
<td>Healing challenges</td>
<td>Unable to cross the lesion</td>
</tr>
<tr>
<td>High morbidity</td>
<td>Inadequate perfusion of wound bed angiosome</td>
</tr>
</tbody>
</table>
Potential PAD Applications and Benefits of Endovascular Fistula Creation

<table>
<thead>
<tr>
<th>Potential Applications</th>
<th>Potential Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endovascular tibial <em>in situ</em> bypass</td>
<td>Avoid surgical trauma</td>
</tr>
<tr>
<td>AV reversal</td>
<td>Preserve saphenous vein</td>
</tr>
<tr>
<td>Patency assist to failing bypass</td>
<td>Expand patient options</td>
</tr>
</tbody>
</table>

DISCLAIMER: The everlinQ endoAVF System is not currently approved for use in lower limb salvage. The everlinQ™ 4 endoAVF System is not available for sale and currently approved for use. The Device has been issued European CE Mark and Health Canada Medical Device License for the creation of an arteriovenous fistula for hemodialysis. The everlinQ™ endoAVF System is not available for sale in the United States and is under FDA review.
TVA everlinQ endoAVF System

Creates a fistula without open surgery to minimize vessel trauma\(^1\) associated with the negative remodeling that leads to flow limiting stenosis\(^2,3\).

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1. TVA Medical data on file. GLP Animal Studies.
Demonstrated Clinical Success in Dialysis Access

**Advantages Demonstrated in Clinical Studies**

- High technical success rate with low complications rate
- High usability with low intervention rate
- High patency at 12 months

Images of an endoAVF at day 30 viewed from a dissected iliac artery of a sheep model.

**DISCLAIMER:** Sheep model. These case images are shared for informational purposes only. The everlinQ endoAVF System has been issued European CE Mark and Health Canada Medical Device License for the creation of an arteriovenous fistula for hemodialysis. The everlinQ™ endoAVF System is not available for sale in the United States and is under FDA review.

endoBypass Concept

- Concomitate Vein
- Tibial Artery
- Concomitate Veins

Tibial Artery

Concomitate Veins

POSTERIOR TIBIAL ARTERY

V
endoBypass Concept

Utilizing the concomitant veins to bypass the occlusion

- Create a fistula distal and proximal to the occlusion
- Reroute arterialized flow through the concomitante vein
- Perfuse the distal tissue
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Utilizing the concomitant veins to bypass the occlusion
Proof of Concept: Methods

**Design:** Preclinical cadaveric feasibility study for endovascular tibial *in situ* bypass

**Study model:**
- Perfused cadaver legs ($n = 4$)
- Occlusions simulated via embolization devices

**Assessment:**
- Distal perfusion: radiographic visualization of flow via the target vein
- Free of fistula extravasation: no radiographic evidence of blood in the tissue surrounding the fistula creation site
Proof of Concept: Procedure

- Arterial Antegrade Delivery
- Posterior Tibial Venous Delivery
- everlinQ RF Aligned And Activated
- ~2 sec later
- Arteriogram
- Proximal Fistula
Proof of Concept: Procedure

- Posterior Tibial Venous Delivery
- Retrograde dual approach
- Posterior Tibial Artery Delivery
- Proximal Fistula
- Arteriogram
- PTA Across Fistulas
Proof of Concept: Outcomes

Technical success was achieved in all limbs. Minimal to no extravasation was observed.
• The **in Situ endoBypass** procedure has the potential to provide an additional option for below-the-knee revascularization

• The everlinQ System has demonstrated proof-of-concept in a perfused cadaveric lower limb model to perform the **in Situ endoBypass** procedure

• Clinical study is planned for late 2017
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