Early clinical experience with the 4 Fr everlinQ™ endoAVF in creating vascular access for hemodialysis: The EASE Study – 4 Fr

Todd Berland¹, Jason Clement², Jesus Rios³, Adrian Ebner⁴ and William Cohn³

¹NYU Langone Medical Center, New York, NY USA
²Dept. of Radiology, St. Paul’s Hospital, Vancouver, BC Canada
³Texas Heart Institute, Houston, TX USA
⁴Cardiovascular Services, Italian Hospital, Asuncion, Paraguay
Disclosure

Speaker name: Dr. Todd Berland

I have the following potential conflicts of interest to report:

- [x] Consulting (Boston Scientific, Covidien and TVA)
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
# Challenges of Surgical AVF

<table>
<thead>
<tr>
<th>Clinical Outcomes</th>
<th>20-60%</th>
<th>4-9 months</th>
<th>2-3</th>
<th>17-25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary failure rate(^2-^5)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Mean maturation time(^1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Average re-interventions(^1,^7)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Occlusions (thrombosis)(^6)</td>
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</tbody>
</table>

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**Need for innovation to improve AVF outcomes**

DISCLAIMER: 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.

Advantages Demonstrated in Clinical Studies¹-³

- High technical success rates
- High patency at 12 months
- Low complication rates
- Low intervention rates

TVA everlinQ™ 4 endoAVF System

DISCLAIMER: The everlinQ™ 4 endoAVF System is not currently cleared for use or available for sale in any market.
TVA everlinQ™ 4 endoAVF System

**4 Fr System**

- Adds additional creation sites for an endovascular fistula
- Enables wrist access or upper arm access
- Facilitates access site hemostasis

**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.

TVA everlinQ™ 4 endoAVF System

DISCLAIMER: The everlinQ™ 4 endoAVF System is not currently cleared for use or available for sale in any market.
• **Design**: Prospective, single-center study to evaluate the everlinQ™ 4 endoAVF System when used to create an endoAVF in hemodialysis patients.

• **Primary Endpoints**
  – **Safety**: % of patients with one or more serious device-related adverse events within 3 months of creation
  – **Technical Success**: endoAVF successfully created
  – **Procedure success**: endoAVF created and patent at the day 1-7 follow-up
  – **Maturation**:  
    - Brachial artery flow ≥500 ml/min & ≥4 mm vein diameter  
    - **OR**-  
    - Dialyzed using 2 needles via the endoAVF

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EASE Study: Patients To Date

32 patients enrolled

32 patients treated

32 patients

3 un-related deaths
2 missed 30 day f/u

27 patients

Follow-up ongoing

Procedure

Index Procedure
Day(s) 1-7
Days 30-45

Arterial access
- 19 radial
- 9 brachial
- 4 ulnar

Fistula location
- 20 radial/radial
- 12 ulnar/ulnar

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## EASE Study: Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Summary (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender: Male</td>
<td>97% (31/32)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>51.4 ± 12.7</td>
</tr>
<tr>
<td>BMI &gt; 25</td>
<td>51.6% (16/31)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>90% (27/30)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>56.3% (18/32)</td>
</tr>
<tr>
<td>Pre-dialysis</td>
<td>3.0% (1/32)</td>
</tr>
</tbody>
</table>

Data displayed as Mean±SD (N)

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EASE Study: Safety

• No device-related adverse events
• 1 procedure-related adverse event
  – The endoAVF was successfully created
  – Wire perforation of the ulnar vein and covered stent was placed covering the patent endoAVF
• 3 non-related serious adverse events
  – 3 deaths
    • 1 pneumonia by infection of influenza type B
    • 1 CVC infection
    • 1 Myocardial infarction

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EASE Study: Initial Results

- **100%** Successful endoAVF creation, n = 32
- **97%** Procedure success, n = 32

**Outcomes**

- **97% (31/32) Procedure success**
  - After successful endoAVF creation, fistula was stented due to wire perforation that occurred at beginning of procedure
  - Minimal learning curve

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EASE Study: Maturation within 30d

**endoAVF Maturation**

- 81% (22/27) reached maturation by 30d f/u
  - 2 thrombosed
  - 1 was sacrificed during an intervention
  - 1 had low flow at 30d f/u
  - 1 procedure failure
- 18 have been cannulated by 30d f/u

*Maturation* = Brachial artery flow ≥500 ml/min & ≥4 mm vein diameter, or dialyzed using 2 needles via the endoAVF

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In Summary

- everlinQ™ 4 endoAVF System demonstrated high technical success from multiple access approaches and creation sites

- Initial outcomes for the 4 Fr system appear similar to the current 6Fr system, specifically:
  - High technical success rate
  - Low complications (no access site complications)
  - High maturation rate within 30 days

- Ongoing follow-up will assess usability and patency for endoAVFs created with the 4Fr system

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\textsuperscript{1}NYU Langone Medical Center, New York, NY USA
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\textsuperscript{3}Texas Heart Institute, Houston, TX USA
\textsuperscript{4}Cardiovascular Services, Italian Hospital, Asuncion, Paraguay