Significant reduction in radiation using the 4 Fr. instead of 6 Fr. WavelinQ endoAVF system in creating endovascular AV-Fistulas

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Disclosure

Speaker name: Dr. med. Tobias Steinke

I have the following potential conflicts of interest to report:

- Consulting (BD/Bard/TVA medical/Meritmedical)
  - Employment in industry
  - Stockholder of a healthcare company
  - Owner of a healthcare company
  - Other(s)
  - I do not have any potential conflict of interest
Catheters are aligned using magnets.

Flexible spacers keep the catheters in place.

Radiofrequency electrode cuts through the vessel walls.

6 Fr over-the-wire catheters are used for the procedure.

6 Fr rapid exchange catheters are used initially.

Creates an AVF without open surgery to minimize vessel trauma for high fistula usability with low interventions\(^1-4\).

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1. TVA Medical data on file. GLP Animal Studies.
EVERLINQ ENDOAVF SYSTEM

1. Generation
- Venous 6 Fr catheter
- Arterial 6 Fr catheter

2. Generation
- Venous 6 Fr catheter
- Arterial 6 Fr catheter
- Venous 4 Fr catheter
- Arterial 4 Fr catheter
Small profile, Expanded Fistula Locations, Streamlined Procedure

- 4 Fr Rapid Exchange Catheters
  for vessel access and navigation

- Square Magnets
  for automatic alignment

- Rotational Indicators
  for easy alignment confirmation

- Radiofrequency electrode
  for endoAVF creation

DISCLAIMER:
The everlinQ, everlinQ 4, and everlinQ S endoAVF Systems have been issued European CE Mark for the creation of an arteriovenous fistula for hemodialysis and are not approved for sale in the United States.
4 FRENCH PROCEDURE ACCESS OPTIONS

Same Direction: From Wrist

Opposite Direction: From Wrist and Upper Arm
BRACHIAL VENOUS ACCESS / CASE VIDEO

Courtesy of Rob Jones and Nick Inston, Queen Elizabeth Hospital in Birmingham, UK
WAVELINQ 4 FRENCH ENDOAVF PROCEDURE

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### Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Düsseldorf (4Fr / all Pat.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients evaluated</td>
<td>10 / 30</td>
</tr>
<tr>
<td>Dialysis patients</td>
<td>3/10 (30%)</td>
</tr>
<tr>
<td>Age (median, min.-max.)</td>
<td>60 (19-84)</td>
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<tr>
<td>Gender: male</td>
<td>8/10 (80%)</td>
</tr>
<tr>
<td>BMI (median, min.-max.)</td>
<td>28,8 (21,6-54,0)</td>
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<tr>
<td>Diabetes</td>
<td>6 / 10 (60%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>8 / 10 (80%)</td>
</tr>
<tr>
<td>Hyperuricemia</td>
<td>6 / 10 (60%)</td>
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</tbody>
</table>
Mean baseline vein diameter: 2.2 ± 0.2 mm

1 patient out of 10 patients experienced a procedure-related serious adverse event in our 4 Fr series (bleeding at the anastomotic site)

Only 1 patient out of 30 patients experienced a serious adverse event (all cases 6 Fr. and 4 Fr.)
RADIATION DOSE Gy/cm²

4 French

6 French
Using the 6 Fr. system we had an average radiation dose of 2.15 Gy/cm^2 (minimal 0.82, maximal 4.89, median 1.77 Gy/cm^2).

Using the 4 Fr. system we more than halved the radiation exposure with an average of 0.91 Gy/cm^2 (minimal 0.41, maximal 1.74, median 0.78 Gy/cm^2).
<table>
<thead>
<tr>
<th>Name</th>
<th>Procedure</th>
<th>Dose area product Gy/cm²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steinke</td>
<td>4 Fr endoAVF</td>
<td>0,91</td>
</tr>
<tr>
<td></td>
<td>6 Fr endoAVF</td>
<td>2,15</td>
</tr>
<tr>
<td>Radosa</td>
<td>6 Fr endoAVF</td>
<td>46,4</td>
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<tr>
<td>Majewska</td>
<td>PTS Fem</td>
<td>6,3-70</td>
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<tr>
<td></td>
<td>PTS Iliac</td>
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<td></td>
<td>Carotid</td>
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<td></td>
<td>Coro</td>
<td>27,2</td>
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<td></td>
<td>Coro PTA</td>
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<tr>
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<td>Coro PTS</td>
<td>97</td>
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</table>

Steinke 2018 Endovaskuläre Anastomosetechniken in der Shuntchirurgie, Gefässchirurgie, 23(6), 412-419, DOI 10.1007/s00772-018-0466-9


**WAVELINQ™ 4F EndoAVF System** proximal forearm location enables a variety of strategies to provide patients with a functional fistula.

**Using wrist access:**

- more options to get vessel access
- shorter operating time
- less exposition to radiation
- better hemostasis
THANK YOU
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