COVERA™ Vascular Covered Stents – Innovation in AV Access

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Dr. Rajan has been compensated by Bard Peripheral Vascular, Inc. to participate in this presentation.
Patency after Creation of Access with AV Grafts and AV Fistulae

How to best treat the failing AV Access?
Treatment of Failing AV Access

The Optimized Care Protocol

- Retrospective, observational review study to evaluate the influence of a new optimized care protocol on the incidence of revisions and patency rates in patients.

- Optimized Care Protocol (OCP)
  - Bimonthly multidisciplinary Meeting with Vascular Surgeons, Nephrologists, Interventional Radiologist, Dialysis Nurse and Ultrasound Technician
  - Focus on pre-operative planning and post-operative surveillance.

# Treatment of Failing AV Access

## Results

<table>
<thead>
<tr>
<th></th>
<th>Group 1 Prior OCP</th>
<th>Group 2 Post OCP</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>72</td>
<td>74</td>
<td></td>
</tr>
<tr>
<td>Post operative revisions</td>
<td>N = 63</td>
<td>N = 48</td>
<td>&lt;0.894</td>
</tr>
<tr>
<td>Surgical</td>
<td>60</td>
<td>23</td>
<td>&lt;0.019</td>
</tr>
<tr>
<td>Radiology</td>
<td>3</td>
<td>25</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total Revision Rate</td>
<td>88%</td>
<td>63%</td>
<td></td>
</tr>
<tr>
<td>12 month Primary Patency</td>
<td>36 %</td>
<td>49 %</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12 month Secondary Patency</td>
<td>47 %</td>
<td>70 %</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Conclusions

- More effective logistics
- Significant decrease of surgical revisions
- Significant increase of endovascular balloon interventions
- Less patient morbidity
- Higher primary and secondary patencies

Flu et al., J. Vasc. Surg 2008;48:659-68
Endovascular Treatment
Primary Patency by Access Type

Review of 12 year data from 439 accesses in 364 hemodialysis patients in a single center.

# Summary of Interventions to achieve Secondary Patency

<table>
<thead>
<tr>
<th></th>
<th>Forearm Fistula (n=209)</th>
<th>Upper Arm Fistula (n=74)</th>
<th>Prosthetic Grafts (n=156)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balloon Angioplasty</td>
<td>311</td>
<td>136</td>
<td>279</td>
</tr>
<tr>
<td>Declot Procedures</td>
<td>60</td>
<td>39</td>
<td>158</td>
</tr>
<tr>
<td>Number of Stents used</td>
<td>18</td>
<td>37</td>
<td>80</td>
</tr>
<tr>
<td>Total Procedures</td>
<td>389</td>
<td>212</td>
<td>517</td>
</tr>
<tr>
<td>Procedures per patient year</td>
<td>1,8</td>
<td>2,9</td>
<td>3,3</td>
</tr>
</tbody>
</table>

PTA versus Bare Metal Stents

Three Randomized controlled studies

6 Month Access Circuit Primary Patency

- Beathard (1993), n=58
  - Stent: 72%
  - PTA: 64%

- Quinn (1995), n=59
  - Stent: 27%
  - PTA: 31%

- Hoffer (1997), n=34
  - Stent: 12%
  - PTA: 23%
Bare Metal Stents

- No better patency than PTA
- Only recommended for failed PTA (where surgery is not an option) or rupture*
- Increase cost compared to POBA
- Add time to procedure
- New problem: In-stent stenosis

*NKF KDOQI Guideline 6.6.1.
BARD EPTFE COVERED STENTS
CLINICAL DATA
6 Month Treatment Area Primary Patency

PTA [n=97]  23.0%

FLAIR® Stent Graft [n=93]  51.0%

p<0.001
PIVOTAL STUDY

Graft-to-Vein Anastomosis

6 Month Access Circuit Primary Patency

- PTA [n=93]: 20.0%
- FLAIR® Stent Graft [n=97]: 38.0%

p = 0.008
Treatment Area Primary Patency through 12 and 24 Months

- **PTA [n=132]**
  - 12 Months: 25.0%
  - 24 Months: 14.0%
  - p<0.001

- **FLAIR® Stent Graft [n=138]**
  - 12 Months: 48.0%
  - 24 Months: 27.0%
  - p<0.001
In-stent Restenosis in the venous outflow of the access circuit.

**Percentage of Post Intervention Lesion Patency through 6 Months**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Patency</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTA [n=111]</td>
<td>10.0%</td>
<td></td>
</tr>
<tr>
<td>FLUENCY® PLUS Stent Graft [n=109]</td>
<td>65.0%</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Indicated for the treatment of stenoses in the upper extremity venous outflow of patients dialyzing with an arterio-venous (AV) access graft or fistula.
• Highly flexible Nitinol base stent architecture
• Full encapsulation with two ePTFE layers
• Carbon Impregnation on Luminal Surface
Straight Configuration

For use in anatomies where the outflow vein diameter is $\leq$ inflow vein (or graft) diameter.

Courtesy S. Trerotola, M.D.
For use in anatomies where the outflow vein diameter is > inflow vein (or graft) diameter.

• In a review of 58 imaging studies it was found that 66% swingpoint lesions in Transposed Basilic Fistulas showed a diameter increase (data on file)

• In the FLAIR® Pivotal Study, 84% graft vein anastomoses needed a flared stent graft for the treatment of stenosis at the graft-vein anastomosis. (NEJM)
Fracture Resistance

Range of Motion Clinical Study (RoM Study)
Fracture Resistance

• Prospective Clinical Study

• IRB approved, written informed consent

• Principal Investigator:

Theodore F. Saad, M.D.
Medical Director, Vascular Access Interventional Program
Newark (DE) United States

• Purpose: Characterize the range of motion a permanent implant would be exposed to when implanted in the cephalic arch and at a swingpoint of basilic vein transpositions.
Fracture Resistance

- 30 Patients enrolled
  - 15 brachiocephalic AV Fistulae
  - 15 brachiobasilic AV Fistulae

- Venograms were obtained at three different arm positions:
  - Arm adducted
  - Arm abducted at 90°
  - Arm elevated
Fracture Resistance

Brachiocephalic AV Fistula

Arm down

Arm out

Arm up
Fracture Resistance

Brachiocephalic AV Fistula
Fracture Resistance

Brachiobasilic AV Fistula
Fracture Resistance

Brachiobasilic AV Fistula
Fracture Resistance

Based on the RoM Study Measurements, Bending Fatigue Durability Testing was developed for the COVERA™ Vascular Covered Stent.

- Test samples were subjected to > 10 M cycles.
- At final inspection, no strut fracture was observed.

Note: Bench testing may not be predictive of clinical outcomes.
Thank you
COVERA™ Vascular Covered Stent

Prescriptive Information

Prior to use, please see the complete „Instructions for Use“ for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operator’s Instructions.

INDICATIONS
The COVERA™ Vascular Covered Stent is indicated for the treatment of stenoses in the upper extremity venous outflow of patients dialyzing with an arterio-venous (AV) access graft or fistula.

CONTRAINDICATIONS
There are no known contraindications for the COVERA™ Vascular Covered Stent.

WARNINGS
- This device should be used only by physicians who are familiar with the complications, side effects, and hazards commonly associated with dialysis access shunt revisions and endovascular procedures.
- DO NOT expose the covered stent to temperatures higher than 680 °F (360 °C). ePTFE decomposes at elevated temperatures, producing highly toxic decomposition byproducts.
- DO NOT use the device if packaging / pouch is damaged.
- The COVERA™ Vascular Covered Stent device is supplied sterile and is intended for SINGLE USE ONLY. DO NOT resterilize and/or reuse the device.

WARNINGS (CONTINUED)
Reuse, resterilization, reprocessing and/or repackaging may create a risk to the patient or user, may lead to infection or compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness, or death of the patient.

Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications or death.

- DO NOT use in patients with uncorrectable coagulation disorders.
- DO NOT use in patients with bacteremia or septicaemia and/or evidence of fistula or graft infection.
- DO NOT use in patients that cannot be adequately pre-medicated.
- DO NOT use in patients who have a known allergy or sensitivity to contrast media.
- DO NOT use in patients with known hypersensitivity to nickel-titanium or tantalum.
Instructions for Use

WARNINGS (CONTINUED)

- DO NOT use in patients whose AV access grafts have been implanted less than 30 days or in an immature fistula.
- DO NOT use the device in patients where full expansion of an appropriately sized PTA balloon catheter could not be achieved during pre-dilation with an angioplasty balloon.
- Placing a covered stent across a vessel side branch may impede blood flow and hinder or prevent future procedures.
- Covered stent placement beyond the ostium of the cephalic vein into the axillary/subclavian vein may hinder or prevent future access.
- DO NOT place a flared covered stent with the flared end in a straight vessel segment since this may lead to flow turbulences.
- The device has not been tested for tracking and deployment around an AV loop graft.

PRECAUTIONS (CONTINUED)

- DO NOT use a kinked delivery system.
- During covered stent release DO NOT hold the 30 cm long distal catheter assembly segment as it must be free to move and slide into the white stability sheath.
- Careful attention by the operator is warranted to mitigate the potential for distal migration of the covered stent during deployment.
- The covered stent cannot be post dilated beyond its labeled diameter. The flared distal end does not require post dilation.
- The safety and effectiveness of the device when placed across an aneurysm or a pseudo-aneurysm has not been evaluated.
- The safety and effectiveness of the device when used in central veins has not been evaluated.
- The safety and effectiveness of the device when placed across a previously placed bare metal stent has not been evaluated.
- The safety and effectiveness of the device when placed across the antecubital fossa has not been evaluated.
- The safety and effectiveness of the device when used in pediatrics has not been evaluated.
- The effects of direct cannulation of the covered stent have not been evaluated. Notify the patient that the covered stent should not be directly cannulated for hemodialysis and that applying pressure to the implant area should be avoided.
- The device has not been tested for use in an overlapped condition with a bare metal stent or covered stent.
- Higher deployment force maybe encountered with longer length covered stents.

PRECAUTIONS

- Prior to covered stent implantation refer to the sizing table (Table 1) and read the Instructions for Use.
- The delivery system is not intended for any use other than covered stent deployment.
- The covered stent (implant) cannot be repositioned after total or partial deployment.
- Once partially or fully deployed, the covered stent cannot be retracted or remounted onto the delivery system.
- If unusual resistance is met during covered stent system introduction, the system should be removed and another covered stent system should be used.
- DO NOT introduce or manipulate the delivery system without an appropriately sized guidewire and without fluoroscopic guidance.
POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

Complications and Adverse Events associated with the use of the COVERA™ Vascular Covered Stent may include the usual complications associated with endovascular stent and covered stent placement and dialysis shunt revisions.

Potential complications may include, but are not limited to:
Thrombotic occlusion, restenosis requiring reintervention, pseudoaneurysm, vessel rupture, dissection, extravasation, perforation, pain, infection, hemorrhage, hematoma, arm or hand edema, steal syndrome, congestive heart failure, cerebrovascular accident, allergic reaction, rash, reaction to contrast, fever, sepsis, prolonged bleeding, ventricular fibrillation, face or neck edema, bleeding at access site, hemoptysis and death.

Covered stent specific events that could be associated with clinical complications include:
Misplacement, migration, embolism, fracture, kinking and insufficient covered stent expansion.

Delivery System specific events that could be associated with clinical complications include:
Bond joint failures, detachment of parts, incompatibility with accessory devices, premature deployment, inaccurate deployment, failure to deploy, high deployment forces, delivery system kinking, no visibility under fluoroscopy, inability to track to target location and blood leakage from delivery system.
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