EVALUATION OF A NOVEL BIOABSORBABLE AND NON-SYNTHETIC VASCULAR CLOSURE DEVICE: FISH IN DAILY ROUTINE

Marcus Treitl, MD; Maximilian F. Reiser, MD; Karla Maria Treitl, MD
INTRODUCTION

- **Manual compression (MC) for closure of arterial access**
  - 15 – 20 min followed by 4- 6h immobilization
  - *Reported Time to Hemostasis (TTH): 16 Min (FDA PMA filing P930038)*
  - *Patient discomfort, maybe leading to noncompliance*
  - *Bleeding*
  - *Limited in obese patients and with coagulopathy or anticoagulation*

- **Since mid 1990s development of vascular closure devices (VCDs)**
  - Safely achieve complete hemostasis and closure of arteriotomy
  - Reduction of access related complications
  - Promise of improving workflow and patient comfort

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DRAWBACKS OF VCDs

- **Especially active VCDs introduce foreign bodies**
  - Collagen or Synthetics like PGA, PEG, etc.
  - Typically induce inflammatory response: Cause for scarred groin (*frequent re-puncture!*)

- **Many Contraindications**
  - Puncture of SFA, PFA, bifurcation, above IEA, multiple punctures required
  - Heavy arterial calcification
  - Small arterial caliber
  - Vessel tortuosity
  - Re-puncture within 30 days

- **New complications**
  - Distal embolization
  - Deployment failure
  - Infection
FISH: FEMORAL INTRODUCTER SHEATH & HEMOSTASIS

- **Active VCD, under development since early 2000s**
  - Morris Innovative Inc., Bloomington, IN, USA
  - Intra- and extravascular sealing with t-shaped and wired piece of porcine SIS (small intestinal mucosa; Cook Biotech™)
    - Biologic material known from therapy of burns
    - Less inflammatory response
    - Resorbed within 90 days

- **Benefits**
  - Less scarring of access site
  - Less limitations than other VCD
    - Puncture site location, access vessel size ($\geq$ 3mm), calcification
  - Might be used as working sheath in some versions
  - Lower risk of distal embolization since made from one piece
FISH: OVERVIEW

- **FISH Control close**
  - 6 and 7F
  - Cuff stabilizer

- **FISH Combi close**
  - 5, 6, 7 and 8F
  - No Cuff stabilizer

- **How it works**
FISH: AVAILABLE DATA

- FDA approval for use in diagnostic procedures (PMA)
- Preliminary study in the US (2004 – 6)
  - 297 patients
    - FISH: 139 diagnostic / 52 interventional pts.
- Results
  - Mean time to hemostasis: 6 minutes
  - Mean time to mobilization: 2 hours
  - Technical success: 97.9% (4 device failures)
  - FISH: One severe bleeding (0.72%), 3 hematoma, 2 pseudoaneurysms
AIM OF STUDY

- To evaluate the
  - Feasibility
  - Efficacy
  - Safety
- ...of remodeled FISH Control close aVCD for routine use in peripheral endovascular intervention
- Pilot study
PATIENT SELECTION

- Prospective evaluation with ethics committee approval
- Consecutive patients with indication for endovascular treatment of peripheral artery disease of the lower limb
  - Inclusion criteria:
    - Informed consent to participate in study
    - Procedure done with 6 or 7F access sheath
    - Access vessel diameter ≥ 3mm
  - Exclusion criteria:
    - Skin infection at access site
    - Other VCD than FISH recently implanted within last 30 days at planned access site
    - INR > 1.5
    - Denial of study participation
  - No influence of: thrombolysis, puncture site, BMI, anticoagulation, renal failure, stage of PAOD, sex, recent use of FISH at same access site
STUDY ENDPOINTS

According to SIR guidelines, acceptable major complications are:
- Manual compression
- VCD use: reported 0–3, acceptable 0–3%


- Bleedings requiring transfusion
- Pseudoaneurysm (PA)
- Device embolization
- Acute occlusion of the access vessel
- Access site infection

- Small hematomas

Minor complications:
- No or nominal therapy, no consequence; no prolonged hospital stay
PROCEDURE AND FOLLOW UP

- **Procedure:** always 5.000 IU Heparin i.v.
  - Antegrade or retrograde puncture of common femoral artery (CFA)
  - Implantation of FISH according to IFU
    - Physician has used > 20 devices prior to study
  - Short manual compression until hemostasis
  - Sterile wound dressing
  - Immobilization and sand sack for 1hr
  - In case of device failure / prolonged manual compression until hemostasis
    - Compression bandage for 24hrs / immobilization for 6hrs

- **Post-procedural follow-up the next day / prior to discharge / 6months:**
  - Clinical inspection and palpation
  - Duplex ultrasound of access site and outflow (embolization of device?)
## PATIENT CHARACTERISTICS

<table>
<thead>
<tr>
<th>Patient count</th>
<th>132</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td>88 male / 44 female</td>
</tr>
<tr>
<td><strong>Mean age</strong></td>
<td>71.5yrs (41 – 98yrs)</td>
</tr>
<tr>
<td><strong>Mean BMI</strong></td>
<td>28.2 (23 – 35)</td>
</tr>
<tr>
<td><strong>Renal failure</strong></td>
<td>32 (24.2%)</td>
</tr>
<tr>
<td><strong>Critical limb ischemia</strong></td>
<td>55 (41.7%)</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>59 (44.7%)</td>
</tr>
<tr>
<td><strong>Thrombocytes</strong></td>
<td>280.000</td>
</tr>
<tr>
<td><strong>Mean INR</strong></td>
<td>1.1</td>
</tr>
<tr>
<td><strong>ASA or Clopidogrel alone</strong></td>
<td>85%</td>
</tr>
<tr>
<td><strong>Dual anti-platelet regimen</strong></td>
<td>13%</td>
</tr>
<tr>
<td><strong>Anticoagulation / Heparin</strong></td>
<td>17%</td>
</tr>
<tr>
<td><strong>Glycoprotein IIb/IIIA inhibitors</strong></td>
<td>0</td>
</tr>
</tbody>
</table>
## PROCEDURAL CHARACTERISTICS

<table>
<thead>
<tr>
<th>Patient count</th>
<th>132</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior intervention same access site (no other VCD)</td>
<td>37  (28%)</td>
</tr>
<tr>
<td>Antegrade puncture</td>
<td>95  (72%)</td>
</tr>
<tr>
<td>6F</td>
<td>125  (94.7%)</td>
</tr>
<tr>
<td>Mean access vessel diameter</td>
<td>6.5  (3.8 – 8.2)</td>
</tr>
<tr>
<td>Visible calcification of punctured vessel</td>
<td>52  (39.4%)</td>
</tr>
<tr>
<td>Heavily calcified</td>
<td>8  (6.1%)</td>
</tr>
<tr>
<td>Thrombolysis with rt-PA during procedure</td>
<td>7  (5.3%)</td>
</tr>
<tr>
<td>Re-puncture after FISH</td>
<td></td>
</tr>
<tr>
<td>next day</td>
<td>n = 6</td>
</tr>
<tr>
<td>within 12 months</td>
<td>n = 12</td>
</tr>
<tr>
<td>Palpable scarring / resistance</td>
<td>0</td>
</tr>
<tr>
<td>Device displacement</td>
<td>0</td>
</tr>
</tbody>
</table>
# RESULTS

<table>
<thead>
<tr>
<th></th>
<th>FISH Control Close</th>
<th>FISH Historical data</th>
<th>Manual compression (published data*)</th>
<th>AngioSeal (published data*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>132</td>
<td>191</td>
<td>-</td>
<td>435 – 4,525</td>
</tr>
<tr>
<td>Technical success</td>
<td>97% (n=128)</td>
<td>97.9%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Device failures</td>
<td>1.5% (n=2)</td>
<td>2.1% (n=4)</td>
<td>-</td>
<td>N/A</td>
</tr>
<tr>
<td>TTH [sec]</td>
<td>45 [0 – 136]</td>
<td>360</td>
<td>960 – 1,500</td>
<td>&lt; 60</td>
</tr>
<tr>
<td>TTA [hrs]</td>
<td>1.1 [1 – 4]</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Major complications</td>
<td>2 PA (1.5%)</td>
<td>1 BI (0.72%)</td>
<td>0 – 3%</td>
<td>0.8 – 3.6%</td>
</tr>
<tr>
<td>Minor complications</td>
<td>3 SH (2.3%)</td>
<td>3 SH / 2 PA (2.6%)</td>
<td>N/A</td>
<td>7%</td>
</tr>
<tr>
<td>Pain during implant</td>
<td>n = 6 (4.5%)</td>
<td>N/A</td>
<td>Sometimes observed</td>
<td>Often observed</td>
</tr>
<tr>
<td>Late device failures</td>
<td>0</td>
<td>-</td>
<td>-</td>
<td>N/A</td>
</tr>
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IMMEDIATE RE-PUNCTURE 1 DAY AFTER FISH 6F

- Male, 40yrs
- Treatment for right renal artery occlusion 1 day before
  - 6F FISH used for closure, successfully
- Acute re-occlusion the next day re-puncture necessary
  - No intraluminal visible foreign body
  - No device displacement
FOLLOW-UP AFTER 6F FISH

- Male, 78yrs
- Repeat treatment for multi-focal PAOD
- Retrograde 6F procedure and FISH left CFA 12 months ago
- Angiographic follow-up
CONCLUSION

- **FISH Control close device is**
  - Easy-to-use, safe, and potent vascular closure device for interventional procedures
    - Mean TTH 45 sec
    - No device embolization / infection / displacement, even in case of failure!
  - Comparable low major complication rate of 1.5%
  - In our observation no palpable / relevant scarring of access site
  - No device displacement / embolization in case of early re-puncture observed
  - Broader range of suitable vessel diameters starting from 3mm
  - Is not contraindicated in case of calcification (device failure may occur)

- **Remark:**
  - Adequate preparation of puncture channel necessary (oozing possible)
THANK YOU VERY MUCH FOR YOUR ATTENTION!

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