Technical Aspects for Treating AV Dialysis Fistulae with the IN.PACT DCB

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Disclosure

Speaker name: Andrew Holden

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
Failing Hemodialysis Vascular Access and underlying End-Stage Renal Disease: Facts & Figures

2.7M+ Global ESRD population grows at 7% rate/annum

<table>
<thead>
<tr>
<th>Country</th>
<th>Prevalent population (* per million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>1,870</td>
</tr>
<tr>
<td>China</td>
<td>2,260</td>
</tr>
<tr>
<td>Japan</td>
<td>325</td>
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<tr>
<td>EU</td>
<td>490</td>
</tr>
</tbody>
</table>

The path from ESRD to AV access failure (US 2011)

- **ESRD** (End Stage Renal Disease)
- **RRT** (Renal Replacement Therapies)

ESRD Prevalent pop.:
- 490k

RRT:
- 8% Peritoneal dialysis
- 22% Renal Transplant
- 69% Hemodialysis (HD)

HD Vascular Access Types:
- 12% Catheters
- 80% AVF - 5% AVG

AV Access Maintenance:
- Surgical
- Dial Catheter
- Endovascular (~54k proc.)

High shear stress gradients damage endothelial cells in anastomotic regions.

Histological differences between veins and arteries produce incongruent wall stretching and intimal proliferation.

Connect high pressure artery to low pressure vein.

Immediate increase in blood flow through both artery and vein (Increased wall shear stress (WSS)).

Causes acute vaso-dilation & thickening of venous wall in attempt to reduce WSS.

Wall thickening in veins caused by WSS is called venous arterialization (medial thickening).

Angle of the AV anastomoses influences hemodynamics and thus the strength of the shear stress (obtuse angle less favourable).

Recurrent punctures cause traumatic intimal proliferation.

Lee et al. ASN 2009, FC 297
Restenosis Intervention – Some Facts

- Stenoses involve the access vein in ~ 60% cases, AV anastomosis in 20% and central veins in 20%
- Approximately 60% are single stenoses, 40% multiple
- Rule of thirds – approximately 1/3\textsuperscript{rd} cases are de novo stenoses, 1/3\textsuperscript{rd} first restenosis, 1/3\textsuperscript{rd} recurrent restenosis
- Stenoses are often resistant to dilatation and high pressure balloons / cutting balloons are required to achieve nominal diameters in 35-40% of cases
Endovascular Treatment Options

• Gold standard: Plain balloon angioplasty
  – Primary patency rates\cite{1}
    • >50% @ 1 year for AVF
    • >50% @ 6 months for AVG
    • Bail-out Stenting

• High pressure balloons / cutting balloons
  – 1 study reports superior primary patency for cutting vs high-pressure balloons\cite{2}
    • Aftab SA et al: 6M PP: 66.4% and 39.9%

• PTA vs. BMS
  – 1 study has reported improved primary patency for the BMS group
    • Kakisis JD et al\cite{3}: 12M 14% vs 49%

• Stent grafts in AVG
  – 2 studies have reported significantly better primary patency
    • Haskal ZJ et al\cite{4}: 6M 51% vs. 23%
    • Karnabatidis D et al\cite{5}: 12M 61.4% (stent graft) vs. 8.6% (PTA/BMS)

\cite{1} Vesely TM, Siegel JB. J Vasc Interv Radiol. 2005;16(12):1593-1603.
Restenosis – The Problem!

- Although many dialysis access stenoses are fibrotic and difficult to dilate with POBA, we now have technologies to optimize the acute result.
- However, all of these treatment strategies are associated with unacceptable restenosis rates.
- Most haemodialysis patients are on long term, costly and invasive dialysis access surveillance and re-intervention programmes.
- Hence the interest in DCBs to potentially modify this process and improve durability.
Restenosis – The Problem!

Courtesy Prof TAY Kiang Hiong – RCT of Cutting Balloon Angioplasty (CBA) vs High Pressure Balloon Angioplasty (HPBA) in Haemodialysis AV Access
## RCTs: DCB vs PTA

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<thead>
<tr>
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<tbody>
<tr>
<td><strong>Design</strong></td>
<td>Prospective, randomized, single centre</td>
<td>Prospective, randomized, single centre</td>
<td>Prospective, randomized, single centre</td>
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<tr>
<td><strong>Devices</strong></td>
<td>IN.PACT DCB vs. High-pressure PTA</td>
<td>IN.PACT DCB vs. High Pressure PTA</td>
<td>SeQuent Please vs. POBA</td>
</tr>
<tr>
<td><strong># Patients</strong></td>
<td>40 (1:1)</td>
<td>40 (1:1)</td>
<td>10 (20 lesions; 1:1)</td>
</tr>
<tr>
<td><strong>Primary Endpoint</strong></td>
<td>Primary Patency 6M / 12M</td>
<td>TLR-free survival</td>
<td>Freedom from TLR (FTLR)</td>
</tr>
<tr>
<td><strong>Anastomosis</strong></td>
<td>AVF and AVG</td>
<td>AVF</td>
<td>AVF</td>
</tr>
</tbody>
</table>
| **Outcomes: DCB vs. control** | 6M: 70% vs 25% 12M : 35% vs 5%  
  \( p < 0.001 \)  | TLR-free survival: 308 vs 161 days  
  \( p = 0.04 \)  | FTLR: 251T vs. 103T  
  6M PP 70% vs. 0%  
  12M PP 20% vs. 0%  
  \( p < 0.01 \)  |

## Single-arm Studies & Retrospective Analyses

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<tbody>
<tr>
<td><strong>Design</strong></td>
<td>Prospective, single centre</td>
<td>Retrospective, single centre</td>
<td>Retrospective, single centre</td>
<td>Retrospective, single centre</td>
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<tr>
<td><strong>DCB</strong></td>
<td>Unbekannt</td>
<td>IN.PACT DCB</td>
<td>Cardionovum + Cutting balloon</td>
<td>Lutonix</td>
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<tr>
<td><strong># Patients</strong></td>
<td>26</td>
<td>37</td>
<td>50</td>
<td>39</td>
</tr>
<tr>
<td><strong>Primary Endpoint</strong></td>
<td>Primay Patency @ 6M / 12M / 24M</td>
<td>TLR-free survival</td>
<td>Primary Patency @ 8M</td>
<td>Primary Patency @ 6M</td>
</tr>
<tr>
<td><strong>Anastomosis</strong></td>
<td>AVF</td>
<td>AVF</td>
<td>AVF + AVG</td>
<td>AVF + AVG</td>
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<tr>
<td></td>
<td>6M: 96.1%</td>
<td>12M TLR-free: 69% vs. 19% p &lt; 0.001</td>
<td>8M: 87.7%</td>
<td>6M: 72.2%</td>
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<td>12M: 81/8%</td>
<td></td>
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<td></td>
<td>24M: 57.8%</td>
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Meta analysis of different therapies suggest a potential role for DCB in AV Access

Expert Review of Medical Devices

Cutting balloons, covered stents and paclitaxel-coated balloons for the treatment of dysfunctional dialysis access

Panagiotis Kitrou, Stavros Spiliopoulos, Dimitris Karnabatidis & Konstantinos Katsanos
<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental Events</th>
<th>Control Events</th>
<th>Total</th>
<th>Total</th>
<th>Weight</th>
<th>Odds Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2.1 Cutting balloons</td>
<td></td>
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<tr>
<td>Aftab et al. 2014</td>
<td>24</td>
<td>36</td>
<td>14</td>
<td>35</td>
<td>8.4%</td>
<td>3.00 [1.14, 7.90]</td>
</tr>
<tr>
<td>Rasuli et al. 2015</td>
<td>2</td>
<td>18</td>
<td>5</td>
<td>19</td>
<td>3.8%</td>
<td>0.35 [0.06, 2.10]</td>
</tr>
<tr>
<td>Saleh et al. 2014</td>
<td>150</td>
<td>316</td>
<td>127</td>
<td>307</td>
<td>14.8%</td>
<td>1.28 [0.93, 1.76]</td>
</tr>
<tr>
<td>Vesely et al. 2005</td>
<td>83</td>
<td>173</td>
<td>68</td>
<td>167</td>
<td>13.7%</td>
<td>1.34 [0.87, 2.06]</td>
</tr>
<tr>
<td>Wu et al. 2008</td>
<td>36</td>
<td>36</td>
<td>16</td>
<td>36</td>
<td>8.2%</td>
<td>3.33 [1.22, 9.00]</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>578</strong></td>
<td><strong>563</strong></td>
<td><strong>48.8%</strong></td>
<td></td>
<td>1.55 [1.02, 2.36]</td>
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<tr>
<td></td>
<td>284</td>
<td>229</td>
<td></td>
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</tr>
<tr>
<td>Heterogeneity: Tau² = 0.10; Chi² = 7.95, df = 4 (P = 0.09); I² = 50%</td>
<td></td>
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<tr>
<td>Test for overall effect: Z = 2.03 (P = 0.04)</td>
<td></td>
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<tr>
<td>1.2.2 Covered stents</td>
<td></td>
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<tr>
<td>Carmona et al. 2016</td>
<td>14</td>
<td>33</td>
<td>1</td>
<td>11</td>
<td>2.8%</td>
<td>7.37 [0.84, 64.43]</td>
</tr>
<tr>
<td>Haskal et al. 2016</td>
<td>37</td>
<td>138</td>
<td>18</td>
<td>132</td>
<td>11.7%</td>
<td>2.32 [1.24, 4.33]</td>
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<tr>
<td>Karnabatidis et al. 2013</td>
<td>21</td>
<td>35</td>
<td>2</td>
<td>20</td>
<td>4.5%</td>
<td>13.50 [2.70, 67.52]</td>
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<tr>
<td>Rajan et al. 2015</td>
<td>2</td>
<td>9</td>
<td>0</td>
<td>5</td>
<td>1.4%</td>
<td>3.67 [0.15, 92.65]</td>
</tr>
<tr>
<td>Vesely et al. 2016</td>
<td>75</td>
<td>146</td>
<td>51</td>
<td>148</td>
<td>12.3%</td>
<td>2.04 [1.07, 3.86]</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>360</strong></td>
<td><strong>316</strong></td>
<td><strong>33.7%</strong></td>
<td></td>
<td><strong>2.85 [1.63, 4.98]</strong></td>
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<tr>
<td></td>
<td>149</td>
<td>72</td>
<td></td>
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<tr>
<td>Heterogeneity: Tau² = 0.12; Chi² = 6.05, df = 4 (P = 0.20); I² = 34%</td>
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<tr>
<td>Test for overall effect: Z = 3.66 (P = 0.0002)</td>
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<tr>
<td>1.2.3 Paclitaxel-coated balloons</td>
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<tr>
<td>Kitrou et al. 2014</td>
<td>7</td>
<td>20</td>
<td>1</td>
<td>20</td>
<td>2.7%</td>
<td>10.23 [1.12, 93.34]</td>
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<tr>
<td>Kitrou et al. 2015</td>
<td>4</td>
<td>20</td>
<td>0</td>
<td>20</td>
<td>1.6%</td>
<td>11.18 [0.56, 222.98]</td>
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<tr>
<td>Lai et al. 2014</td>
<td>2</td>
<td>10</td>
<td>0</td>
<td>10</td>
<td>1.5%</td>
<td>6.18 [0.26, 146.78]</td>
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<td>Massmann et al. 2015</td>
<td>7</td>
<td>10</td>
<td>7</td>
<td>15</td>
<td>4.2%</td>
<td>2.67 [0.49, 14.46]</td>
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<td>Swinson et al. 2015</td>
<td>26</td>
<td>37</td>
<td>7</td>
<td>37</td>
<td>7.4%</td>
<td>19.43 [2.43, 309.93]</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>97</strong></td>
<td><strong>102</strong></td>
<td><strong>17.5%</strong></td>
<td></td>
<td><strong>7.42 [3.38, 16.29]</strong></td>
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<tr>
<td></td>
<td>46</td>
<td>15</td>
<td></td>
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<tr>
<td>Heterogeneity: Tau² = 0.00; Chi² = 1.89, df = 4 (P = 0.76); I² = 0%</td>
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<tr>
<td>Test for overall effect: Z = 5.00 (P &lt; 0.00001)</td>
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<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>1035</strong></td>
<td><strong>981</strong></td>
<td><strong>100.0%</strong></td>
<td></td>
<td><strong>2.60 [1.74, 3.88]</strong></td>
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</tr>
<tr>
<td></td>
<td>479</td>
<td>316</td>
<td></td>
<td></td>
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<tr>
<td>Heterogeneity: Tau² = 0.26; Chi² = 35.21, df = 14 (P = 0.001); I² = 60%</td>
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</tbody>
</table>
| Test for overall effect: Z = 4.66 (P < 0.00001)  
Test for subgroup differences: Chi² = 12.43, df = 2 (P = 0.002), I² = 83.9%
How I use IN.PACT DCB in Arterio-venous Fistula Intervention

• Consider a DCB in all restenosis cases, especially those with recurrent restenosis
• Stenoses associated with significant thrombus or aneurysmal dilatation should be managed differently (thrombectomy, thrombolysis, covered stents)
• The primary role of the DCB is as an anti-restenosis strategy
• It is therefore vital to optimise the angioplasty result (residual < 30%) BEFORE DCB using whatever strategy is required (POBA, CBA, HPBA)
• The anti-restenosis benefit of a DCB is likely to be minimal if there is a suboptimal acute result
How I use IN.PACT DCB in Arterio-venous Fistula Intervention

• Accurate balloon sizing is important (often upsize balloon by 1 mm compared to nominal or up to 1.3:1)
• Good analgesia (+/- infiltration of lesion with LA) is important to allow aggressive angioplasty
• Peri-procedural anticoagulation (heparin bolus)
• Leave DCB inflated for at least 2 minutes
• Post-dilate if residual > 30% post – DCB
• Standard post-procedural care. Consider DAPT for at least 1 month post-procedure but no evidence for longer therapy
Proposed Strategy for Managing Dialysis Access Stenoses

1. Failing/failed vascular access
   - Thrombosis?
     - YES: Thrombolysis/Thrombectomy
       - Success?
         - YES: High-pressure Balloon 1:1
           - Recoil > 30%?
             - YES: Consider cutting/scoring balloon
             - NO: Rupture?
               - YES: Covered stent
               - NO: Drug-Coated Balloon
                 - Repeat balloon angioplasty
                   - YES: Recoil > 30%?
                     - YES: Covered stent
                     - NO: Hemodialysis
                   - NO: Hemodialysis
                 - NO: New access or central catheter
               - NO: Rupture?
                 - YES: Covered stent
                 - NO: Drug-Coated Balloon
                   - Repeat balloon angioplasty
                     - YES: Recoil > 30%?
                       - YES: Covered stent
                       - NO: Hemodialysis
                     - NO: Hemodialysis
                 - NO: Thrombolysis/Thrombectomy
                   - YES: High-pressure Balloon 1:1
                     - Recoil > 30%?
                       - YES: Consider cutting/scoring balloon
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
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                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
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                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
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                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
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                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
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                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
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                       - NO: Rupture?
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                           - Repeat balloon angioplasty
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                       - NO: Rupture?
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                             - NO: Hemodialysis
                       - NO: Rupture?
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                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
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                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
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                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
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                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
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                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
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                               - NO: Hemodialysis
                             - NO: Hemodialysis
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                         - YES: Covered stent
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                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
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                               - NO: Hemodialysis
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                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
                               - YES: Covered stent
                               - NO: Hemodialysis
                             - NO: Hemodialysis
                       - NO: Rupture?
                         - YES: Covered stent
                         - NO: Drug-Coated Balloon
                           - Repeat balloon angioplasty
                             - YES: Recoil > 30%?
Case Example # 1 – 8th January 2016
Restenosis – Radiocephalic AVF
Case Example # 2 – 1st April 2015
De Novo Presentation – Brachiocephalic AVF
Case Example # 2 – 1\textsuperscript{st} April 2015
De Novo Presentation – Brachiocephalic AVF
Case Example # 2 – 11\textsuperscript{th} January 2016
Restenosis– Brachiocephalic AVF
LEFT
8.0mm x 40mm Armada
Nominal @ 6atms

LEFT
8.0mm x 40mm Armada
8.4mm @ 12atms

LEFT
3.0mm x 40mm Armada
8.6mm @ 16atms
Case Example # 3 – 8th August 2016
Restenosis– Brachiocephalic AVF
IN.PACT AV Access IDE Trial

Purpose:
To evaluate the safety and efficacy of the IN.PACT™ AV Access DCB compared to PTA for treatment of subjects presenting with de-novo or non-stented restenotic obstructive lesions of native AVF in the upper extremity.

Design:
• Prospective, global, multicenter, randomized, single-blinded study
• ~30 Global Sites (US, Japan & New Zealand)
• 330 patients
• 24 month follow-up
• 1:1 randomization
• Lesions up to 10 cm in length in the AVF

Principal Investigators:
• Robert Lookstein, MD (New York, USA)
• Andrew Holden (Auckland, New Zealand)
• Hiroaki Haruguchi, MD (Tokyo, Japan)

Study to start in second half of 2017!
Primary Safety Endpoint:

**Serious Adverse Event Rate through 30 Days**
Defined as the Serious Adverse Event (SAE) rate involving the AV access circuit through 30 days post-procedure

Primary Efficacy Endpoint:

**Primary Patency Rate through 6 Months**
Defined as freedom from clinically-driven target lesion revascularization (CD-TLR) or access circuit thrombosis measured at 6 months post-procedure
Conclusions

• Stenoses of haemodialysis access circuits are common and major patient and cost burden.
• Strategies are now available to optimise acute interventional results but restenosis is a major challenge.
• DCBs have the most promising evidence out of all endovascular modalities for restenosis but most studies are small / retrospective.
• Excellent procedural technique is important, particularly lesion preparation prior to the DCB.
• The Medtronic IN.PACT AV Access Study will provide robust level 1 evidence on a global scale.
Technical Aspects for Treating AV Dialysis Fistulae with the IN.PACT DCB

Andrew Holden
Auckland Hospital
Auckland, New Zealand

LINC 2017 – 26th January 2017