Newly-designed Multilayer Flow Modulator for Residual Dissection after Proximal Repair of Acute Aortic Dissection

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Disclosure

Speaker name: Zhenghua Xiao

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)

- [x] I do not have any potential conflict of interest
Aortic Dissection

Type A

Ascending + Total Arch Replacement

+ Elephant Trunk Implantation

Type B

Transcatheter EndoVascular Aortic Repair (TEVAR)
Distal Residual Dissection
need further repair
Multilayer Flow Modulator (MFM)

- STENTGRAFT: Physical Exclusion
- Physiological Exclusion of the Aneurysm

✓ Aneurysm sac shrank and absorbed
✓ Patent branch vessels
## Contrast between three aortic braided stent

<table>
<thead>
<tr>
<th>Method</th>
<th>endovascular</th>
<th>endovascular</th>
<th>Open surgery, sutured with prosthetic vessel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication</td>
<td>Thoracoabdominal aneurysm</td>
<td>Aortic dissection Thoracoabdominal aneurysm</td>
<td>Acute type A aortic dissection</td>
</tr>
<tr>
<td>Braiding technology</td>
<td>Composite multilayer braiding by machine</td>
<td>Back and forth braiding craft Composite multilayer braiding by machine</td>
<td>Machine + handcraft Single layer braiding</td>
</tr>
<tr>
<td>Rough edge</td>
<td>Proximal &amp; distal rough edge</td>
<td>Back and forth braiding technology Decreasing damage on proximal and distal landing zone</td>
<td>Proximal rough edge is covered for suture</td>
</tr>
<tr>
<td>Material</td>
<td>Cobalt-chromium alloy</td>
<td>Super thin nickel-titanium wire</td>
<td>Nickel-titanium wire</td>
</tr>
<tr>
<td>Release mechanism</td>
<td>Without post-release or secondary localization technology</td>
<td>Stent can be retrieved and re-localized even 90% released Accurate localization and easy operation</td>
<td>Used in open surgery</td>
</tr>
<tr>
<td>Type design</td>
<td>Only straight type</td>
<td>Straight/cone/shunt/window types cover the whole aorta used in abdominal aorta containing branch vessels</td>
<td>Only used in acute type A aortic dissection, combined with prosthetic vessel in open surgery Auxiliary instrument</td>
</tr>
<tr>
<td>Procedure</td>
<td>CE approval in 2012</td>
<td>Finish the first recruitment in 2019.08</td>
<td>CE approval FDA breakthrough device in 2019</td>
</tr>
</tbody>
</table>
Dec, 2018 - Aug, 2019
Residual dissection after proximal repair of TAAD/TBAD

Exclusion
※ chronic (> 3mths)
※ Renal dysfunction
※ Allergic to alloy
※ Rupture
※ Stroke, MI (<6mths)
※ Marfan’s syndrome

Inclusion
※ TEVAR within 10wks,
  Open surgery within 30days
※ Involvement of all visceral branches
※ Patent distal false lumen

112 Pts: 56 Control, 56 FDMS

1,3,6,12 mths after surgery/enrollment

Safety Index
• Stent-related Mortality
• Stent-related severe event

Validity Index
• T/FL diameter
• Branch artery diameter
• Branch artery patency rate
• FL thrombosis

Echo-Blood flow
• Celiac trunk
• Mesenteric
• Renal arteries

3-D Reconstruction
(Minics Research 17.0)
• T/FL volume
• Computed flow dynamics

Multicenter, prospective, randomized
ChiCTR1900023638
➢ Angiography

Pre-operation

Post-operation
Contrast-enhanced Computed Tomography

- Thrombosis of the false lumen
- Patent branch artery

1M post-operation  6M post-operation  12M post-operation
## Baseline Characteristics
— West China Hospital

<table>
<thead>
<tr>
<th>No. of Patients</th>
<th>FDMS group</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>14 (77.8%)</td>
<td>16 (88.9%)</td>
</tr>
<tr>
<td>Age(y)</td>
<td>51.82 ± 10.01</td>
<td>54.23 ± 10.30</td>
</tr>
</tbody>
</table>

### Primary Surgery

<table>
<thead>
<tr>
<th>Type</th>
<th>FDMS group</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open after TAAD</td>
<td>5 (27.8%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>TEVAR after TBAD</td>
<td>7 (38.9%)</td>
<td>9 (50%)</td>
</tr>
<tr>
<td>New-onset TBAD</td>
<td>6 (33.3%)</td>
<td>9 (50%)</td>
</tr>
</tbody>
</table>

### Concomitant Diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>FDMS group</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>17 (94.4%)</td>
<td>18 (100.0%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>2 (11.1%)</td>
<td>4 (22.2%)</td>
</tr>
</tbody>
</table>

TAAD/TBAD, type A/B aortic dissection
### Follow-up Data (on-going)

#### Safety Index

<table>
<thead>
<tr>
<th></th>
<th>FDMS group</th>
<th>Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No. of Patients</strong></td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td><strong>Follow-up</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean follow-up (mths)</td>
<td>5.53 ± 2.71</td>
<td>5.40 ± 3.27</td>
</tr>
<tr>
<td>Drop out</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Clinical Outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent-related mortality</td>
<td>0(0%)</td>
<td>0(0%)</td>
</tr>
<tr>
<td>Patent branch vessels</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

No stent-related mortality & morbidity
## Follow-up Data (on-going)
### Validity Index

<table>
<thead>
<tr>
<th>Pre-post operation</th>
<th>FDMS group</th>
<th>Controls</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Patients</td>
<td>18</td>
<td>18</td>
<td>—</td>
</tr>
</tbody>
</table>

### Diameter

<table>
<thead>
<tr>
<th>True lumen min (mm)</th>
<th>FDMS group</th>
<th>Controls</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>L 2</td>
<td>6.2±3.7</td>
<td>1.1±2.6</td>
<td>P&lt;0.01</td>
</tr>
<tr>
<td>L 3</td>
<td>7.5±3.4</td>
<td>0.9±2.9</td>
<td></td>
</tr>
</tbody>
</table>

### Area

<table>
<thead>
<tr>
<th>True lumen (cm²)</th>
<th>FDMS group</th>
<th>Controls</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>L 2</td>
<td>0.47±0.37</td>
<td>0.29±0.51</td>
<td>P&lt;0.01</td>
</tr>
<tr>
<td>L 3</td>
<td>0.71±0.69</td>
<td>0.07±0.41</td>
<td>P&lt;0.05</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>False lumen (cm²)</th>
<th>FDMS group</th>
<th>Controls</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>L 2</td>
<td>-0.67±0.81</td>
<td>-0.17±0.85</td>
<td>P&lt;0.05</td>
</tr>
<tr>
<td>L 3</td>
<td>-0.56±0.55</td>
<td>0.07±0.69</td>
<td></td>
</tr>
</tbody>
</table>

L2: Plane below renal arteries; L3: Plane above the iliac bifurcation

Pre-operation

6 mths Post-operation
MFM facilitates positive remodeling

Shrinkage of the FL

- FDMS group
  - 13.0 ± 4.64 cm³
- Controls
  - 2.67 ± 4.64 cm³

P < 0.05
Echo: Changes of the blood flow in branch vessels

Origins of the branch vessels

<table>
<thead>
<tr>
<th>Branch vessels</th>
<th>$\Delta$ volume of flow (CC/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>True lumen (n=107)</strong></td>
<td>$P=0.09$</td>
</tr>
<tr>
<td>FDMS group (n=51)</td>
<td>59.21 ± 52.86</td>
</tr>
<tr>
<td>Controls (n=56)</td>
<td>18.15 ± 15.94</td>
</tr>
<tr>
<td><strong>Mixed-lumen (n=80)</strong></td>
<td>$P=0.08$</td>
</tr>
<tr>
<td>FDMS group (n=44)</td>
<td>94.69 ± 234.36</td>
</tr>
<tr>
<td>Controls (n=36)</td>
<td>21.88 ± 97.68</td>
</tr>
<tr>
<td><strong>False lumen (n=37)</strong></td>
<td>$P=0.11$</td>
</tr>
<tr>
<td>FDMS group (n=16)</td>
<td>44.6 ± 62.09</td>
</tr>
<tr>
<td>Controls (n=21)</td>
<td>11.2 ± 53.53</td>
</tr>
</tbody>
</table>
Opinions & Conclusions:
Newly-designed FDMS is a promising device

- Surgeons friendly device

Simplicity

Distal controlled deployment-recapture even after 90% deployment
Opinions & Conclusions:
Newly-designed FDMS is a promising device

- Surgeons friendly device
- Simplicity
- All branch vessels patent, no stent-related adverse events

Safety

Short-term ✓

Long-term ?

Preoperative
Postoperative
Preoperative
Postoperative
Opinions & Conclusions:
Newly-designed FDMS is a promising device

- Surgeons friendly device
- Simplicity
- All branch vessels patent, no stent-related adverse events

Safety

- Short-term
- Long-term

✓ Anterograde/retrograde
✓ 14F sheath
✓ Branch artery revascularization
Opinions & Conclusions:
Newly-designed FDMS is a promising device

- Surgeons friendly device

- All branch vessels patent, no stent-related adverse events

- True lumen expansion, FL shrinkage/thrombosis

Safety
- Short-term: ✔️
- Long-term: ?

Effectiveness
- Short-term: ✔️
- Long-term: ?

Simplicity
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