Long-Term Results of MFM® Bare Stents for the treatment of Aortic Dissection and Aortic Aneurysms

IS IT TIME TO THINK OUTSIDE THE BOX? AN EXPERT REVIEW
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National Expert French Supreme Court
CHP Parly 2 France

No Conflict of interest

At 1 year, endovascular repair with the MFM appears to be safe and effective, while successfully preserving branch vessel patency. Follow-up ongoing.

On the basis of the data from this study, the MFM can be assumed safe and effective for treatment of TAAA when used according to the Instructions for Use.

4Y data published

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Dr. Claude Vaislic
Sang Thrombose Vaisseaux (2017): 29-3

The current role of MULTILAYER FLOW MODULATOR STENTS in COMPLEX AORTIC PATHOLOGY

Dr. Claude Vaislic

Off data published
TBAD: Is there a place for the MFM®?

Since 2008, more than 110 papers were published and more than 3,500 patient treated

- 2 systematic reviews, 3 literature reviews
- 15+ papers about the use of the MFM® into aortic dissections (of which a series of 38 patients)
- 20+ papers about prospective clinical investigations/registries/clinical series

Amongst the total of published papers

- 21% Papers about MFM® concept, technical papers, commentaries
- 5% Literature reviews, systematic reviews
- 9% Papers quoting the MFM®, Generic papers
- 11% Papers relating the use of the MFM® for aortic dissection
- 36% Case reports, case series reports
- 18% Prospective Clinical Investigations, Registries, single or multicenters clinical series

MFM® treatment of AD
7 years of follow up

- 40Y Male (Jehovah Witness)
- Type A dissection repair in 2003
- Dissection type B (aneurysmal) repair in 2010 by MFM®, false lumen exclusion

Dr. Vaislic, Dr de Cassin

MFM® treatment of AD
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Dr. Vaislic, Dr de Cassin

MFM® treatment of AD
7 years of follow up

- 69 years old male
- Type A dissection repair in 2006
- Dissection type B (aneurysmal) repair in 2010 by MFM®, false lumen exclusion

Dr. Vaislic, Dr de Cassin
• 69 years old male
• Type B dissection
• Previous ascending aorta surgical repair
• Demonstration of exclusion of false lumen with the MFM® and branches patency

MFM® treatment of AD
7 years of follow up

MFM® treatment of AD: 7 years of follow up

MFM® treatment of AD
3 years of follow up

• 28 Years old Female
• Aortic root replacement
• Type B Dissection
• Normal prognosis: There is no solution

MFM® treatment of AD
3 years of follow up

MFM® treatment of AD
7 years of follow up

• 28 Years old Female
• Aortic root replacement
• Type B Dissection
• Normal prognosis: There is no solution
The MFM® for the treatment of AD: published case report

- Visible Reduction of the False Lumen size and flow
- @M11 – Vestigial Flow in the False Lumen to keep on feeding the Intercostals and Lumbar Arteries (without the MFM®, Paraplegia is the prognosis)

MFM® treatment of AD: 3 years of follow up

- 28 years old female
- History of aortic root replacement
- Normal prognosis: no solution

MFM® for the treatment of AD: 2 years of follow-up

- 28 years old female
- Heavy smoker
- History of aortic root replacement
- Normal prognosis: no solution

MFM® treatment of AD: 3 years of follow up

- 74 years old male
- Previous Stent Graft for type B dissection 7 Years before MFM® placement
- 5 years of follow-up: branches patent and dissection stabilization

MFM® treatment of AD: 5 years of follow up

- 74 years old male
- Previous Stent Graft for type B dissection 7 Years before MFM® placement
- 5 years of follow-up: branches patent and dissection stabilization
MFM® treatment of AD
5 years of follow up

- 74 years old male
- Previous Stent Graft for type B dissection 7 Years before MFM® placement
- 5 years of follow-up: branches patent and dissection stabilization

66 Years old Male
Type B Dissection
2003 Stent graft
2010 MFM

Global MFM® Registry

The MFM® for the treatment of AD: results of the Global Registry (Sultan et al.)

- 38 patients
- 12 months of FU
- Technical Success of 97.4%
- Mean of 1.96 devices used
- 165 covered branches (109 visceral)
- All cause survival at 12 months of 85.3%
- 3 deaths, not device related
  - 0% paraplegia
  - 0% Stroke
  - 0% renal impairment
  - 0% visceral insult

At 12 Months Results Are Superior to INSTEAD, IRAD, ADSORB Studies
The MFM® for the treatment of AD: results of the Global Registry (Sultan et al.)

First safety results at 1 year from a series of 38 patients suffering from chronic type B dissection are superior to other treatments.

<table>
<thead>
<tr>
<th>Open Surgical Repair</th>
<th>Stent-Graft</th>
<th>MFM®</th>
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</thead>
<tbody>
<tr>
<td>30-days mortality</td>
<td>Up to 13,7%</td>
<td>0,0%</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>Up to 13,4%</td>
<td>0,0%</td>
</tr>
<tr>
<td>Paraplegia events</td>
<td>Up to 12,5%</td>
<td>0,0%</td>
</tr>
<tr>
<td>Stroke</td>
<td>Up to 11,8%</td>
<td>0,0%</td>
</tr>
</tbody>
</table>

Positive aortic remodeling occurring over time (% change compared to baseline)

<table>
<thead>
<tr>
<th>True Lumen</th>
<th>False Lumen</th>
<th>Thrombus</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRE</td>
<td>193.7 ± 170.8 (58.7-673.1)</td>
<td>207.7 ± 158.1 (19.3-620.8)</td>
</tr>
<tr>
<td>M12</td>
<td>215.2 ± 119.4 (110.4-440.1)</td>
<td>68.3 ± 50.3 (13.3-139.4)</td>
</tr>
<tr>
<td>% Change at M12</td>
<td>+21.5%</td>
<td>-67,1%</td>
</tr>
</tbody>
</table>

Decrease in False Lumen Volume is 3 times greater than the increase in True Lumen Volume (Due to radial force and lamination - decompression)

The MFM® in Chronic Aortic Dissection: unpublished data collection from a series of 22 patients

Ongoing Clinical Trial:

Dragon Study Europe is an international, multicenter, prospective, non-randomized study. It is designed to evaluate safety and performance of the MFM® for the treatment of chronic type B aortic dissection.

<table>
<thead>
<tr>
<th>Pathology Characteristics</th>
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</thead>
<tbody>
<tr>
<td>Type A</td>
</tr>
<tr>
<td>Type B</td>
</tr>
<tr>
<td>SG or Graft already in place</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TAAO group</th>
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</thead>
<tbody>
<tr>
<td>Iliac Involvement</td>
</tr>
<tr>
<td>Subclavian Involvement</td>
</tr>
</tbody>
</table>
Results

- No Dissection-Related Death (no post-operative deaths in the first 30 days)
- No Paraplegia Nor Stroke
- No Renal Impairment
- No Loss of Branch Patency
- No Rupture
- No Device Failure

The MFM® in Chronic Aortic Dissection: unpublished data collection from a series of 22 patients

Comparison of PRE data and Discharge Data*

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>True Lumen Vol/Total (%)</td>
<td>49</td>
<td>66 (+15%)</td>
</tr>
<tr>
<td>False Lumen Vol/Total (%)</td>
<td>51</td>
<td>34 (-17%)</td>
</tr>
</tbody>
</table>

Effect of the radial force of the MFM® immediately at discharge

Comparison of PRE data and Discharge Data*

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</tr>
</thead>
<tbody>
<tr>
<td>True Lumen Vol/Total (%)</td>
<td>32</td>
<td>39 (+7%)</td>
</tr>
<tr>
<td>False Lumen Vol/Total (%)</td>
<td>68</td>
<td>61 (-7%)</td>
</tr>
</tbody>
</table>

The MFM® in Chronic Aortic Dissection: unpublished data collection from a series of 22 patients

Branches

<table>
<thead>
<tr>
<th>Branches</th>
<th>PRE</th>
<th>POST</th>
<th>M3</th>
<th>M6</th>
<th>M12</th>
<th>M18</th>
<th>M24</th>
<th>M36</th>
<th>M48</th>
<th>M60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (N)</td>
<td>(N=22)</td>
<td>(N=6)</td>
<td>(N=3)</td>
<td>(N=13)</td>
<td>(N=8)</td>
<td>(N=2)</td>
<td>(N=1)</td>
<td>(N=1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Number of branches</td>
<td>189</td>
<td>60</td>
<td>30</td>
<td>130</td>
<td>80</td>
<td>29</td>
<td>20</td>
<td>10</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Involved in AD</td>
<td>104</td>
<td>39</td>
<td>12</td>
<td>96</td>
<td>63</td>
<td>23</td>
<td>16</td>
<td>8</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>% Patenty of branches involved in AD (ex PRE)</td>
<td>96.2 (N=100)</td>
<td>100 (N=39)</td>
<td>100 (N=12)</td>
<td>96.9 (N=13)</td>
<td>98.4 (N=62)</td>
<td>91.3 (N=31)</td>
<td>87.5 (N=14)</td>
<td>75.0 (N=6)</td>
<td>75.0 (N=6)</td>
<td></td>
</tr>
<tr>
<td>% Maintained Patency</td>
<td>100.0%</td>
<td>100.0%</td>
<td>99.0%</td>
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* For the same patients with data available at both PRE and Discharge.
Conclusions

Type B aortic dissections are still left without optimal solutions!

- Complicated Type B aortic Dissection: 20% mortality by day 2 and 25% by day 30
- 30% of aortic dissections are complicated, with only 50% survival in hospital
- TEVAR has proven to be an effective solution with a survival up to 2 times compared with Medical Management
- TEVAR induces positive aortic remodeling but still causes:
  - up to 13.7% of 30-days mortality
  - up to 12.5% of paraplegia events
  - up to 34% of renal failure
  - Up to 11.8% of stroke

Type B aortic dissections are still left without optimal solutions!

Conclusions

The MFM® has been used to treat Aortic Dissections.
Clinical Data demonstrate that the MFM® is safe and performant and is able to:
1. Stabilize/decrease the false lumen and avoid risk of rupture
2. Increase true lumen volume
3. Keep all branches patent, namely intercostals and visceral (no risk of paraplegia, visceral ischemia)
4. Favorize positive aortic remodeling

Conclusions

Based on those data:
We suggest that MFM repair should be considered for patients with aortic dissections.