**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**

Claude Vaislic MD
Cardiovascular Surgeon
National Expert French Supreme Court
CHP Parly 2 France

**No Conflict of interest**

"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."

Dr. Claude Vaislic
Minerva Medica MFM-Dedicated Textbook

4Y 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
- 10+ 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 regarding MFM® concept, technical papers, commentaries
- 5% Literature reviews, systematic review
- 9% Papers presenting the use of the MFM® in complex aortic pathology
- 11% Papers regarding the use of MFM® in aneurysm cases
- 36% Case reports, case series reports
- 18% Prospective Clinical Investigations, Registry, 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 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 7 years of follow up

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

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

MFM® treatment of AD 7 years of follow up

- 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
**Global MFM® Registry: Dissection Study**

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 3.96 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.)**

<table>
<thead>
<tr>
<th>Literature source</th>
<th>Open Surgical Repair</th>
<th>Stent-Graft</th>
<th>MFM®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retroperitoneal Approach (Tan, B. R., De Silva, R. P., Wang, T., &amp; Yan, T. D. (2014).</td>
<td>11.1% (up to 31%)</td>
<td>Up to 13.7%</td>
<td>2.6% (not aortic/device-related)</td>
</tr>
<tr>
<td>Retroperitoneal Approach (Tan, B. R., De Silva, R. P., Wang, T., &amp; Yan, T. D. (2014).</td>
<td>11.1% (up to 31%)</td>
<td>Up to 13.7%</td>
<td>2.6% (not aortic/device-related)</td>
</tr>
<tr>
<td>Devascularization/Debranching (Kamman, A. V., de Beaufort, H. W. L., van Bogerijen, G. H. W., Nauta, F. J. H., Heijmen, R. H., Moll, F. L., … Trimarchi, S. (2016).</td>
<td>11.1% (up to 31%)</td>
<td>Up to 13.7%</td>
<td>2.6% (not aortic/device-related)</td>
</tr>
<tr>
<td>Contemporary Management Strategies for Chronic Type B Aortic Dissections: A Systematic Review. PLoS ONE, 11(5)</td>
<td>11.1% (up to 31%)</td>
<td>Up to 13.7%</td>
<td>2.6% (not aortic/device-related)</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>True Lumen</th>
<th>False Lumen</th>
<th>Thrombus</th>
</tr>
</thead>
<tbody>
<tr>
<td>M0 (PRE)</td>
<td>193.7 ± 170.8 (58.7-617.1)</td>
<td>207.7 ± 158.1 (19.3-620.8)</td>
</tr>
<tr>
<td>M12</td>
<td>215.2 ± 119.6 (110.4-430.1)</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.

Pr Dr Ralf Kolvenbach, Pr Dr Andreas Greinert, Pr Dr Michel Jacobs/OA Dr Claude Vaislic Dr Houman Jalaie, Dr Reda M. Barchiche, Dr Victor Costache, Dr Ioan Popescu, Dr Vanesa Burea, Pr Ivo Petrov, Dr Mariana Konteva, Dr Valeri Gelev, Pr Domenico Palombo, Dr Ugur Gocen, Assist. Prof. Dr. Mustafa Akbulut, Prof. Dr. Selim İşbir, Pr Uei Pua, Pr Jong Yun Won, Pr Do Yun Lee, Pr Keun Her, Dr Ivan Vulev, Pr Sherif Sultan, Pr Dr Tomislav Klokočovnik, Dr Dimitrij Kuhelj, Dr Priemo Trunk, Dr Elhaouati Rachid.

Pathology Characteristics

<table>
<thead>
<tr>
<th>Type</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>1</td>
<td>4.0%</td>
</tr>
<tr>
<td>Type B</td>
<td>21</td>
<td>95.7%</td>
</tr>
</tbody>
</table>

SG or Graft already in place: 3 (13.1%)

TBAD group

<table>
<thead>
<tr>
<th>Involvement</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iliac Involvement</td>
<td>5</td>
<td>22.7%</td>
</tr>
<tr>
<td>Subclavian Involvement</td>
<td>8</td>
<td>36.4%</td>
</tr>
</tbody>
</table>

22 patients with Chronic Aortic Dissection

Mean age: 56.7 years [27-86]

Longest FU: 5Y

Treated with a mean number of 2,7 MFM®

26.1% of patients with CPMS extensions

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

Results

<table>
<thead>
<tr>
<th>Ratio Vol Lumen/ Vol Tot</th>
<th>N</th>
<th>Baseline</th>
<th>Discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>True Lumen/ False Lumen</td>
<td>27</td>
<td>41 (15%)</td>
<td></td>
</tr>
<tr>
<td>False Lumen/ Total vol</td>
<td>73</td>
<td>59 (14%)</td>
<td></td>
</tr>
</tbody>
</table>

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

Comparaison of PRE data and Discharge Data*

*For the same patients with data available at both Pre and Discharge
The MFM® in Chronic Aortic Dissection: unpublished data collection from a series of 22 patients

<table>
<thead>
<tr>
<th>PRE</th>
<th>POST</th>
<th>M3</th>
<th>M6</th>
<th>M12</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>22</td>
<td>6</td>
<td>3</td>
<td>13</td>
</tr>
<tr>
<td>MFM® Fracture</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Aorta Patency</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Patient with Thrombosis in False Lumen</td>
<td>50% (n=3)</td>
<td>100% (n=3)</td>
<td>61.5% (n=8)</td>
<td>37.5% (n=3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Branches</th>
<th>PRE</th>
<th>POST</th>
<th>M3</th>
<th>M6</th>
<th>M12</th>
<th>M24</th>
<th>M36</th>
<th>M48</th>
<th>M60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients [N]</td>
<td>(N=21)</td>
<td>(N=6)</td>
<td>(N=3)</td>
<td>(N=13)</td>
<td>(N=8)</td>
<td>(N=3)</td>
<td>(N=2)</td>
<td>(N=1)</td>
<td>(N=1)</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>
</tr>
<tr>
<td>N in AD</td>
<td>104</td>
<td>19</td>
<td>12</td>
<td>96</td>
<td>63</td>
<td>23</td>
<td>16</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>% Patency of branches involved in AD [vs PRE]</td>
<td>96.2% (N=100)</td>
<td>100.0% (N=39)</td>
<td>100.0% (N=12)</td>
<td>96.9% (N=93)</td>
<td>98.4% (N=62)</td>
<td>91.3% (N=21)</td>
<td>87.5% (N=16)</td>
<td>75.0% (N=4)</td>
<td>75.0% (N=4)</td>
</tr>
<tr>
<td>% Maintained Patency</td>
<td>100.0%</td>
<td>100.0%</td>
<td>99.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

In regards with branches occluded from departure, 100% branches patency is maintained at 12, 24, 36 and 48 months.

Results need to be confirmed in a larger series and at longer follow-up, YET the MFM® appears as a safe and performant solution for AD:
- The MFM® induces positive aortic remodeling (FL volume decrease and TL volume increase)
- The MFM® is able to keep all branches patent during follow-up
- Has been used safely in Chronic, Acute and Subacute TBAD and Type A AD as well

Conclusions

Type B aortic dissections are still left without optimal solutions!

- Complicated Type B aortic Dissection: 20% mortality by day 2 and 35% 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!

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

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