Update on the Status of Multilayer Flow Modulating (MLFM) Stents for the Treatment of Aortic Aneurysms & Dissections

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Disclosure

I do not have any Conflict of Interest to this subject & lecture.

The „Bernoulli Principle“
The Bernoulli Law & The Bernoulli Effect

Bernoulli Law

\[ P = \frac{1}{2} \rho v^2 + \rho g h \]

The second term in this equation is known as the kinetic pressure. The effect described by this law is called the Bernoulli effect and is sometimes known as the Bernoulli principle.

For a heuristic derivation of this law, picture a pipe through which an ideal fluid is flowing at a steady rate. Let a subscript 1 denote fluid parcels at an initial point down the pipe, and a subscript 2 denote fluid parcels further down the pipe. Then the work done by pressure force at the "Landing Zone" is:

\[ W = P \Delta V \]

The Flow Principle

Secular Aneurysms

Without branches

With branches

Implant Procedure

3. implant procedure

Implant the stent with the deployment balloon while deploying the stent via sheath.
1. Optimising the ratio between length/radial force at the “Landing Zone”s

2. Respect the differences between the systolic/diastolic diameter (in mm) of the aorta.

3. To be able to keep long term the “Bernoulli Effect” inside the vessel is possible only by the constant form of the device.

It is possible through an optimized (calibrated) radial force during the deployment of the device at both “Landing Zone”s.

The Advantages of the MARS – MFM /Multilayer flow Modulator/ Device

A - No anatomical (but morphological) limitation for the deployment
B - No dependence of the position of the side branches or of the narrow neck diameters or of the numbers of the branches
C - Significant reduction in time of deployment.
D - There is a 90 % reduction of flow-velocity and a 20-30 % reduction of the shear force on the vessel wall in the sack of the aneurysm.
E - The aneurysm will be closed by time (do not ask when???) by physiologic organised clots.
F - After a short time period of the device-deployment, the flow becomes laminar from turbulent in the fusiform type of aneurysms inside the device.
G - There is a definitive endothelial growth (real or pseudo?) inside the device.

Disadvantages of the MARS – MFM Stent and The „Open Questions“ to the future

A - The Radial Force: middle part and at the two ends of the device
B - The real pressure relationship inside vs. outside of the MFM device ?/ real risk for a real rupture / Thrombus formation ?
C - A detailed deployment technique description of the device !
D - The exact parameters and form of the device after expansion?
E - The real vitalisation – “Endothel” – of the device???
Patient 1: Large Aortic Arch Aneurysm caused N. Recurrens Paresis with Displacement of the Trachea to the Right

Fast Stent Expansion caused less Expansion & Adaption to the Aortic Wall with Significant Proximal Endoleak

Endoleak Typ I, II.

Missing second device into the thoracic aneurysm

Patient 1: MFM Device postoperative Follow Up

Fast Deployment caused limited Device Expansion & Aortic Wall Adaption with Significant Distal-Proximal Endoleaks Typ I, II.

Two years before indication

2009

Empties of the Aneurysm

2011

2 years control with MFM

2011

4 years control with MFM

2015

Rest flow after 4 years

Patient 2: Multiple Aortic Arch Local Dissections, Plaque Ruptures

Prolonged, “Step-wise” Expansion Time and Technique of the Device and by that no Endoleak

Patient 2: Multiple Aortic Arch Local Dissections, Plaque Ruptures

Prolonged, “Step-wise” Expansion Time and Technique of the Device and by that no Endoleak

1. Exact Positioning of the Device

- With calculated Shortening

2. No significant Endoleak with an optimal Expansion
**Postoperative Follow Up - Patient 2**

*Preop. Aorta Status*

Patient died in 2013 after a spontaneous Vertebral Artery Bleeding without any relevant symptomatic before

**Future Indications for the MFM Stent: For Type „A“ Aortic Dissections and Aorta Ascendens Aneurysmas with a Short Proximal „Landing Zone“**

**Patient 3: MFM Device postoperative Follow Up**

Fast Depoyment caused Malposition and Distorsion at both MFM Devices, Correction by Two Medtronic Valiant Stent

**Postoperative Result after MFM Implantation into the Aortic Arch**

- Placement Success: (1 Stent in Stent with migration) 4 (80 %)
- Procedural Survival rate: 5 (100 %)
- Survival rate after 30 & 90 days: 5 (100 %)
- Postop. Aneurysm Rupture (after 4 years): 0 (0 %)
- Postop. Aneurysm Dilatation (after 4 years): 1 (20 %)
- Significant Endoleak Typ I. or II. (after 4 years): 1 (20 %)
- Late Torsion & Fracture: 0 (0 %)
- Patients Symptoms Reduction: 5 (100 %)
- Thrombus development in the sack or in the false Lumen: partial after 4 years 5

**Patients Data with Transcarotid TAVI (Core-Valve, Medtronic Inc.) Combined Carotis TEA**

<table>
<thead>
<tr>
<th>Preop. Data</th>
<th>1 year Postop. Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age: 82 +/- 2.3; M/F: 2/1 Gender: (Male/Female)</td>
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</tr>
<tr>
<td>Aortic V Gradient (mmHg): 77 +/- 6.1</td>
<td>82 +/- 4.4</td>
</tr>
<tr>
<td>Aortic V. Stenosis ( cm): 0.6 +/-8.1</td>
<td>0.4 +/- 0.4</td>
</tr>
<tr>
<td>LV Ejection Fraction (%): 46 +/- 1.2</td>
<td>55 +/- 1.1</td>
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<tr>
<td>Preop. Stroke &amp; TIA:</td>
<td>5 (100 %)</td>
</tr>
<tr>
<td>Preop. Insufficiency:</td>
<td>5 (100 %)</td>
</tr>
<tr>
<td>Carotid Artery Stenosis:</td>
<td>5 (100 %)</td>
</tr>
<tr>
<td>Perc. Atrial Fibrillation:</td>
<td>5 (100 %)</td>
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<tr>
<td>Coronary Artery Disease</td>
<td>5 (100 %)</td>
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</table>

**Patients Data with Multilayer Flow Modulating Device (MLFM)**

<table>
<thead>
<tr>
<th>Preop. Data</th>
<th>1 Year Postop. Data</th>
<th>4 Year Postop. Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age: 82 +/- 2.3; M/F: 2/1 Gender: (Male/Female)</td>
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</tr>
<tr>
<td>Aortic Aneurysm Reduction: 0 (100 %)</td>
<td>Aortic Aneurysm Reduction: 1 (20 %)</td>
<td></td>
</tr>
<tr>
<td>Aortic Rupture: 0 (0 %)</td>
<td>Aortic Rupture: 0 (0 %)</td>
<td></td>
</tr>
<tr>
<td>Death: 0 (0 %)</td>
<td>Death: 0 (0 %)</td>
<td></td>
</tr>
<tr>
<td>Sign. Endoleak: 0 (0 %)</td>
<td>Sign. Endoleak: 0 (0 %)</td>
<td></td>
</tr>
<tr>
<td>Postop. Stroke &amp; TIA: 0 (0 %)</td>
<td>Postop. Stroke &amp; TIA: 0 (0 %)</td>
<td></td>
</tr>
<tr>
<td>Renal Insufficiency: 100 (100 %)</td>
<td>Renal Insufficiency: 0 (0 %)</td>
<td></td>
</tr>
<tr>
<td>Thrombus Formation: 5 (100 %)</td>
<td>Thrombus Formation: 5 (100 %)</td>
<td></td>
</tr>
<tr>
<td>Patients Symptoms reduction: 5 (100 %)</td>
<td>Patients Symptoms reduction: 5 (100 %)</td>
<td></td>
</tr>
<tr>
<td>Patient Elev. Quality of Life: 5 (100 %)</td>
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</table>
The MFM conduit is a safe concept and device for the treatment of the small-middle size (4-6 cm) aortic arch aneurysms and for chronic & local dissections. 

- There is a definitive endothelial growth into the entire conduit.
- Both in the saccular and fusiform aneurysm the side branches by the “Bernoulli Effect” stayd patent & the size of the aneurysm sack reduced. (Bernoulli effect P\i - V-flow \h)
- Each device segment (3 cm) needs a 2 Min. period to accommodate to the wall.
- The entire aorta must be stented both at aneurysms and at dissections.

The Future Goals:
1. More flexible & hydrophil catheter and sheath has to be developed.
2. The pressure Gradient - tension pressure “Inside vs. Outside” – of the conduit have to be measured perioperatively and followed in “Long Term” Randomized Multicentre Studies together common with the thrombus formation in the aneurysm sack.
3. We need at each patient a Detailed Guideline, the exact data about shortening & optimal length of the landing zone of the conduit during the deployment.