Do we need a New Solution for Complex Aortic Pathologies?

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Conflict of Interest

• Consultant
  Medtronic
  TriVascular
  SilkroadMedical

The Concept

The Multilayer Flow Modulator

Endothelialization

The flow lamination excludes the aneurysm from the blood circulation by inducing a physiological thrombus formed of lines of Zahn.

The MFM® gets endothelialized, permitting the reduction process to start.

The Concept

Saccular Aneurysm with branches

Thrombus organized in lines of Zahn

When the MFM May Not Be Effective:

Due to Technical Errors

• Lack of sufficient proximal and distal healthy zone to avoid peri-MFM leak (it needs at least 2cm for enough sealed wall apposition)

• Lack of sufficient overlapping; it needs at least 3cm. (the overlapping in front the branches does not effect the lamination of the flow)

• The large size must be inserted in the small one to avoid endoleak type III

• The Stenosed branches must be treated prior to MFM deployment

IFU

CONTRAINDICATIONS

• Inadequate Arterial Access (due to tortuosity, calcifications, occlusion)
• Absence of Healthy Landing Zone
• Presence/ Suspician of Infection, Mycotic Aneurysm
• Chronic/ Acute Obstruction of Contralateral True Branches (i.e., Main Arteries, Phlebothrombosis, Vascular Abnormalities)
• Presence of Aneurysm
• Patient undergoing Chemotherapy treatment
• Presence of Polyvascular Pathologies
• Chronic Aneurysm
• Prior Anticoagulation
• History of Coagulation Problems
• Shaggy Aorta
• Pleural Effusion
• Takayasu Arteritis
• Arterio-venous fistula
• Pregnant or breastfeeding woman
• Patients who cannot tolerate contrast agents
Contra indications - Porcellaine Aorta, Le Riche Syndrome

Contra indication - Rupture & Contained Rupture

Contra indication - Shaggy Syndrome

Contra indication - Marfan Syndrome

Contra indication - Type A Dissection ??

MFM Proof of Concept

- Challenging cases in the Aorta
  - Ascending Aorta
  - Aortic Arch
  - Descending Aorta
  - Aortic Dissection Type B
**Multilayer Stents in the Aorta**

1 MFM Fitting
2 Overlapping MFM Stent Fitting
3 Overlapping MFM Stent Fitting

**Results Post-processing**
Flow Streamlines: Pre vs 1 MFM (Anterior View)

**Results Post-processing**
Outflows Arch Branches: Pre vs 1 MFM (Anterior View)

**Results Post-processing**
Force @ Wall: Pre vs 1 MFM (Anterior View)

**Results Post-processing**
Flow Streamlines: Pre vs 1 MFM (Anterior View)
MFM® in Aortic Dissection Type B

Case One
DA_213_002

74 Years old Female
- Dissection type B (true lumen)
- false lumen

- Previous Ascending Aorta Replacement for sintetic Dacron
- History of Smoking, Hypertension
- Thoracic Pain pre-procedure
- Dissection total Length: 461mm
**Case Two**

77 Years old Male
- Dissection type B (true lumen, false lumen)
- Previous Ascending Aorta Replacement by Dacron (Green Arrow)
- Previous Carotid and Renal Arteries Treatment
- History of:
  - Coronary Artery Disease
  - Morbid Obesity
  - Hypertension
  - COPD
  - Renal Impairment

**Case Three**

- 28 Years Old Female Patient with Type B Dissection
- Normal prognosis: There is no solution

**CONCLUSION:**

More than 3500 MFM® have been placed in Aortic & Peripheral indications

- There is a proof of Concept
  - The 3D technology has unique features that promotes
    - Laminar flow
    - Organized, physiological healing (Lines of Zahn)
    - Increased Perfusion -> existing branches and arteries
    - Promotes endothelialization
  - Clinical Data shows that The MFM technology is safe and efficient when used according the IFU
Clinical Trial for Dissection Type B

➢ Primary results for Dissection B are Very Promising

Dragon Study is a worldwide clinical trial for Dissection type B is ongoing & under Regulatory Process.

Study Title: EVALUATION OF SAFETY AND EFFICACY OF THE MULTILAYER FLOW MODULATOR FOR THE TREATMENT OF TYPE B AORTIC DISSECTION WITHOUT ACUTE COMPLICATIONS.

Study Design: An International, Multicenter, Prospective, Non-randomized Study

Leading PI: Prof. Dr. Med. Ralf Kolvenbach

Countries: Germany (EC pending)
UK (EC pending)
Brasil (Regulatory Process)
Romania (EC approval)
Belgium (Regulatory Process)
China (Regulatory Process)

If you are interested to be part of the Dragon Study please contact me @: ralf.kolvenbach@gmail.com or contact Cardiatis @: clinic@cardiatis.com

Thank You