

Why MLFM Bare Metal Stents Should Be the Treatment of Choice for Visceral, Peripheral & Iliac Aneurysms: Advantages & Has Rupture been Universally Prevented. What About TAAs ?



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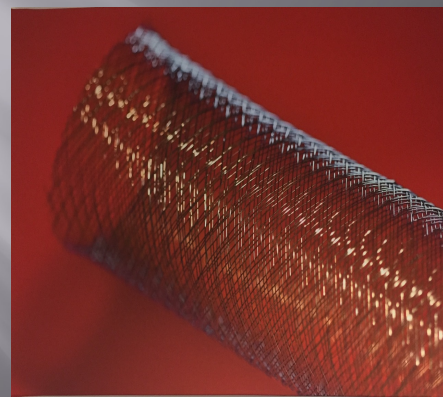
## Financial Disclosure

- ☐ I have the following financial relationships to disclose:
  - Grants / Research & Clinical Study Support :  
WL Gore
  - Non-compensated Advisory Boards:  
Intact Vascular & Intressa (formerly Cardiatis)

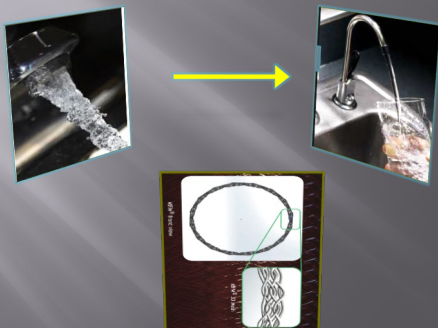
## MFM DEVICES

### ? What is an MFM Device

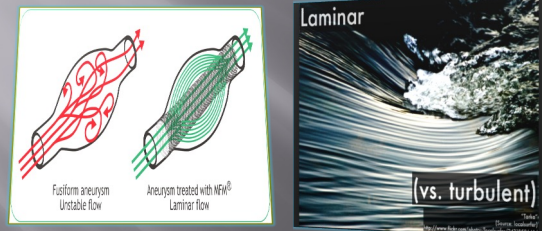
- ☐ Multiple variations of porous self-expanding endografts
  - no standardized characterization
- ☐ Theoretical mechanisms proposed and validated with computerized flow models
- ☐ Been evaluated in multiple clinical applications



### Tap Water Analogy: Filter with 50-60% Porosity



### The MFM® Converts Turbulence to Lamination



## MFM DEVICES

- Animal evaluations
  - rapid incorporation of stent matrix when opposed to vessel wall
  - side branch patency maintained up to 1 yr

## Aortic Explant Histology (9 months)



Macro photographs of the explant and location of histologic sections. Explant at 9 months



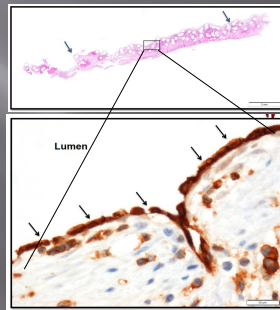
Endothelialized

## Endothelium at 3 Months - Human Explant



MFM® piece Explant (3 months) Endoluminal lining with neo-endothelium.

Pr. Edelman, MIT  
Pr. Kostache ( Roumania)  
Pr. Sultan  
Pr White



## MFM DEVICES

- Cerebral Devices (multiple MFM devices that have been proven effective to treat cerebral aneurysms)
  - Balt Silk +
  - Pipeline
  - Surpass
  - Fred
  - Casper
  - Intressa (formerly) Cardiatis

## MFM Devices for Visceral & Peripheral Arteries

- Several reports of clinical studies
  - mixed results with limited reports, mostly small patient series

### Research Article

#### Treatment of Aortic and Iliac Artery Aneurysms with Multilayer Flow Modulator: Single Centre Experiences

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Received 5 January 2018; Accepted 20 February 2018; Published 31 May 2018

Academic Editor: Bhagwan Satiani

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**Objective.** Presenting early and midterm results of aortic and iliac artery aneurysms treated with Multilayer Flow Modulators (MFM). **Methods.** We retrospectively reviewed the medical records of 23 patients (19 males and 4 females) who are admitted to our clinic between April of 2018 and February of 2016, diagnosed with thoracoabdominal aortic aneurysm and/or iliac aneurysm, and treated using MFM. The patients were followed up for the development of potential clinical presentations for 12 months. **Results.** MFM implantation was successfully completed in all the patients. During the process, two patients developed endoleak and so they were treated with postdilatation that was performed through balloon intervention, whereby the patients fully recovered. Although a short-term ischemic cerebrovascular event occurred in one of the patients 36 hours after the MFM, the patient recuperated without any noticeable neurological sequelae. Overall, three patients died after the procedure: one of whom died in hospital three days following the intervention due to acute renal failure, while the second one lost his life at the end of the first month due to the occlusion of superior mesenteric and celiac arteries. The third patient died at the end of the third month due to acute myocardial infarction. The rest of the patients developed no complications or had no mortality at their 12-month follow-ups. **Conclusion.** MFM can be preferred as an alternative approach in the treatment of aorta and iliac artery aneurysms including major lateral branches. The present results should be confirmed with additional future studies conducted with larger patient groups for longer periods.

## Endovascular repair of peripheral and visceral aneurysms with the Cardiatis multilayer flow modulator: one-year results from the Italian Multicenter Registry

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Collaborators, Affiliations  
PMID: 23046324 DOI: 10.1583/EVT-12-3930MR2.1

### Abstract

**Purpose:** To assess the efficacy of the Cardiatis multilayer flow modulator (CMFM), a bare cobalt alloy self-expanding stent, in the treatment of peripheral and visceral artery aneurysms.

**Methods:** In this multicenter (n=22), prospective, voluntary registry, 54 patients (47 men; mean age 68 years, range 19-87) who underwent CMFM deployment for peripheral (n=35) or visceral aneurysms (n=19) in a variety of target arteries were enrolled between June 2009 and June 2010. Among the 54 lesions, 44 had a total of 53 side branches. The main effectiveness endpoint was stent and side branch patency with no aneurysm rupture or reperfusion at 1, 6, and 12 months after stent implantation. Outcome measures were complete aneurysm thrombosis and sac shrinkage. The safety endpoint was

**Methods:** In this multicenter (n=22), prospective, voluntary registry, 54 patients (47 men; mean age 68 years, range 19-87) who underwent CMFM deployment for peripheral (n=35) or visceral aneurysms (n=19) in a variety of target arteries were enrolled between June 2009 and June 2010. Among the 54 lesions, 44 had a total of 53 side branches. The main effectiveness endpoint was stent and side branch patency with no aneurysm rupture or reperfusion at 1, 6, and 12 months after stent implantation. Outcome measures were complete aneurysm thrombosis and sac shrinkage. The safety endpoint was freedom of complications (death, aneurysm rupture, endoleak, need for reintervention, stent foreshortening, stent occlusion, and access-site sequelae). Aneurysms were categorized as saccular (type I) or fusiform (type II) without a side branch or with branch(es) in the sac (subtype A), neck (subtype X), or both (subtype AX). Kaplan-Meier estimates were calculated for primary and secondary endpoints. Sac shrinkage was correlated to aneurysm morphology and presence/absence of mural thrombus.

**Results:** Technical success was achieved in all patients. Mortality at 1 year was 5.5% (n=3), including 1 perioperative death. Six patients were lost to follow-up. There was no aneurysm rupture. Six (11.1%) stents occluded over the 1-year period; 3 asymptomatic patients were not treated, 2 symptomatic patients had successful stent dilation to restore patency, and 1 symptomatic patient required bypass (the only side branch lost). Cumulative primary and secondary patency estimates were 86.9% and 90.7% at 1 year. The cumulative side branch patency was 96.1% and the freedom from all complications was 83.0% at 1 year. Complete aneurysm thrombosis was recorded in 42 (93.3%) of 45 patients at 1 year. Percent diameter reduction was 15.5%, 3.8%, and 11.0% at 1, 6, and 12 months (p<0.05), respectively. Presence of mural thrombus did not influence the time course of shrinkage (p>0.05), while complex lesion anatomy (presence of side branches) delayed shrinkage (p<0.05).

**Conclusion:** Results at 1 year show that CMFM can be safely used in the treatment of PAA and VAA, with good results in terms of freedom from rupture, patency of the stents and side branches, complete aneurysm thrombosis, shrinkage, and acceptable freedom from morbidity and mortality.

Review Ther Adv Cardiovasc Dis. 2024 Jan-Dec;18:17539447241283736.  
doi:10.1177/17539447241283736.

## Role of multilayer flow modulator stents in the treatment of arterial aneurysms

Rasit Dinc <sup>1</sup>, Evren Ekingen <sup>2</sup>

Affiliations  
PMID: 39418136 PMID: PMC11489923 DOI: 10.1177/17539447241283736

### Abstract

Arterial aneurysms remain a significant public health problem because they often result in death when ruptured; therefore, they require immediate medical treatment. Endovascular aneurysm repair (EVAR) has recently become the primary treatment option, owing to the fewer side effects compared to those with open surgery. However, stents used for conventional EVAR often cause side-branch occlusion, which alters the perfusion of vital organs. Recently, multilayer flow modulator (MFM) stents have been used as a new treatment for arterial aneurysms. These stents appear to be feasible owing to their unique design consisting of an uncoated three-dimensionally braided multilayered structure. MFM stents generally remodelate laminar flow and reduce the flow velocity in the aneurysmal sac, leading to thrombosis, which causes the aneurysm to shrink over time. Thus, they reduce the risk of mortality.

NO DATA PROVIDED

Case Reports Vasa. 2012 Sep;41(5):383-7. doi: 10.1024/0301-1526/a000227.

## Multilayer stent in the treatment of popliteal artery aneurysms

George A Antoniou <sup>1</sup>, Andrew Schiro, J Vincent Smyth, David Murray, Finn Farquharson, Ferdinand Serracino-Inglott

Affiliations  
PMID: 22915538 DOI: 10.1024/0301-1526/a000227

### Abstract

Endovascular repair of popliteal artery aneurysms is an emerging treatment in high risk surgical patients. The location in a functionally demanding anatomical area creates limitations in terms of endograft patency. Technological advancements have been conscripted in an effort to circumvent such constraints. The multilayer stent technology effects through haemodynamic modulation. We used the multilayer stent to treat 6 asymptomatic popliteal artery aneurysms in 3 patients. All procedures were successfully accomplished without any complications. Over a mean follow up period of 9 months, thrombosis occurred in two limbs, and blood flow was restored with thrombolysis, achieving a primary and secondary patency rate at 6 months of 67 % and 100 %, respectively. Partial or complete thrombosis of the aneurysm sac was achieved in all aneurysms. Even though the use of the multilayer stent in popliteal artery aneurysms was safe in the short term, our experience showed that close surveillance is required.

Multicenter Study Vascular. 2018 Oct;26(5):556-563. doi: 10.1177/1708538118771258.  
Epub 2018 Apr 17.

## Early and mid-term results in the endovascular treatment of popliteal aneurysms with the multilayer flow modulator

Alessandro Ucci <sup>1</sup>, Ruggiero Curci <sup>2</sup>, Matteo Azzarone <sup>1</sup>, Claudio Bianchini Massoni <sup>1</sup>, Antonio Bozzani <sup>3</sup>, Carla Marcatò <sup>4</sup>, Enrico Maria Marone <sup>3</sup>, Paolo Perini <sup>1</sup>, Tiziano Tecchio <sup>1</sup>, Antonio Freyrie <sup>1</sup>, Angelo Argentero <sup>3</sup>

Affiliations  
PMID: 29665749 DOI: 10.1177/1708538118771258

### Abstract

Background The endovascular approach became an alternative to open surgical treatment of popliteal artery aneurysm over the last few years. Heparin-bonded stent-grafts have been employed for endovascular popliteal artery aneurysm repair, showing good and stable results. Only few reports about the use of multilayer flow modulator are available in literature, providing small patient series and short follow-up. The aim of this study is to report the outcomes of patients with popliteal artery aneurysm treated with the multilayer flow modulator in three Italian centres. Methods We retrospectively analysed a series of both symptomatic and asymptomatic patients with popliteal artery aneurysm treated with the

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J ENDOVASC THER  
2008;15:231-236

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• CASE REPORT

### Treatment of Renal Artery Aneurysm With the Multilayer Stent

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<sup>1</sup>Cabinet de Cardiologie, Nancy, France; <sup>2</sup>Global Research Institute, Apollo Clinic, Hyderabad, India; <sup>3</sup>Pantelimon General Hospital, Athens, Greece; <sup>4</sup>Cardiatis, Ixelles, Belgium; <sup>5</sup>Polyclinic Bois-Bernard, France; <sup>6</sup>Neuroradiology Department, University Hospital, Geneva, Switzerland; <sup>7</sup>Laboratory of Hemodynamics and Cardiovascular Technology, School of Life Sciences, Swiss Federal Institute of Technology, Lausanne, Switzerland; <sup>8</sup>Institute Biomedical Technology, Gent, Belgium; <sup>9</sup>Institut National de Recherches Aéronautiques, Jouy-en-Josas, France; <sup>10</sup>ULB, University of Geneva, Switzerland.

**Purpose:** To describe a new type of stent consisting of a 3-dimensional (3D) braided tube made of 2 interconnected layers without any covering to treat a renal artery aneurysm.

**Case Report:** A 78-year-old hypertensive man with multiple comorbidities was incidentally found to have a large (28×30 mm) saccular aneurysm in the main (90%) renal artery involving the inferior renal artery. Via a percutaneous femoral approach, a 6×30-mm Multilayer stent was deployed easily in front of the aneurysm neck covering the inferior renal artery. Blood flow inside the sac was immediately and significantly reduced. All the renal artery branches remained patent. Blood pressure returned to normal after the procedure. At 6 months, angiography showed complete shrinkage of the aneurysm wall; all the inferior renal artery branches remained patent.

**Conclusion:** The 3D multilayer fluid modulating stent concept appears to be a viable alternative for renal aneurysm exclusion. A larger study is underway to evaluate this new stent in other peripheral aneurysms.

J Endovasc Ther 2008;15:231-236

**Key words:** renal artery, aneurysm, stent, stent design, fluid modulating stent, hemodynamics

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2008;15:231-236

**Figure 1** ♦ (A) A large (28×30-mm) saccular aneurysm of the right renal artery at the hilum of the kidney. Six-month follow-up angiogram (B) and CT scan (C) after treatment with the Multilayer stent.

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**Figure 6** ♦ Scanning electron photomicrographs showing (A) the patent branch vessel in the explanted segment with the Multilayer stent in situ. (B) Endothelial growth over the Multilayer stent stops at the boundary of the branch vessel.

## MFM for TAA

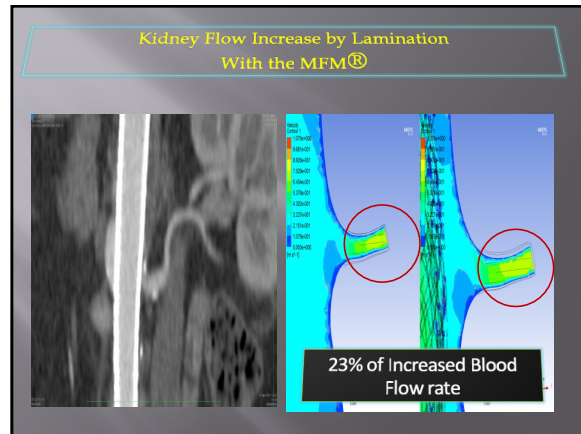
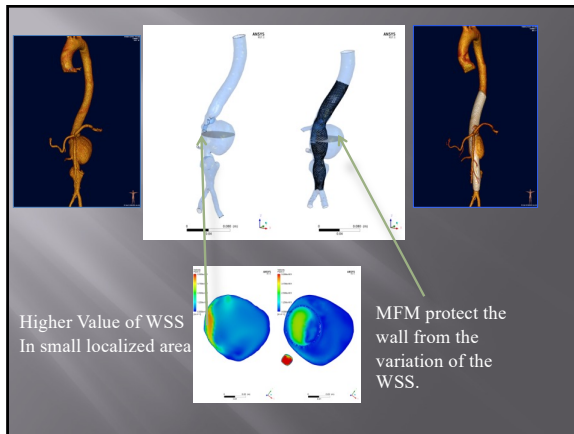
Patient CFD\_090\_020 - CFD IV

CFD simulation results for Patient CFD\_090\_020 - CFD IV, showing velocity and pressure distributions in the renal artery before and after stent placement.

Patient CFD\_090\_020 - CFD IV

Pre At 3 Months

Pre and At 3 Months images showing the renal artery and stent placement, along with corresponding CT scans.



### Systematic Review and Patient-Level Meta-analysis of the Streamliner Multilayer Flow Modulator in the Management of Complex Thoracoabdominal Aortic Pathology

Niamh Hynes, MRCS, MMSc, MD<sup>1,2\*</sup>, Sherif Sultan, MCh, MD, FRCS, PhD<sup>1,2\*</sup>, Ala Elhelali, MSc<sup>1,3</sup>, Edward B. Diethrich, MD<sup>4</sup>, Edel P. Kavanagh, PhD<sup>1</sup>, Mohamed Sultan, BSc<sup>1</sup>, Florian Stefanov, PhD<sup>1,3</sup>, Patrick Delassus, PhD<sup>2</sup>, and Liam Morris, PhD<sup>2</sup>

**Results:** Fifteen articles (3 multicenter cohort studies, 3 observational cohort studies, and 9 case reports) were included, presenting 71 patients (mean age 68.8±12.3 years; 139 men). The mean aneurysm diameter was 6.7±1.6 cm (95% CI 6.4 to 6.9 cm). Technical success reported in 15 studies was 77.2%. Aneurysm-related survival at 1 year was 78.7% (95% CI 71.7% to 84.4%). One-year all-cause survival was 53.7% (95% CI 46.0% to 61.3%). There were no reported cases of spinal cord ischemia, renal insult, or stroke.

**Conclusion:** The SMFM can be safely utilized in some patients with complex thoracoabdominal pathologies provided operators adhere to the IFU. The SMFM is a novel technology with no long-term published data on its sustained effectiveness and a lack of comparative studies. Randomized clinical trials, registries, and continued assessment are essential before this low-modulating technology can be widely disseminated.

### Multilayer Flow Modulator Treatment of Abdominal and Thoracoabdominal Aortic Aneurysms With Side Branch Coverage: Outcomes From a Prospective Single-Center Moroccan Registry

Amira Benjelloun, MD<sup>1</sup>, Michel Henry, MD<sup>2</sup>, Mustapha Taberkant, MD<sup>3</sup>, Abdelaziz Berrado, PhD<sup>4</sup>, Rachid El Houati, MD<sup>5</sup>, and Abdelkader Semlali, MD<sup>6</sup>

**Purpose:** To evaluate endovascular repair of thoracoabdominal aortic aneurysms (TAAAs) and abdominal aortic aneurysms (AAA) using the Multilayer Flow Modulator (MFM) in high-surgical-risk patients with at least one covered branch vessel.

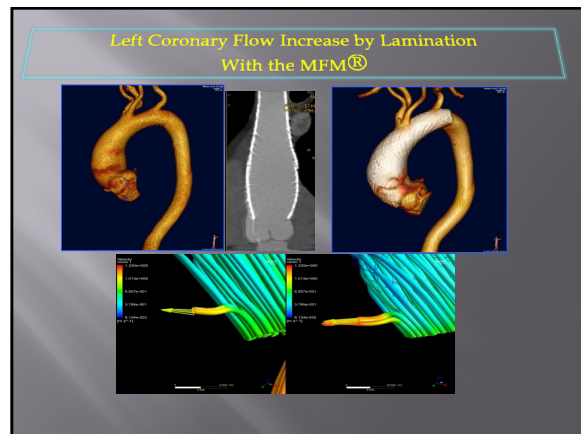
**Methods:** In this prospective single-center nonrandomized trial, 18 patients (mean age 61.1 years; 16 men) with TAAA (n=10, mean diameter 74.4 mm) and AAA (n=8, mean diameter 67.8 mm) were treated with the MFM between June 2009 and September 2012. The primary safety endpoints were all-cause mortality at 30 days and 12 months and neurological complications. The primary efficacy endpoint was overall procedure success, defined as patency of covered branch vessels, reductions in aneurysm diameter, and sac thrombus formation.

**Results:** The technical success rate was 100% (53 study devices implanted, mean stented length 372 mm). Through mean follow-up of 13.4 months, all 61 covered branch vessels remained patent; there were no neurologic complications, ruptures, or instances of device migration, kinking, or fracture. Three patients died, 2 of unrelated causes and one of an undetermined cause. Only one reintervention with an additional MFM implanted at 5 years was required for a type I endoleak in a young patient with natural growth. Carefully planned and executed diameter and volume measurements demonstrated aneurysm shrinkage and progressive sac thrombus formation for both patient groups.

**Conclusion:** Through midterm follow-up, treatment of high-surgical-risk TAAA and AAA patients with the MFM appears to be safe and effective, maintaining branch vessel patency and reducing rupture risk through reduction of aneurysm diameter and modulation of flow dynamics. Longer term follow-up is needed.

### MFM for TAA

- Initial IFU from Cardiatis described limit TAA size to 6 cm
  - contraindicated for ruptures or infection
- Multiple studies have evaluated device for TAAs with mixed results
- Current protocols focused on MFM for dissections where results are very promising
- Current data supports that Intressa is effective for cerebral aneurysms and dissections
- TAA indication yet to be determined



## Intressa In Clinical Practice

- “Disruptive” technology with need for studies that clearly documents continued patency and delineates the requirement for predilation of arterial lesions to preserve patency
  - appears to be similar to current indications predilation of branch vessels for fenestrated and branched procedures

## Role of MFM in Clinical Practice

- Where does it work?
  - small diameter, intracranial aneurysms
- Large diameter applications less well documented
  - “Tubular” large vessel lesions ie., IMH, penetrating ulcers, dissections
  - Aneurysm studies have not convincing (limited long-term follow-up in registry studies, with aneurysm stabilization but increasing diameter in large aneurysms, or associated with endoleaks
- Many reports of failure were contraindications – infection, ruptures, or outside the IFU, ie., land in normal artery both ends, overlap long and oversized, etc

## THE MULTILAYER FLOW MODULATOR (MFM®)

