JOURNAL OF INDIAN COLLEGE OF CARDIOLOGY 6S (2016) 26–36

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Short Communication

# The Multilayer Flow Modulator stent for the treatment for arterial aneurysms: Concept, Indications and Contraindications

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ARTICLE INFO

*Article history:*
Received 3 September 2015
Accepted 5 November 2015
Available online 31 December 2015

## 1. Introduction

Arterial aneurysms may present without symptoms and are frequently discovered as an incidental finding on diagnostic imaging studies, such as echocardiography or computed tomography performed for unrelated medical problems. Alternatively, aneurysms can cause symptoms such as pain, compression of adjacent structures, thromboembolism or rupture. As a result, aneurysms represent a life-threatening condition with an overall mortality rate of 20–75% depending on the location of the aneurysm.

Peripheral arterial aneurysms (PAA) and visceral arterial aneurysms (VAA) are relatively uncommon diseases and are traditionally treated surgically. There is a particularly significant increase in operative risk when surgery is emergent. Increasingly, both PAA and TAA are being treated using endovascular techniques, including embolization coils and covered stents. These techniques have a number of disadvantages and drawbacks. For example, when a PAA or VAA has patent side branches, a covered stent is not a viable treatment option due to the loss of important collaterals which can lead to severe complications.

Abdominal aortic aneurysms (AAA) and thoracoabdominal aortic aneurysms (TAAA) are traditionally treated surgically. Despite recent improvements in surgical technique, the operative risk remains high. Both hybrid and endovascular aneurysm-repair techniques have been developed in order to reduce the morbidity and mortality rates. Recently, new devices, such as branched and fenestrated aortic stent-grafts, and new techniques, such as chimneys, have been developed for repair of AAA and TAAA in order to decrease the operative risk. Technical success of these new procedures has been high, particularly when performed in select centers of excellence. Even with skilled operators, there is an increased risk, due to both complexity of the disease and endovascular techniques, of endoleak, renal impairment, stroke, paraplegia and death compared to standard endovascular and surgical techniques.

For these reasons, we have used a new method of aneurysm repair, the Multilayer Flow Modulator (MFM), which relies on a novel stent design to treat patients with PAA, VAA, AAA and TAAA. The purposes of this manuscript are to: (1) report our experience with the MFM, (2) review the published literature regarding the outcomes of patients treated with the MFM and (3) develop initial treatment guidelines regarding the MFM.

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http://dx.doi.org/10.1016/j.jicc.2015.11.005
1561-8811/© 2016

## 2. The Multilayer Flow Modulator (MFM): concept[1–4]

The MFM (Cardiatis, Isnes, Belgium) is a self-expanding tubular stent composed of a three-dimensional (3D) mesh consisting of several interconnecting layers of a braided cobalt alloy wire (Phynox®). The device has CE mark approval for both peripheral and visceral aneurysms and for aortic aneurysms, where at least one side branch arises from the aneurysm sac.

For treatment of PAA and VAA, the MFM is available in diameters ranging from 5 to 16 mm and in lengths ranging from 30 to 150 mm. The 6–12 F Teflon-coated delivery system is 110 cm in usable length and navigates over a 0.025-in. guidewire. For treatment of AAA and TAAA, the MFM is available in diameters ranging from 25 to 45 mm and in lengths ranging from 50 to 200 mm. The 18–20 F Teflon-coated delivery system is 100 cm in usable length and is delivered over a 0.035-in. stiff guidewire. The device is deployed by means of a pull-back mechanism and is preferentially introduced percutaneously through the femoral artery or alternatively can be delivered through surgical cut-down of the femoral or iliac arteries. When iliofemoral access is unsuitable, the MFM can safely be introduced via the brachial artery, subclavian artery or transapical.

The MFM is characterized by optimal 3D porosity, high radial force, flexibility, corrosion-resistance, durability, radiopacity and MRI compatibility. The key principles of this device were defined through extensive in vitro tests, theoretical simulations (computerized fluid dynamics, lattice Boltzmann method and molecular modeling) and in vivo studies: The MFM converts blood flow within the aneurysm from turbulent to laminar and decreases the velocity; all of which promote the formation overtime of an organized stable sac thrombus (into strats, known as lines of Zahn). When a side branch arises from the aneurysm, laminar blood flow is channeled through the sac for direct perfusion of the branch along with improved inflow into the collateral circulation. The MFM modulates blood-flow dynamics within the sac by relieving local peak wall shear stress (PWSS), achieving stabilization of aneurysm-sac pressure and preserving side-branch patency (Figs. 1–6).

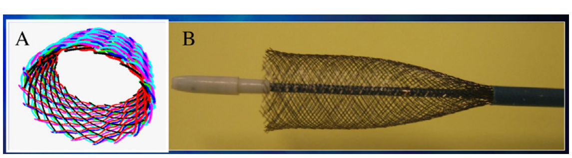


**Fig. 1 – The MFM: (A) a diagram of the 3D geometry of the MFM and (B) the MFM self expandable stent.**

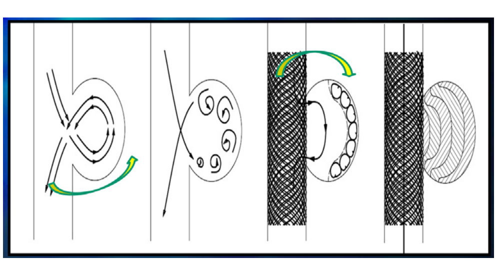

**Fig. 2 – Saccular aneurysm without branch.**
**The MFM:**
**•Removes the stress from the neck**
**•Inverses the flow**
**•Breakdowns and reduces the vortex velocity by 90%**
**Immediate thrombosis of the aneurysm.**

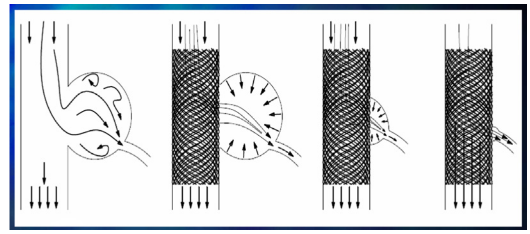

**Fig. 3 – Saccular aneurysm with branch.**
**The MFM:**
**•Channeled the flow to the branch**
**•Allows for physiological shrinkage while preserving collateral**

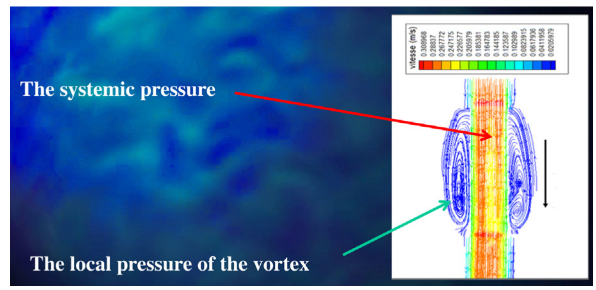


**Fig. 4 – Fusiform aneurysm with the two pressures: systemic pressure and local pressure of the vortex.**

## 3. Indications – clinical results

### 3.1. *Peripheral and visceral aneurysms*

#### 3.1.1. *Personal series*

43 patients (32 males, mean age 62 ± 8 years) were treated for PAA or VAA with the MFM (iliac: 23, femoral: 1, popliteal: 5, renal: 9, mesenteric: 2, celiac trunk: 1, carotid: 2, subclavian: 2). 1 patient had 3 aneurysms. In total, 58 MFM devices were implanted (diameter 5–14 mm, length: 40–120 mm) by either a femoral (42 cases) or brachial approach (1 case: right subclavian aneurysm) through a 6–12 F sheath. Intracranial embolic protection (Accunet®, Abbott Vascular, Abbott Park, IL, USA) was used during treatment of carotid artery aneurysms. Follow-up was performed with either a duplex or CT scan, depending on the location of the aneurysm. Technical success was achieved in all cases (100%) with no peri-procedural complications. At 30-days, 1 popliteal artery thrombosis occurred (the patient stopped the antiplatelet therapy) and was successfully treated by fibrinolysis and angioplasty.

During the follow-up (mean 16 ± 8 months), there were no aneurysm-related deaths and 1 all-cause death, which