

# openheart Endovascular management of renal artery aneurysms using the multilayer flow modulator

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## ABSTRACT

**Objective:** Our aim was to describe our experience of the Multilayer Flow Modulator (MFM, Cardiatis, Isnes, Belgium) used in the treatment of type III renal artery aneurysms (RAA).

**Methods:** This is a single-centre study. 3 patients (2 men and 1 woman; mean age 59 years; range 41–77 years) underwent treatment of a type III renal artery aneurysm using the MFM. The indications were a 23.9 mm type III RAA at the bifurcation of the upper and lower pole vessels, with 4 side branches; a 42.4 mm type III saccular RAA at the renal hilum; and a 23 mm type III RAA at the origin of the artery, supplying the upper pole.

**Results:** Patients had a mean follow-up of 27 months, and were assessed by perioperative renal function tests, and repeat postoperative CT scan. There were no immediate postoperative complications or mortality. The first patient's aneurysm shrank by 8.6 mm, from 23.9 to 15.3 mm over 19 months, with all 4 side branches remaining patent. The largest aneurysm at 42.4 mm completely thrombosed, while the renal artery remained patent to the kidney. The final patient refused to have any follow-up scans but had no deterioration in renal function below 30 mL/min, and no further symptoms reported.

**Conclusions:** The MFM is safe and effective in the management of patients with complex renal artery aneurysms. The MFM can be used to treat branched or distal renal artery aneurysms with exclusion of the aneurysm from the circulation, while successfully preserving the flow to the side branches and kidney. Initial results are promising, however, longer follow-up and a larger cohort are required to prove the effectiveness of this emerging technology.



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## INTRODUCTION

Renal artery aneurysms (RAA) are a rare but serious pathology. They are found in 0.7% of autopsies and up to 1% of angiographic investigations.<sup>1</sup> They can lead to renovascular hypertension, thromboembolic events and rupture. Rupture of RAA is associated with a significant mortality or loss of a kidney, especially during pregnancy.<sup>2</sup> RAA are classified

## KEY QUESTIONS

### What is already known about this subject?

► The Multilayer Flow Modulator (MFM, Cardiatis, Isnes, Belgium) has been used to treat peripheral, visceral and aortic aneurysms. Previous studies show that it has also been used with success to treat renal artery aneurysms. The MFM design allows blood to perfuse through the mesh in a manner that maintains collateral branch patency, while modulating the flow from turbulent to laminar within the device and the aneurysm sac. Laminar flow in the aneurysm encourages the formation of organised thrombus, thereby stabilising aneurysm size and reducing risk of rupture.

### What does this study add?

► This study outlines our own centre's mid-term experience with treating complex renal artery aneurysms. These patients would otherwise have been treated via open surgery. The results presented affirm those already available, showing successful intervention with the MFM. It encourages aneurysm sac shrinkage, while maintaining collateral branch patency.

### How might this impact on clinical practice?

► Currently, the treatment of renal artery aneurysms includes renal artery reconstruction, with or without bypass, with an autologous conduit, aneurysmectomy and endovascular treatment with stenting and catheter-directed embolisation. Endovascular treatment can now give patients an option with reduced perioperative time, hospital stay, mortality and morbidities that are associated with major abdominal surgery.

according to the angiographic classification system.<sup>3</sup> Type I RAA are saccular and arise from either the main renal artery trunk, or proximally from a large segmental artery; type II are a fusiform shape and occur at the main renal artery or proximal segmental artery; type III aneurysms are more distal, affecting the small segmental or intraparenchymal artery. Associated diseases of RAA

include hypertension (73%), renal artery fibrodysplasia (34%), systemic atherosclerosis (25%), and extrarenal aneurysms (6.5%). There is twice the incidence in women than men,<sup>4</sup> with 55% of RAA being asymptomatic.<sup>4</sup> It is generally accepted that aneurysms of 20 mm or greater in diameter should be treated.<sup>5</sup> Moreover, those of childbearing age or antenatal with evidence of emboli, and symptomatic patients (with pain, hypertension or haematuria), or rapidly expanding aneurysms should be treated.

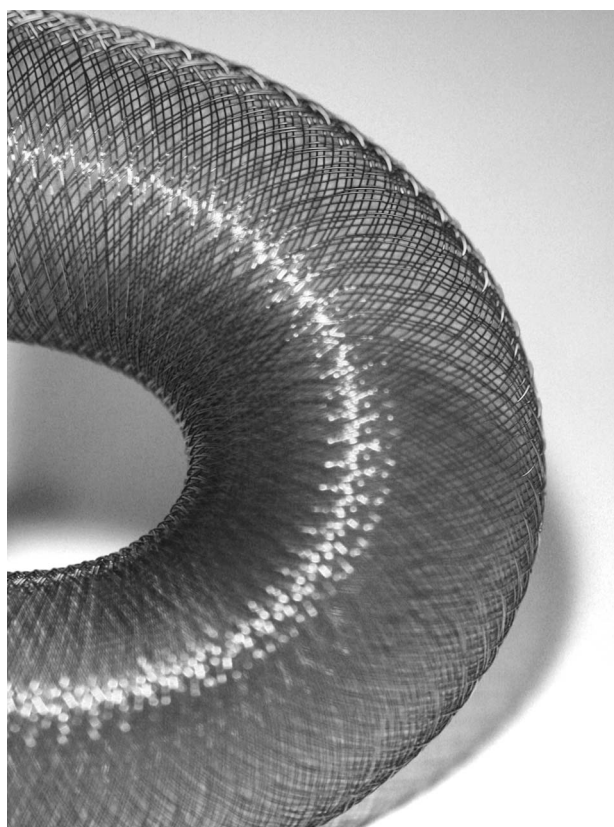
An alternative modality of treatment of RAA is the Multilayer Flow Modulator (MFM; Cardiatis, Isnes, Belgium; [figure 1](#)), which disagrees in terms of concept with conventional treatment modes. The MFM is currently widely used in aortic,<sup>6</sup> visceral,<sup>7</sup> and peripheral aneurysm repair,<sup>8</sup> and aortic dissection.<sup>9</sup> Previous studies by Polydorou *et al*,<sup>8</sup> Henry *et al*,<sup>10 11</sup> Meyer *et al*,<sup>12</sup> Flis *et al*<sup>13</sup> and Ruffino and Rabbia<sup>14</sup> show it has also been used with success to treat renal artery aneurysms. It harnesses the body's innate physiological processes to modulate the aneurysm with no risk of critical shuttering or loss of native side branches. The MFM also offers less operative trauma, shorter procedure time and reduced hospital stay. It's simplicity, consistency and reproducibility of results attracted enthusiasm among interventionists. Our aim was to describe our mid-term experience of the MFM stent, used in the treatment of

complex RAA, assessing patency of side branches and aneurysm shrinkage.

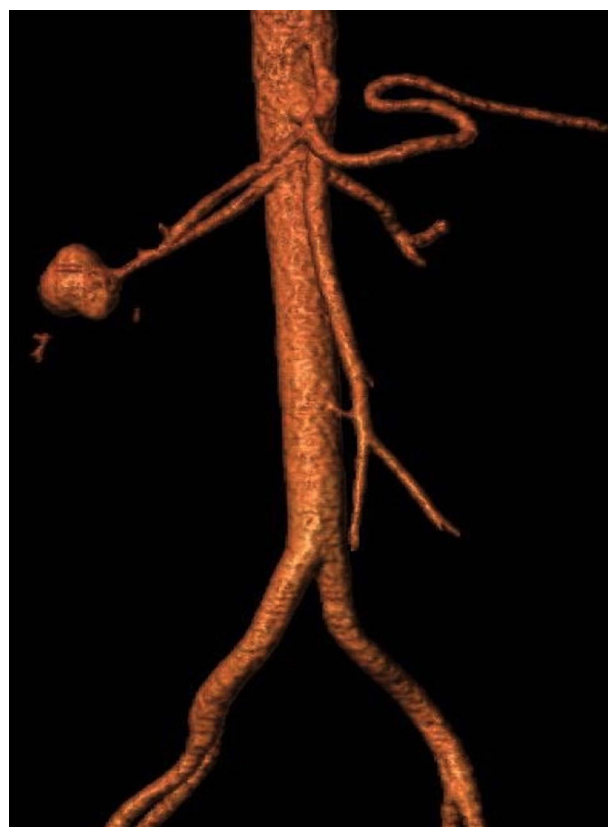
## METHODS

Three patients (2 men and 1 woman) with a mean age of 59 years and range 41–77 years underwent RAA repair with the MFM. Preoperative work-up consisted of a contrast-enhanced CT scan with 1 mm axial slices. All patients were symptomatic and presented with constant pain in the right side of the abdomen or loin. One patient had a history of hypertension, and the CT scan showed bilateral renal cysts. The indications were a 23.9 mm type III right renal artery aneurysm at the bifurcation of the upper and lower pole vessels with four side branches ([figure 2](#)); a 42.4 mm type III right renal artery saccular aneurysm ([figure 3](#)); and a 23 mm type III right renal artery aneurysm coming off the upper pole artery ([figure 4](#)).

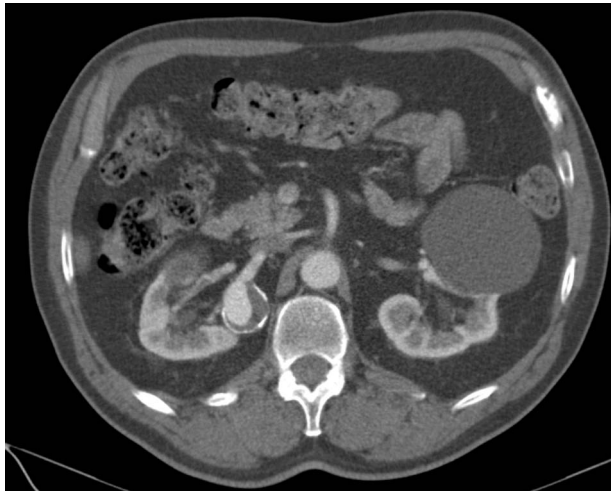
The diameters and lengths of each aneurysm and the arterial landing zones were measured via CT scan. A 6×60 mm (diameter × length), 8×50 mm and 6×30 mm MFM devices were selected. MFM intervention was performed under endotracheal general anaesthesia. An intraoperative loading dose of 4000 IU heparin was given intravenously to the patient. Duplex-guided percutaneous cannulation of the right common femoral artery with a 5F sheath was then carried out. The



**Figure 1** The Multilayer Flow Modulator (Cardiatis, Isnes, Belgium).



**Figure 2** Three-dimensional reconstruction of a type III right renal artery aneurysm (case 1).



**Figure 3** CT angiography showing a type III saccular right renal artery aneurysm, with decreased cortex to medulla parenchyma ratio (case 2).

Terumo guide wire was advanced into the aorta and then replaced with a 7F destination sheath. The renal vessel was cannulated with a paediatric selective visceral catheter. The 7F sheath was then advanced inside the renal artery. The MFM was deployed in the target vessel with oversizing by 15%, and landed distally in the largest runoff side branch. Once the procedure was complete, the guide wires were withdrawn and closure of the right femoral puncture was carried out with a Perclose device (Abbott Laboratories, Illinois, USA). Preoperative and postoperative estimated glomerular filtration rate (eGFR) to assess renal function during the procedure was also measured, defined as severe kidney damage below 30 mL/min. Primary technical success was defined as no immediate failures and no postoperative complications, including stent thrombosis, migration and infection. Primary clinical success was defined as



**Figure 4** CT angiography showing an upper pole type III right renal artery aneurysm (case 3).

freedom of mortality due to aneurysm rupture, and shrinkage or stabilisation of the aneurysm sac.

## RESULTS

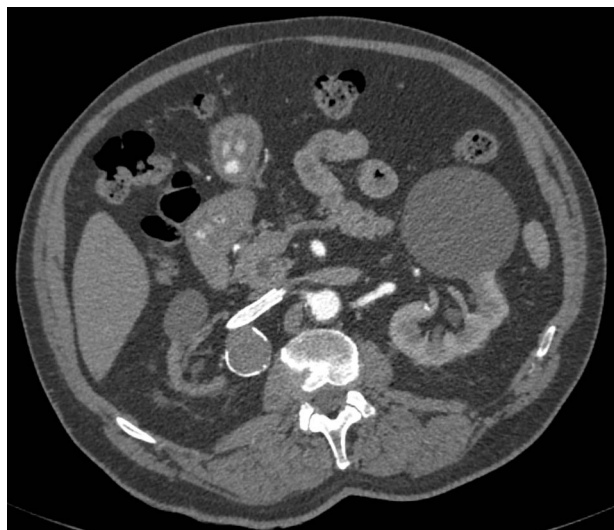
Postoperative follow-up with CT angiography was conducted at 6 and 19 months for case 1, and 35 and 47 months for case 2. One patient (case 3) refused further follow-up CT scans. Mean follow-up was 27 months. Case 2 was carried out in 2009, while cases 1 and 3 were carried out 2011. Primary technical success was 100%. There were no immediate failures and no postoperative complications including stent thrombosis, migration and infection.

Case 1 showed a normal preoperative eGFR of >90 mL/min, which remained unchanged postoperatively. Final follow-up CT scan (19 months) showed the aneurysm shrunk by 36% (from 23.9 to 15.3 mm) with all four side



**Figure 5** (A) Digital subtraction angiogram during postdeployment of the Multilayer Flow Modulator (MFM) in the right renal artery, demonstrating patency of all side branches (case 1). (B) Follow-up (19 months) CT angiography showing aneurysm side branch patency (case 1).



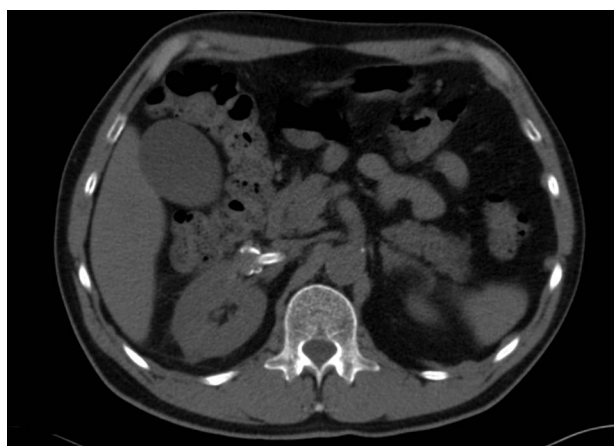


**Figure 6** Follow-up (47 months) CT angiography of a type III saccular right renal artery aneurysm (RAA) showing no contrast agent entering the aneurysm sac with sac thrombosis (case 2).

branches remaining patent postoperatively (figure 5). Case 2 recorded a preoperative eGFR of 69 mL/min, which declined postoperatively to 55 mL/min. The aneurysm had completely thrombosed in a final follow-up CT scan (47 months; figure 6). Aneurysm shrinkage of 9.4% (from 42.4 to 38.4 mm) was measured. Case 3 had a preoperative eGFR of >90 mL/min, which declined postoperatively to 74 mL/min. A perioperative CT scan was carried out showing the deployed MFM (figure 7). This patient refused follow-up CT scans, however; it was noted that this patient did not experience any severe deterioration in renal function or further symptoms.

## DISCUSSION

Treatment options for RAA include renal artery reconstruction, with or without bypass, with an autologous conduit, aneurysmectomy, and endovascular treatment



**Figure 7** Perioperative (4 days) CT angiography of a type III right renal artery aneurysm (RAA), showing the deployed Multilayer Flow Modulator (MFM) (case 3).

with stenting and catheter-directed embolisation. Open surgery to treat these aneurysms involves major abdominal surgery with its concomitant mortalities and morbidities, such as unplanned nephrectomy or dialysis-dependant renal failure. In a case series of a high volume centre in 96 operated patients, eight patients had unplanned nephrectomies due to technical complications.<sup>4</sup> An endovascular approach is becoming an increasingly popular route of repair, however, if an RAA has single or multiple arterial branches exiting directly from the aneurysm sac, endovascular methods of treatment may result in obstruction of the branch or branches, reducing perfusion to the kidney. In complex hilar aneurysm cases involving multiple arterial branches, extracorporeal vascular reconstruction with auto-transplantation is often the only feasible option of repair. The MFM, therefore, provides a viable new off-the-shelf endovascular treatment option for RAA.

With a porosity of approximately 65–75%, the MFM design allows blood to perfuse through the mesh in a manner that maintains collateral branch patency, while modulating the flow from turbulent to laminar within the device and the aneurysm sac. Laminar flow in the aneurysm encourages the formation of organised thrombus, thereby stabilising aneurysm size and reducing risk of rupture. The MFM has been used successfully to treat peripheral and visceral artery aneurysms,<sup>7 8 10–16</sup> complex thoracoabdominal aneurysms, and aortic type B dissections,<sup>6 9 17–19</sup> These studies reported successful treatment of the aneurysms by reduction in flow velocity within the aneurysm sac and surrounding branches, leading to the formation of an organised thrombus.

The introduction of the MFM to the mainstream vascular practice has forced us to re-evaluate our core concepts of aneurysm management and add the fourth dimension of time for the conclusion of a clinical outcome, moreover, it shifted our focus from anatomical to physiological therapies. The key components of MFM function are its manipulation of blood flow, preservation and enhancement of flow into arterial side branches, compliance, encouragement of endothelialisation and influence on thrombus formation, all of which reduce peak wall stresses while simultaneously enhancing wall strength and promoting healing.<sup>20 21</sup>

Type III interlobar and/or intraparenchymal RAA, have previously been managed by super-selective embolisation techniques, in order to limit the number of vessels being occluded. This results in thrombosis of the end arteries and renal infarction. Moreover, there is an increase in hypertension, and non-target embolisation with migration of coils into the main renal artery and systemic circulation.<sup>3 22–29</sup> Type III intrahilar RAA require adequate distal vascular control for reconstruction, and an ex vivo approach is always recommended.<sup>30</sup> This major surgery can only be done in high deliberate practice volume centres, but patients' demand for less invasive techniques allow us to use the MFM.

There have been complications reported in relation to the MFM such as stent foreshortening and dislocation.<sup>31–33</sup> These types of complications are often related to the fact that this technology was globally disseminated prior to controlled clinical trials and was indiscriminately used by eager operators who experimented with the device. This resulted in dismal clinical outcomes. Cases in which the MFM is contraindicated have been reported previously.<sup>34</sup>

From our experience, treatment of RAA with the MFM is a promising avenue. Primary technical success was 100%. There were no immediate failures and no postoperative complications, including stent thrombosis, migration and infection. All operations were performed via a percutaneous femoral approach with all stents being deployed without any complication. One case showed complete thrombosis of the aneurysm sac at follow-up 47 months postoperatively. The four collateral branches arising from the aneurysm in one patient remained patent 19 months postoperatively, and there was no significant compromise to renal function subsequent to the implantation. Postoperative outcomes in the literature showed that the MFM proved a safe technique during perioperative hospital stays, with no reported deaths, paraplegia, cerebrovascular accident, visceral or renal compromise.<sup>9–12 20–22</sup>

## CONCLUSION

On the basis of our clinical experience, treatment of renal artery aneurysms with the MFM appears to be a safe viable alternative to other current surgical treatments. The MFM has shown its ability to treat branched or distal renal artery aneurysms with exclusion of the aneurysm from the circulation, while successfully preserving the flow to the side branches and kidney, avoiding autotransplantation of the kidney. Sac shrinkage occurred over the duration of the follow-up with no complications, such as branch occlusion, device migration or thrombosis. A larger cohort of patients, with longer follow-up is required to prove the efficacy of this emerging disruptive technology.

**Contributors** SS designed the whole study and is the guarantor. SS, MBA, RF, EPK, ME and VL collected the data. SS, EPK, RF, ME, MBA, NH, FS, VL and AE drafted the manuscript.

**Competing interests** None declared.

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