ORIGINAL ARTICLE

Multilayer flow modulator stents in aortic aneurysms: an overview based on preliminary experience

Stents moduladores de flujo multicapa en aneurismas aórticos toracoabdominales: una descripción basada en experiencia preliminar

Omer Tanyeli[1], Sefer Kaya[2], Metin Onur-Beyaz[2], İbrahim Demir[3], Iyad Fansa[2], Ahmet Kırbaş[4], and Niyazi Gormus[1]*

[1]Department of Cardiovascular Surgery, Meram Faculty of Medicine, Konya; [2]Department of Cardiovascular Surgery, Hatay Mustafa Kemal University Tayfur Ata Sökmen Faculty of Medicine, Hatay; [3]Department of Cardiovascular Surgery, Kirsehir Education and Research Hospital, Kirsehir; [4]Department of Cardiovascular Surgery, Health Science University Ümraniye Education and Research Hospital, İstanbul. Turkey

Abstract

Objective: *Analyze the approach of the multilayer flow modulator (MFM) based on the results obtained in patients treated with Stena MFM® (S-MFM).* **Methods***: It was evaluated 6-month follow-up outcomes of 12 patients (nine men and three females; mean age 60 years, range 34-79 years) underwent aneurysm repair with the S-MFM between July 2022 and December 2022. All patients undergoing S-MFM were patients at high risk of mortality and/or morbidity for open surgical repair and endovascular aneurysm repair, including thoracic Endovascular Aortic Repair (TEVAR) or fenestrated endovascular aortic repair (FEVAR).* **Results:** *The control angiograms confirmed successful patency in the lumen of the main aorta and the branches in all cases. Complete aneurysm thrombosis was detected in all patients on computed tomography angiography at 6-month follow-up. The technical success was 100%, and no case required immediate intervention. Significant complications, such as ruptures, stent migrations, retractions, thrombosis, fractures were not observed.* **Conclusions:** *The present data show the MFM approach may be an attractive alternative for complex aortic aneurysms. While it shrinks the aneurysm sac and protects the side branch blood flow, it reduces mortality and morbidity risks.*

Keywords: *Aortic aneurysm. Multilayer flow modulator. Peripheral arterial diseases.*

Resumen

Objetivo: *Analizar el enfoque del modulador de flujo multicapa basándose en nuestros resultados en pacientes tratados con Stena Multilayer Flow Modulator® (S-MFM).* **Métodos:** *Se evaluaron los resultados del seguimiento a 6 meses de 12 pacientes (9 hombres y 3 mujeres; edad promedio 60 años, rango 34-79 años) sometidos a reparación de aneurisma con S-MFM entre julio de 2022 y diciembre de 2022. Todos los pacientes que recibieron S-MFM eran de alto riesgo de mortalidad o morbilidad para reparación quirúrgica abierta y reparación endovascular, incluyendo reparación aórtica endovascular torácica (TEVAR) o reparación aórtica endovascular fenestrada (FEVAR).* **Resultados:** *Las angiografías de control confirmaron la permeabilidad exitosa en la luz de la aorta principal y las ramas en todos los casos. En el seguimiento de 6 meses, en la angiografía por tomografía computarizada se detectó trombosis completa del aneurisma en todos los pacientes. El éxito técnico fue del 100% y ningún caso requirió intervención inmediata. No se observaron complicaciones importantes, como roturas, migraciones del stent, retracciones, trombosis o fracturas.* **Conclusiones:** *Los datos actuales muestran que el enfoque del modulador de flujo multicapa puede ser una alternativa atractiva para los aneurismas aórticos complejos. Si bien encoge el saco del aneurisma y protege el flujo sanguíneo de la rama lateral, reduce los riesgos de mortalidad y morbilidad.*

Palabras clave: *Aneurisma aórtico. Modulador de flujo multicapa. Enfermedades arteriales periféricas.*

Correspondence:
İbrahim Demir
E-mail: ibrahimd128@gmail.com

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Introduction

The aortic aneurysm (AA), which is locally caused by weakening and dilation of the aortic wall, remains a major public health problem in the world[1]. Although most patients with aneurysms usually do not have symptoms, the aneurysm can be fatal in up to 80% of cases when the aneurysm ruptures[2]. Currently there is no drug therapy to limit the progression of AA and continues to challenge clinicians around the world[1,3]. Efforts to reduce the clinical problems associated with AA have focused on early detection and subsequently improved surgical management. For more than 40 years, the conventional approach has been open surgical repair, which is replacement of the aneurysmal aortic segment with a synthetic graft, although it is associated with high morbidity and mortality[3].

In recent decades, endovascular aneurysm repair (EVAR) has rapidly become the main treatment option due to the significant reduction in mortality rate and shorter hospital stay, recovery, and return to basic functional capacity compared to open surgical repair[2,4]. In this methodology, the stent grafts are placed within the aneurysmal sac with proximal and distal fixation to healthy arterial segments[3]. Several EVAR approaches, including endovascular thoracic aortic repair (TEVAR), have been validated as safe and feasible strategies for patients with favorable aortic anatomy[5].

Unfortunately, it is not possible to apply EVAR or TEVAR procedures in complex aneurysms involving some important side branches. Treatment options for these conditions have been greatly expanded with windowed EVAR (FEVAR), branched EVAR, and chimney-EVAR. However, their application is hampered by high costs and the need for individual customization, which leads to delays in the manufacture and planning of devices. For this reason, its use is limited and is not particularly suitable for emergencies[6,7].

In this context, the multilayer flow modulator (MFM) has recently been developed and entered clinical practice. The concept is based on hemodynamic principles and stents act as a flow modulator both to maintain side branch perfusion and to reduce the flow velocity vortex and allow thrombosis within the aneurysm[8,9]. Since MFM devices placed in the aorta usually involve the aortic branches, it is crucial to maintain branch perfusion. It is easier to apply and does not require specific preparation from the patient[10].

This article gives an overview of the MFM based on the results of 12 patients treated with Stena-MFM® (S-MFM), a partially new product from Invamed (Ankara, Turkey). The published literature in this area has also been reviewed.

Methods

From July 2022 to December 2022, twelve patients (nine men and three females; mean age 60 years, range 34-79 years) from two different centers (in the cardiovascular departments of Meram and Mustafa Kemal hospitals, Turkey), underwent aneurysm repair with the S-MFM. Written informed consent was obtained from all participants, in accordance with the principles of the Declaration of Helsinki[11].

The number of patients treated in the centers, excluding the MFM procedure, is 215. Some of these patients were treated using open surgery and some using classical endovascular methods.

Ethics committee approval for this study was received from Hatay Mustafa Kemal University Local Ethics Committee (meeting date: March 17, 2022, decision no: 09).

Technical considerations for S-MFM

The S-MFM® is a knitted 5-layer tubular mesh stent made of a super-elastic biomedical metal alloy. Its self-expanding property makes the stent flexible and adaptable to the target area. It eliminates the need to individualize and subsequently make the S-MFM ready for use regardless of the vascular nature of the patient.

The multilayer braided design and low profile ensure extra durability. Its widened ends provide support compatibility with the aortic wall and optimal sealing at the proximal and distal descent sites, preventing the risk of type I and III leaks. There are also radiopaque tantalum markers at both ends to increase traceability.

The stent sizes are prepared in different models with a diameter of 25-45 mm and a length of 80-200 mm. The delivery system is compatible with 0.035” guide wire. The distribution system is compatible with 0.035” guide wire with a diameter of 18F-20F and a length of 100 cm. The Y sheath is attached to the pusher. The sheath locks into the holder when tightened to prevent premature activation of the multilayer system.

Characteristics of the patient and procedural aspects

All patients undergoing S-MFM were patients at high risk of mortality and/or morbidity for open surgical

repair and EVAR, including TEVAR or FEVAR. All patients underwent a pre-operative diagnostic study, including total aortic contrast computed tomography (CT) scans reconstructed from 1mm axial slices. In this way, the diameters and lengths of the aneurysms and landing zones and all aortic branches were evaluated in terms of the extent of any narrowing.

S-MFM interventions were performed under endotracheal general anesthesia with continuous invasive blood pressure monitoring. Depending on the patient, a combination of percutaneous femoral access with a closure device and surgical access was used. In all cases, S-MFMs were introduced under systemic heparinization through an 18F and 20F introducer inserted into the right femoral artery. To cross the artery, a 0.035-inch hydrophilic guidewire was used (Inwire, Invamed, Ankara, Turkey). Control angiograms were performed using a 5F graduated pigtail catheter through the left femoral artery. S-MFM sizing was meticulously selected, taking into account 15-25% oversizing compared to the native aortic diameter, regardless of the diameter of the aneurysm. Vascular closure device (AngioTEN, Invamed, Ankara, Turkey) was used to close the femoral artery puncture in all cases.

Technical success was defined as successful insertion and placement of the S-MFM without additional surgical intervention or mortality during the procedure or within the first 24 h after the procedure. The absence of significant kinks, twists, or obstruction was considered a marker of successful stent deployment.

For the present preliminary cases, post-operative CT angiography follow-up was planned at the 6th month. At the end of the 6th month, the maximum diameter of the sac was measured in the stretch images and the volumes of the aneurysms, including the thrombi, were calculated using a special vascular analysis software package according to the European Society of Cardiology guidelines[12]. All procedures were performed in accordance with established best practices and protocols.

Table 1 summarizes the characteristics of the aneurysm, the location of the S-MFM stents placed for each case, and the percentages of proximal and distal oversize.

Table 1. Outlined characteristics of aneurysms and stents

Case #	Size and localization in aorta	Stent site	Oversizing (%)
1	55 mm, Crawford type 1	Arcus aorta	Proximal: 20 Distal: 15
2	59 mm, Crawford type 4	Abdominal aorta	Proximal: 20 Distal: 20
3	56 mm, Crawford type 2	Thoracic abdominal aorta	Proximal: 20 Distal: 15
4	57 mm, Crawford type 1	Arcus aorta	Proximal: 22 Distal: 15
5	60 mm, Crawford type 2	Arcus aorta	Proximal: 20 Distal: 15
6	60 mm, Crawford type 4	Abdominal aorta	Proximal: 20 Distal: 15
7	55 mm, Crawford type 3	Thoracic abdominal aorta	Proximal: 20 Distal: 20
8	59 mm, Crawford type 4	Abdominal aorta	Proximal: 25 Distal: 15
9	78 mm, Crawford type 3	Thoracic abdominal aorta	Proximal: 20 Distal: 20
10	57 mm, Crawford type 4	Abdominal aorta	Proximal: 20 Distal: 15
11	65 mm, Crawford type 4	Abdominal aorta	Proximal: 25 Distal: 20
12	55 mm, Crawford type 2	Arcus aorta	Proximal: 20 Distal: 15

mm: millimeter.

Results

In all cases, the control angiograms confirmed normal patency of the aorta and S-MFM, and all overstented branch arteries remained patent without recorded ischemic events (Fig. 1).

Complete aneurysm thrombosis was detected in all patients on CT angiography at 6-month follow-up. The volume of the aneurysm sac was found to be slightly reduced in all cases, with an overall mean of 2.36% (Table 2 and Fig. 2).

Significant complications, such as ruptures, stent migrations, retractions, thrombosis, and fractures were not observed during this period. None of the cases required immediate intervention. The placement of S-MSM was technically successful in all patients. No endoleak (type I) associated with incomplete or ineffective placement of the stent at the proximal and distal ends was observed.

As summarized in table 3, the key metrics, such as the duration of the procedure and fluoroscopy, blood loss, and contrast volume were consistent with established standards[13].

The vascular surgeons mentioned in the study participated in the procedures and the most important

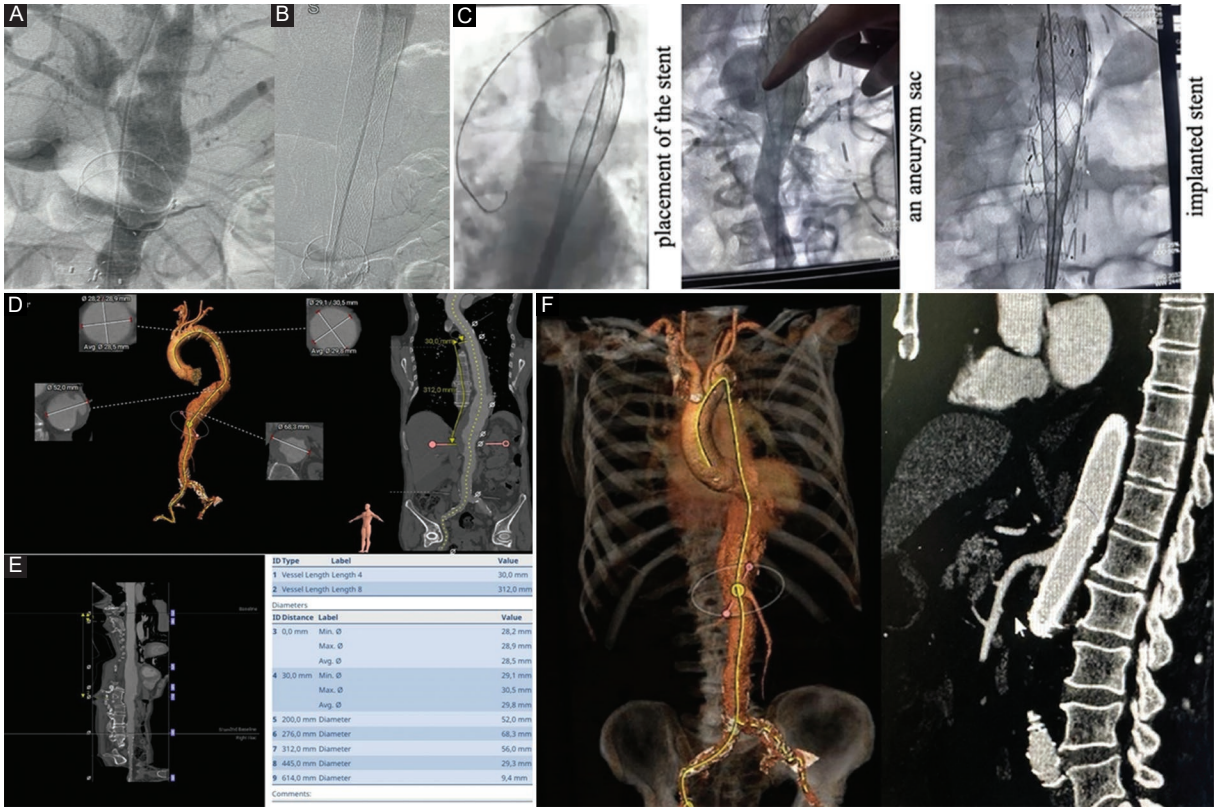

Figure 1. *Image of control angiograms regarding aortic aneurysm and Stena Multilayer Flow Modulator® (S-MFM) placement.* **A***: infrarenal aneurysm at the level of the celiac artery and superior mesenteric artery in a patient who had previously undergone aortobifemoral bypass surgery.* **B:** *simultaneous image of the Stena Multilayer Stent (Invamed, Turkey) with the procedure, applying 28 × 100 mm and 26 × 100 mm just below it.* **C:** *successful placement of the S-MFM.* **D:** *pre-procedural vascular metrics. The level of the celiac trunk and superior mesenteric artery are shown with a circle.* **E:** *post-procedural vascular metrics. The level of the celiac trunk and superior mesenteric artery are shown with a circle.* **F:** *even after S-MFM placement, patency and blood flow of the superior mesenteric artery continues (shown with circle and arrow in the left and right figure, respectively).*

Table 2. Impact of the S-MFM on aneurysm sac volume.

Case#	Baseline (mL)	At 6 months (mL)	Change (%)
1	193.2	193.1	0.05
2	250.5	243.5	−2.79
3	98.7	96.8	−1.92
4	105.6	102.3	−3.12
5	365.8	357.7	−2.21
6	241.4	238.0	−1.40
7	123.5	119.7	−3.07
8	95.3	91.2	−4.30
9	138.6	138.5	0.07
10	120.9	117.6	−2.72
11	216.0	208.5	−3.47
12	122.1	118.2	−3.19
Mean	172.63	168.75	−2.36

mL: milliliter.

problem encountered was the risk of early rupture. This is because the sac is still filling despite the pressure reflected on the aneurysm wall in the early period. In addition, bleeding problems in the femoral artery region may be observed due to the femoral incision made during the early period. No post-operative HCT decrease of <10%, tachycardia or hypotension developed in any patient and no bleeding or rupture was observed.

Discussion

AA is usually seen in men 65 years of age. Most of the time, the diagnosis is made as a result of screening performed for another reason. Screening programs show that the prevalence of AA is decreasing in this age group in high-income countries[13]. This is probably related to the improvement in treatment options and the availability of this facility in developed countries. However, the global death rate from AA increased by 12%

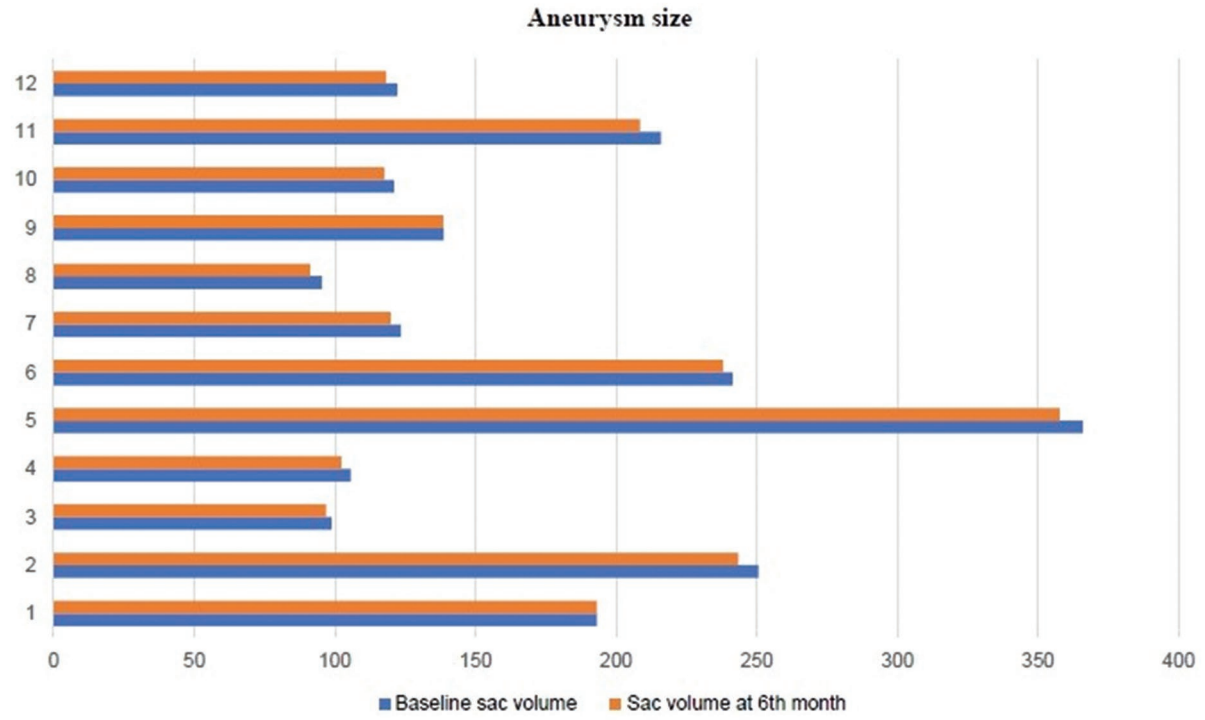

Figure 2. *Schematic demonstration of the impact of Stena-multilayer flow modulator on aneurysm sac volume.*

Table 3. Key operational metric details

Case #	Procedure time (min)	Fluoroscopy time (min)	Blood loss (mL)	Contrast volume (mL)
1	65	22	< 100	55
2	55	21	< 100	70
3	50	31	< 100	45
4	45	24	< 100	55
5	70	21	120	70
6	55	23	< 100	50
7	50	27	< 100	55
8	55	32	< 100	70
9	55	24	< 100	60
10	45	28	< 100	55
11	50	30	< 100	65
12	55	29	< 100	50
Mean	54.17	26	-	58.33

during this period[13]. This is probably because AA is recognized as a cause of death in low- and middle-income countries.

At present, there are no specific guidelines for the treatment of AA[13]. Although open surgical repair is the gold standard and even present case series on the treatment of AA, it still has high mortality and morbidity rates, such as paraplegia and renal failure that require dialysis[10,14]. In recent years, endovascular methods have become the first treatment option not only due to their minimal invasiveness, but also with the hope that they can prevent adverse events related to open surgery based on initial data[14]. However, there are several limitations to this technology, such as the problem of implantation due to the complex peripheral anatomy caused by the large branches in the immediate vicinity of the aneurysm[8,14]. The clinical results are also unsatisfactory[15].

In this respect, flow-diverting stents (FDSs) that have recently been developed offer an encouraging option. Conceptually, FDSs alter blood flow from aneurysm turbulence to laminar in the main artery. The special design of the FDSs allows one to reduce the flow velocity vortex within the aneurysm and to support laminar flow in the main artery and lateral branches. By inducing positive shear stresses, it also promotes endothelialization of the graft and thrombosis in the aneurysmal sac[8].

One of the most important problems encountered is the filling of the aneurysm sac after stent application and the

risk of early rupture. As stated in the sources, the procedure was performed with the expectation that the tension reflected on the sac wall would decrease over time.

In addition, as observed in cranial aneurysm treatments, multilayer stents do not prevent the branches from feeding, as well as reducing the tension of the aneurysm sac.

Apart from the S-MFM®, several MFM stents, such as the Streamliner Aortic MFM (Cardiatis, Isnes, Belgium) with flow guidance concept, have shown satisfactory results in terms of technical success, aneurysm thrombosis and shrinkage, and branch vessel patency[13]. These stents are easier to apply and do not require pre-preparation, such as a patient-specific design[10]. The first patient-level meta-analysis study revealed a 30-day mortality rate of 2.9% with SMFM when used in patients with complex thoracic aortic pathology. Furthermore, there were no incidences of paraplegia, stroke, or renal failure[16].

In our preliminary study of 12 cases, control angiograms confirmed continued blood flow in the main aorta and lateral branch arteries without significant adverse events or death. The technical success rate was 100% and all patients had complete aneurysm thrombosis.

The MFM technology has advantages over a single-layer bare metal stent. This is because unique multiple layers allow for flow modulation and pressure distribution across the layers. When blood flows through the first layer of the MFM, the pressure is reduced across the layers. This eventual reduction in pressure at the aneurysm sac corresponds to an increase in velocity across the stent. The immediate reduction in wall stress can be up to 55%[14]. As with the S-MSM, the self-expanding design further supports hemodynamic modulation by increasing laminar flow in the lumen of the main aorta and vital branches while reducing the flow velocity vortex in the aneurysm sac.

Although the mean total volume of the MFM-treated aortic sac increases by 6-7% in the first 3 months, the mean total volume of the sac begins to decrease after 6 months[14]. This is likely a result of the body's inflammatory and other physiological responses. The mean decreasing in aneurysm sac volume of 2.36% at the end of the 6th month was consistent with these observations.

Study limitations

This study has some limitations. The sample size was relatively small and users of the S-MFM® had no experience with this product, although they had experience in the treatment of AAs. The usability, safety, efficacy, and placement of S-MSM were evaluated based on the results of the perioperative period and the 6th month. There was no short-, medium-, or long-term evaluation. The study also did not have a control arm. Detailed results are not also available for other equivalent products to make a definitive assessment with all dimensions.

Conclusions

MFM technology could be an attractive alternative to surgery or other endovascular techniques for AAs, for reasons such as shrinking the aneurysm sac and preserving the side branch blood flow. It reduces the risks of mortality and morbidity, including kidney failure and paraplegia. MFM stents can be successfully placed even in a patient with complex aortic anatomy. Its ready-to-use structure, which does not require adaptation to the individual, allows it to be easily applied to complex AAs and prevents time loss. Although the present research results and the unique design of the technology encourage it for use, further research and longer follow-up are required to fully understand the clinical implications.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of humans and animals. The authors declare that no experiments involving humans or animals were conducted for this research.

Confidentiality, informed consent, and ethical approval. This is a retrospective study, so it was exempted from ethics committee approval. The study results were endorsed by the Ethics Committee of Hatay Mustafa kemal University.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing of this manuscript.

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