

Peripheral multilayer flow modulator stents: short-term outcomes

Stents moduladores de flujo multicapa periféricos: resultados a corto plazo

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Abstract

Objectives: Peripheral artery pathologies continue to be a significant public health problem worldwide. Endovascular techniques have rapidly become the main treatment option in recent times. Multilayer flow modulator (MFM) stents, a newer technology, have three important properties that provide them the potential to overcome these problems: porosity, flexibility, and low-profile structure. This article aims to present the short-term follow-up results of stents (MFM) used in peripheral artery pathologies. **Methods:** Three-month follow-up outcomes were evaluated in 67 patients (41 men and 22 females; mean age 66.7 years, range 53-84 years) who underwent aneurysm repair with Stena Peripheral MFM Stent® (Invamed, Turkey) between January and December 2023. **Results:** Sixty-three peripheral vascular stents were applied, including 37 iliac artery and 26 superficial femoral arteries. No occlusion, fracture, or displacement of the MFM was observed. It should be 63 instead of 67. There were no findings associated with compression or stent kinking. **Conclusions:** The short- and medium-term results of MFM stents in peripheral artery pathologies may be considered satisfactory for both technical success and collateral patency. MFM stents may be a viable and safe alternative to traditional endovascular surgery or endovascular.

Keywords: Peripheral arterial diseases. Aneurysm. Multilayer flow modulator stents.

Resumen

Objetivo: Los stents moduladores de flujo multicapa (MFM), una tecnología novedosa, tienen tres propiedades importantes que les brindan el potencial para superar problemas: porosidad, flexibilidad y estructura de bajo perfil. Este artículo tiene como objetivo presentar los resultados del seguimiento a corto plazo de los stents MFM utilizados en patologías de arterias periféricas. **Métodos:** Se evaluaron los resultados del seguimiento a 3 meses de 67 pacientes (41 hombres y 22 mujeres; edad media 66.7 años, rango 53-84 años) que se sometieron a reparación de aneurisma con Stena Peripheral Multilayer Flow Modulator Stent® (SP-MFM, Invamed, Turquía) entre enero y diciembre de 2023. **Resultados:** Se aplicaron 63 stents vasculares periféricos, incluyendo 37 de arteria iliaca y 26 de arteria femoral superficial. No se observó oclusión, fractura ni desplazamiento del stent MFM. El éxito clínico, primario y secundario, fue del 92.0% y el 100%, respectivamente. **Conclusiones:** Los resultados a corto y medio plazo de los stents MFM en patologías de arterias periféricas pueden considerarse satisfactorios, tanto para el éxito técnico como para la permeabilidad colateral. Los stents MFM pueden ser una alternativa viable y segura a la cirugía endovascular tradicional o endovascular.

Palabras clave: Enfermedades arteriales periféricas. Aneurisma. Stents moduladores de flujo multicapa.

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Introduction

Peripheral arterial diseases (PAD), such as aneurysms and occlusion, are a significant burden on the population worldwide. Although they are usually asymptomatic, if left untreated, they can cause severe ischemia in the extremities and even cause loss of limb.¹⁻³ They are most frequently seen in the lower extremities.⁴

The gold standard in the treatment of PAD remains controversial. Before the introduction of endovascular techniques, the traditional approach was open surgery.^{5,6} However, open surgical repairs, such as ligation and bypass, are associated with high rates of perioperative complications such as neurological events, infection, seroma, and hematoma. In aneurysms, despite open repair, there is a 30% chance that the aneurysm will expand over time.² Endovascular techniques have recently become the main treatment option in peripheral aneurysms, resulting in shorter hospital stays, fewer post-operative complications, and comparable short- and medium-term patency rates.^{1,5,6} One of the main disadvantages of conventional endovascular treatment with a covered stent graft is the occlusion of side branches. Covered stents also have limited flexibility, making them often unsuitable for complex anatomies.⁷

The flow modulator stent concept has been a popular approach in clinical practice, especially for arterial aneurysms. These stents have unique designs consisting of a three-dimensional multilayer braided structure and uncoated. They are low profile and flexible. Due to these unique features, multilayer flow modulator (MFM) can easily adapt to the diameter, morphology, size, and course of the target artery.⁷ It allows thrombosis to occur within the aneurysm sac, causes it to gradually shrink, and allows the collateral branches to remain patent.⁸

In this article, the objective of this study was to present preliminary short-term follow-up results of peripheral arterial pathologies treatment using Stena Peripheral MFM Stent® (SP-MFM) (Invamed, Turkey).

Methods

Study design

A total of 63 patients (41 were men and 22 were women) with lower extremity aneurysms were treated with SP-MFM stents between January and December

2023. The age of patients was 53-84 (mean 66.7). The patients were followed for 3 months. Patients with inadequate arterial access, aneurysms with inadequate proximal or distal necks, ruptured aneurysms, malignancy, or death within the first 3 months were excluded from the study.

According to the principles of the Declaration of Helsinki, written informed consent was received from all participants. Ethics approval was obtained from the Hatay Mustafa Kemal University Local Ethics Board for this study (meeting date: June 07, 2023, decision no: 03).

Approach

Doppler ultrasound (DUSG) was performed for pathology diagnosis. Computed tomography angiogram (CTA) was performed in all cases for pre-operative planning. SP-MFM stents of different sizes (6-60 mm in diameter and 9-100 mm in length) were used depending on the anatomical characteristic of the vascular pathology (Fig. 1). The procedures were performed under local anesthesia in all patients. The procedures were performed under ultrasound, and common femoral artery access was preferred for access during the interventions. However, in patients with difficulty in intervention due to occlusion of the femoral artery, retrograde access was provided through the popliteal artery.

Intravenous heparin (5000 IU) was administered to all patients during the procedure. After the procedure, the patients received dual antiplatelet therapy consisting of acetylsalicylic acid 100 mg and clopidogrel 75 mg, as well as pantoprazole 40 mg to protect the stomach for at least 1 month. All patients were recommended to use 100 mg of acetylsalicylic acid daily for life.

All patients were controlled with DUSG and discharged within 24-48 h after the procedure. During the 3-month follow-up period, patients were evaluated with manual hand-held DUSG by the cardiovascular surgery unit in the outpatient clinic. At the end of the 3rd month, all patients were also evaluated with CTA.

Endpoints

Freedom from early (first 30 days after treatment) or late (more than 30 days after treatment) sac thrombosis and SP-MFM patency were the primary endpoints. Collateral patent vessels, limb salvage, and

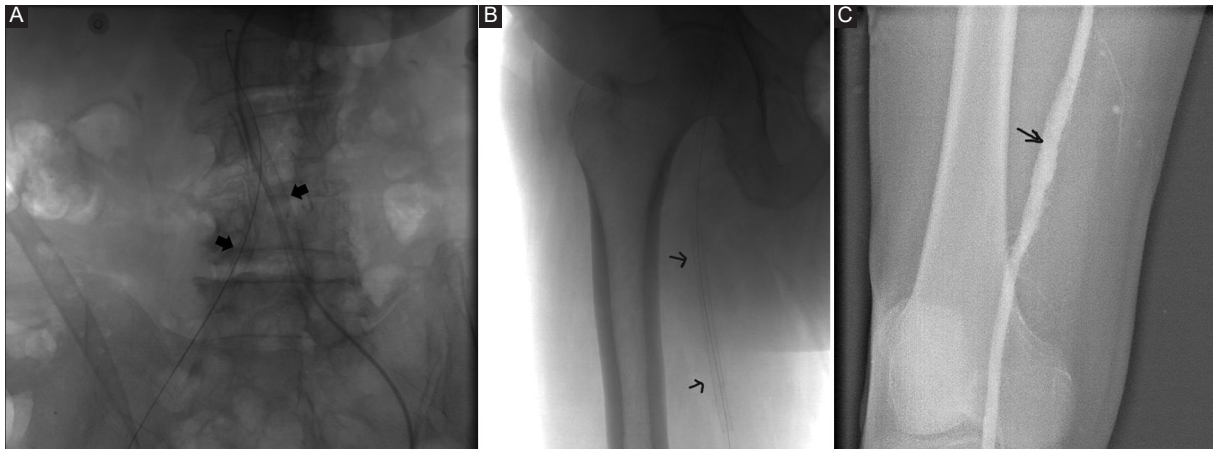


Figure 1. Computed tomography angiogram image examples from patients with iliac and superficial femoral artery stents (black arrows). **A:** application of bilateral iliac aneurysm stent (9 × 100 mm). **B:** superficial femoral artery stent (7 × 80 mm). **C:** superficial femoral artery stent (6 × 100 mm).

stent-related complications during follow-up were secondary endpoints.

Aneurysm sac thrombosis was defined as the absence of contrast substance in the aneurysm sac in the CTA control. Primary patency was defined as the continuous flow of blood through the device without requiring any intervention after deployment. Secondary patency was defined as the continuation of blood flow through the device regardless of interventions after complete occlusion.

Technical overview of SP-MFM

The SP-MFM[®] is a 5-layer tubular braided stent made of a self-expanding radiopaque metal alloy. It is designed for the treatment of peripheral aneurysms. Its self-expandability allows it to easily adapt to the target area and provides it with high resistance to bending and fatigue.

There are models in different sizes, 5-16 mm in diameter, and 20-200 mm in length. The 18F-20F size delivery system is compatible with the 0.035-inch guidewire.

Results

Sixty-three peripheral vascular stents were applied, 37 of which were in the iliac artery and 26 in the superficial femoral artery. Depending on the location of the arterial pathology and whether the arteries were open or closed, access was achieved through the femoral route in 45 patients and the popliteal route in 18 patients, retrograde or antegrade.

Technical success was 100%. No MFM occlusion, fracture, or displacement was observed. There were no findings associated with stent compression or bending during leg flexion. No renal dysfunction was observed in any of the patients.

There was no mortality during the follow-up period. A patient underwent amputation within the 1st month due to a clinical condition, but not related to the stent. At follow-up at the end of the 3rd month, it was determined that the stent showed 50% or more occluded segments in four of the patients evaluated by CTA. These patients underwent additional intervention with balloon angioplasty and, if necessary, additional stent placement (Fig. 2). Ultimately, 4 (6.35%) of the patients required endovascular reintervention at 3 months of follow-up.

In 58 patients (92.0%), control angiograms confirmed that primary patency of the lumen of the parent arteries was achieved successfully without the need for additional intervention. When we excluded the amputated patient, the secondary clinical success was 100%. All branch arteries remained patent, with no recorded ischemic events.

Discussion

Open surgery still maintains its importance in the treatment of PADs because it produces good results, especially in the long term. However, major advances in endovascular techniques that allow the treatment of PAP with shorter hospital stays, fewer post-operative complications, and comparable

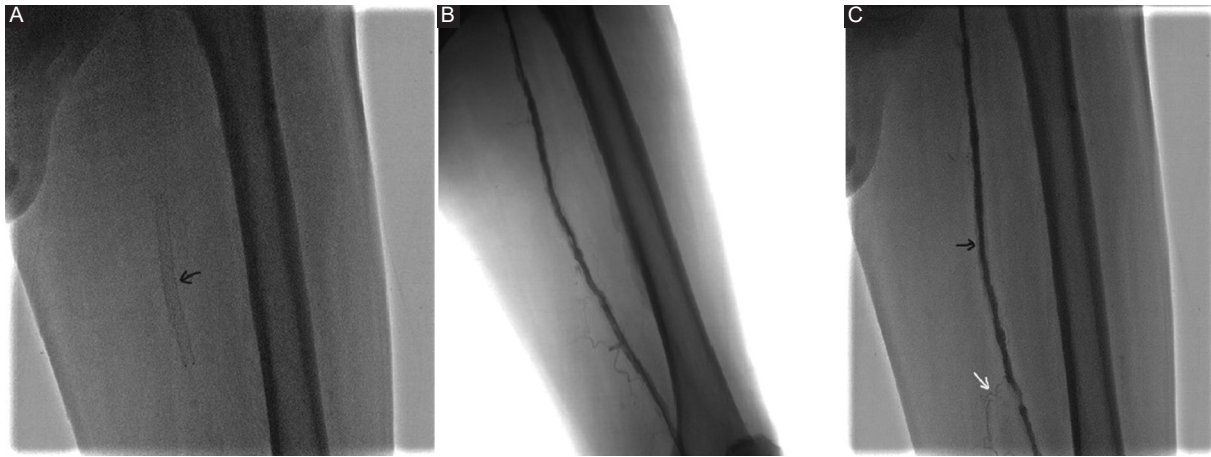


Figure 2. Post-intervention computed tomography angiogram images of superficial femoral artery. **A:** multilayer flow modulator (MFM) stent (black arrow) inserted immediately after the intervention. **B:** MFM stent inserted and balloon angioplasty assisted. **C:** the 3rd month of follow-up. It can be easily seen that the parent artery remains patent, and blood flow continues to the collateral artery (white arrow).

short- and medium-term patency rates have made endovascular techniques a topic of interest as an alternative treatment.⁶ One of the main weaknesses of stent placement in peripheral arteries is that its constant flexion in extremity joints requires unique resistance and flexibility. Another weakness is that these conventional covered stents often cause total ischemia in the limb due to occlusion of the already fewer collaterals.⁹

In the study by Henry et al. in 2008, it was observed that there was a significant decrease in blood flow in renal artery aneurysm sacs with three-dimensional multilayer stents and even patency in the branches of the renal artery was preserved.⁵ Since then, the MFM concept has shown encouraging results in various arteries, including extremity artery pathologies such as popliteal artery aneurysms.¹⁰⁻¹² Flexion in the limb joints is significantly associated with the risk of displacement, occlusion, or fracture of conventional stents by grafts. Stents in the femoropopliteal segment are extremely vulnerable to these risks.¹³ Technical advances in the design and construction of stent manufacturing have led to the development of flexible, self-expanding uncoated, multilayered, and porous stents. Porosity, flexibility, and low-profile structure are three important unique features of the MFM.² The flexibility and low profile provide self-expandable properties of MFM stents. This ultimately facilitates their deployment (including small arteries), allows easy adaptation to the target site, and provides them with high kinking and fatigue resistance.^{6,12,14} Due to their porosity, MFM stents also preserve side branch

perfusion. When applied to aneurysms, it shrinks the aneurysm by reducing the flow rate vortex and allowing thrombosis to occur within the aneurysm.¹⁰⁻¹²

MFM stents generally have similar basic properties. Data on the use of MFM in peripheral artery pathologies are quite limited. The experience with Cardiatis MFM (Cardiatis, Isnes, Belgium), which has been approved for the management of peripheral aneurysms in European countries since May 2009, is encouraging. Ruffino et al. reported a 100% rate of sac thrombosis at 12 months after MFM stent application to the popliteal region in six cases, but did not detect stent occlusion.¹⁴ In the experience of Antoniou et al. in six cases, they reported 67% primary patency and 100% secondary patency at 6-month follow-up.¹⁵ Ucci et al. reported primary, primary-assisted, and secondary patency rates of 70.1%, 86% and 90.3%, respectively, in the popliteal arteries in a series of 23 patients at 24 months. A case of stent fracture was reported in a patient.⁶

In our preliminary study of 63 cases, the technical success was 100%. Primary patency obtained in 58 patients (92.0%). One patient underwent amputation, but the cause was not related to the stent. Four of the patients with 50% or more segment occlusion underwent balloon angioplasty and, when necessary, additional stent intervention. Our secondary clinical success was 100%.

Conclusions

The short- and medium-term results of MFM stents in peripheral artery pathologies seem satisfactory in

terms of technical success and patency of branch arteries. Observations on occlusion of the MFM stent, fracture or migration, and fatigue resistance are acceptable. They may be considered a viable and safe alternative to traditional open or endovascular treatment. To evaluate the real role, studies with larger patient samples and longer follow-up periods are needed.

Limitations

This study has several limitations. The MFM stent strategy is a relatively new strategy in the treatment of peripheral artery pathologies. Follow-up periods and small sample sizes are relatively limited in providing adequate information on their effectiveness, safety, and application techniques.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of human subjects and animals. The authors declare that no experiments on humans or animals were performed for this research.

Confidentiality, informed consent, and ethical approval. The authors declare that written informed consent was obtained from all participants. Ethical approval for the study was obtained from the Hatay Mustafa Kemal University Local Ethics Board (meeting

date: June 7, 2023; decision no. 03). The authors followed their institution's protocols regarding the confidentiality of patient data.

Declaration on the use of artificial intelligence.

The authors declare that no generative artificial intelligence was used in the writing or creation of the content of this manuscript.

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