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Multi-layer Flow-modulating Stents for Thoraco-abdominal and Peri-renal Aneurysms: The UK Pilot Study

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WHAT THIS PAPER ADDS

Multi-layered flow-modulating stents are a novel technology that has been proposed as a treatment for complex aortic aneurysms. In this pilot study of 14 patients, the device had uncertain influence of the natural history of thoraco-abdominal and peri-renal aneurysms, with ongoing aneurysm growth seen in most patients and device-related complications common. There are patients who are unsuitable for open, conventional, or complex endovascular repair, but these are fewer with the ongoing development of FEVAR and BEVAR and the role of MFMS remains unclear. Significant further development is needed if this novel technology is to have a role in treating aortic aneurysms.

Objective: There remains a population of patients with aortic aneurysms that cannot be treated by conventional endovascular means. Multi-layer flow modulating stents (MFMS) are a novel approach for the treatment of aortic aneurysm; this study reports outcomes of a UK pilot study of first-generation MFMS in thoraco-abdominal (TAAA) and perirenal aneurysms (PAA) in patients who were also unfit for open surgery.

Methods: Patients with TAAA and PAA unfit for open surgery and with no conventional options for endovascular repair were recruited. Follow-up included CTA at 1, 3, 6, and 12 months, then annually. Outcome measures included 30 day mortality, growth-free survival, branch vessel patency, complications, re-intervention, and maximal aortic diameter.

Results: MFMS were implanted in 14 patients (6 PAA, 8 TAAA) between October 2011 and March 2014 with one (7%) 30 day death and 11 (79%) surviving to 12 months. The median aneurysm growth was 9 mm in the first 12 months following implantation. On mean follow-up of 22.8 months, seven (50%) patients had died including one confirmed rupture. AAA diameter remained stable in only two of the surviving patients. Fifty of 51 covered aortic branches remained patent with no embolic episodes or symptoms of ischaemia in any patient. MFMS dislocation occurred in four patients, leading to re-intervention in two. A total of six re-interventions were performed in five patients (35%) with one post-re-intervention death.

Conclusion: These first-generation MFMS were unstable and dislocated frequently. It is uncertain whether MFMS implantation influenced the natural history of these aneurysms as none decreased in size, but two remain stable after a mean of 22.8 months. Although side branch patency was maintained, our results do not support the continued use of these first-generation devices. Further development is needed if this technology is to have a role in treatment of aortic aneurysm.

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INTRODUCTION

Despite the evolution of branched and fenestrated aortic stent grafts, there are patients with complex aortic aneurysms that cannot be treated by endovascular repair. Such patients are often elderly with multiple comorbidities rendering them unfit for open surgery. The multi-layer flow modulating stent (MFMS, Cardiartis, Belgium) is a novel technology that offers the possibility of endovascular treatment for these complex aneurysms. The MFMS is a CE marked, self-expanding multi-layered stent constructed of

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cobalt alloy wires interconnected in five layers. Rather than "excluding" the aneurysm, the MFMS is freely porous but blood-flow through the stent is laminated reducing turbulence in the aneurysm sac leading to sac thrombosis. As the stent is uncovered and highly porous, it can be deployed across the origins of major aortic branches maintaining organ perfusion[1,2] (Fig. 1). Recent studies suggest acceptable early results in aortic aneurysms,[3,4] aortic dissections,[3,4] and peripheral and visceral aneurysms,[5] although the consequences of using this device outside of the instructions for use (IFU) have been well documented.[2,6] This study reports experience with the first-generation MFMS device in a UK pilot study recruiting patients with thoraco-abdominal (TAAA) and peri-renal (PAA) aortic aneurysms.

METHODS

Patients with TAAA and PAA were recruited at two Manchester vascular centres with experience of conventional and complex EVAR. The inclusion and exclusion criteria are available as Supplementary material. All patients were considered for open repair or fenestrated/branched endovascular repair (FEVAR/BEVAR) at the Greater Manchester "complex" multidisciplinary team meeting. The CT scans were discussed and reviewed by at least two consultants experienced in these procedures. Finally, CT images were sent to one of the major manufacturers of complex stent grafts and patients were only treated with MFMS if the patient was turned down for open or FEVAR/BEVAR by this process.

All implantations were performed with approval of the device manufacturer. If the MFMS was to be placed across aortic branches, any stenosis at the origin of the vital side branch was treated by angioplasty and stenting prior to MFMS deployment. For most patients, this was performed as a separate procedure.

The study was approved by the National Research Ethics Service (11/NW/0407), and all patients gave informed consent specifically including clear advice that this was an untested technology that may fail to treat the aneurysm effectively. Patients were prescribed dual antiplatelet therapy (aspirin and clopidogrel) pre-operatively and for at least 3 months following MFMS implantation to aid in maintaining side branch patency. Planned follow-up was by CTA at 1, 3, 6, and 12 months, then annually for 3 years. Outcome measures included (a) growth-free survival, (b) maximal aneurysm diameter, (c) 30 day mortality, (d) aortic side branch patency, and (e) all complications. Complete aneurysm sac thrombosis was defined as no contrast outside the MFMS on arterial phase imaging. Dislocation described complete or partial separation of components, such that blood in the lumen of the MFMS could flow directly into the aneurysm sac without passing through the stent.

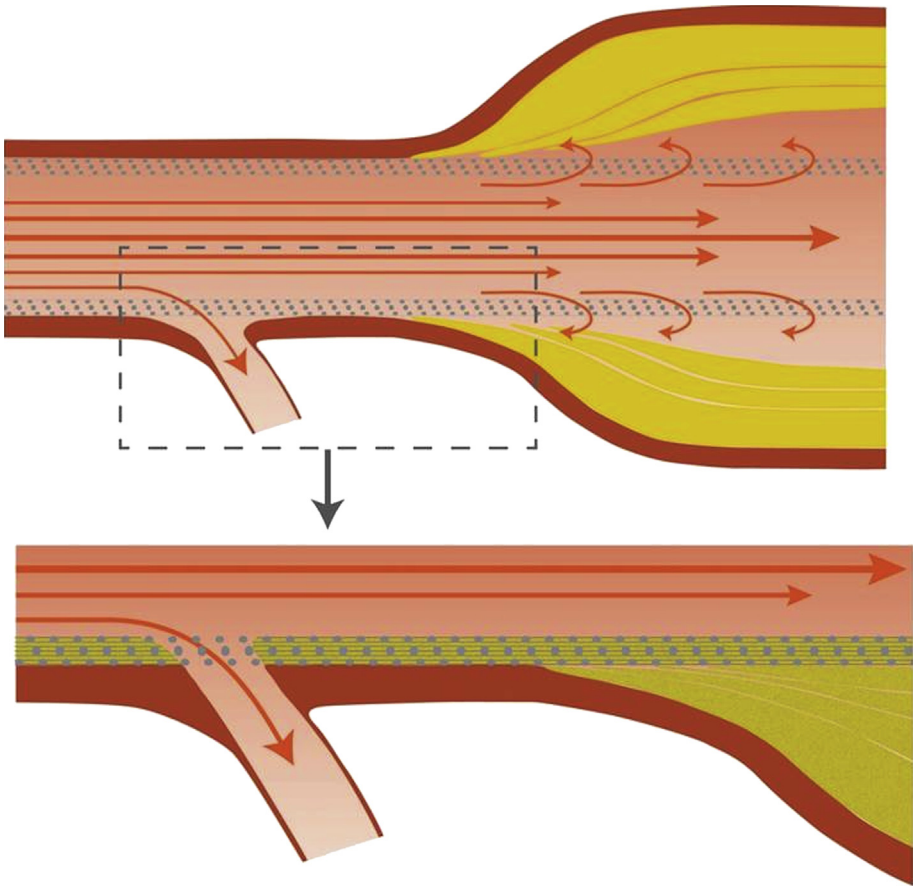

Figure 1. MFMS principle. Flow through the aneurysm is laminated by the MFMS, leading to aneurysm sac thrombosis (top). The porosity of the stent allows deployment across aortic branches while flow is maintained (bottom).