Early and midterm outcome of Multilayer Flow Modulator stent for complex aortic aneurysm treatment in Germany

Walid Ibrahim, MD,[a] Konstantinos Spanos, MD, MSc, PhD,[b] Andreas Gussmann, MD,[c] Christoph A. Nienaber, MD, PhD,[d] Joerg Tessarek, MD, PhD,[e] Heinrich Walter, MD, PhD,[f] Jörg Thalwitzer, MD, PhD,[g] Sebastian E. Debus, MD, PhD,[b] Nikolaos Tsilimparis, MD, PhD,[b] *and* Tilo Kölbel, MD, PhD,[b] *Bad Saarow, Hamburg, Berlin, Lingen, Bad Oeynhausen, and Chemnitz, Germany; and London, United Kingdom*

ABSTRACT

Objective: The objective of this study was to assess the early and midterm outcomes of endovascular repair of complex aortic aneurysm cases using the Multilayer Flow Modulator (MFM; Cardiatis, Isnes, Belgium) endograft in Germany.

Methods: A retrospective study including patients presenting with abdominal aortic aneurysm (AAA), thoracic aortic aneurysm, or thoracoabdominal aortic aneurysm treated with the MFM was conducted in Germany. Mortality and morbidity (in terms of spinal cord ischemia, visceral ischemia, and stroke) at 30 days postoperatively were evaluated. In addition, during follow-up, freedom from reintervention, rupture, and failure mode were also assessed.

Results: Between 2009 and 2014, a total of 61 patients with AAA, thoracoabdominal aortic aneurysm, or thoracic aortic aneurysm were treated with the MFM endograft in 29 hospitals around Germany. However, data of 40 patients with a mean age of 73.4 ± 11.2 years (72.5% male; 29/40) and mean aortic aneurysm diameter of 60.3 ± 16.6 mm from 14 hospitals were available for this retrospective study. Thirty-seven (93%) patients were treated urgently. In 12 cases (12/40 [30%]), patients were treated outside instructions for use because of aortic aneurysm diameter >65 mm. A total of 69 MFM stents were used (1.7/patient). The technical success rate was 95% (38/40). Postoperatively, no patient presented with spinal cord ischemia, renal function deterioration, stroke, or intestinal ischemia, except for one patient who developed multiorgan failure because of early stent migration. The intraoperative and 30-day mortality rate was 0% and 2.5%, respectively. The mean follow-up was 12.9 months (±14.9 months), with a survival rate at 1 month, 6 months, and 12 months of 97%, 78%, and 70%, respectively. Freedom from failure mode (type I or II) at 1 month, 6 months, and 12 months was 97.5%, 88%, and 86%, respectively, and visceral vessel patency was 99.3% (155/156 available). During follow-up, 4 patients (4/39 [10%]) had an aneurysm sac rupture and 10 (10/39 [25%]) underwent a reintervention. Freedom from rupture and freedom from reintervention at 1 month, 6 months, and 12 months were 97.5% and 100%, 96% and 84%, and 86% and 75%, respectively.

Conclusions: The use of the MFM for endovascular treatment of complex aortic aneurysm in urgent cases appears to be technically feasible in terms of mortality and morbidity, with moderate 30-day and acceptable midterm outcomes. Reinterventions may be needed to expand the utility of outcomes. (J Vasc Surg 2018;■:1-9.)

Keywords: Multilayer Flow Modulator; Endovascular aneurysm repair; Open conversion; Failure mode; Spinal cord ischemia

Repair of juxtarenal, pararenal, and suprarenal aneurysms and thoracoabdominal aortic aneurysm (TAAA) remains a challenging treatment issue. Endovascular treatment modalities, such as chimney, fenestrated, and branched endovascular repair, have demonstrated a lower perioperative morbidity and mortality than conventional open repair, with good midterm and long-term results.[1-4] A major limitation of fenestrated and branched endovascular repair is the need for manufactured customization that can take up to 12 weeks, which may exclude the treatment of urgent cases. A standardized off-the-shelf multibranched stent graft, the t-Branch device (Cook Medical, Bloomington, Ind), has recently been approved in Europe; it may cover this gap in urgent cases, although it has been mostly assessed in elective cases.[5,6] However, even this branched off-the-shelf stent graft has limitations in its application according to the anatomic selection criteria.[7] Furthermore, surgeon-modified fenestrated endografts

From the Department of Vascular Medicine and Vascular Surgery, HELIOS Hospital Bad Saarow, Bad Saarow[a]; the Department of Vascular Medicine, German Aortic Center Hamburg, University Heart Center, Hamburg[b]; the Department of Vascular Medicine and Vascular Surgery, HELIOS Hospital Berlin-Buch, Berlin[c]; the Cardiology and Aortic Centre, Imperial College, The Royal Brompton & Harefield NHS Trust, London[d]; the Department of Vascular Surgery, Bonifatius Hospital Lingen, Lingen[e]; the Department of Vascular Surgery and Endovascular Surgery, Bad Oeynhausen Hospital, Bad Oeynhausen[f]; and Klinikum Chemnitz GmbH, Institut für Bildgebende Diagnostik, Chemnitz.[g]

Author conflict of interest: N.T. is a proctor for Cook Medical. T.K. has intellectual property with Cook Medical.

Correspondence: Konstantinos Spanos, MD, MSc, PhD, German Aortic Center Hamburg, University Heart Center, University Hospital Hamburg-Eppendorf, Martinistr 52, Hamburg 20246, Germany (e-mail: spanos.kon@gmail.com).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

https://doi.org/10.1016/j.jvs.2018.01.037

and chimney and snorkel techniques have been described with good outcomes, but they are complex procedures with long operating times and are mostly not approved.[4,8]

An alternative endovascular approach for complex aortic cases is the Multilayer Flow Modulator (MFM; Cardiatis, Isnes, Belgium), which is a three-dimensional self-expandable wire mesh interconnected in layers permitting a porosity of ~65%. Blood flow is allowed through the stent mesh while the stent modulates laminar flow within the device and aneurysm sac. Laminating the flow into collateral vessels arising from the aneurysm preserves their patency. Aneurysm sac exclusion is thought to occur over time with thrombus formation while the blood perfusion into the involved branches is maintained.[9-11]

The MFM has been assessed in previous studies and stood out for its simplicity of deployment and its minimally invasive approach, demonstrating good results in splanchnic and cerebral arteries.[10,12] Immediate availability without the need for customization may render it ideal for use in urgent (nonruptured) patients presenting with complex aortic anatomy. However, there is still controversy as to whether the treatment of aortic aneurysms with the MFM has an effect on the natural history of aortic aneurysms and dissection at all.[13-16]

We conducted this study to assess the perioperative and midterm outcomes of endovascular repair of complex aortic aneurysm cases using the MFM in Germany.

ARTICLE HIGHLIGHTS

- **Type of Research:** Multicenter retrospective cohort study
- **Take Home Message:** Endovascular treatment of thoracic aortic aneurysms or thoracoabdominal aortic aneurysms using a Multilayer Flow Modulator endograft in 40 patients resulted in survival at 1 month, 6 months, and 12 months of 97%, 78%, and 70%, respectively, with 4 patients experiencing aneurysm rupture and 10 patients requiring reintervention.
- **Recommendation:** Endovascular treatment of thoracic aortic aneurysms and thoracoabdominal aortic aneurysms using a Multilayer Flow Modulator endograft in urgent cases appears technically feasible, with acceptable 1-year survival. Aneurysm rupture occurred in 10% after treatment, and one of four patients required reintervention.

METHODS

Selection of patients. Between January 2009 and June 2014, a retrospective study including patients being treated with the MFM was undertaken in Germany (Fig 1). All centers were contacted; however, only patients whose data became available after contacting each hospital were included in the study. Patients with abdominal aortic aneurysm (AAA; infrarenal, para-anastomotic, juxtarenal, pararenal, suprarenal), thoracoabdominal aortic aneurysm (TAAA), thoracic aortic aneurysm (TAA), or aortic dissection were enrolled from 29 hospitals of Germany. The indication for use of the MFM was symptomatic presentation, rapid expansion of the aortic aneurysm diameter, maximum diameter of saccular aneurysm 80 mm, maximum diameter of aneurysm 100 mm, narrow diameter of the access vessels (iliac arteries <7 mm), and exclusion due to anatomic criteria of a manufactured customized device (fenestrated or branched; Cook Medical). The aortic MFM was available in diameters ranging from 16 to 45 mm and in lengths ranging from 80 to 150 mm.

Contraindications to its use were ruptured aortic aneurysm, contained leak of aortic aneurysm, stenotic branches (visceral, great vessels of the head and neck, iliac, coronary), occluded aortoiliac segment, infection associated with previously inserted grafts or endografts, myeloproliferative blood disorders, coagulopathies, and patients with a life expectancy of <6 months.[13] This was a retrospective study, with all data acquired retrospectively. According to the local authorities, Institutional Review Board approval or informed consent of the patient was not deemed necessary for the study.

Demographic data, past medical history, cardiovascular risk factors, preoperative comorbidities, and intraoperative details were collected.

Instructions for use (IFU). According to the IFU for the MFM, the following criterion has to be met: presence of a landing zone with a length of at least 2 cm of normal arterial wall at the proximal and distal ends of the treatment zone into which the MFM stent is deployed. The aneurysm diameter should <65 mm.[15,17] The MFM should be oversized 15% to 25% in comparison to the outer diameter of the normal arterial wall at the proximal and distal landing zones. The length of MFM stent overlap should be 6 cm in straight aorta and 8 cm in angulated connections. In overlapping MFM stents, the smaller diameter stent must be deployed first and the larger diameter stent within the smaller stent. Administration of clopidogrel 75 mg postoperatively, which should be continued daily for at least 12 weeks, is recommended.[13]

End points—definitions. As the general strategy of the MFM includes blood flow through the mesh into target vessels, the usual endoleak classification does not apply for the MFM. We used the definition of failure modes I and II described by Sultan et al,[11] corresponding to endoleak types I and III for stent grafts. Technical success was defined as successful deployment of the MFM stents