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#### **Short Communication**

# Streamliner Multilayer Flow Modulator stents as a therapeutic option in the management of complex thoraco-abdominal aortic pathology report from Global SMFM Registry



Sherif Sultan <sup>a,b,\*</sup>, Edel Kavanagh <sup>b</sup>, Florian Stefanov <sup>b</sup>, Mohamed Sultan <sup>b</sup>, Victor Costache <sup>c</sup>, Ala Elhelali <sup>b</sup>, Violet London <sup>a</sup>, Edward Diethrich <sup>d</sup>, Niamh Hynes <sup>b</sup>

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#### ABSTRACT

Complex thoraco-abdominal aortic aneurysm (TAAA) patients remain a challenge irrespective of treatment choice. The Streamliner Multilayer Flow Modulator (SMFM) is an alternative modality of treatment and it is conceptually at variance with conventional treatment modes.

Preliminary results show that treatment of infra-renal AAA, juxta-renal AAA, Stanford Type B dissection and Crawford Type V by the SMFM device were most successful. Large volumes of more than 450 cm³ in pathologies such as Crawford Type II and Type IV, should be labelled as a contraindication for use of the SMFM. C-reactive protein, haemoglobin, aneurysm volume and maximum diameter all play major roles in successful treatment. The greater the length of the aorta to be covered and the greater the number of stents utilized, the greater the risk of adverse events and mortality. Patient requiring a reintervention with an additional SMFM(s) within 200 days of primary treatment increases mortality. Both length of the pathology and rate of reintervention indicate a severe aortic pathology burden and its aggressive nature.

The SMFM harnesses the body's innate physiological processes to modulate the aneurysm, with no risk of critical shuttering or loss of native side branches. The SMFM offers less operative trauma, shorter procedure times and reduced hospital stays. It offers simplicity, consistency and reproducibility in one treatment. However, the SMFM is not a solution for patients living on borrowed time. It is a promising disruptive technology, only in safe hands and must be utilized under strict instructions for use.

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<sup>&</sup>lt;sup>a</sup> Western Vascular Institute, Department of Vascular and Endovascular Surgery, University College Hospital Galway, Ireland

<sup>&</sup>lt;sup>b</sup> Department of Vascular and Endovascular Surgery, Galway Clinic, Doughiska, Galway, Ireland

<sup>&</sup>lt;sup>c</sup>Department of Cardio-Vascular Surgery, University of Sibiu, Romania

<sup>&</sup>lt;sup>d</sup> Arizona Heart Institute, Phoenix, AZ USA

<sup>\*</sup> Corresponding author. Tel.: +353 91720122; fax: +353 91785871. E-mail address: sherif.sultan@hse.ie (S. Sultan).

#### 1. Introduction

Complex thoraco-abdominal aortic aneurysm (TAAA) patients remain a challenge irrespective of treatment choice. These patients are at high risk of death, renal failure and paraplegia. This high incidence of morbidity and mortality has driven the incentive for discovery of a less invasive, more efficacious and universally reproducible solution for TAAA repair. The Streamliner Multilayer Flow Modulator (SMFM) is an alternative modality of treatment and it is conceptually at variance with conventional treatment modes.

## 2. The SMFM Global Registry

The SMFM Global Registry was established to record data both retrospectively and prospectively for all aortic SMFM implantations globally. To date, 876 patients have been implanted with the SMFM globally, of which we have knowledge pertaining to 452 patients. Currently, the registry contains data on 307 patients. 224 patients are male, 272 patients with TAAA and 35 patients with aortic dissection.

#### 2.1. What is the SMFM?

The SMFM (Cardiatis, Isnes, France) is an endovascular multilayered cobalt alloy bare metal stent graft. Its 3-dimensional design comprises of multiple interlocking layers of cobalt metal wire, braided together to create a mesh. This mesh design alters blood flow from turbulent to laminar as it permeates through to the aneurysm, inducing positive shear stresses along the aortic wall to the point where it promotes endothelialization and thrombosis of the aneurysm. This device differs from traditional endoluminal grafts given that it does not completely exclude blood flow from the aneurysm due to its porosity, rather its design alters the rate and direction of blood flow.

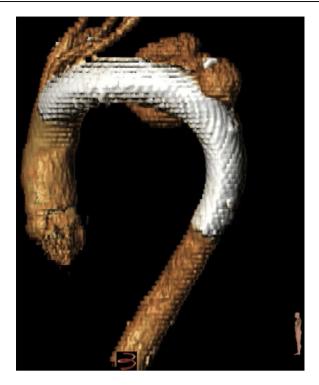


Fig. 1 – Three-dimensional reconstruction of an aortic arch aneurysm treated with the MFM.

### 3. Primary aortic repair

198 patients were treated with 337 SMFM devices as a primary aortic repair, of which 137 were male and 61 were female. 15 patients were aged less than 55 years, 69 patients were aged 55–69 years, 81 patients were aged 70–79 years and 33 patients were aged greater than 80 years. Aneurysm indications included 15 Crawford Type I, 25 Crawford Type II, 20 Crawford Type III, 33 Crawford Type IV, 23 Crawford Type V, 4 suprarenal, 12 juxta-renal, 30 infra-renal, 17 aortic arch aneurysms

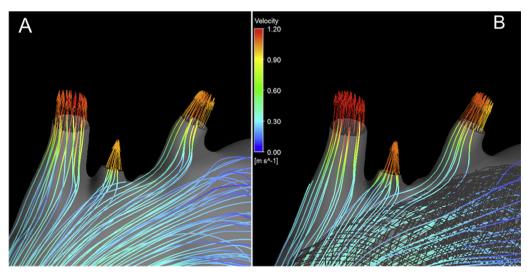


Fig. 2 – Computational fluid dynamics model showing flow velocity vectors (m/s): (A) before and (B) after MFM treatment.

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