Present State of the Multilayer Flow Modulator

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Edward B. Diethrich, MD
Phoenix, Arizona
Conflicts Disclaimer

Unpaid Consult-Cardiatis
Mindset on Endovascular Aneurysm Treatment

Classical

Non-porous barrier between artery lumen and aneurysm

New Science

Flow modulation
Concept may not be well understood by most physicians who believe only in the “Barrier Concept”.

Non porous material between aorta and aneurysm
If we insist on accepting the **Structural Barrier Concept** with its numerous deficiencies like occlusion of vital side branches to visceral and spinal cord blood supply...
We are no better than this.
The science of flow dynamics and computational finite analysis has given us incredible potential to solve complex arterial pathologies.
So What Is the Device?

Multilayer-3D

Virtual Reconstruction

Analytical Reconstruction

It is not stacked Wallstents
So What Is the Science?
First Basic MFM Principle:
Reduction of Stress by Modifying Damaging Vortex

It eliminates the damaging flow vortex pressure and redirects its flow in the same direction as the systemic pressure.
Fusiform Aneurysm

The vortex produces wall damage exerting only 0.4 mmHg or 50 Pascal

Abdominal Aortic Aneurysm

Permently Subjected to the Pressure of the Local Vortex

Weakened tissue
Second Basic MFM Principle: Lamination of Flow

The Multilayer Flow Modulator Does Not Allow the Vortex to be Formed.

Flow Direction

Laminates flow into branch vessels
Second Basic MFM Principle: Lamination of Flow

Flow is Directed into Branched Vessels
Histology

Side Branch Without Neointima

Fibrous Neointima

Perfect Apposition of Stent

Fig. 22

Stent

Branch Orifice

Fibrous Neointima

Stent

Fig. 23
How is the Data Obtained?

CT Scan
Clinical data (DICOM)

Mimics (3D)
Reconstruction 3D geometric mesh

Comsol (FEA)
Fluid & mechanics analysis
Clinical Proof

Dr. Portocarrero
Nancy, France
Geometry Reconstruction

Without MFM

With MFM (equivalent element)
Velocity Field Streamline

Without MFM

With MFM
Pressure

High Stress Value

Stress Value is Decreasing After MFM Stenting

Without MFM

With MFM
Hemodynamic Results

- Lower velocity value
- Lower pressure/wall stress value

Thrombus formation
Finite Element Analysis - Velocity Measurement
Reduction of Stress by Modifying the Damaging Vortex

Arch Vessels

Turbulent Flow
Pre MFM

Perfusion of Arch Vessels
Laminar Flow
Post MFM

ARIZONA HEART FOUNDATION
From High Rupture Risk

Severe Stress

Pre Procedure
Finite Analysis

Low Stress
ASCENDING ARCH ANEURYSM

9 Month Follow-up

8mm Reduction

D\text{\textsubscript{min}}=38.2 \text{ mm}

D\text{\textsubscript{max}}=40.9 \text{ mm}
20 month Follow-up
To No Rupture Risk!

9 month post Multilayer Flow Modulator

Finite Analysis

Low Stress
Conclusion

The Physiology of the Multilayer Flow Modulator Supports its Positive Clinical Results

Thank you,
E. B. Diethrich