WHY MULTILAYER FLOW MODULATING BARE STENTS ARE THE TREATMENT OF CHOICE FOR PERIPHERAL AND VISCERAL ANEURYSMS
WHAT IS THE EVIDENCE: THESE ARE THE RESULTS

INTERVENTIONAL CARDIOLOGIST
CHAIRMAN ASIA PACIFIC VASCULAR SOCIETY
A. BENJELLOUN MD, I. HENRY MD
FRANCE – MOROCCO
NOTHING TO DISCLOSE

WHY MULTILAYER FLOW MODULATING BARE STENTS ARE THE TREATMENT OF CHOICE FOR PERIPHERAL AND VISCERAL ANEURYSMS
WHAT IS THE EVIDENCE: THESE ARE THE RESULTS

PERIPHERAL - VISCERAL ANEURYSMS
TREATMENT
ATHEROSCLEROSIS: MOST OFTEN CAUSE
HOW TO TREAT?

SURGERY: HIGH RISK
MORBIDITY/ MORTALITY (4-25%)

ENDOVASCULAR PROCEDURES
• COVERED STENTS
• STENT-GRAFTS
• BARE STENTS + COILS……

PERIPHERAL - VISCERAL ANEURYSMS
TREATMENT
ALL THESE TECHNIQUES HAVE A NUMBER OF
LIMITATIONS, DISADVANTAGES, DRAWBACKS, COMPLICATIONS
• ENDOLEAKS
• EARLY THROMBOSIS
• BRANCH OCCLUSION — ORGAN INFARCTION
• ANEURYSM RUPTURE …
• INFECTION
• MIGRATION
• DISTAL EMBOLIZATION
• DIFFICULTIES TO DEPLOY COVERED STENTS IN TORTUOUS ANGULATED VESSELS

THE MULTILAYER FLOW MODULATOR

PERIPHERAL - VISCERAL ANEURYSMS
TREATMENT

MULTILAYER FLOW MODULATOR
TECHNOLOGY FOR PAA / VAA
STENT DIAMETER: 5-16 mm
LENGTH: 50 to 150 mm
GUIDE WIRE COMPATIBLE: 0.025
110 cm TEFLO COATED DELIVERY SYSTEM

CONTACT ACTIONS:
Emergency Flow
Clustered Flow
Bilaminar Flow
Pendulum Flow

CLOSED MILITARY COMBAT
APPROACH WAYS
• FEMORAL RETROGRADE
• FEMORAL ANTEGRADE
• CONTRALATERAL
• BRACHIAL

ABOUT 4000 MFM IMPLANTED WORLDWIDE

MFM ACTION Arterial Flow velocity
The sudden and key action of the MFM is on the flow.
The MFM act reversing the degrading flow (with vortex) to a physiological laminar flow aligned to the wall.
This lead to gradual organized thrombus formation (lines of Zahn)
that rebuild the aneurysm wall healing the artery.

MFM ACTION Arterial Flow velocity
The sudden and key action of the MFM is on the flow.
The MFM act reversing the degrading flow (with vortex) to a physiological laminar flow aligned to the wall.
This lead to gradual organized thrombus formation (lines of Zahn)
that rebuild the aneurysm wall healing the artery.
7 YEARS AGO

MALE 57 Y.
ILIAC AN. WITH OCCLUSION OF INT. ILLIAC ARTERY
+ TYPE B AORTIC DISSECTION

MULTILAYER FLOW MODULATOR AORTIC DISSECTION + ILLIAC AN.
AMA. K. MALE 53 Y.

DAY 1 4 YEARS
MULTILAYER FLOW MODULATOR AORTIC DISSECTION + ILLIAC AN.

MULTILAYER FLOW MODULATOR ILLIAC ANEURYSM

MULTILAYER FLOW MODULATOR ILLIAC ANEURYSM
AMA. K. MALE 53 Y.

3 WEEKS

MULTILAYER FLOW MODULATOR CAELIAC TRUNK ANEURYSM

COURTESY J. MATELA
A reduction of the force applied by the flow on the wall is clearly confirmed via numerical simulation.

Un-physiological reversed flow with recirculation regions in the aneurysm sac before the implantation (on the left), is instantly converted into a laminated flow (on the right) leading with time to organized thrombus formation (lines of Zahn).

Clinical evidence

MULTILAYER FLOW MODULATOR
PERIPHERAL - VISCERAL ANEURYSMS
PERSONAL SERIES

- 47 PTS (33 MALES, MEAN AGE 62±8 YEARS)
- LOCATION: PAA: 34, VAA: 13
  - Iliac: 23
  - Femoral: 1
  - Popliteal: 6
  - Renal: 5
  - Mesenteric: 2
  - Celiac Trunk: 2
  - Carotid: 2
  - Subclavian: 2
- 60 MFM IMPLANTED (Ø: 5 TO 14 mm, L: 40 TO 120 mm)
THROUGH 6 TO 12 F SHEATH
- APPROACH WAYS
  - Femoral: 46
  - Right Brachial: 1
11/14/2018
MULTILAYER FLOW MODULATOR
RENAL ANEURYSM

PROOF ON CLINICAL

Explantation
36 months
(3 years)

ORGANIZED & STABLE
THROMBUS

• Reinforcement of the
wall (3") which regulates
the vascular tonus and
strength as a normal wall
• Avoid any rupture

MULTILAYER FLOW MODULATOR
RENAL ANEURYSM

SACCULAR AN.
Ø: 35-45mm

REFUSED SURGERY

M. HENRY
J. MATEJA
MARIBOR SLOVENIA

6 MONTH F.U.

MULTILAYER FLOW MODULATOR
RENAL ANEURYSM

CONTROL CTA

• finally showed excellent result with aneurysm exclusion and all side
branches patent

MULTILAYER FLOW MODULATOR
SUPRA AORTIC VESSELS
ANEURYSMS

MULTILAYER FLOW MODULATOR
FLOW VELOCITY PATTERN
MULTILAYER FLOW MODULATOR
SUB.CLAV. ANEURYSM

BRACHIAL APPROACH

PRECISE STENT PLACEMENT AND DEPLOYMENT

6 MONTH F.U.

■ UP TO APRIL 2013: 128 ANEURYSMS (PAA: 88, VAA: 40)
■ TECHNICAL SUCCESS: 100%
■ VERY LOW COMPLICATION RATE
■ AT 30 DAYS
  • 2 DEATHS NOT DEVICE RELATED (1 PULM. EMBOLISM, 1 M.I.)
  • SURVIVAL RATE: 97.7%

M. HENRY et al. J. CARDIOVASC. SURG. 2013

■ DURING THE FOLLOW UP (RANGE 5 – 36 MONTHS)
  • NO ANEURYSM RUPTURES
  • NO ANEURYSM GROWTH
  • OVERALL SURVIVAL: 95.5%
  • COMPLETE ANEURYSM EXCLUSION: 94.3%
  • WITH SIGNIFICANT SHRINKAGE IN 83%
  • ALL SIDE BRANCHES COVERED BY MFM REMAINED PATENT EXCEPT ONE IN A PT WITH THROMBOPHILIA

■ EXCLUSION WITH THE MFM MAY TAKE SEVERAL WEEKS OR MONTHS, BUT THE ANEURYSMAL WALL IS NO LONGER SUBJECTED TO LOCAL PEAK WALL SHEAR STRESS, THUS PREVENTING AGAINST RUPTURE.

IF YOU WANT GOOD RESULTS YOU MUST RESPECT
■ INSTRUCTIONS FOR USE GIVEN BY COMPANY
■ IMPORTANT TECHNICAL POINTS, HARD ENDPOINTS, GUIDELINES
■ METICULOUS TECHNIQUE
THE MAJORITY OF FAILURES ARE DUE TO

- MFM IMPLANTATION OUTSIDE IFU
- TECHNICAL ERRORS
- POOR PT SELECTION

MULTILAYER FLOW MODULATOR
HARD ENDPOINTS - GUIDELINES

CONTRAINDICATIONS

- PREVIOUSLY RUPTURED ANEURYSM
- STENOTIC BRANCHES (VISCERAL, NECK VESELS, ILIAC) – DILATE BEFORE STENTING
- PATIENT WITH INFECTION (ANEURYSM MYCOTIC...) AND ACTIVE SIGNS OF INFECTION
- INFECTION ASSOCIATED WITH PREVIOUSLY INSERTED GRAFTS OR ENDOGRAPHS?
- PATIENT WITH SEPTICEMIA
- MYELOPROLIFERATIVE BLOOD DISORDERS
- CONNECTIVE TISSUE DISORDERS (MARFAN, EHLE – DANLOS ...?)
- ARTERITIS - ARTERIOVENOUS FISTULA
- MALIGNANCY / USE OF CHEMOTHERAPY AGENTS
- LIFE EXPECTANCY < 6 MONTHS

MULTILAYER FLOW MODULATOR
INSTRUCTIONS FOR USE

THE MULTILAYER FLOW MODULATOR (MFM) REPRESENTS AN ALTERNATIVE TO CURRENT DEVICES (CE MARKED)

- LOCAL PRESSURE , AN. WALLSTRESS ARE IMMEDIATELY RELIEVED ONCE MFM IS IN PLACE, WHICH PROTECTS AGAINST AN. RUPTURE
- PRESERVES COLLATERALS (97 – 100% BRANCH PATENCY )
- PROGRESSIVE SAC THROMBOSIS AND SHRINKAGE DEPENDING ON THE IMPORTANCE OF COLLATERALS, INITIAL AN. SIZE (1,6, 12 .... MONTHS ?)
- DIAMETER REDUCTION

SAVE PROCEDURE. LOW COMPLICATIONS RATE. NO 30 DAY MORTALITY

HARD ENDPOINTS, SEVERE GUIDELINES MUST BE RESPECTED TO HAVE GOOD RESULTS

MFM IS A BREAKTHROUGH, A HOPE, NOT A HOAX

CONCLUSIONS