

**LONG TERM FOLLOW UP WITH THE
MULTILAYER STENT FOR TREATMENT OF
RENAL AND MESENTERIC ANEURYSMS**

F.A.H.A., F.A.C.A., F.E.S.C., F.A.S.A., F.I.C.I.C.

INTERVENTIONAL CARDIOLOGIST

A.

POLYDOROU MD , I. HENRY MD

NANCY – FRANCE

ATHENES - GREECE

***CHIEF PATRON**

GLOBAL VASCULAR INSTITUT

Disclosures

M. HENRY MD

**CONSULTANT
CARDIATIS BELGIUM**

**THE CARDIATIS MULTILAYER STENT IS
NOT APPROVED FOR USE IN THE US
STILL INVESTIGATIONAL**

RENAL ARTERY ANEURYSM

• PREVALENCE

➤ RELATIVELY RARE :

- 0,09% OF THE GENERAL POPULATION
- 1% RENAL ANGIOGRAPHIC PROCEDURES

➤ IN PATIENTS WITH SUSPECTED RENOVASCULAR HYPERTENSION:1,3%

➤ 15 -22% OF ALL VISCERAL ARTERY ANEURYSMS

• ETIOLOGY

➤ ATHEROSCLEROSIS

➤ F.M.D.

➤ CONGENITAL – MARFAN - EHLERS DANLOS SYNDROM

➤ FEMALE PREDILECTION

RENAL ARTERY ANEURYSM

- **MOST ARE ASYMPTOMATIC AND FOUND INCIDENTALLY**
- **SOME PATIENTS COMPLAIN OF FLANK PAIN AND/OR HEMATURIA (30% OF THE CASES)**
- **MAY CONTRIBUTE TO HYPERTENSION (73% OF CASES)**
 - **MECHANICAL EFFECTS ON RENAL ARTERY**
 - **ALTERED RENAL BLOOD FLOW**
 - **EMBOLIZATION TO DISTAL PARENCHYMA**
 - **RENAL ARTERY THROMBOSIS**
 - **CHRONIC RENAL DYSFUNCTION**
- **HIGH RISK OF RUPTURE AND LIFE THREATENING CONDITIONS WITH MORTALITY OF 20 - 75%**
 - **RELATED TO THE SIZE**
 - **HIGHER RISK :**
 - **Ø>2,3 cm**
 - **PREGNANT FEMALES**

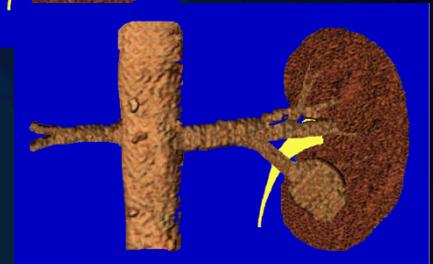
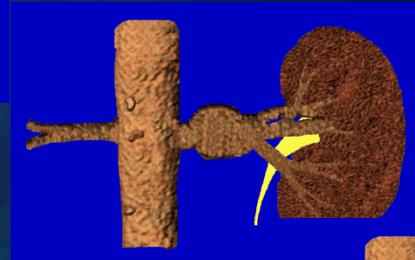
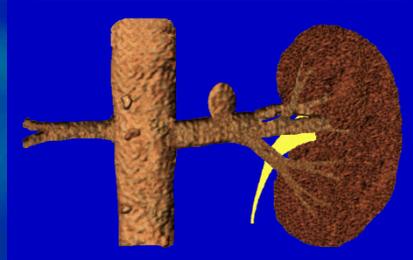
RENAL ARTERY ANEURYSM INDICATIONS FOR TREATMENT

- **SIZE >2cm REGARDLESS OF BLOOD PRESSURE STATUS BUT RUPTURE HAVE BEEN REPORTED WITH AN. < 2cm**
- **SIZE >1cm IF HYPERTENSION DIFFICULT TO CONTROL**
- **INCREASING ANEURYSM SIZE**
- **FEMALE GENDER AND CONCURRENT HYPERTENSION**
- **ACUTE DISSECTION**
- **COEXISTENT RENAL ARTERY STENOSIS**
- **PREGNANCY / YOUNG WOMEN WITH ANTICIPATED PREGNANCY**
- **FLANK PAIN**
- **DISTAL EMBOLI**
- **PATIENT WITH RENAL RISK (SINGLE KIDNEY, RENAL INSUFFICIENCY)**

RENAL ARTERIAL DISEASES ANATOMY

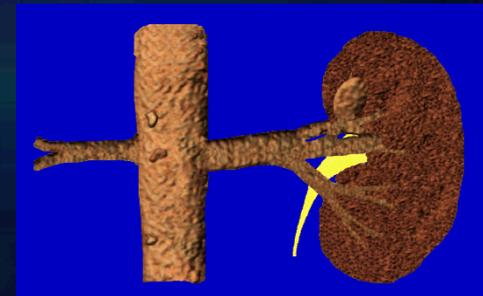
■ TYPES

- SACCCULAR
(MOST OF THE CASES)
- FUSIFORM

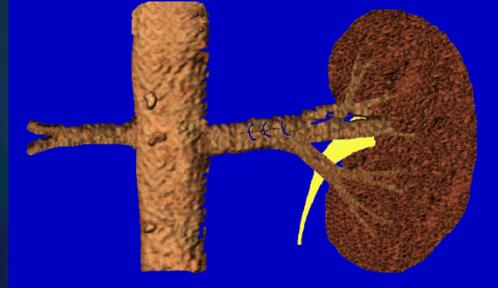


■ LOCATION

- EXTRAPARENCHYMAL
 - CAN INCLUDE MAIN RENAL ARTERY AND OR PRIMARY BRANCHES
- INTRAPARENCHYMAL

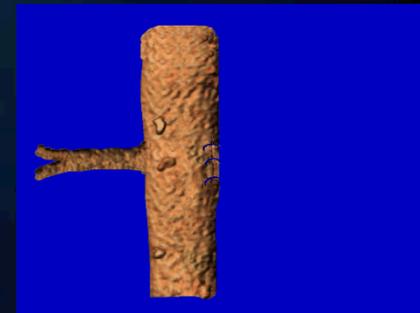
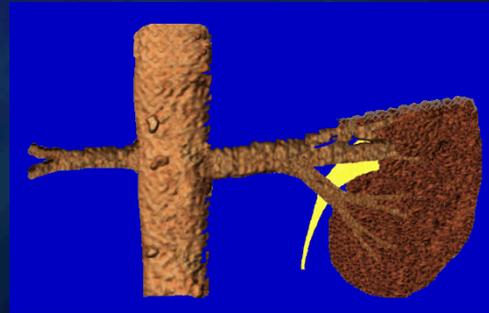


RENAL ARTERY ANEURYSM TREATMENT



■ SURGERY

- IN SITU / EX VIVO REPAIR
- ANEURYSM EXCISION AND RENAL ARTERY REPAIR
- AORTO RENAL BYPASS
- PARTIAL / TOTAL NEPHRECTOMY

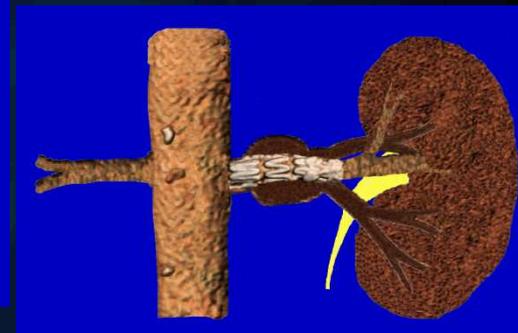
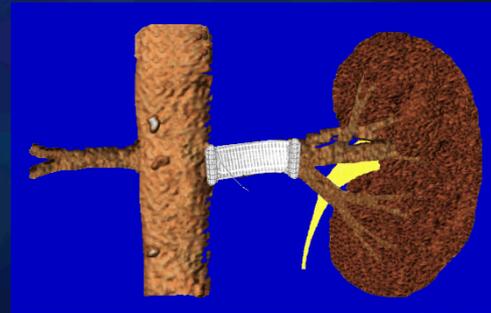


- MORBIDITY / MORTALITY : 10%

RENAL ARTERY ANEURYSM TREATMENT

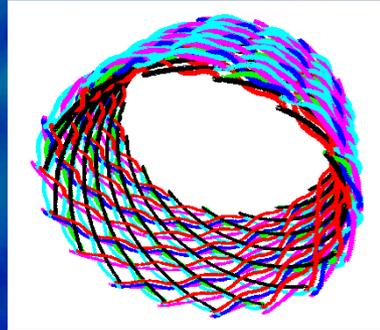
• ENDOVASCULAR TECHNIQUES:

- CATHETER, DIRECTED EMBOLIZATION WITH COILS, DETACHABLE BALLOONS, USE OF ONYX
- BARE METAL STENTS WITH LOW POROSITY
- STENT ASSISTED COIL EMBOLIZATION
- STENT GRAFT:
 - RISK OF BRANCH OCCLUSION AND RENAL INFARCTION, CONTRAINDICATION IF LARGE BRANCHES MUST BE COVERED
 - POSSIBILITY OF DELAYED RECANALIZATION OF THE ANEURYSM DU TO COLLATERAL BRANCHES
 - RISK OF STENT THROMBOSIS

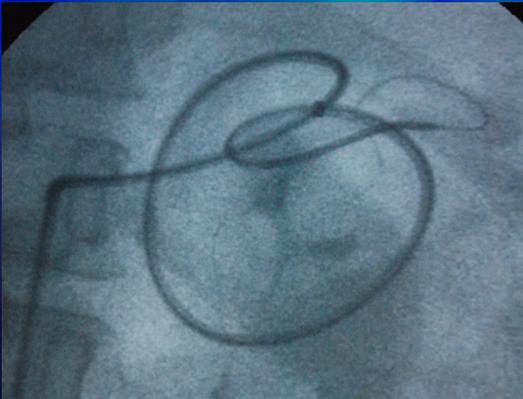


- NEW TECHNIQUE : MULTILAYER STENT

MULTILAYER STENT : 3DIMENSIONAL TECHNOLOGY



Cardiatis Multilayer Stent is a self-expandable device with a tridimensional mesh made of metallic cobalt alloy wires interconnected in multiple layers: this structure allows the mesh layers number to adapt to diameter, morphology, dimension and course of the target artery



The delivery consists of a guided-catheter with a minimally traumatic soft tip

.Stent Diameter : 2-50 mm Length : 30 to 150 mm

Guide wire compatible : 0.018 (small stents) 0.035 (larger stents)

The sheath is connected by a hemostatic Y valve to the delivery: when the valve is closed, the sheath is fixed to the support, as a safety lock.

MULTILAYER STENT

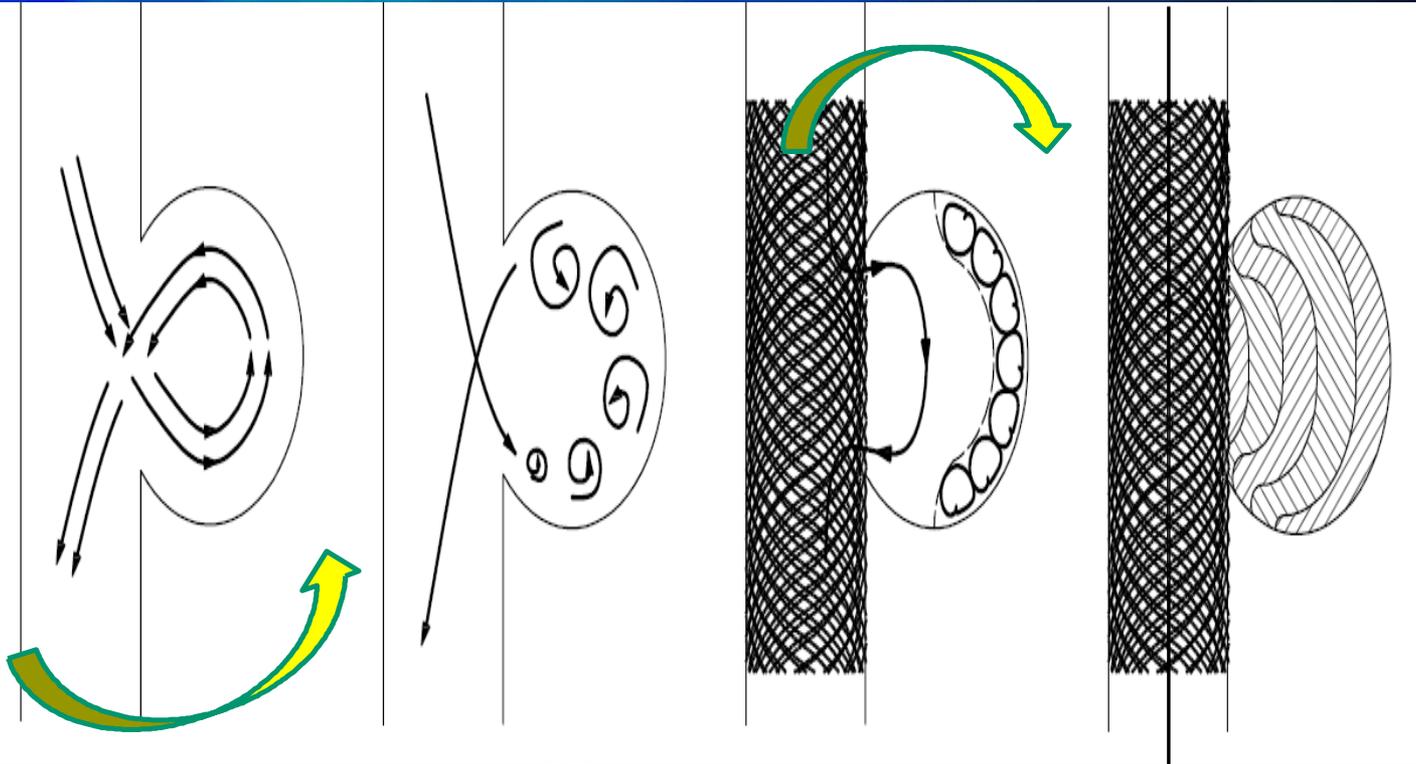
HOW DOES IT WORK ?

EFFECTS ON ANEURYSMS

MULTILAYER STENT

**SACULAR ANEURYSM
WITHOUT COLLATERAL
BRANCH**

SACCULAR ANEURYSM WITHOUT SIDE BRANCH



**STENT REMOVES THE STRESS
FROM THE NECK**

**THE STENT INVERSES THE FLOW ,
BREAKDOWNS AND MODULATES
THE VELOCITY**

REDUCTION OF VORTEX VELOCITY BY 90%

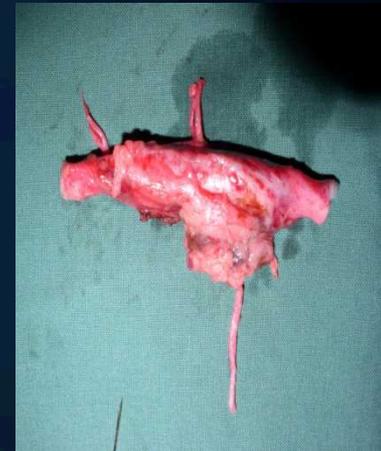
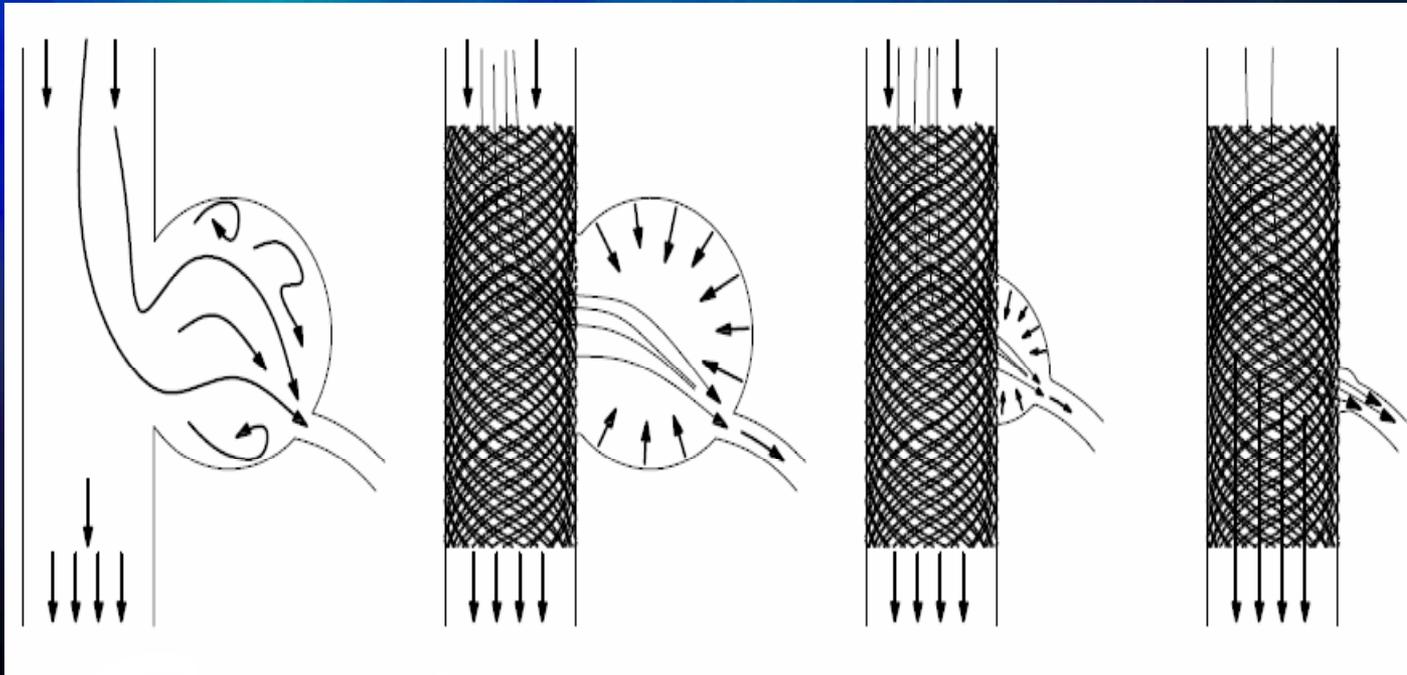
IMMEDIATE THROMBOSIS

MULTILAYER STENT

**SACULAR ANEURYSM
WITH COLLATERAL BRANCH**

SACCULAR ANEURYSM WITH COLLATERAL BRANCH

FLOW DIRECTED THROUGH LAYERS TOWARDS BRANCH
FLOW LAMINATION IN BRANCH KEEPS COLLATERAL PATENT



ALLOWS FOR PHYSIOLOGICAL SHRINKING WHILE PRESERVING
COLLATERAL

MULTILAYER STENT

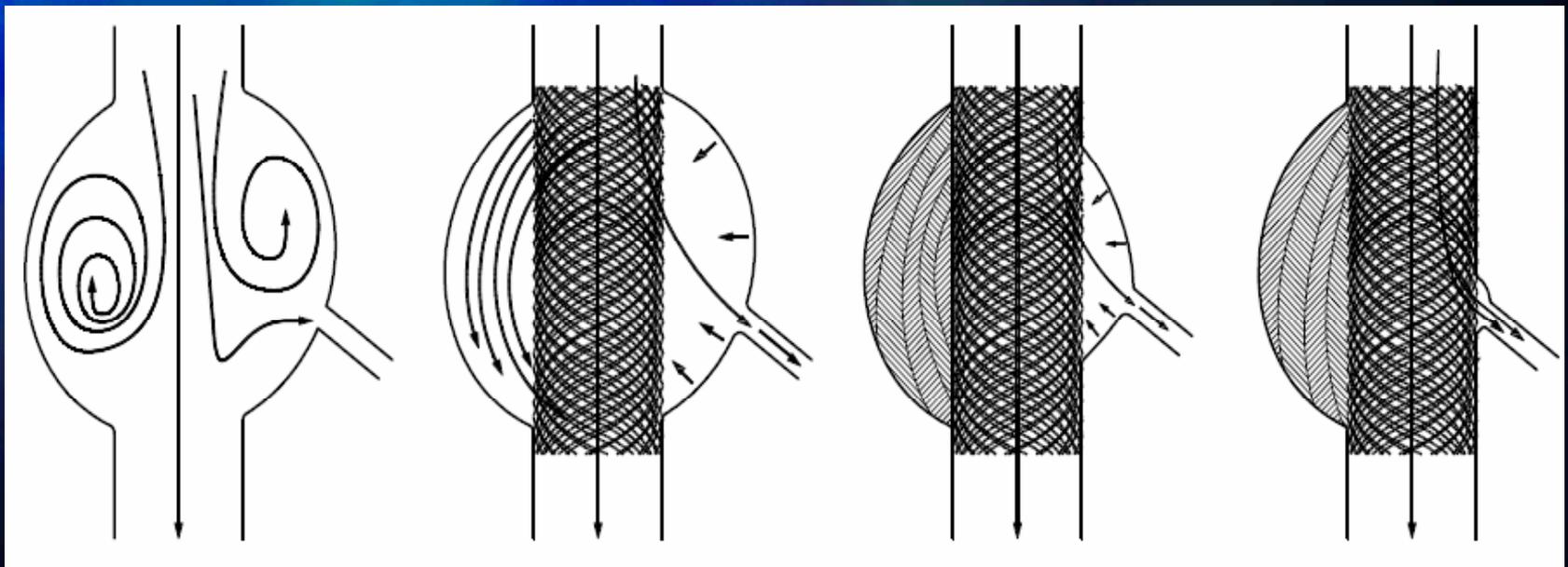
FUSIFORM ANEURYSM

AORTIC ANEURYSM

FUSIFORM ANEURYSM ANEURYSM MODELING

W/O STENT:TURBULENT FLOW

WITH STENT: FLOW LAMINATED ALONG WALL W/O
BRANCH (PHYSIOLOGICAL ORGANISED THROMBUS)



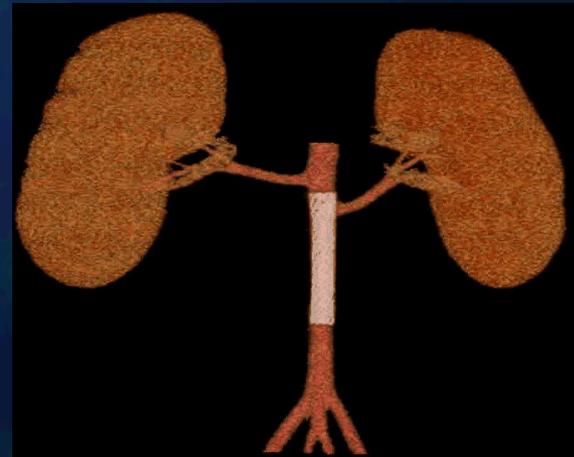
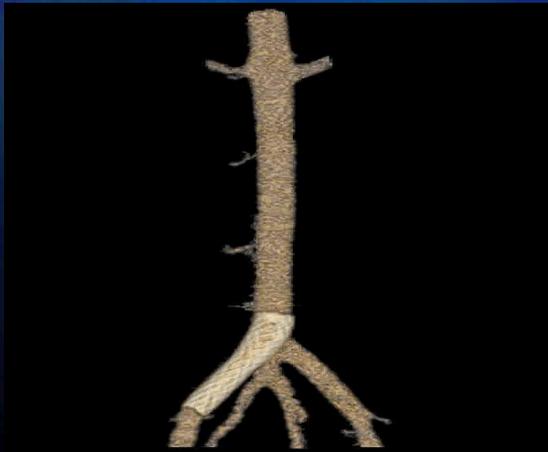
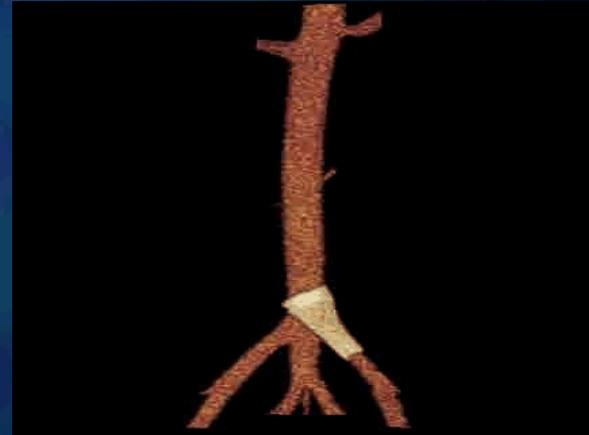
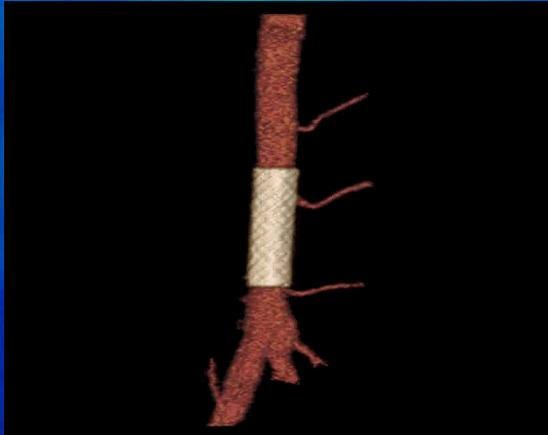
FLOW DIRECTED TO THE BRANCH OTHER SIDE
AND INCREASED IN THIS BRANCH
(PROGRESSIVE COLLAPSE OF ANEURYSMAL WALL)

MULTILAYER STENT

EFFECTS ON COLLATERALS

- LAMINATES THE FLOW IN COLLATERALS
- ALL THE COLLATERALS REMAIN PATENT

MULTILAYER STENT ANIMAL DATA 6 MONTH F.U.



ALL ARTERIES REMAIN PATENTS

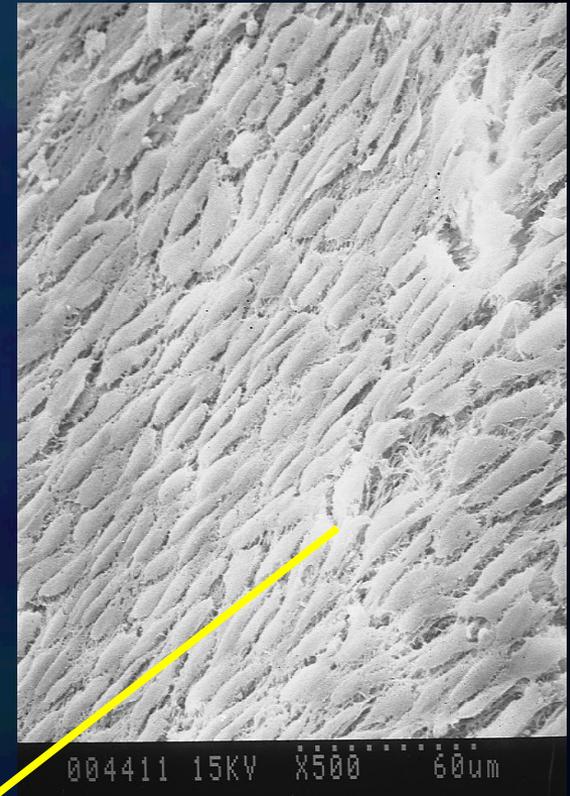
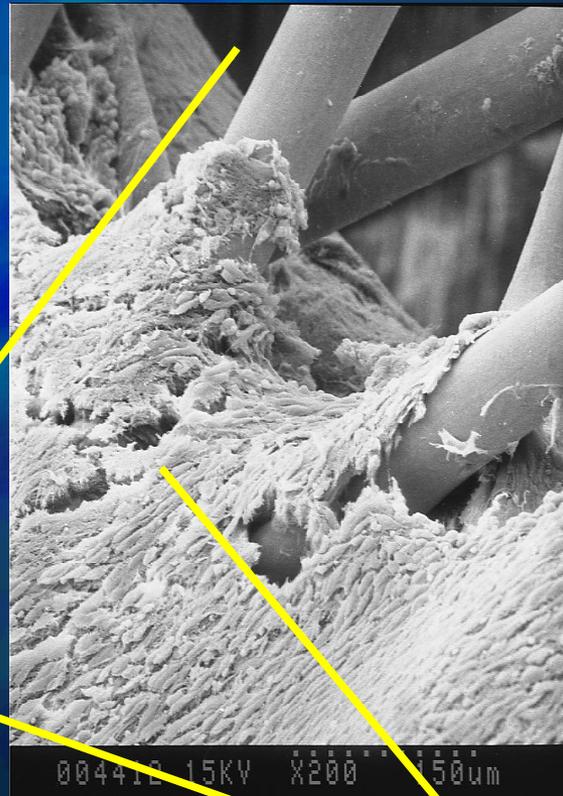
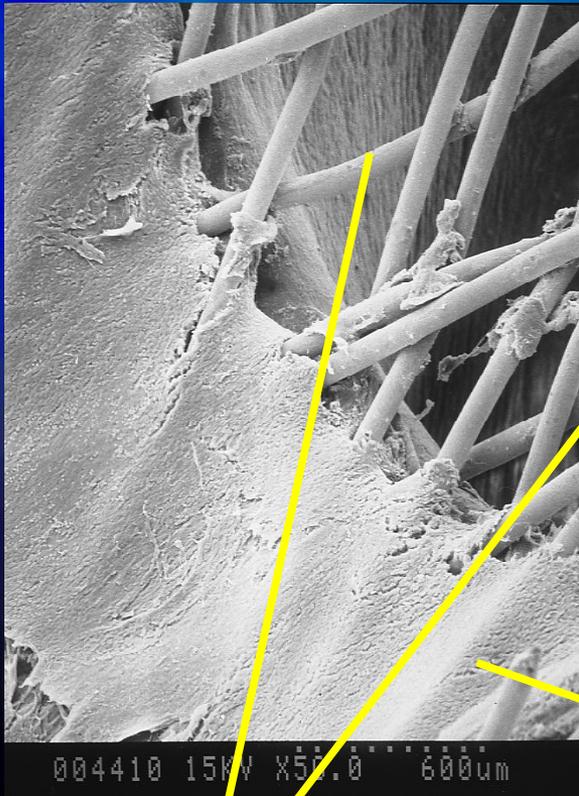
COURTESY DR E. DIETRICH

CLINICAL EFFECTS ON PIG MODEL



**PATENT COLLATERAL
AFTER 1 MONTH**

BRANCH MAGNIFICATION



PATENT BRANCH

**ENDOTHELIAL
CELLS**

MULTILAYER STENT

HUMAN STUDY

**MULTILAYER STENT
RENAL ANEURYSM**

**FIRST HUMAN CASE
RENAL ANEURYSM**

HENRY M. et al J.E.V.T. 2008 ;15:231 -236

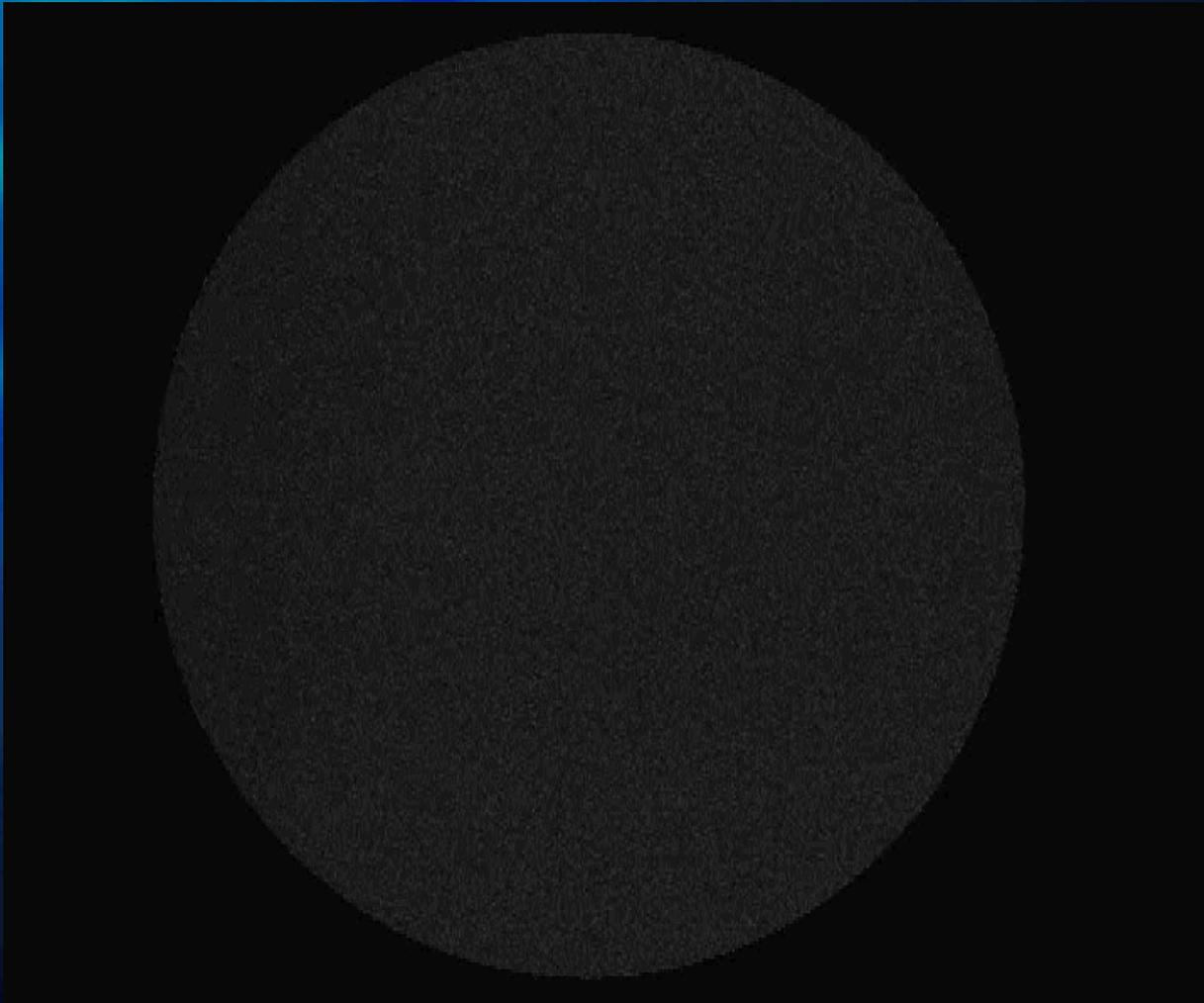
7 CASES

RENAL ANEURYSM

MALE 75Y.OLD
HTN
TRIPLE VESSEL
CORONARY DISEASE
Ø : 28-33mm



MULTILAYER STENT RENAL ANEURYSM



MULTILAYER STENT RENAL ANEURYSM

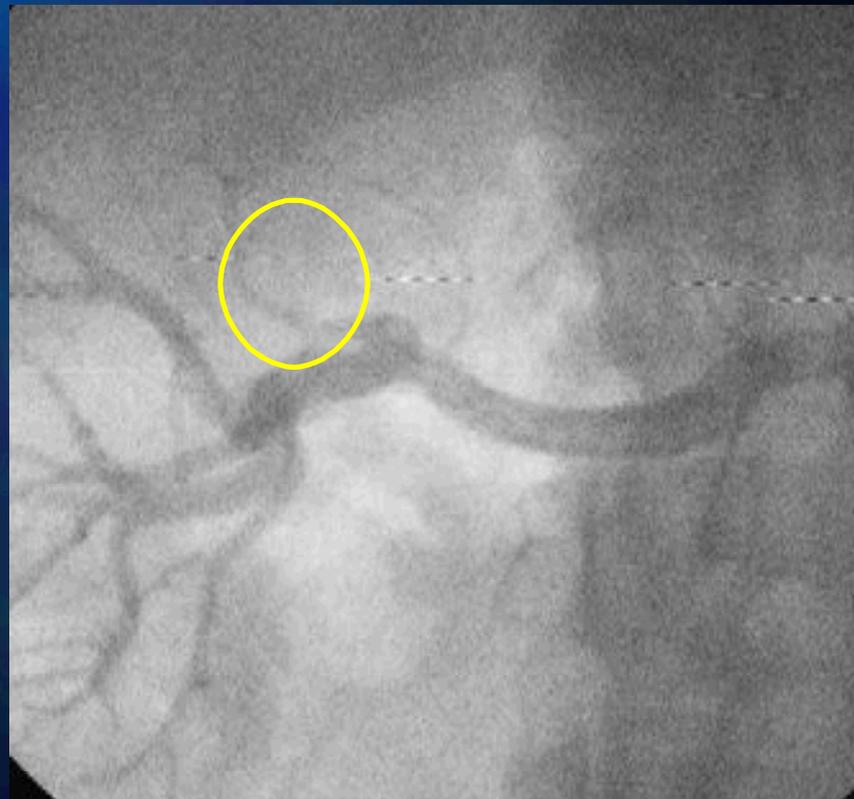
**12 MONTH
FOLLOW-UP**



RENAL ANEURYSM

FIRST HUMAN STUDY

MALE 75Y.OLD HTN TRIPLE VESSEL CORONARY DISEASE

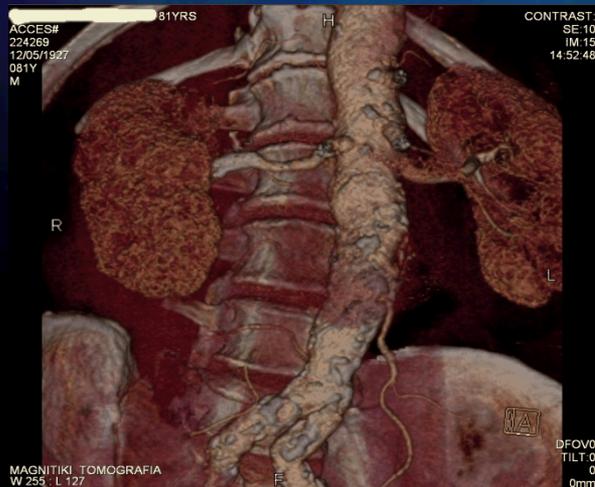
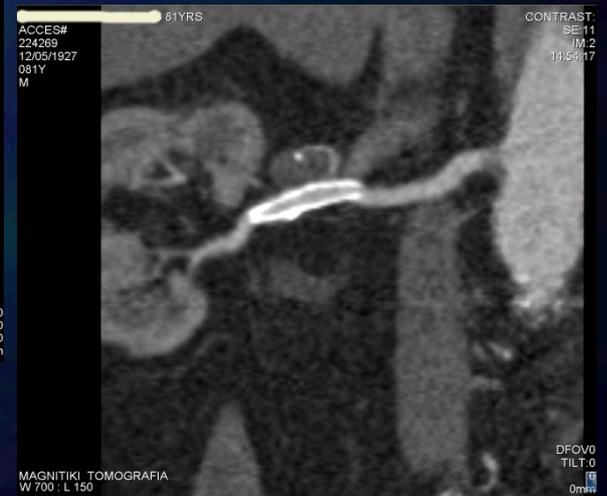
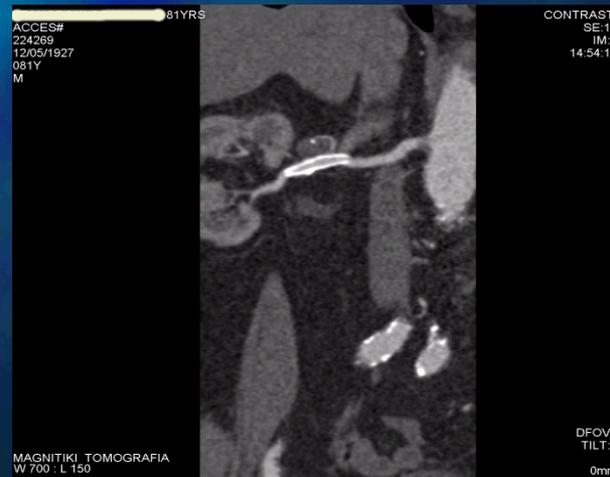


1 YEAR FOLLOW UP

MULTILAYER STENT RENAL ANEURYSM

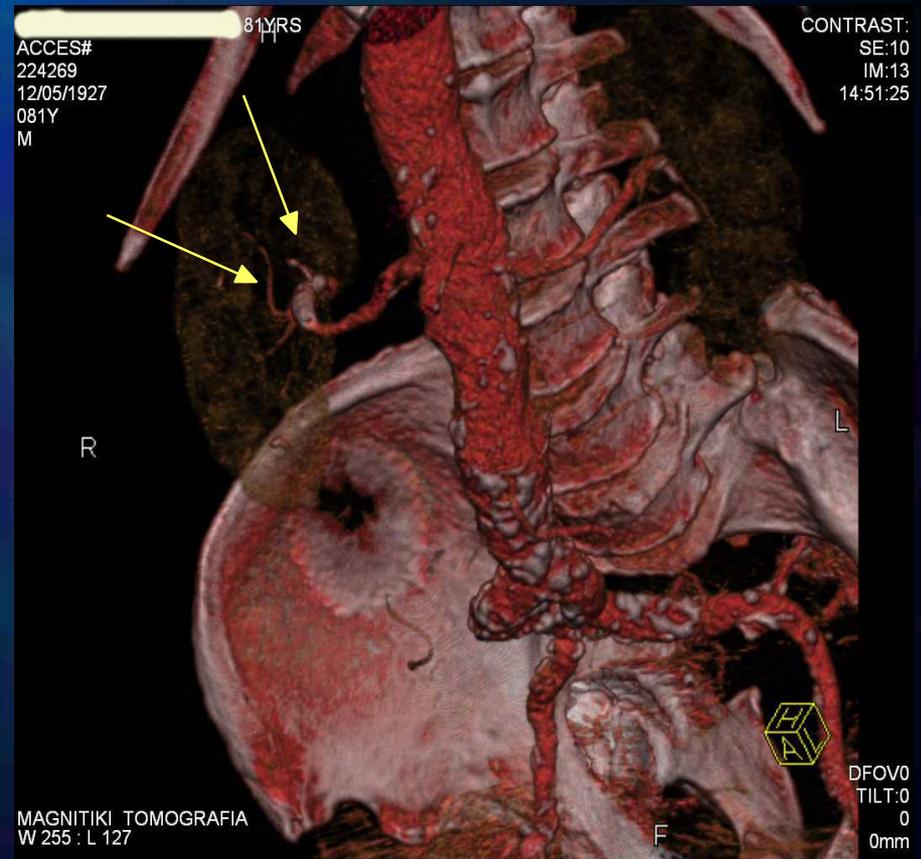
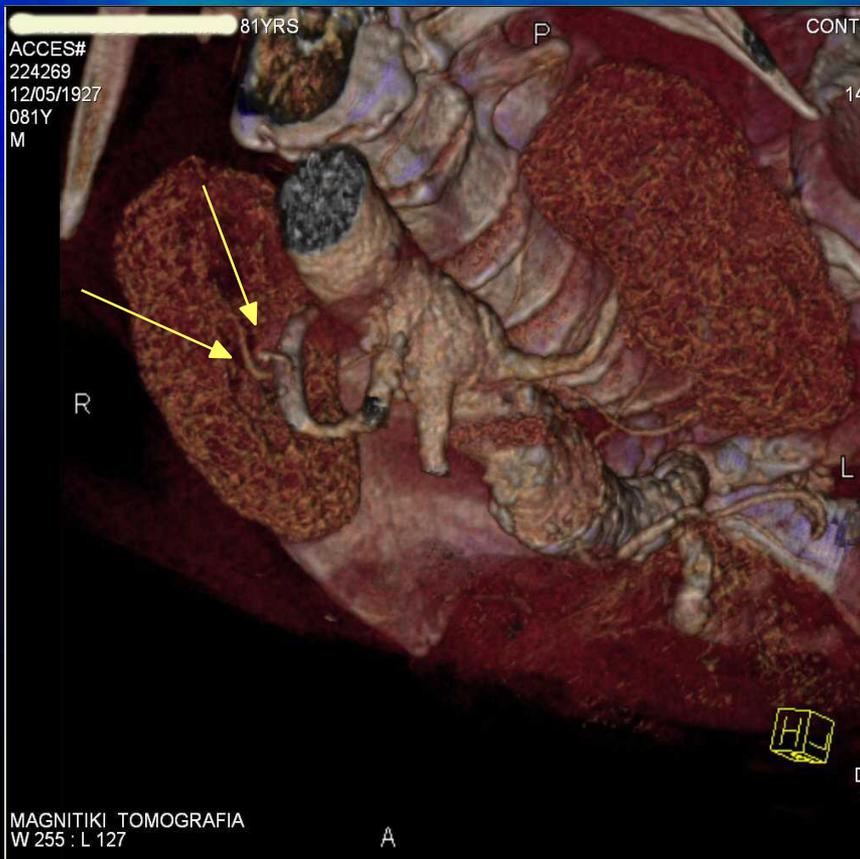
30 MONTH FOLLOW-UP

COMPUTED TOMOGRAPHY SHOWED
EXCELLENT PATENCY OF THE STENT, WITH
A NORMAL KIDNEY AND A TOTAL
THROMBOSIS OF THE ANEURYSM



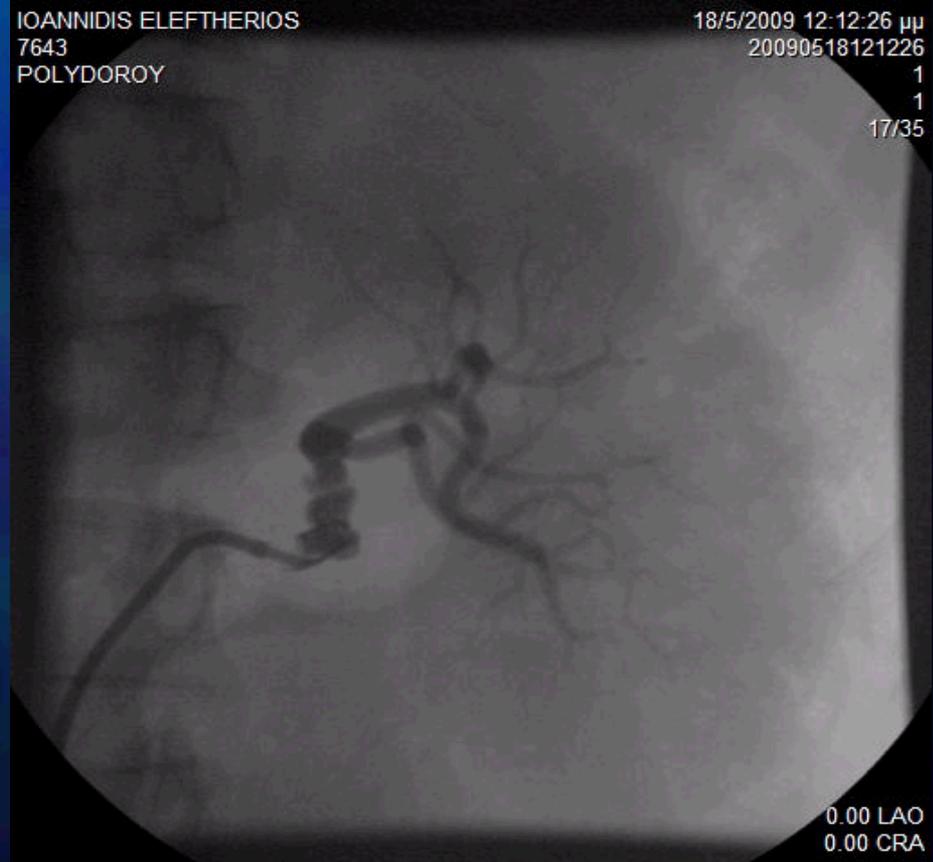
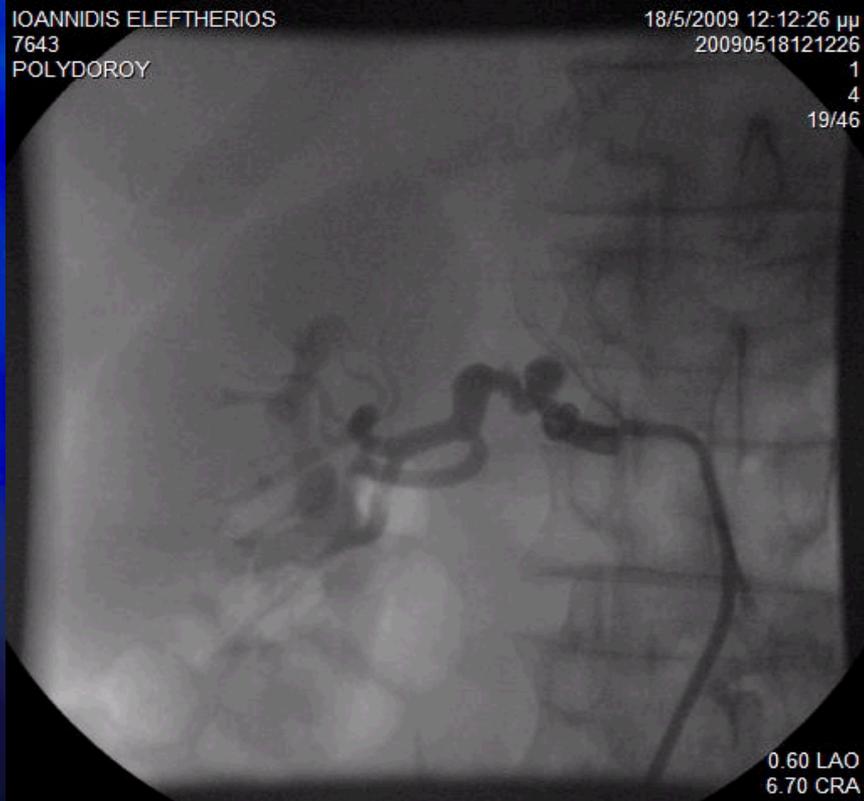
MULTILAYER STENT RENAL ANEURYSM

30 MONTH FOLLOW-UP



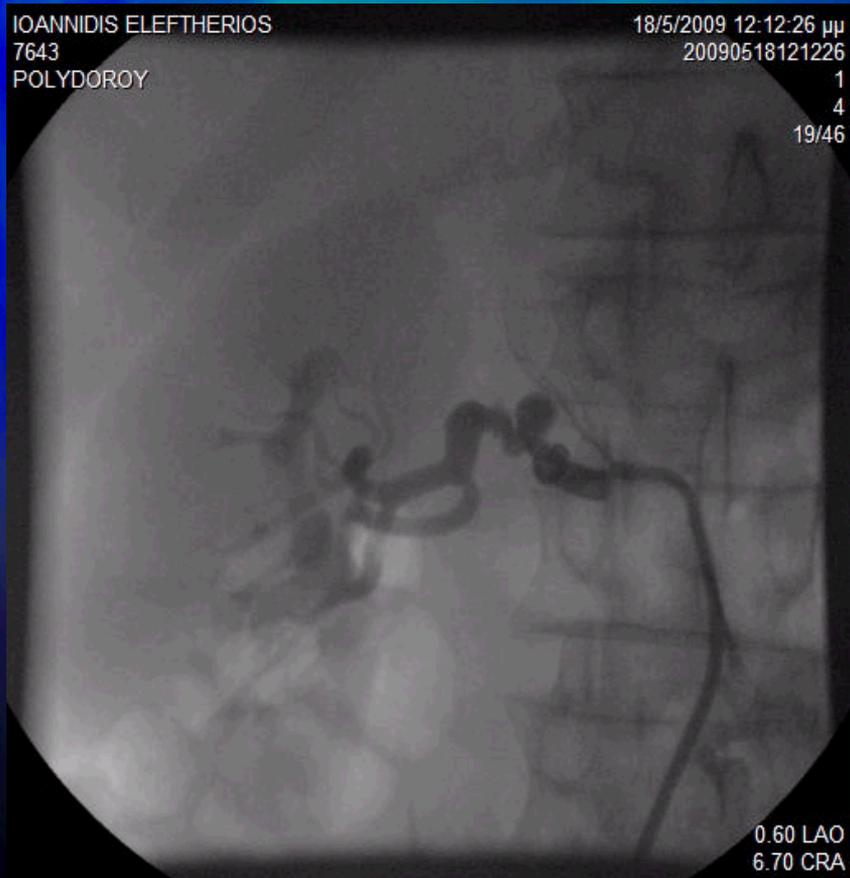
EXCELLENT PATENCY OF COLLATERAL BRANCHES

RENAL ANEURYSM



MALE 45Y HTA F.M.D.

RENAL ANEURYSM



24 HOURS

MALE 46Y. HTN F.M.D.

BILATERAL RENAL ANEURYSMS

- 53 YEARS OLD PATIENT
- BILATERAL RENAL ANEURYSM
- LEFT RENAL TRANSPLANTATION - 13 YEARS AGO
- MULTILAYER STENT RENAL ANEURYSM - 3 YEARS AGO FOR RIGHT



BILATERAL RENAL ANEURYSMS



**LEFT SIDE
SURGERY
13 YEARS AGO**

BILATERAL RENAL ANEURYSMS

**RIGHT
MULTILAYER**



CT SCAN AT 1 MONTH



CT SCAN AT 6 MONTHS

RIGHT SACCULAR CALCIFIED RENAL ANEURYSM

MULTILAYER STENT



**PRE
TREATMENT**



**AT
1 MONTH**



**AT
3 MONTHS**

RIGHT SACCULAR RENAL ANEURYSM

OSPEDALE CODOGNO

17/02/2010

09:53:30

VR : Quality

Progressive : On

Srs:3

678 %



5cm

RIGHT SACCULAR RENAL ANEURYSM



RIGHT SACCULAR RENAL ANEURYSM

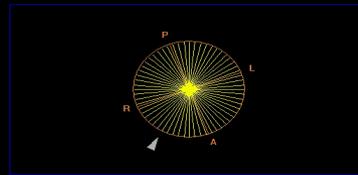
OSPEDALE CODOGNO

17/02/2010

09:53:30

VR : Quality

Progressive : On



A.O. LODI

19/04/2010

12:10:52

VR : Quality

Progressive : On



**SHRINKAGE
AT 2 MONTHS**

RIGHT SACCULAR RENAL ANEURYSM

PROCEDURE

- clopidogrel 75 mg - 5 days prior the procedure
- mild anxiolytic therapy before the procedure
- normal coagulation and renal functional parameters
- femoral access 9 FR renal sheath left, 5 FR sheath right; 5 Fr SIM1 catheter
- 5000 IE Heparin



RIGHT SACCULAR RENAL ANEURYSM

PROCEDURE

- deployment of a 5 x 40 mm MARS over a roadrunner extra stiff 0,18 wire



RIGHT SACCULAR RENAL ANEURYSM

PROCEDURE

control angiography



RIGHT SACCULAR RENAL ANEURYSM

PROCEDURE

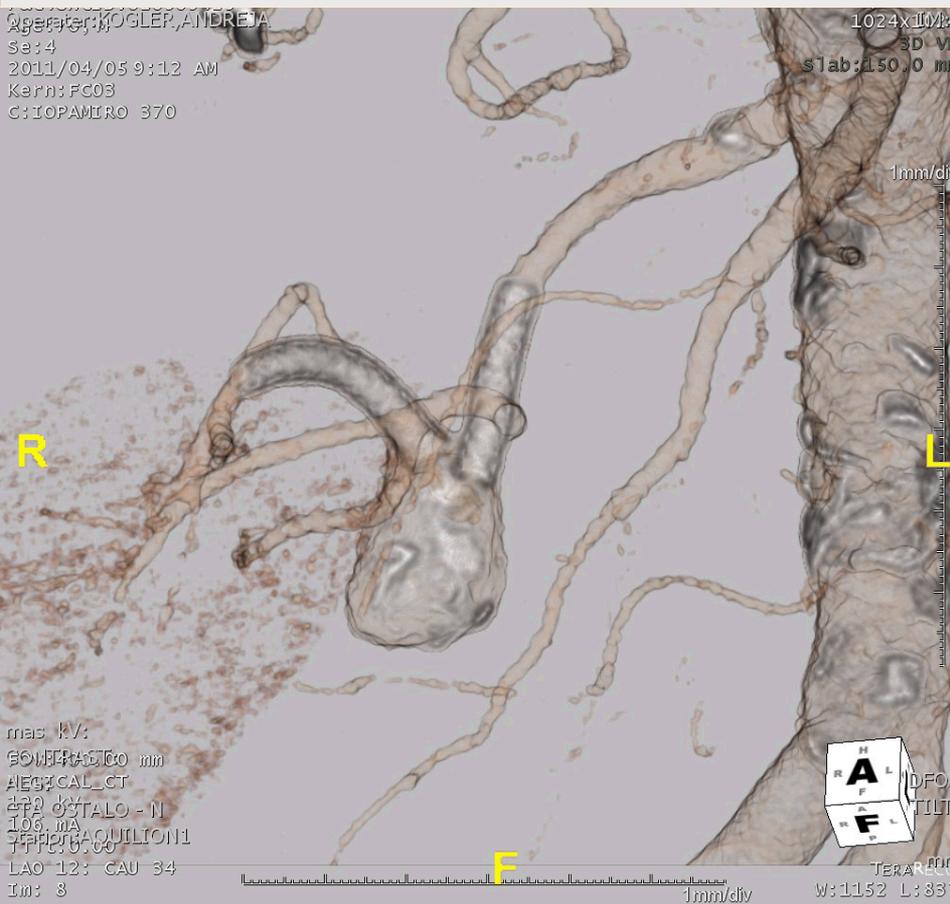
deployment of another 5 x 30 mm MARS stent



RIGHT SACCULAR RENAL ANEURYSM

CONTROL CTA after 1 month

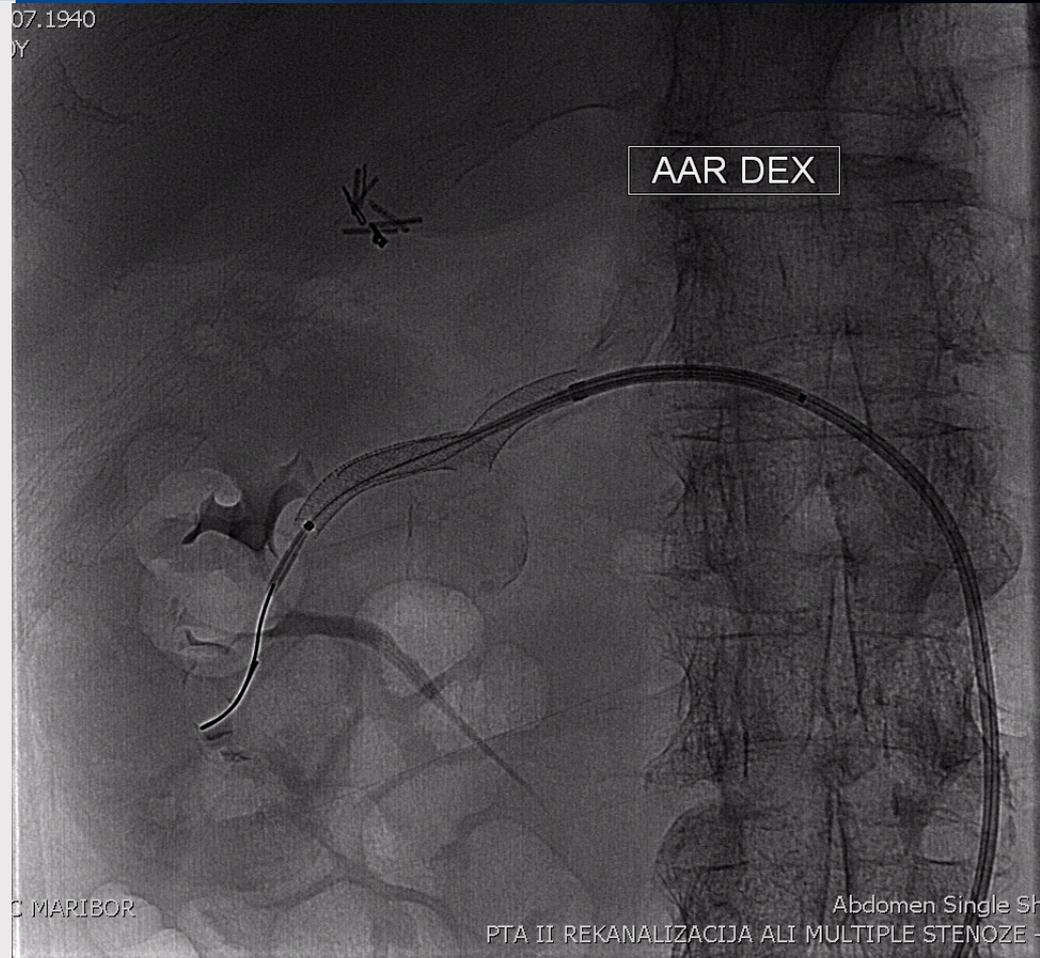
- both stents slipped apart and partially in the aneurysmal sac



RIGHT SACCULAR RENAL ANEURYSM

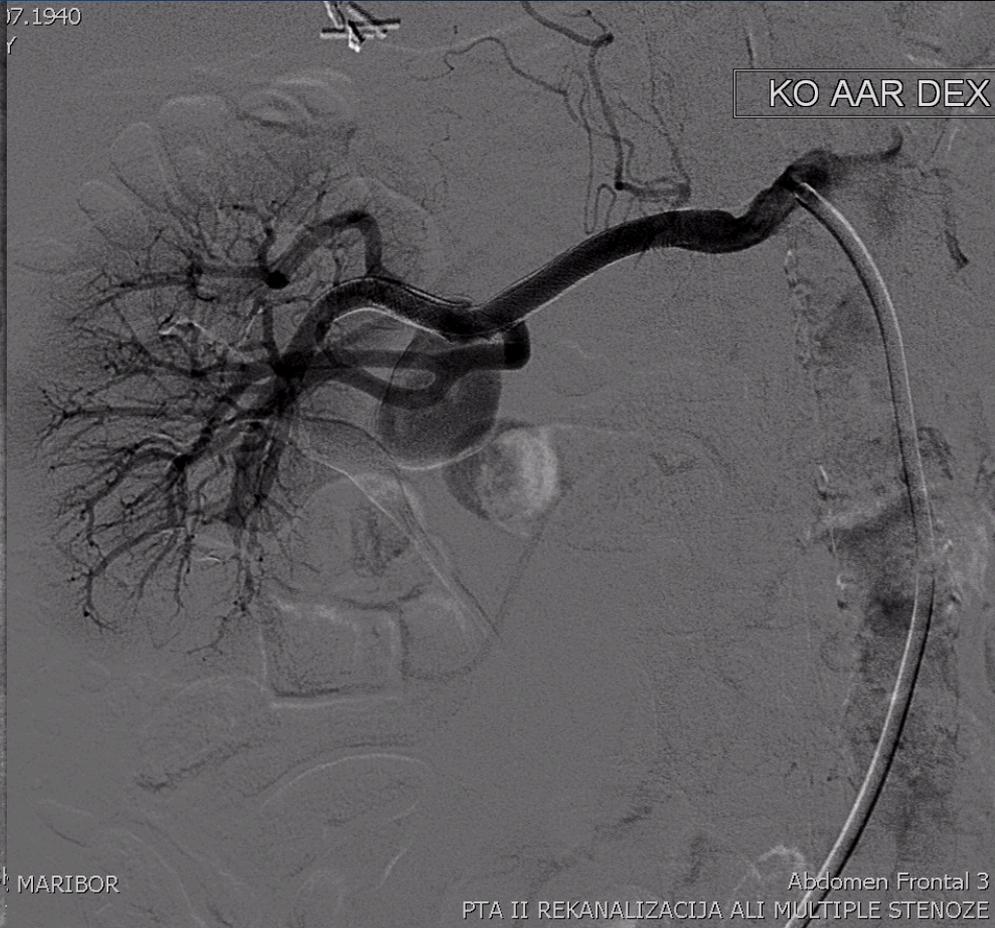
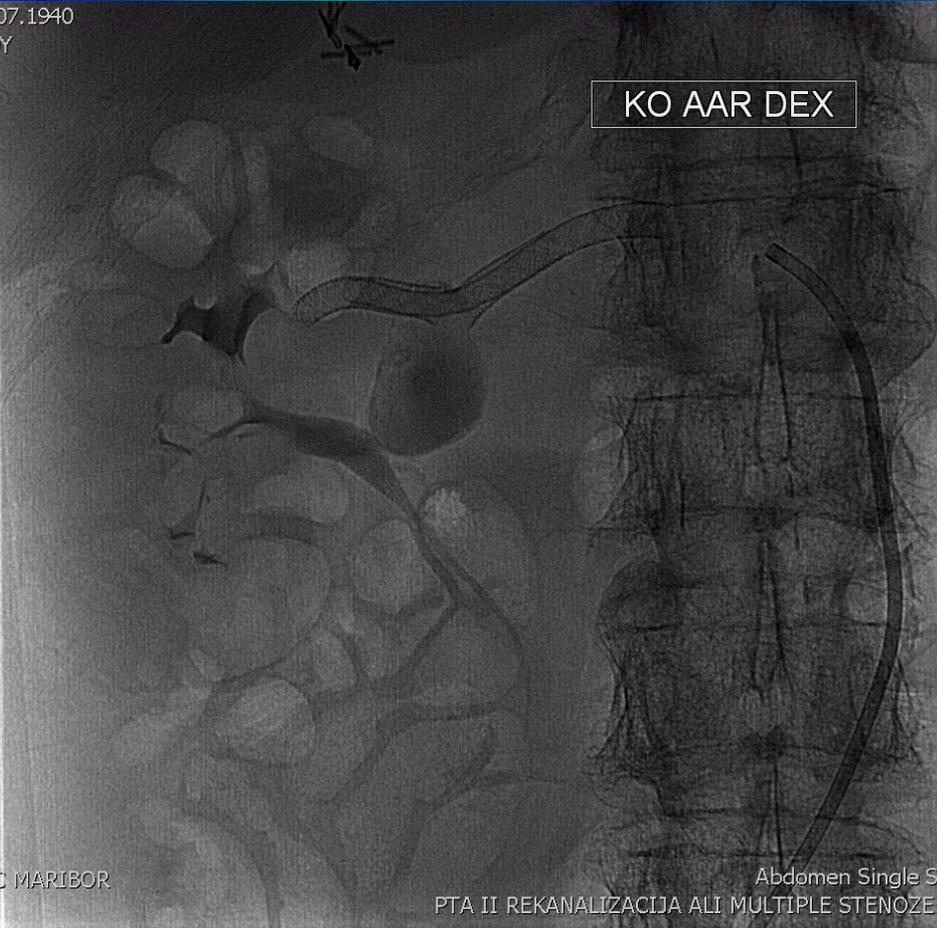
PROCEDURE 2

- femoral acces, 8 FR renal sheath
- passage with a Terumo guide wire and a Sos omni catheter through lumen of both stents
- 5000 IE Heparin
- deployment of MARS 6 x 60 mm
- clopidogrel for 3 months



RIGHT SACCCULAR RENAL ANEURYSM

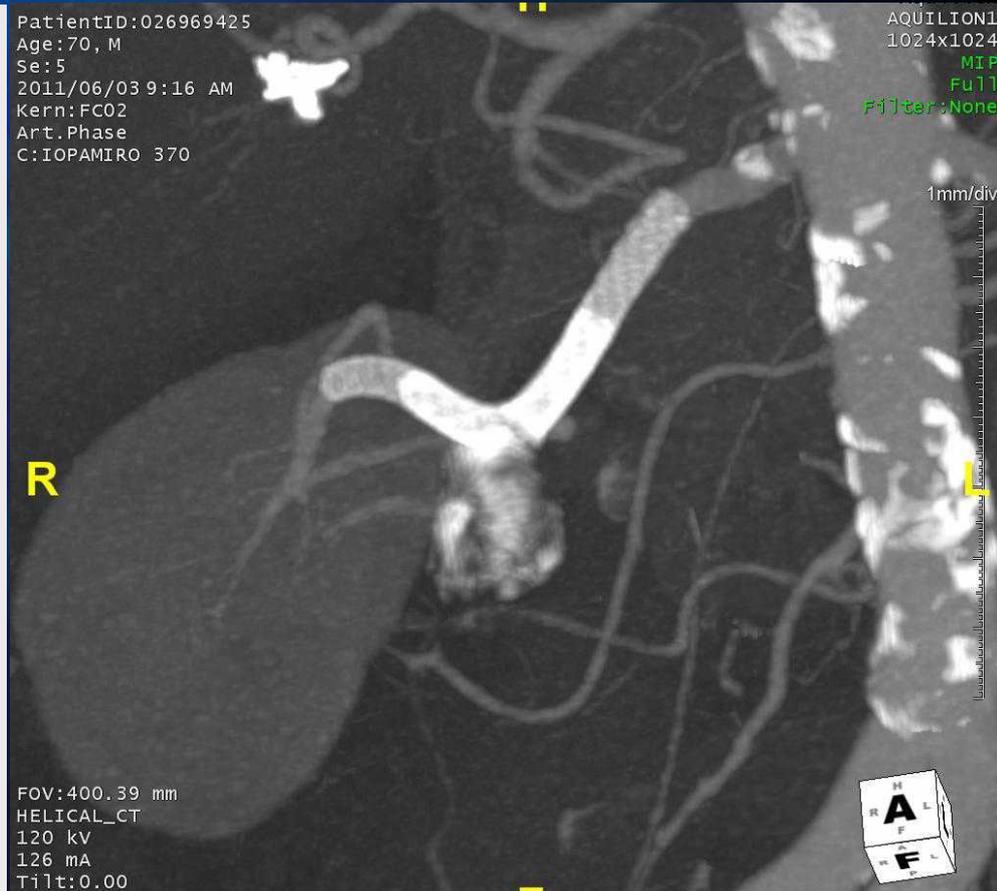
PROCEDURE 2



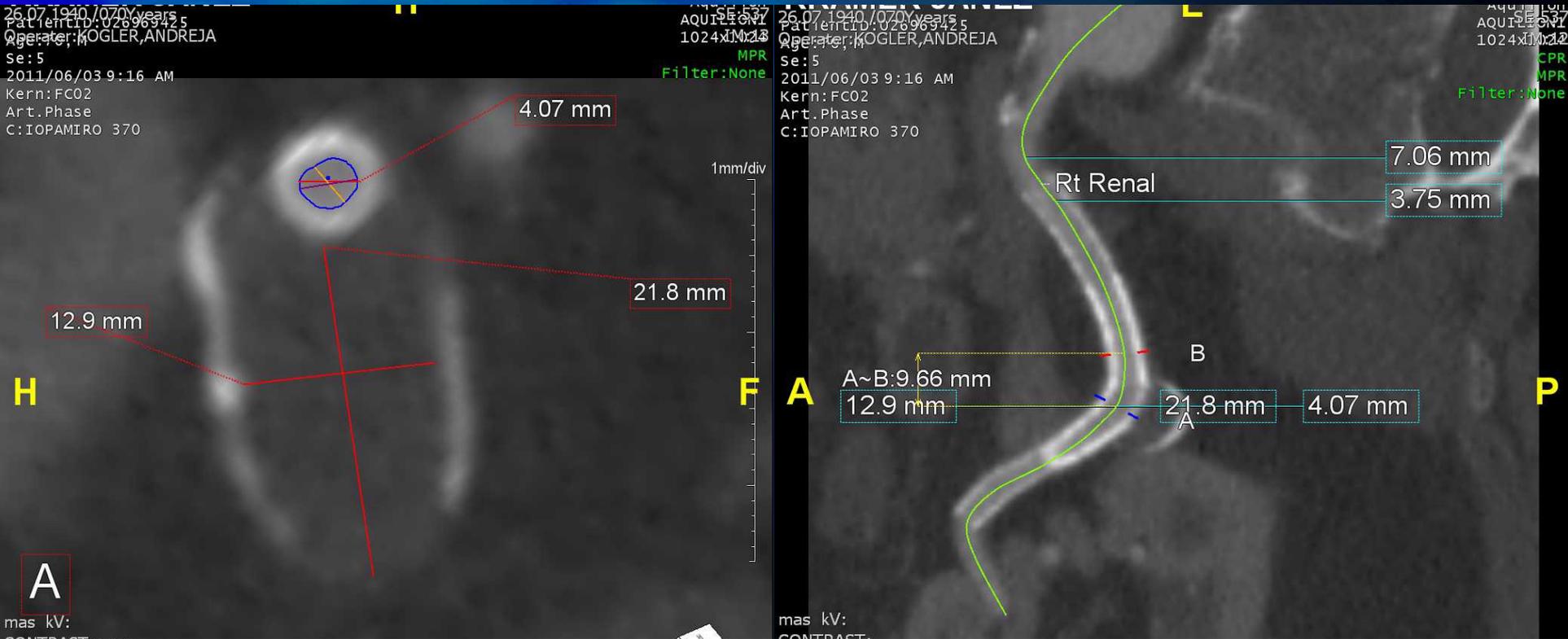
RIGHT SACCULAR RENAL ANEURYSM

CONTROL CTA

- one month after third stent deployment
- good patency without migration of the stents
- aneurysm exclusion and minor aneurysmal sac shrinkage
- all blood vessels patent, also that one arising from the stent



RIGHT SACCULAR RENAL ANEURYSM CONTROL CTA



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

LEFT SACCULAR RENAL ANEURYSM

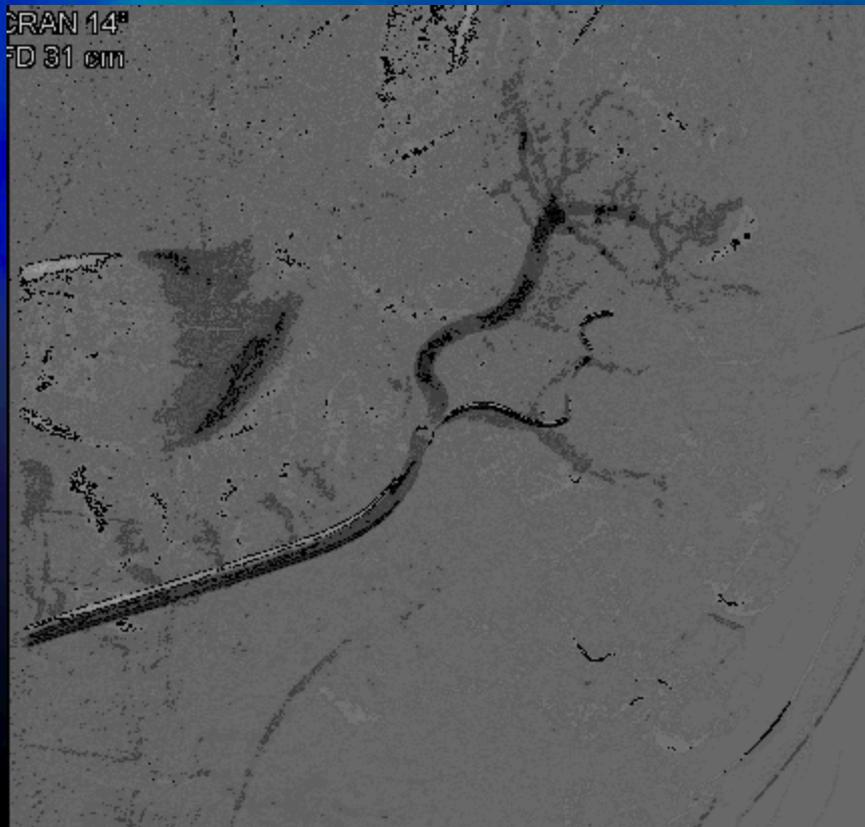
F. 56 Y.

**SOLITARY KIDNEY
(RIGHT RENAL CANCER)**

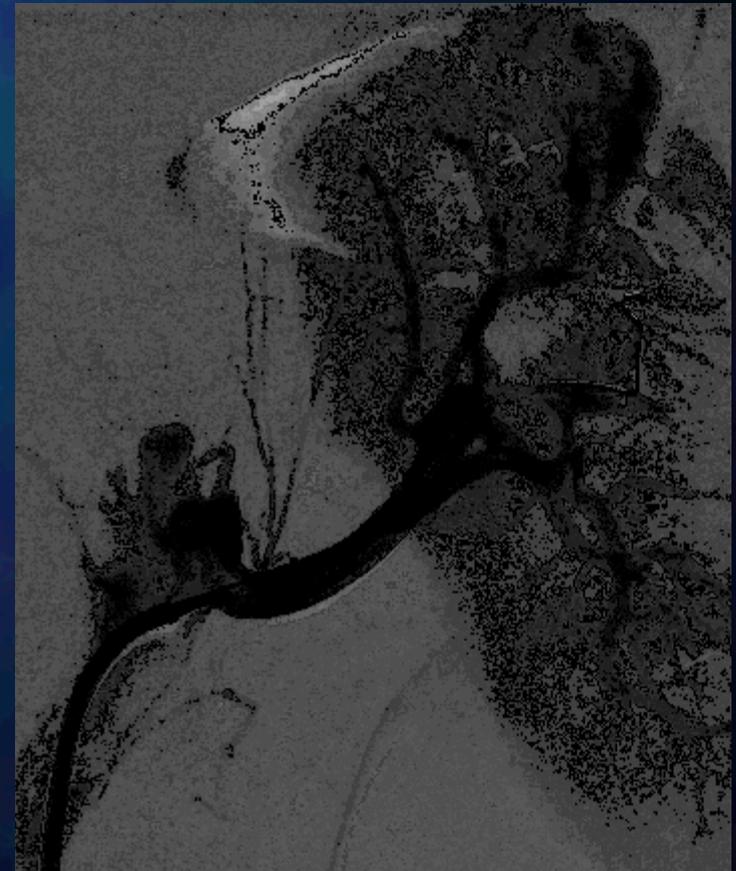
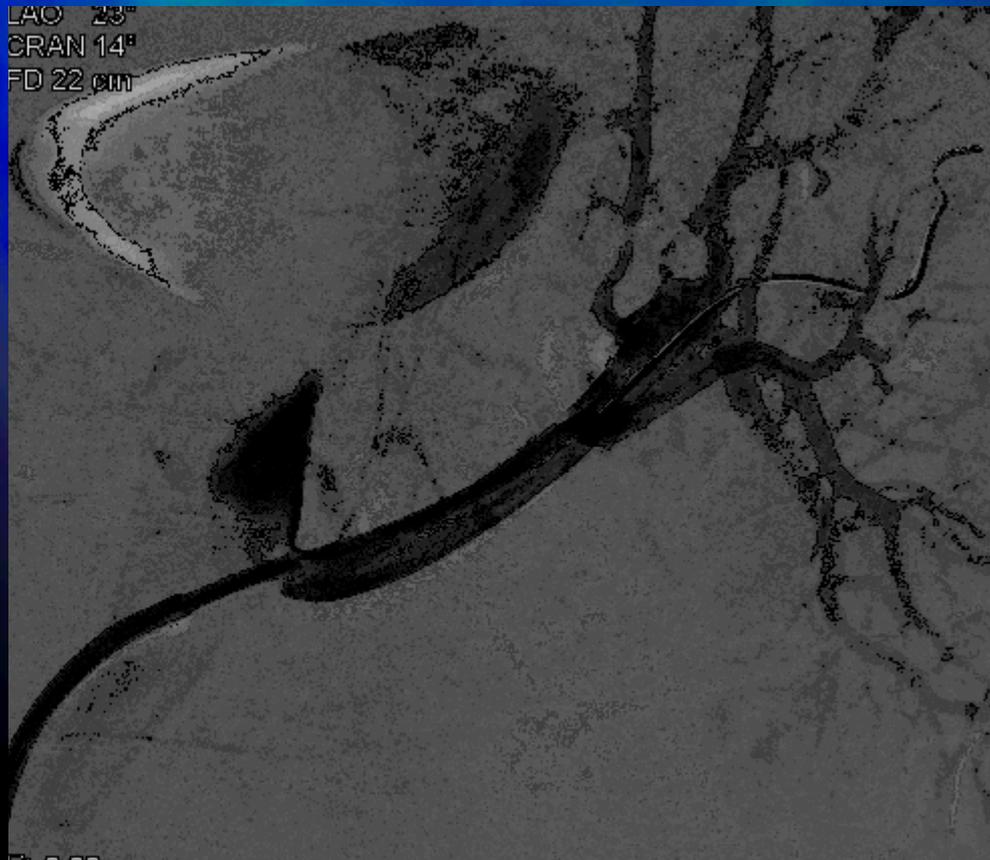
H.T.A.



LEFT SACCULAR RENAL ANEURYSM



LEFT SACCULAR RENAL ANEURYSM



MULTILAYER STENT RENAL ANEURYSM

RESULTS

- *Successful deployment in all patients*
- *100% occlusion of the aneurysms with side branches remaining patent*

MULTILAYER STENT

MESENTERIC ANEURYSM

MULTILAYER STENT MESENTERIC ANEURYSM

M. 37Y.

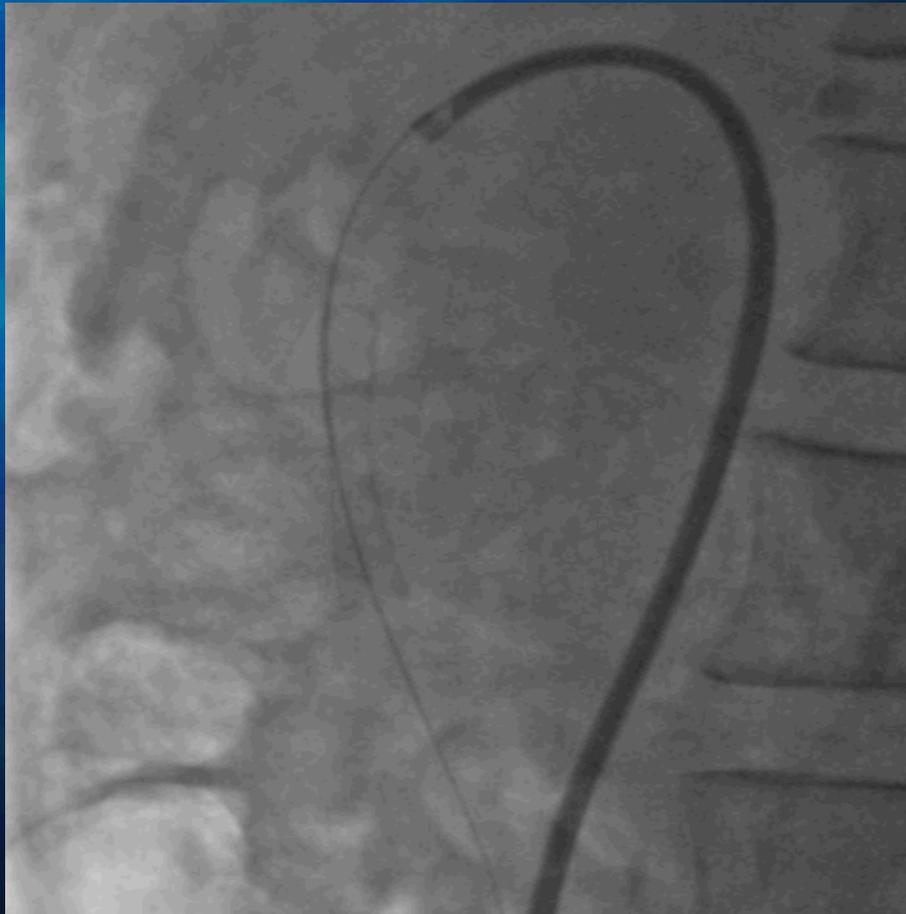
ABDOMINAL PAIN



MULTILAYER STENT MESENTERIC ANEURYSM



MULTILAYER STENT MESENTERIC ANEURYSM

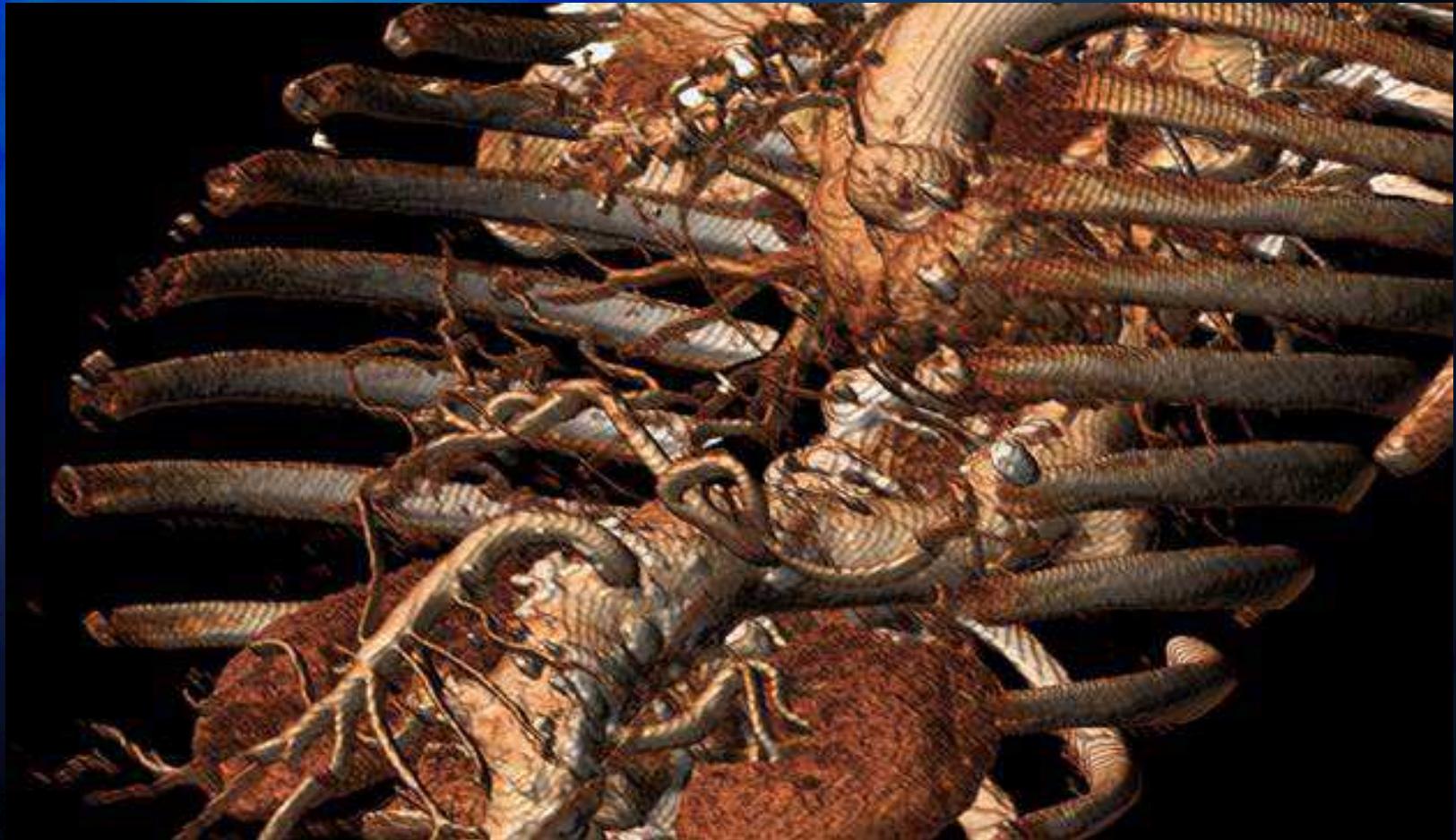


MULTILAYER STENT MESENTERIC ANEURYSM



AFTER 10 mn

MULTILAYER STENT MESENTERIC ANEURYSM



AFTER 1 YEAR

MULTILAYER STENT CONCLUSIONS

- **THE MULTILAYER STENT REPRESENTS AN ALTERNATIVE TO CURRENT DEVICES FOR THE TREATMENT OF PERIPHERAL AND VISCERAL ANEURYSMS (CE MARK)**
- **SUITABLE FOR ALL TYPES OF ANEURYSMS: AAA ,TAAA (STUDY IN FRANCE IN 25 CENTERS - CE MARK FOR TAAA)**
- **COULD ALSO BE USED TO TREAT DISSECTIONS (ONGOING STUDIES)**
- **THEORETICAL BASIC PRINCIPLES OF THE DEVICE ARE VERY ATTRACTIVE**
- **THE MOST IMPORTANT.....IT PRESERVES THE COLLATERALS AND IMPROVES THEIR FLOW**

MULTILAYER STENT CONCLUSIONS

- **SAC THROMBOSIS DOES NOT USUALLY OCCUR IMMEDIATELY. SEVERAL FACTORS (COLLATERAL BRANCHES AND THEIR IMPORTANCE...) COULD PLAY A ROLE AND HAVE TO BE STUDIED AND DETERMINED**
- **PRELIMINARY CLINICAL RESULTS ARE SATISFACTORY AND PROMISING**
- **LARGER EXPERIENCE AND LONGER FOLLOW UP ARE NEEDED**