

# Treatment Strategies to Optimize Endovascular Outcomes of TASC C / D Aortoiliac Lesions

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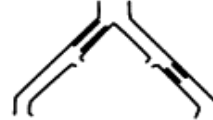
# Disclosure Statement of Financial Interest

I, Philip Green DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.



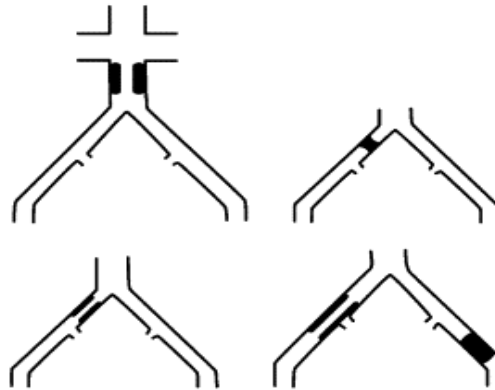
### Type A lesions

- Unilateral or bilateral stenoses of CIA
- Unilateral or bilateral single short ( $\leq 3$  cm) stenosis of EIA



### Type B lesions:

- Short ( $\leq 3$ cm) stenosis of infrarenal aorta
- Unilateral CIA occlusion
- Single or multiple stenosis totaling 3–10 cm involving the EIA not extending into the CFA
- Unilateral EIA occlusion not involving the origins of internal iliac or CFA



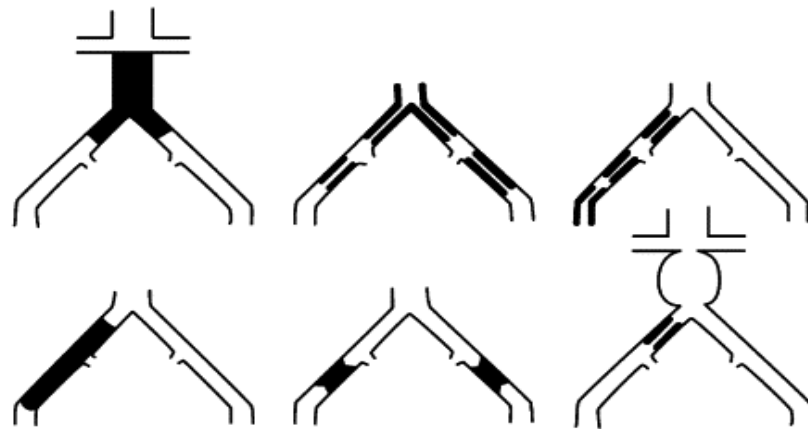
### Type C lesions

- Bilateral CIA occlusions
- Bilateral EIA stenoses 3–10 cm long not extending into the CFA
- Unilateral EIA stenosis extending into the CFA
- Unilateral EIA occlusion that involves the origins of internal iliac and/or CFA
- Heavily calcified unilateral EIA occlusion with or without involvement of origins of internal iliac and/or CFA



### Type D lesions

- Infra-renal aortoiliac occlusion
- Diffuse disease involving the aorta and both iliac arteries requiring treatment
- Diffuse multiple stenoses involving the unilateral CIA, EIA, and CFA
- Unilateral occlusions of both CIA and EIA
- Bilateral occlusions of EIA
- Iliac stenoses in patients with AAA requiring treatment and not amenable to endograft placement or other lesions requiring open aortic or iliac surgery



# Surgical Therapy

- TASC II suggests surgical therapy for type C and D lesions.
- Surgical options for AIOD are anatomic versus extra-anatomic bypass graft or endarterectomy.
  - 5 year Graft patency
    - Aortic bifurcation grafts – 90%
      - 75% 10 yrs
    - Axillary-unifemoral graft – 51% (44 to 79%)
    - Axillary-bifemoral bypass - 71% (50 to 76%)
    - Femoral-femoral crossover graft – 75% (55 to 92%)
- Patient comorbidities should be taken into account when considering surgery.

# Endovascular Therapy

- Single center 43 patient study
- “kissing” self-expanding common iliac stents for aorto-iliac bifurcation disease
- Primary patency rate of 89%, 82%, and 68% at 2, 5, and 10 years
- Secondary patency rates were 93%, 93%, and 86% at 2, 5, and 10 years



# Example Kissing Stents



# 42F with familial hypercholesterolemia, smoker, severe claudication

- ABI 0.66 (right)
- ABI 0.82 (left)
- Peak velocity 383 cm/s left iliac
- Peak Velocity 251 cm/s left iliac



Image size: 512 x 512

View size: 605 x 599

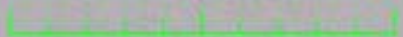
WL: 128 W/W: 256

L000465013 ( 42 y , 41 y )

Cardiac — Pelvis-Iliac 3 fps

R:201511110752489

8



Zoom: 118% Angle: 0

Im: 1/17

Uncompressed

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Made In OsiriX



L0  
Cardiac — Left

512  
599

L00046501  
Cardiac — Left Coronary  
R20



3:0

Image size: 512 x 512  
View size: 599 x 599  
WL: 127 WW: 184

L000465013 ( 42 y, 41 y )  
Cardiac - Fluoroscopy  
R201511110752489  
15

Zoom: 117% Angle: 0  
Irr: 1/24  
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Image size: 512 x 512

View size: 599 x 599

WL: 128 WW: 256

L000465013 ( 42 y , 41 y )

Cardiac - 1 Upper Leg 3 fps

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16

Zoom: 117% Angle: 0

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# Follow Up

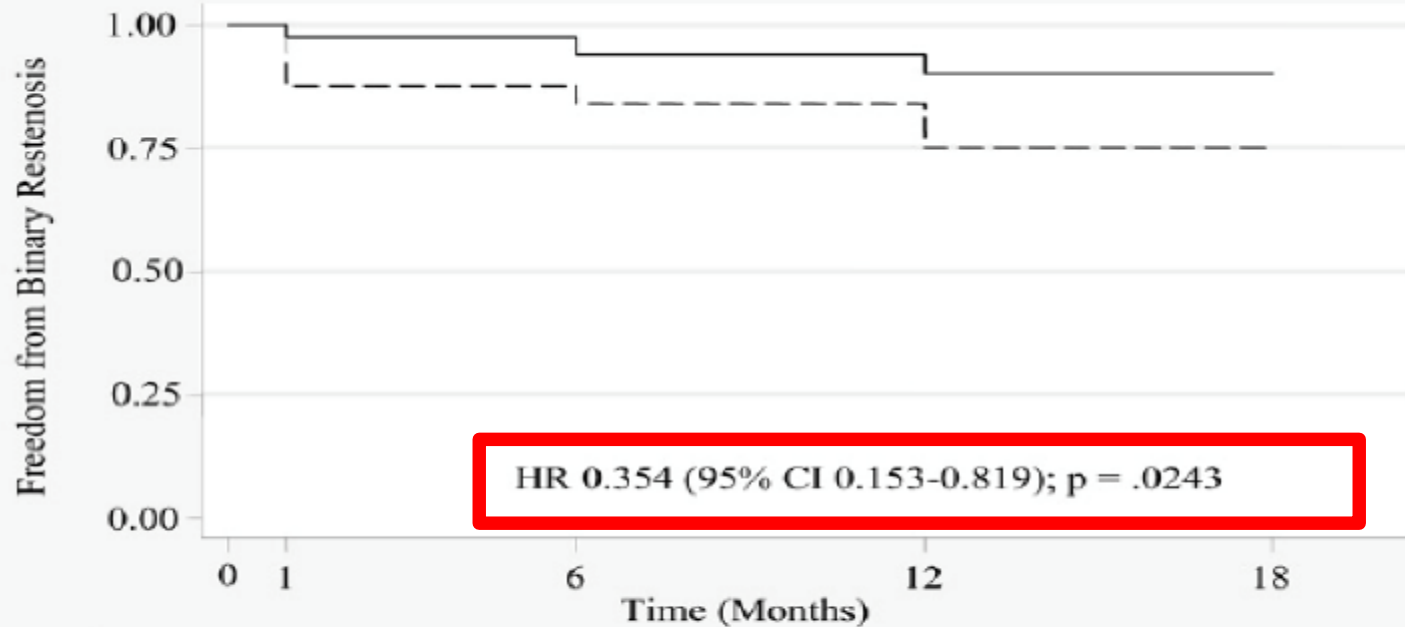
- Claudication resolved, ABI 0.91/0.95
- Quit smoking
- LDL ~40 on Praluent (PCSK9 inhibitor)



# COBEST Trial

- Randomized, multicenter trial of covered balloon expandable stents vs. other, non-covered stents for iliac artery stenosis
- 168 iliac arteries in 125 patients
- Included TASC B-D lesions.
- Conducted in Australia.

# Overall Improved Freedom From Restenosis

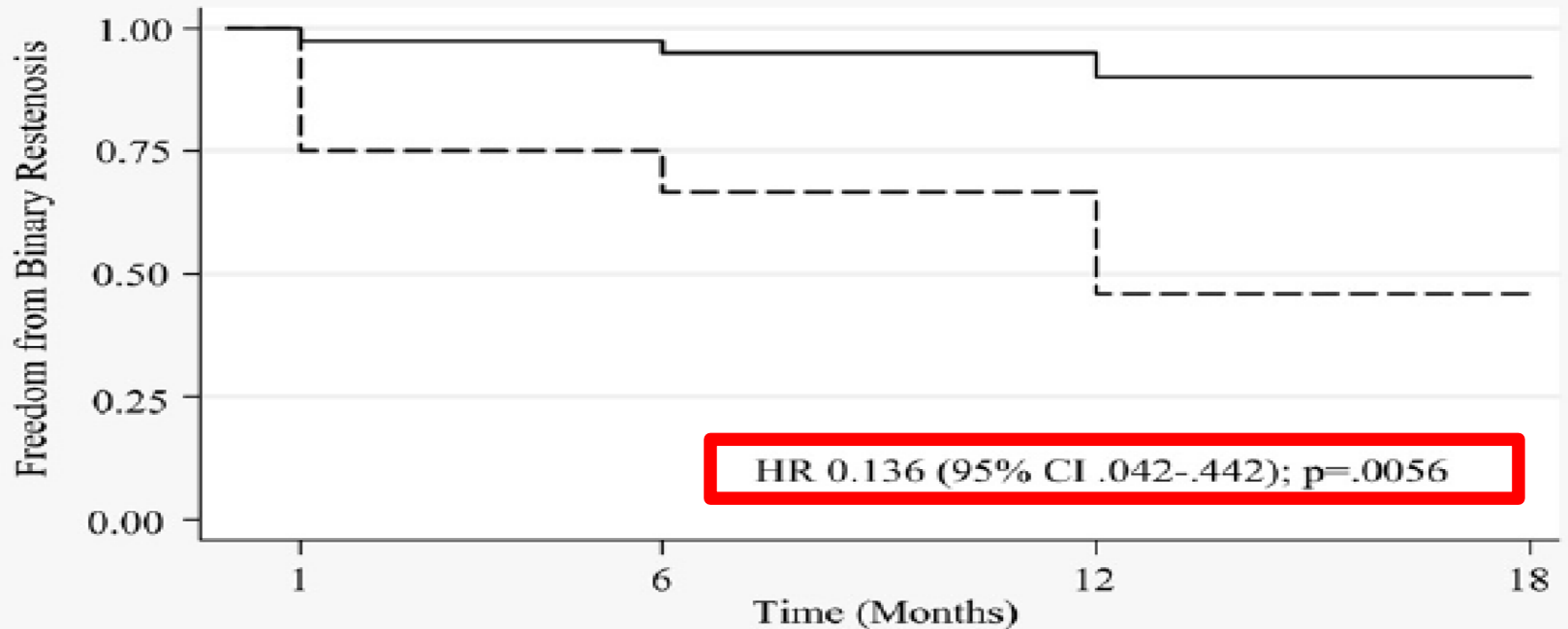


## Number at risk

	0	1	6	12	18
V12 Stent Group	83	82	80	77	73
Bare Stent Group	85	81	70	66	58

— V12 Stent      - - - - Bare Stent

# TASC C/D Lesions

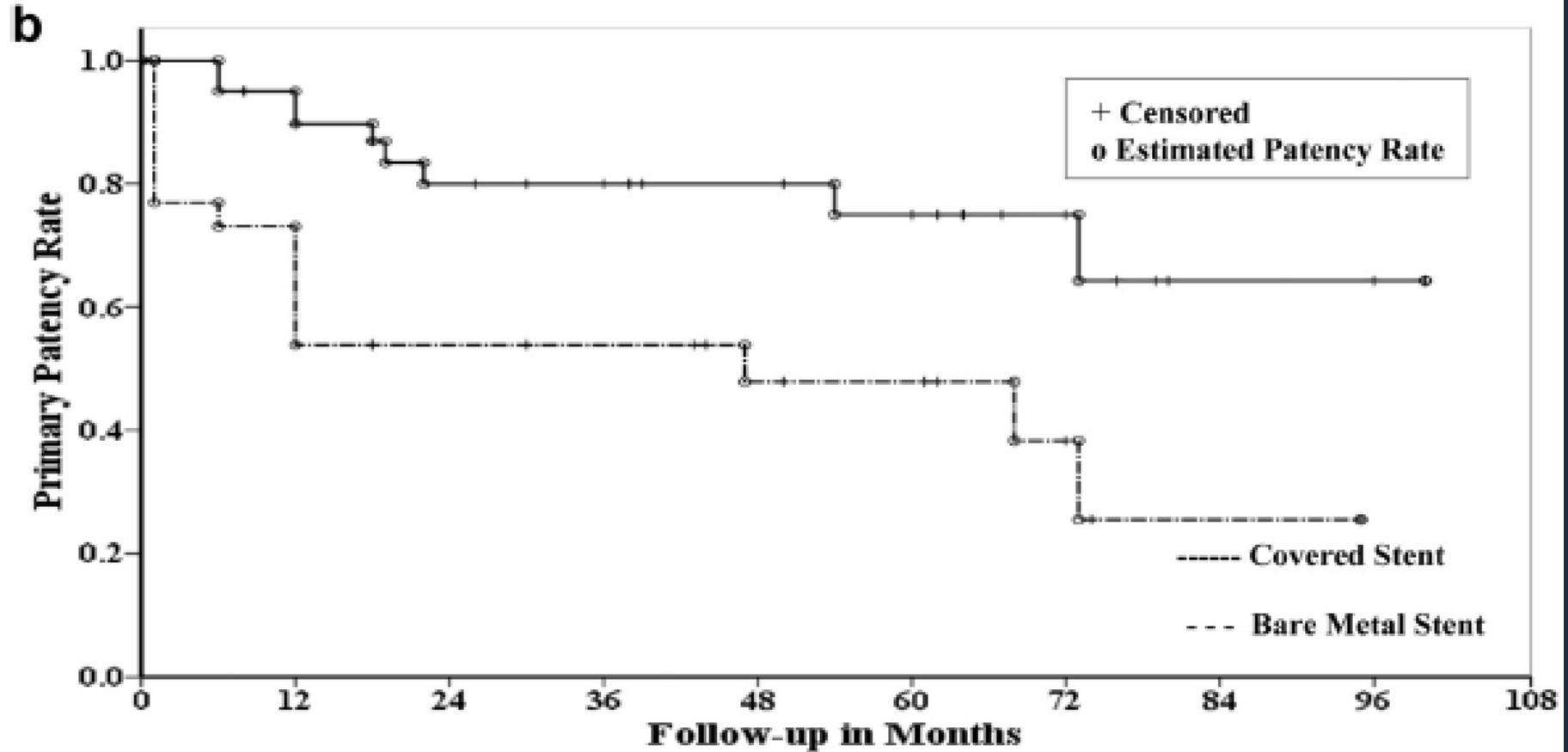


**Number at risk**  
V12 Stent Group  
Bare Stent Group

40	39	38	35
24	18	16	11

— V12 Stent      - - - - Bare Stent

# Five Year Primary Patency of TASC C/D Lesions in the COBEST Trial

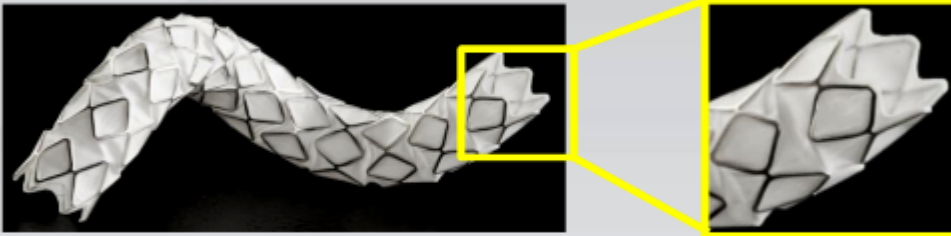




# Viabahn VBX

## FEATURES

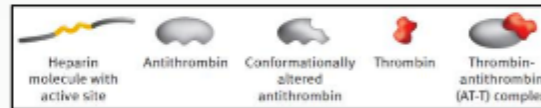
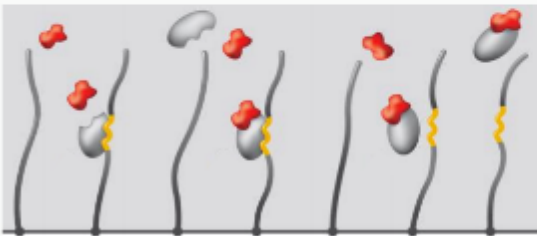
- Discrete, ePTFE-connected stainless steel rings-----→



- 0.035" guidewire compatible, ultrathin ePTFE balloon cover-----→



- CBAS<sup>®</sup> Heparin Surface on the device similar to VIABAHN<sup>®</sup> endoprosthesis and TIGRIS<sup>®</sup> vascular stent-----→



## BENEFITS

- Flexibility, conformability and trackability
- High radial strength
- Minimal foreshortening

- Improved endoprosthesis retention on delivery catheter

- Thromboresistant surface



# Pivotal Study of a Next-Generation Balloon-Expandable Stent-Graft for Treatment of Iliac Occlusive Disease

- N = 134 patients
- 32% with TASC II C or D lesions
- 42% kissing iliac stents at aortic bifurcation
- 96.9% primary patency at 9 months
  - 95.3% primary patency in TASC C/D

# Disadvantages to “kissing” stents

- Aortic bifurcations
  - calcification
  - aortic thrombus
  - size or geometric mismatch between the native vessels
- The limb competition of two “crossed” kissing stents in a diseased distal aorta can lead to significant flow compromise.
- Loss of native bifurcation compromises “up & over” access in the future
- Limited options for treatment of more proximal aortic disease in the future



# CERAB Technique

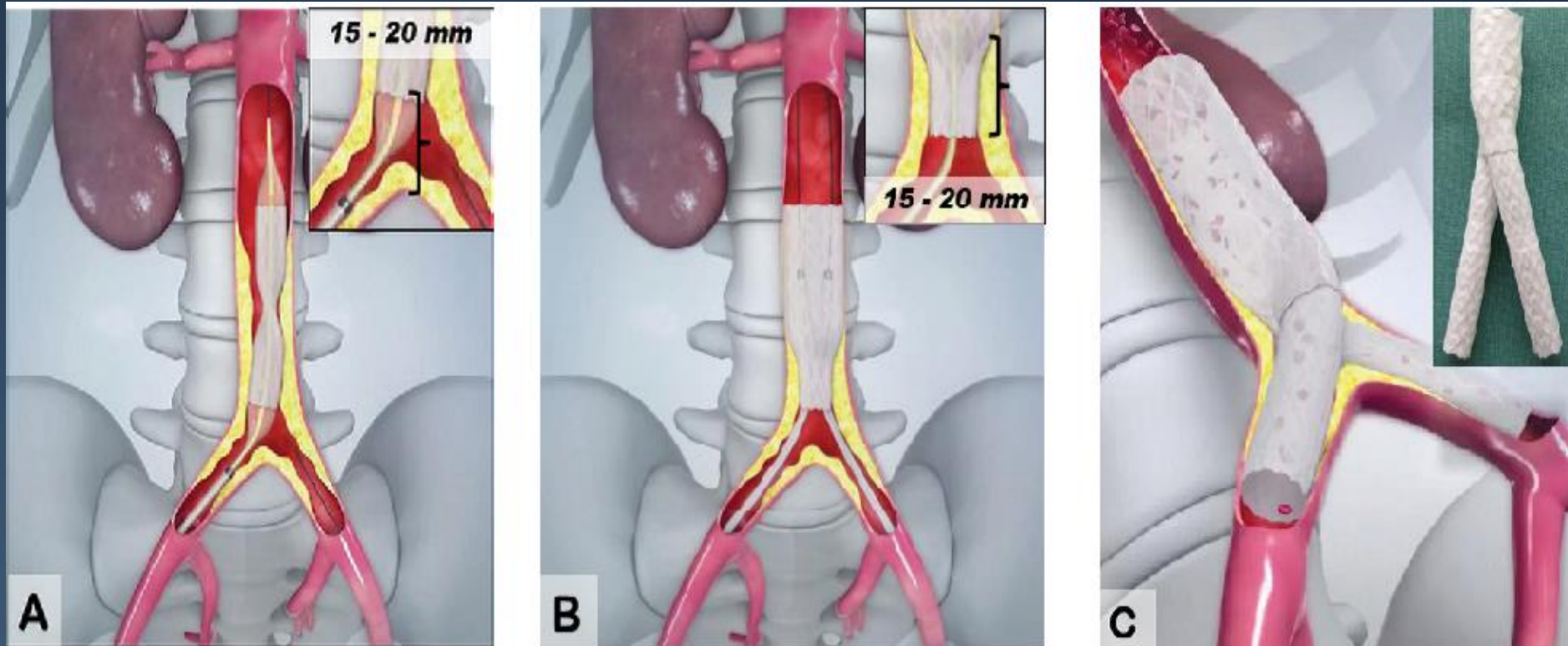


Figure A During the first step of the CERAB procedure a 12-mm balloon expandable stent is positioned and deployed 15-20mm above the aortic bifurcation

Figure B During second step of the CERAB procedure the proximal part of the aortic covered stent is overdilated to adapt to the aortic wall

Figure C The CERAB configuration is completed by simultaneous inflation of two iliac covered stents in the conic segment, thereby molding the first one around the latter two

# Patient GE

- **59 year old woman**
- **s/p CABG**
- **DM2**
- **Active smoker**
- **Rutherford Class III claudication**
  - **Severely symptomatic at less than one block**
  - **No rest pain, no ulcers**
- **L ABI 0.78**
- **R ABI 0.72**

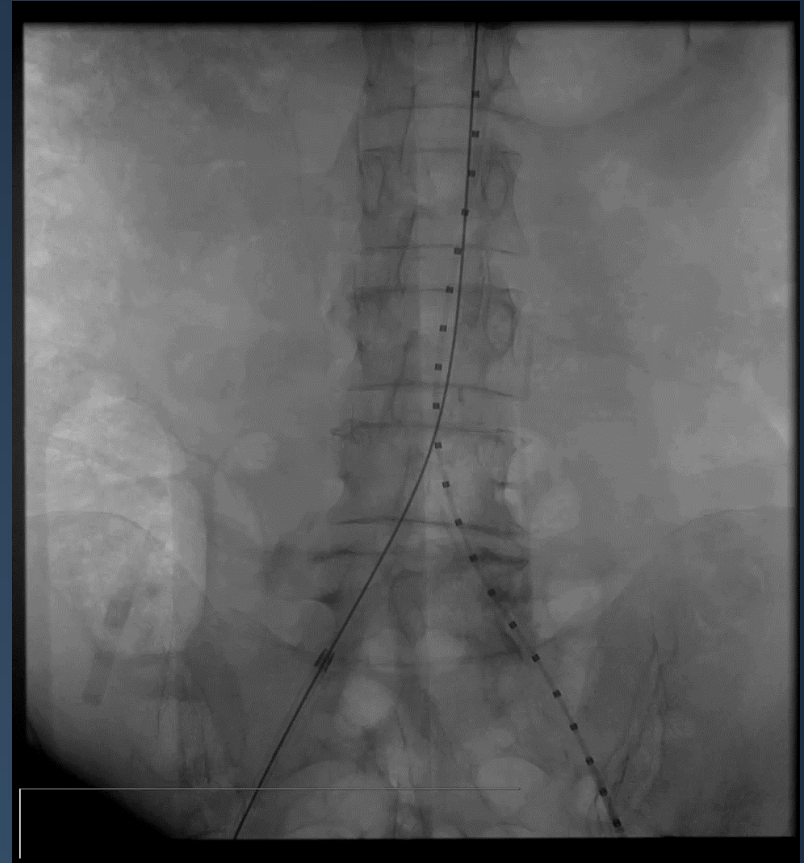


# CT

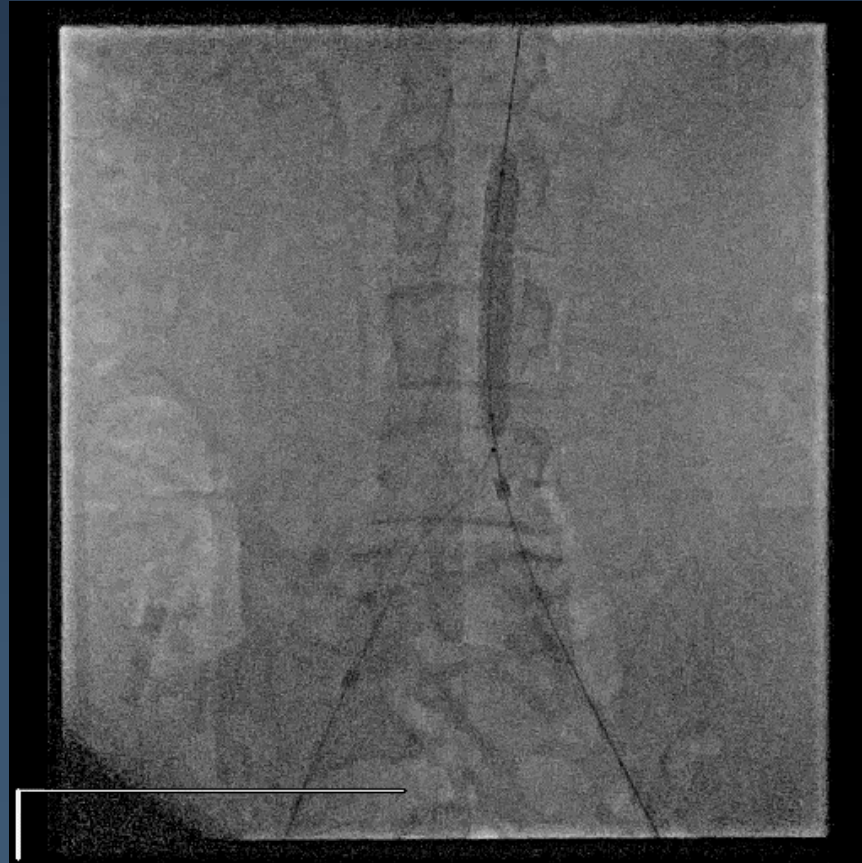
- Severe stenosis of the infrarenal aorta.
- Right - severe stenosis of the proximal common iliac and proximal external iliac arteries.
- Left - moderate to severe stenosis of the proximal common iliac, external and internal iliac arteries.



# Angiogram



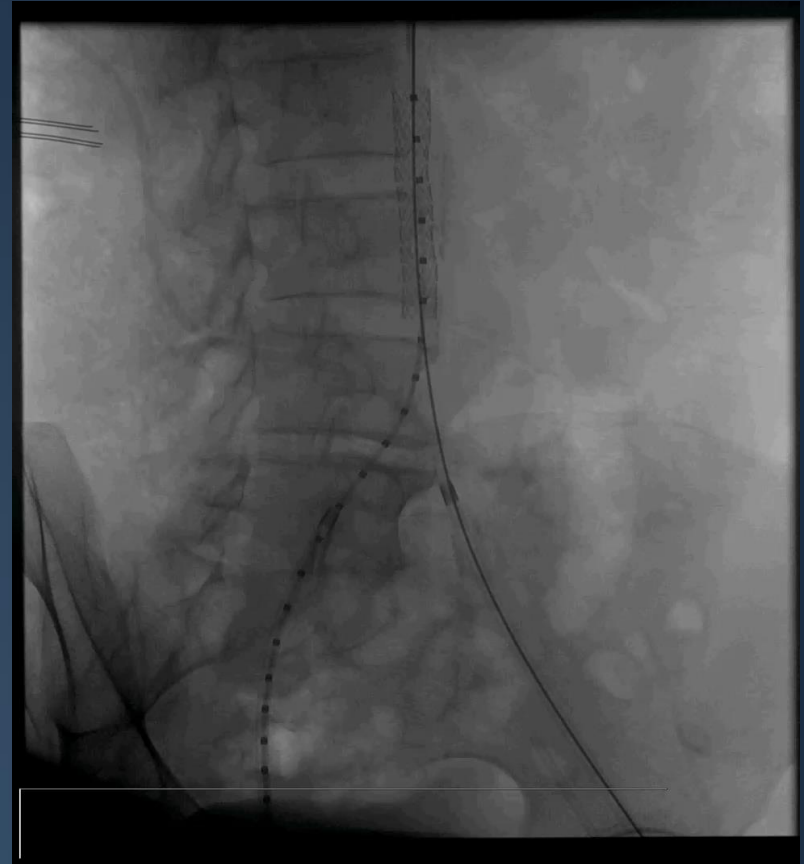
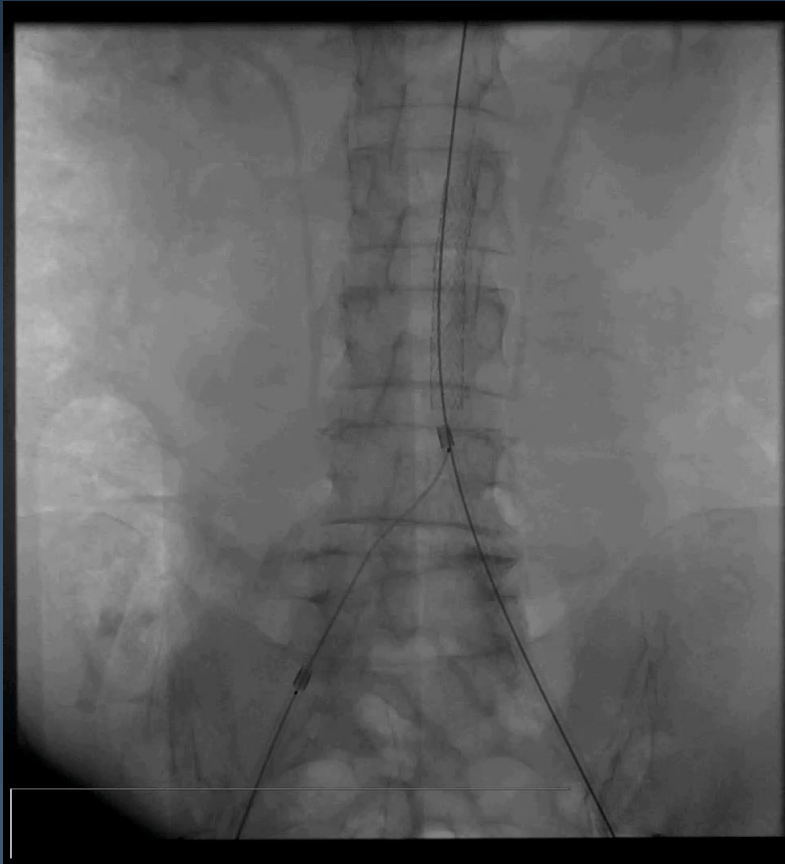
# Intervention



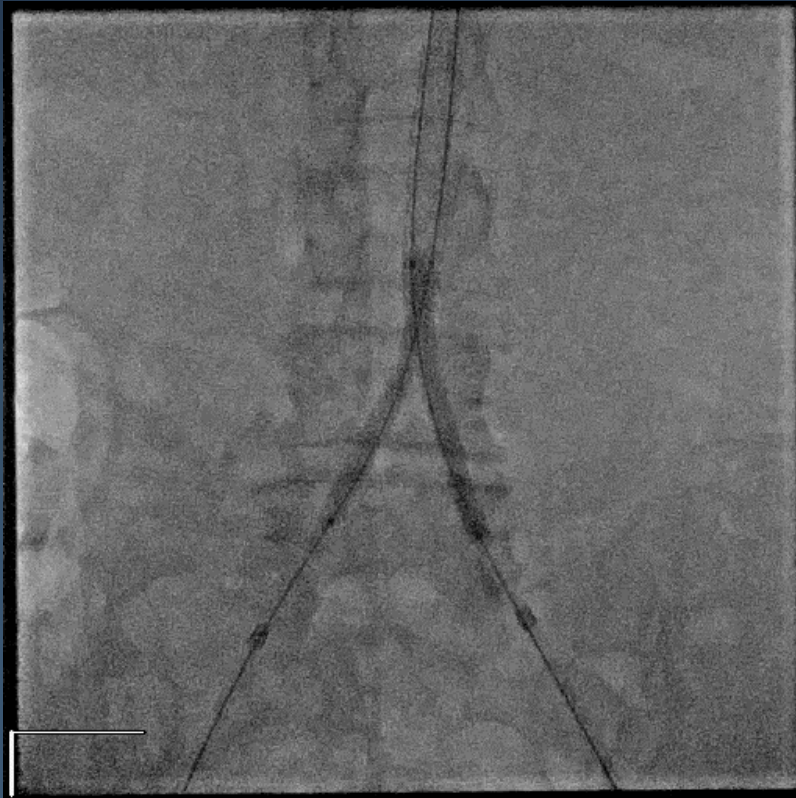
Viabahn VBX 8 x 59



# Intervention



# Intervention



Bilateral Viabahn VBX 6 x 59

# Intervention



Absolute Pro 7 x 60 to both iliacs



# Patient GE

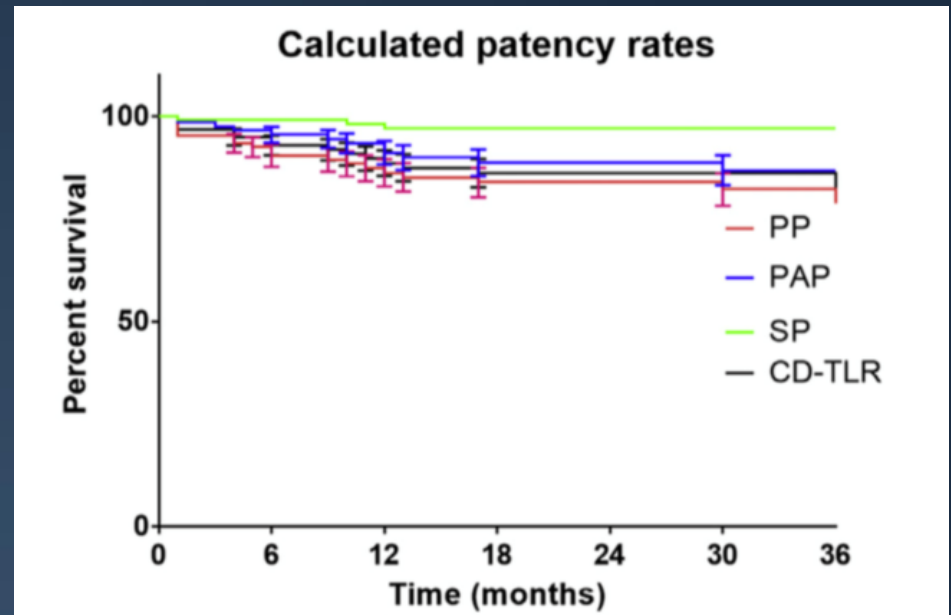
- 3 months later minimal claudication at 6 blocks



# CERAB

## 3 year outcome data

- N=130
- 89% TASC D
- 68% claudication
- 32% CLI
- 67% percutaneous
- 30D complication
  - Minor 33%
  - Major 7%

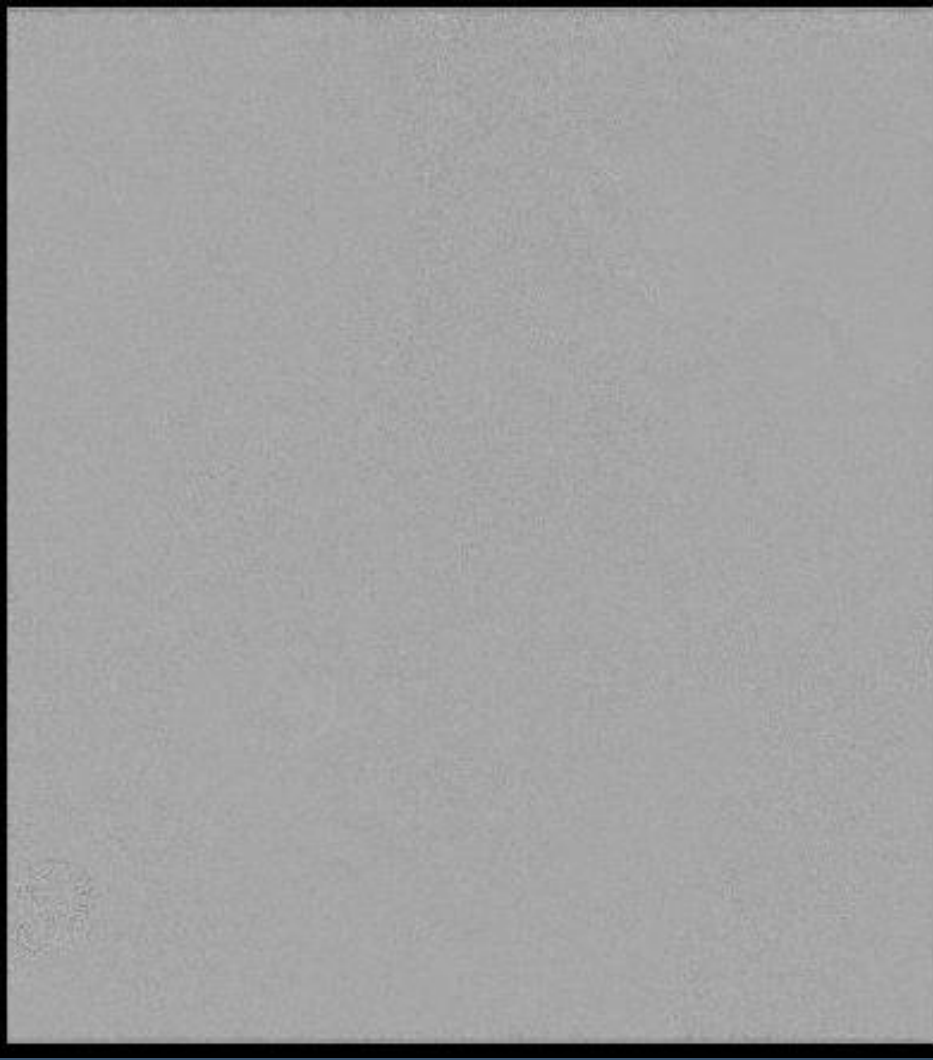


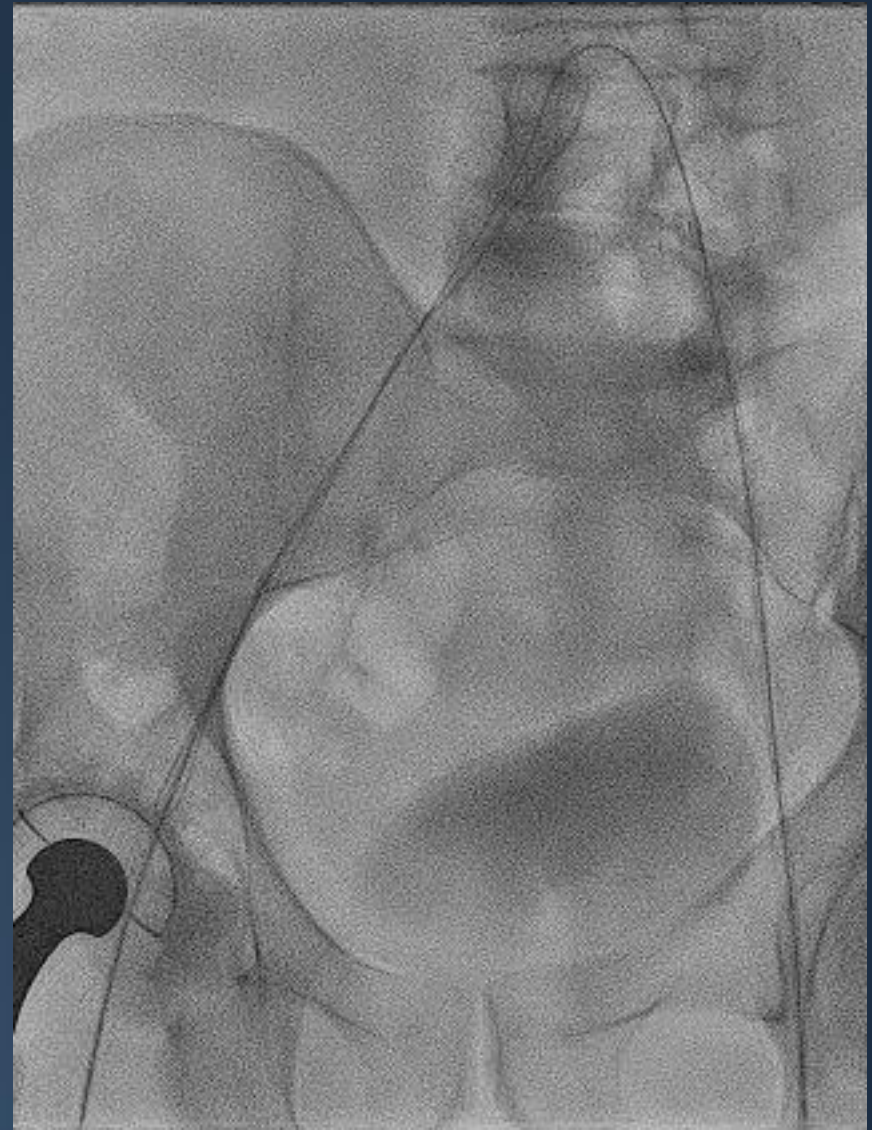
Primary, primary assisted, and secondary patency was 82%, 87%, and 97% at 3 years.

# 57M former smoker

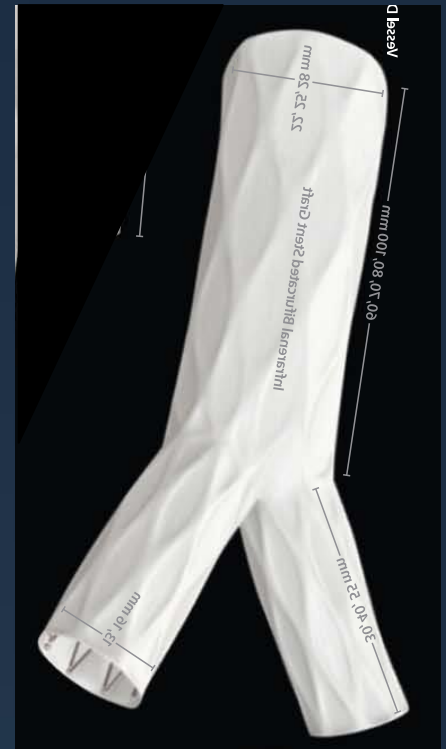
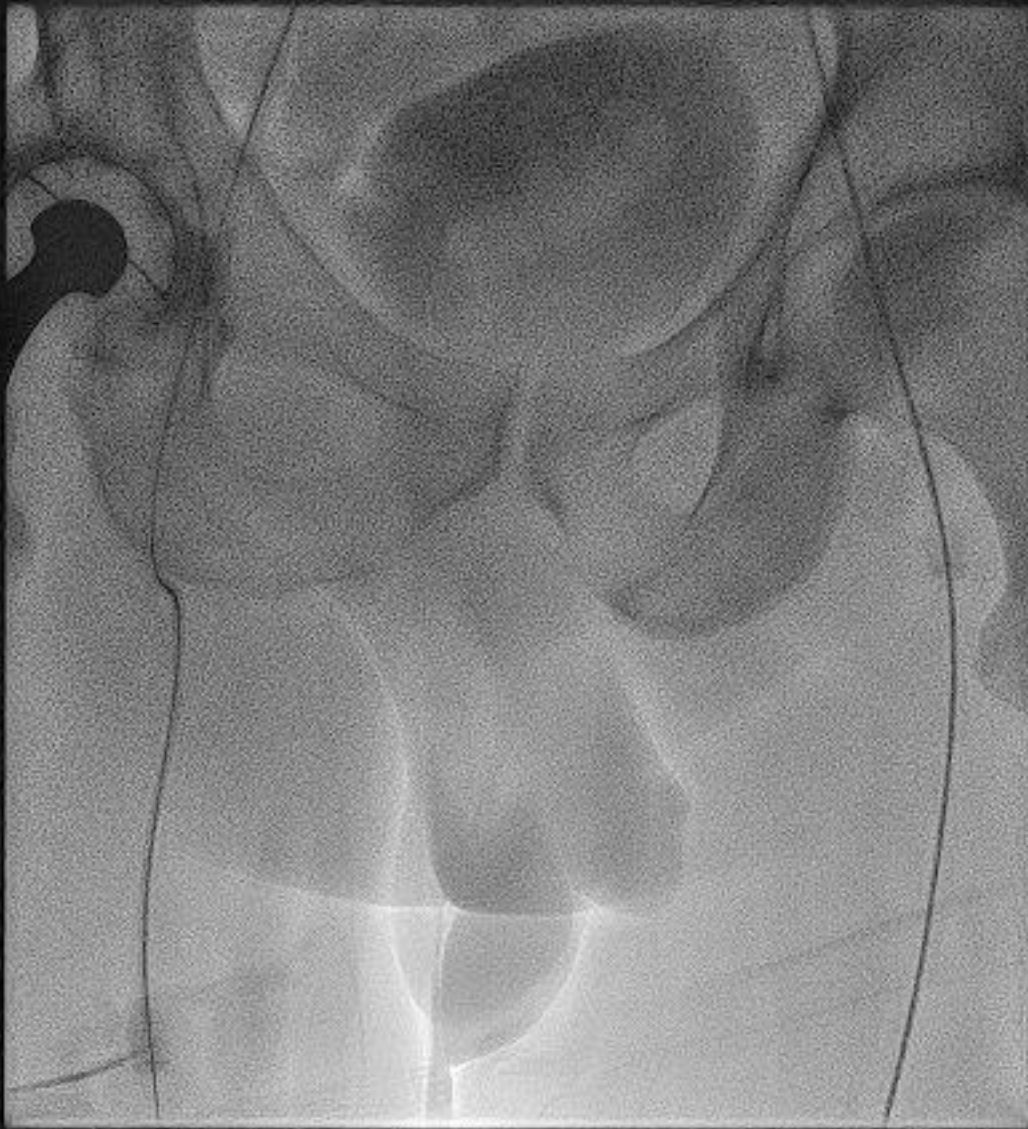
- Non obstructive CAD
- Carotid stenosis s/p stenting
- Right sided claudication with no femoral pulse on exam
- CTA showed complete occlusion of right common iliac, external iliac, and common femoral with reconstitution of distal CFA



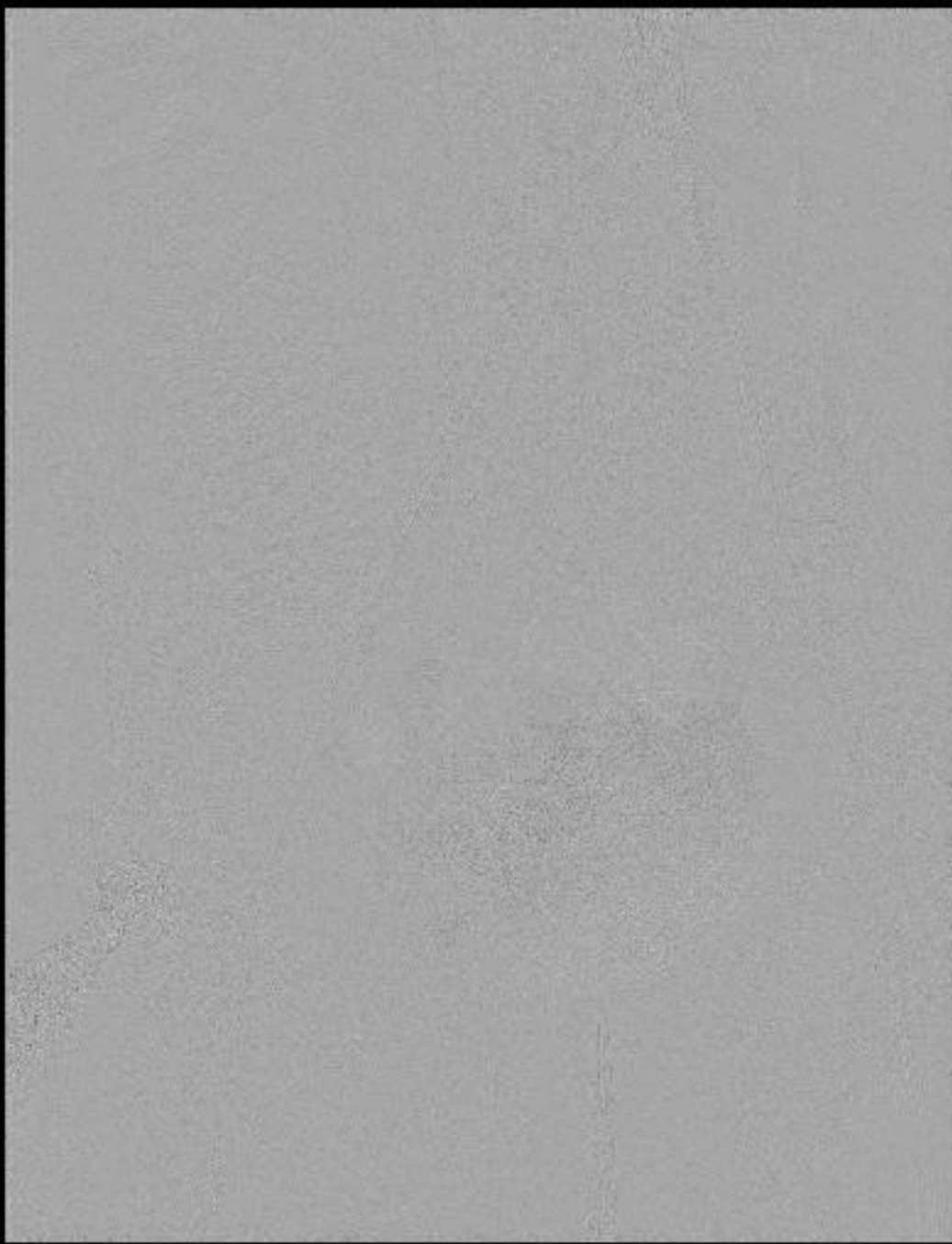








Left CFA: 18F OD  
Preclose with  
perclos x 2  
RSFA: 7F



- Claudication completely resolved
- Sees me for regular clinical f/u



# Treatment of Aortoiliac Occlusive Disease (AIOD) with the Endologix AFX Unibody Endograft

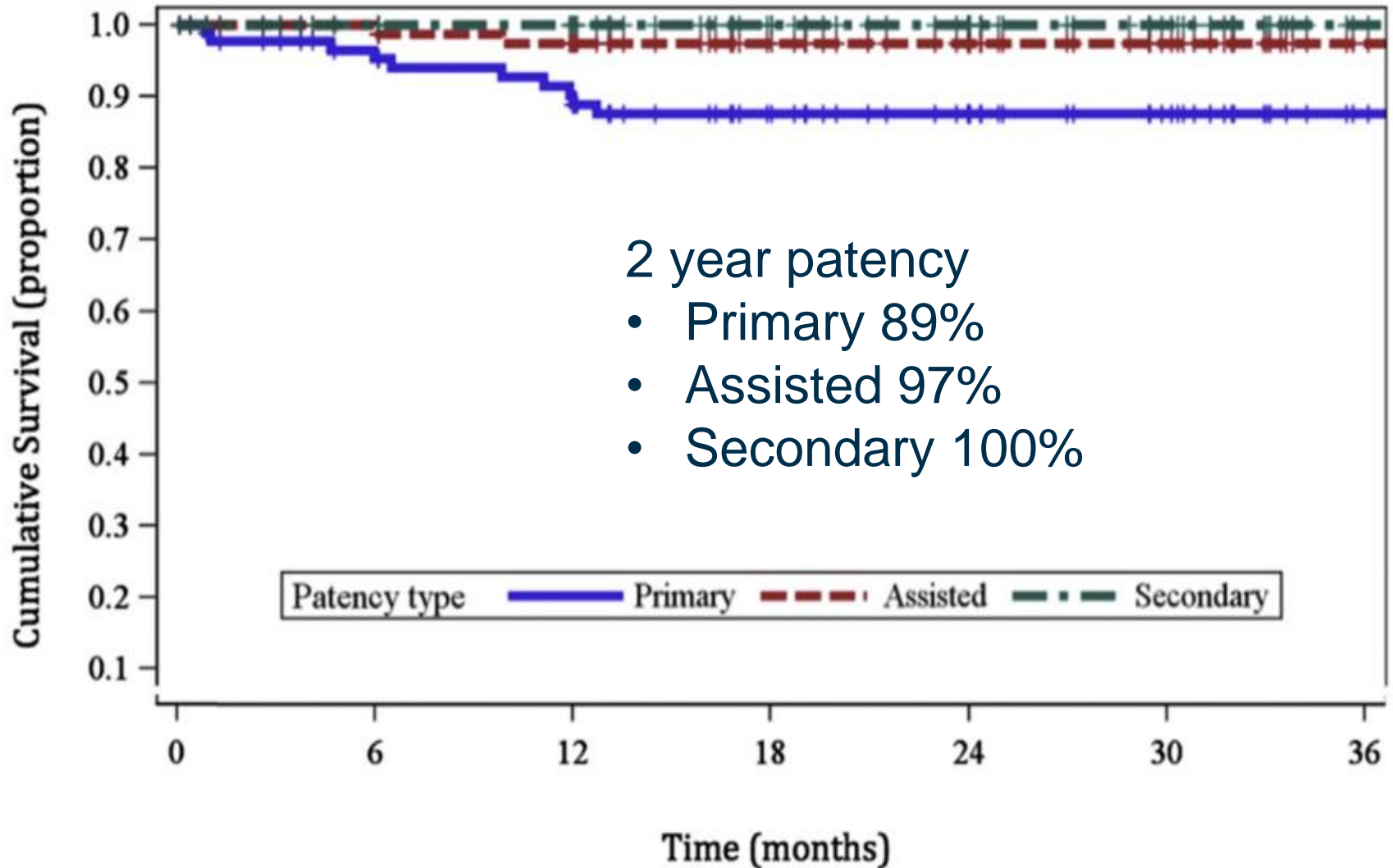
T.S. Maldonado et al. Eur J Vasc Endovasc Surg  
(2016) 52, 64-74



# Study Design

- 10 center retrospective study conducted between 2012 – 2014
- AFX unibody stent graft (approved for AAA) but used to treat AIOD
- AAA (aortic diameter  $> 3.5$  cm) excluded
- Outcomes
  - Procedural success
  - 30D mortality
  - Acute complication
  - Rutherford classification / ABI
  - Patency (primary, assisted, secondary)

# Patency



68M smoker with chronic buttock/thigh claudication  
with new right calf pain and cool right foot

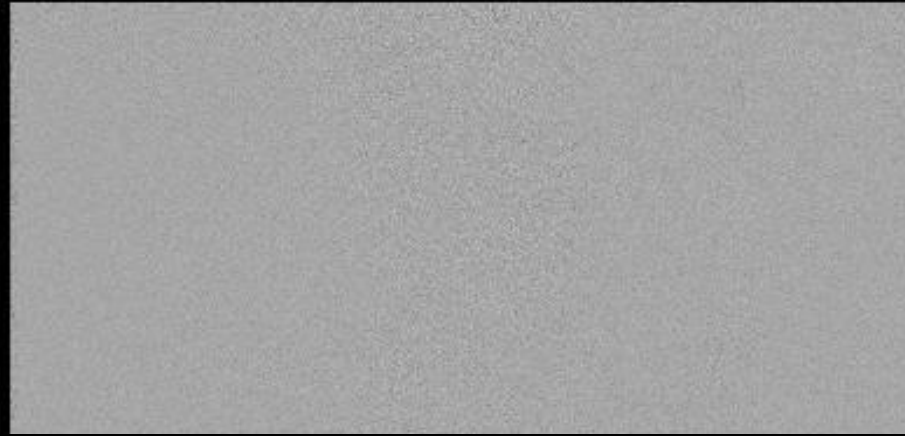


68M smoker with chronic buttock/thigh claudication  
with new right calf pain and cool right foot



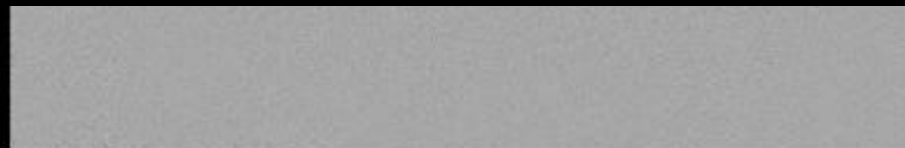


68M smoker with chronic buttock/thigh claudication  
with new right calf pain and cool right foot



## Aorto-Bifem Bypass

- Uncomplicated
- Discharged po day 5
- Foot warm
- No claudication



# Conclusions

- Treatment of aorto-iliac occlusive disease is evolving
- Traditional “kissing stents” & CERAB remain options
- The application of dedicated AAA devices to treat AIOD is feasible and provides anatomic advantages
- Despite high morbidity aorto-bifemoral bypass surgery remains the gold standard and is still the safest option in select circumstances
- Comparative prospective research is needed to solidify the evidence base for AIOD

